REGISTRATION REPORT
Part A

Risk Management

Product name:	**Ascra Xpro**
Product code:	**102000027828**
Active Substance:	**Bixafen 65 g/L** **Fluopyram 65 g/L** **Prothioconazole 130 g/L**

COUNTRY: Germany

Central Zone

Zonal Rapporteur Member State: Germany

NATIONAL ASSESSMENT

Applicant:	**Bayer CropScience**
Date:	**21 December 2017**

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PART A – Risk Management

This document describes the acceptable use conditions required for the registration of Ascra Xpro (102000027828) containing bixafen, fluopyram and prothioconazole in Germany.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-8 and Part C and where appropriate the addendum for Germany. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to BIX+FLU+PTZ EC 260 where that data has not been considered in the EU review. Otherwise assessments for the safe use of BIX+FLU+PTZ EC 260 have been made using endpoints agreed in the EU review of bixafen, fluopyram and prothioconazole.

This document describes the specific conditions of use and labelling required for Germany for the first registration of Ascra Xpro (102000027828).

Appendix 4 of this document provides a copy of the final product authorisation in Germany.

Appendix 2: The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions drawn by the competent authority. The final version of the label is not available, because the layout is the sole responsibility of the applicant and will not be checked again.

Appendix 3 letter of access: Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.

1 Details of the application

1.1 Application background

This application was submitted by Bayer CropScience on 14.05.2014.

The application was for approval of Ascra Xpro (102000027828), an emulsifiable concentrate containing bixafen (65 g/L), fluopyram (65 g/L) and prothioconazole (130 g/L) for use as a fungicide on cereals.

1.2 Annex I inclusion

Bixafen was approved for inclusion into Annex I in accordance with Regulation (EC) No 1107/2009, Council Directive 91/414/EEC (Implementing Regulation (EU) No. 350/2013, dated 17 April 2013) with the entry into force of 1 October 2013. Fluopyram was included into Annex I of Regulation (EC) No1107/2009, (Implementing Regulation (EU) No.802/2013, dated 22 August 2013) with the entry into force of 1 February 2014. Prothioconazole was included in Annex I of Directive 91/414, (Directive 2008/44/EC dated 4 April 2008) with the entry into force on 1 August 2008.

The product has not been evaluated as the representative formulation during the Annex I inclusion of bixafen, fluopyram or prothioconazole. This dossier is submitted in order to allow the first registration of this product for uses on cereals Germany.

Bixafen

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bixafen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013 shall be taken into account. According to Annex I of the Implementing Regulation for bixafen, Member States must pay particular attention to:

- the residues of bixafen and of its metabolites in rotational crops
  (In agreement with the RMS for bixafen – CRD in the UK -, this point is being addressed by the initiation of new rotational crop studies.)
- the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions
- the risk to aquatic organisms
- the risk to soil and sediment-dwelling organisms

Fluopyram

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bixafen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account. In the Annex I Inclusion Regulation for fluopyram there are specific provisions under Part B which need to be considered related to ecotoxicology. In this overall assessment Member States shall pay particular attention to the risk to birds and aquatic organisms. The applicant shall submit confirmatory information as regards:

- the long-term risk to insectivorous birds;
- the potential for causing endocrine disrupting effects in non-target vertebrates other than mammals.

Conditions of use shall include risk mitigation measures, where appropriate.

The applicant shall submit to the Commission, Member States and the Authority the information set out in point 1 by 1 February 2016 and the information set out in point 2 within two years after adoption of the corresponding OECD test guidelines on endocrine disruption.

Prothioconazole

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review reports on the active substances prothioconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account.

In the Annex I Inclusion Directive for prothioconazole Member States must pay particular attention to:

- the operator safety in spray applications. Conditions of use shall include adequate protective measures,

- the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate,
- the protection of birds and small mammals. Risk mitigation measures shall be applied, where appropriate.

Conditions of use shall include risk mitigation measures, where appropriate.

The concerned Member States shall request the submission of:

- information to allow the assessment of consumer exposure to triazole metabolite derivatives in primary crops, rotational crops, and products of animal origin,
- a comparison of the mode of action of prothioconazole and the triazole metabolite derivatives to allow the assessment of the toxicity resulting from the combined exposure to these compounds,
- information to further address the long-term risk to granivorous birds and mammals arising from the use of prothioconazole as a seed treatment.

These concerns have been addressed within the current submission.

For bixafen, the EFSA conclusion of the peer review (EFSA Journal 2012; 10(11): 2917) and the draft Review Report are considered to provide the relevant scientific information for the review of the product. For fluopyram, the EFSA conclusion of the peer review (EFSA Journal 2013; 11(4): 3052) and the Review Report (SANCO/11456/2013 rev 2: draft) finalised on 16 July 2013 are considered to provide the relevant scientific information for the review of the product. The review report for prothioconazole (SANCO/11209/2010 Rev. 2) and the (EFSA Scientific Report (2007) 106, 1-98) are considered to provide the relevant scientific information for the review of the product.

1.3 Regulatory approach

To obtain approval the product BIX+FLU+PTZ EC 260 must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed end-points. This application was submitted in order to allow the first approval of this product in Germany. in accordance with the above.

1.4 Data protection claims

Where the applicant claims protection for information supporting registration of Ascra Xpro, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B and Part C.

1.5 Letters of Access

Letter of Access is not necessary. The applicant is owner of all necessary data.

2 Details of the authorisation

2.1 Product identity

Product Name	ASCRA Xpro, 102000027828
Authorization Number (for re-registration)	008219-00

Function	fungicide
Applicant	Bayer CropScience Deutschland GmbH
Composition	65 g/L bixafen 65 g/L fluopyram 130 g/L prothioconazole
Formulation type	Emulsifiable concentrate [Code: EC]
Packaging	1 – 15 L jerry can HDPE/PA or HDPE/EVOH

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not proposed.

2.2.2 Classification and labelling under Regulation (EC) No 1272/2008

The following labelling is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard classes and categories:	
Acute Tox. 4, Skin Sens. 1, Eye Dam. 1, STOT SE 3, Repr. 2	
Hazard pictograms:	
GHS05	corrosion
GHS07	exclamation mark
GHS08	health hazard
GHS09	environment
Signal word:	
Danger	
Hazard statements:	
H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.
H361d	Suspected of damaging the unborn child.
H410	Very toxic to aquatic life with long lasting effects.
Precautionary statemtents:	
P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.
P201	Obtain special instructions before use.
P264	Wash ... thoroughly after handling.
P270	Do no eat, drink or smoke when using this product.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water/...
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P310	IF exposed or concerned: Immediately call a POISON CENTER or a doctor/physician.
P362+P364	Take off contaminated clothing and wash before reuse.
P391	Collect spillage.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P410	Protect from sunlight
P501	Dispose of contents/container to ...
Special rule for labelling of PPP:	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.

Further labelling statements under Regulation (EC) No 1272/2008:
EUH 208 - Contains prothioconazole. May produce allergic reactions.

2.2.3 Standard phrases under Regulation (EC) No 547/2011

None

2.3 Other phrases notified under Regulation (EC) No 547/2011

2.3.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Human health protection	
SB001	Avoid any unnecessary contact with the product. Misuse can lead to health damage.
SB005	If medical advice is needed, have product container or label at hand.
SB010	Keep out of the reach of children.
SB111	Concerning the requirements for personal protective gear for handling the plant protection product the material safety data sheet and the instructions for use of the plant protection product as well as the guideline "Personal protective gear for handling plant protection prod-ucts" of the Federal Office of Consumer Protection and Food Safety (www.bvl.bund.de) must be observed.
SB166	Do not eat, drink or smoke when using this product.
SB199	When applying the product with tractor-mounted, trailed or self-propelled application equipment, only vehicles with closed pressurized cabins (e.g. cabin category 3, if no respiratory protective equipment or particle-filtering masks are necessary or category 4, if gas-tight respiratory protective equipment is needed acc. to EN 15695-1 and -2) are suited to replace personal protective equipment during application. During all other activities outside of the cabin the prescribed personal protective equipment must be worn. In order to avoid contamination of the cabin, it is not permitted to enter the cabin with contaminated personal protective equipment (it should be deposited e.g. in an appropriate storage facility). Contaminated gloves should be washed before removing the gloves and hands should be washed before entering the cabin with pure water, respectively.
SE110	Wear tight fitting eye protection when handling the undiluted product.
SF266	Treated areas/crops may not be entered until the spray coating has dried. While entering the treated areas/crops long work clothing, protective gloves and sturdy shoes must be worn.
SS110	Wear standard protective gloves (plant protection) when handling the undiluted product.
SS120	Wear standard protective gloves (plant protection) when handling/applying the product ready for application.
SS2101	Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.
SS2202	Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when applying/handling the product ready for application.

SS610	Wear a rubber apron when handling the undiluted product.
Integrated pest management (IPM)/sustainable use	
WH952	The indication identifying the mode of action must be assigned directly to each corresponding name of the active substance as supplementary information on the packaging and in the instructions for use.
NN2001	The product is classified as slightly harmful for populations of relevant beneficial insects.
NN3002	The product is classified as harmful for populations of relevant predatory mites and spiders.
WMFC2	Mode of action (FRAC-group): C2 (for bixafen)
WMFG1	Mode of action (FRAC-group): G1 (for prothioconazole)
WMFC2	Mode of action (FRAC group): C2 (for fluopyram)
Ecosystem protection	
NW 262	The product is toxic for algae.
NW 264	The product is toxic for fish and aquatic invertebrates.
NW 265	The product is toxic for higher aquatic plants.
NW 468	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use	
NB6641	The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorisation is applied. (B4)

2.3.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions (mandatory labelling):
See 2.4 (Product uses)

Integrated pest management (IPM)/sustainable use	
WW7041 for uses -007, -011, -013 and -032	Resistance to this active substance, or an active substance contained in this product, was proved to exist. Application only within the framework of a suitable resistance management.
Ecosystem protection	
NW 605-1	When applying the product on areas adjacent to surface waters – except only occasionally

00-001 to 00-007; 00-015 to 00-019 00-022 to 00-033	but including periodically water bearing surface waters – the product must be applied with equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 ('Bundesanzeiger' [Federal Gazette] No 205, p. 9780) as amended. Depending on the drift reduction classes for the equipment stated below, the following buffer zones must be kept from surface waters. In addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times for drift reduction classes marked with "*". Drift reduction by 90% * 75 % 5 50% 5 m
NW 606 00-001 to 00-007; 00-015 to 00-019 00-022 to 00-033	The only case in which the product may be applied without loss reducing equipment is when at least the buffer zone stated below is kept from surface waters – except only occasionally but including periodically water bearing surface waters. Violations may be punished by fines of up to 50 000 Euro. Buffer zone of 10 m
NW701 00-001 to 00-007; 00-015 to 00-019 00-022 to 00-033	Between treated areas which have an incline of more than 2 % and surface waters – including periodically but excluding occasionally water-bearing surface waters – there must be a buffer zone under complete plant cover. The buffer zone's protective function must not be impaired by the use of implements. It must be at least 5 m wide. This buffer zone is not necessary if: -sufficient catching systems are available for the water and soil transported by run-off, which do not flow into surface water or are not connected with the urban drainage system or -the product is used for conservation or no-tillage methods.
NW605-1 00-008 to 00-014; 00-020 to 00-021	When applying the product on areas adjacent to surface waters – except only occasionally but including periodically water bearing surface waters – the product must be applied with equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 ('Bundesanzeiger' [Federal Gazette] No 205, p. 9780) as amended. Depending on the drift reduction classes for the equipment stated below, the following buffer zones must be kept from surface waters. In addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times for drift reduction classes marked with "*". Drift reduction by 90% * 75 % 5 50% 5 m
NW606 00-008 to 00-014; 00-020 to 00-021	The only case in which the product may be applied without loss reducing equipment is when at least the buffer zone stated below is kept from surface waters – except only occasionally but including periodically water bearing surface waters. Violations may be punished by fines of up to 50 000 Euro. Buffer zone of 5 m

2.4 Product uses

- Insert the GAPs for which the product will be approved

The draft Part A will be applicant's proposal for product use; this should be modified by the reviewer following the evaluation.

PPP (product name/code) Ascra Xpro
active substance 1 Prothioconazole
active substance 2 Fluopyram
active substance 3 Bixafen

Formulation type: EC
Conc. of as 1: 130 g/L
Conc. of as 2: 65 g/L
Conc. of as 3: 65 g/L

Applicant: Bayer CropScience
Zone(s): central EU

professional use ☒
non professional use ☐

Verified by MS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			PHI (days)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	wheat TRZSS	F	stem break of cereals *Pseudocercosporella herpotrichoides* PSDCHE	spraying	BBCH 30 - 32 from spring at beginning of infestation and/or when first	a) 1 b) 2	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b)	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (10 m) NW701

						symptoms become visible			as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha			
002	DE	wheat TRZSS	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (10 m) NW701
003	DE	wheat TRZSS	F	leaf spot of wheat *Septoria tritici* SEPTTR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (10 m) NW701
004	DE	wheat TRZSS	F	tan spot of cereals *Drechslera tritici-repentis* PYRNTR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (10 m) NW701
005	DE	wheat TRZSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 61 from spring at beginning of	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (10 m)

						infestation and/or when first symptoms become visible			as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha			NW701
006	DE	wheat TRZSS	F	stripe rust of grasses *Puccinia striiformis* PUCCST	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (10 m) NW701
007	DE	wheat TRZSS	F	septoria leaf spot *Septoria nodorum* LEPTNO	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F*	WW7041: Resistance to this active substance, or an active substance contained in this product, was proved to exist. Application only within the framework of a suitable resistance management. NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (10 m) NW701
008	DE	barley HORVX	F	stem break of cereals *Pseudocercosporella herpotrichoides* PSDCHE	spraying	BBCH 30 - 34 from spring at beginning of infestation and/or	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (5 m)

						when first symptoms become visible			b) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha			
009	DE	barley HORVX	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (5 m)
010	DE	barley HORVX	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (5 m)
011	DE	barley HORVX	F	net blotch *Pyrenophora teres* PYRNTE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha	100 - 400	F*	WW7041: Resistance to this active substance, or an active substance contained in this product, was proved to exist. Application only within the framework of a suitable resistance management. NW605-1 (90%: *; 75%: 5; 50%: 5 m)

												NW606 (5 m)
012	DE	barley HORVX	F	brown rust of barley *Puccinia hordei* PUCCHD	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (5 m)
013	DE	barley HORVX	F	Ramularia leaf spot disease *Ramularia collo-cygni* RAMUCC	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha	100 - 400	F*	WW7041: Resistance to this active substance, or an active substance contained in this product, was proved to exist. Application only within the framework of a suitable resistance management. NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (5 m)
014	DE	barley HORVX	F	decrease of non-parasitic leaf spots YBFMI	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (5 m)

015	DE	rye SECCE	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (10 m) NW701
016	DE	rye SECCE	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F*	The use cannot be authorised due to insufficient efficacy trials, conducted only with 1 application not with 2 applications applied for. Therefore, use no.030 can be authorised with 1 application because enough trials were submitted for that use. NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (10 m) NW701
017	DE	triticale TTLSS	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (10 m) NW701

018	DE	triticale TTLSS	F	septoria-species *Septoria spp.* SEPTSP	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (10 m) NW701
019	DE	triticale TTLSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F*	The use cannot be authorised due to insufficient efficacy trials NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (10 m) NW701
020	DE	oat AVESS	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha	100 - 400	F*	The use cannot be authorised due to insufficient efficacy trials NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (5 m)
021	DE	oat AVESS	F	crown rust of oats *Puccinia coronata* PUCCCA	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b) as1: 156 g as/ha	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (5 m)

						become visible			as2: 78 g as/ha as3: 78 g as/ha			
022	DE	wheat TRZSS	F	stem break of cereals *Pseudocercosporella herpotrichoides* PSDCHE	spraying	BBCH 30 - 32 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (10 m) NW701 Use was withdrawn by the applicant because it is covered by the same use with 2 applications.
023	DE	wheat TRZSS	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (10 m) NW701 Use was withdrawn by the applicant because it is covered by the same use with 2 applications.
024	DE	wheat TRZSS	F	leaf spot of wheat *Septoria tritici* SEPTTR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (10 m) NW701 Use was withdrawn by the applicant because it is covered by the same use with 2 applications.
025	DE	wheat TRZSS	F	tan spot of cereals *Drechslera tritici-repentis* PYRNTR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (10 m) NW701

						when first symptoms become visible			b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha			Use was withdrawn by the applicant because it is covered by the same use with 2 applications.
026	DE	wheat TRZSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (10 m) NW701 Use was withdrawn by the applicant because it is covered by the same use with 2 applications.
027	DE	wheat TRZSS	F	stripe rust of grasses *Puccinia striiformis* PUCCST	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (10 m) NW701 Use was withdrawn by the applicant because it is covered by the same use with 2 applications.
028	DE	wheat TRZSS	F	septoria leaf spot *Septoria nodorum* LEPTNO	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (10 m) NW701 Use was withdrawn by the applicant because it is covered by the same use with 2 applications.
029	DE	rye SECCE	F	leaf blotch of cereals *Rhynchosporium secalis*	spraying	BBCH 30 - 61 from spring at	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m)

				RHYNSE		beginning of infestation and/or when first symptoms become visible			as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha			NW606 (10 m) NW701 Use was withdrawn by the applicant because it is covered by the same use with 2 applications.
030	DE	rye SECCE	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (10 m) NW701
031	DE	triticale TTLSS	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F*	NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (10 m) NW701 Use was withdrawn by the applicant because it is covered by the same use with 2 applications.
032	DE	triticale TTLSS	F	septoria-species *Septoria spp.* SEPTSP	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F*	WW7041: Resistance to this active substance, or an active substance contained in this product, was proved to exist. Application only within the framework of a suitable resistance management.

												NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (10 m) NW701 Use was withdrawn by the applicant because it is covered by the same use with 2 applications.
033	DE	triticale TTLSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F*	The use cannot be authorised due to insufficient efficacy trials. Use was withdrawn by the applicant. NW605-1 (90%: *; 75%: 5; 50%: 5 m) NW606 (10 m) NW701

* The PHI is covered by the conditions of use and/or the vegetation period remaining between the application of the plant protection product and the use of the product (e. g. harvest) or the setting of a PHI in days is not required resp.

Remarks:

(1) Numeration of uses in accordance with the application/as verified by MS
(2) Member State(s) or zone for which use is applied for
(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(4) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(5) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds, developmental stages
(6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(7) Growth stage of treatment(s) (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(8) The maximum number of applications possible under practical conditions of use for each single application and per year (permanent crops) or crop (annual crops) must be provided
(9) Min. interval between applications (days) were relevant
(10) The application rate of the product a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. kg or L product / ha)
(11) The application rate of the active substance a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. g or kg / ha)
(12) The range (min/max) of water volume under practical conditions of use must be given (L/ha)
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions/minor use etc.

3 Risk management

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties (Part B, Section 1, Points 2 and 4)

Overall Summary:

The product 'Bixafen + Fluopyram + Prothioconazole EC 260 (65+65+130 g/L) is an emulsifiable concentrate All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a clear light brown liquid with a rancid odour. It is not explosive, has no oxidising properties. It has a self-ignition temperature of 360 °C. In aqueous solution, it has a pH value around 6.

The stability data indicate a shelf life of at least 2 years at ambient temperature in HDPE/PA and HDPE/EVOH.

The formulation must be protected from sunlight (P410), otherwise the content of the relevant impurity prothioconazol-desthio could increase above the acceptable level.

The technical characteristics are acceptable for an emulsifiable concentrate formulation.

Implications for labelling: none

Compliance with FAO specifications:
There are no FAO specifications published.

Compliance with FAO guidelines:
The product Ascra Xpro complies with the general requirements for EC formulations according to the FAO/WHO manual (2016).

Compatibility of mixtures:
No tank mixtures are recommended.

Nature and characteristics of the packaging:
Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

Nature and characteristics of the protective clothing and equipment:
Information regarding the required protective clothing and equipment for the safe handling of Ascra Xpro has been provided and is considered to be acceptable.

3.1.2 Methods of analysis (Part B, Section 2, Point 5)

3.1.2.1 Analytical method for the formulation (Part B, Section 2, Point 5.2)

The active substances bixafen, fluopyram and prothioconazole (this ingredient is stabilized by L-cysteine-hydrochloride-monohydrate) are dissolved in acetonitril / water, chromatographed on a HPLC reversed phase system with UV-detection and external calibration. The method is sufficiently validated.

There is no CIPAC method available for the determination of bixafen orfluopyram or prothioconazole in EC-formulations like BIX+FLU+PTZ EC 260 (65+65+130 g/l).
The method for the determination of prothioconazole-desthio in the formulation was found to be valid.
The method for the determination of the impurity toluene in formulations was found to be valid.

3.1.2.2 Analytical methods for residues (Part B, Section 2, Points 5.3 – 5.8)

Adequate analytical methods are available to monitor all compounds given in the respective residue definition of bixafen, fluopyram and prothioconazole in food of plant and animal origin, soil, water and air.
Bixafen residues can be monitored by LC-MS/MS. Fluopyram residues can be monitored in food of plant origin by GC-MS and in food of animal origin, soil, water and air by LC-MS/MS. Prothioconazole residues can be monitored in food of plants and soil by GC-MS and LC-MS/MS and in food of animal origin, water and air by LC-MS/MS.
Methods for body fluids and tissues are not required, because bixafen, fluopyram and prothioconazole are not considered to be toxic or very toxic (T / T+) nor are they classified according to GHS as follows: Acute toxicity (cat. 1 - 3), CMR (cat. 1) or STOT (cat. 1).

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

Acute toxicity studies for Ascra Xpro were not evaluated as part of the EU review of bixafen, fluopyram or prothioconazole. Therefore, all relevant data were provided and are considered adequate.
Ascra Xpro, containing 65 g/L bixafen, 65 g/L fluopyram and 130 g/L prothioconazole is toxic in respect to acute oral toxicity (H302) and has a low toxicity in respect dermal toxicity. It is not irritating to the rabbit skin but to the rabbit eye (H318). It has been found to be sensitizing to mouse skin (H317).

3.1.3.2 Operator Exposure

Operator exposure to Ascra Xpro was not evaluated as part of the EU review of bixafen, fluopyram or prothioconazole for this submitted rate/crop. Therefore all relevant data and risk assessments have been provided and are considered to be adequate.
Operator exposure was assessed against the AOEL agreed in the EU review (bixafen 0.13 mg/kg bw/d, metabolite M44 0.3 mg/kg bw/d, fluopyram 0.05 mg/kg bw/d, prothioconazole 0.2 mg/kg bw/d, desthio-prothioconazole 0.01 mg/kg bw/d). According to the model calculations (German Model), it can be concluded that the risk for the operator using Siltra Xpro in cereals is acceptable with the use of personal protective equipment described in 2.3.1.

3.1.3.3 Bystander Exposure

The bystander and/or resident exposure estimations indicated that the acceptable operator exposure level (AOEL) for bixafen, fluopyram and prothioconazole will not be exceeded under conditions of intended uses.

3.1.3.4 Worker Exposure

The worker exposure was estimated using the model “German model”. If prediscribed PPE is worn the estimated consumption of AOEL was below 15 % for all active substances and relevant metabolites.

Implications for labelling resulting from operator, worker, bystander assessments:

See 2.2

3.1.3.5 Groundwater Metabolites

As described in Part B.8 the bixafen-metabolite M44 is of no toxicological relevance in the groundwater.

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

Fundamental residue data on bixafen and prothioconazole like metabolism are already evaluated previously and is described in detail in the respective DARs.
The data available is considered sufficient for risk assessment. An exceedance of the current MRLs in cereals (bixafen: 0.5 mg/kg for barley and oats, 0.05 mg/kg for wheat, rye, triticale and spelt; fluopyram: 0.1 mg/kg for barley and oats; 0.8 mg/kg for wheat, rye, triticale and spelt; prothioconazole: 0.2 mg/kg for barley; 0.05 mg/kg for oats and rye, 0.1 mg/kg for wheat, triticale and spelt) as laid down in Reg. (EU) 396/2005 is not expected.
It is noted however that EFSA identified a data gap for bixafen "to provide rotational crop field trials on cereals, leafy vegetables and root vegetables at a dose rate covering the calculated minimum plateau concentration of bixafen and to determine the residue levels of bixafen and metabolites M21, M43, M44 and M20". Germany believes that the issue of residues in rotational crops has already been sufficiently elucidated with respect to the GAPs applied for in Germany. Since

(i) the intended and authorized uses of bixafen in Germany are only on cereals and continuous cultivation and treatment with bixafen is unlikely,
(ii) residues in rotational crops seen in the confined studies were only slightly above 0.01 mg/kg and consisted predominantly of bixafen and bixafen-desmethyl (M21),
(iii) the experimental conditions in the confined study (bare soil application) and the plateau calculation parameters were very conservative,

MRL compliance for rotational crops under realistic field conditions is assumed.

3.1.4.2 Consumer exposure

An estimation of dietary intake using EFSA PRIMo results in a maximum consumption of the respective ADIs/ARfDs below 100 %.

Substance	ADI/ARfD	Model / Diet	ADI/ARfD Consumption
Bixafen	ADI: 0.02 mg/kg bw/d	TMDI, EFSA PRIMo, NL children	11 %
	ARfD: 0.2 mg/kg bw	IESTI, EFSA PRIMo, UK infants	< 1 %
Fluopyram	ADI: 0.012 mg/kg bw/d	NEDI, German NVS II, DE children	89 %
	ARfD: 0.5 mg/kg bw	IESTI, EFSA PRIMo rev.2, NL adults	< 1 %
Prothioconazole	ADI: 0.01 mg/kg bw/d	IEDI, EFSA PRIMo rev.2, WHO cluster diet B	10 %
	ARfD: 0.01 mg/kg bw	IESTI, EFSA PRIMo rev.2, NL adults	4 %

The chronic and the short-term intake of bixafen fluopyram and prothioconazole residues are unlikely to present a public health concern.

3.1.5 Environmental fate and behaviour (Part B, Section 5, Point 9)

A full exposure assessment for the plant protection product Ascra Xpro in its intended uses in cereals is documented in detail in the core assessment of the plant protection product Ascra Xpro dated from June 2015 performed by Germany.

The following chapters summarise specific exposure assessment for soil and surface water and the specific risk assessment for groundwater for the authorization of Ascra Xpro in Germany according to its intended use in cereals (Use No. 00-001 to 00-033).

For reasons of better readability the intended uses in of the plant protection product Ascra Xpro in Germany are summarised as follows:

Group*	**Crop/ growth stage**	**Application method / Drift scenario**	**Number of applications, Minimum application interval, interception, application time**	**Application rate, cumulative (g as/ha)**	**Soil effective application rate (g as/ha)**
A/ 00-001 to 00-007; 00-015 to 00-019	cereals (wheat, rye, triticale) BBCH 30-61	spraying / field crops	2 x, 14 d, 19.04. 1. 70 % 2. 70 %	Bixafen 2 x 97.5 = 195 Fluopyram 2 x 97.5 = 195 Prothioconazole 2 x 195 = 390	Bixafen 1. 29.25 2. 29.25 = 58.5 Fluopyram 1. 29.25 2. 29.25 = 58.5 Prothioconazole 1. 58.5 2. 58.5 = 117
B/ 00-008 to 00-014; 00-020 to 00-021	cereals (barley, oats) BBCH 30-61	spraying / field crops	1 x, 19.04. 70 %	Bixafen 78 Fluopyram 78 Prothioconazole 156	Bixafen 23.4 Fluopyram 23.4 Prothioconazole 46.8
C/ 00-022 to 00-033	cereals (wheat, rye, triticale) BBCH 30-61	spraying / field crops	1 x, 19.04. 70 %	Bixafen 97.5 Fluopyram 97.5 Prothioconazole 195	Bixafen 29.25 Fluopyram 29.25 Prothioconazole 58.5

* For administrative purposes, each intended use of a plant protection product in Germany is assigned with an individual use number from the German Federal Office of Consumer Protection and Food Safety (BVL).

Prothioconazole

Degradation in soil of Prothioconazole is rather fast with a half time (geo mean) of 1.8 days under laboratory conditions. During degradation of the active substance two soil metabolites occur – M01 and M04. The two metabolites show also a fast degradation in soil with DT_{50} values around 10 days.

The active ingredient is not stable. Therefore, the Koc-value was calculated with PcKocwin V 2.0 to 2920. Furthermore, the Koc of Prothioconazole was calculated using aged residues leaching studies to 1765. The metabolite M01 is also well adsorbed to soil with a Kfoc of 2556. Also the metabolite M-04 is strongly adsorbed to soil with Kfoc 575.

The degradation behaviour of Prothioconazole water/sediment systems showed that Prothioconazole rapidly dissipated in both systems. The DT50 values of Prothioconazole were calculated to be ca. 2 – 24 days referring to the entire system The metabolites exceeding 10% of the applied radioactivity in the entire system were identified as JAU 6476-S-methyl (M01), JAU 6476-desthio (M04) and 1,2,4-triazole (M13). Among these metabolites, JAU 6476-desthio (M04) and 1,2,4-triazole (M13) were detected in the water layer at > 10% of the applied radioactivity. In the sediment extracts JAU 6476-desthio (M04) was the only major metabolite.

Bixafen
Under laboratory conditions the degradation of Bixafen in soil is negligible. The occurring metabolite M44 demonstrates slow degradation behaviour in soil with a DT_{50} of (geo.mean.) 154.5 days.
Under field conditions a slow degradation could be observed with a DT_{50} of (geo.mean) 200.3 days.
DT90 values are above one year accumulation in soil occurs and is confirmed by 8 year accumulation study.

The active substance is strongly adsorbed to the soil with a (arith.mean) Kfoc 3869. The metabolite shows only a weak adsorption with a Kfoc of (arith.mean) 6.

In the water sediment-system dissipation time in the water-phase could be demonstrated to be around 25 days. Concerning the whole system a default half-time of 1000 days was considered.

Fluopyram
Fluopyram is only slowly degraded in soil. Half-lives are in a range of 160 to 830 days under laboratory conditions. Neither a high amount of bound residues (< 15 %) nor a high rate of mineralization (< 24 %) was observed. Under field condition shorter DT50 values could be derived but still the DT90 is clearly above a year. Due to the long degradation times in soil also possible chronic effects on soil organisms have to be assessed. Kfoc for Fluopyram is in a medium range with 233 to 400 mg/L.

In the water/sediment study a DT 50 in the water phase of 110 days was demonstrated. The active substance is translocated into the sediment to a max. degree of 70 % after 120 days.

No relevant soil metabolites have to be considered.

Metabolites

Bixafen

No new study on the fate and behaviour of Bixafen or Ascra Xpro has been performed. Hence no potentially new metabolites need to be considered for environmental risk assessment.

The risk assessment for the metabolites of Bixafen has already been performed for EU approval (see EFSA Journal 2012; (11):2917). The metabolite M44 is considered ecotoxicologically not relevant. Therefore no new risk assessment hence no exposure assessment for these metabolite is necessary.

However, in the specific groundwater risk assessment for Germany considering the entry path surface run-off and drainage with subsequent bank filtration the soil metabolites of Bixafen are included.

Fluopyram

No new study on the fate and behaviour of Fluopyram or Ascra Xpro has been performed. Hence no potentially new metabolites need to be considered for environmental risk assessment.

The risk assessment for the metabolite of Fluopyram has already been performed for EU approval (see SANCO/11456/2013 rev 2 – 16/07/2013).

Prothioconazole

No new study on the fate and behaviour of Prothioconazole or Ascra Xpro has been performed. Hence no potentially new metabolites need to be considered for environmental risk assessment.

The risk assessment for the metabolites of Prothioconazole has already been performed for EU approval (see SANCO/3923/07 – 10/12/2007). Therefore no new risk assessment hence no exposure assessment for these metabolites is necessary.

However, the leaching potential into groundwater of the soil metabolites of Prothioconazole will be assessed for the application of the plant protection product and its intended uses in cereals.

Additionally, the soil metabolites of Prothioconazole were also included in the groundwater risk assessment considering the entry path surface run-off and drainage with subsequent bank filtration.

3.1.5.1 Predicted Environmental Concentration in Soil (PECsoil) (Part B, Section 5, Points 9.4 and 9.5)

For the intended use of the plant protection product Ascra Xpro in cereals according to use No A

PECsoil was calculated for the active substance Bixafen considering a soil depth of 1 cm. Due to the slow degradation of the active substance Bixafen in soil the accumulation potential of Bixafen was considered. Therefore PEC_{soil} used for risk assessment comprises background concentration in soil (PEC_{accu}) deducated from the soil accumulation study (Heinemann, Weuthen 2013) given for a depth of 10 cm and the maximum annual soil concentration PEC_{act} considering the relevant soil depth of 5.0 cm.

A factor of 3.7 between the concentration resulting from one application and the background concentration is derived from the soil accumulation study by Heinemann, Weuthen (2013).

As no plateau was not reached during the 8 years of the study, an extrapolation of the background concentration was performed by ZRMS. The measured background concentration after 8 years for a substance with a DT_{50} of 1235 days represents only 80% of the calculated background concentration for a substance with such a long DT_{50} value. Further, as no plateau was reached, we used additionally an uncertainty factor of 10 for the low background concentration.

Based on all informations about the degradation in soil of Bixafen coming from laboratory studies, field studies, and the soil accumulation study, Bixafen is very persistent. In this respect, the behaviour of Bixafen in soil is source of great concern.

Finally, this revised background concentration was added to the maximum annual soil concentration PEC_{act} in a soil depth of 20 cm.

Table: Overview PECsoil values relevant for risk assessment

active substance/ formulation	**soil relevant application rate (g/ha)**	**soil depth$_{act}$ (cm)**	**PEC$_{act}$ (mg/kg)**	**tillage depth (cm)**	**PEC$_{bkgd}$ (mg/kg)**	**PEC$_{accu}$ = PEC$_{act}$ + PEC$_{bkgd}$ (mg/kg)**
Ascra Xpro	2 x 455	1.0	6.0667	-	-	-

Ascra Xpro	2 x 455	2.5	2.4267	-	-	-
Bixafen	2 x 29.25	1.0	0.3885	20	0.7566	1.1451
Fluopyram	2 x 29.25	2.5	0.1494	20	0.0235	0.1730
Prothioconazole	2 x 58.5	1.0	0.3968	-	-	-
JAU6476-S-methyl (M01)	2 x 8.6	1.0	0.0950	-	-	-
JAU6476-desthio (M04)	2 x 30.3	1.0	0.3724	-	-	-

* Ascra Xpro-density: 1.010 g/ml, 1.5 L/ha applied

PECsoil was calculated for the active substance Fluopyram considering a soil depth of 2.5 cm. Due to the slow degradation of the active substance Fluopyram in soil the accumulation potential of Fluopyram was considered. Therefore PECsoil used for risk assessment comprises background concentration in soil (PECaccu) considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops) and the maximum annual soil concentration PECact considering the relevant soil depth of 2.5 cm or 1.0 cm, respectively.

PECsoil was calculated for the active substance Prothioconazole considering a soil depth of 1.0 cm. Due to the fast degradation of the active substance Prothioconazole in soil the accumulation potential of Prothioconazole was not considered.

The results for PEC soil for the active substances and the metabolites were used for the eco-toxicological risk assessment.

However, in order to investigate the high persistency of bixafen due to the exposure under field conditions in agricultural practice, this product authorisation has to be combined with

- a 2 years monitoring study regarding the environmental fate of bixafen in soils.

Consequences for authorization:

The submission of the data is mandatory until 31.12.2020.

3.1.5.2 Predicted Environmental Concentration in Ground Water (PECGW) (Part B, Section 5, Point 9.6)

1. Direct leaching into groundwater

Results of modelling with FOCUS PELMO 5.5.3 show that the active substance Bixafen is not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended of Ascra Xpro uses in cereals according to use group A.

For the metabolite M44 concentrations of ≥ 0.1µg/L in groundwater cannot be excluded.

Table: PEC_{GW} at 1 m soil depth for Bixafen and its metabolites for the application of Ascra Xpro in cereals (based on geom. mean for DT_{50} value and arithm. mean for K_{Foc})

Crop/Group/use	**Scenario**	**80th percentile PEC_{GW} at 1 m soil depth (µg L^{-1})**

No.		groundwater model: FOCUS PELMO 5.5.3		
		Bixafen	**metabolite M44**	
A/Wintercereals	**Châteaudun**	<0.001	0.486	
	Hamburg	<0.001	1.652	
	Jokioinen	<0.001	2.158	
	Kremsmünster	<0.001	1.036	
	Okehampton	<0.001	1.115	
	Piacenza	<0.001	0.863	
	Porto	<0.001	0.808	
	Sevilla	<0.001	0.272	
	Thiva	<0.001	0.386	

Results of modelling with FOCUS PELMO 5.5.3 show that the active substance Fluopyram is not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended of Ascra Xpro uses in cereals according to use group A.

For the metabolite of Fluopyram concentrations of ≥ 0.1µg/L in groundwater can be excluded.

Results of modelling with FOCUS PELMO 5.5.3 show that the active substance Prothioconazole is not expected to penetrate into groundwater at concentrations of ≥ 0.1 µg/L in the intended of Ascra Xpro uses in cereals according to use group A.

For the metabolites of Prothioconazole concentrations of ≥ 0.1 µg/L in groundwater can be excluded.

2. Ground water contamination by bank filtration due to surface water exposure via run-off and drainage

As the reduction by bank filtration is assumed to be 100 % for Bixafen, no calculation is necessary.

According modelling with EXPOSIT 3.01, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance Fluopyram due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

According modelling with EXPOSIT 3.01, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance Prothioconazole due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

According to modelling with EXPOSIT 3.01, groundwater contamination at concentrations ≥ 0.1 µg/L by the soil metabolites of Prothioconazole due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

3.1.5.3 Predicted Environmental Concentration in Surface Water (PECSW) (Part B, Section 5, Points 9.7 and 9.8)

For the intended use of the plant protection product Ascra Xpro in cereals according to use No A PECsw was calculated for the active substances Bixafen, Fluopyram and Prothioconazole considering the two routes of entry (i) spraydrift and volatilization with subsequent deposition and (ii) run-off, drainage separately.

The calculation of concentrations in surface water was based on spray drift data by Rautmann and Ganzelmeier.
The vapour pressure at 20 °C of the active substance Bixafen is < 10^{-5} Pa. Hence the active substance Bixafen is regarded as non-volatile. Therefore, exposure of surface water by the active substance Bixafen due to deposition following volatilization was not considered.
The vapour pressure at 20 °C of the active substance Fluopyram is < 10^{-5} Pa. Hence the active substance Fluopyram is regarded as non-volatile. Therefore, exposure of surface water by the active substance Fluopyram due to deposition following volatilization was not considered.
The vapour pressure at 20 °C of the active substance Prothioconazole is < 10^{-5} Pa. Hence the active substance Prothioconazole is regarded as non-volatile. Therefore, exposure of surface water by the active substance Prothioconazole due to deposition following volatilization was not considered.
The concentrations of the active substance Bixafen, Fluopyram and Prothioconazole in adjacent ditch due to surface run-off and drainage were calculated using the model EXPOSIT.

Table: Summary of PEC_{sw} values for the intended use in cereals (use group A – covers use groups B and C) used for German risk assessment

active substance/ formulation (2 appl. 82 Perc)	**PECsw Spray-Drift (incl. volatilisation)** [µg/L] – with 1 m default buffer - scenario agriculture	**PECsw run-off** [µg/L] – without buffer	**PECsw drainage** [µg/L] – scenario autumn/winter/early spring	**PECsw drainage** [µg/L] – scenario spring/summer
Prothioconazole	2.852	n.c.	n.c.	n.c.
JAU 6476-desthio	2.852	0.40	0.03	0.01
Bixafen	1.316	0.19	0.03	0.01
Fluopyram	1.316	n.c.	n.c.	n.c.
Preparation Ascra Xpro	19.854	-	-	-

n.c. - not calculated

The results for PEC surface water for the active substance and its metabolites were used for the eco-toxicological risk assessment.

3.1.5.4 Predicted Environmental Concentration in Air (PECAir) (Part B, Section 5, Point 9.9)

The vapour pressure at 20 °C of the active substance Bixafen is < 10^{-5} Pa. Hence the active substance Bixafen is regarded as non-volatile. Therefore, exposure of surface water by the active substance Bixafen due to deposition following volatilization was not considered.
The vapour pressure at 20 °C of the active substance Fluopyram is < 10^{-5} Pa. Hence the active substance Fluopyram is regarded as non-volatile. Therefore, exposure of surface water by the active substance Fluopyram due to deposition following volatilization was not considered.
The vapour pressure at 20 °C of the active substance Prothioconazole is < 10^{-5} Pa. Hence the active substance Prothioconazole is regarded as non-volatile. Therefore, exposure of surface water by the active substance Prothioconazole due to deposition following volatilization was not considered.

Implications for labelling resulting from environmental fate assessment:

For the authorization of the plant protection product Ascra Xpro following labeling and conditions of use are mandatory:
Classification and labelling
Based on the data on the active substance Bixafen the plant protection product Ascra Xpro is considered to be not readily degradable in the sense of the CLP regulation.
Standard Phrases for special risks and safety precautions under Regulation (EU) 547/2011 Annex II and III / conditions of use
none
Further data requirements:

3.1.6 Ecotoxicology (Part B, Section 6, Point 10)

A full risk assessment according to Uniform Principles for the plant protection product Ascra Xpro in its intended uses in cereals is documented in detail in the core assessment of the plant protection product Ascra Xpro dated from May 2017 performed by Germany. The intended use of Ascra Xpro in Germany is generally covered by the uses evaluated in the course of the core assessment.
The following chapters summarise specific risk assessment for non-target organisms and hence risk mitigation measures for the authorization of Ascra Xpro in Germany according to its intended use in cereals (use No. 00-001 to 00-033).

3.1.6.1 Effects on Terrestrial Vertebrates (Part B, Section 6, Points 10.1 and 10.3)

The risk assessment for effects on birds and other terrestrial vertebrates was carried out according to the European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438).

Table: Endpoints used for risk assessment for birds and mammals

Test system	Species	Results
Prothioconazole		
Acute toxicity	*Colinus virginianus* (Bobwhite quail)	LD_{50} > 2000 mg/kg bw
Reproductive toxicity	*Anas platyrhynchos*	NOEL 78 mg/kg bw/d
Acute toxicity	*rat*	LD_{50} > 6200 mg/kg bw
Reproductive toxicity	*rat*	NOEL parental = 9.7 mg/kg bw/d
JAU 6476-Desthio (prothioconazol metabolite)		
Acute toxicity	*Colinus virginianus* (Bobwhite quail)	LD_{50} > 2000 mg/kg bw
Reproductive toxicity	*Colinus virginianus* (Bobwhite quail)	NO(A)EL 14.8 mg/kg bw/d
Acute toxicity	*mouse*	LD50 = 2235 mg a.i./kg bw
Reproductive toxicity	*rat*	NOAELoffspring=10 mg/kg bw/day)
Bixafen		
Acute toxicity	*Colinus virginianus* (Bobwhite quail)	LD_{50} > 2000 mg/kg bw
Reproductive toxicity	*Colinus virginianus* (Bobwhite quail)	NOEL 24.5 mg/kg bw/d
Acute toxicity	*rat*	LD50 > 5000 mg/kg bw
Reproductive toxicity	*rat*	NOAEL = 33.3 mg a.s./kg/day
Fluopyram		
Acute toxicity	*Colinus virginianus* (Bobwhite quail)	LD_{50} > 2000 mg/kg bw
Reproductive toxicity	*Colinus virginianus* (Bobwhite quail)	NOEL 4.5 mg/kg bw/d (corresponding to 50 mg/kg feed)
Acute toxicity	*rat*	LD_{50} > 2000 mg/kg bw
Reproductive toxicity	*rat*	NOAEL=14.5 mg a.s./kg/day
Preparation Ascra Xpro		
Acute toxicity	*rat*	LD_{50} = 1420 mg/kg bw * (calculated)

* Endpoint differing from LoEP (not included) / New study submitted LD_{50}

Based on the presumptions of the screening step and Tier 1, the calculated TER values for the acute and long-term risk resulting from an exposure of birds to the active substances bixafen, fluopyram and prothioconazole as well as the prothioconazole-metabolites JAU 6476-desthio and JAU-6476-S-methyl according to the intended use of the formulation Ascra Xpro in cereals achieve the acceptability criteria TER ≥ 10 and TER ≥ 5, respectively, according to commission implementing regulation (EU) No

546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for birds.

3.1.6.2 Effects on Aquatic Species (Part B, Section 6, Point 10.2)

Results of aquatic risk assessment for the intended for uses of Ascra Xpro in cereals based on FOCUS Surface Water PEC values is presented in the core assessment, Part B, Section 6, chapter 6.4.

Substance, RAC – Regulatory acceptable Concentration (µg/L)	**Endpoint**
Bixafen: RAC: 0.46 (NOEC 4.6 µg/L, AF 10)	LC_{50} = 95 µg/L
	NOEC = 4.6 µg/L
	EC_{50} = 1200 µg/L
	NOEC = 50 µg/L
	NOEC = 15.6 µg/L
	E_bC_{50} = 59.8 µg/L
Fluopyram: RAC: 13.5 (NOEC 135 µg/L, AF 10)	LC_{50} = 1780 µg/L
	NOEC = 135 µg/L
	EC_{50} = > 434 µg/L
	NOEC = 1250 µg/L
	NOEC = 1390 µg/L
	E_bC_{50} = 3970 µg/L
Prothioconazole-metabolite JAU 6476-desthio: RAC: 0.334 µg/L (NOEC 3.34 µg/L, AF10)	LC_{50} = 6630 µg/L
	NOEC = 3.34 µg/L
	EC_{50} = 10000 µg/L
	NOEC = 100 µg/L
	NOEC = 2000 µg/L
	E_bC_{50} = 73 µg/L
Prothioconazole RAC: 1.71 µg/L (E_bC_{50} = 17.1 µg/L, AF10)	E_bC_{50} = 17.1 µg/L
ASCRA XPRO :	LC_{50} = 1770 µg/L
	EC_{50} = 3390 µg/L
	E_yC_{50} = 1910 µg/L

AF – Assessment Factor

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilization with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route.

1. Exposure by spraydrift and deposition following volatilization

Based on the relevant toxicity of the Prothioconazole-metabolite JAU 6476-desthio, the calculated TER values for the risk to aquatic organism resulting from an exposure of surface water by spraydrift to Ascra Xpro according to the uses summarized as group A only achieve the acceptability criteria of TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2 if appropriate risk mitigation measures (5 m buffer stripe or drift reducing technique > 50 %) are applied.

The uses summarized as group B and C only achieve also the acceptability criteria of TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2 if appropriate risk mitigation measures (5 m buffer stripe) are applied.

2. Exposure by surface run-off and drainage

The concentrations of Bixafen, Fluopyram and Prothioconazole in adjacent ditch due to surface runoff and drainage were calculated using the model EXPOSIT.

The calculated TER values for the risk to aquatic organisms resulting from an exposure of surface water by Prothioconazole-metabolite JAU 6476-desthio due to run-off and drainage according to the use group A only achieve the acceptability criteria of TER ≥ 100 or 10 respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. if appropriate risk mitigation measures (10 m buffer stripe) are applied

Consequences for authorization:

For the authorization of the plant protection product Ascra Xpro the following labelling and conditions of use are mandatory:

Required Labelling

NW 262	bixafen: *P. subcapitata* NOEC < 0.0156 mg/L ASCRA XPRO: *P. subcapitata* NOEC = 0.75 mg/L
NW 264	bixafen: *O. mykiss:* LC_{50} = 0.095 mg/L, *P. promelas*: NOEC = 0.0046 mg/L ASCRA XPRO: *O. mykiss:* LC_{50} = 1.77 mg/L
NW 265	prothioconazole: *L. gibba* NOEC = 0.00334 mg/L

Safety precautions / Conditions of use

ASCRA XPRO

All uses	NW 468
Use group A, C	NW 605-1/606 (common: 10 m, 50 %: 5 m, 75 %: 5 m, 90 %: * m)
Use group A, C	NW 701
Use group B	NW 605-1/606 (common: 5 m, 50 %: 5 m, 75 %: 5 m, 90 %: * m)

3.1.6.3 Effects on Bees and Other Arthropod Species (Part B, Section 6, Points 10.4 and 10.5)

Bees

Effects on bees for Ascra Xpro were not evaluated as part of the EU review of bixafen, fluopyram or prothioconazole. Therefore, all relevant data and risk assessments for Ascra Xpro with the proposed use pattern were provided and are considered adequate.

Bees may be exposed to Ascra Xpro by direct spraying while bees are foraging on flowers and weeds, through contact with fresh or dried residues or by oral uptake of contaminated pollen, nectar and honey dew.

The risks of Ascra Xpro to honey-bees were assessed from hazard quotients between toxicity endpoints, estimated from acute oral and contact studies with active ingredient and formulated product, and the maximum single application rate of 1.5 L formulation/ha (*1515 g formulation/ha*).

Toxicity

Test substance	Exposure route	LD_{50}	Reference
Ascra Xpro	oral 48 h	> 312 µg product/bee	Schmitzer S., (2013) report number: 81781035
	contact 48 h	> 200 µg product/bee	
bixafen tech.	oral 48 h	> 121.4 µg as/bee *	EFSA Journal 2012; 10(11): 2917
	contact 48 h	> 100 µg as/bee *	
fluopyram tech.	oral 48 h	>102.3 µg as/bee *	EFSA Journal 2013;11(4): 3052
	contact 48 h	> 100 µg as/bee *	
prothioconazole tech.	oral 48 h	> 71 µg as/bee *	EFSA Scientific Report (2007) 106, 1-98
	contact 48 h	> 200 µg as/bee *	

* EU agreed endpoint

Hazard quotients

Hazard quotients for oral and contact exposure according to EPPO (2003) Environmental risk assessment scheme for plant protection products (Chapter 10: Honeybees (PP 3/10(2)). Bulletin OEPP/EPPO Bulletin 33: 141-145) were calculated as follows:

Hazard Quotient = max. application rate [g product/ha] / LD_{50} [µg product/bee]

Test substance	Max. single	Exposure	LD_{50}	Hazard	HQ

	application rate [g product/ha]	route	[µg product/bee]	quotient (HQ)	trigger
Ascra Xpro	1515	oral	> 312 µg	< 4.86	50
		contact	> 200 µg	< 7.58	

All the hazard quotients are considerably less than 50, indicating that the intended uses pose a low risk to bees. Therefore, a low risk to bees is expected from the application of Ascra Xpro according to the recommended use pattern.

Other non-target arthropods

Based on the calculated drift rates of ASCRA XPRO in off-field areas, the calculated TER values taking into account the endpoint on *T.pyri* with am ER50 > 675 ml/ha describing the risk resulting from an exposure of non-target arthropods to ASCRA XPRO according to the GAP of the formulation achieve the acceptability criteria of TER ≥ 10 (Tier 1), according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target arthropods due to the intended use of ASCRA XPRO in cereals according to the label.

3.1.6.4 Effects on Earthworms and Other Soil Marco-organisms (Part B, Section 6, Point 10.6)

Table: Relevant endpoints for risk assessment of soil organisms

Species	Test item	Time scale Acute -EC50 / chronic -NOEC	Endpoint [mg/kg soil dw]
Eisenia fetida	Bixafen	Acute	> 1000
		Chronic	100
	Prothioconazole	Acute	> 1000
		Chronic	> 0.67
	JAU 6476-S-methyl	Acute	> 1000
		Chronic	50
	JAU 6476-desthio	Acute	> 500
		Chronic	0.5
	Fluopyram	Acute	500
		Chronic	5.71
	Ascra Xpro	Acute	-
		Chronic	89
Folsomia candida	Bixafen	Chronic	7.74
	Prothioconazole	Chronic	64
	JAU 6476-S-methyl	Chronic	15.8
	JAU 6476-desthio	Chronic	31.3
	Fluopyram	Chronic	No data

	Ascra Xpro	Chronic	50
Hypoaspis aculeifer	Bixafen	Chronic	6.15
	Ascra Xpro	Chronic	89

Based on the predicted concentrations of the active substances and the formulation ASCRA XPRO in soils, the TER values describing the acute and longterm risk for earthworms and other non-target soil organisms following exposure to ASCRA XPRO according to the GAP of the formulation achieve the acceptability criteria TER ≥ 10 resp. TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for soil organisms due to the intended use of ASCRA XPRO in cereals according to the label.

However, in order to investigate the high persistency of bixafen due to the exposure under field conditions in agricultural practice as well as the evidence of effects towards soil organisms in the field, this product authorisation has to be combined with

- a 2 years monitoring study on collembolans treated with a bixafen-containing product for all indications.

For details please refer to the core assessment Part B, section 6, chapter 6.7.

Consequences for authorization:

The submission of the following data is mandatory within 4 years after authorization:

- Results of a 2 years monitoring study on collembolans treated with a bixafen-containing product

3.1.6.5 Effects on organic matter breakdown (Part B, Section 6, Point 10.6)

Since no risk was identified for soil fauna, soil micro-organisms and non-target arthropods from the use of Ascra XPro in cereals, data on the effects on organic matter breakdown (litterbag) is not required although the active substance bixafen meet(s) the trigger on degradation in soil.

3.1.6.6 Effects on Soil Non-target Micro-organisms (Part B, Section 6, Point 10.7)

Based on the predicted concentrations of bixafen and ASCRA XPRO in soils, the risk to soil microbial processes following exposure to bixafen and ASCRA XPRO according to the GAP of the formulation ASCRA XPRO is considered to be acceptable according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.

3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna) (Part B, Section 6, Point 10.8)

Terrestrial plants

Relevant for the risk assessment is an ER_{50} > 1.5 L/ha as result of the vegetative vigour and also the seedling emergence study with the formulation.

Based on the predicted drift rates of ASCRA XPRO in off-field areas, the TER values describing the risk for non-target plants following exposure to ASCRA XPRO according to the GAP of the formulation achieve the acceptability criteria TER ≥ 10 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an

acceptable risk for non-target terrestrial plants due to the intended use of ASCRA XPRO in cereals according to the label.

Implications for labelling resulting from ecotoxicological assessment:

For the authorization of the plant protection product Ascra Xpro the following labelling and conditions of use are mandatory:

Classification and labelling

Relevant toxicity	Active substance: bixafen (content 6 %) LC_{50} = 0.095 mg/L (*O. mykiss*) M-factor = 10 NOEC = 0.0046 mg/L (*P. promelas*) M-factor = 10 Formulation Ascra XPro LC_{50} = 1.77 mg/L (*O. mykiss*) M-factor = -/-
Classification and labelling according to Regulation 1272/2008	
Hazard sysmbol	GHS09
Signal word	Warning
Hazard statement	H410

Standard Phrases for special risks and safety precautions under Regulation (EU) 547/2011 Annex II and III / conditions of use

All uses:

NW 468 Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

Use Group A

NW 605-1/606 When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water bearing surface waters - the product must be applied with equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 ('Bundesanzeiger' [Federal Gazette] No 205, p. 9780) as amended. Depending on the drift reduction classes for the equipment stated below, the following buffer zones must be kept from surface waters. In addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times for drift reduction classes marked with "*".Drift reduction by 90% *

75 % 5 m

50% 5 m

Common 10 m

NW 701 Between treated areas which have an incline of more than 2 % and surface waters - including periodically but excluding occasionally water-bearing surface waters - there must be a buffer zone under complete plant cover. The buffer zone's protective function must not be impaired by the use of implements. It must be at least 10 m wide. This buffer zone is not necessary if: -sufficient catching systems are available for the water and soil transported by run-off, which do not flow into surface water or are not connected with the urban drainage system or -the product is used for conservation or no-tillage methods.

Use group B

NW 605-1/606 When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water bearing surface waters - the product must be applied with equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 ('Bundesanzeiger' [Federal Gazette] No 205, p. 9780) as amended. Depending on the drift reduction classes for the equipment stated below, the following buffer zones must be kept from surface waters. In addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times for drift reduction classes marked with "*".Drift reduction by 90% *

75 % 5 m

50% 5 m

Common 5 m

Use group c

NW 605-1/606 When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water bearing surface waters - the product must be applied with equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 ('Bundesanzeiger' [Federal Gazette] No 205, p. 9780) as amended. Depending on the drift reduction classes for the equipment stated below, the following buffer zones must be kept from surface waters. In addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times for drift reduction classes marked with "*".Drift reduction by 90% *

75 % 5 m

50% 5 m

Common 10 m

NW 701 Between treated areas which have an incline of more than 2 % and surface waters - including periodically but excluding occasionally water-bearing surface waters - there must be a buffer zone under complete plant cover. The buffer zone's protective function must not be impaired by the use of implements. It must be at least 10 m wide. This buffer zone is not necessary if: -sufficient catching systems are

available for the water and soil transported by run-off, which do not flow into surface water or are not connected with the urban drainage system or -the product is used for conservation or no-tillage methods.

Other labels

NW 262	The product is toxic for algae.
NW 264	The product is toxic for fish and aquatic invertebrates.
NW 265	The product is toxic for higher aquatic plants.

3.1.7 Efficacy (Part B, Section 7, Point 8)

The plant protection product Ascra Xpro was developed by Bayer CropScience as a new fungicide product for the control of foliar diseases in cereals. It belongs to the SDH and DMI group of fungicides and has shown efficacy against a broad spectrum of the most economically important cereal diseases caused by fungi from the classes of Basidiomycetes, Ascomycetes and Deuteromycetes.

It is an EC formulation containing 65 g/L bixafen, 65 g/L fluopyram and 130 g/L prothioconazole.

The mixture bixafen, fluopyram and prothioconazole EC 260 combines the spectrum of activity of two broad spectrum carboxamides (SDHIs) with that of a typical broad spectrum de-methylation-inhibitor (DMI), and provides at the same time an efficient tool for resistance prevention by mixing products with different modes of action. Data showed that the addition of fluopyram to bixafen and prothioconazole when applied as an EC 260 co-formulation contributes to an extra activity against *Erysiphe graminis*, *Septoria tritici* and *Pyrenophora tritici-repentis* on wheat and against *Puccinia hordei*, *Pyrenophora teres* and *Ramularia collo-cygni* on barley.

Efficacy data

Data from the minimum effective dose study have shown that the rate of 1.2 L/ha in barley and oats and 1.5 L/ha in wheat, rye and triticale is needed to achieve an effective and reliable control of the main diseases.

Applied once or twice per season the formulation provided good levels of control, consistent or superior with that achieved by the reference products Aviator Xpro and Tracker (Champion/Bell) on key foliar diseases of triticale, rye and oats and, reflecting the good to excellent disease control and crop safety, delivered substantial yield benefits over the untreated.

For the applicant the high level of control and yield benefit, generated from a large data set was very consistent across the different climatic EPPO zones discussed with no differences in the level of disease control delivered by Ascra Xpro on any of the pathogens targeted. Overall, the data support the GAP and use pattern proposed.

Adverse effects

Studies have shown that undesirable effects are not expected on succeeding crops, adjacent crops, part of plants used for propagating purposes and beneficial organisms.

Studies have demonstrated that adverse effects on processing procedures are unlikely.

The resistance management intended for Ascra Xpro has been proposed and is believed to be very effective at protecting the efficacy of the product on the long term.

Ascra Xpro is classified as slightly harmful for populations of relevant beneficial insects and as harmful for populations of relevant predatory mites and spiders.

All the data regarding the efficacy of the product have been submitted. These data demonstrate that Ascra Xpro fulfils all criteria for the authorization of preparations described in Directive 97/57/EC (Uniform Principles, Annex VI to Directive 91/414/EEC). No phytotoxicity, effects on neighbouring or following crops were observed.
The uses 016, 019, 020 and 033 are insufficiently supported by efficacy trials and cannot be authorised.

3.2 Conclusions

With respect to physical, chemical and technical properties of the formulation an authorisation can be granted.
With respect to analytical methods (formulation), an authorisation can be granted.
With respect to analytical methods for residues, an authorisation can be granted.
With respect to toxicology, residues and consumer protection an authorisation can be granted.

All the hazard quotients are considerably less than 50, indicating that the intended uses pose a low risk to bees. Therefore, a low risk to bees is expected from the application of Ascra Xpro according to the recommended use pattern and can be labelled as not harmful to honey bees.

With respect to efficacy, the uses 001-015, 017-018, 021, and 030 can be authorised. Uses no. 022 – 029, and 031 - 033 were withdrawn by the applicant because they are covered by the same use with 2 applications. An authorisation for the uses 016, 019, 020, and 033 cannot be granted due to insufficient efficacy trials.

With respect to fate and ecotoxicology assessment, an authorisation can be granted. Considering an application in accordance with the evaluated use pattern and good agricultural practice as well as strict observance of the conditions of use no harmful effects on groundwater or adverse effects on the ecosystem are to be apprehended.

3.3 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

Annex II and III point	**Data**
KIIA 7.12	2 years monitoring study regarding the environmental fate of bixafen in soils.

KIIIA 10.6.6	2 years monitoring study on collembolans treated with a bixafen-containing product for all indications.

Appendix 1 – Copy of the product authorisation

See Appendix 4.

Appendix 2 – Copy of the product label

The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions made by the competent authority. The final version of the label has to fulfil the requirements according to Article 16 of Directive 91/414/EEC.

Appendix 3 – Letter of Access

Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.

Appendix 4 – Copy of the product authorisation

See below.

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
Dienstsitz Braunschweig • Postfach 15 64 • 38005 Braunschweig

Bayer CropScience
Deutschland GmbH
Registrierung & PGA
Elisabeth-Selbert-Straße 4 a
40764 Langenfeld

Dr. Claudia Bock
Referentin

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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.008219-00/00.105123
(bitte bei Antwort angeben)

DATUM 21. Dezember 2017

ZV1 008219-00/00

Ascra Xpro

Zulassungsverfahren für Pflanzenschutzmittel

Bescheid

Das oben genannte Pflanzenschutzmittel

mit den Wirkstoffen:	130 g/l	Prothioconazol
	65 g/l	Bixafen
	65 g/l	Fluopyram

Zulassungsnummer: 008219-00

Versuchsbezeichnungen: BAY-21070-F-0-EC

Antrag vom: 14. Mai 2014

wird auf der Grundlage von Art. 29 der Verordnung (EG) Nr. 1107/2009 des Europäischen Parlaments und des Rates vom 21. Oktober 2009 über das Inverkehrbringen von Pflanzenschutzmitteln und zur Aufhebung der Richtlinien 79/117/EWG und 91/414/EWG des Rates (ABl. L 309 vom 24.11.2009, S. 1), wie folgt zugelassen:

Zulassungsende

Die Zulassung endet am 31. Juli 2019.

Festgesetzte Anwendungsgebiete bzw. Anwendungen

Es werden folgende Anwendungsgebiete bzw. Anwendungen festgesetzt (siehe Anlage 1):

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
008219-00/00-007	Blatt- und Spelzen-bräune (Septoria nodorum)	Weizen	
008219-00/00-010	Blattfleckenkrankheit (Rhynchosporium secalis)	Gerste	
008219-00/00-015	Blattfleckenkrankheit (Rhynchosporium secalis)	Roggen	
008219-00/00-005	Braunrost (Puccinia recondita)	Weizen	
008219-00/00-004	DTR-Blattdürre (Drechslera tritici-re-pentis)	Weizen	
008219-00/00-009	Echter Mehltau (Ery-siphe graminis)	Gerste	
008219-00/00-017	Echter Mehltau (Ery-siphe graminis)	Triticale	
008219-00/00-002	Echter Mehltau (Ery-siphe graminis)	Weizen	
008219-00/00-006	Gelbrost (Puccinia striiformis)	Weizen	
008219-00/00-021	Haferkronenrost (Puccinia coronata)	Hafer	
008219-00/00-008	Halmbruchkrankheit (Pseudocercospo-rella herpotrichoides)	Gerste	
008219-00/00-001	Halmbruchkrankheit (Pseudocercospo-rella herpotrichoides)	Weizen	
008219-00/00-014	Minderung nichtpa-rasitärer Blattflecken	Gerste	

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
008219-00/00-011	Netzfleckenkrankheit (Pyrenophora teres)	Gerste	
008219-00/00-018	Septoria-Arten (Septoria spp.)	Triticale	
008219-00/00-003	Septoria-Blattdürre (Septoria tritici)	Weizen	
008219-00/00-013	Sprenkelkrankheit (Ramularia collo-cygni)	Gerste	
008219-00/00-012	Zwergrost (Puccinia hordei)	Gerste	

Festgesetzte Anwendungsbestimmungen

Es werden folgende Anwendungsbestimmungen gemäß § 36 Abs. 1 S. 1 des Gesetzes zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz - PflSchG) vom 6. Februar 2012 (BGBl. I S. 148, 1281), zuletzt geändert durch Artikel 4 Absatz 84 des Gesetzes vom 18. Juli 2016 (BGBl. I S. 1666), festgesetzt:

(NW468)
Anwendungsflüssigkeiten und deren Reste, Mittel und dessen Reste, entleerte Behältnisse oder Packungen sowie Reinigungs- und Spülflüssigkeiten nicht in Gewässer gelangen lassen. Dies gilt auch für indirekte Einträge über die Kanalisation, Hof- und Straßenabläufe sowie Regen- und Abwasserkanäle.
Begründung:
Die im o.g. Pflanzenschutzmittel enthaltenen Wirkstoffe Bixafen und Prothioconazol weisen aufgrund ihrer Toxizität ein hohes Gefährdungspotenzial für aquatische Organismen auf. Jeder Eintrag von Rückständen in Oberflächengewässer, der den Eintrag als Folge der bestimmungsgemäßen und sachgerechten Anwendung des Mittels entsprechend der guten fachlichen Praxis übersteigt, würde daher zu einer Gefährdung des Naturhaushaltes aufgrund von nicht akzeptablen Auswirkungen auf Gewässerorganismen führen. Da ein erheblicher Anteil der in Oberflächengewässern nachzuweisenden Pflanzenschutzmittelfrachten auf Einträge aus kommunalen Kläranlagen zurückzuführen ist, muss dieser Gefährdung durch die bußgeldbewehrte Anwendungsbestimmung durchsetzbar begegnet werden.

Siehe anwendungsbezogene Anwendungsbestimmungen in Anlage 1, jeweils unter Nr. 3.

Verpackungen

Gemäß § 36 Abs. 1 S. 2 Nr. 1 PflSchG sind für das Pflanzenschutzmittel die nachfolgend näher beschriebenen Verpackungen für den beruflichen Anwender zugelassen:

Verpackungs-art	Verpackungs-material	Anzahl		Inhalt		
		von	bis	von	bis	Einheit
Kanister	HDPE/EVOH	1	10	1,00	15,00	l
Kanister	HDPE/PA	1	10	1,00	15,00	l

Die Verpackungen für den beruflichen Anwender sind wie folgt zu kennzeichnen:
Anwendung nur durch berufliche Anwender zulässig.

Auflagen

Die Zulassung wird mit folgenden Auflagen gemäß § 36 Abs. 3 S. 1 PflSchG verbunden:

Kennzeichnungsauflagen:

(NN2001)
Das Mittel wird als schwach schädigend für Populationen relevanter Nutzinsekten eingestuft.

(NN3002)
Das Mittel wird als schädigend für Populationen relevanter Raubmilben und Spinnen eingestuft.

(NW262)
Das Mittel ist giftig für Algen.

(NW264)
Das Mittel ist giftig für Fische und Fischnährtiere.

(NW265)
Das Mittel ist giftig für höhere Wasserpflanzen.

(SB001)
Jeden unnötigen Kontakt mit dem Mittel vermeiden. Missbrauch kann zu Gesundheitsschäden führen.

(SB005)
Ist ärztlicher Rat erforderlich, Verpackung oder Etikett des Produktes bereithalten.

(SB010)
Für Kinder unzugänglich aufbewahren.

(SB111)
Für die Anforderungen an die persönliche Schutzausrüstung beim Umgang mit dem Pflanzenschutzmittel sind die Angaben im Sicherheitsdatenblatt und in der Gebrauchsanweisung des Pflanzenschutzmittels sowie die BVL-Richtlinie "Persönliche Schutzausrüstung beim Umgang mit Pflanzenschutzmitteln" des Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit (www.bvl.bund.de) zu beachten.

(SB166)
Beim Umgang mit dem Produkt nicht essen, trinken oder rauchen.

(SB199)
Wenn das Produkt mittels an den Traktor angebauten, gezogenen oder selbstfahrenden Anwendungsgeräten ausgebracht wird, dann sind nur Fahrzeuge, die mit geschlossenen Überdruckkabinen (z. B. Kabinenkategorie 3, wenn keine Atemschutzgeräte oder partikelfiltrierenden Masken benötigt werden oder Kabinenkategorie 4, wenn gasdichter Atemschutz erforderlich ist (gemäß EN 15695-1 und -2)) ausgestattet sind, geeignet, um die persönliche Schutzausrüstung bei der Ausbringung zu ersetzen. Während aller anderen Tätigkeiten außerhalb der Kabine ist die vorgeschriebene persönliche Schutzausrüstung zu tragen. Um die Kontamination des Kabineninnenraumes zu vermeiden, ist es nicht erlaubt, die Kabine mit kontaminierter persönlicher Schutzausrüstung zu betreten (diese sollte in einer entsprechenden Vorrichtung aufbewahrt werden). Kontaminierte Handschuhe sollten vor dem Ausziehen abgewaschen werden, beziehungsweise sollten die Hände vor Wiederbetreten der Kabine mit klarem Wasser gereinigt werden.

(SE110)
Dicht abschließende Schutzbrille tragen beim Umgang mit dem unverdünnten Mittel.

(SF266)
Behandelte Flächen/Kulturen erst nach dem Abtrocknen des Spritzbelages wieder betreten. Dabei sind lange Arbeitskleidung, festes Schuhwerk und Schutzhandschuhe zu tragen.

(SS110)
Universal-Schutzhandschuhe (Pflanzenschutz) tragen beim Umgang mit dem unverdünnten Mittel.

(SS120)
Universal-Schutzhandschuhe (Pflanzenschutz) tragen bei Ausbringung/Handhabung des anwendungsfertigen Mittels.

(SS2101)
Schutzanzug gegen Pflanzenschutzmittel und festes Schuhwerk (z.B. Gummistiefel) tragen beim Umgang mit dem unverdünnten Mittel.

(SS2202)
Schutzanzug gegen Pflanzenschutzmittel und festes Schuhwerk (z.B. Gummistiefel) tragen bei der Ausbringung/Handhabung des anwendungsfertigen Mittels.

(SS610)
Gummischürze tragen beim Umgang mit dem unverdünnten Mittel.

(WMFC2)
Wirkungsmechanismus (FRAC-Gruppe): C2

(WMFG1)
Wirkungsmechanismus (FRAC-Gruppe): G1

Siehe anwendungsbezogene Kennzeichnungsauflagen in Anlage 1, jeweils unter Nr. 2.

Sonstige Auflagen:

(WH952)
Auf der Verpackung und in der Gebrauchsanleitung ist die Angabe zur Kennzeichnung des Wirkungsmechanismus als zusätzliche Information direkt jedem entsprechenden Wirkstoff-namen zuzuordnen.

Vorbehalt

Dieser Bescheid wird mit dem Vorbehalt der nachträglichen Aufnahme, Änderung oder Ergänzung von Anwendungsbestimmungen und Auflagen verbunden.

Angaben zur Einstufung und Kennzeichnung gemäß Verordnung (EG) Nr. 1272/2008

Signalwort:

(S2) Gefahr

Gefahrenpiktogramme:

(GHS05) Ätzwirkung

(GHS07) Ausrufezeichen

(GHS08) Gesundheitsgefahr

(GHS09) Umwelt

Gefahrenhinweise (H-Sätze):

(H302)

Gesundheitsschädlich bei Verschlucken.

(H317)

Kann allergische Hautreaktionen verursachen.

(H318)

Verursacht schwere Augenschäden.

(H335)

Kann die Atemwege reizen.

(H361d)

Kann vermutlich das Kind im Mutterleib schädigen.

(H410)

Sehr giftig für Wasserorganismen mit langfristiger Wirkung.

(EUH 208-0200)

Enthält Prothioconazol. Kann allergische Reaktionen hervorrufen.

(EUH 401)

Zur Vermeidung von Risiken für Mensch und Umwelt die Gebrauchsanleitung einhalten.

Sicherheitshinweise (P-Sätze):

(P101)

Ist ärztlicher Rat erforderlich, Verpackung oder Kennzeichnungsetikett bereithalten.

(P102)

Darf nicht in die Hände von Kindern gelangen.

(P201)
Vor Gebrauch besondere Anweisungen einholen.

(P264)
Nach Gebrauch ... gründlich waschen.

(P270)
Bei Gebrauch nicht essen, trinken oder rauchen.

(P280)
Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen.

(P302+P352)
BEI BERÜHRUNG MIT DER HAUT: Mit viel Wasser/... waschen.

(P305+P351+P338)
BEI KONTAKT MIT DEN AUGEN: Einige Minuten lang behutsam mit Wasser spülen. Eventuell vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen.

(P308+P310)
BEI Exposition oder falls betroffen: Sofort GIFTINFORMATIONSZENTRUM oder Arzt anrufen.

(P362+P364)
Kontaminierte Kleidung ausziehen und vor erneutem Tragen waschen.

(P391)
Verschüttete Mengen aufnehmen.

(P403+P233)
An einem gut belüfteten Ort aufbewahren. Behälter dicht verschlossen halten.

(P405)
Unter Verschluss aufbewahren.

(P410)
Vor Sonnenbestrahlung schützen.

(P501)
Inhalt/Behälter ... zuführen.

Abgelehnte Anwendungsgebiete bzw. Anwendungen

Für folgende Anwendungsgebiete bzw. Anwendungen lehne ich Ihren Antrag ab (siehe Anlage 2):

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
008219-00/00-016	Braunrost (Puccinia recondita)	Roggen	
008219-00/00-019	Braunrost (Puccinia recondita)	Triticale	
008219-00/00-020	Echter Mehltau (Erysiphe graminis)	Hafer	

Hinweise

Auf dem Etikett und in der Gebrauchsanleitung kann angegeben werden:
(NB6641)
Das Mittel wird bis zu der höchsten durch die Zulassung festgelegten Aufwandmenge oder Anwendungskonzentration, falls eine Aufwandmenge nicht vorgesehen ist, als nicht bienengefährlich eingestuft (B4).

Weitere Hinweise und Bemerkungen
Zu KIIIA1 4.1
Die von Ihnen in Part B1 aufgeführte Option einer Verpackung in weiß pigmentierten HDPE/PA Flaschen wird zunächst nicht berücksichtigt, da keine Daten zum Anstieg des Gehaltes der relevanten Verunreinigung Prothioconazol-Desthio vorliegen.

Zu KIIIA1 2.7.5
Für die im Bericht Gueldner, W., Hoppe, M., 2016; M-555918-01-1 genannten Gehalte der relevanten Verunreinigung Prothioconazol-Desthio nach 6 Monaten wäre eine Bestimmung zusätzlich nach zwei Jahren Lagerung sinnvoll.

Vorsorglich weise ich darauf hin, dass bisher mitgeteilte Forderungen bestehen bleiben, soweit sie noch nicht erfüllt sind.

Unterbleibt eine Beanstandung der vorgelegten Gebrauchsanleitung, so ist daraus nicht zu schließen, dass sie als ordnungsgemäß angesehen wird. Die Verantwortung des Zulassungsinhabers für die Übereinstimmung mit dem Zulassungsbescheid bleibt bestehen.

Hinsichtlich der Gebühren erhalten Sie einen gesonderten Bescheid.

Rechtsbehelfsbelehrung

Gegen diesen Bescheid kann innerhalb eines Monats nach Bekanntgabe Widerspruch erhoben werden. Der Widerspruch ist bei dem Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Messeweg 11/12, 38104 Braunschweig, schriftlich oder zur Niederschrift einzulegen.

Mit freundlichen Grüßen
im Auftrag

gez. Dr. Martin Streloke
Abteilungsleiter

Dieses Schreiben wurde maschinell erstellt und ist daher ohne Unterschrift gültig.

Anlage

Anlage 1 zugelassene Anwendung: 008219-00/00-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Halmbruchkrankheit (Pseudocercosporella herpotrichoides)
Pflanzen/-erzeugnisse/Objekte:	Weizen
Verwendungszweck:	

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 32
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	2
Anwendungstechnik:	spritzen
Aufwand:	
-	1,5 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Weizen Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten

Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% 5 m, 90% *
Begründung:
Das Pflanzenschutzmittel Ascra XPro bzw. der Metabolit JAU 6476-desthio des darin enthaltenen Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3.34 µg/L. Ausgehend von den geltenden Modellen zur Abdrift (hier: EVA 3) und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 605-1/606 für alle beantragten Anwendungen erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Bixafen in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
10 m
Begründung:
Siehe unter NW605-1.

(NW701)
Zwischen behandelten Flächen mit einer Hangneigung von über 2 % und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - muss ein mit einer geschlossenen Pflanzendecke bewachsener Randstreifen vorhanden sein. Dessen Schutzfunktion darf durch den Einsatz von Arbeitsgeräten nicht beeinträchtigt werden. Er muss eine Mindestbreite von 10 m haben. Dieser Randstreifen ist nicht erforderlich, wenn: - ausreichende Auffangsysteme für das abgeschwemmte Wasser bzw. den abgeschwemmten Boden vorhanden sind, die nicht in ein Oberflächengewässer münden, bzw. mit der Kanalisation verbunden sind oder - die Anwendung im Mulch- oder Direktsaatverfahren erfolgt.
Begründung:
Der im Pflanzenschutzmittel Ascra XPro enthaltene Metabolit JAU 6476-desthio des Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3,34 µg/L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 50,6 mg/L; DT50 Boden = 57 d; KOC = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01

und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 701 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten JAU 6476-desthio in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

Anlage 1 zugelassene Anwendung: 008219-00/00-002

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Echter Mehltau (Erysiphe graminis)

Pflanzen/-erzeugnisse/Objekte: Weizen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Abstand:	14 bis 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	1,5 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Weizen Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten

Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% 5 m, 90% *
Begründung:
Das Pflanzenschutzmittel Ascra XPro bzw. der Metabolit JAU 6476-desthio des darin enthaltenen Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3.34 µg/L. Ausgehend von den geltenden Modellen zur Abdrift (hier: EVA 3) und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 605-1/606 für alle beantragten Anwendungen erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Bixafen in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
10 m
Begründung:
Siehe unter NW605-1.

(NW701)
Zwischen behandelten Flächen mit einer Hangneigung von über 2 % und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - muss ein mit einer geschlossenen Pflanzendecke bewachsener Randstreifen vorhanden sein. Dessen Schutzfunktion darf durch den Einsatz von Arbeitsgeräten nicht beeinträchtigt werden. Er muss eine Mindestbreite von 10 m haben. Dieser Randstreifen ist nicht erforderlich, wenn: - ausreichende Auffangsysteme für das abgeschwemmte Wasser bzw. den abgeschwemmten Boden vorhanden sind, die nicht in ein Oberflächengewässer münden, bzw. mit der Kanalisation verbunden sind oder - die Anwendung im Mulch- oder Direktsaatverfahren erfolgt.
Begründung:
Der im Pflanzenschutzmittel Ascra XPro enthaltene Metabolit JAU 6476-desthio des Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3,34 µg/L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 50,6 mg/L; DT50 Boden = 57 d; KOC = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01

und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 701 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten JAU 6476-desthio in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

Anlage 1 zugelassene Anwendung: 008219-00/00-003

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Septoria-Blattdürre (Septoria tritici)

Pflanzen/-erzeugnisse/Objekte: Weizen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Abstand:	14 bis 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	1,5 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Weizen Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten

Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% 5 m, 90% *
Begründung:
Das Pflanzenschutzmittel Ascra XPro bzw. der Metabolit JAU 6476-desthio des darin enthaltenen Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3.34 µg/L. Ausgehend von den geltenden Modellen zur Abdrift (hier: EVA 3) und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 605-1/606 für alle beantragten Anwendungen erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Bixafen in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
10 m
Begründung:
Siehe unter NW605-1.

(NW701)
Zwischen behandelten Flächen mit einer Hangneigung von über 2 % und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - muss ein mit einer geschlossenen Pflanzendecke bewachsener Randstreifen vorhanden sein. Dessen Schutzfunktion darf durch den Einsatz von Arbeitsgeräten nicht beeinträchtigt werden. Er muss eine Mindestbreite von 10 m haben. Dieser Randstreifen ist nicht erforderlich, wenn: - ausreichende Auffangsysteme für das abgeschwemmte Wasser bzw. den abgeschwemmten Boden vorhanden sind, die nicht in ein Oberflächengewässer münden, bzw. mit der Kanalisation verbunden sind oder - die Anwendung im Mulch- oder Direktsaatverfahren erfolgt.
Begründung:
Der im Pflanzenschutzmittel Ascra XPro enthaltene Metabolit JAU 6476-desthio des Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3,34 µg/L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 50,6 mg/L; DT50 Boden = 57 d; KOC = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01

und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 701 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten JAU 6476-desthio in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

Anlage 1 zugelassene Anwendung: 008219-00/00-004

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: DTR-Blattdürre (Drechslera tritici-repentis)

Pflanzen/-erzeugnisse/Objekte: Weizen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Abstand:	14 bis 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	1,5 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Weizen Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten

Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% 5 m, 90% *
Begründung:
Das Pflanzenschutzmittel Ascra XPro bzw. der Metabolit JAU 6476-desthio des darin enthaltenen Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3.34 µg/L. Ausgehend von den geltenden Modellen zur Abdrift (hier: EVA 3) und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 605-1/606 für alle beantragten Anwendungen erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Bixafen in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
10 m
Begründung:
Siehe unter NW605-1.

(NW701)
Zwischen behandelten Flächen mit einer Hangneigung von über 2 % und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - muss ein mit einer geschlossenen Pflanzendecke bewachsener Randstreifen vorhanden sein. Dessen Schutzfunktion darf durch den Einsatz von Arbeitsgeräten nicht beeinträchtigt werden. Er muss eine Mindestbreite von 10 m haben. Dieser Randstreifen ist nicht erforderlich, wenn: - ausreichende Auffangsysteme für das abgeschwemmte Wasser bzw. den abgeschwemmten Boden vorhanden sind, die nicht in ein Oberflächengewässer münden, bzw. mit der Kanalisation verbunden sind oder - die Anwendung im Mulch- oder Direktsaatverfahren erfolgt.
Begründung:
Der im Pflanzenschutzmittel Ascra XPro enthaltene Metabolit JAU 6476-desthio des Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3,34 µg/L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 50,6 mg/L; DT50 Boden = 57 d; KOC = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01

und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 701 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten JAU 6476-desthio in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

Anlage 1 zugelassene Anwendung: 008219-00/00-005

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Braunrost (Puccinia recondita)

Pflanzen/-erzeugnisse/Objekte: Weizen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Abstand:	14 bis 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	1,5 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Weizen Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten

Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% 5 m, 90% *
Begründung:
Das Pflanzenschutzmittel Ascra XPro bzw. der Metabolit JAU 6476-desthio des darin enthaltenen Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3.34 µg/L. Ausgehend von den geltenden Modellen zur Abdrift (hier: EVA 3) und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 605-1/606 für alle beantragten Anwendungen erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Bixafen in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
10 m
Begründung:
Siehe unter NW605-1.

(NW701)
Zwischen behandelten Flächen mit einer Hangneigung von über 2 % und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - muss ein mit einer geschlossenen Pflanzendecke bewachsener Randstreifen vorhanden sein. Dessen Schutzfunktion darf durch den Einsatz von Arbeitsgeräten nicht beeinträchtigt werden. Er muss eine Mindestbreite von 10 m haben. Dieser Randstreifen ist nicht erforderlich, wenn: - ausreichende Auffangsysteme für das abgeschwemmte Wasser bzw. den abgeschwemmten Boden vorhanden sind, die nicht in ein Oberflächengewässer münden, bzw. mit der Kanalisation verbunden sind oder - die Anwendung im Mulch- oder Direktsaatverfahren erfolgt.
Begründung:
Der im Pflanzenschutzmittel Ascra XPro enthaltene Metabolit JAU 6476-desthio des Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3,34 µg/L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 50,6 mg/L; DT50 Boden = 57 d; KOC = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01

und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 701 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten JAU 6476-desthio in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

Anlage 1 zugelassene Anwendung: 008219-00/00-006

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Gelbrost (Puccinia striiformis)

Pflanzen/-erzeugnisse/Objekte: Weizen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Abstand:	14 bis 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	1,5 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Weizen Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten

Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% 5 m, 90% *
Begründung:
Das Pflanzenschutzmittel Ascra XPro bzw. der Metabolit JAU 6476-desthio des darin enthaltenen Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3.34 µg/L. Ausgehend von den geltenden Modellen zur Abdrift (hier: EVA 3) und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 605-1/606 für alle beantragten Anwendungen erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Bixafen in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
10 m
Begründung:
Siehe unter NW605-1.

(NW701)
Zwischen behandelten Flächen mit einer Hangneigung von über 2 % und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - muss ein mit einer geschlossenen Pflanzendecke bewachsener Randstreifen vorhanden sein. Dessen Schutzfunktion darf durch den Einsatz von Arbeitsgeräten nicht beeinträchtigt werden. Er muss eine Mindestbreite von 10 m haben. Dieser Randstreifen ist nicht erforderlich, wenn: - ausreichende Auffangsysteme für das abgeschwemmte Wasser bzw. den abgeschwemmten Boden vorhanden sind, die nicht in ein Oberflächengewässer münden, bzw. mit der Kanalisation verbunden sind oder - die Anwendung im Mulch- oder Direktsaatverfahren erfolgt.
Begründung:
Der im Pflanzenschutzmittel Ascra XPro enthaltene Metabolit JAU 6476-desthio des Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3,34 µg/L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 50,6 mg/L; DT50 Boden = 57 d; KOC = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01

und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 701 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten JAU 6476-desthio in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

Anlage 1 zugelassene Anwendung: 008219-00/00-007

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Blatt- und Spelzenbräune (Septoria nodorum)

Pflanzen/-erzeugnisse/Objekte: Weizen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Abstand:	14 bis 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	1,5 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

(WW7041)
Für den Wirkstoff, bzw. einen Wirkstoff dieses Mittels, wurden Resistenzen nachgewiesen. Anwendung nur im Rahmen eines geeigneten Resistenzmanagements.

2.3 Wartezeiten

(F)	Freiland: Weizen Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender

Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% 5 m, 90% *
Begründung:
Das Pflanzenschutzmittel Ascra XPro bzw. der Metabolit JAU 6476-desthio des darin enthaltenen Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3.34 µg/L. Ausgehend von den geltenden Modellen zur Abdrift (hier: EVA 3) und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 605-1/606 für alle beantragten Anwendungen erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Bixafen in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
10 m
Begründung:
Siehe unter NW605-1.

(NW701)
Zwischen behandelten Flächen mit einer Hangneigung von über 2 % und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - muss ein mit einer geschlossenen Pflanzendecke bewachsener Randstreifen vorhanden sein. Dessen Schutzfunktion darf durch den Einsatz von Arbeitsgeräten nicht beeinträchtigt werden. Er muss eine Mindestbreite von 10 m haben. Dieser Randstreifen ist nicht erforderlich, wenn: - ausreichende Auffangsysteme für das abgeschwemmte Wasser bzw. den abgeschwemmten Boden vorhanden sind, die nicht in ein Oberflächengewässer münden, bzw. mit der Kanalisation verbunden sind oder - die Anwendung im Mulch- oder Direktsaatverfahren erfolgt.
Begründung:
Der im Pflanzenschutzmittel Ascra XPro enthaltene Metabolit JAU 6476-desthio des Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss

von 3,34 µg/L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 50,6 mg/L; DT50 Boden = 57 d; KOC = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01 und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 701 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten JAU 6476-desthio in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

Anlage 1 zugelassene Anwendung: 008219-00/00-008

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Halmbruchkrankheit (Pseudocercosporella herpotrichoides)
Pflanzen/-erzeugnisse/Objekte:	Gerste
Verwendungszweck:	

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 34
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	spritzen
Aufwand:	
-	1,2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Gerste Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten

Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% 5 m, 90% *
Begründung:
Das Pflanzenschutzmittel Ascra XPro bzw. der Metabolit JAU 6476-desthio des darin enthaltenen Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3.34 µg/L. Ausgehend von den geltenden Modellen zur Abdrift (hier: EVA 3) und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 605-1/606 für alle beantragten Anwendungen erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Bixafen in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
Begründung:
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 008219-00/00-009

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Echter Mehltau (Erysiphe graminis)

Pflanzen/-erzeugnisse/Objekte: Gerste

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	spritzen
Aufwand:	
-	1,2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Gerste Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände

zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% 5 m, 90% *
Begründung:
Das Pflanzenschutzmittel Ascra XPro bzw. der Metabolit JAU 6476-desthio des darin enthaltenen Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3.34 µg/L. Ausgehend von den geltenden Modellen zur Abdrift (hier: EVA 3) und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 605-1/606 für alle beantragten Anwendungen erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Bixafen in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
Begründung:
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 008219-00/00-010

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Blattfleckenkrankheit (Rhynchosporium secalis)

Pflanzen/-erzeugnisse/Objekte: Gerste

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	spritzen
Aufwand:	
-	1,2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Gerste Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände

zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% 5 m, 90% *
Begründung:
Das Pflanzenschutzmittel Ascra XPro bzw. der Metabolit JAU 6476-desthio des darin enthaltenen Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3.34 µg/L. Ausgehend von den geltenden Modellen zur Abdrift (hier: EVA 3) und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 605-1/606 für alle beantragten Anwendungen erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Bixafen in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
Begründung:
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 008219-00/00-011

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Netzfleckenkrankheit (Pyrenophora teres)

Pflanzen/-erzeugnisse/Objekte: Gerste

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	spritzen
Aufwand:	
-	1,2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

(WW7041)
Für den Wirkstoff, bzw. einen Wirkstoff dieses Mittels, wurden Resistenzen nachgewiesen. Anwendung nur im Rahmen eines geeigneten Resistenzmanagements.

2.3 Wartezeiten

(F)	Freiland: Gerste Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmin-

dernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% 5 m, 90% *
Begründung:
Das Pflanzenschutzmittel Ascra XPro bzw. der Metabolit JAU 6476-desthio des darin enthaltenen Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3.34 µg/L. Ausgehend von den geltenden Modellen zur Abdrift (hier: EVA 3) und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 605-1/606 für alle beantragten Anwendungen erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Bixafen in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
Begründung:
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 008219-00/00-012

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Zwergrost (Puccinia hordei)

Pflanzen/-erzeugnisse/Objekte: Gerste

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	spritzen
Aufwand:	
-	1,2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Gerste Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände

zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% 5 m, 90% *
Begründung:
Das Pflanzenschutzmittel Ascra XPro bzw. der Metabolit JAU 6476-desthio des darin enthaltenen Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3.34 µg/L. Ausgehend von den geltenden Modellen zur Abdrift (hier: EVA 3) und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 605-1/606 für alle beantragten Anwendungen erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Bixafen in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
Begründung:
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 008219-00/00-013

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Sprenkelkrankheit (Ramularia collo-cygni)

Pflanzen/-erzeugnisse/Objekte: Gerste

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	spritzen
Aufwand:	
-	1,2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

(WW7041)
Für den Wirkstoff, bzw. einen Wirkstoff dieses Mittels, wurden Resistenzen nachgewiesen. Anwendung nur im Rahmen eines geeigneten Resistenzmanagements.

2.3 Wartezeiten

(F)	Freiland: Gerste Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmin-

dernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% 5 m, 90% *
Begründung:
Das Pflanzenschutzmittel Ascra XPro bzw. der Metabolit JAU 6476-desthio des darin enthaltenen Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3.34 µg/L. Ausgehend von den geltenden Modellen zur Abdrift (hier: EVA 3) und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 605-1/606 für alle beantragten Anwendungen erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Bixafen in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
Begründung:
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 008219-00/00-014

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Minderung nichtparasitärer Blattflecken

Pflanzen/-erzeugnisse/Objekte: Gerste

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	spritzen
Aufwand:	
-	1,2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Gerste Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände

zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% 5 m, 90% *
Begründung:
Das Pflanzenschutzmittel Ascra XPro bzw. der Metabolit JAU 6476-desthio des darin enthaltenen Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3.34 µg/L. Ausgehend von den geltenden Modellen zur Abdrift (hier: EVA 3) und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 605-1/606 für alle beantragten Anwendungen erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Bixafen in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
Begründung:
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 008219-00/00-015

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Blattfleckenkrankheit (Rhynchosporium secalis)

Pflanzen/-erzeugnisse/Objekte: Roggen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Abstand:	14 bis 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	1,5 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Roggen Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten

Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% 5 m, 90% *
Begründung:
Das Pflanzenschutzmittel Ascra XPro bzw. der Metabolit JAU 6476-desthio des darin enthaltenen Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3.34 µg/L. Ausgehend von den geltenden Modellen zur Abdrift (hier: EVA 3) und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 605-1/606 für alle beantragten Anwendungen erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Bixafen in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
10 m
Begründung:
Siehe unter NW605-1.

(NW701)
Zwischen behandelten Flächen mit einer Hangneigung von über 2 % und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - muss ein mit einer geschlossenen Pflanzendecke bewachsener Randstreifen vorhanden sein. Dessen Schutzfunktion darf durch den Einsatz von Arbeitsgeräten nicht beeinträchtigt werden. Er muss eine Mindestbreite von 10 m haben. Dieser Randstreifen ist nicht erforderlich, wenn: - ausreichende Auffangsysteme für das abgeschwemmte Wasser bzw. den abgeschwemmten Boden vorhanden sind, die nicht in ein Oberflächengewässer münden, bzw. mit der Kanalisation verbunden sind oder - die Anwendung im Mulch- oder Direktsaatverfahren erfolgt.
Begründung:
Der im Pflanzenschutzmittel Ascra XPro enthaltene Metabolit JAU 6476-desthio des Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3,34 µg/L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 50,6 mg/L; DT50 Boden = 57 d; KOC = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01

und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 701 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten JAU 6476-desthio in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

Anlage 1 zugelassene Anwendung: 008219-00/00-017

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Echter Mehltau (Erysiphe graminis)

Pflanzen/-erzeugnisse/Objekte: Triticale

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Abstand:	14 bis 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	1,5 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Triticale Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten

Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% 5 m, 90% *
Begründung:
Das Pflanzenschutzmittel Ascra XPro bzw. der Metabolit JAU 6476-desthio des darin enthaltenen Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3.34 µg/L. Ausgehend von den geltenden Modellen zur Abdrift (hier: EVA 3) und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 605-1/606 für alle beantragten Anwendungen erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Bixafen in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
10 m
Begründung:
Siehe unter NW605-1.

(NW701)
Zwischen behandelten Flächen mit einer Hangneigung von über 2 % und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - muss ein mit einer geschlossenen Pflanzendecke bewachsener Randstreifen vorhanden sein. Dessen Schutzfunktion darf durch den Einsatz von Arbeitsgeräten nicht beeinträchtigt werden. Er muss eine Mindestbreite von 10 m haben. Dieser Randstreifen ist nicht erforderlich, wenn: - ausreichende Auffangsysteme für das abgeschwemmte Wasser bzw. den abgeschwemmten Boden vorhanden sind, die nicht in ein Oberflächengewässer münden, bzw. mit der Kanalisation verbunden sind oder - die Anwendung im Mulch- oder Direktsaatverfahren erfolgt.
Begründung:
Der im Pflanzenschutzmittel Ascra XPro enthaltene Metabolit JAU 6476-desthio des Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3,34 µg/L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 50,6 mg/L; DT50 Boden = 57 d; KOC = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01

und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 701 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten JAU 6476-desthio in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

Anlage 1 zugelassene Anwendung: 008219-00/00-018

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Septoria-Arten (Septoria spp.)

Pflanzen/-erzeugnisse/Objekte: Triticale

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Abstand:	14 bis 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	1,5 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Triticale Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten

Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% 5 m, 90% *
Begründung:
Das Pflanzenschutzmittel Ascra XPro bzw. der Metabolit JAU 6476-desthio des darin enthaltenen Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3.34 µg/L. Ausgehend von den geltenden Modellen zur Abdrift (hier: EVA 3) und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 605-1/606 für alle beantragten Anwendungen erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Bixafen in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
10 m
Begründung:
Siehe unter NW605-1.

(NW701)
Zwischen behandelten Flächen mit einer Hangneigung von über 2 % und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - muss ein mit einer geschlossenen Pflanzendecke bewachsener Randstreifen vorhanden sein. Dessen Schutzfunktion darf durch den Einsatz von Arbeitsgeräten nicht beeinträchtigt werden. Er muss eine Mindestbreite von 10 m haben. Dieser Randstreifen ist nicht erforderlich, wenn: - ausreichende Auffangsysteme für das abgeschwemmte Wasser bzw. den abgeschwemmten Boden vorhanden sind, die nicht in ein Oberflächengewässer münden, bzw. mit der Kanalisation verbunden sind oder - die Anwendung im Mulch- oder Direktsaatverfahren erfolgt.
Begründung:
Der im Pflanzenschutzmittel Ascra XPro enthaltene Metabolit JAU 6476-desthio des Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3,34 µg/L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 50,6 mg/L; DT50 Boden = 57 d; KOC = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01

und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 701 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten JAU 6476-desthio in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

Anlage 1 zugelassene Anwendung: 008219-00/00-021

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Haferkronenrost (Puccinia coronata)

Pflanzen/-erzeugnisse/Objekte: Hafer

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	spritzen
Aufwand:	
-	1,2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Hafer Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände

zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% 5 m, 90% *
Begründung:
Das Pflanzenschutzmittel Ascra XPro bzw. der Metabolit JAU 6476-desthio des darin enthaltenen Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3.34 µg/L. Ausgehend von den geltenden Modellen zur Abdrift (hier: EVA 3) und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 605-1/606 für alle beantragten Anwendungen erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Bixafen in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
Begründung:
Siehe unter NW605-1.

Anlage 2 nicht zugelassene Anwendung: 008219-00/00-016

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Braunrost (Puccinia recondita)

Pflanzen/-erzeugnisse/Objekte: Roggen

Verwendungszweck:

2 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Abstand:	14 bis 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	1,5 l/ha in 100 bis 400 l Wasser/ha

3 Begründung

Wirksamkeit:
Nach Abschnitt 6 - Wirksamkeitsdaten - der Verordnung (EU) Nr. 284/2013 zur Festlegung der Datenanforderungen zu Pflanzenschutzmittel müssen die vorgelegten Daten für eine Bewertung des Pflanzenschutzmittels ausreichen. Die vorgelegten Daten müssen hinreichend bestätigen, dass die Anwendungsmuster für das Pflanzenschutzmittel repräsentativ für die Regionen und alle dort voraussichtlichen Bedingungen sind, für die der Einsatz des Mittels bestimmt ist.
Nach dem EPPO Standard PP1/226 müssen für eine Hauptkultur und eine Hauptkrankheit 10-15 Versuche eingereicht werden. Es wurden keine Versuche, die mit der beantragten Anwendung übereinstimmen, eingereicht, eine Zulassung wird daher abgelehnt.

Anlage 2 nicht zugelassene Anwendung: 008219-00/00-019

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Braunrost (Puccinia recondita)

Pflanzen/-erzeugnisse/Objekte: Triticale

Verwendungszweck:

2 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Abstand:	14 bis 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	1,5 l/ha in 100 bis 400 l Wasser/ha

3 Begründung

Wirksamkeit:
Nach Abschnitt 6 - Wirksamkeitsdaten - der Verordnung (EU) Nr. 284/2013 zur Festlegung der Datenanforderungen zu Pflanzenschutzmittel müssen die vorgelegten Daten für eine Bewertung des Pflanzenschutzmittels ausreichen. Die vorgelegten Daten müssen hinreichend bestätigen, dass die Anwendungsmuster für das Pflanzenschutzmittel repräsentativ für die Regionen und alle dort voraussichtlichen Bedingungen sind, für die der Einsatz des Mittels bestimmt ist.
Nach dem EPPO Standard PP1/226 müssen für eine Hauptkultur und eine Hauptkrankheit 10-15 Versuche eingereicht werden. Es sind nur 5 Versuche eingereicht worden, eine Zulassung wird daher abgelehnt.

Anlage 2 nicht zugelassene Anwendung: 008219-00/00-020

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Echter Mehltau (Erysiphe graminis)

Pflanzen/-erzeugnisse/Objekte: Hafer

Verwendungszweck:

2 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	spritzen
Aufwand:	
-	1,2 l/ha in 100 bis 400 l Wasser/ha

3 Begründung

Wirksamkeit:
Nach Abschnitt 6 - Wirksamkeitsdaten - der Verordnung (EU) Nr. 284/2013 zur Festlegung der Datenanforderungen zu Pflanzenschutzmittel müssen die vorgelegten Daten für eine Bewertung des Pflanzenschutzmittels ausreichen. Die vorgelegten Daten müssen hinreichend bestätigen, dass die Anwendungsmuster für das Pflanzenschutzmittel repräsentativ für die Regionen und alle dort voraussichtlichen Bedingungen sind, für die der Einsatz des Mittels bestimmt ist.
Nach dem EPPO Standard PP1/226 muss für eine Nebenkultur und eine Hauptkrankheit mehr als ein Versuch eingereicht werden. Es ist nur 1 Versuch eingereicht worden, eine Zulassung wird daher abgelehnt.

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
Dienstsitz Braunschweig • Postfach 15 64 • 38005 Braunschweig

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Referentin

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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.008219-00/00.105123
(bitte bei Antwort angeben)

DATUM 17. Januar 2018

ZV1 008219-00/00

Ascra Xpro

Zulassungsverfahren für Pflanzenschutzmittel

Änderungsbescheid

Die Zulassung des oben genannten Pflanzenschutzmittels

mit den Wirkstoffen:	130 g/l	Prothioconazol
	65 g/l	Bixafen
	65 g/l	Fluopyram

Zulassungsnummer: 008219-00

Versuchsbezeichnungen: BAY-21070-F-0-EC

Antrag vom: 14. Mai 2014

Zulassungsbescheid vom: 21. Dezember 2017

ändere ich wie folgt:

Zusätzliche Anwendungsgebiete bzw. Anwendungen

Die Zulassung wird um folgende Anwendungsgebiete bzw. Anwendungen erweitert (siehe Anlage 1):

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
008219-00/00-030	Braunrost (Puccinia recondita)	Roggen	

Nicht mehr zugelassene Anwendungsgebiete bzw. Anwendungen

Folgende Anwendungsgebiete bzw. Anwendungen werden aus den in Anlage 2 genannten Gründen bei der Zulassung nicht mehr vorgesehen:

- keine -

Abgelehnte Anwendungsgebiete bzw. Anwendungen

Für folgende Anwendungsgebiete bzw. Anwendungen lehne ich Ihren Antrag ab (siehe Anlage 2):

- keine -

Anwendungsgebiete bzw. Anwendungen in geänderter Fassung

Folgende Anwendungsgebiete bzw. Anwendungen werden aufgehoben und durch die in der Anlage 1 beschriebenen ersetzt:

- keine -

Festgesetzte Anwendungsbestimmungen

Anwendungsbestimmungen gemäß § 36 Abs. 1 S. 1 des Gesetzes zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz - PflSchG) vom 6. Februar 2012 (BGBl. I S. 148, 1281), zuletzt geändert durch Artikel 4 Absatz 84 des Gesetzes vom 18. Juli 2016 (BGBl. I S. 1666):

Folgende Anwendungsbestimmungen werden zusätzlich festgesetzt:

- keine -

Folgende Anwendungsbestimmungen sind nicht mehr festgesetzt:

- keine -

Siehe anwendungsbezogene Anwendungsbestimmungen in Anlage 1, jeweils unter Nr. 3.

Auflagen

Auflagen gemäß § 36 Abs. 3 S. 1 PflSchG:

Siehe anwendungsbezogene Kennzeichnungsauflagen in Anlage 1, jeweils unter Nr. 2.

Die Zulassung wird mit folgenden Auflagen gemäß § 36 Abs. 5 PflSchG verbunden:

Dem Bundesamt für Verbraucherschutz und Lebensmittelsicherheit sind Unterlagen zu den nachfolgend aufgeführten Punkten und den dabei jeweils genannten Terminen vorzulegen:
Antragspunkt:
KIIA 7.12 (Bixafen)
Termin:
31. Dezember 2020
Forderung:
Durchführung einer zulassungsbegleitenden mehrjährigen Bodenmonitoringstudie mit Bixafen enthaltenden Produkten nach Absprache des Studiendesigns mit dem Umweltbundesamt.
Begründung:
In einer Bodenakkumulationsstudie (Heinemann, 2011, Studiennummer: MEF-11/204) mit dem Wirkstoff Bixafen wurde auf dem deutschen Standort "Monheim" innerhalb der Studiendauer von 8 Jahren keine Plateaukonzentration des Wirkstoffs erreicht. Es ist daher die Durchführung einer zulassungsbegleitenden Bodenmonitoringstudie erforderlich, um zu überprüfen, ob die auf Basis der Bodenakkumulationsstudie zur Risikobewertung verwendeten PECsoil Werte hinreichend konservativ sind, um die tatsächlich im Boden auftretenden Konzentrationen abzudecken. Das Studienprotokoll wurde mit dem Umweltbundesamt bereits im Rahmen einer anderen Produktzulassung (ZV1 026998-00/00) besprochen.

Antragspunkt:
KIIIA 10.6.6 (Bixafen)
Termin:
31. Dezember 2020
Forderung:
Vorlage einer zwei-jährigen Monitoringstudie an Bodenmakroorganismen mit dem beantragten Produkt nach Absprache des Studiendesigns mit dem Umweltbundesamt.

Begründung:
Zulassungsbegleitende Durchführung einer zweijährigen Bodenmonitoringstudie mit Produkten, die den Wirkstoff Bixafen enthalten. Ein Studiendesign wurde mit dem Umweltbundesamt bereits im Rahmen einer anderen Produktzulassung (ZV1 026998-00/00) besprochen. Die Vorlage der Ergebnisse o.g. Studie ist notwendig, da auf Basis der verfügbaren Unterlagen das Risiko für Bodenmakroorganismen nicht vollständig ausgeräumt ist. Nach Auswertung des Umweltbundesamtes wurden bereits in der niedrigsten Testkonzentration signifikante Effekte auf die Population der Collembolen festgestellt.

Unter Berücksichtigung der für die Erarbeitung dieser Unterlagen sowie ihrer Prüfung erforderlichen Zeitdauer sind die Studien zu den oben genannten Terminen vorzulegen. Ich weise darauf hin, dass mir § 36 Abs. 5 S. 3 PflSchG für den Fall der nicht fristgerechten Erfüllung dieser Auflage die Möglichkeit eröffnet, das Ruhen der Zulassung anzuordnen. Ferner eröffnet mir in diesem Fall § 49 Abs. 2 Nr. 2 VwVfG auch die Möglichkeit des Widerrufs der Zulassung.

Angaben zur Einstufung und Kennzeichnung gemäß Verordnung (EG) Nr. 1272/2008

- keine Änderung -

Hinweise

Auf dem Etikett und in der Gebrauchsanleitung kann zusätzlich angegeben werden:

- entfällt -

Auf dem Etikett und in der Gebrauchsanleitung ist nicht mehr anzugeben:

- entfällt -

Weitere Hinweise und Bemerkungen

Vorsorglich weise ich darauf hin, dass bisher mitgeteilte Forderungen bestehen bleiben, soweit sie noch nicht erfüllt sind.

Rechtsbehelfsbelehrung

Gegen diesen Bescheid kann innerhalb eines Monats nach Bekanntgabe Widerspruch erhoben werden. Der Widerspruch ist bei dem Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Messeweg 11/12, 38104 Braunschweig, schriftlich oder zur Niederschrift einzulegen.

Mit freundlichen Grüßen
im Auftrag

gez. Dr. Karsten Hohgardt
stellvertretender Abteilungsleiter

Dieses Schreiben wurde maschinell erstellt und ist daher ohne Unterschrift gültig.

Anlage

Anlage 1 zugelassene Anwendung: 008219-00/00-030

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Braunrost (Puccinia recondita)

Pflanzen/-erzeugnisse/Objekte: Roggen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
Anwendungstechnik:	spritzen
Aufwand:	
-	1,5 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Roggen Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände

zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% 5 m, 90% *
Begründung:
Das Pflanzenschutzmittel Ascra XPro bzw. der Metabolit JAU 6476-desthio des darin enthaltenen Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3.34 µg/L. Ausgehend von den geltenden Modellen zur Abdrift (hier: EVA 3) und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 605-1/606 für alle beantragten Anwendungen erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Bixafen in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
10 m
Begründung:
Siehe unter NW605-1.

(NW701)
Zwischen behandelten Flächen mit einer Hangneigung von über 2 % und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - muss ein mit einer geschlossenen Pflanzendecke bewachsener Randstreifen vorhanden sein. Dessen Schutzfunktion darf durch den Einsatz von Arbeitsgeräten nicht beeinträchtigt werden. Er muss eine Mindestbreite von 10 m haben. Dieser Randstreifen ist nicht erforderlich, wenn: - ausreichende Auffangsysteme für das abgeschwemmte Wasser bzw. den abgeschwemmten Boden vorhanden sind, die nicht in ein Oberflächengewässer münden, bzw. mit der Kanalisation verbunden sind oder - die Anwendung im Mulch- oder Direktsaatverfahren erfolgt.
Begründung:
Der im Pflanzenschutzmittel Ascra XPro enthaltene Metabolit JAU 6476-desthio des Wirkstoffs Prothioconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für Oncorhynchus mykiss von 3,34 µg/L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 50,6 mg/L; DT50 Boden = 57 d; KOC = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01 und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnis

die Anwendungsbestimmung NW 701 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten JAU 6476-desthio in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 6/9, Kapitel 6.5).

REGISTRATION REPORT
Part B

Section 1: Identity, physical and chemical properties, other information

Detailed summary of the risk assessment

Product code: 102000027828

Active Substance: Bixafen 65 g/L
Fluopyram 65 g/L
Prothioconazole 130 g/L

Central Zone
Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Bayer CropScience

Submission Date: 14/05/2014

Date: October 2017

Table of Contents

Introduction

This document summarises the information related to the identity, the physical and chemical properties, the data on application, further information and the classification for the product BIX+FLU+PTZ EC 260 (65+65+130 g/L) containing the active substances bixafen, fluopyram and prothioconazole .

Bixafen was approved for inclusion into Annex I in accordance with Regulation (EC) No 1107/2009, Council Directive 91/414/EEC (Implementing Regulation (EU) No. 350/2013, dated 17 April 2013) with the entry into force of 1 October 2013. Fluopyram was included into Annex I of Regulation (EC) No 1107/2009, (Implementing Regulation (EU) No.802/2013, dated 22 August 2013) with the entry into force of 1 February 2014. Prothioconazole was included in Annex I of Directive 91/414, (Directive 2008/44/EC dated 4 April 2008) with the entry into force on 1 August 2008.

The product has not been evaluated as the representative formulation during the Annex I inclusion of the active substances bixafen fluopyram or prothioconazole.

The following table provides the EU endpoints to be used in the evaluation.

Agreed EU End-points

End-Point	**Bixafen** (Reg. (EU) No 350/2013)	**Fluopyram** (Reg. (EU) No 802/2013)	**Prothioconazole** (Reg. (EU) No 540/2011)
Purity of active substance	min 950 g/kg	min 960 g/kg	min 970 g/kg
Relevant impurities	–	–	Toluene: < 5 g/kg Prothioconazole-desthio*: < 0.5 g/kg

* (2-(1-Chlorocyclo-propyl)-1-(2-chlorophenyl)-3-(1,2,4-triazol-1-yl)-propan-2-ol):

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

Information on the detailed composition of BIX+FLU+PTZ EC 260 (65+65+130 g/L) can be found in the confidential dossier of this submission (Registration Report - Part C).

IIIA 1 IDENTITY OF THE PLANT PROTECTION PRODUCT

IIIA 1.1 Applicant

Bayer CropScience Deutschland GmbH
Elisabeth-Selbert Straße 4a
40764 Langenfeld
Germany

Contact person: Stefanie Kretschmer
Tel.No.: +49 (0)2173/ 2076245
e-mail: stefanie.kretschmer@bayer.com

IIIA 1.2 Manufacturer of the Preparation, Manufacturer and Purity of the Active Substance(s)

IIIA 1.2.1 Manufacturer(s) of the preparation

Confidential information - data provided separately (Part C).

IIIA 1.2.2 Manufacturer(s) of the active substance(s)

Confidential information - data provided separately (Part C).

IIIA 1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

Bixafen
Purity: min 950 g/kg

Fluopyram
Purity: min 960 g/kg

Prothioconazole

Purity:	min 970 g/kg	
Relevant impurities:	Toluene	max 5 g/kg
	Prothioconazole-desthio	max 0.5 g/kg

Further information/justification is provided in Part C.

IIIA 1.3 Trade Names and Manufacturer's Code Numbers for the Preparation

Trade name: Ascra Xpro EC 260

Company code number: 102000027828 (specification No.)

80513666 (material No.)

BIX+FLU+PTZ EC 65+65+130 G (internal name)

Bixafen+ Fluopyram + Prothioconazole EC 260 (65+65+130 g/L)

IIIA 1.4 Detailed Quantitative and Qualitative Information on the Composition of the Preparation

IIIA 1.4.1 Content of active substance and formulants

The formulation was not the representative formulation.

Pure active substance:

content of pure bixafen:	65 g/L
content of pure fluopyram:	65 g/L
content of pure prothioconazole:	130 g/L
limits bixafen:	58.5 - 71.5 g/L
limits fluopyram:	58.5 - 71.5 g/L
limits prothioconazole:	122.2 - 137.8 g/L

Technical active substance:

content of technical bixafen at minimum purity (95.0 %):	68.4 g/L	(6.77 % w/w)
content of technical fluopyram at minimum purity (96.0 %):	67.7 g/L	(6.70 % w/w)
content of technical prothioconazole at minimum purity (97.0 %):	134.0 g/L	(13.26 % w/w)

None of the active substances in the formulation are present in the form of a salt, ester, anion or cation.

Further information on the active substances and on the certified limits of formulants is considered confidential and is provided separately (Part C).

IIIA 1.4.2 Certified limits of each component

This is not an EC data requirement/ not required by regulation (EU) 2011/545.

IIIA 1.4.3 Common names and code numbers for the active substance(s)

Data Point	Type	Name/Code Number		
1.4.3.1	ISO common name	Bixafen	Fluopyram	Prothioconazole
1.4.3.2	CAS No.	581809-46-3	658066-35-4	178928-70-6
1.4.3.2	EINECS No.	–	–	–
1.4.3.2	CIPAC No.	819	807	745
1.4.3.2	ELINCS	–	–	–
1.4.3.3	Salt, ester anion or cation present	–	–	–

IIIA 1.4.4 Co-formulant details: identity, structure, codes, trade name, specification and function.

CONFIDENTIAL information - data provided separately (Part C).

IIIA 1.4.5 Formulation process

IIIA 1.4.5.1 Description of formulation process

This is not an EC data requirement/ not required regulation (EU) 2011/545.

IIIA 1.4.5.2 Discussion of the formation of impurities of toxicological concern

Bixafen and fluopyram do not contain any impurities of toxicological or ecotoxicological concern.

Toluene and prothioconazole-desthio are relevant impurities of technical prothioconazole and therefore may be present in the formulation.

IIIA 1.5 Type of Preparation and Code

Type : Emulsifiable concentrate Code : EC

IIIA 1.6 Function

The product will be used as fungicide.

IIIA 1.7 Other/Special Studies

None.

IIIA 2 PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

Table 1: Summary of the physical, chemical and technical properties of the plant protection product

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Colour, odour and physical state (IIIA 2.1)	Visual assessment and organoleptic determination	Batch 2013-002135: 66.0 g/Lbixafen 64.6 g/Lfluopyram 129 g/L prothioconazole	The preparation is a clear light brown liquid with a rancid odour.	Y	Gueldner, W., Hoppe, M., 2013, M-468936-01-1	Acceptable
Explosive properties (IIIA 2.2.1)	EEC A 14	Batch 2013-002135	Not explosive in the sense of EEC guidelines A14	Y	Keldenich, H.P., 2013, M-462429-01-1	Acceptable.
Oxidizing properties (IIIA 2.2.2)	EEC A 21	Batch 2013-002135	No oxidizing properties in the sense of EEC Guideline A.21	Y	Keldenich, H.P., 2013, M-462429-01-1	Acceptable.
Flash point (IIIA 2.3.1)	EEC A 9	Batch 2013-002135	148 °C	Y	Keldenich, H.P., 2013, M-462429-01-1	Acceptable.
Flammability (IIIA 2.3.2)			not applicable as the preparation is a liquid			Acceptable.
Auto-flammability	EEC A 15	Batch 2013-002135	Auto-ignition at 360 °C.	Y	Keldenich, H.P., 2013,	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
(IIIA 2.3.3)					M-462429-01-1	
Acidity or alkalinity and pH (IIIA 2.4.1)			The test was not conducted, because the pH value of the diluted product was between 4 and 10.			Acceptable.
pH of a 1% aqueous dilution, emulsion or dispersion (IIIA 2.4.2)	CIPAC MT 75	Batch 2013-002135	Before storage and after 2 weeks at 54°C: deionised water, 20 °C: 5.9	Y	Gueldner, W., Hoppe, M., 2013, M-468936-01-1 Gueldner, W., Hoppe, M., 2013, M-468934-01-1	Acceptable.
Kinematic viscosity (IIIA 2.5.1)	OECD 114	Batch 2013-002135	Calculated values: 63.0 mm²/s (20 °C, 20 s^{-1}) 63.0 mm²/s (20 °C, 100 s^{-1}) 24.9 mm²/s (40 °C, 20 s^{-1}) 25.1 mm²/s (40 °C, 100 s^{-1}) Newtonian liquid	Y	Gueldner, W., Hoppe, M., 2013, M-468936-01-1 Gueldner, W., Hoppe, M., 2013, M-468934-01-1	Acceptable. Viscosity does not trigger H304
Dynamic viscosity (IIIA 2.5.2)	OECD 114	Batch 2013-002135	20 °C, shear rate = 20 s^{-1}: 63.7 mPa s 20 °C, shear rate 100 s^{-1}: 63.7 mPa s 40 °C, shear rate 20 s^{-1}: 24.8 mPa s 40 °C, shear rate = 100 s^{-1}:25.0 mPa s	Y	Gueldner, W., Hoppe, M., 2013, M-468936-01-1 Gueldner, W., Hoppe, M., 2013, M-468934-01-1	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Surface tension (IIIA 2.5.3)	EEC A 5	Batch 2013-002135	0.1 %, deionised water, 20 °C: 32.0 mN/m neat, 25 °C: 28.0 mN/m	Y	Gueldner, W., Hoppe, M., 2013, M-468936-01-1 Gueldner, W., Hoppe, M., 2013, M-468934-01-1	Acceptable. .
Relative density (IIIA 2.6.1)	EEC A 3	Batch 2013-002135	Before storage: d_4^{20} = 1.010 After 2 weeks, 54 °C: d_4^{20} = 1.009	Y	Gueldner, W., Hoppe, M., 2013, M-468936-01-1 Gueldner, W., Hoppe, M., 2013, M-468934-01-1	Acceptable.
Bulk or tap density (IIIA 2.6.2)			Not required as the preparation is not a powder or granule.			Acceptable.
Storage Stability after 14 days at 54º C (IIIA 2.7.1)	CIPAC MT 46.3	Batch 2013-002135	Storage material: COEX/EVOH Content of bixafen: before storage: 66.0 g/L after storage: 65.9 g/L Content of fluopyram: before storage: 64.6 g/L after storage: 64.6 g/L Content of prothioconazole: before storage: 129 g/L after storage: 129 g/L	Y	Gueldner, W., Hoppe, M., 2013, M-468936-01-1	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			Content of JAU6476-desthio before storage: 0.0020 % after storage: 0.0039 % A significant increase of foam volume after 1 min was observed. Appearance, pH, density, and emulsion properties remained unchanged.			
			Storage material: COEX/PA Content of bixafen: before storage: 66.0 g/L after storage: 65.8 g/L Content of fluopyram: before storage: 64.6 g/L after storage: 64.6 g/L Content of prothioconazole: before storage: 129 g/L after storage: 129 g/L Content of JAU6476-desthio before storage: 0.0020 % after storage: 0.0054 % A significant increase of foam volume after one min was observed. Appearance, pH, density, and emulsion properties remained unchanged.	Y	Gueldner, W., Hoppe, M., 2013, M-468934-01-1	Acceptable

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Stability after storage for other periods and/or temperatures (IIIA 2.7.2)			Not relevant as the preparation is stable for 2 weeks at 54 °C			Acceptable.
Minimum content after heat stability testing (IIIA 2.7.3)		Batch 2013-002135	Not necessary, the decrease of the active substance did not exceed 5 %.	Y	Gueldner, W., Hoppe, M., 2013, M-468936-01-1	Acceptable.
				Y	Gueldner, W., Hoppe, M., 2013, M-468934-01-1	
Effect of low temperatures on stability (IIIA 2.7.4)	CIPAC MT 39.3	Batch 2013-002135	No separated material, homogeneous liquid.	Y	Gueldner, W., Hoppe, M., 2013, M-468936-01-1 Gueldner, W., Hoppe, M., 2013, M-468934-01-1	Acceptable.
Ambient temperature shelf life (IIIA 2.7.5)		Batch 2013-002135	Storage material: COEX/PA temperature: 18.7 – 25.0 °C Content of bixafen: before storage: 66.0 g/L after storage: 65.7 g/L Content of fluopyram: before storage: 64.6 g/L	Y	Gueldner, W., Hoppe, M., 2015, M-541863-01-1	Acceptable P410 – protect from sunlight, see statement below A statement has been requested from the applicant on the significant increase of

<table>
<tr><th>Test or study & Annex point</th><th>Method used / deviations</th><th>Test material purity and specification</th><th>Findings</th><th>GLP
Y/N</th><th>Reference</th><th>Acceptability / comments</th></tr>
<tr><td></td><td></td><td></td><td>after storage: 64.0 g/L

Content of prothioconazole:
before storage: 129 g/L
after storage: 128 g/L

Content of JAU6476-desthio
before storage: 0.0020 %
after storage: 0.0086 %

0.0043 % (protected from sunlight)

A significant increase of foam volume after one min was observed. Appearance, pH, density, and emulsion properties remained unchanged.
<table>
<tr><th>test</th><th>initial</th><th>after 2 a</th></tr>
<tr><td>colour</td><td>light brown, clear</td><td>yellow brown, clear</td></tr>
<tr><td>odour</td><td>rancid</td><td>slightly fishy</td></tr>
<tr><td>pH</td><td>5.9</td><td>5.9</td></tr>
<tr><td>relative density</td><td>1.010</td><td>1.010</td></tr>
</table></td><td></td><td></td><td>foam volume after storage.</td></tr>
</table>

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			<table><tr><td>persistant foam 1 min</td><td>0 mL</td><td>38 mL</td></tr><tr><td>emulsion properties</td><td colspan="2">no problems at 0.3 and 1.5 % in water A and D</td></tr></table> No negative effects on packaging was observed, weight change < 0.1 %.			
		Batch 2013-002135:	Storage material: COEX/EVOH temperature: 18.7 – 25.0 °C Content of bixafen: before storage: 66.0 g/L after storage: 65.2 g/L Content of fluopyram: before storage: 64.6 g/L after storage: 63.6 g/L Content of prothioconazole: before storage: 129 g/L after storage: 127 g/L Content of JAU6476-desthio before storage: 0.0020 % after storage: **0.0072 %** 0.0045 % (protected	Y	Gueldner, W., Hoppe, M., 2015, M-541914-01-1	Acceptable P410 – protect from sunlight, see statement below A statement has been requested from the applicant on the significant increase of foam volume after storage.

<table>
<tr><th>Test or study & Annex point</th><th>Method used / deviations</th><th>Test material purity and specification</th><th>Findings</th><th>GLP
Y/N</th><th>Reference</th><th>Acceptability / comments</th></tr>
<tr><td></td><td></td><td></td><td>from sunlight)
A significant increase of foam volume after one min was observed. Appearance, pH, density, and emulsion properties remained unchanged.
<table>
<tr><th>test</th><th>initial</th><th>after 2 a</th></tr>
<tr><td>colour</td><td>light brown, clear</td><td>yellow brown, clear</td></tr>
<tr><td>odour</td><td>rancid</td><td>slightly fishy</td></tr>
<tr><td>pH</td><td>5.9</td><td>5.9</td></tr>
<tr><td>relative density</td><td>1.010</td><td>1.010</td></tr>
<tr><td>persistant foam
1 min</td><td>0 mL</td><td>55 mL</td></tr>
<tr><td>emulsion properties</td><td colspan="2">no problems at 0.3 and 1.5 % in water A and D</td></tr>
</table></td><td></td><td></td><td></td></tr>
</table>

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			No negative effects on packaging was observed, weight change < 0.1 %.			
		batch 2015-008154	After 6 month of storage in COEX/EVOH and COEX/PA the increase of the content of prothio-conazole-desthio is significantly lower when the containers are stored in cardboard box (to protect from sunlight).		Güldner, W., Hoppe, M., 2016	Additional information
	Statement		After 2 years of storage at ambient temperature, the content of the impurity Prothioconazole-desthio (JAU6476-desthio) was found to be above the acceptable value of 0.0064 % based on the analysis of a first sample for each packaging material. However this initial data was not confirmed by the analysis of a second sample for each packaging material stored in the same conditions. The samples of Bixafen+fluopyram+-prothioconazole EC 260 with the Prothioconazole-desthio content above the acceptable limit (respectively 0.0086 % and 0.0072 % in COEX/PA and COEX/EVOH) remained in the laboratory for a prolonged time without proper	N	Cousin, Linke-Ritzer 2016	Acceptable P410 – protect from sunlight must be written on the label, outer container and in the MSDS. During use, the container have to be stored at room temperature in the original cardboard box. As an additional option, the product could be packed in 5 L white-pigmented HDPE bottles coextruded with an

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			protection from sunlight before that their chemical analysis was performed. In contrast to this observation, the samples with the content of Prothioconazole-desthio below the acceptable limit (0.0043 % and 0.0045 %), used for checking the first analytical data, were protected from sunlight before analysis. In order to explain this untypical difference of data collected for the original study with the product and to investigate the effect of light, additional 2-year storage stability studies at ambient temperature were started in September 2015. After 6 months of storage at ambient temperature, the content of prothioconazole-desthio was found to be well below the acceptable value of 0.0064 % and the data showed that the formation of Prothioconazole-desthio in the mixture bixafen + fluopyram + prothioconazole EC260 is lower when containers are protected from sunlight in cardboard boxes (see 2.7.5/03). Therefore, the protection of containers from sunlight during storage and handling allows to limit the formation of the impurity Prothioconazole-desthio in the			internal barrier layer made of PA. For this option further information on the increase of the relevant impurity P.-desthio is requested.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			product Bixafen+fluopyram+prothio-conazole EC 260. In the manufacturing sites, bottles are filled and packed in cardboard boxes in an automatic production line and therefore are protected from sunlight during production, transport and storage until the distribution of the product and the use by farmers. The following precautionary statement will be written on the label, outer container and MSDS: "P410 Protect from sunlight". During use containers will have to be stored at room temperature, protected from the sunlight and in its original cardboard box. As an additional option, the product could be packed in 5 L white-pigmented HDPE bottles coextruded with an internal barrier layer made of PA in order to improve the protection of containers from sunlight. The specifications of this packaging are exactly the same as the natural HDPE / PA packaging proposed in the dossier.			
Shelf life in months (if less than 2 years) (IIIA 2.7.6)			Please refer to 2.7.5			Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Wettability (IIIA 2.8.1)			Not relevant for liquid formulations			Acceptable.
Persistence of foaming (IIIA 2.8.2)	CIPAC MT 47.2	Batch 2013-002135:	CIPAC water D, 1.5 %: Before storage 10s: 51 mL 1 min: 0 mL 3 min: 0 mL 12 min: 0 mL 2 weeks, 54 °C 10s: 68 mL 1 min: 27 mL 3 min: 10 mL 12 min: 6 mL	Y	Gueldner, W., Hoppe, M., 2013, M-468936-01-1	Acceptable. A statement has been requested from the applicant on the significant increase of foam volume after storage.
			CIPAC water D, 1.5 %: Before storage 10s: 51 mL 1 min: 0 mL 3 min: 0 mL 12 min: 0 mL 2 weeks, 54 °C 10s: 69 mL 1 min: 21 mL 3 min: 11 mL 12 min: 6 mL	Y	Gueldner, W., Hoppe, M., 2013, M-468934-01-1	
Suspensibility (IIIA 2.8.3.1)			Not applicable as the preparation is an emulsifiable concentrate			Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Spontaneity of dispersion (IIIA 2.8.3.2)			Not applicable as the preparation is an emulsifiable concentrate			Acceptable.
Dilution stability (IIIA 2.8.4)			Not applicable as the preparation is an emulsifiable concentrate			Acceptable.
Dry sieve test (IIIA 2.8.5.1)			Not applicable as the preparation is an emulsifiable concentrate			Acceptable.
Wet sieve test (IIIA 2.8.5.2)			Not applicable as the preparation is an emulsifiable concentrate			Acceptable.
Particle size distribution (IIIA 2.8.6.1)			Not applicable as the preparation is an emulsifiable concentrate			Acceptable.
Nominal size range of granules (IIIA 2.8.6.2)			Not applicable as the preparation is an emulsifiable concentrate			Acceptable.
Dust content (IIIA 2.8.6.3)			Not applicable as the preparation is an emulsifiable concentrate			Acceptable.
Particle size of dust (IIIA 2.8.6.4)			Not applicable as the preparation is an emulsifiable concentrate			Acceptable.
Friability and attrition (IIIA 2.8.6.5)			Not applicable as the preparation is an emulsifiable concentrate			Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Emulsifiability (IIIA 2.8.7.1) Emulsion stability (IIIA 2.8.7.2) Re-emulsifiability (IIIA 2.8.7.3)	CIPAC MT 36.3	Batch 2013-002135: 66.0 g/Lbixafen 64.6 g/Lfluopyram 129 g/L prothioconazole	0.3 % and 1.5 % in CIPAC water A and water D: Initial and after 2 weeks at 54 °C Initial emulsification: spontaneously Separation after 30 min: none Separation after 2 h: none Separation after 24 h: none Re-emulsification after 24 h: completely separation after 24.5 h: none	Y	Gueldner, W., Hoppe, M., 2013, M-468936-01-1 Gueldner, W., Hoppe, M., 2013, M-468934-01-1	Acceptable. Test was conducted at highest and lowest in use tank concentration.
Flowability (IIIA 2.8.8.1)			Not applicable as the preparation is an emulsifiable concentrate			Acceptable.
Pourability (including rinsed residue) (IIIA 2.8.8.2)			Not applicable as the preparation is an emulsifiable concentrate			Acceptable.
Dustability following accelerated storage (IIIA 2.8.8.3)			Not applicable as the preparation is an emulsifiable concentrate			Acceptable.
Physical compatibility of tank mixes (IIIA 2.9.1)			Not applicable (tank mixtures with other pesticides are not recommended)			Acceptable.
Chemical			Not applicable (tank mixtures with			Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
compatibility of tank mixes (IIIA 2.9.2)			other pesticides are not recommended)			
Distribution to seed (IIIA 2.10.1)			Not required as the preparation is not intended for seed treatment purposes.			
Adhesion to seeds (IIIA 2.10.2)			Not required as the preparation is not intended for seed treatment purposes.			
Miscibility (IIIA 2.11)			Not required by regulation (EU) 2011/545.			Acceptable.
Dielectric breakdown (IIIA 2.12)			Not required by regulation (EU) 2011/545.			Acceptable.
Corrosion characteristics (IIIA 2.13)			Not required by regulation (EU) 2011/545.			Acceptable.
Container material (IIIA 2.14)			Not required by regulation (EU) 2011/545.			Acceptable.
Other/special studies (IIIA 2.15)			Not required by regulation (EU) 2011/545.			Acceptable.

IIIA 2.16 Summary and Evaluation of Data Presented Under Points 2.1 to 2.15

The product 'Bixafen + Fluopyram + Prothioconazole EC 260 (65+65+130 g/L) is an emulsifiable concentrate All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a clear light brown liquid with a rancid odour. It is not explosive, has no oxidising properties. It has a self ignition temperature of 360 °C. In aqueous solution, it has a pH value around 6.

The stability data indicate a shelf life of at least 2 years at ambient temperature in HDPE/PA and HDPE/EVOH.

The formulation must be protected from sunlight (P410), otherwise the content of the relevant impurity prothioconazol-desthio will rise above the acceptable level.

The technical characteristics are acceptable for an emulsifiable concentrate formulation.

Experimental testing of the product's physico-chemical and technical characteristics:

See Appendix 3

Implications for labelling:

No labelling necessary due to physical or chemical properties described above.

IIIA 3 DATA ON APPLICATION OF THE PLANT PROTECTION PRODUCT

IIIA 3.1 Field of Use

Insert information.

IIIA 3.2 Nature of the Effects on Harmful Organisms

Insert information on mode of action and effects.

IIIA 3.3 Details of Intended Use

IIIA 3.3.1 Details of existing and intended uses

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.3.2 Details of harmful organisms against which protection is afforded

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.3.3 Effects achieved

Please refer to Part B Section 7.

IIIA 3.4 Proposed Application Rates (Active Substance and Preparation)

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.5 Concentration of the Active Substance in the Material Used

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.6 Method of Application, Type of Equipment Used and Volume of Diluent

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.7 Number and Timings of Applications, Timing, Growth Stages (of Crop and Harmful Organism) and Duration of Protection

IIIA 3.7.1 Maximum number of applications and their timings

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.7.2 Growth stages of crops or plants to be protected

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.7.3 Development stages of the harmful organism concerned

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.7.4 Duration of protection afforded by each application

Please refer to Part B Section 7.

IIIA 3.7.5 Duration of protection afforded by the maximum number of applications

Please refer to Part B Section 7.

IIIA 3.8 Necessary Waiting Periods or Other Precautions to Avoid Phytotoxic Effects on Succeeding Crops

IIIA 3.8.1 Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops

Please refer to Part B Section 7.

IIIA 3.8.2 Limitations on choice of succeeding crops

Please refer to Part B Section 7.

IIIA 3.8.3 Description of damage to rotational crops

Please refer to Part B Section 7.

IIIA 3.9 Proposed Instructions for Use as Printed on Labels

Please refer to Registration Report – Part A, Appendix 2 for the relevant country.

IIIA 3.10 Other/Special Studies

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA 4 FURTHER INFORMATION ON THE PLANT PROTECTION PRODUCT

IIIA 4.1 Packaging and Compatibility with the Preparation

Packaging Summary

Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

IIIA 4.1.1 Description and specification of the packaging

The product 'Bixafen + Fluopyram + Prothioconazole EC 260 (65+65+130 g/L) is to be marketed in high-density polyethylene containers with an inner barrier, e.g., polyamide (PA/PE). They are sealed by foil seals, protected by screw caps of polyethylene.

1-15 litre bottle/canister:	material:	- PA / adhesive / HDPE, - EVOH / adhesive / HDPE
	opening:	50-63 mm
	closure:	Screw cap to fit container neck as defined in ECPA One Trip Container Guidelines. Injection moulded of PE or PP.
	seal:	HF seal or internal wad

IIIA 4.1.2 Suitability of the packaging and closures

Packaging materials & solutions have been tested and comply with Annex A.5 of ADR (European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR -1990) respectively Annex V of RID respectively of IMDG – Code.

IIIA 4.1.3 Resistance of the packaging material to its contents

Report:	Gueldner, W.; Hoppe, M., 2013
Title:	Storage stability at elevated temperature and cold stability of bixafen + fluopyram + prothioconazole EC 260 (65+65+130 g/L) Packaging material: COEX/EVOH - Final report (14 days) - BIX+FLU+PTZ EC 260 (65+65+130) G Bayer CropScience, Report No.: FM0183(PKF03)G01
Document No:	M-468936-01-1
Guidelines:	Regulation (EU) No 545/2011.Annex III 2.7.1, EEC 94/37, Manual on Development and Use of FAO Specifications for Plant Protection Products (Jan. 1999)

GLP	No

The product was visually checked for influence on the original container after 2 weeks storage in accordance to EC regulations and in compliance with GLP principles. The product had no adverse effects on the container, seal and closure after 2 weeks storage at 54°C.

Package: 1L COEX/EVOH bottle.

Weight loss after 2 weeks month: < 0.1 %.

Report:	Gueldner, W.; Hoppe, M., 2013
Title:	Storage stability at elevated temperature and cold stability of bixafen + fluopyram + prothioconazole EC 260 (65+65+130 g/L) Packaging material: COEX/PA - Final report (14 days) - BIX+FLU+PTZ EC 260 (65+65+130) G Bayer CropScience, Report No.: FM0183(PKF02)G01,
Document No:	M-468934-01-1
Guidelines:	Regulation (EU) No 545/2011.Annex III 2.7.1, EEC 94/37, Manual on Development and Use of FAO Specifications for Plant Protection Products (Jan. 1999)
GLP	No

The product was visually checked for influence on the original container after 2 weeks storage in accordance to EC regulations and in compliance with GLP principles. The product had no adverse effects on the container, seal and closure after 2 weeks storage at 54°C.

Package: 1L COEX/PAbottle.

Weight loss after 2 weeks month: < 0.1 %.

IIIA 4.2 Procedures for Cleaning Application Equipment

IIIA 4.2.1 Procedures for cleaning application equipment and protective clothing

General statement

All application equipment and contaminated protective clothing should be washed/cleaned with water or a diluted detergent solution and thoroughly rinsed. Care should be taken not to spill the contaminated washings from application equipment into waste water channels. Contaminated cleaning liquids should be disposed of safely according to local regulations.

Application equipment:

Product left over in field spraying equipment which has not been sufficiently cleaned may cause damage during sequential treatment of sensitive crops. As a consequence, cleaning out of field spraying equipment is an essential part of the recommendations for use of plant protection product.

Procedure:

Empty the spraying equipment completely on the field just sprayed. Remove all filters and nozzles, scrub clean and rinse them with clean water. Put 10 % clean water into tank to cover the agitator. Operate a tank flushing system if fitted. Circulate water through the pump and controls for at least one minute. Drain sprayer, collect washings. Repeat procedure once more. Pump last washing water out through boom feed hoses and pipes. Collect washings. Clean off the outside of the sprayer using minimum water volumes. Collect washings. Replace cleaned nozzles and filters. Collect and put all washings back into the tank and spray out on the field headland, or otherwise safely dispose of them. Ensure the sprayer systems are completely drained before storage. Store Plant Protection Equipment in a properly designated store.

Protective clothing:

All contaminated clothing should be washed/cleaned through with a dilute detergent solution and thoroughly rinsed with clean water.

- Impermeable overalls, boots and face shields should be washed clean and dried.
- Permeable overalls should be laundered after use.
- Disposable overalls and gloves should be washed and disposed of as contaminated waste.
- Gloves and boots should be washed clean, if necessary on the insides as well.

IIIA 4.2.2 Effectiveness of the cleaning procedures

Report:	Friessleben, R., 2008
Title:	Summary and conclusive report of studies on spray tank cleaning realized in the years 2000 - 2008
Document No:	M-357166-01-1
Guidelines:	None
GLP	No

The report summarizes the results of trials on tank cleaning realized in the years 2000 - 2008. These trials were carried out because registration of crop protection products requires specific information on the cleaning of sprayer tanks to avoid damages during subsequent treatments. During this period, 72 studies were conducted, in which a total of 60 active substances (16 fungicides, 33 herbicides, 3 safeners, 7 insecticides and 1 growth regulator) were tested. All tests were done with the same spraying equipment and under the same test protocol, thus the differences found in the results reflect the different behaviour of active substances and formulation systems.

Within this report it has been shown that cleaning efficacy does not depend on chemical or formulation related parameters and therefore a global statement on tank cleaning efficacy is justified. The results can be summarized as follows:

1. The established cleaning procedure, including two rinsing processes and the careful cleaning of all filters, is able to remove or reduce active substances leftover down to neglectable quantities.

2. By following the tank cleaning recommendation product groups (herbicides, fungicides, insecticides, and growth regulators), formulations and concentrations differ only quantitatively. The cleaning success follows an exponential function. From one cleaning step to the next one, the initial concentration is reduced by at least one order of magnitude.

3. After filling the tank with fresh water, the active substance concentrations in all trials are either below the Limit of Quantification or are not relevant as far as biological effects during follow-up treatments are concerned.

4. According to the extensive number of results available, the recommendations on the product label regarding tank cleaning can apply equally to all products.

As a conclusion it can be proposed that no further studies for individual formulations need to be performed.

IIIA 4.3 Re-entry Periods to Protect Man, Livestock and the Environment

IIIA 4.3.1 Pre-harvest interval (in days) for each relevant crop

See section 4.

IIIA 4.3.2 Re-entry period (in days) for livestock, to areas to be grazed

See section 4.

IIIA 4.3.3 Re-entry period (in hours or days) for man to crops, buildings or spaces treated

See section 4.

IIIA 4.3.4 Withholding period (in days) for animal feeding stuffs

See section 4.

IIIA 4.3.5 Waiting period (in days) between application and handling of treated products

See section 4.

IIIA 4.3.6 Waiting period (in days) between last application and sowing or planting succeeding crops

See section 4.

IIIA 4.3.7 Information on specific conditions under which the preparation may or may not be used

See section 4.

IIIA 4.4 Statement of the Risks Arising and the Recommended Methods and Precautions and Handling Procedures to Minimise Those Risks

Report:	Anonymous, 2014

Title:	Safety data sheet BIX+FLU+PTZ EC 65+65+130A G

The safety data sheet complies with actual EEC regulations and is based on the present state of knowledge.

IIIA 4.4.1 Warehouse storage

Please refer to the safety data sheet (KIIIA 4.4/01).

IIIA 4.4.2 User level storage

Please refer to the safety data sheet (KIIIA 4.4/01).

IIIA 4.4.3 Transport

Please refer to the safety data sheet (KIIIA 4.4/01).

IIIA 4.4.4 Fire

Please refer to the safety data sheet (KIIIA 4.4/01).

IIIA 4.4.5 Nature of protective clothing proposed

Please refer to the safety data sheet (KIIIA 4.4/01).

IIIA 4.4.6 Characteristics of protective clothing proposed

Please refer to the safety data sheet (KIIIA 4.4/01).

IIIA 4.4.7 Suitability and effectiveness of protective clothing and equipment

Please refer to the safety data sheet (KIIIA 4.4/01).

IIIA 4.4.8 Procedures to minimise the generation of waste

Please refer to the safety data sheet (KIIIA 4.4/01).

IIIA 4.4.9 Combustion products likely to be generated in the event of fire

Please refer to the safety data sheet (KIIIA 4.4/01).

IIIA 4.5 Detailed Procedures for Use in the Event of an Accident During Transport, Storage or Use

IIIA 4.5.1 Containment of spillages

Please refer to the safety data sheet (KIIIA 4.4/01).

IIIA 4.5.2 Decontamination of areas, vehicles and buildings

Please refer to the safety data sheet (KIIIA 4.4/01).

IIIA 4.5.3 Disposal of damaged packaging, adsorbents and other materials

Please refer to the safety data sheet (KIIIA 4.4/01).

IIIA 4.5.4 Protection of emergency workers and bystanders

Please refer to the safety data sheet (KIIIA 4.4/01).

IIIA 4.5.5 First aid measures

Please refer to the safety data sheet (KIIIA 4.4/01).

IIIA 4.6 Neutralisation Procedure for Use in the Event of Accidental Spillage

Any chemical treatment at the location of an accidental spillage would be difficult to control in terms of efficiency and safety and is therefore not recommended. In this event collect and dispose of the residues and contaminated materials through controlled incineration according to the procedure described under 4.7.

IIIA 4.6.1 Details of proposed procedures for small quantities

Please refer to point 4.6.

IIIA 4.6.2 Evaluation of products of neutralization (small quantities)

Please refer to point 4.6.

IIIA 4.6.3 Procedures for disposal of small quantities of neutralized waste

Please refer to point 4.6.

IIIA 4.6.4 Details of proposed procedures for large quantities

Please refer to point 4.6.

IIIA 4.6.5 Evaluation of products of neutralization (large quantities)

Please refer to point 4.6.

IIIA 4.6.6 Procedures for disposal of large quantities of neutralized waste

Please refer to point 4.6.

IIIA 4.7 Pyrolytic Behaviour of the Active Substance

Since the halogen content of both active substances is below 60%, combustion under controlled conditions in a waste incineration plant is unlikely to result in the formation of halogenated dibenzo-dioxins and dibenzo-furans at unacceptable levels. Special studies are not triggered.

IIIA 4.8 Disposal Procedures for the Plant Protection Product

IIIA 4.8.1 Detailed instructions for safe disposal of product and its packaging

As containers are combustible (HDPE), burn the emptied containers in a commercial incinerator. Otherwise, they should be rendered unusable, e.g. by puncturing, and disposed of in accordance with local regulations.

Do not reuse an empty pesticide container for any purpose unless:

- it is specifically designed to be returned and refilled and you are doing so in line with the label instructions; or

- you are filling it with an identical pesticide product transferred from a damaged container.

Before disposing of rigid, non-returnable containers, you should always thoroughly rinse them in line with the label instructions.

If there are no instructions, you should:

- use purpose-made container-rinsing equipment in line with the manufacturer's instructions (for example, pressure rinsing devices forming part of many sprayer induction bowls); or

- rinse containers by hand at least three times (or until the container is visibly clean) with clean water. Add the rinsings to the spray solution.

You should always rinse containers immediately after emptying them, once you have allowed the product to drain fully into the equipment that is applying it. You should also rinse contaminated closures (caps and seals) and any contamination on the outside of containers. All rinsings should be added to the spray solution. If, for any reason, you have container rinsings which you cannot add to the application equipment (for example, if you are not applying the pesticide as a spray or dipping solution), you should collect the contaminated rinsings in a suitable, labelled container, and store it in a safe place.

You should then dispose of the rinsings and leftover quantities of undiluted product in line with the local guidance, for example, Code of practice for using plant protection products, Defra January 2006.

Leftover quantities of the product may be burned in a commercial incinerator.

Incineration under controlled conditions according to the EEC Directive 94/37 is the preferred and the most environmentally acceptable means to safely dispose of the active substance as well as plant production products containing it, contaminated materials or packaging.

Report:	KIIIA 4.8.1/01, Schneider, K, 2008
Title:	Bixafen: Incineration as a safe means of disposal and pyrolytic behaviour under controlled conditions.
Document No:	M- 298415-01-1
Guidelines:	EU Directive 91/414/EEC modified by Directive 94/37/EC (Statement).
GLP	Not relevant

Since bixafen contains more than 1% of halogens, incineration under the following controlled conditions is recommended as a safe means of disposal :

temperature above 1100 °C

residence time greater than 2 seconds

presence of more than 6% of oxygen

Exhaust gases should not exceed:

10 mg/m^{-3} Hydrochloric Acid as an average on 24 hours

1 mg/m^{-3} Hydrofluoric Acid as an average on 24 hours

Report:	KIIIA 4.8.1/02, Bogdoll, B., 2008

Title:	Fluopyram - Statement on the pyrolytic behaviour under controlled conditions and on the controlled incineration as a safe means of disposal - AE C656948
Document No:	M-297296-01-2
Guidelines:	EU Directive 91/414/EEC Annex II, 3.8.1, amended by Directive 94/37/EC, Annex I, 3.8.1
GLP	Not relevant

As fluopyram contains more than 1 % of halogens, incineration is recommended as a safe means of disposal and the controlled conditions recommended are:

- temperature above 1100 °C

- residence time greater than 2 seconds

- presence of more than 6 % of oxygen.

Exhaust gases should not exceed:

- 10 mg/m3 hydrogen chloride as an average on 24 hours

- 1 mg/.m3 hydrogen fluoride as an average on 24 hours.

Report:	KIIIA 4.8.1/03, Schneider, K, 2008
Title:	Prothioconazole: Incineration as a safe means of disposal and pyrolytic behaviour under controlled conditions.
Document No:	M-302076-01-1
Guidelines:	EU Directive 91/414/EEC modified by Directive 94/37/EC (Statement).
GLP	Not relevant

Since prothioconazole (JAU 6476) contains more than 1% of halogens, incineration under the following controlled conditions is recommended as a safe means of disposal :

temperature above 1100 °C

residence time greater than 2 seconds

presence of more than 6% of oxygen

Exhaust gases should not exceed:

10/mg.m-3 Hydrochloric Acid as an average on 24 hours

IIIA 4.8.2 Methods other than controlled incineration for disposal

Applications that involve controlled incineration with energy recovery are considered to be the most environmentally-acceptable means of disposal of the active substance as well as plant production products

containing it, contaminated materials or packaging. However, where local recycling schemes exist, these should also be considered if conditions can be met.

IIIA 4.9 Other/Special Studies

No additional studies were performed.

IIIA 11 FURTHER INFORMATION

IIIA 11.1 Information of Authorisations in Other Countries

see EU pesticide data base (http://ec.europa.eu/sanco_pesticides/public/)

IIIA 11.2 Information on Established Maximum Residue Limits (MRL) in Other Countries

MRLs are set at European level, see Regulation (EC) No. 396/2005.

IIIA 11.3 Justified Proposals for Classification and Labelling

Proposals for classification and labelling of Bixafen + Fluopyram + Prothioconazole EC 260 (65+65+130 g/L) in accordance with the EC Directive on dangerous preparations 1999/45/EC and Directive 2001/59/EC (as amended) are presented below:

Physico-chemical properties

Table 11.3-1 Physico-chemical properties

Study Type	Findings (triggered risk phrase)	Reference
Explosivity	Not explosive (-)	Keldenich, H.P., 2013, M-462429-01-1
Oxidizing properties	Not oxidizing (-)	Keldenich, H.P., 2013, M-462429-01-1
Flammability	Auto-ignition temperature is 360 °C	Keldenich, H.P., 2013, M-462429-01-1
Content of hydrocarbon	< 10 % (w/w)	

Table 11.3-1 Physico-chemical properties

Study Type	Findings (triggered risk phrase)	Reference
Viscosity (dynamic)	24.9 mPas (at a shear rate of 20 s^{-1} at 40 °C) 25.1 mPas (at a shear rate of 100 s^{-1} at 40 °C)	Gueldner, W., Hoppe, M., 2013, M-468936-01-1
Surface tension	neat product: 28.0 mN/m 32.0 mN/m at 0.1 %	Gueldner, W., Hoppe, M., 2013, M-468936-01-1

The formulation should be protected from sunlight (P410), as otherwise the content of the relevant impurity prothioconazole-desthio will increase significantly.

Toxicology

see section 3.

Ecotoxicology/Environment

see section 6.

IIIA 11.4 Proposals for Risk and Safety Phrases

Please refer to Registration Report – Part A.

IIIA 11.5 Proposed Label

Please refer to Registration Report – Part A.

IIIA 11.6 Specimens of Proposed Packaging

Specimens of the packaging were not provided as there was no request.

Appendix 1: List of data used in support of the evaluation

Annex point/ reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant)	Data protection claimed	Owner	How considered in dRR Study-Status / Usage*
KIIIA 2.1 KIIIA 2.4.2 KIIIA 2.5.1 KIIIA 2.5.2 KIIIA 2.5.3 KIIIA 2.6.1 KIIIA 2.7.1 KIIIA 2.7.3 KIIIA 2.7.4 KIIIA 2.8.2 KIIIA 2.8.7.1 KIIIA 2.8.7.2 KIIIA 2.8.7.3 KIIIA 4.1.3	Gueldner, W.; Hoppe, M.	2013	Storage stability at elevated temperature and cold stability of bixafen + fluopyram + prothioconazole EC 260 (65+65+130 g/L) - Packaging material: COEX/EVOH - Final report (14 days) - BIX+FLU+PTZ EC 260 (65+65+130) G Report No.: FM0183(PKF03)G01, Edition Number: M-468936-01-1 GLP/GEP: yes, unpublished	Y	Bayer CropScience = BCS	1
KIIIA 2.2.1 KIIIA 2.2.2 KIIIA 2.3.1 KIIIA 2.3.3	Keldenich, H. P.	2013	Safety-relevant data of bixafen + fluopyram + prothioconazole EC 260 (65+65+130 g/L) Bayer Technology Services GmbH, Leverkusen. Germany Report No.: 2013/00657, Edition Number: M-462429-01-1 GLP/GEP: yes, unpublished	Y	BCS	1
KIIIA 2.4.2 KIIIA 2.5.1 KIIIA 2.5.2 KIIIA 2.5.3 KIIIA 2.6.1 KIIIA 2.7.1 KIIIA 2.7.3 KIIIA 2.7.4 KIIIA 2.8.2 KIIIA 2.8.7.1 KIIIA 2.8.7.2 KIIIA 2.8.7.3 KIIIA 4.1.3	Gueldner, W.; Hoppe, M.	2013	Storage stability at elevated temperature and cold stability of bixafen + fluopyram + prothioconazole EC 260 (65+65+130 g/L) - Packaging material: COEX/PA - Final report (14 days) - BIX+FLU+PTZ EC 260 (65+65+130) G Report No.: FM0183(PKF02)G01, Edition Number: M-468934-01-1 GLP/GEP: yes, unpublished	Y	BCS	1

Annex point/ reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant)	Data protection claimed	Owner	How considered in dRR Study-Status / Usage*
KIIIA1 2.7.5	Gueldner, W.; Hoppe, M.	2015	Shelf life of bixafen + fluopyram + prothioconazole EC 260 Packaging material: **Coex/PA** final report Report No.: M-541863-01-1 FM0183(SLF02)G01 GLP: yes, unpublished	Y	BCS	1
KIIIA1 2.7.5/02	Gueldner, W.; Hoppe, M.	2015	Shelf life of bixafen + fluopyram + prothioconazole EC 260 Packaging material: **Coex/EVOH** final report Report No.: M-541914-01-1 FM0183(SLF03)G01 GLP: yes, unpublished	Y	BCS	1
KIIIA1 2.7.5/03	Gueldner, W.; Hoppe, M.	2016	Content of active substances and relevant impurity JAU6476-desthio before and after storage for 6 month at ambient temperature … final report (**6 month**) Report No.: M-555918-01-1 FM0183(STM00)N01 GLP: yes, unpublished	Y	BCS	5
KIIIA1 2.7.5/04	Cousin, J.; Linke-Ritzer, P.	2016	Bixafen+fluopyram+prothioconazole EC 260 2-year storage shelf life at ambient temperature Statement M-570249-01-1 GLP: no, unpublished	Y	BCS	1
KIIIA 4.2.2 /01	Friesslebe n, R.	2008	Summary and conclusive report of studies on spray tank cleaning realized in the years 2000 - 2008 Tessenderlo Kerley Inc., Report No.: M-357166-01-1, Edition Number: M-357166-01-1 GLP/GEP: n.a., unpublished	Y	BCS	1

Annex point/ reference No	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Report-No.** **GLP or GEP status (where relevant)**	**Data protection claimed**	**Owner**	**How considered in dRR** **Study-Status / Usage***
KIIIA 4.4 /01	Anon.	2014	BIX+FLU+PTZ EC 65+65+130A G Report No.: M-481044-01-1, Edition Number: M-481044-01-1 GLP/GEP: n.a., unpublished	No	-public data-	5
KIIIA 4.8.1	Schneider, K.	2008	Bixafen Incineration as a safe means of disposal and pyrolytic behaviour under controlled conditions Code: BYF 00587 Report No.: M-298415-01-1, Edition Number: M-298415-01-1 GLP/GEP: no, unpublished	Yes	BCS	5
KIIIA 4.8.1	Bogdoll, B.	2008	Fluopyram - Statement on the pyrolytic behaviour under controlled conditions and on the controlled incineration as a safe means of disposal - AE C656948 Report No.: AF08/011, Edition Number: M-297296-01-2 GLP/GEP: n.a., unpublished	Yes	BCS	5
KIIIA 4.8.1	Schneider, K.	2008	Prothioconazole - Incineration as a safe means of disposal and pyrolytic behaviour under controlled conditions Report No.: M-302076-01-1, Edition Number: M-302076-01-1 GLP/GEP: no, unpublished	Yes	BCS	5

* 1 accepted (study valid and considered for evaluation)
2 not accepted (study not valid and not considered for evaluation)
3 not considered (study not relevant for evaluation)
4 not submitted but necessary (study not submitted by applicant but necessary for evaluation)
5 supplemental (additional information, alone not sufficient to fulfil a data requirement, considered for evaluation)

Appendix 2: Critical Uses – Justification and GAP tables

GAP rev. (No), date: year-month-day

PPP (product name/code)	**product name / code**	**Formulation type:**	**type**
active substance 1	**active substance 1**	**Conc. of as 1:**	**conc.**
active substance 2	**active substance 2**	**Conc. of as 2:**	**conc.**
active substance …	**active substance ...**	**Conc. of as:…**	**conc.**
safener safener		**Conc. of safener:**	**conc.**
synergist	**synergist**	**Conc. of synergist:**	**conc.**
Applicant:	**company**	**professional use**	☐
Zone(s):northern/central/southern/EU		**non professional use**	☐

Verified by MS: yes/no

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001												
002												
003												
004												
005												

Appendix 3: Experimental testing of the product's physico-chemical and technical characteristics:

The following physical, chemical and technical properties of the plant protection product were experimentally tested:

density, colour, pH, surface tension, storage stability at high temperatures (14 d at 54 °C), low temperature stability (7 d at 0 °C), persistent foaming and emulsion properties.

Some deviations from the data submitted by the applicant were detected for pH and persistent foaming after accelerated storage, but these differences are not considered as critical.

The formulation complies with the chemical, physical and technical criteria which are stated for this type of formulation in the FAO/WHO manual (2016).

REGISTRATION REPORT
Part B

Section 2: Analytical Methods
Detailed summary of the risk assessment

Product code:	**102000027828**	
Active Substance:	**Bixafen**	**65 g/L**
	Fluopyram	**65 g/L**
	Prothioconazole	**130 g/L**

Central Zone
Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant:	**Bayer CropScience**
Submission Date:	**14/05/2014**
Date:	**October 2017**

Table of Contents

IIIA 5 METHODS OF ANALYSIS

This document summarises the information related to the analytical methods for the plant protection product BIX+FLU+PTZ EC 260 (65+65+130 g/l) which contains the active substances bixafen, fluopyram and prothioconazole.

Bixafen was approved for inclusion into Annex I in accordance with Regulation (EC) No 1107/2009, Council Directive 91/414/EEC (Implementing Regulation (EU) No. 350/2013, dated 17 April 2013) with the entry into force of 1 October 2013. Fluopyram was included into Annex I of Regulation (EC) No 1107/2009, (Implementing Regulation (EU) No 802/2013, dated 22 August 2013) with the entry into force of 1 February 2014. Prothioconazole was included in Annex I of Directive 91/414/EEC, (Directive 2008/44/EC dated 4 April 2008) with the entry into force on 1 August 2008.

This product was not the representative formulation. The product has not been previously evaluated according to Uniform Principles.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

Information on the detailed composition of product can be found in the confidential dossier of this submission (Registration Report - Part C).

IIIA 5.1 Analytical Standards and Samples

IIIA 5.1.1 Samples of the preparation

A sample of the preparation was provided by the applicant but no analysis of the contents of the active substances or the relevant impurities toluene and prothioconazole-desthio was performed.

IIIA 5.1.2 Analytical standards for the pure active substance

Analytical standards of bixafen, fluopyram or prothioconazole were not provided because there was no request.

IIIA 5.1.3 Samples of the active substance as manufactured

No samples were provided because there was no request.

IIIA 5.1.4 Analytical standards for relevant metabolites and all other components included in the residue definition

No samples were provided because there was no request.

IIIA 5.1.5 Samples of reference substances for relevant impurities

No samples were provided because there was no request.

IIIA 5.2 Methods for the Analysis of the Plant Protection Product

IIIA 5.2.1 Description of the analytical methods for the determination of the active substance in the plant protection product

Please refer to chapter 5.2.2 as BIX+FLU+PTZ EC 260 (65+65+130 g/l) contains more than one active substance.

IIIA 5.2.2 For preparations containing more than one active substance, description of method for determining each in the presence of the other

The following analytical method for the determination of the active substances in the plant protection product performed on BIX+FLU+PTZ EC 260 (65+65+130 g/l has not previously been reviewed.

Report:	IIIA 5.2.2/01, Michel, A., 2013
Title:	Determination of bixafen, fluopyram and prothioconazole in formulations ; Assay - HPLC, external standard
Document No:	AM018212MF2 M-430584-02-1
Guidelines:	SANCO/3030/99 rev. 4
GLP	No

Report:	IIIA 5.2.2/02, Kienow, A.; Michel, A.; 2013
Title:	Validation of HPLC-method AM018212MF2 - Determination of bixafen, fluopyram and prothioconazole in formulations - bixafen + fluopyram + prothioconazole EC 260 (65+65+130 g/L)
Document No:	VB2-AM006906MF1 M-460510-01-1
Guidelines:	SANCO/3030/99 rev. 4
GLP	Yes

Method description

The analytes are determined by reversed-phase HPLC on a XBridge Shield RP18 column (50 x 4.6 mm, dp = 2.5 µm) at 30 °C column temperature, using isocratic elution and external calibration. Injection volume is 3 µl. The separation is achieved by using gradient flow conditions for the detection and quantification of the actives (2 ml/min). Detection is performed with a UV detector at 272 nm. The mobile phase consists of 450 ml acetonitrile, 545 ml water and 5 ml sulfuric acid. The analytes are quantified by comparing the specific response ratios of the samples with those of standards of known quality.

Method validation

It was with respect to precision, accuracy, linearity and specificity proved that the method is suitable for the determination of bixafen, fluopyram and prothioconazole in the EC-formulation.

Table containing the validation of the method (formulation BIX+FLU+PTZ EC 260 (65+65+130 g/l)

Analyte	**Linearity n = 6**	**Accuracy n = 6 Mean [%]**	**Repeatability n = 6 [%RSD]**	**Specificity/Interferences**
Bixafen	50 - 150 % of expected concentration	101.0	0.16 RSDr = 2.02 (mean content	UV-spectra of analyte in sample and reference item show no spectral differences. The retention time of analyte and reference

	12.44 – 43.26 mg/100 mL r = 0.99998		6.5 %)	are identical. No interferences were noted. Chromatograms of formulation with and without active substances present were submitted.
Fluopyram	50 - 150 % of expected concentration 10.49 – 49.46 mg/100 mL r = 0.99999	100.8	0.45 RSDr = 2.03 (mean content 6.4 %)	
Prothioconazole	50 - 150 % of expected concentration 25.19 – 92.77 mg/100 mL r = 0.99041	99.8	0.22 RSDr = 1.82 (mean content 13.0 %)	

Summary
The active substances bixafen, fluopyram and prothioconazole (this ingredient is stabilized by L-cysteine-hydrochloride-monohydrate) are dissolved in acetonitril / water, chromatographed on a HPLC reversed phase system with UV-detection and external calibration.
The method is sufficiently validated according to SANCO 3030/99 rev 4 and can be applied for formulation BIX+FLU+PTZ EC 260 (65+65+130 g/l).

IIIA 5.2.3 Applicability of existing CIPAC methods

There is no CIPAC method available for the determination of bixafen, fluopyram or prothioconazole in EC-formulations like BIX+FLU+PTZ EC 260 (65+65+130 g/l).

IIIA 5.2.4 Description of analytical methods for the determination of relevant impurities

Prothioconazole contains prothioconazole-desthio as relevant impurity. The content must not exceed 0.5 g/kg in the technical material.

Report:	IIIA 5.2.4/01, Schulz, 2012
Title:	Determination of prothioconazole-desthio (SXX 0665) in formulations - Assay HPLC-MS/MS, external standard - Amendment no. 1 - Previous report number: M-078059-02-1
Document No:	2001-0051702-10 M-450152-01-1
Guidelines:	SANCO/3030/99 rev. 4
GLP	No

Report:	IIIA 5.2.4/02, Kienow, A; Schulz, F.; 2013
Title:	Validation of HPLC-MS/MS -method 2001-0051702-10 - Determination of prothioconazole-desthio in formulations - bixafen + fluopyram + prothioconazole EC 260 (65+65+130 g/L)
Document No:	VB45-2001-0051702 M-458207-01-1
Guidelines:	SANCO/3030/99 rev. 4
GLP	Yes

Method description

The analytes are determined by reversed-phase HPLC on an Xterra RP 18 column (50 x 4.6 mm, dp= 3.5 µm) at 40 °C column temperature, using isocratic elution. Injection volume is 20 µl. The separation is achieved by using gradient flow conditions for the detection and quantification of the actives (0.5 ml/min). After MS/MS detection, the quantitative evaluation is carried out by comparing the peak areas with those of reference substances, using an external standard. The mobile phase consists of 500 ml acetonitrile and 500 ml water.

Method validation

Method 2001-0051702-10 has been completely validated on a 'Bixafen + Fluopyram + Prothioconazole EC 260 (65+65+130 g/L)' by checking the parameters linearity, precision, accuracy, specificity and interference from other substances.

Table containing the validation of the method (formulation BIX+FLU+PTZ EC 260 (65+65+130 g/l)

Analyte	**Linearity n = 6**	**Accuracy n = 6 Mean [%]**	**Repeatability n = 6 [%RSD]**	**Specificity/Interferences**
Prothioconazole-desthio	0.051 – 2.531 mg/100 mL r = 1.0000	recovery level I (0.00025 %): 106.7 recovery level II (0.0069 %): 85.0	4.37 RSDr = 6.9 (mean content 0.0019 %)	Specifity confirmed by retention time and MS-spectrum No interferences were noted. Chromatograms of formulation with and without active substances present were submitted.

LOQ = 0.0003 %

Summary

The HPLC-method for the determination of prothioconazole-desthio in the formulation was found to be valid, as it is fully validated according to SANCO 3030/99 rev.4.

Prothioconazole-desthio (JAU 6476-desthio), an impurity of prothioconazole, was found only below 0.01 % in the preparation 'Bixafen + Fluopyram + Prothioconazole EC 260 (65+65+130 g/L)' before and after storage. There is no degradation of prothioconazole to prothioconazole-desthio measurable.

Prothioconazole contains toluene as relevant impurity. The content must not exceed 5 g/kg in the technical material.

Report:	IIIA 5.2.4/03, Schulz; F. 2009
Title:	Determination of toluene in formulations Assay - GLC, internal standard
Document No:	AM012408MF2 M-319820-02-1
Guidelines:	SANCO/303/99 rev. 4
GLP	No

Report:	IIIA 5.2.4/04, Kienow, A.; Schulz, F.; 2013
Title:	Validation of GLC-method AM015911MF1 - Determination of the impurity toluene in formulations - bixafen + fluopyram + prothioconazole EC 260 (65+65+130 g/L)
Document No:	VB20-AM012408MF2
Guidelines:	SANCO/3030/99 rev. 4
GLP	Yes

Method description

After addition of a reference substance (o-xylol) as internal standard and dilution with a suitable solvent (acetone) the content is determined by gas chromatography with capillary column connection on a fused silica column (0.2 mm x 25 m,0.33 µm) at approximately 300°C (detector temperature) and 260°C injection temperature, using internal calibration and a FID detector.. Injection volume is 1 µl. The separation is achieved by using helium gas, split ratio: 1:100.

Method validation

Method AM015911MF1 has been completely validated on toluene in the formulation 'Bixafen + Fluopyram + Prothioconazole EC 260 (65+65+130 g/L)' by checking the parameters linearity, precision, accuracy, specificity and interference from other substances.

Table containing the methods and validation of the methods (formulation BIX+FLU+PTZ EC 260 (65+65+130 g/l)

Analyte	**Linearity n = 6**	**Accuracy n = 6 Mean [%]**	**Repeatability n = 6 [%RSD]**	**Specificity/Interferences**
toluene	15 - 175 % of expected concentration 0.0554 – 0.7091 mg/20 mL r = 0.99986	recovery level I (0.01684 %): 112.1 recovery level II (0.1096 %): 95.6	3.08 RSDr = 4.54 (mean content 0.03 %)	Specifity was confirmed by retention time and GC-MS spectra. No interferences were noted. Chromatograms of formulation with and without active substances present were submitted.

LOQ = 0.0168 %

Summary
The GC-method for the determination of the impurity toluene in the formulation is fully validated according to SANCO 3030/99 rev. 4.

IIIA 5.2.5 Description of analytical methods for the determination of formulants

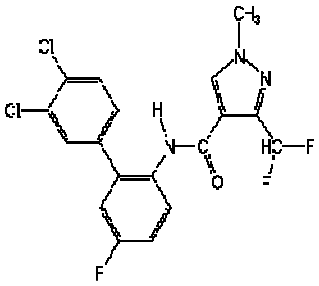
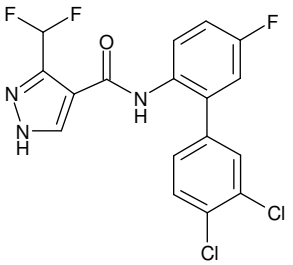
No formulants with toxicological or ecotoxicological relevant compounds are present in the formulation. Therefore, no analytical methods for the determination of formulants are necessary.

IIIA 5.3 Description of Analytical Methods for the Determination of Residues

IIIA 5.3.1 Evaluation of Bixafen

The conclusions regarding the peer review of the analytical methods for residues of bixafen are summarized in EFSA Journal 2012;10(11):2917 (ASB2012-14631).

Table 5.3-1: Information on the active substance bixafen

Name of component of residue definition **Substance code** **IUPAC name** **Formula**	**Structural formula**
Bixafen, BYF00587 *N*-(3′,4′-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide $C_{18}H_{12}Cl_2F_3N_3O$	
BYF 00587-desmethyl; desmethyl-bixafen N-(3',4'-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1H-pyrazole-4-carboxamide $C_{17}H_{10}Cl_2F_3N_3O$	

IIIA 5.3.1.1 Overview of residue definitions and levels for which compliance is required

The current legal residue definition for food of plant and animal origin is the same as the one proposed in the Draft Assessment Report (incl. its addenda) and in the respective EFSA conclusion.

Table 5.3-2: Relevant residue definitions

Matrix	Relevant residue	Reference Remarks
Plant material	Bixafen	Regulation (EU) No 834/2013; annex IIIA; EFSA Journal 2012;10(11):2917, ASB2012-14631
Foodstuff of animal origin	Sum of bixafen and desmethyl bixafen expressed as bixafen	Regulation (EU) No 834/2013; annex IIIA; EFSA Journal 2012;10(11):2917, ASB2012-14631
Soil	Bixafen	EFSA Journal 2012;10(11):2917, ASB2012-14631
Surface water	Bixafen	EFSA Journal 2012;10(11):2917, ASB2012-14631
Drinking/ground water	Bixafen	EFSA Journal 2012;10(11):2917, ASB2012-14631
Air	Not residue relevant	Not classified as Xi, Xn, T, T+, EFSA Journal 2012;10(11):2917, ASB2012-14631
Body fluids/tissue	Not residue relevant	Not classified as T / T+, EFSA Journal 2012;10(11):2917, ASB2012-14631

Table 5.3-3: Levels for which compliance is required

Matrix	MRL	Reference for MRL/level Remarks
Plant, high water content	0.01 mg/kg	Regulation (EU) No 834/2013; annex IIIA
Plant, acidic commodities	0.01 mg/kg	Regulation (EU) No 834/2013; annex IIIA
Plant, dry commodities	0.01 mg/kg	Regulation (EU) No 834/2013; annex IIIA
Plant, high oil content	0.01 mg/kg	Regulation (EU) No 834/2013; annex IIIA
Meat	0.02 mg/kg	Regulation (EU) No 834/2013; annex IIIA
Milk	0.02 mg/kg	Regulation (EU) No 834/2013; annex IIIA
Eggs	0.02 mg/kg	Regulation (EU) No 834/2013; annex IIIA
Fat	0.02 mg/kg	Regulation (EU) No 834/2013; annex IIIA
Liver, kidney	0.02 mg/kg	Regulation (EU) No 834/2013; annex IIIA

Matrix	MRL	Reference for MRL/level Remarks
Soil	0.05 mg/kg	Common limit
Drinking water	0.1 µg/L	General limit for drinking water
Surface water	4.6 µg/L	NOEC *Pimephales promelas,* EFSA Journal 2012;10(11):2917, ASB2012-14631
Air	Not required	Not classified as Xi, Xn, T, T+, EFSA Journal 2012;10(11):2917, ASB2012-14631
Tissue (meat or liver)	Not required	Not classified as T / T+, EFSA Journal 2012;10(11):2917, ASB2012-14631
Body fluids	Not required	Not classified as T / T+, EFSA Journal 2012;10(11):2917, ASB2012-14631

IIIA 5.3.1.2 Description of Analytical Methods for the Determination of Residues of Bixafen in Plant Matrices (OECD KIII A 5.3.1)

An overview of the acceptable methods and the data gaps (if appropriate) for analysis of bixafen in plant matrices is given in the following tables.

Table 5.3-4: Overview of independently validated methods and confirmatory methods for food and feed of plant origin (always required for first 4 matrix types)

Matrix type	Primary method	ILV	Confirmatory method
High water content	Bardel & Schöning, 2006*	Not required[1]	Bardel & Schöning, 2006*
Acidic	Bardel & Schöning, 2006*	Ballesteros & Portet, 2008*	Bardel & Schöning, 2006*
Fatty	Bardel & Schöning, 2006*	Ballesteros & Portet, 2008*	Bardel & Schöning, 2006*
Dry	Bardel & Schöning, 2006*	Ballesteros & Portet, 2008*	Bardel & Schöning, 2006*
Difficult	Not required for the intended GAP	Not required for the intended GAP	Not required for the intended GAP

*EU agreed method (see Draft Assessment Report)
[1] Formally necessary but not required in this case because the applicability of the method for matrices with high water content is beyond doubt due to the successful validation in acidic matrices.

Table 5.3-5: Statement on extraction efficiency

	Method for products of plant origin
Required, available from:	Sur, Kuhnke & Justus, 2007 ASB2009-5824
Not required, because:	

For the detailed evaluation of studies on extraction efficiency it is referred to Appendix 2.

Table 5.3-6: Methods suitable for the determination of residues (enforcement) in products of plant origin

Author(s), year	Matrix group	Method LOQ	Principle of method	Comment	Evaluated in section
Bardel & Schöning, 2006 ASB2009-5826	High water content, acidic, dry, fatty	0.01 mg/kg	LC-MS/MS, Synergi Hydro RP, ESI+, m/z 414→394, 414→266	Confirmation included	B.5.2 of DAR ASB2011-11716
Ballesteros & Portet, 2008 ASB2009-5827	Acidic, dry, fatty	0.01 mg/kg	LC-MS/MS, Synergi Hydro RP, ESI+, m/z 414→394, 414→266	Confirmation included, ILV of Bardel & Schöning, 2006	B.5.2 of DAR ASB2011-11716

IIIA 5.3.1.3 Description of Analytical Methods for the Determination of Residues of Bixafen in Animal Matrices (OECD KIII A 5.3.1)

An overview of the acceptable methods and the data gaps (if appropriate) for analysis of bixafen (residue definition: the sum of bixafen and desmethyl bixafen expressed as bixafen) in animal matrices is given in the following tables.

Table 5.3-7: Overview of independently validated methods and confirmatory methods for food and feed of animal origin (if appropriate)

Matrix type	Primary method	ILV	Confirmatory method
Milk	Billian & Druskus, 2007*	Ballesteros, 2008*	Billian & Bruskus, 2007*
Eggs	Billian & Druskus, 2007*	Ballesteros, 2008*	Billian & Bruskus, 2007*
Meat	Billian & Druskus, 2007*	Not required	Billian & Bruskus, 2007*
Fat	Billian & Druskus, 2007*	Ballesteros, 2008*	Billian & Bruskus, 2007*
Kidney, liver	Billian & Druskus, 2007*	Ballesteros, 2008*	Billian & Bruskus, 2007*

*EU agreed method (see Draft Assessment Report)

Table 5.3-8: Statement on extraction efficiency

	Method for products of animal origin
Required, available from:	Spiegel & Koester, 2007 ASB2009-5940
Not required, because:	

The study on extraction efficiency was evaluated in the DAR, section B.7.2. 1. Sufficient extraction efficiency using acetonitrile/water as solvent is proven.

Table 5.3-9: Methods suitable for the determination of residues (enforcement) in products of animal origin

Author(s), year	Matrix	Method LOQ	Principle of method	Comment	Evaluated in section

Author(s), year	Matrix	Method LOQ	Principle of method	Comment	Evaluated in section
Billian & Druskus, 2007 ASB2009-5830	Meat, milk, egg, fat, liver, kidney	0.02 mg/kg	LC-MS/MS, Synergi Polar RP, ESI+, m/z 414→394, 414→266 (bixafen); Luna HST C18, ESI+, m/z 400→380, 400→360 (desmethyl-bixafen)	Confirmation included, validated LOQ: 0.01 mg/kg for each component	B.5.2 of DAR ASB2011-11716
Ballesteros, 2008 ASB2009-5831	Milk, egg, fat, liver	0.02 mg/kg	LC-MS/MS, Synergi Polar RP, ESI+, m/z 414→394, 414→266 (bixafen); ESI-, m/z 398→378, 398→358 (desmethyl-bixafen)	Confirmation included, validated LOQ: 0.01 mg/kg for each component, ILV of Billian & Druskus, 2007	B.5.2 of DAR ASB2011-11716

IIIA 5.3.1.4 Description of Methods for the Analysis of Bixafen in Soil (OECD KIII A 5.4)

An overview of the acceptable methods and the data gaps (if appropriate) for analysis of bixafen in soil is given in the following tables.

Table 5.3-10: Overview of suitable primary and confirmatory methods for soil

Component(s) of residue definition	Primary method	Confirmatory method
Bixafen	Brumhard & Freitag, 2006*	Brumhard & Freitag, 2006*

*EU agreed method (see Draft Assessment Report)

Table 5.3-11: Methods for soil

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in section
Brumhard & Freitag, 2006 ASB2009-5833	0.005 mg/kg	LC-MS/MS, Purospher Star RP 18, ESI+, m/z 414→394, 414→266	Confirmation included	B.5.3.1 of DAR, ASB2011-11716

IIIA 5.3.1.5 Description of Methods for the Analysis of Bixafen in Water (OECD KIII A 5.6)

An overview of the acceptable methods and the data gaps (if appropriate) for analysis of bixafen in surface and drinking water is given in the following table.

Table 5.3-12: Overview of suitable primary and confirmatory methods for water

Component(s) of residue definition	Matrix	Primary method	Confirmatory method
Bixafen	Surface water	Krebber & Braune, 2008*	Krebber & Braune, 2008*

*EU agreed method (see Draft Assessment Report)

Table 5.3-13: Methods for surface water

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in section
Krebber & Braune, 2008 ASB2009-5837	0.05 µg/L	LC-MS/MS, Luna C18, ESI+, m/z 414→394; 414→266	Confirmation included, also acceptable for drinking water	B.5.3.2 of DAR ASB2011-11716

IIIA 5.3.1.6 Description of Methods for the Analysis of Bixafen in Air (OECD KIII A 5.7)

An overview of the acceptable methods for analysis of bixafen in air is given in the following table. Analytical methods for bixafen in air are not required according to the guideline SANCO/825/00 rev. 8.1 because it is not classified as Xi, Xn, T or T+.

Table 5.3-14: Overview of suitable primary and confirmatory methods for air

Component(s) of residue definition	Primary method	Confirmatory method
Bixafen	Class, 2007*	Class, 2007*

*EU agreed method (see Draft Assessment Report)

Table 5.3-15: Methods for air

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in section
Class, 2007 ASB2009-5838	10 µg/m^3	LC-MS/MS; Waters XTerra MS C18, ESI+, m/z 414→394; 414→266	Confirmation included	B.5.3.3 of DAR ASB2011-11716

IIIA 5.3.1.7 Description of Methods for the Analysis of Bixafen in Body Fluids and Tissues (OECD KIII A 5.8)

Methods for body fluids and tissues are not required, because bixafen is not considered to be toxic or very toxic (T / T+) nor is it classified according to GHS as follows: Acute toxicity (cat. 1 - 3), CMR (cat. 1) or STOT (cat. 1).

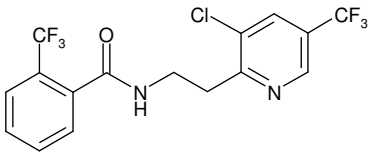
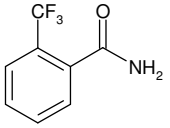
IIIA 5.3.1.8 Other Studies/ Information

None

IIIA 5.3.2 Evaluation of Fluopyram

The conclusions regarding the peer review of the analytical methods for residues of fluopyram are summarized in EFSA Journal 2013; 11(4):3052 (ASB2013-5375).

Table 5.3-16: Information on the active substance fluopyram

Name of component of residue definition **Substance code** **IUPAC name** **Formula**	**Structural formula**
Fluopyram; AE C656948; N-[2-{33-chhloro-5-(trifluoromethyl)pyridin-2-yl]ethyl}-2-(trifluoromethyl)benzamide; $C_{16}H_{11}ClF_6N_2O$	
Fluopyram-benzamide; M25, AE C656948-benzamide, AE F148815, BCS-AA10014; 2-(trifluoromethyl)benzamide; $C_8H_6F_3NO$	

IIIA 5.3.2.1 Overview of residue definitions and levels for which compliance is required

Compared to the residue definition proposed in the Draft Assessment Report (incl. its addenda) the current legal residue definition is identical.

Table 5.3-17: Relevant residue definitions

Matrix	**Relevant residue**	**Reference** **Remarks**
Plant material	Fluopyram	Regulation (EU) No 2017/978, annex III part A
Foodstuff of animal origin	Sum of fluopyram and fluopyram-benzamide (M25) expressed as fluopyram	Regulation (EU) No 2017/978, annex III part A
Soil	Fluopyram	EFSA conclusion, EFSA Journal 2013; 11(4):3052 ASB2013-5375
Surface water	Fluopyram	EFSA conclusion, EFSA Journal 2013; 11(4):3052 ASB2013-5375
Drinking/ground water	Fluopyram	EFSA conclusion, EFSA Journal 2013; 11(4):3052 ASB2013-5375
Air	Fluopyram	Classified as Xn EFSA conclusion, EFSA Journal 2013; 11(4):3052 ASB2013-5375
Body fluids/tissue	Not residue relevant	Not classified as T / T+

Table 5.3-18: Levels for which compliance is required

Matrix	MRL	Reference for MRL/level Remarks
Plant, high water content	0.01 mg/kg	Regulation (EU) No 2017/978, annex III part A
Plant, acidic commodities	0.01 mg/kg	Regulation (EU) No 2017/978, annex III part A
Plant, dry commodities	0.01 mg/kg	Regulation (EU) No 2017/978, annex III part A
Plant, high oil content	0.01 mg/kg	Regulation (EU) No 2017/978, annex III part A
Plant, difficult matrices hops seed spices	 3 mg/kg 0.1 mg/kg	Regulation (EU) No 2017/978, annex III part A
Meat	0.2 mg/kg	Regulation (EU) No 2017/978, annex III part A
Milk	0.3 mg/kg	Regulation (EU) No 2017/978, annex III part A
Eggs	0.3 mg/kg	Regulation (EU) No 2017/978, annex III part A
Fat	0.2 mg/kg	Regulation (EU) No 2017/978, annex III part A
Liver, kidney	0.7 mg/kg	Regulation (EU) No 2017/978, annex III part A
Soil	0.05 mg/kg	Common limit
Drinking water	0.1 µg/L	General limit for drinking water
Surface water	440 µg/L	Mortality, EC_{50} *C. virginica* EFSA conclusion, EFSA Journal 2013; 11(4):3052, ASB2013-5375
Air	15 µg/m^3	AOEL sys: 0.05 mg/kg bw/d, EFSA conclusion, EFSA Journal 2013; 11(4):3052, ASB2013-5375
Tissue (meat or liver)	Not required	Not classified as T / T+
Body fluids	Not required	Not classified as T / T+

IIIA 5.3.2.2 Description of Analytical Methods for the Determination of Residues of Fluopyram in Plant Matrices (OECD KIII A 5.3.1)

An overview of the acceptable methods and possible data gaps for analysis of fluopyram in plant matrices is given in the following tables. New studies were not provided.

Table 5.3-19: Overview of independently validated methods and confirmatory methods for food and feed of plant origin (always required for first 4 matrix types)

Matrix type	Primary method	ILV	Confirmatory method
High water content	Rzepka, Jungklaus, 2007 *	Class, 2007 *	Rzepka, Jungklaus, 2007 *
Acidic	Rzepka, Jungklaus, 2007 *	Class, 2007 *	Rzepka, Jungklaus, 2007 *
Fatty	Rzepka, Jungklaus, 2007 *	Class, 2007 *	Rzepka, Jungklaus, 2007 *
Dry	Rzepka, Jungklaus, 2007 *	Class, 2007 *	Rzepka, Jungklaus, 2007 *
Difficult	Not required for the intended GAP	Not required for the intended GAP	Not required for the intended GAP

*EU agreed method (see Draft Assessment Report)

Table 5.3-20: Statement on extraction efficiency

	Method for products of plant origin
Required, available from:	Fischer, 2008 *; ASB2008-5500
Not required, because:	

*EU agreed method (see Draft Assessment Report)

Table 5.3-21: Methods suitable for the determination of residues (enforcement) in products of plant origin

Author(s), year	Matrix group	Method LOQ	Principle of method	Comment	Evaluated in section
Rzepka, Jungklaus, 2007; ASB2008-5497	High water content, acidic, dry, fatty	0.01 mg/kg	GC-MS, DB-5MS column, m/z 223, 273, 396	Confirmation included, validation of EN 12393	B.5.2.1 of DAR, ASB2011-9692
Class, 2007; ASB2008-5499	High water content, acidic, dry, fatty	0.01 mg/kg	GC-MS, VF-17MS column, m/z 223, 273, 396	Confirmation included, ILV of Rzepka, Jungklaus, 2007	B.5.2.1 of DAR, ASB2011-9692

IIIA 5.3.2.3 Description of Analytical Methods for the Determination of Residues of Fluopyram in Animal Matrices (OECD KIII A 5.3.1)

An overview of the acceptable methods and possible data gaps for analysis of fluopyram in animal matrices is given in the following tables. New studies were not provided.

Table 5.3-22: Overview of independently validated methods and confirmatory methods for food and feed of animal origin (if appropriate)

Matrix type	Primary method	ILV	Confirmatory method
Milk	Schoening, Willmes, 2008 *	Portet, 2008 *	Schoening, Willmes, 2008 *
Eggs	Schoening, Willmes, 2008 *	Portet, 2008 *	Schoening, Willmes, 2008 *
Meat	Schoening, Willmes, 2008 *	Portet, 2008 *	Schoening, Willmes, 2008 *

Fat	Schoening, Willmes, 2008 *	Not required	Schoening, Willmes, 2008 *
Kidney, liver	Schoening, Willmes, 2008 *	Portet, 2008 *	Schoening, Willmes, 2008 *

*EU agreed method (see Draft Assessment Report)

Table 5.3-23: Statement on extraction efficiency

	Method for products of animal origin
Required, available from:	Justus, Koester, 2008 *; ASB2008-5394
Not required, because:	

*EU agreed method (see Draft Assessment Report)

Table 5.3-24: Methods suitable for the determination of residues (enforcement) in products of animal origin

Author(s), year	**Matrix**	**Method LOQ**	**Principle of method**	**Comment**	**Evaluated in section**
Schoening, Willmes, 2008; ASB2008-5508	Milk, eggs, meat, fat, liver, kidney	0.01 mg/kg	LC-MS/MS, Luna HTS C18 column, ESI+, m/z 397→173, 397→208 (fluopyram), m/z 190→170, 190→150 (benzamide metabolite)	Confirmation included, LOQ expressed as fluopyram	B.5.2.3 of DAR, ASB2011-9692
Portet, 2008; ASB2008-5509	Milk, eggs, meat, liver	0.01 mg/kg	Luna HTS C18 column, ESI+, m/z 397→173, 397→208 (fluopyram), m/z 190→170, 190→150 (benzamide metabolite)	Confirmation included, LOQ expressed as fluopyram, ILV of Schoening, Willmes, 2008	B.5.2.3 of DAR, ASB2011-9692

IIIA 5.3.2.4 Description of Methods for the Analysis of Fluopyram in Soil (OECD KIII A 5.4)

An overview of the acceptable methods and possible data gaps for analysis of fluopyram in soil is given in the following tables. New studies were not provided.

Table 5.3-25: Overview of suitable primary and confirmatory methods for soil

Component(s) of residue definition	**Primary method**	**Confirmatory method**
Fluopyram	Brumhard, Schneider, 2008 *	Brumhard, Schneider, 2008 *

*EU agreed method (see Draft Assessment Report)

Table 5.3-26: Methods for soil

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in section
Brumhard, Schneider, 2008; ASB2008-5512	0.001 mg/kg	LC-MS/MS, C8 column, ESI+, m/z 397→173, 397→208	Confirmation included	B.5.3.1 of DAR, ASB2011-9692

IIIA 5.3.2.5 Description of Methods for the Analysis of Fluopyram in Water (OECD KIII A 5.6)

An overview of the acceptable methods and possible data gaps for analysis of fluopyram in surface and drinking water is given in the following table. New studies were not provided.

Table 5.3-27: Overview of suitable primary and confirmatory methods for water

Component(s) of residue definition	Matrix	Primary method	Confirmatory method
Fluopyram	Drinking water, surface water	Ripperger, 2008 *	Ripperger, 2008 *

*EU agreed method (see Draft Assessment Report)

Table 5.3-28: Methods for drinking water and surface water

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in section
Ripperger, 2008 ASB2008-5532	0.05 µg/L	LC-MS/MS, Aqua C18 column, ESI+, m/z 397→173, 397→143	Confirmation included	B.5.3.2 of DAR, ASB2011-9692

IIIA 5.3.2.6 Description of Methods for the Analysis of Fluopyram in Air (OECD KIII A 5.7)

An overview of the acceptable methods and possible data gaps for analysis of fluopyram in air is given in the following table.

Table 5.3-29: Overview of suitable primary and confirmatory methods for air

Component(s) of residue definition	Primary method	Confirmatory method
Fluopyram	Bacher, 2008 *	Bacher, 2008 *

*EU agreed method (see Draft Assessment Report)

Table 5.3-30: Methods for air

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in section

Bacher, 2008 ASB2008-5534	4 µg/m^3	LC-MS/MS, Aqua C18 column, ESI+, m/z 397→173, 397→143	Confirmation included	B.5.3.3 of DAR, ASB2011-9692

IIIA 5.3.2.7 Description of Methods for the Analysis of Fluopyram in Body Fluids and Tissues (OECD KIII A 5.8)

Methods for body fluids and tissues are not required, because fluopyram is not considered to be toxic or very toxic (T / T+) nor is it classified according to GHS as follows: Acute toxicity (cat. 1 - 3), CMR (cat. 1) or STOT (cat. 1).

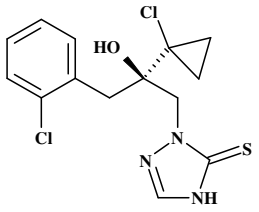
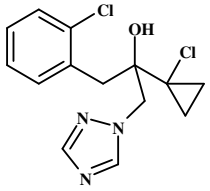
IIIA 5.3.2.8 Other Studies/ Information

Several other studies were provided with this application. They were not considered in the assessment because the data requirements are already fulfilled with the studies mentioned above.

IIIA 5.3.3 Evaluation of Prothioconazole

The conclusions regarding the peer review of the analytical methods for residues of prothioconazole are summarized in EFSA Scientific Report (2007) 106, 1-98 (ASB2012-3641).

Table 5.3-31: Information on the active substance prothioconazole

Name of component of residue definition **Substance code** **IUPAC name** **Formula**	**Structural formula**
Prothioconazole JAU6476 (RS)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-Thione $C_{14}H_{15}Cl_2N_3OS$	
Prothioconazole-desthio; JAU6476-desthio, M04; 2-(1-chlorocycloproyl)1-(2-chlorophenyl)-3-(1,2,4-triazol-1-yl)-propan-2-ol $C_{14}H_{15}Cl_2N_3O$	

IIIA 5.3.3.1 Overview of residue definitions and levels for which compliance is required

The current legal residue definition for food of plant is the same as the one proposed in the Draft Assessment Report (incl. its addenda) and in the respective EFSA conclusion. For food of animal origin, the current legal residue definitions differs from the one proposed in the EFSA conclusion (see below)

Table 5.3-32: Relevant residue definitions

Matrix	Relevant residue	Reference Remarks
Plant material	Prothioconazole-desthio (sum of isomers)	Regulation (EU) 2016/1902, annex II EFSA Scientific Report (2007) 106, 1-98, ASB2012-3641
Foodstuff of animal origin	Prothioconazole-desthio (sum of isomers)	Regulation (EU) 2016/1902, annex II EFSA's Reasoned opinion on the review of the existing MRLs; ASB2014-5347
	Sum of prothioconazole-desthio and its glucuronide conjugate, expressed as prothioconazole-desthio[1]	EFSA Scientific Report (2007) 106, 1-98, ASB2012-3641
Soil	Prothioconazole prothioconazole-desthio	EFSA Scientific Report (2007) 106, 1-98, ASB2012-3641
Surface water	Prothioconazole prothioconazole-desthio	EFSA Scientific Report (2007) 106, 1-98, ASB2012-3641
Drinking/ground water	Prothioconazole prothioconazole-desthio	EFSA Scientific Report (2007) 106, 1-98, ASB2012-3641
Air	Prothioconazole prothioconazole-desthio	EFSA Scientific Report (2007) 106, 1-98, ASB2012-3641
Body fluids/tissue	Not residue relevant	Not classified as T / T+ Regulation (EC) No 1272/2008
Body fluids/tissue	Prothioconazole-desthio[1]	proposed classification: T, EFSA Scientific Report (2007) 106, 1-98, ASB2012-3641)

[1] This residue definition was not considered in the assessment.

Table 5.3-33: Levels for which compliance is required

Matrix	MRL	Reference for MRL/level Remarks
Plant, high water content	0.01 mg/kg	Regulation (EU) 2016/1902, annex II
Plant, acidic commodities	0.01 mg/kg	Regulation (EU) 2016/1902, annex II
Plant, dry commodities	0.01mg/kg	Regulation (EU) 2016/1902, annex II
Plant, high oil content	0.01 mg/kg	Regulation (EU) 2016/1902, annex II
Meat	0.01 mg/kg	Regulation (EU) 2016/1902, annex II
Milk	0.01 mg/kg	Regulation (EU) 2016/1902, annex II
Eggs	0.01 mg/kg	Regulation (EU) 2016/1902, annex II
Fat	0.01 mg/kg	Regulation (EU) 2016/1902, annex II
Liver, kidney	0.01 mg/kg	Regulation (EU) 2016/1902, annex II
Soil	0.05 mg/kg	Common limit
Drinking water	0.1 µg/L	General limit for drinking water
Surface water	308 µg/L (prothioconazole)	NOEC *Oncorhynchus mykiss*

Matrix	MRL	Reference for MRL/level Remarks
	3.3 µg/L (JAU-6476-desthio)	NOEC *Oncorhynchus mykiss* EFSA Scientific Report (2007) 106, 1-98, ASB2012-3641
Air	60 µg/m³ (prothioconazole) 3 µg/m³ (JAU 6476-desthio)	AOEL sys: 0.2 mg/kg bw/d AOEL sys: 0.01 mg/kg bw/d; EFSA Scientific Report (2007) 106, 1-98, ASB2012-3641
Tissue (meat or liver)	Not required	Not classified as T / T+, Regulation (EC) No 1272/2008
Body fluids	Not required	Not classified as T / T+, Regulation (EC) No 1272/2008

IIIA 5.3.3.2 Description of Analytical Methods for the Determination of Residues of Prothioconazole in Plant Matrices (OECD KIII A 5.3.1)

An overview of the acceptable methods and the data gaps (if appropriate) for analysis of residues of prothioconazole in plant matrices is given in the following tables. For the detailed evaluation of new studies it is referred to Appendix 2.

Table 5.3-34: Overview of independently validated methods and confirmatory methods for food and feed of plant origin (always required for first 4 matrix types)

Matrix type	Primary method	ILV	Confirmatory method
High water content	Weeren & Pelz, 2000*	Class, 2001*	Brumhard & Stuke, 2008
Acidic	Weeren & Pelz, 2000*	Not required	Brumhard & Stuke, 2008
Fatty	Weeren & Pelz, 2000*	Not required	Brumhard & Stuke, 2008
Dry	Weeren & Pelz, 2000*	Class, 2001*	Brumhard & Stuke, 2008
Difficult	Not required for the intended GAP	Not required for the intended GAP	Not required for the intended GAP

*EU agreed method (see Draft Assessment Report)

Table 5.3-35: Statement on extraction efficiency

	Method for products of plant origin
Required, available from:	Haas, 2001, RIP2002-1041
Not required, because:	

For the detailed evaluation of studies on extraction efficiency it is referred to Appendix 2.

Table 5.3-36: Methods suitable for the determination of residues (enforcement) in products of plant origin

Author(s), year	Matrix group	Method LOQ	Principle of method	Comment	Evaluated in section
Weeren & Pelz, 2000 MET2002-402	High water content, acidic, dry, fatty	0.02 mg/kg[1]	GC-MS, m/z 186	No confirmation; official German method under §64, L 00.00-34	DAR, vol. 3, B.5.2 ASB2010-10593
Class, 2001 MET2002-403	High water content, dry	0.02 mg/kg[1]	GC-MS, m/z 186, 188, 125	Official German method under §64, L 00.00-34; confirmation included, ILV of MET2002-402	DAR, vol. 3, B.5.2 ASB2010-10593
Brumhard & Stuke, 2008 ASB2008-6472	High water content, acidic, dry, fatty	0.01 mg/kg	LC-MS/MS, RP18 column, ESI+, m/z 312→70 312→125	Confirmation included	Appendix 2

[1] LOQ not sufficient for MRLs lowered with Regulation (EU) 2016/1902. However, since the notifier submitted the application prior to Regulation (EU) 2016/1902 coming into effect, these methods are still considered acceptable.

IIIA 5.3.3.3 Description of Analytical Methods for the Determination of Residues of Prothioconazole in Animal Matrices (OECD KIII A 5.3.1)

An overview of the acceptable methods and the data gaps (if appropriate) for analysis of residues of prothioconazole in animal matrices is given in the following tables. For the detailed evaluation of the new studies it is referred to Appendix 2.

Table 5.3-37: Overview of independently validated methods and confirmatory methods for food and feed of animal origin (if appropriate)

Matrix type	Primary method	ILV	Confirmatory method
milk	Heinemann, 2001a* Heinemann, 2001b*	Dubey, 2001*	Freitag, 2007
eggs	Billian & Wolters, 2006	Bacher, 2006	Bacher, 2006
meat	Heinemann, 2001a*	Dubey, 2001*	Freitag, 2007
fat	Heinemann, 2001a*	Not required	Freitag, 2007
kidney, liver	Heinemann, 2001a*	Dubey, 2001*	Schwarz & Class, 2007

*EU agreed method (see Draft Assessment Report)

Table 5.3-38: Statement on extraction efficiency

	Method for products of animal origin
Required, available from:	Weber, Weber & Spiegel, 2002, RIP2002-1046
Not required, because:	

For the detailed evaluation of the study on extraction efficiency it is referred to Appendix 2.

Table 5.3-39: Methods suitable for the determination of residues (enforcement) in products of animal origin

Author(s), year	Matrix	Method LOQ	Principle of method	Comment	Evaluated in section
Heinemann, 2001a MET2002-400	Milk, meat, fat, liver, kidney	0.01 mg/kg	LC-MS/MS, Superspher 60 RP Select B, ESI+, m/z 328→70 (hydroxydesthio-metabolites), m/z 312→70 (prothio-conazole-desthio)	For prothiocona-zole-desthio and its glucuronide conjugate after hydrolysis; no confirmation	DAR, vol. 3; B.5.2 ASB2010-10593
Heinemann, 2001b MET2002-401	Milk	0.004 mg/kg	LC-MS/MS, Superspher 60 RP Select B, ESI+, m/z 328→70 (hydroxydesthio-metabolites), m/z 312→70 (prothio-conazole-desthio)	For prothiocona-zole-desthio and its glucuronide conjugate after hydrolysis; no confirmation	DAR, vol. 3; B.5.2 ASB2010-10593
Dubey, 2001 MET2002-404	Milk; meat, liver	0.004 mg/kg 0.01 mg/kg	LC-MS/MS, Superspher 60 RP Select B, ESI+, m/z 328→70 (hydroxydesthio-metabolites), m/z 312→70 (prothio-conazole-desthio)	ILV of Heinemann, 2001a and Heinemann, 2001b	DAR, vol. 3; B.5.2 ASB2010-10593
Billian & Wolters, 2006 ASB2010-11620 ASB2013-9506	Milk, eggs, meat, fat, liver, kidney	0.01 mg/kg	LC-MS/MS, Phenyl-hexyl column, ESI+, m/z 312→70, 312→125 (prothioconazole-desthio)	Confirmation included	Appendix 2
Bacher, 2006 ASB2011-13494	Meat, milk, eggs	0.01 mg/kg	LC-MS/MS, Phenyl-hexyl column, ESI+, m/z 312→70, 312→125 (pro-thioconazole-desthio)	Confirmation included, ILV of Billian & Wolters, 2006	Appendix 2
Freitag, 2007 ASB2008-275	Meat, liver, kidney, fat milk	0.01 mg/kg 0.004 mg/kg	LC-MS/MS, Superspher 60 RP Select B, ESI+, m/z 312→70, 312→125 (pro-thioconazole-desthio)	Confirmation included, selectivity of both transitions for liver and kidney not proven	Appendix 2

Author(s), year	Matrix	Method LOQ	Principle of method	Comment	Evaluated in section
Schwarz & Class, 2007 ASB2008-276	Meat, liver milk	0.01 mg/kg 0.004 mg/kg	LC-MS/MS, Superspher 60 RP selec B, ESI+, m/z 312→70, 312→125 (pro-thioconazole-desthio)	Confirmation included, ILV of Freitag, 2007	Appendix 2

IIIA 5.3.3.4 Description of Methods for the Analysis of Prothioconazole in Soil (OECD KIII A 5.4)

An overview of the acceptable methods and the data gaps (if appropriate) for analysis of the residues of prothioconazole in soil is given in the following tables. For the detailed evaluation of the new study it is referred to Appendix 2.

Table 5.3-40: Overview of suitable primary and confirmatory methods for soil

Component(s) of residue definition	Primary method	Confirmatory method
Prothioconazole	Schramel, 2000*	Brumhard, 2005
Prothioconazole-desthio	Schramel, 2000*	Brumhard, 2005 Steinhauer, 2001*

*EU agreed method (see Draft Assessment Report)

Table 5.3-41: Methods for soil

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Schramel, 2000 MET2002-405	0.006 mg/kg	LC-MS/MS, Superspher 60 RP select B, ESI+, m/z 344→326 (prothio-conazole), m/z 312→70 (prothiocona-zole-desthio)	No confirmation	DAR, vol. 3, B.5.2 ASB2010-10593
Steinhauer, 2001 MET2002-407	0.01 mg/kg	GC-MS, DB-5 MS column, EI, m/z 186	No confirma-tion, only for prothioconazole -desthio	DAR, vol. 3, B.5.2 ASB2010-10593
Brumhard, 2005 MET2005-358	0.006 mg/kg	LC-MS/MS, Superspher 60 RP Select B, ESI+, m/z 344→326, 344→189 (prothioconazole), m/z 312→70, 312→125 (prothioconazole-desthio)	Confirmation included	Appendix 2

IIIA 5.3.3.5 Description of Methods for the Analysis of Prothioconazole in Water (OECD KIII A 5.6)

An overview of the acceptable methods and the data gaps (if appropriate) for analysis of the residues of prothioconazole in surface and drinking water is given in the following table. For the detailed evaluation of the new study it is referred to Appendix 2.

Table 5.3-42: Overview of suitable primary and confirmatory methods for water

Component(s) of residue definition	Matrix	Primary method	Confirmatory method
Prothioconazole	Drinking water, surface water	Sommer, 2001*	Brumhard, 2005
Prothioconazole-desthio	Drinking water, surface water	Sommer, 2001*	Brumhard, 2005

*EU agreed method (see Draft Assessment Report)

Table 5.3-43: Methods for surface water

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Sommer, 2001 MET2002-411	0.1 µg/L prothio-conazole 0.05 µg/L prothioconazole-desthio	LC-MS/MS, RP18, ESI+, m/z 344→326 (prothioconazole) m/z 312→70 (prothioconazole-desthio)	No confirma-tion, validated for surface water, but also accepted for drinking water	DAR, vol. 3, B.5.2 ASB2010-10593
Brumhard, 2005 MET2005-359	0.05 µg/L pro-thioconazole 0.05 µg/L prothioconazole-desthio	LC-MS/MS, RP18, ESI+, m/z 344→326, 344→189 (prothio-conazole) m/z 312→70, 312→125 (prothioconazole-desthio)	Confirmation incuded, validated for surface water, but also accepted for drinking water	Appendix 2

IIIA 5.3.3.6 Description of Methods for the Analysis of Prothioconazole in Air (OECD KIII A 5.7)

An overview of the acceptable methods and possible data gaps for analysis of prothioconazole residues in air is given in the following table.

Table 5.3-44: Overview of suitable primary and confirmatory methods for air

Component(s) of residue definition	Primary method	Confirmatory method
Prothioconazole	Maasfeld, 2000a*	Not required
Prothioconazole-desthio	Maasfeld, 2000b*	Not required

*EU agreed method (see Draft Assessment Report)

Table 5.3-45: Methods for air

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Maasfeld, 2000a MET2002-408	15 µg/m³	LC-MS/MS, Superspher 60 RP Select B, ESI-, m/z 342→100	only for pro-thioconazole; no confirmation	DAR, vol. 3, B.5.2 ASB2010-10593
Maasfeld, 2000b MET2005-361	0.6 µg/m³	LC-MS/MS, Superspher 60 RP Select B, ESI+, 312→70	only for prothioconazole -desthio, no confirmation	DAR, vol. 3, B.5.2 ASB2010-10593

IIIA 5.3.3.7 Description of Methods for the Analysis of Prothioconazole in Body Fluids and Tissues (OECD KIII A 5.8)

Methods for body fluids and tissues are not required, because prothioconazole is not considered to be toxic or very toxic (T / T+) nor is it classified according to GHS as follows: Acute toxicity (cat. 1 - 3), CMR (cat. 1) or STOT (cat. 1).

IIIA 5.3.3.8 Other Studies/ Information

None

IIIA 5.4 Conclusion on the availability of analytical methods for the determination of residues

Bixafen:
Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

Fluopyram:
Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

Prothioconazole:
Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

Appendix 1 – List of data submitted in support of the evaluation

Annex point/ reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not	Data protection claimed	Owner	How considered in dRR Study-Status / Usage*
KIIIA 5.2.2 /01	Michel, A.	2012	Determination of bixafen, fluopyram and prothioconazole in formulations ; Assay - HPLC, external standard Report No.: AM018212MF2, Edition Number: M-430584-02-1 GLP/GEP: no, unpublished	Yes	Bayer CropScience	1
KIIIA 5.2.2 /02	Kienow, A. ; Michel, A.	2013	Validation of HPLC-method AM018212MF2 - Determination of bixafen, fluopyram and prothioconazole in formulations - bixafen + fluopyram + prothioconazole EC 260 (65+65+130 g/L) Report No.: VB1-AM018212MF2, Edition Number: M-460510-01-1 GLP/GEP: Yes, unpublished	Yes	Bayer CropScience	1
KIIIA 5.2.4 /01	Schulz, F.	2001	Determination of prothioconazole-desthio (SXX 0665) in formulations - Assay HPLC-MS/MS, external standard - Amendment no. 1 - Previous report number: M-078059-02-1 Report No.: 2001-0051702-10, Edition Number: M-450152-01-1 GLP/GEP: no, unpublished	Yes	Bayer CropScience	1
KIIIA 5.2.4 /02	Kienow, A. ; Schulz, F.	2013	Validation of HPLC-MS/MS - method 2001-0051702-10 - Determination of prothioconazole-desthio in formulations - bixafen + fluopyram + prothioconazole EC 260 (65+65+130 g/L) Report No.: VB45-2001-0051702, Edition Number: M-458207-01-1 GLP/GEP: Yes, unpublished	Yes	Bayer CropScience	1

Annex point/ reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not	Data protection claimed	Owner	How considered in dRR Study-Status / Usage*
KIIIA 5.2.4 /03	Schulz, F.	2008	Determination of the impurity toluene in formulations ; assay - GLC, internal standard Report No.: AM012408MF2, Edition Number: M-319820-02-1 GLP/GEP: no, unpublished	Yes	Bayer CropScience	1
KIIIA 5.2.4 /04	Kienow, A. ; Schulz, F.	2013	Validation of GLC-method AM015911MF1 - Determination of the impurity toluene in formulations - bixafen + fluopyram + prothioconazole EC 260 (65+65+130 g/L) Report No.: VB20-AM015911MF1, Edition Number: M-460509-01-1 GLP/GEP: Yes, unpublished	Yes	Bayer CropScience	1

* 1 accepted (study valid and considered for evaluation)
2 not accepted (study not valid and not considered for evaluation)
3 not considered (study not relevant for evaluation)
4 not submitted but necessary (study not submitted by applicant but necessary for evaluation)
5 supplemental (additional information, alone not sufficient to fulfil a data requirement, considered for evaluation)

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
	Canada; Germany; USA;	2011	Fluopyram: Draft Assessment Report, Volume 1-3 ASB2011-9692			
	EFSA	2007	Conclusion regarding the peer review of the pesticide risk assessment of the active substance prothioconazole EFSA Scientific Report (2007) 106, 1-98 ASB2012-3641			
	EFSA	2012	Conclusion on the peer review of the pesticide risk assessment of the active substance Bixafen EFSA Journal 2012;10(11):2917 ASB2012-14631			
	EFSA	2012	Conclusion on the peer review of the pesticide risk assessment of the active substance Fluopyram EFSA Journal 2013;11(4):3052 ASB2013-5375			
	EFSA	2014	Reasoned opinion on the review of the existing maximum residue levels (MRLs) for Prothioconazole according to Article 12 of Regulation (EC) No 396/2005 EFSA Journal 2014;12(5):3689 ASB2014-5347			

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
	United Kingdom	2004	Prothioconazole: (Draft Assessment Report) Vol. 1-4 GLP: Open Published: Yes ASB2010-10593			
	United Kingdom	2011	Bixafen: Draft Assessment Report (DAR) ASB2011-11716			
KIIA 4.3	Ballard, T. D.	2008	FDA PAM multiresidue method (MRM) testing for AE C656948 and AE F148815 (benzamide metabolite) RAGMP108 ! 07-0060 ! M-299332-01-1 GLP: Open Published: Open BVL-1782911, ASB2008-5510	Yes	Bayer CropScience	N
KIIA 4.3	Ballesteros, C.	2008	Independent laboratory validation of the analytical method 01063 for the determination of residues of BYF00587 and its metabolite BYF00587-desmethyl in/on animal tissues, milk and eggs by HPLC-MS/MS 01063 ! MR-08/004 ! 07-09 ! M-296906-01-1 GLP: Open Published: Open BVL-2188307, ASB2009-5831	Yes	Bayer CropScience	Y
KIIA 4.3	Ballesteros, C.; Portet, M.	2008	Independent laboratory validation of the analytical method 00983 for the determination of residues of BYF 00587 in/on plant matrices by HPLC-MS/MS 00983 ! MR-08/005 ! 07-07 ! M-296264-01-1 GLP: Open Published: Open BVL-2188303, ASB2009-5827	Yes	Bayer CropScience	Y
KIIA 4.3	Bardel, P.; Schöning, R.	2006	Analytical method 00983 for the determination of residues of BYF00587 in/on plant matrices by HPLC-MS/MS (incl. amendment No. 1 dated 2007-09-06) 00983 ! MR-06/029 ! P 622061004 ! M-276019-01-1 ! M-276019-02-1 GLP: Open Published: Open BVL-2188302, ASB2009-5826	Yes	Bayer CropScience	Y
KIIA 4.3	Billian, P.	2006	Analytical method 01008 for the determination of residues of JAU 6476, JAU-desthio, JAU 6476-3-hydroxy-desthio, JAU 6476-4-hydroxy-desthio, JAU 6476-5-hydroxy-desthio, and JAU 6476-6-hydroxy-desthio in/on matrices of plant origin by HPLC-MS/MS 01008! MR-06/119 ! M-279010-01-1 GLP: Open Published: Open BVL-2189084, ASB2009-13479	Yes	Bayer CropScience	N
KIIA 4.3	Billian, P.; Druskus, M.	2007	Analytical method 01063 for the determination of residues of BYF00587 and its metabolite BYF00587-desmethyl in/on animal tissues, milk and eggs by HPLC-MS/MS (incl. amendment No. 1 dated 2008-02-04) 01063 ! MR-07/279 ! P683070616 ! M-294142-01-1 ! M-294142-02-1 GLP: Open Published: Open BVL-2188306, ASB2009-5830	Yes	Bayer CropScience	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 4.3	Billian, P.; Wolters, A.	2006	Analytical method 01009 for the determination of residues of JAU 6476-desthio, JAU 6476-3-hydroxy-desthio, JAU 6476-4-hydroxy-desthio, JAU 6476-3,4-dihydroxy-desthio, and JAU 6476-4,5-dihydroxy-desthio in/on matrices of animal origin by HPLC-MS/MS 01009 ! MR-06/120 ! P683061806 GLP: Open Published: Open BVL-2189085, ASB2010-11620	Yes	Bayer CropScience	Y
KIIA 4.3	Brungardt, J. N.	2008	An analytical method for the determination of residues of AE C656948 in crop matrices using LC-MS/MS GM-001-P07-01 ! M-297568-01-2 GLP: Open Published: Open BVL-1782891, ASB2008-5489	Yes	Bayer CropScience	N
KIIA 4.3	Class, T.	2007	Independent laboratory validation of DFG Method S 19 for the determination of residues of fluopyram (AE C656948) in plant material P 1351 G ! P/B 1351 G ! P612077509 ! M-293940-01-2 GLP: Open Published: Open BVL-1782901, ASB2008-5499	Yes	Bayer CropScience	Y
KIIA 4.3	Class, Th.	2001	Independent laboratory validation of DFG method S19 (extended revision) for the determination of residues of JAU 6476-desthio (Bayer method 00086/M033) in plant materials P 484 G ! P/B 484 G ! MO-01-010487 ! M-033019-01-1 GLP: Open Published: Open BVL-2189090, MET2002-403	Yes	Bayer CropScience	Y
KIIA 4.3	Class, Th.	2006	Assessment of the applicability of the DFG S19 method (extended and revised version) for the determination of residues of BYF 00587 P 1045 G ! P/B 1045 G ! P602061007 ! M-273106-01-1 GLP: Open Published: Open BVL-2188304, ASB2009-5828	Yes	Bayer CropScience	N
KIIA 4.3	Class, Th.	2007	Assessment of the applicability of the DFG S19 method for the determination of residues of fluopyram (AE C656948) and its benzamide metabolite AE F148815 P 1304 G ! P/B 1304 G ! P682077506 ! M-291433-01-2 GLP: Open Published: Open BVL-1782897, ASB2008-5495	Yes	Bayer CropScience	N
KIIA 4.3	Diot, R.	2007	Analytical method 00984 for the determination of residues of AE C656948 and its metabolites (AE F148815, AE C657188, BCS-AA10139, BCS-AA10065 and AE 1344122) and tebuconazole in/on plant material by HPLC-MS/MS MR-06/030 ! 06-02 ! M-283301-01-2 ! 00984 GLP: Open Published: Open BVL-1782887, ASB2008-5486	Yes	Bayer CropScience	N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 4.3	Dubey, L.	2001	Independent laboratory validation of Bayer methods 00655 and 00655/M001 for the determination of residues of JAU6476-3-hydroxy-desthio, JAU6476-4-hydroxy-desthio, and JAU6476-desthio in/on matrices of animal origin by HPLC-MS/MS A-14-01-01 ! MO-01-020167 ! M-081595-01-1 GLP: Open Published: Open BVL-2189102, MET2002-404	Yes	Bayer CropScience	Y
KIIA 4.3	Freitag, T.	2007	Analytical method 00655/M002 for the determination of residues of JAU6476-desthio, JAU6476-3-hydroxy-desthio and JAU6476-4-hydroxy-desthio in/on matrices of animal origin by HPLC-MS/MS 00655/M002 ! MR-06/199 ! P 683 06 1810 ! M-284607-01-1 GLP: Open Published: Open BVL-2189089, ASB2008-275	Yes	Bayer CropScience	Y
KIIA 4.3	Heinemann, O.	2000	Analytical determination of residues of JAU 6476 and dethio-JAU 6476 in/on cereals by HPLC-MS/MS (Method-No. 00598) 00598 ! MR-401/99 ! P60293002 ! MO-00-004870 ! M-028457-01-1 GLP: Open Published: Open BVL-2189087, MET2002-397	Yes	Bayer CropScience	N
KIIA 4.3	Heinemann, O.	2000	Analytical determination of residues of JAU6476 and JAU6476-desthio in/on cereals and canola by HPLC-MS/MS (method modification 00598/M001) 00598/M001 ! MR-689/99 ! MO-00-012122 ! M-047681-01-1 GLP: Open Published: Open BVL-2189099, MET2002-398	Yes	Bayer CropScience	N
KIIA 4.3	Heinemann, O.	2001	Analytical determination of residues of JAU6476-sulfonic acid and JAU6476-dethio in/on cereals and canola by HPLC-MS/MS (Method-No. 00647) 00647 ! MR-458/00 ! P602003004 ! MO-01-008792 ! M-054655-01-1 GLP: Open Published: Open BVL-2189100, MET2002-399	Yes	Bayer CropScience	N
KIIA 4.3	Heinemann, O.	2001	Analytical determination of residues of JAU6476-3-hydroxy-desthio, JAU6476-4-hydroxy-desthio, and JAU6476-desthio in/on matrices of animal origin by HPLC-MS/MS (Method-No. 00655) 00655 ! MR-537/00 ! P603003006 ! MO-01-002620 ! M-037709-01-1 GLP: Open Published: Open BVL-2189097, MET2002-400	Yes	Bayer CropScience	Y
KIIA 4.3	Heinemann, O.	2001	Analytical determination of residues of JAU6476-3-hydroxy-desthio, JAU6476-4-hydroxy-desthio, and JAU6476-desthio in milk by HPLC-MS/MS (00655/M001) 00655/M001 ! MR-170/01 ! P603013001 ! MO-01-009555 ! M-021546-01-1 GLP: Open Published: Open BVL-2189088, MET2002-401	Yes	Bayer CropScience	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 4.3	Justus, K.; Kuhnke, G.	2008	Extraction efficiency testing of the residue method for the determination of BYF 00587 and BYF 00587-desmethyl using aged radioactive residues from a confined rotational crop study MEF-07/436 ! M9991613-8 ! M-296876-01-1 GLP: Open Published: Open BVL-2188301, ASB2009-5825	Yes	Bayer CropScience	N
KIIA 4.3	Klempner, A.	2008	Request for waiver of the requirement for radiovalidation of analytical method for the determination of AE C656948 residues in plant matrices MEF-07/171 ! RAGMP023 ! M-299240-01-2 GLP: Open Published: Open BVL-1782893, ASB2008-5490	Yes	Bayer CropScience	N
KIIA 4.3	Opitz, B.; Huser Schwarz, N.	2005	Statement regarding further requests for Proline EC 250, Annex IIIA, 5.2 in Germany MO-05-005881 ! M-248137-01-1 GLP: Open Published: Open BVL-2189103, MET2005-324	Yes	Bayer CropScience	N
KIIA 4.3	Portet, M.	2008	Independent laboratory validation of the analytical method 01079 for the determination of residues of fluopyram (AE C656948) and AE F148815 in/on animal tissues, eggs and milk by HPLC-MS/MS MR-08/053 ! 08-02 ! M-299473-01-2 GLP: Open Published: Open BVL-1782909, ASB2008-5509	Yes	Bayer CropScience	Y
KIIA 4.3	Rzepka, S.; Jungklaus, N.	2007	Validation of DFG method S 19 (L 00.00-34) for the determination of fluopyram (AE C656948) in plant matrices P682077508 ! BAY-0706V ! G07-0121 ! M-292714-01-2 GLP: Open Published: Open BVL-1782899, ASB2008-5497	Yes	Bayer CropScience	Y
KIIA 4.3	Schöning, R.	2006	Analytical method 01012 for the determination of residues of BYF 00587 and its metabolite BYF00587-desmethyl in/on plant matrices by HPLC-MS/MS (incl. amendment No. 1 dated 2008-01-25) 01012 ! MR-06/131 ! P602064715 ! M-277851-01-1 ! M-277851-02-1 GLP: Open Published: Open BVL-2188299, ASB2009-5823	Yes	Bayer CropScience	N
KIIA 4.3	Schöning, R.	2007	Modification M001 of the analytical method 00984 for the determination of residues of AE C656948 and its metabolites (AE F148815, AE C657188 and BCS-AA10139) and tebuconazole in/on plant material by LC-MS/MS (incl. amendment dated 07.02.2008, pages 265-270) 00984/M001 ! MR-06/201 ! P602064731 ! M-295145-02-2 GLP: Open Published: Open BVL-1782889, ASB2008-5488	Yes	Bayer CropScience	N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 4.3	Schöning, R.; Billian, P.	2007	Analytical method 01061 for the determination of residues of fluopyram (AE C656948) and its metabolites AE F148815, BCS-AA 10627 and BCS-AA 10650 in/on animal tissues, milk and eggs by HPLC-MS/MS (incl. amendment dated 2008-01-15, pages 202-204) MR-07/299 ! P603074726 ! M-295705-02-2 ! 01061 GLP: Open Published: Open BVL-1782905, ASB2008-5501	Yes	Bayer CropScience	N
KIIA 4.3	Schöning, R.; Willmes, J.	2007	Analytical method 01036 for the determination of residues of BYF00587 and its metabolite BYF00587-desmethyl in/on animal tissues by HPLC-MS/MS (incl. amendment No. 1 dated 2008-02-04) 01036 ! MR-07/221 ! P603074701 ! M-293285-01-1 ! M-293285-02-1 GLP: Open Published: Open BVL-2188305, ASB2009-5829	Yes	Bayer CropScience	N
KIIA 4.3	Schöning, R.; Willmes, J.	2008	Analytical method 01079 for the determination of residues of fluopyram (AE C656948) and AE F148815 in/on animal tissues, eggs and milk by HPLC-MS/MS MR-07/348 ! P683074742 ! M-296867-01-2 ! 01079 GLP: Open Published: Open BVL-1782907, ASB2008-5508	Yes	Bayer CropScience	Y
KIIA 4.3	Spiegel, K.	2008	Extraction efficiency testing of the residue analytical method 00984/M001 for the determination of AE C656948 residues in grapes using aged radioactive residues MEF-08/109 ! M9991743-2 ! M-299200-01-2 GLP: Open Published: Open BVL-1782895, ASB2008-5494	Yes	Bayer CropScience	N
KIIA 4.3	Sur, R.; Kuhnke, G.; Justus, K.	2007	Extraction efficiency testing of the residue method for the determination of BYF 00587 and BYF 00587-desmethyl using aged radioactive residues from a wheat metabolism study MEF-07/356 ! M9991593-5 ! M-294920-01-1 GLP: Open Published: Open BVL-2188300, ASB2009-5824	Yes	Bayer CropScience	Y
KIIA 4.3	Weeren, R. D.; Pelz, S.	2000	Validation of DFG method S 19 (extended revision) for the determination of residues of JAU 6476-desthio in materials of plant and animal origin (Method-No. 00086/M033) 00086 / M033 ! BAY-0005V ! G00-0033 ! MO-00-016073 ! M-027637-01-1 GLP: Open Published: Open BVL-2189098, MET2002-402	Yes	Bayer CropScience	Y
KIIA 4.3, KIIA 6.3	Fischer, D. R.	2008	AE C656948 500 SC - Magnitude of the residue in/on fruiting vegetables (crop group 8) RAGMP041 ! M-299989-01-1 GLP: Open Published: Open BVL-1782903, BVL-1783126, ASB2008-5500	Yes	Bayer CropScience	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 4.3, KIIIA1 5.3.1	Bacher, R.	2006	Independent laboratory validation of Bayer CropScience method No. 01009 for the determination of residues of JAU 6476-desthio, JAU 6476-3-hydroxy-desthio, JAU 6476-4-hydroxy-desthio, JAU 6476-3,4-dihydroxy-desthio, and JAU 6476-4,5-... P 1111 G ! M-279818-01-1 GLP: Open (1) Yes (1) Published: No (1) Open (1) BVL-2189121, BVL-2629862, ASB2011-13494	Yes	Bayer CropScience	Y
KIIA 4.3, KIIIA1 5.3.1	Brumhard, B.; Stuke, S.	2007	Analytical method 01013 for the simultaneous determination of residues of the active items BYF00587, prothioconazole, tebuconazole, trifloxystrobin and the metabolites BYF00587-desmethyl, JAU6476-desthio (SXX0665) and CGA321113 in/on plant material by HPLC-MS/MS (incl. amendment No. 0001 dated 2007-08-23 and amendment No. 0002 dated 2008-02-18) 01013 ! MR-06/138 ! P 602 065523 ! M-283439-01-1 ! M-283439-02-1 ! M-283439-03-1 GLP: Open (2) Yes (1) Published: No (1) Open (2) BVL-2188298, BVL-2189105, BVL-2629854, ASB2008-6472	Yes	Bayer CropScience	Y
KIIA 4.3, KIIIA1 5.3.1	Christian, I.	2012	Prothioconazole: Method of analysis (including ILV) to monitor prothioconazole-desthio-glucuronide in products of animal origin M-440058-01-1 GLP: No (1) Open (1) Published: No (1) Open (1) BVL-2625304, BVL-2629856, ASB2015-1736	Yes	Bayer CropScience	N
KIIA 4.3, KIIIA1 5.3.1	Freitag, T.	2006	Analytical method 00979 for the determination of residues of JAU 6476 3 hydroxy desthio, JAU 6476 4 hydroxy desthio, JAU 6476 5 hydroxy desthio, and JAU 6476 6 hydroxy desthio in/on matrices of plant origin by HPLC-MS/MS 00979 ! M-267072-01-1 GLP: Open (1) Yes (1) Published: No (1) Open (1) BVL-2625305, BVL-2629857, ASB2012-5961	Yes	Bayer CropScience	N
KIIA 4.3, KIIIA1 5.3.1	Freitag, T.	2013	Analytical method 00655/M002 for the determination of residues of JAU6476-desthio, JAU6476-3-hydroxy-desthio and JAU6476-4-hydroxy-desthio in/on matrices of animal origin by HPLC-MS/MS - Amendment no. 1 - incl. report dated 21.02.2007 MR-06/199 ! M-284607-02-1 ! P 683061810 GLP: Open (1) Yes (1) Published: No (1) Open (1) BVL-2456934, BVL-2629863, ASB2013-9507	Yes	Bayer CropScience	N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 4.3, KIIIA1 5.3.1	Freitag, T.; Daniels, M.	2009	Analytical method 00979/M001 for the determination of residues of JAU 6476-a-hydroxy-desthio, JAU 6476-3-hydroxy-desthio, JAU 6476-4-hydroxy-desthio, JAU 6476-5-hydroxy-desthio, and JAU 6476-6-hydroxy-desthio in/on matrices of plant origin by HPLC-MS/MS 00979/M001 ! M-328686-01-1 GLP: Open (1) Yes (1) Published: No (1) Open (1) BVL-2378255, BVL-2629858, ASB2012-5962	Yes	Bayer CropScience	N
KIIA 4.3, KIIIA1 5.3.1	Freitag, Th.	2004	Supplement E001 to method 00647 for the determination of residues of prothioconazole-desthio in/on broccoli, brussels sprout, cauliflower, head cabbage, leek, tomato, sugar beet, pea and spinach by HPLC-MS/MS 00647/E001 ! MR-066/03 ! P602031801 ! MO-04-002874 ! M-001085-01-1 GLP: Open (1) Yes (1) Published: No (1) Open (1) BVL-1948014, BVL-2629860, ASB2008-6521	Yes	Bayer CropScience	N
KIIA 4.3, KIIIA1 5.3.1	Glaubitz, J.; Ballmann, C.	2013	Modification M003 of the residue analytical method 00984 for the determination of AE C656948, its metabolite AE F148815 and tebuconazole in/on orange (fruit), wheat (grain), wheat (straw), bean (seed), lettuce (head), rape (seed) and hop (dry cone) by HPLC-MS/MS and a Cross validation of the analytical methods 00984 and 00984/M003 M-467323-01-1 ! MR-12/036 GLP: Open (1) Yes (1) Published: No (1) Open (1) BVL-2624361, BVL-2629855, ASB2015-1734	Yes	Bayer CropScience	N
KIIA 4.3, KIIIA1 5.3.1	Lakaschus, S.; Amann, S.; Winter, O. et al.	2013	Validation of the BCS method no. 01207 (based on modified QuEChERS method) for the determination of selected BCS analytes and their metabolites in carrot, apple, orange, oilseed rape seed and beans M-424756-02-1 ! S10-00279 GLP: Open (1) Yes (1) Published: No (1) Open (1) BVL-2624362, BVL-2629859, ASB2015-1735	Yes	Bayer CropScience	N
KIIA 4.3, KIIIA1 5.3.1	Schulte, G.; Oel, D.	2013	Analytical method 01009 for the determination of residues of JAU 6476-desthio,JAU 6476-3-hydroxy-desthio, JAU 6476-4-hydroxy-desthio, JAU 6476-3,4- dihydroxy-desthio, and JAU 6476-4,5-dihydroxy-desthio in/on matrices of animal origin by HPLC-MS/MS - Amendment no. 1 - incl. report dated 26.10.2006 MR-06/120 ! M-279725-02-1 ! P 683 06 1806 GLP: Open (1) Yes (1) Published: No (1) Open (1) BVL-2456930, BVL-2629861, ASB2013-9506	Yes	Bayer CropScience	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 4.3, KIIIA1 5.3.1	Schwarz, T.; Class, T.	2007	Independent laboratory validation of Bayer CropScience method 00655/M002 for the determination and confirmation of residues of JAU6476-desthio, JAU6476-3-hydroxy-desthio and JAU6476-4-hydroxy-desthio in/on matrices of animal origin by HPLC-MS/MS P 1226 G ! P/B 1226 G ! P613060603 ! M-286824-01-1 GLP: Open (1) Yes (1) Published: No (1) Open (1) BVL-2189086, BVL-2629864, ASB2008-276	Yes	Bayer CropScience	Y
KIIA 4.4	Brumhard, B.	2006	Analytical method 00973 for the determination of residues of AE C656948 in soil by HPLC-MS/MS 00973 ! MR-179/05 ! P601050003 ! M-265498-01-3 GLP: Open Published: Open BVL-1782913, ASB2008-5511	Yes	Bayer CropScience	N
KIIA 4.4	Brumhard, B.; Freitag, Th.	2006	Analytical method 00952 for the determination of residues of BYF 00587 in soil by HPLC-MS/MS 00952 ! MR-118/05 ! P 601 05 0002 ! M-281557-01-1 GLP: Open Published: Open BVL-2188309, ASB2009-5834	Yes	Bayer CropScience	N
KIIA 4.4	Brumhard, B.; Koch, V.	2007	Analytical method 00952 / M001 for the determination of residues of BYF00587 and BYF00587-desmethyl (BCS-AA-10008) in soil by HPLC-MS/MS 00952 / M001 ! MR-07/289 ! P601071813 ! M-294593-01-1 GLP: Open Published: Open BVL-2188310, ASB2009-5835	Yes	Bayer CropScience	N
KIIA 4.4	Brumhard, B.; Schneider, U.	2008	Analytical Method 01068 for the determination of residues of AE C656948 in soil by HPLC-MS/MS 01068 ! P681071820 ! MR-07/319 ! M-296215-01-2 GLP: Open Published: Open BVL-1782915, ASB2008-5512	Yes	Bayer CropScience	Y
KIIA 4.4	Freitag, T.; Schneider, U.	2007	Analytical method 01023 for the determination of residues of AE C656948 and its metabolites AE C656948-benzamide (AE F148815), AE C656948-7-hydroxy (BCS-AA-10065) and AE C656948-PCA in soil by HPLC-MS/MS 01023 ! MR-06/187 ! M-287801-01-2 GLP: Open Published: Open BVL-1782917, ASB2008-5513	Yes	Bayer CropScience	N
KIIA 4.4	Schramel, O.	2000	Residue analytical method 00610 (MR-643/99) for the determination of JAU6476 and the metabolites JAU6476-desthio and JAU6476-S-methyl in soil by HPLC-MS/MS 00610 ! MR-643/99 ! P60190026 ! MO-00-010405 ! M-041798-01-1 GLP: Open Published: Open BVL-2189107, MET2002-405	Yes	Bayer CropScience	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 4.4	Sommer, H.	1998	Method 00520 (MR-342/98) for liquid chromatographic determination of JAU 6476 and SXX 0665 on application verification pads 00520 ! MR-342/98 ! P60180006 ! MO-99-001441 ! M-006167-01-1 GLP: Open Published: Open BVL-2189108, MET2002-406	Yes	Bayer CropScience	N
KIIA 4.4	Steinhauer, S.	2001	Enforcement method 00086/M038 for the determination of the residues of JAU 6476-desthio in soil - Validation of DFG method S 19 (extended revision) - 00086/M038 ! BAY-0107V ! G01-0026 ! MO-01-015298 ! M-067970-01-1 GLP: Open Published: Open BVL-2189106, MET2002-407	Yes	Bayer CropScience	Y
KIIA 4.4, KIIA 4.6	Brumhard, B.; Freitag, Th.	2006	Analytical method 00959 for the determination of residues of BYF00587 in soil by HPLC-MS/MS 00959 ! MR-140/05 ! P681050015 ! M-281595-01-1 GLP: Open Published: Open BVL-2188308, BVL-2188312, ASB2009-5833	Yes	Bayer CropScience	Y
KIIA 4.4, KIIA 4.6	Netzband, D. J.	2008	Independent laboratory validation of "Analytical method 01023 for the determination of residues of AE C656948 and its metabolites AE C656948-benzamide (AE F148815), AE C656948-7-hydroxy (BCS-AA-10065) and AE C656948-PCA in soil by HPLC-MS/MS" on soil and sediment RAGMP101 ! M-299544-01-1 GLP: Open Published: Open BVL-1782919, BVL-1782929, ASB2008-5520	Yes	Bayer CropScience	N
KIIA 4.4, KIIIA1 5.4	Brumhard, B.	2005	Modification M001 of method 00610 for the determination of JAU6476 and the metabolites JAU6476-desthio and JAU6476-S-methyl in soil by HPLC-MS/MS MR-183/04 ! 00610 M001 ! 00610/M001 ! P681040016 ! MO-05-001933 ! M-243729-01-1 GLP: Open (1) Yes (1) Published: No (1) Open (1) BVL-2189109, BVL-2629865, MET2005-358	Yes	Bayer CropScience	Y
KIIA 4.5	Krebber, R.; Braune, M.	2008	Analytical method 01073 for the determination of bixafen (BYF 00587) in drinking and surface water by HPLC-MS/MS 01073 ! MR-07/336 ! P 684 077020 ! M-296389-01-1 GLP: Open Published: Open BVL-2188311, ASB2009-5837	Yes	Bayer CropScience	Y
KIIA 4.5	Krebber, R.; Daniels, M.	2007	Analytical method 01051 for the determination of Fluopyram (AE C656948) in drinking and surface water by HPLC-MS/MS 01051 ! MR-07/283 ! P 684 077021 ! M-291398-01-2 GLP: Open Published: Open BVL-1782921, ASB2008-5530	Yes	Bayer CropScience	N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 4.5	Ripperger, R. J.	2008	Determination of Fluopyram (AE C656948) in water by LC/MS/MS GM-003-W08-01 ! M-299112-01-1 GLP: Open Published: Open BVL-1782923, ASB2008-5531	Yes	Bayer CropScience	N
KIIA 4.5	Ripperger, R. J.	2008	Independent laboratory validation of analytical method 01051 for the determination of fluopyram (AE C656948) in drinking and surface water by HPLC-MS/MS RAGMP087-1 ! M-298722-02-1 GLP: Open Published: Open BVL-1782925, ASB2008-5532	Yes	Bayer CropScience	Y
KIIA 4.5	Sommer, H.	2001	Enforcement method 00684 for determination of JAU6476 and JAU6476-desthio in drinking and surface water by HPLC-MS/MS 00684 ! MR-105/01 ! P 684 007002 ! MO-01-019621 ! M-079449-01-1 GLP: Open Published: Open BVL-2189091, MET2002-411	Yes	Bayer CropScience	Y
KIIA 4.5, KIIIA1 5.6	Brumhard, B.	2005	Modification M001 of method 00684 for the determination of JAU6476 and JAU6476-desthio in drinking and surface water by HPLC-MS/MS MR-184/04 ! 00684 M001 ! 00684/M001 ! P684047047 ! MO-05-001939 ! M-243734-01-1 GLP: Open (1) Yes (1) Published: No (1) Open (1) BVL-2189094, BVL-2629866, MET2005-359	Yes	Bayer CropScience	Y
KIIA 4.6	Netzband, D. J.	2008	Analytical method for the determination of residues of AE C656948 and its metabolites AE C656948-benzamide, AE C656948-7-hydroxy, and AE C656948-PCA in soil and sediment using LC/MS/MS GM-002-S07-01 ! M-300037-01-1 GLP: Open Published: Open BVL-1782927, ASB2008-5533	Yes	Bayer CropScience	N
KIIA 4.7	Bacher, R.	2008	Fluopyram: Analytical method for determination in air P605087512 ! M-296842-01-1 GLP: Open Published: Open BVL-2079977, ASB2008-5534	Yes	Bayer CropScience	Y
KIIA 4.7	Class, Th.	2007	BYF 00587: Analytical method for the determination of BYF 00587 in air P 1243 G ! P/B 1243 G ! P605077505 ! M-289587-01-1 GLP: Open Published: Open BVL-2188313, ASB2009-5838	Yes	Bayer CropScience	Y
KIIA 4.7	Maasfeld, W.	2002	Method for the determination of JAU 6476 in air by HPLC-MS/MS (Method-No. 00724) 00724 ! P 605 00 6005 ! MR-601/01 ! MO-02-001202 ! M-032554-01-1 GLP: Open Published: Open BVL-2189093, MET2002-408	Yes	Bayer CropScience	Y
KIIA 4.7	Maasfeld, W.	2002	Method for the determination of JAU 6476-desthio (SXX 0665) in air by HPLC-MS/MS (Method-No. 00731) MR-003/02 ! 00731 ! P 605 00 6012 ! MO-02-002585 ! M-036729-01-1 GLP: Open Published: Open BVL-2189104, MET2005-361	Yes	Bayer CropScience	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 4.7, KIIIA1 5.7	Anft, T.; Bardel, P.	2005	Modification M001 of method 00731 for the determination of residues of JAU 6476-desthio (SXX 0665) in air by HPLC/MS/MS MR-166/04 ! 00731/M001 ! P 606 04 1201 ! MO-05-001163 ! M-242870-01-1 GLP: Open (1) Yes (1) Published: No (1) Open (1) BVL-2189095, BVL-2629867, MET2005-360	Yes	Bayer CropScience	N
KIIA 4.9	Sommer, H.	1999	Method for the determination of JAU 6476 and SXX 0665 in test water from aquatic toxicity tests by HPLC (Method-No. 00586) 00586 ! MR-291/99 ! P 604 97053 ! MO-99-006491 ! M-012801-01-1 GLP: Open Published: Open BVL-2189092, MET2002-409	Yes	Bayer CropScience	N
KIIA 4.9	Sommer, H.	2001	Method for determination of JAU6476-S-methyl in test water from aquatic toxicity tests by HPLC-UV (Method-No. 00699) 00699 ! MR-250/01 ! P 604 017004 ! MO-01-011779 ! M-052730-01-1 GLP: Open Published: Open BVL-2189096, MET2002-410	Yes	Bayer CropScience	N
KIIA 6.2.1	Haas, M.	2001	Extraction efficiency testing of the residue method (00647) for the determination of JAU6476 residues in spring wheat using aged radioactive residues MR-084/01 ! MO-01-011835 ! M 9991102-1 GLP: Open Published: Open BVL-1982404, RIP2002-1041	Yes	Bayer CropScience	Y
KIIA 6.2.2	Justus, K.; Koester, J.	2008	Metabolism of [phenyl-UL-14C]AE C656948 in the laying hen MEF-06/329 ! M01819173 ! M-297093-01-2 GLP: Open Published: Open BVL-1783082, ASB2008-5394	Yes	Bayer CropScience	Y
KIIA 6.2.3	Spiegel, K.; Koester, J.	2007	Metabolism of [pyrazole-5-14C]BYF 00587 in the lactating goat MEF-06/316 ! M51819178 ! M-296034-01-1 GLP: Open Published: Open BVL-1994738, BVL-1994738, ASB2009-5940	Yes	Bayer CropScience	Y
KIIA 6.2.3	Weber, H.; Weber, E.; Spiegel, K.	2002	[Phenyl-UL-14C]JAU6476-desthio: Absorption, distribution, excretion, and metabolism in the lactating goat including the validation of the residue analytical method for the determination of JAU6476-desthio, JAU6476-3-hydroxy-desthio and JAU6476-4-hydroxy-desthio residues in animal matrices using aged radioactive residues MR-091/01 ! Part 2 - MO-02-003998 ! M91819091 GLP: Open Published: Open BVL-1982415, RIP2002-1046	Yes	Bayer CropScience	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
MIIIA1 Sec 2	Applicant	2014	Bixafen + Fluopyram + Prothioconazole / Ascra Xpro (102000027828): Analytical methods - Tier 2, IIIA-5 - Draft Registration Report - Part B - Core assessment M-484417-01-1 ! MIII / Sec. 2 GLP: Open Published: No BVL-2629989, BVL-2629990, ASB2015-2189	Open	Bayer CropScience	N

* Y Yes , relied on
N No, not relied on
Add: Relied on, study not submitted by applicant but necessary for evaluation

Appendix 2 – Detailed evaluation of the additional studies relied upon

A 1.1 Analytical methods for Bixafen

A 1.1.1 Extraction efficiency of enforcement methods for foodstuff

A 1.1.1.1 Analytical method 1

Reference: OECD: KIIIA 5.3.1

Report: Extraction efficiency testing of the residue method for the determination of BYF 00587 and BYF 00587-desmethyl using aged radioactive residues from a wheat metabolism study; Sur, R.; Kuhnke, G.; Justus, K., 2007, MEF-07/356 ! M9991593-5 ! M-294920-01-1, ASB2009-5824

Guideline(s): Yes: US EPA OPPTS 860.1380

Deviations: Not applicable

GLP: Yes

Acceptability: Yes

Materials and methods

The extraction efficiency is tested using aged radioactive residues of [dichlorophenyl-UL-^{14}C]-BYF00587 in wheat forage, grain and straw. The sample material is extracted with acetonitrile/water (4/1, v/v) in a microwave oven. The samples are measured by HPLC with UV- and radioactivity flow through detection. The extraction solvent is identical with that in the proposed monitoring method for plant matrices of Bardel & Schöning, 2006.

Results and discussions

The extraction efficiency is expressed as the amount of bixafen extracted by the residue analytical method compared to the amount extracted in the metabolism study. For forage, the extraction efficiency was 98.9 %. For wheat straw and grain the extraction efficiency was 98.9 % and 98.7 % for bixafen, respectively. Only minor amounts of bixafen-desmethyl (< 2 %) are extracted.

Conclusion

The extraction efficiency for residue analytical methods using an acetonitrile/water mixture as extraction solvent is proven.

Comments of zRMS:	Acceptable.

A 1.2 Analytical methods for Prothioconazole

A 1.2.1 Methods for enforcement of residues in food and feed of plant origin

A 1.1.1.2 Analytical method 1

Reference:	OECD; KIIIA, 5.3.1
Report	Analytical method 01013 for the simultaneous determination of residues of the active Items BYF00587, prothioconazole, tebuconazole, trifloxystrobin and the metabolites BYF00587-desmethyl, JAU6476-desthio (SXX0665) and CGA321113 in/on plant material by HPLC-MS/MS; Brumhard, B.; Stuke, S. 2008; method no. 01013, report no. MR-06/138 incl. amendment, ASB2008-6472
Guideline(s):	Yes: SANCO 3029/99, SANCO/825/00 rev. 7, OPPTS 860.1340
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Bayer method no. 01013 is a data collection method (multi method) for the determination of the relevant residues of bixafen, prothioconazole, tebuconazole and trifloxystrobin in plant materials. However, in the context of this dossier, only the information related to prothioconazole-desthio residues is summarized.

Plant material (citrus fruit, pea green seed, wheat grain, rape seed and corn green material) are extracted using a mixture of acetonitrile/water (4/1; v/v) containing cysteine hydrochloride. The samples were filtrated, diluted with methanol/water (4/6, v/v) + 50 g/L cysteine hydrochloride and analysed without further cleanup. Quantification is performed by LC-MS/MS using a Luna C18 column and monitoring m/z 312→70, 312→125 for JAU6476-desthio after electrospray ionization in positive mode. A stable isotope labeled internal standard is used for calibration.

Results and discussions

Table A 1: Recovery results from method validation of prothioconazole-desthio using the primary analytical method. Standards were prepared in methanol/water (4/6, v/v) + 50 g/L cysteine hydrochloride.

Matrix	Fortification level (mg/kg)	No of samples per fortification	Mean recovery	RSD (%)	Comments

		level			
citrus fruit	0.01 0.1	5 5	104 96	3.3 7.0	m/z 312→70
peas fruit	0.01 0.1	5 5	107 99	7.0 2.2	m/z 312→70
rape seed	0.01 0.1	5 5	97 95	7.1 5.6	m/z 312→70
wheat grain	0.01 0.1	5 5	99 96	2.6 3.6	m/z 312→70
corn green material	0.01 0.1	5 5	115 100	4.2 2.1	m/z 312→70

Table A 2: Recovery results from method validation of prothioconazole-desthio using the confirmatory analytical method. Standards were prepared in methanol/water (4/6, v/v) + 50 g/L cysteine hydrochloride.

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
citrus fruit	0.01 0.1	5 5	109 98	7.8 5.7	m/z 312→125
peas fruit	0.01 0.1	5 5	100 109	5.4 3.0	m/z 312→125
rape seed	0.01 0.1	5 5	96 95	4.7 6.4	m/z 312→125
wheat grain	0.01 0.1	5 5	97 92	5.0 2.6	m/z 312→125
corn green material	0.01 0.1	5 5	107 96	5.2 2.0	m/z 312→125

Table A 3: Characteristics for the analytical method used for the quantitation of prothioconazole-desthio residues in dry, fatty, acidic and high water content matrices

	Prothioconazole-desthio, m/z 312→70	Prothioconazole-desthio, m/z 312→125
Calibration function	Y=0.8383 *X+0.0031 Y as Area Response factor analyt//ISTD X as ng/mL R=0.9995	No data
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.005 – 10 ng/mL	
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.0005 – 1 mg/kg	
Does the calibration consist of at least 3 levels	Yes	

(duplicated points) or 5 levels (single points)? (yes/ no)		
Assessment of matrix effects is presented (yes/no)	No	
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	

Conclusion

The method of Brumhard & Stuke, 2008 is validated for the quantification of prothioconazole-desthio in acidic, dry, fatty and high water content plant material. The limit of quantification is 0.01 mg/kg.

Comments of zRMS:	Acceptable.

A 1.2.2 Methods for enforcement of residues in food and feed of animal origin

A 1.1.1.3 Analytical method 1

Reference: OECD, KIIIA, 5.3.1

Report: Analytical method 01009 for the determination of residues of JAU 6476-desthio, JAU 6476-3-hydroxy-desthio, JAU 6476-4-hydroxy-desthio, JAU 6476-3,4-dihydroxy-desthio, and JAU 6476-4,5-dihydroxy-desthio in/on matrices of animal origin by HPLC-MS/MS; Billian & Wolters; 2006, method no. 01009, report no. MR-06/120, ASB2010-11620 incl. Amendment no. 1 ASB2013-9506

Guideline(s): Yes: SANCO/825/00 rev. 7

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

The samples (milk, meat, eggs, fat, liver and kidney) were extracted with acetonitrile/water (4/1, v/v) using a high-speed blender. After concentration to an aqueous reminder the solutions were refluxed for 2 hours with 5 N HCl. This hydrolysis step cleaves conjugates and is suitable for analysing the glucuronide conjugate of JAU6476-desthio. Quantification is performed by LC-MS/MS using a Luna Phenyl-Hexyl column and monitoring m/z 312→70, 312→125 for prothioconazole-desthio after electrospray ionization in positive mode. Matrix-matched standards are used for calibration.

Results and discussions

Table A 4: Recovery results from method validation of prothioconazole-desthio using the primary analytical method. Standards were prepared in blank matrix.

Matrix	Fortification level (mg/kg)	No of samples per fortification	Mean recovery	RSD (%)	Comments

		level			
Milk	0.01 0.1	5 5	92 97	6.3 9.2	m/z 312→70
Meat	0.01 0.1	5 5	92 91	7.4 7.0	m/z 312→70
Kidney	0.01 0.1	5 5	92 91	4.3 5.6	m/z 312→70
Liver	0.01 0.1	5 5	95 99	2.1 0.9	m/z 312→70
Fat	0.01 0.1	5 5	90 86	4.1 2.2	m/z 312→70
Egg	0.01 0.1	5 5	92 88	1.9 2.3	m/z 312→70

Table A 5: Recovery results from method validation of prothioconazole-desthio using the confirmatory analytical method. Standards were prepared in blank matrix.

Matrix	**Fortification level (mg/kg)**	**No of samples per fortification level**	**Mean recovery**	**RSD (%)**	**Comments**
Milk	0.01 0.1	5 5	91 95	5.1 8.0	m/z 312→125
Meat	0.01 0.1	5 5	93 91	6.8 6.9	m/z 312→125
Kidney	0.01 0.1	5 5	92 87	6.4 4.5	m/z 312→125
Liver	0.01 0.1	5 5	93 97	3.0 1.7	m/z 312→125
Fat	0.01 0.1	5 5	91 87	6.0 2.1	m/z 312→125
Egg	0.01 0.1	5 5	88 88	3.9 2.1	m/z 312→125

Table A 6: Characteristics for the analytical method used for the quantitation of prothioconazole-desthio residues in milk

	Prothioconazole-desthio, m/z 312→70	**Prothioconazole-desthio, m/z 312→125**
Calibration function	Y=17568*X+519, R=0.9998	Y=9244*X+243, R=0.9998
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.25 – 10 ng/mL	0.25 – 10 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.005 – 0.2 mg/kg	0.005 – 0.2 mg/kg

	Prothioconazole-desthio, m/z 312→70	**Prothioconazole-desthio, m/z 312→125**
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes	Yes
Assessment of matrix effects is presented (yes/no)	No	No
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Table A 7: Characteristics for the analytical method used for the quantitation of prothioconazole-desthio residues in meat

	Prothioconazole-desthio, m/z 312→70	**Prothioconazole-desthio, m/z 312→125**
Calibration function	Y=374096*X +6684, R=0.9995	Y=158456*X +2462, R=0.9996
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.25 – 10 ng/mL	0.25 – 10 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.005 – 0.2 mg/kg	0.005 – 0.2 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes	Yes
Assessment of matrix effects is presented (yes/no)	No	No
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Table A 8: Characteristics for the analytical method used for the quantitation of prothioconazole-desthio residues in kidney

	Prothioconazole-desthio, m/z 312→70	**Prothioconazole-desthio, m/z 312→125**
Calibration function	Y=14594*X+27, R=0.9996	Y=7769*X+216, R=0.9988
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.25 – 10 ng/mL	0.25 – 10 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.005 – 0.2 mg/kg	0.005 – 0.2 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes	Yes
Assessment of matrix effects is presented (yes/no)	No	No
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Table A 9: Characteristics for the analytical method used for the quantitation of prothioconazole-desthio residues in liver

	Prothioconazole-desthio, m/z 312→70	**Prothioconazole-desthio, m/z 312→125**
Calibration function	Y=15135*X+608, R=0.9997	Y=8297*X+308, R=0.9996
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.25 – 10 ng/mL	0.25 – 10 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.005 – 0.2 mg/kg	0.005 – 0.2 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes	Yes
Assessment of matrix effects is presented (yes/no)	No	No
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Table A 10: Characteristics for the analytical method used for the quantitation of prothioconazole-desthio residues in fat

	Prothioconazole-desthio, m/z 312→70	**Prothioconazole-desthio, m/z 312→125**
Calibration function	Y=30581*X+1134, R=0.9986 (MS machine1) Y=386547*X+21162, R=0.9991 ((MS machine2)	Y=15479*X+1419, R=0.9988(MS machine1) Y=164687*X+6924, R=0.9991 (MS machine2)
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.25 – 10 ng/mL	0.25 – 10 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.005 – 0.2 mg/kg	0.005 – 0.2 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes	Yes
Assessment of matrix effects is presented (yes/no)	No	No
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Table A 11: Characteristics for the analytical method used for the quantitation of prothioconazole-desthio residues in egg

	Prothioconazole-desthio, m/z 312→70	**Prothioconazole-desthio, m/z 312→125**
Calibration function	Y=14930*X+44, R=0.9996	Y=7966*X+8, R=0.9994
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.25 – 10 ng/mL	0.25 – 10 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.005 – 0.2 mg/kg	0.005 – 0.2 mg/kg
Does the calibration consist of at least 3 levels	Yes	Yes

(duplicated points) or 5 levels (single points)? (yes/ no)		
Assessment of matrix effects is presented (yes/no)	No	No
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Conclusion

The method is validated for the quantification of prothioconazole-desthio residues in animal matrices (meat, milk, fat, liver, kidney, eggs). The method includes a hydrolysis step. It determines also the conjugates of prothioconazole-desthio and corresponds to the residue definition for monitoring. The method is also validated for further metabolites (JAU6476-3-hydroxy-desthio, JAU6476-4-hydroxy-desthio, JAU6476-3,4-dihydroxy-desthio and JAU6476-4,5-dihydroxy-desthio). This part is not described here because these metabolites are not included in the residue definition. The limit of quantification is 0.01 mg/kg. Because of the validation of two MS/MS transitions an additional confirmatory method is not required. The study shows some deficiencies. Calibration graphs are only available for milk. However, this point is of minor importance because the slopes, the intercepts and the regression coefficients are provided for all matrices. Also data to prove the applicability of the method for the glucuronide conjugate of prothioconazole-desthio are missing. Since the validation of hydrolysis steps is not clearly defined in the SANCO/825/00 guideline, no further work is required. Chromatograms for meat, eggs, fat and liver or kidney are presented in Amendment no. 1.

Comments of zRMS:	Acceptable. For deficiencies see above.

A 1.1.1.4 Independent laboratory validation

Reference: OECD: KIIIA, 5.3.1

Report: Independent laboratory validation of Bayer CropScience method No. 01009 for the determination of residues of JAU 6476-desthio, JAU 6476-3-hydroxy-desthio, JAU 6476-4-hydroxy-desthio, JAU 6476-3,4-dihydroxy-desthio, and JAU 6476-4,5-dihydroxy-desthio in/on matrices of animal origin by HPLC-MS/MS; Bacher; R. 2006; report no. P/B 1111G, study no. P613060597, ASB2011-13494

Guideline(s): Yes: SANCO/825/00 rev. 7

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

The method of Billian & Wolters, 2006 was validated for meat, milk and eggs in an independent laboratory. The ILV uses the same extraction and measurement procedure with only minor modification. Quantification is performed by LC-MS/MS using a Luna Phenyl-Hexyl column and monitoring m/z 312→70, 312→125 for prothioconazole-desthio after electrospray ionization in positive mode. Matrix-matched standards are used for calibration.

Results and discussions

Table A 12: Recovery results from the independent laboratory validation of prothioconazole-desthio in milk, meat, eggs using the primary analytical method. Standards were prepared in blank matrix extract.

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
Meat	0.01 0.1	5 5	99 97	1 1	m/z 312→70
Milk	0.01 0.1	5 5	101 101	2 3	m/z 312→70
Eggs	0.01 0.1	5 5	90 87	1 4	m/z 312→70

Table A 13: Recovery results from the independent laboratory validation of prothioconazole-desthio in milk, meat, eggs using the confirmatory analytical method. Standards were prepared in blank matrix extract.

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
Meat	0.01 0.1	5 5	97 96	2 1	m/z 312→125
Milk	0.01 0.1	5 5	101 101	2 3	m/z 312→125
Eggs	0.01 0.1	5 5	89 86	3 3	m/z 312→125

Table A 14: Characteristics for the analytical method used for the independent laboratory validation of prothioconazole-desthio residues in meat

	Prothioconazole-desthio, m/z 312→70	Prothioconazole-desthio, m/z 312→125
Calibration function	Y=186000*X-3020, R=0.9988	Y=111000*X-1640, R=0.9985
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.1 – 10 ng/mL	0.1 – 10 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.002 – 0.2 mg/kg	0.002 – 0.2 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes	Yes
Assessment of matrix effects is presented (yes/no)	No	No
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Table A 15: Characteristics for the analytical method used for the independent laboratory validation of prothioconazole-desthio residues in milk

	Prothioconazole-desthio, m/z 312→70	**Prothioconazole-desthio, m/z 312→125**
Calibration function	Y=76100*X+906, R=0.9996	Y=45500*X+293, R=0.9997
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.1 – 10 ng/mL	0.1 – 10 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.002 – 0.2 mg/kg	0.002 – 0.2 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes	Yes
Assessment of matrix effects is presented (yes/no)	No	No
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Table A 16: Characteristics for the analytical method used for the independent laboratory validation of prothioconazole-desthio residues in eggs

	Prothioconazole-desthio, m/z 312→70	**Prothioconazole-desthio, m/z 312→125**
Calibration function	Y=187000*X-6250, R=0.9986	Y=112000*X-4350, R=0.9982
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.1 – 10 ng/mL	0.1 – 10 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.002 – 0.2 mg/kg	0.002 – 0.2 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes	Yes
Assessment of matrix effects is presented (yes/no)	No	No
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Conclusion

The study validates the method of Billian & Wolters in an independent laboratory. The limit of quantification is 0.01 mg/kg. Because of the validation of two MS/MS transitions an additional confirmatory method is not required. The method is also validated for further metabolites (JAU6476-3-hydroxy-desthio, JAU6476-4-hydroxy-desthio, JAU6476-3,4-dihydroxy-desthio and JAU6476-4,5-dihydroxy-desthio). This part is not described here because these metabolites are not included in the residue definition. The study shows some deficiencies. Calibration graphs are only available for milk. However, this point is of minor importance because the slopes, the intercepts and the regression coefficients are provided for all matrices. Also data to prove the applicability of the method for the glucuronide conjugate of prothioconazole-desthio are missing. Since the validation of hydrolysis steps is not clearly defined in the SANCO/825/00 guideline, no further work is required.

Comments of zRMS:	Acceptable. For deficiencies see above.

A 1.1.1.5 Analytical method 2

Reference: OECD: KIIIA, 5.3.1

Report: Analytical method 00655/M002 for the determination of residues of JAU6476-desthio, JAU6476-3-hydroxy-desthio and JAU6476-4-hydroxy-desthio in/on matrices of animal origin by HPLC-MS/MS, Freitag, T.; 2007, report no. MR-06/199, method no. 00655/M002, ASB2008-275

Guideline(s): Yes: SANCO/3029/99, SANCO/825/00 rev. 7

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

The homogenized animal material (meat, liver, kidney) are extracted with acetonitrile/water (4/1, v/v). The solutions are evaporated to an aqueous reminder. Milk samples are diluted with water. Fat samples are blended with acetonitrile/water (4/1, v/v) and hexane. After centrifugation the supernatant is partitioned with acetonitrile/n-hexane (1/2, v/v). The acetonitrile phase is evaporated to an aqueous reminder. A hydrolysis step with 5 N HCl for 2 hours under reflux is performed. After neutralization a cleanup using a ChemElut cartridge is done. Elution is performed by ethyl acetate/cyclohexane (85/15, v/v). The eluates are reduced to dryness and dissolved in acetonitrile/water (1/1, v/v). Quantification is performed by LC-MS/MS using a Superspher 60 RP select B column and monitoring m/z 312→70, 312→125 for JAU6476-desthio after electrospray ionization in positive mode. Matrix-matched standards are used for calibration.

Results and discussions

Table A 17: Recovery results from method validation of prothioconazole-desthio in meat, fat, liver, kidney and milk using the primary analytical method. Standards were prepared in blank matrix extract.

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
Meat	0.01 0.1	5 5	91 89	3.5 1.7	m/z 312→70
Liver	0.01 0.1	5 5	87 88	3.5 2.4	m/z 312→70
Kidney	0.01 0.1	5 5	81 90	12.1 5.2	m/z 312→70
Fat	0.01 0.1	5 5	89 88	0.5 7.8	m/z 312→70
Milk	0.004 0.04	5 5	88 90	7.7 1.1	m/z 312→70

Table A 18: Recovery results from method validation of prothioconazole-desthio in meat, fat, liver, kidney and milk using the confirmatory analytical method. Standards were prepared in blank matrix extract.

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
Meat	0.01 0.1	5 5	92 91	3.1 1.6	m/z 312→125
Liver	0.01 0.1	5 5	86 88	3.0 3.3	m/z 312→125
Kidney	0.01 0.1	5 5	80 89	11.1 6.6	m/z 312→125
Fat	0.01 0.1	5 5	89 88	1.7 7.0	m/z 312→125
Milk	0.004 0.04	5 5	82 91	7.6 1.8	m/z 312→125

Table A 19: Characteristics for the analytical method used for the quantitation of prothioconazole-desthio residues in meat

	Prothioconazole-desthio, m/z 312→70	Prothioconazole-desthio, m/z 312→125
Calibration function	Y=41493*X-48, R=0.9920	Y=23937*X+66, R=0.9921
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.1 – 20 ng/mL	0.1 – 20 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.001 – 0.2 mg/kg	0.001 – 0.2 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes	Yes
Assessment of matrix effects is presented (yes/no)	No	No
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Table A 20: Characteristics for the analytical method used for the quantitation of prothioconazole-desthio residues in liver

	Prothioconazole-desthio, m/z 312→70	Prothioconazole-desthio, m/z 312→125
Calibration function	Y=46556*X+848, R=0.9917	Y=26745*X+17, R=0.9917
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.1 – 20 ng/mL	0.1 – 20 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.001 – 0.2 mg/kg	0.001 – 0.2 mg/kg

Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes	Yes
Assessment of matrix effects is presented (yes/no)	No	No
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Table A 21: Characteristics for the analytical method used for the quantitation of prothioconazole-desthio residues in kidney

	Prothioconazole-desthio, m/z 312→70	**Prothioconazole-desthio, m/z 312→125**
Calibration function	Y=47489*X-445, R=0.9928	Y=27317*X-333, R=0.9918
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.1 – 20 ng/mL	0.1 – 20 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.001 – 0.2 mg/kg	0.001 – 0.2 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes	Yes
Assessment of matrix effects is presented (yes/no)	No	No
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Table A 22: Characteristics for the analytical method used for the quantitation of prothioconazole-desthio residues in fat

	Prothioconazole-desthio, m/z 312→70	**Prothioconazole-desthio, m/z 312→125**
Calibration function	Y=41811*X-16, R=0.9903	Y=24073*X+82, R=0.9902
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.1 – 20 ng/mL	0.1 – 20 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.001 – 0.2 mg/kg	0.001 – 0.2 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes	Yes
Assessment of matrix effects is presented (yes/no)	No	No
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Table A 23: Characteristics for the analytical method used for the quantitation of prothioconazole-desthio residues in milk

	Prothioconazole-desthio, m/z 312→70	**Prothioconazole-desthio, m/z 312→125**
Calibration function	Y=40526*X+378, R=0.9997	Y=23057*X+251, R=0.9999
Accepted calibration range in concentration units	0.04 – 8 ng/mL	0.04 – 8 ng/mL

(e.g. in µg/ml or ng/µl)		
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.0004 – 0.08 mg/kg	0.0004 – 0.08 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes	Yes
Assessment of matrix effects is presented (yes/no)	No	No
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Conclusion

A method for the quantification of residues of prothioconazole-desthio including conjugates is validated. The limit of quantification is 0.01 mg/kg for meat, fat, liver and kidney and 0.004 mg/kg for milk. The method is also validated for further metabolites (JAU6476-3-hydroxy-desthio, JAU6476-4-hydroxy-desthio). This part is not described here because these metabolites are not included in the residue definition. The study shows some deficiencies. Calibration graphs are missing for fat, liver and kidney. However, this point is of minor importance because the slopes, the intercepts and the regression coefficients for all matrices are given. Also data to prove the applicability of the method for the glucuronide conjugate of prothioconazole-desthio are missing. Since the validation of hydrolysis steps is not clearly defined in the SANCO/825/00 guideline, no further work is required. Chromatograms for liver and kidney are missing to prove the selectivity of the method for these matrices. No additional confirmatory method is necessary because two MS/MS transitions were validated.

Comments of zRMS:	Acceptable. For deficiencies see above.

A 1.1.1.6 Independent laboratory validation

Reference:	OECD: KIIIA, 5.3.1
Report	Independent laboratory validation of Bayer CropScience method 00655/M002 for the determination and confirmation of residues of JAU6476-desthio, JAU6476-3-hydroxy-desthio and JAU6476-4-hydroxy-desthio in/on matrices of animal origin by HPLC-MS/MS; Schwarz, T & Class T., 2007; report no. P1226G, study no. P613060603, ASB2008-276
Guideline(s):	Yes: SANCO/825/00 rev. 7
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The method of Freitag, 2007 was validated for meat, milk, liver and fat in an independent laboratory. The ILV uses the same extraction and measurement procedure with only slightly modifications. Quantification is performed by LC-MS/MS using a Superspher 60 RP select B column and monitoring m/z 312→70, 312→125 for JAU6476-desthio after electrospray ionization in positive mode. Matrix-matched standards

are used for calibration.

Results and discussions

Table A 24: Recovery results from the independent laboratory validation of prothioconazole-desthio in milk, meat, liver and fat using the primary analytical method. Standards were prepared in blank matrix extract.

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
Milk	0.004 0.04	5 5	83 90	2 3	m/z 312→70
Meat	0.01 0.1	5 5	83 89	1 4	m/z 312→70
Liver	0.01 0.1	5 5	89 88	2 3	m/z 312→70
Fat	0.01 0.1	5 5	73 71	5 2	m/z 312→70

Table A 25: Recovery results from the independent laboratory validation of prothioconazole-desthio in milk, meat, liver and fat using the confirmatory analytical method. Standards were prepared in blank matrix extract.

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
Milk	0.004 0.04	5 5	82 90	3 3	m/z 312→125
Meat	0.01 0.1	5 5	82 89	2 4	m/z 312→125
Liver	0.01 0.1	5 5	89 89	2 3	m/z 312→125
Fat	0.01 0.1	5 5	73 71	4 2	m/z 312→125

Table A 26: Characteristics for the analytical method used for the independent laboratory validation of prothioconazole-desthio residues in milk

	Prothioconazole-desthio, m/z 312→70	Prothioconazole-desthio, m/z 312→125
Calibration function	Y=72700*X+2460, R=0.9971	Y=45000*X+1650, R=0.9973
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.1 – 10 ng/mL	0.1 – 10 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.001 – 0.1 mg/kg	0.001 – 0.1 mg/kg
Does the calibration consist of at least 3 levels	Yes	Yes

	Prothioconazole-desthio, m/z 312→70	**Prothioconazole-desthio, m/z 312→125**
(duplicated points) or 5 levels (single points)? (yes/ no)		
Assessment of matrix effects is presented (yes/no)	No	No
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Table A 27: Characteristics for the analytical method used for the independent laboratory validation of prothioconazole-desthio residues in meat

	Prothioconazole-desthio, m/z 312→70	**Prothioconazole-desthio, m/z 312→125**
Calibration function	Y=71900*X+1770, R=0.9970	Y=44700*X+1020, R=0.9973
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.2 – 20 ng/mL	0.2 – 20 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.002 – 0.2 mg/kg	0.002 – 0.2 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes	Yes
Assessment of matrix effects is presented (yes/no)	No	No
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Table A 28: Characteristics for the analytical method used for the independent laboratory validation of prothioconazole-desthio residues in liver

	Prothioconazole-desthio, m/z 312→70	**Prothioconazole-desthio, m/z 312→125**
Calibration function	Y=88200*X-778, R=0.9993	Y=54900*X-448, R=0.9994
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.2 – 20 ng/mL	0.2 – 20 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.002 – 0.2 mg/kg	0.002 – 0.2 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes	Yes
Assessment of matrix effects is presented (yes/no)	No	No
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Table A 29: Characteristics for the analytical method used for the independent laboratory validation of prothioconazole-desthio residues in fat

	Prothioconazole-desthio, m/z 312→70	**Prothioconazole-desthio, m/z 312→125**

Calibration function	Y=86900*X-1830, R=0.9997	Y=54300*X-1200, R=0.9998
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.2 – 20 ng/mL	0.2 – 20 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.002 – 0.2 mg/kg	0.002 – 0.2 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes	Yes
Assessment of matrix effects is presented (yes/no)	No	No
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Conclusion

The method for quantification of prothioconazole-desthio including conjugates is successfully validated in an independent laboratory. The limit of quantification is 0.004 mg/kg for milk and 0.01 mg/kg for meat, fat and liver. The method is also validated for further metabolites (JAU6476-3-hydroxy-desthio, JAU6476-4-hydroxy-desthio). This part is not described here because these metabolites are not included in the residue definition. Nevertheless, the study shows some deficiencies. Calibration graphs are missing for fat, liver and meat. However, this point is of minor importance because the slopes, the intercepts and the regression coefficients are provided for all matrices. Also data to prove the applicability of the method for glucuronide conjugates of prothioconazole-desthio are missing. Because the validation of hydrolysis steps is not clearly defined in the SANCO/825/00 guideline, no further work is required. No additional confirmatory method is necessary because two MS/MS transitions were validated.

Comments of zRMS:	Acceptable. For deficiencies see above.

A 1.2.3 Description of Methods for the Analysis of Soil

A 1.1.1.7 Analytical method 1

Reference:	OECD: KIIIA, 5.4
Report	Modification M001 of method 00610 for the determination of JAU6476 and the metabolites JAU6476-desthio and JAU6476-S-methyl in soil by HPLC-MS/MS; Brumhard, B. 2005; method no. 00610/M001, report no. MR-183/04, MET2005-358
Guideline(s):	Yes: SANCO/8225/00 rev. 7
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The soil samples (Höfchen) are extracted with acetonitrile/water/cysteine hydrochloride (800/200/0.1, v/v/v) by mechanical shaking. The extracts are filtered and an aliquot is diluted with water. Quantification is performed by LC-MS/MS using a Superspher 60 RP select B column and monitoring m/z 312→70, 312→125 for prothioconazole-desthio and m/z 344→326, 344→189 for prothioconazole after electrospray ionization in positive mode. Matrix-matched standards are used for calibration.

Results and discussions

Table A 30: Recovery results from method validation of prothioconazole in soil using the analytical method. Standards were prepared in blank matrix extracts.

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
Soil Höfchen	0.006 0.06	5 5	105 104	1.6 2.7	m/z 344→326
Soil Höfchen	0.006 0.06	5 5	103 103	2.6 2.6	m/z 344→189

Table A 31: Recovery results from method validation of prothioconazole-desthio in soil using the analytical method. Standards were prepared in blank matrix extracts.

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery (%)	RSD (%)	Comments
Soil Höfchen	0.006 0.06	5 5	102 101	1.2 3.0	m/z 312→125
Soil Höfchen	0.006 0.06	5 5	104 101	2.3 2.9	m/z 312→70

Table A 32: Characteristics for the analytical method used for the quantitation of prothioconazole residues in soil

	Prothioconazole, m/z 344→326	Prothioconazole, m/z 344→189
Calibration function	Y=45736*X-1987, R=0.9999	Y=9815*X-481, R=0.9998
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.5 – 50 ng/mL	0.5 – 50 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.003 – 0.29 mg/kg	0.003 – 0.29 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes	Yes
Assessment of matrix effects is presented (yes/no)	No	No
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Table A 33: Characteristics for the analytical method used for the quantitation of prothioconazole-desthio residues in soil

	Prothioconazole-desthio, m/z 312→125	**Prothioconazole-desthio, m/z 312→70**
Calibration function	Y=17748*X-894, R=0.9998	Y=26522*X-1231, R=0.9997
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.5 – 50 ng/mL	0.5 – 50 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.003 – 0.29 mg/kg	0.003 – 0.29 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes	Yes
Assessment of matrix effects is presented (yes/no)	No	No
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Conclusion

The method of Brumhard, 2005a is validated for the quantification of prothioconazole and prothioconazole-desthio in soil. The limit of quantification is 0.006 mg/kg for each compound. The validation of two MS/MS transitions is included. Therefore an additional confirmatory method is not necessary.

Comments of zRMS:	Acceptable.

A 1.2.4 Description of Methods for the Analysis of Water

A 1.1.1.8 Analytical method 1

Reference: OECD: KIIIA; 5.6

Report: Modification M001 of method 00684 for the determination of JAU6476 and JAU6476-desthio in drinking and surface water by HPLC-MS/MS, Brumhard, B.; 2005; method no. 00684/M001, report no. MR-184/04, MET2005-359

Guideline(s): Yes: SANCO/825/00 rev. 7

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

The water samples (surface water) are directly injected into the LC-MS/MS system after addition of acetic acid and cysteine hydrochloride. Quantification is performed by LC-MS/MS using a Superspher 60 RP select B column and monitoring m/z 312→70, 312→125 for prothioconazole-desthio and m/z 344→326, 344→189 for prothioconazole after electrospray ionization in positive mode. Matrix-matched standards are used for calibration.

Results and discussions

Table A 34: Recovery results from method validation of prothioconazole in surface water using the analytical method. Standards were prepared in blank matrix extracts.

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
Surface water Surface water	0.05 0.5	5 5	10250 / 96.7 93968 / 96.9	3.4 2.6	m/z 344→326
Surface water Surface water	0.05 0.5	5 5	2188 / 98.3 20548 / 97.5	4.2 2.5	m/z 344→189

Table A 35: Recovery results from method validation of prothioconazole-desthio in surface water using the analytical method. Standards were prepared in blank matrix extracts.

Matrix	Fortification level (µg/L)	No of samples per fortification level	Mean peak area (units)/ Mean recovery (%)	RSD (%)	Comments
Surface water Surface water	0.05 0.5	5 5	11176 / 95.6 119000 / 99.0	3.6 1.6	m/z 312→125
Surface water Surface water	0.05 0.5	5 5	17948 / 100 186113 / 99.4	0.6 2.0	m/z 312→70

Table A 36: Characteristics for the analytical method used for the quantitation of prothioconazole residues in water

	Prothioconazole, m/z 344→326	Prothioconazole, m/z 344→189
Calibration function	Y=208196*X+467, R=0.9996	Y=45340*X+89, R=0.9992
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.04 – 10 ng/mL	0.04 – 10 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.04 – 10 µg/L	0.04 – 10 µg/L
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes	Yes

Assessment of matrix effects is presented (yes/no)	Yes	Yes
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Table A 37: Characteristics for the analytical method used for the quantitation of prothioconazole-desthio residues in soil

	Prothioconazole-desthio, m/z 312→125	**Prothioconazole-desthio, m/z 312→70**
Calibration function	Y=247951*X-860, R=0.9996	Y=386818*X-1549, R=0.9998
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.04 – 10 ng/mL	0.04 – 10 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.04 – 10 µg/L	0.04 – 10 µg/L
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes	Yes
Assessment of matrix effects is presented (yes/no)	Yes	Yes
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Conclusion

The method of Brumhard, 2005b is validated for the quantification of prothioconazole and prothioconazole-desthio in surface water. The limit of quantification is 0.05 µg/L for each compound. The validation of two MS/MS transitions is included. Therefore an additional confirmatory method is not necessary. The limit of quantification is sufficient for EU drinking water limit. The method is also accepted for drinking water.

Comments of zRMS:	Acceptable.

A 1.2.5 Extraction efficiency of enforcement methods for foodstuff

A 1.1.1.9 Analytical method 1

Reference: OECD: KIIIA 5.3.1

Report: Extraction efficiency testing of the residue method (00647) for the determination of JAU 6476 residues in spring wheat using aged radioactive residues; Haas, M. 2001; report no. MR-084/01, project ID. M-052963-01-1, RIP2002-1041

Guideline(s): Not stated

Deviations: Not applicable

GLP: Yes

Acceptability: Yes

Materials and methods

The extraction efficiency of residue analytical method of Brumhard & Stuke, 2008 (ASB2008-6472) using acetonitrile/water as solvent in wheat grain, forage and straw is tested. The sample material with aged radioactive residue was taken from metabolism study after spray application of [phenyl-UL-^{14}C]-prothioconazole.

Results and discussions

The extraction efficiency is expressed as the extracted amount of prothioconazole-desthio (relevant residue for monitoring) extracted by the residue analytical method compared to the metabolism study. For forage, the extraction efficiency was 83.8 %. For wheat straw and grain the extraction efficiency was 68.9 % and 103.6% for prothioconazole-desthio, respectively.

Conclusion

The extraction efficiency for residue analytical method using an acetonitrile/water mixture as extraction solvent is proven.

Comments of zRMS:	Acceptable.

A 1.1.1.10 Analytical method 2

Reference: OECD: KIIIA 5.3.1

Report [PhenylUL-14C]JAU6476-desthio – Absorption, Distribution, Excretion, and metabolism in the lactating goat including validation of the residue analytical method for the determination of JAU6476-desthio, JAU6476-3-hydroxy-desthio and JAU6476-4-hydroxy-desthio residues in animal matrices using aged radioactive residues; Weber, H, Weber, E., Spiegel, K., 2002; report no. MR-091/01 Part 2; RIP2002-1046

Guideline(s): Not stated

Deviations: Not applicable

GLP: Yes

Acceptability: Yes

Materials and methods

The extraction efficiency of residue analytical method for the quantification of prothioconazole-desthio was tested using aged residues. Muscle, liver, kidney, round muscle, ornamental fat and milk are used as representative matrices. The extraction and hydrolysis is performed according to the method of Heinemann, 2001 (MET2002-400) using acetonitrile/water as extraction solvent.

Results and discussions

The extraction efficiency is expressed as the amount of prothioconazole-desthio (component of the residue definition) extracted by the residue analytical method compared to the metabolism study. For milk

and muscle the amount of prothioconazole-desthio was equal or lower than 0.01 mg/kg. The extraction efficiency was 93.5 % for liver and 107 % for kidney. For fat significantly higher residues (39.0 % TRR, 0.093 mg/kg) are detected after extraction by using the residue analytical method compared to the results of the metabolism study (12.3 % TRR, 0.028 mg/kg).

Conclusion

The extraction efficiency for residue analytical method using an acetonitrile/water mixture as extraction solvent is proven.

Comments of zRMS:	Acceptable.

REGISTRATION REPORT
Part B

Section 3 Mammalian Toxicology
Detailed summary of the risk assessment

Product name:
Ascra Xpro
Active Substances:
Bixafen 65 g/L
Fluopyram 65 g/L
Prothioconazole 130 g/L

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Bayer CropScience
Date: 02/11/2017

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3 Mammalian Toxicology (IIIA 7)

3.1 Summary

Table 3.1-1: Information on Ascra Xpro*

Product name and code	Ascra Xpro, BAY 21070 F (BAY-21070-F-0-EC)
Formulation type	Emulsifiable concentrate
Active substance(s) (incl. content)	Bixafen; 65 g/L Fluopyram; 65 g/L Prothioconazole; 130 g/L
Function	Fungicide
Product already evaluated as the 'representative formulation' during the Annex I inclusion	No
Product previously evaluated in an other MS according to Uniform Principles	No

* Information on the detailed composition of Ascra Xpro can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

In accordance with the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 3.1-2: Justified proposals for classification and labelling

C&L according to Regulation (EC) No 1272/2008	
Hazard class(es), categories:	Acute Tox. 4, Skin Sens. 1, Eye Dam. 1, STOT SE 3, (Repr. 2[1)])
Signal word:	Danger
Hazard statement(s):	302-317-318-335-(361d[1)])
Precautionary statement(s):	101-102(-201[1)])-264-270-280-302+352-305+351+338-308+310-362+364-403+233-405-501
Additional labelling phrases:	To avoid risks to human health and the environment, comply with the instructions for use [EUH401].
	Contains prothioconazol (CAS-No. 178928-70-6). May produce an allergic reaction [EUH208].

[1)] Up to now, no legal classification; therefore not considered for Ascra Xpro, yet

Table 3.1-3: Summary of risk assessment for operators, workers, bystanders and residents for Ascra Xpro

	Result	**PPE / Risk mitigation measures**
Operators	Acceptable	- Avoid any unnecessary contact with the product. Misuse can lead to health damage [SB001]. - Concerning the requirements for personal protective gear for handling the plant protection product the material safety data sheet and the instructions for use of the plant protection product as well as the guideline "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety (www.bvl.bund.de) must be observed. [SB111].

		- When applying the product with tractor-mounted, trailed or self-propelled application equipment, only vehicles with closed pressurized cabins (e.g. cabin category 3, if no respiratory protective equipment or particle-filtering masks are necessary or category 4, if gas-tight respiratory protective equipment is needed acc. to EN 15695-1 and -2) are suited to replace personal protective equipment during application. During all other activities outside of the cabin the prescribed personal protective equipment must be worn. In order to avoid contamination of the cabin, it is not permitted to enter the cabin with contaminated personal protective equipment (it should be deposited e.g. in an appropriate storage facility). Contaminated gloves should be washed before removing the gloves and hands should be washed before entering the cabin with pure water, respectively [SB199]. - Wear tight fitting eye protection when handling the undiluted product [SE110]. - Wear standard protective gloves (plant protection) when handling the undiluted product [SS110]. - Wear standard protective gloves (plant protection) when handling/applying the product ready for application [SS120]. - Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product [SS2101]. - Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when applying/handling the product ready for application [SS2202]. - Wear a rubber apron when handling the undiluted product [SS610].
Workers	Acceptable	- Treated areas/crops may not be entered until the spray coating has dried. [SF245-01] - For successive work/inspection within the first 7 days after application, working clothes and sturdy footwear (e.g. rubber boots) must be worn.[1)] [SFneu].
Bystanders	Acceptable	None
Residents	Acceptable	None

[1)] Note: Three days after application are sufficient but the BfR concept considers only 2, 7, 14 and 28 days as re-entry intervall based on the non dietary risk assessment.

Risk assessment according to the German model has shown that the estimated exposure towards bixafen, fluopyram, prothioconazole, and its toxicologically relevant metabolite desthio-prothioconazole in Ascra Xpro will not exceed the particular systemic AOEL for operators, workers, bystanders, and residents. Operator exposure will be below systemic AOEL only, if prescribed PPE is worn.

Risk assessment according to the UK-POEM has shown that the estimated exposure towards fluopyram, prothioconazole, and the toxicologically relevant metabolite desthio-prothioconazole in Ascra Xpro will exceed the particular systemic AOEL for operators even if PPE is worn.
With respect to prothioconazole and dethio-prothioconazole, operator exposure studies carried out by the applicant (see Section 3.6.2.2 and Appendix 4) demonstrated that Ascra Xpro can be used safely provided that described PPE is worn and that the tractor is equipped with a closed cabin.
Moreover, operator exposure towards fluopyram falls below AOEL when the EFSA calculator is applied according to the 'Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products' (EFSA Journal 2014; 12(10):3874) and provided that workwear and gloves are worn (see Appendix 3).

Further reduction of exposure is to be expected due to necessary PPE allocated according to dangerous substances regulations.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and bystanders/residents is presented in Table 3.1-4.

Table 3.1-4 Critical uses and overall conclusion of exposure assessment

1	2	3	4	5	6	7	8			
Crops [1] and situation (e.g. growth stage of crop)	**F/G or I [2]**	**Application**		**Application rate**		**Remarks:** (e.g. surfactant (L /ha)) critical gap for operator, worker, bystander or resident exposure based on [*Exposure model*]	**Acceptability of exposure assessment**			
		Method / Kind (incl. application technique [3])	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**kg as/ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min / max**		**Operator**	**Worker**	**Bystander**	**Residents**
Cereals	F	LCTM	2 (14 days)	Binoxafen a) 0.0975 b) 0.195 Fluopyram a) 0.0975 b) 0.195 Prothioconazole a) 0.195 b) 0.390	100-400	German Model				
						UK POEM				

	Exposure acceptable without PPE / risk mitigation measures
	Further refinement and/or risk mitigation measures required
	Exposure not acceptable/ Evaluation not possible

[1] Pooled critical GAPS with the same max. application rate per application and using the same application technique
[2] F: field or outdoor application, G: greenhouse application, I: indoor application
[3] e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

3.2 Toxicological Information on Active Substances

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 3.2-1.

Table 3.2-1: Information on active substance Bixafen

Information on absorption rates of the active ingredient		
	Value	Source
oral	100 %	EFSA Journal 2012;10(11):2917 [ASB2012-14631]
inhalative	100 %	(default)

Reference doses		
	Value	Source
Bixafen		
ADI	0.02 mg/kg bw	EFSA Journal 2012;10(11):2917 [ASB2012-14631]
AOEL systemic	0.13 mg/kg bw/d	EFSA Journal 2012;10(11):2917 [ASB2012-14631]
ARfD	0.2 mg/kg bw	EFSA Journal 2012;10(11):2917 [ASB2012-14631]
Metabolite M44		
ADI	0.3 mg/kg bw	EFSA Journal 2012;10(11):2917 [ASB2012-14631]
ARfD	Not necessary	EFSA Journal 2012;10(11):2917 [ASB2012-14631]

Classification and proposed labelling	
with regard to toxicological data (according to the criteria in Reg. 1272/2008)	Regulation (EC) No 1272/2008 (as amended): substance not listed Proposal zRMS Germany: none additional

Table 3.2-2: Information on active substances Fluopyram

Information on absorption rates of the active ingredient		
	Value	Source
oral	> 93 %; correction of AOEL for limited oral absorption/bioavailability: n.n.	EFSA Journal 2013;11(4):3052 (2012-12-13) [ASB2013-5375]
inhalative	100 %	(default)

Reference doses		
	Value	Source
ADI	0.012 mg/kg bw	EFSA Journal 2013;11(4):3052 (2012-12-13) [ASB2013-5375]
AOEL-S	0.05 mg/kg bw/d	EFSA Journal 2013;11(4):3052 (2012-12-13) [ASB2013-5375]
ARfD	0.5 mg/kg bw	EFSA Journal 2013;11(4):3052 (2012-12-13) [ASB2013-5375]

Classification and proposed labelling	
with regard to toxicological data (according to the criteria in Reg. (EC) No 1272/2008, as amended)	Regulation (EC) No 1272/2008 (as amended): substance not listed Proposal zRMSGermany (according to ECHA): no classification necessary

Table 3.2-3: Information on active substances Prothioconazol

Information on absorption rates of the active ingredient		
	Value	Source
oral	> 90 %; correction of AOEL for limited oral absorption/bioavailability: n.n.	EFSA Scientific Report (2007) 106, 1-98 (2007-07-12) [ASB2012-3641]
inhalative	100 %	(default)

Reference doses		
	Value	Source
Prothioconazole		
ADI	0.05 mg/kg bw	EFSA Scientific Report (2007) 106, 1-98 (2007-07-12) [ASB2012-3641]
AOEL-S	0.2 mg/kg bw/d	EFSA Scientific Report (2007) 106, 1-98 (2007-07-12) [ASB2012-3641]
ARfD	0.2 mg/kg bw	EFSA Scientific Report (2007) 106, 1-98 (2007-07-12) [ASB2012-3641]

Prothioconazole metabolite JAU 6476-desthio		
ADI	0.01 mg/kg bw	EFSA Scientific Report (2007) 106, 1-98 (2007-07-12) [ASB2012-3641]
AOEL-S	0.01 mg/kg bw/d	EFSA Scientific Report (2007) 106, 1-98 (2007-07-12) [ASB2012-3641]
ARfD	0.01 mg/kg bw	EFSA Scientific Report (2007) 106, 1-98 (2007-07-12) [ASB2012-3641]
Triazole acetic acid		
ADI	0.02 mg/kg bw	PRAPeR 14 (2007-01-01)
ARfD	0.06 mg/kg bw	PRAPeR 14 (2007-01-01)
Triazole alanine		
ADI	0.1 mg/kg bw	PRAPeR 14 (2007-01-01)
ARfD	0.1 mg/kg bw	PRAPeR 14 (2007-01-01)
Triazole lactic acid		
ADI	0.02 mg/kg bw	EFSA Journal 2011;9(1):1967, 1-71 (2010-12-17) [ASB2012-749]
ARfD	0.06 mg/kg bw	EFSA Journal 2011;9(1):1967, 1-71 (2010-12-17) [ASB2012-749]
Triazole, 1,2,4-		
ADI	0.02 mg/kg bw	PRAPeR 14 (2007-01-01)
ARfD	0.06 mg/kg bw	PRAPeR 14 (2007-01-01)

Classification and proposed labelling	
with regard to toxicological data (according to the criteria in Reg. (EC) No 1272/2008, as amended)	**Prothioconazole:** Regulation (EC) No 1272/2008 (as amended): substance not listed Proposal zRMS Germany (according to EFSA): Warning, Repr.2, H361d **Impurity: deschloro prothioconazole:** Regulation (EC) No 1272/2008 (as amended): substance not listed Proposal zRMS Germany: Warning, Skin Sens. 1, H317 **Prothioconazole metabolite JAU 6476-desthio:** Regulation (EC) No 1272/2008 (as amended): substance not listed Proposal zRMS Germany (according to EFSA): Danger, Repr. 1B, H360D

3.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for Ascra Xpro is given in Table 3.3-1. Full summaries of studies on the product are presented in Appendix 2. MSDS on Ascra Xpro can be found in the confidential dRR Part C.

Table 3.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for Ascra Xpro

Type of test, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD_{50} oral, rat (OECD 423)	300-2000 mg/kg bw	Yes	H302	[redacted], 2013a; ASB2015-1913
LD_{50} dermal, rat (OECD 402)	>2000 mg/kg bw	Yes	None	[redacted], 2013b; ASB2015-1914
LC_{50} inhalation	Not submitted, not necessary. Justification presented in Annex 2.[1]			
Skin irritation, rabbit (OECD 404)	Non-irritant	Yes	None	[redacted], 2013c; ASB2015-1915
Eye irritation, rabbit (OECD 405)	Irritant	Yes	H318	[redacted], 2013d; ASB2015-1916
Skin sensitisation, mouse (OECD 429, LLNA)	Sensitising	Yes	H317	[redacted], 2013; ASB2015-1917
Supplementary studies for combinations of plant protection products	No data – not required			

[1]The estimated LC_{50} is greater than 5 mg/L air. Thus, no classification is required.

Table 3.3-2: Additional toxicological information relevant for classification/labelling of Ascra Xpro

	Substance (Concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of the product (acc. to the criteria in Reg. 1272/2008)
Toxicological properties of active substance(s) (relevant for classification of product)	Prothioconazole (12.9 % (w/w))	H361d (criteria > 3 %)	EFSA conclusion[1]	H361d[2]
Toxicological properties of non-active substance(s) (relevant for classification of product)	N,N-Dimethyl-decanamide (CAS-No. 14433-76-2, 50.7 % (w/w))	H335 (criteria e.g. ≥ 20 %)	ECHA registration report[3]	H335
Further toxicological information	No data – not required			

[1] EFSA Scientific Report 2007;106:1-98 (ASB2012-3641)
[2] Up to now, no legal classification; therefore not yet considered for Ascra Xpro
[3] http://echa.europa.eu/de/registration-dossier/-/registered-dossier/15021

3.4 Toxicological evaluation of groundwater metabolites

3.4.1 Metabolite M44 of Bixafen

The metabolite BYF 00587-desmethyl-pyrazole-4-carboxylic acid (M44) is predicted to occur in groundwater above 0.1 µg/L. The toxicological relevance assessment of this metabolite according to the

EU guidance document Sanco/221/2000-rev.10 - final 25 February 2003) is presented in Section 8 of this dRR/RR.

3.5 Dermal Absorption (IIIA 7.6)

A summary of the dermal absorption endpoints for the active substances in Ascra Xpro are presented in Table 3.5-1.

Table 3.5-1: Dermal absorption endpoints for active substances in Ascra Xpro

	Bixafen		**Fluopyram**	
	Value	**Reference**	**Value**	**Reference**
Concentrate	25 %	Guidance on dermal absorption, EFSA Journal 2012;10(4):2665; ASB2012-6959	25 %	Guidance on dermal absorption, EFSA Journal 2012;10(4):2665
Dilution (1:67)	75 %	Guidance on dermal absorption, EFSA Journal 2012;10(4):2665	75 %	Guidance on dermal absorption, EFSA Journal 2012;10(4):2665
	Prothioconazole[1)]		**Desthio-prothioconazole[2)]**	
	Value	**Reference**	**Value**	**Reference**
Concentrate	25 %	Guidance on dermal absorption, EFSA Journal 2012;10(4):2665	25 %	Guidance on dermal absorption, EFSA Journal 2012;10(4):2665
Dilution	75 %	Guidance on dermal absorption, EFSA Journal 2012;10(4):2665	75 %	Guidance on dermal absorption, EFSA Journal 2012;10(4):2665

1) dilution factor = 1:67

2) dilution factor = 1:133 based on an assumed conversion of prothioconazole to desthio-prothioconazole of 50 % in the case of dermal exposure (see summary of field studies, Appendix 4)

3.5.1 Justification for proposed values - bixafen

No data on dermal absorption for bixafen in Ascra Xpro is available. Justification for default values according to Guidance on Dermal Absorption (EFSA Journal 2012; 10(4):2665) are presented in Table 3.5-2.

Table 3.5-2: Default dermal absorption endpoints for bixafen

	Value	**Justification for value**
Concentrate	25 %	Concentration in product > 5 %
Dilution	75 %	Concentration in dilution < 5 %

3.5.2 Justification for proposed values - fluopyram

No data on dermal absorption for fluopyram in Ascra Xpro is available. Justification for default values according to Guidance on Dermal Absorption (EFSA Journal 2012; 10(4):2665) are presented in Table 3.5-3.

Table 3.5-3: Default dermal absorption endpoints for fluopyram

	Value	Justification for value
Concentrate	25 %	Concentration in product > 5 %
Dilution	75 %	Concentration in dilution < 5 %

3.5.3 Justification for proposed values - prothioconazole

No data on dermal absorption for prothioconazol in Ascra Xpro is available. Justification for default values according to Guidance on Dermal Absorption (EFSA Journal 2012; 10(4):2665) are presented in Table 3.5-4.

Table 3.5-4: Default dermal absorption endpoints for prothioconazole

	Value	Justification for value
Concentrate	25 %	Concentration in product > 5 %
Dilution	75 %	Concentration in dilution < 5 %

3.5.4 Justification for proposed values – desthio-prothioconazole

No data on dermal absorption for desthio-prothioconazol in Ascra Xpro is available. Justification for default values according to Guidance on Dermal Absorption (EFSA Journal 2012; 10(4):2665) are presented in Table 3.5-5.

Table 3.5-5: Default dermal absorption endpoints for desthio-prothioconazole

	Value	Justification for value
Concentrate	25 %	Assumed concentration in product > 5 %
Dilution	75 %	Assumed concentration in dilution < 5 %

3.6 Exposure Assessment of Plant Protection Product

Table 3.6-1: Product information and toxicological reference values used for exposure assessment

Product name and code	Ascra Xpro, BAY 21070 F (BAY-21070-F-0-EC)	
Formulation type	Emulsifiable concentrate	
Category	Fungicide	
Container size(s), short description	1-15 L bottles/canisters of PA/HDPE and EVOH/HDPE with 50-63 mm openings	
Active substance(s) (incl. content)	**Bixafen** 65 g/L	**Fluopyram** 65 g/L
AOEL systemic	0.13 mg/kg bw/d	0.05 mg/kg bw/d
Inhalative absorption	100 %	100 %
Oral absorption	100 %	100 %
Dermal absorption	Concentrate: 25 % Dilution: 75 % (Dilution rate: 1:267) Default	Concentrate: 25 % Dilution: 75 % (Dilution rate: 1:267) Default
Active substance(s) (incl. content)	**Prothioconazole** 130 g/L	**Desthio-prothioconazole**[1)] Relevant metabolite
AOEL systemic	0.2 mg/kg bw/d	0.01 mg/kg bw/d
Inhalative absorption	100 %	100 %
Oral absorption	100 %	100 %
Dermal absorption	Concentrate: 25 % Dilution: 75 % (Dilution rate: 1:267,	Concentrate: 25 % Dilution: 75 %

	'worst case') Default	Default

1) risk assessment based on an assumed conversion of prothioconazole to desthio-prothioconazole of 50 % in the case of dermal exposure and 100 % for inhalative exposure (see summary of field studies, Appendix 4)

3.6.1 Selection of critical use(s) and justification

The critical GAP used for the exposure assessment of the plant protection product is shown in Table 3.1-4.

3.6.2 Operator exposure (IIIA 7.3)

3.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of Ascra Xpro according to the critical use(s) is presented in Table 3.6-2. The outcome of the estimation is presented in Table 3.6-3 and Table 3.6-4. Detailed calculations are in Appendix 3.

Table 3.6-2: Exposure models for intended uses

Critical use(s)	Cereals (max. 1.5 L product/ha)
Model(s)	German model [Uniform Principles for Safeguarding the Health of Applicators of Plant Protection Products (Uniform Principles for Operator Protection), Mitteilungen aus der Biologischen Bundesanstalt für Land-und Forstwirtschaft, Berlin-Dahlem, Heft 277, 1992]
	Revised UK-POEM [Estimation of Exposure and Absorption of Pesticides by Spray Operators, Scientific subcommittee on Pesticides and British Agrochemical Association Joint Medical Panel Report (UK MAFF), 1986 and the Predictive Operator Exposure Model (POEM) V 1.0, (UK MAFF), 1992]

Table 3.6-3: Estimated operator exposure-1

		Bixafen		Fluopyram	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops Application rate:		0.0975 kg a.s./ha		0.0975 kg a.s./ha	
German Model Body weight: 70 kg	no PPE[1)]	0.059	45.7	0.059	119
	+ Gloves mixing/loading + Protective suite + Gloves application	0.003	2.47	0.003	6.43
UK POEM Application volume: 100 L/ha Container: 10 L, 45 mm closure Body weight: 60 kg	no PPE[2)]	0.724	557	0.724	1448
	+ Gloves mixing/loading + Gloves application	0.101	77.9	0.101	203

1) no PPE: Operator wearing T-shirt and shorts

2) no PPE: Operator wearing long sleeved shirt, long trousers ("permeable") but no gloves

Table 3.6-4: Estimated operator exposure-2

		Prothioconazole		Relevant metabolite desthio-prothioconazole	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops Application rate:		0.195 kg a.s./ha		0.0975 kg a.s./ha or 0.195 kg a.s./ha[3)]	
German Model Body weight: 70 kg	no PPE[1)]	0.119	59.4	0.059	594
	+ Gloves mixing/loading + Protective suite + Gloves application	0.006	3.22	0.003	32.6
UK POEM Application volume: 100 L/ha Container: 10 L, 45 mm closure Body weight: 60 kg	no PPE[2)]	1.45	724	0.725	7250
	+ Gloves mixing/loading + Gloves application	0.203	101	0.102	1022

1) no PPE: Operator wearing T-shirt and shorts

2) no PPE: Operator wearing long sleeved shirt, long trousers ("permeable") but no gloves

3) risk assessment based on an assumed conversion of prothioconazole to desthio-prothioconazole of 50 % in the case of dermal exposure and 100 % for inhalative exposure (see summary of field studies, Appendix 4)

3.6.2.2 Measurement of operator exposure

Three operator exposure studies were conducted to determine the exposure to prothioconazole and its metabolite desthio-prothioconazole in the field under real use conditions for a refined risk assessment.
All three studies are summarized in the report by Maasfeld et al. (2009) ASB2010-11547. Detailed considerations and calculations as well as an overall summary and conclusion of the field studies are presented in Appendix 4.
The risk for operators derived from the exposure to prothioconazole or desthio-prothioconazole and expressed in % syst. AOEL is calculated as follows:

% syst. AOEL = (D x DA x TA + I x IA x TA) / (BW x syst. AOEL)

D:	specific dermal exposure value from field studies [mg/kg a.s.]
I:	specific inhalation exposure value from field study [mg/kg a.s.]
DA:	dermal absorption = 75 % (dilution, 'worst case')
IA:	inhalation absorption = 100 %
TA:	total amount of active substance handled per day = 10 kg prothioconazole/day (50 ha)
BW:	body weight = 70 kg

The results for prothioconazole and desthio-prothioconazole are given in the tables below. The exposure to prothioconazole and its metabolite desthio-prothioconazole is below the respective syst. AOEL provided that protective gloves and one layer of workwear and sturdy footwear are worn by the operator during mixing/loading and application and vehicles with closed cabins are used during application (see study description). The actual exposure to prothioconazole amounts to 0.68 % of the syst. AOEL, the actual exposure for desthio-prothioconazole amounts to 14.4 % of the syst. AOEL.

Table 3.6-5: Estimated operator exposure to prothioconazole (75th percentile)

Route of exposure	Specific exposure [mg/kg a.s.]	Estimated exposure [mg/person/day]	Estimated systemic exposure [mg/person/day]	% syst. AOEL
$D_{potential\ body}$	0.116	1.16	0.87	
$D_{potential\ hands}$	1.06	10.6	7.95	
$D_{potential}$	1.176	11.76	8.82	**63.0**
$D_{actual\ body}$	0.010	0.10	0.075	
$D_{actual\ hands}$	0.002	0.02	0.015	
D_{actual}*	0.012	0.12	0.09	**0.64**
I_m	0.00022	0.0022	0.0022	
I_a	0.00031	0.0031	0.0031	
I	0.00053	0.0053	0.0053	**0.04**
Total (potential)				**63.0**
Total (actual)				**0.68**

* protective gloves and one layer of workwear and sturdy footwear during mixing/loading and application, closed cabin during application

Table 3.6-6: Estimated operator exposure to desthio-prothioconazole (max. values)

Route of exposure	Specific exposure [mg/kg a.s.]	Estimated exposure [mg/person/day]	Estimated systemic exposure [mg/person/day]	% syst. AOEL
$D_{potential}$	0.251	2.51	1.8825	268.9
D_{actual}*	0.013	0.13	0.0609375	13.9
$I_{m/a}$	0.00034	0.0034	0.0034	0.5
Total (potential)				**269.4**
Total (actual)				**14.4**

* protective gloves and one layer of workwear and sturdy footwear during mixing/loading and application, closed cabin during application

3.6.3 Worker exposure (IIIA 7.5)

3.6.3.1 Estimation of worker exposure

Table 3.6-7 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with Ascra Xpro according to the critical use(s). The outcome of the estimation is presented in Table 3.6-8 and Table 3.6-9. Detailed calculations are in Appendix 3.

Table 3.6-7: Exposure models for intended uses

Critical use(s)	Cereals (max. 2 x 1.5 L product/ha)
Model	German re-entry model, Krebs et al. (2000) [Uniform Principles for Safeguarding the Health of Workers Re-entering Crop Growing Areas after Application of Plant Protection Products, Nachrichtenbl. Deut. Pflanzenschutzdienst., 52(1), p. 5-9]

Table 3.6-8: Estimated worker exposure-1

		Bixafen		Fluopyram	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Number of applications and application rate:		2 x 0.0975 kg a.s./ha		2 x 0.0975 kg a.s./ha	
2 hours/day[1)] TC: 1400 cm^2/person/h[2)]	no PPE[3)]	0.061	46.9	0.061	121.9
	with PPE[4)]	0.007	5.3 [5)]	0.007	13.7[5)]

DFR: 1 µg/cm²/kg a.s. Body weight: 60 kg	No PPE[3), 6)]			0.046	91.4 [6)]

1) 2 h/day for professional applications for maintenance, inspection or irrigation activities etc.
2) EFSA, 2014. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal, 12(10):3874.
3) No PPE: potential exposure, TC: 12500 cm²/person/h
4) With PPE: worker wearing work wear and sturdy footwear (e.g. rubber boots)
5) At 3 µg/cm²/kg a.s. DFR exposure amounts to 15.9 % AOEL for bixafen and 41.1 % AOEL for fluopyram
6) MAF of 1.5 based on a default DT_{50} of 30 days and an intervall of 14 days; for 3 µg/cm²/kg a.s. exopuse amounts to 274% of the AOEL

Table 3.6-9: Estimated worker exposure-2

		Prothioconazole		**Relevant metabolite: desthio-prothioconazole**	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Number of applications and application rate:		2 x 0.195 kg a.s./ha		2 x 0.0975 kg a.s./ha[5)]	
2 hours/day[1)] TC: 1400 cm²/person/h[2)] DFR Prothioconazole[6)]: 0.059 µg/cm² DFR Metabolite[6)]: 0.116 µg/cm² Body weight: 60 kg	no PPE[3)]	0.018	9.2 [6)]	0.036	362.5 [6)]
	with PPE[4)]	0.0021	1[6)]	0.0041	40.6 [6)]
2 hours/day[1)] TC: 1400 cm²/person/h[2)] DFR desthio-prothioconazole; 3 days after application [7)]: 0.012 µg/cm² Body weight: 60 kg	no PPE[3)]			0.036	37.5 [7)]
	with PPE[4)]			0.0004	4.2 [7)]

1) 2 h/day for professional applications for maintenance, inspection or irrigation activities etc.
2) EFSA, 2014. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal, 12(10):3874.
3) No PPE: potential exposure, TC: 12500 cm²/person/h
4) With PPE: worker wearing work wear and sturdy footwear (e.g. rubber boots)
5) Risk assessment based on an assumed conversion of prothioconazole to desthio-prothioconazole of 50 % in the case of dermal exposure (see summary of field studies, Appendix 4)
6) Refined DFR according to Stuke 2013 (see Appendix 4).
Note: Because the application conditions are comparable to the conditions in the study, the determined max. DFR value for prothioconazole and desthio-prothioconazole are used without normalisation.
7) Refined DFR according to Stuke 2013 (see Appendix 4). The determined max. DFR value for desthio-prothioconazole three days after application is used without normalisation.

Refinement of generic DFR value (IIIA1 7.7)

A study for the refinement of prothioconazole and desthio-prothioconazole DFRs has been submitted by the applicant (cf. Stuke, S.; 2013, ASB2014-1765, see Appendix 4). The derived DFR values equal 0.059 µg/cm² for prothioconazole and 0.116 µg/cm² for desthio-prothioconazole.

3.6.3.2 Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses when assigned PPEs are worn, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

3.6.4 Bystander and resident exposure (IIIA 7.4)

3.6.4.1 Estimation of bystander and resident exposure

Table 3.6-10 shows the exposure model(s) used for estimation of bystander and resident exposure to bixafen, fluopyram, prothioconazole, and its relevant metabolite desthio-prothioconazole. The outcome of the estimation is presented in Table 3.6-11 and Table 3.6-12. Detailed calculations are in Appendix 3.

Table 3.6-10: Exposure models for intended uses

Critical use(s)	Cereals (max. 2 x 1.5 L product/ha)
Model	Martin, S. et al. (2008) [Guidance for Exposure and Risk Evaluation for Bystanders and Residents Exposed to Plant Protection Products During and After Application; J. Verbr. Lebensm. 3 (2008): 272-281 Birkhäuser Verlag Basel] and Bundesanzeiger (BAnz), 06 January 2012, Issue No. 4, pp. 75-76

Table 3.6-11: Estimated bystander and resident exposure-1

	Bixafen		**Fluopyram**	
Model data	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops Application rate: 0.0975 kg a.s./ha			0.0975 kg a.s./ha	
Bystanders (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.003	2.6	0.003	6.8
Bystanders (children) Drift rate: 2.77 % (1 m) Body weight: 16.15 kg	0.003	2.0	0.003	5.3
Residents (adult) Drift rate: 2.38 % (1 m) Body weight: 60 kg	0.0004	0.3	0.0004	0.9
Residents (children) Drift rate: 2.38 % (1 m) Body weight: 16.15 kg	0.0006	0.5	0.0006	1.3

Table 3.6-12: Estimated bystander and resident exposure-2

	Prothioconazole		**Relevant metabolite**	
Model data	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops Application rate: 0.195 kg a.s./ha			0.0975 kg a.s./ha or 0.195 kg a.s./ha[1)]	
Bystanders (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.007	3.4	0.003	33.8
Bystanders (children)	0.005	2.6	0.003	26.4

Drift rate: 2.77 % (1 m) Body weight: 16.15 kg				
Residents (adult) Drift rate: 2.38 % (1 m) Body weight: 60 kg	0.001	0.4	0.0004	4.2
Residents (children) Drift rate: 2.38 % (1 m) Body weight: 16.15 kg	0.001	0.6	0.0006	6.3

1) risk assessment based on an assumed conversion of prothioconazole to desthio-prothioconazole of 50 % in the case of dermal exposure and 100 % for inhalative exposure (see summary of field studies, Appendix 4)

3.6.4.2 Measurement of bystander and/or resident exposure

Since the bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for bixafen, fluopyram, prothioconazole, and its relevant metabolite desthio-prothioconazole will not be exceeded under conditions of intended uses, a study to provide measurements of bystander/resident exposure was not necessary and was therefore not performed.

3.6.5 Statement on combined exposure

The product is a mixture of three active substances and a relevant metabolite.

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by §4 (3b) of Regulation (EC) No. 1107/2009 should only be performed, if harmonised scientific methods accepted by the authorities are available.

Currently, only combined exposure for the operator is assessed in Germany.

Table 3.6-13: Risk assessment from combined exposure (longer term exposure)

Application scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
Operators – Outdoor, field crop tractor mounted, downward application, PPEs during: - mixing/loading + Gloves - application + Protective suite + Gloves	Bixafen	0.025
	Fluopyram	0.064
	Prothioconazol	0.032
	desthio-Prothioconazol	0.326
	Cumulative risk Operators (HI)	**0.447**

The Hazard Index will be < 1. Thus, combined exposure to the active substance and the metabolite in Ascra Xpro is not expected to present a risk for operators. No further refinement of the assessment is required.

Appendix 1 Reference list

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
	EFSA	2007	Conclusion regarding the peer review of the pesticide risk assessment of the active substance prothioconazole EFSA Scientific Report (2007) 106, 1-98 ASB2012-3641			
	EFSA	2012	Conclusion on the peer review of the pesticide risk assessment of the active substance Bixafen EFSA Journal 2012;10(11):2917 ASB2012-14631			
	EFSA	2012	Conclusion on the peer review of the pesticide risk assessment of the active substance Fluopyram EFSA Journal 2013;11(4):3052 ASB2013-5375			
	EFSA	2011	Conclusion on pesticide peer review: Conclusion on the peer review of the pesticide risk assessment of the active substance difenoconazole EFSA Journal 2011;9(1):1967, 1-71 ASB2012-749			
IIIA1 7.1.6	[redacted]	2013	Bixafen + Fluopyram + Prothioconazole EC 65+65+130 g/L: Local lymph node assay in the mouse - Final Report M-467203-01-1 ! 13/137-037E GLP: Yes Published: No BVL-2629907, ASB2015-1917	Yes	Bayer CropScience	Y
IIIA1 7.3.3	[redacted]	2009	Operator exposure and safety to Prothioconazole containing products in spray applications M-327173-01-1 GLP: No Published: No BVL-2629909, ASB2010-11547	Yes	BAY Bayer CropScience	Y
IIIA1 7.7.1	Stuke, S.	2013	Determination of the dislodgeable foliar residues (DFR) of Prothioconazole in/on wheat after spray application of JAU 6476 & KWG 4168 EC 460 in the field in Germany 12-2901 ! RAAAN168 ! M-455270-01-1 GLP: Yes Published: No BVL-2500291, BVL-2614697, BVL-2629911, BVL-2689151, BVL-2959596, ASB2014-1765	Yes	Bayer CropScience	Y
IIIA1 7.1.2	[redacted]	2013	Bixafen + Fluopyram + Prothioconazole EC 65+65+130 g/L: Acute dermal toxicity study in rats - Final Report M-461508-01-1 ! 13/137-002P GLP: Yes Published: No BVL-2629904, ASB2015-1914	Yes	Bayer CropScience	Y
IIIA1 7.1.4	[redacted]	2013	Bixafen + Fluopyram + Prothioconazole EC 65+65+130 g/L: Acute skin irritation study in rabbits - Final Report M-461510-01-1 ! 13/137-006N GLP: Yes Published: No BVL-2629905, ASB2015-1915	Yes	Bayer CropScience	Y
IIIA1 7.1.1	[redacted]	2013	Bixafen + Fluopyram + Prothioconazole EC 65+65+130 g/L: Acute oral toxicity study in rats - Final Report M-463048-01-1 ! 13/137-001P GLP: Yes Published: No BVL-2629903, ASB2015-1913	Yes	Bayer CropScience	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
IIIA1 7.1.5	[redacted]	2013	Bixafen + Fluopyram + Prothioconazole EC 65+65+130 g/L: Acute eye irritation study in rabbits - Final Report M-463964-01-1 ! 13/137-005N GLP: Yes Published: No BVL-2629906, ASB2015-1916	Yes	Bayer CropScience	Y

*Y, Yes/relied on; N, No/not relied on; Add, Additional, Relied on/study not submitted by applicant but necessary for evaluation

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Bridging was not necessary, as studies were performed with the product under assessment.

A 2.2 Acute oral toxicity (IIIA1 7.1.1)

Comments of zRMS:	Study acceptable according to mentioned guidelines, used in evaluation

Reference:	OECD KIIIA1 7.1.1
Report	Bixafen + Fluopyram + Prothioconazole EC 65+65+130 g/L: Acute oral toxicity study in rats - Final Report [redacted], 2013, M-463048-01-1 ! 13/137-001P, ASB2015-1913
Guideline(s):	OECD Guideline 423 (2001) EU Method B.1 tris (2008) EPA OPPTS 870.1100 (1998)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No, according to available information.

Materials and methods

Test material (Lot/Batch No.)	BIXAFEN+FLUOPYRAM+PROTHIOCONAZOLE EC 65+65+130 g/L (2013-002135)
Species	Rat, RccHan:WIST
No. of animals (group size)	3 x 3 females
Dose(s)	2000 (group 1) and 300 (groups 2 and 3) mg/kg bw
Exposure	Once by gavage
Vehicle/Dilution	Distilled Water
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 1: Results of acute oral toxicity study in rats of BIXAFEN+FLUOPYRAM+PROTHIOCONAZOLE EC 65+65+130 g/L

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD50 (mg/kg bw) (14 days)
Group 1				
2000	2/3/3	24 hours (1 rat)	Day 1 (2 rats)	<2000
Group 2				
300	0/0/3	-	-	>300
Group 3				
300	0/0/3	-	-	>300

* Number of animals which died/number of animals with clinical signs/number of animals used

Table A 2: Summary of findings of acute oral toxicity study in rats of BIXAFEN+FLUOPYRAM+PROTHIOCONAZOLE EC 65+65+130 g/L

Mortality:	Yes, mortality occurred at 2000 mg/kg bw. No mortality occurred at 300 mg/kg bw.
Clinical signs:	Yes, clinical signs of toxicity were observed at 2000 mg/kg bw (decreased activity, hunched back, prone position, piloerection, could to touch, respiratory rate decreased). No clinical signs were observed at 300 mg/kg bw.
Body weight:	Body weight gain was considered to be normal.
Macroscopic examination:	Apparent abnormalities in 2 animals at 2000 mg/kg bw (stomach foci; yellow liquid in stomach, duodenum, and jejunum; brown liquid in urinary bladder; red discoloration of non-collapsed lungs). No abnormalities were observed at 300 mg/kg bw.

Conclusion

Under the experimental conditions, the oral LD_{50} of BIXAFEN+FLUOPYRAM+PROTHIOCONAZOLE EC 65+65+130 g/L is between 300 and 2000 mg/kg bw in rats. Thus, labelling with Warning, H302 is required according to Regulation (EC) No. 1272/2008.

A 2.3 Acute percutaneous (dermal) toxicity (IIIA1 7.1.2)

Comments of zRMS:	Study acceptable according to mentioned guidelines, used in evaluation

Reference:	OECD KIIIA1 7.1.2
Report	Bixafen + Fluopyram + Prothioconazole EC 65+65+130 g/L: Acute dermal toxicity study in rats - Final Report [redacted], 2013, M-461508-01-1 ! 13/137-002P, ASB2015-1914
Guideline(s):	OECD Guideline 402 (1987) EPA OPPTS 870.1200 (1998)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No, according to available information.

Materials and methods

Test material (Lot/Batch No.)	BIXAFEN+FLUOPYRAM+PROTHIOCONAZOLE EC 65+65+130 g/L (2013-002135)
Species	Rat, RccHan:WIST
No. of animals (group size)	5 rats/sex
Dose(s)	2000 mg/kg bw
Exposure	24 hours (dermal, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	Residual test substance removed with body temperature water.

Table A 3: Results of acute dermal toxicity study in rats of BIXAFEN+FLUOPYRAM+PROTHIOCONAZOLE EC 65+65+130 g/L

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD50 (mg/kg bw) (14 days)
Male rats				
2000	0/0/5	-	-	>2000
Female rats				
2000	0/0/5	-	-	>2000

* Number of animals which died/number of animals with clinical signs/number of animals used

Table A 4: Summary of findings of acute dermal toxicity study in rats of BIXAFEN+FLUOPYRAM+PROTHIOCONAZOLE EC 65+65+130 g/L

Mortality:	No mortality occurred.
Clinical signs:	No clinical signs of toxicity were observed.
Body weight:	Body weight gain was considered to be normal.
Macroscopic examination:	The necropsies performed at the end of the study revealed no apparent findings.

Conclusion

Under the experimental conditions, the dermal LD_{50} of BIXAFEN+FLUOPYRAM+PROTHIOCONAZOLE EC 65+65+130 g/L is higher than 2000 mg/kg bw in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.4 Acute inhalation toxicity (IIIA1 7.1.3)

Comments of zRMS:	Waiving acceptable, based on data and information supplied by the applicant

A study on acute inhalation toxicity has not been submitted and is not considered necessary as the criteria laid down in Regulation (EU) No 284/2013 do not apply for the product. No study has to be carried out where the plant protection product:

- is not a gas or liquefied gas;
- is not a smoke generating plant protection product or fumigant;
- is not used with fogging/misting equipment;
- is not a vapour releasing plant protection product;
- is not supplied in an aerosol dispenser;
- is not in a form of a powder or granules containing a significant proportion (> 1 % on a weight basis) of particles of a diameter < 50 µm (confirmation of applicant data not possible);
- is not to be applied from aircraft in cases where inhalation exposure is relevant;
- does not contain an active substance with a vapor pressure > 1 x 10^{-2} Pa (vapour pressure of bixafen, fluopyram, and prothioconazole at 25 °C: 4.6 x 10^{-5} mPa, 1.2 x 10^{-3} mPa, and 4.0 x 10^{-3} mPa, respectively) and is not to be used in enclosed spaces such as warehouses or glasshouses and
- is not to be applied by spraying.

According to the calculation method, no classification is required, as the estimated LC_{50} is greater than 5 mg/L air.

A 2.5 Skin irritation (IIIA1 7.1.4)

Comments of zRMS:	Study acceptable with minor deficiencies according to mentioned guidelines, used in evaluation

Reference: OECD KIIIA1 7.1.4

Report	Bixafen + Fluopyram + Prothioconazole EC 65+65+130 g/L: Acute skin irritation study in rabbits - Final Report [redacted], 2013, M-461510-01-1 ! 13/137-006N, ASB2015-1915
Guideline(s):	OECD Guideline 404 (2002) EPA OPPTS 870.2500 (1998) EU Method B.4 (2008)
Deviations:	Yes Animal housing room humidity is partly above 70 %. The mentioned deviation is not thought to alter study outcome.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No, according to available information.

Materials and methods

Test material (Lot/Batch No.)	BIXAFEN+FLUOPYRAM+ PROTHIOCONAZOLE EC 65+65+130 g/L (2013-002135)
Species	Rabbit, New Zealand White
No. of animals (group size)	3 males
Initial test using one animal	Yes
Exposure	0.5 mL (4 hours, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	3 days
Remarks	After exposure, skin was flushed with lukewarm tab water.

Results and discussions

Table A 5: Skin irritation of BIXAFEN+FLUOPYRAM+ PROTHIOCONAZOLE EC 65+65+130 g/L

Animal No.		Scores after treatment *				Mean scores (24-72 h)	Reversible (day)
		1 h	24 h	48 h	72 h		
1	Erythema Oedema	0 0	0 0	0 0	0 0	0 0	- -
2	Erythema Oedema	0 0	0 0	0 0	0 0	0 0	- -
3	Erythema Oedema	0 0	0 0	0 0	0 0	0 0	- -

* scores in the range of 0 to 4

Clinical signs:	No clinical signs of toxicity were observed.

Conclusion

Under the experimental conditions, BIXAFEN+FLUOPYRAM+ PROTHIOCONAZOLE EC 65+65+130 g/L is not a skin irritant. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.6 Eye irritation (IIIA1 7.1.5)

Comments of zRMS:	Study acceptable with minor deviations from mentioned guidelines, used in evaluation

Reference: OECD KIIIA1 7.1.5

Report: Bixafen + Fluopyram + Prothioconazole EC 65+65+130 g/L: Acute eye irritation study in rabbits - Final Report
[redacted], 2013, M-463964-01-1 ! 13/137-005N,
ASB2015-1916

Guideline(s): OECD Guideline 405 (2012)
EPA OPPTS 870.2400 (1998)
EU Method B.5 (2008)

Deviations: Yes
Animal housing room humidity is partly above 70 %. The mentioned deviation is not thought to alter study outcome.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study): No, according to available information.

Materials and methods

Test material (Lot/Batch No.)	BIXAFEN+FLUOPYRAM+PROTHIOCONAZOLE EC 65+65+130 g/L (2013-002135)
Species	Rabbit, New Zealand White
No. of animals (group size)	3 males
Initial test using one animal	Yes
Exposure	0.1 mL (single instillation in conjunctival sac)
Irrigation (time point)	1 hour post exposure
Vehicle/Dilution	None
Post exposure observation period	21 days
Remarks	Test product pH = 4.5. Administration of a systemic analgesic (buprenorphine, 0.01 mg/kg) 60 minutes prior to exposure. Five minutes prior to exposure, a topical ocular analgesic (humacain) was applied to both eyes. Eight to nine hours after exposure, a systemic analgesic and a nonsteroidal anti-inflammatory drug (meloxicam, 0.5 mg/kg) was administered by subcutaneous injection.

Results and discussions

Table A 6: Eye irritation of BIXAFEN+FLUOPYRAM+PROTHIOCONAZOLE EC 65+65+130 g/L

Animal No.		Scores after treatment *				Mean scores (24-72 h)	Reversible (day)
		1 h	24 h	48 h	72 h		
1	Corneal opacity	1	1	1	1	1	Not reversible
	Iritis	0	0	0	0	0	-
	Redness conjunctivae	2	2	2	2	2	Not reversible
	Chemosis conjunctivae	3	1	1	1	1	21

2	Corneal opacity Iritis Redness conjunctivae Chemosis conjunctivae	1 0 2 3	1 0 2 2	1 0 2 2	1 0 2 2	1 0 2 2	Not reversible - Not reversible 21
3	Corneal opacity Iritis Redness conjunctivae Chemosis conjunctivae	1 0 2 3	1 0 2 3	1 0 2 3	1 0 2 2	1 0 2 2.7	14 - Not reversible Not reversible

* scores in the range of 0 to 4 for cornea opacity and chemosis, 0 to 3 for redness of conjunctivae and 0 to 2 for iritis

Clinical signs:	No clinical signs of toxicity were observed.

Conclusion

Under the experimental conditions, BIXAFEN+FLUOPYRAM+PROTHIOCONAZOLE EC 65+65+130 g/L is an eye irritant. Thus, labelling with Danger, H318 is required according to Regulation (EC) No. 1272/2008.

A 2.7 Skin sensitisation (IIIA1 7.1.6)

Comments of zRMS:	Study acceptable with minor deficiencies according to mentioned guidelines, used in evaluation

Reference: OECD KIIIA1 7.1.6

Report: Bixafen + Fluopyram + Prothioconazole EC 65+65+130 g/L: Local lymph node assay in the mouse - Final Report
[redacted], 2013, M-467203-01-1 ! 13/137-037E,
ASB2015-1917

Guideline(s): OECD Guideline 429 (2010)

Deviations: Yes
Animal housing room humidity is partly above 70 %. Cell strainer mesh size for cell suspension is not given. Subsequent incubation took place at 2-8 instead of 4 °C. The mentioned minor deviations are not thought to impact study outcome.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study): No, according to available information.

Materials and methods

Test material (Lot/Batch No.)	BIXAFEN+FLUOPYRAM+PROTHIOCONAZOLE EC 65+65+130 g/L (2013-002135)
Species	Mouse, CBA/J Rj strain
No. of animals (group size)	Test substance group: 3 x 4 female mice Vehicle control goup: 1 x 4 female mice Positive control group: 1 x 4 female mice
Range finding:	Yes
Exposure (concentration(s), no. of applications)	100 %, 50 %, and 25 % (w/v), 3 x 25 µL/ear
Vehicle	1% aqueous Pluronic® PE9200

Reliability check	α-Hexylcinnamaldehyde (HCA) (25 % (w/v)) in 1% aqueous Pluronic® PE9200
Remarks	The washing of lymph node cell suspension was conducted by addition of PBS, consecutive centrifugation, and supernatant discarding. The authors of the study subtracted a background DPM signal prior to SI calculation. This approach was not followed in this study evaluation, as it is not included in the guideline. However, results are not altered by this approach. The EC3-value was reported to be 26.4 %.

Results and discussions

Table A 7: Results of skin sensitisation study of BIXAFEN+FLUOPYRAM+PROTHIOCONAZOLE EC 65+65+130 g/L

	No. of animals	Concentration [%]	DPM / group	Stimulation index (SI)
BIXAFEN+FLUOPYRAM+PROTHIOCONAZOLE EC 65+65+130 g/L	4	100	18846	15.6
	4	50	9742	8.1
	4	25	3210	2.7
Test Vehicle Control Group	4	0	1210	1.0
Positive control	4	25	17429	14.4

Clinical signs:	None

Conclusion

Under the experimental conditions, BIXAFEN+FLUOPYRAM+PROTHIOCONAZOLE EC 65+65+130 g/L is a skin sensitiser. Thus, classification is required with Warning, H317 according to Regulation (EC) No. 1272/2008.

A 2.8 Supplementary studies for combinations of plant protection products (IIIA1 7.1.7)

There are no supplementary studies.

A 2.9 Data on co-formulants (III1 7.9)

A 2.9.1 Material safety data sheet for each co-formulant

Material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.9.2 Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.10 Studies on dermal absorption (IIIA 7.6)

There are no supplementary studies.

A 2.11 Other/Special Studies

There are no other/special studies.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (IIIA1 7.3.1)

A 3.1.1 Calculations for bixafen

Table A 8: Input parameters considered for the estimation of operator exposure

Formulation type:	EC		**Application technique:**	Field Crop Tractor Mounted (FCTM)	
Application rate (AR):	0.0975	kg a.s./ha			
Area treated per day (A):	20	ha	**Dermal hands m/l ($D_{M(H)}$):**	2.4	mg/person/kg a.s.
Dermal absorption (DA):	25	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	0.38	mg/person/kg a.s.
	75	% (dilution)	**Dermal body appl. ($D_{A(B)}$):**	1.6	mg/person/kg a.s.
Inhalation absorption (IA):	100	%	**Dermal head appl. ($D_{A(C)}$):**	0.06	mg/person/kg a.s.
Body weight (BW):	70	kg/person	**Inhalation m/l (I_M):**	0.0006	mg/person/kg a.s.
AOEL	0.13	mg/kg bw/d	**Inhalation appl. (I_A):**	0.001	mg/person/kg a.s.

Table A 9: Estimation of operator exposure towards bixafen using the German model

Without PPE			**With PPE[1)]**		
Operators: Systemic dermal exposure after application in Getreide-Arten					
Dermal exposure during mixing/loading					
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times DA) / BW$			$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times PPE^{1)} \times DA) / BW$		
(2.4 x 0.0975 x 20 x 25%) / 70			(2.4 x 0.0975 x 20 x 0.01 x 25%) / 70		
External dermal exposure	4.68	mg/person	External dermal exposure	0.0468	mg/person
External dermal exposure	0.066857	mg/kg bw/d	External dermal exposure	0.000669	mg/kg bw/d
Systemic dermal exposure	**0.016714**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000167**	**mg/kg bw/d**
Dermal exposure during application					
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times DA) / BW$			$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times PPE \times DA) / BW$		
(0.38 x 0.0975 x 20 x 75%) / 70			(0.38 x 0.0975 x 20 x 0.01 x 75%) / 70		
External dermal exposure	0.741	mg/person	External dermal exposure	0.00741	mg/person
External dermal exposure	0.010586	mg/kg bw/d	External dermal exposure	0.000106	mg/kg bw/d
Systemic dermal exposure	**0.007939**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000079**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times DA) / BW$			$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times PPE \times DA) / BW$		
(1.6 x 0.0975 x 20 x 75%) / 70			(1.6 x 0.0975 x 20 x 0.05 x 75%) / 70		
External dermal exposure	3.12	mg/person	External dermal exposure	0.156	mg/person
External dermal exposure	0.044571	mg/kg bw/d	External dermal exposure	0.002229	mg/kg bw/d
Systemic dermal exposure	**0.033429**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001671**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$			$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times PPE \times DA) / BW$		
(0.06 x 0.0975 x 20 x 75%) / 70			(0.06 x 0.0975 x 20 x 1 x 75%) / 70		
External dermal exposure	0.117	mg/person	External dermal exposure	0.117	mg/person
External dermal exposure	0.001671	mg/kg bw/d	External dermal exposure	0.001671	mg/kg bw/d
Systemic dermal exposure	**0.001254**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001254**	**mg/kg bw/d**
Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$			Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		
Total external dermal exposure	8.658	mg/person	Total external dermal exposure	0.32721	mg/person
Total external dermal exposure	0.123686	mg/kg bw/d	Total external dermal exposure	0.004674	mg/kg bw/d
Total systemic dermal exposure	**0.059336**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.003172**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in Getreide-Arten					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M \times AR \times A \times IA) / BW$			$SIE_{OM} = (I_M \times AR \times A \times PPE \times IA) / BW$		
(0.0006 x 0.0975 x 20 x 100%) / 70			(0.0006 x 0.0975 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.00117	mg/person	External inhalation exposure	0.00117	mg/person
External inhalation exposure	0.000017	mg/kg bw/d	External inhalation exposure	0.000017	mg/kg bw/d
Systemic inhalation exposure	**0.000017**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000017**	**mg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A \times AR \times A \times IA) / BW$			$SIE_{OA} = (I_A \times AR \times A \times PPE \times IA) / BW$		

(0.001 x 0.0975 x 20 x 100%) / 70			(0.001 x 0.0975 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.00195	mg/person	External inhalation exposure	0.00195	mg/person
External inhalation exposure	0.000028	mg/kg bw/d	External inhalation exposure	0.000028	mg/kg bw/d
Systemic inhalation exposure	**0.000028**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000028**	**mg/kg bw/d**
Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$			Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$		
Total external inhalation exposure	0.00312	mg/person	Total external inhalation exposure	0.00312	mg/person
Total external inhalation exposure	0.000045	mg/kg bw/d	Total external inhalation exposure	0.000045	mg/kg bw/d
Total systemic inhalation exposure	**0.000045**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.000045**	**mg/kg bw/d**
Total systemic exposure: $SE_O = SDE_O + SIE_O$			Total systemic exposure: $SE_O = SDE_O + SIE_O$		
Total systemic exposure	4.15662	mg/person	Total systemic exposure	0.225128	mg/person
Total systemic exposure	**0.05938**	**mg/kg bw/d**	**Total systemic exposure**	**0.003216**	**mg/kg bw/d**
% of AOEL	**45.7**	**%**	**% of AOEL**	**2.5**	**%**

1) reduction factor for gloves is 0.01 (professional appl.)

Table A 10: Estimation of operator exposure towards bixafen using the UK-POEM- without PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)					
Active substance	**Bixafen**				
Product	Ascra Xpro				
Formulation type	organic solvent-based				
Concentration of a.s.	65	mg/mL			
Dose	1.5	L preparation/ha	(0.098 kg a.s./ha)		
Application volume	100	L/ha			
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Container	10 litres 45 mm closure				
Work rate/day	50	ha			
Duration of spraying	6	h			
PPE during mix./loading	None				
PPE during application	None				
Dermal absorption from product	25	%			
Dermal absorption from spray	75	%			
EXPOSURE DURING MIXING AND LOADING					
Container size	10	Litres			
Hand contamination/operation	0,1	mL			
Application dose	1.5	Litres product/ha			
Work rate	50	ha/day			
Number of operations	8	/day			
Hand contamination	0.8	mL/day			
Protective clothing	None				
Transmission to skin	100	%			
Dermal exposure to formulation	0.8	mL/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Application volume	100	spray/ha			
Volume of surface contamination	10	mL/h			
Distribution	Hands		Trunk	Legs	
	65%		10%	25%	
Clothing	None		Permeable	Permeable	
Penetration	100%		5%	15%	
Dermal exposure	6.5		0.05	0.375	mL/h
Duration of exposure	6	h			
Total dermal exposure to spray	41.55	mL/day			
ABSORBED DERMAL DOSE					
	Mix/load			Application	
Dermal exposure	0.8	mL/day		41.55	mL/day
Concen. of a.s. product or spray	65	mg/mL		0.975	mg/mL

Dermal exposure to a.s.	52	mg/day	40.511	mg/day
Percent absorbed	25	%	75	%
Absorbed dose	13	mg/day	30.383	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.01	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	0.975	mg/mL		
Inhalation exposure to a.s.	0.059	mg/day		
Percent absorbed	100	%		
Absorbed dose	0.059	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	43.442	mg/day		
Operator body weight	60	kg		
Operator exposure	0.724	mg/kg bw/day		
Amount of AOEL	**556.9**	**%**		

Table A 11: Estimation of operator exposure towards bixafen using the UK-POEM-with PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)				
Active substance	**Bixafen**			
Product	Ascra Xpro			
Formulation type	organic solvent-based			
Concentration of a.s.	65	mg/mL		
Dose	1.5	L preparation/ha	(0.098 kg a.s./ha)	
Application volume	100	L/ha		
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Container	10 litres 45 mm closure			
Work rate/day	50	ha		
Duration of spraying	6	h		
PPE during mix./loading	Gloves			
PPE during application	Gloves			
Dermal absorption from product	25	%		
Dermal absorption from spray	75	%		
EXPOSURE DURING MIXING AND LOADING				
Container size	10	Litres		
Hand contamination/operation	0,1	mL		
Application dose	1.5	Litres product/ha		
Work rate	50	ha/day		
Number of operations	8	/day		
Hand contamination	0.8	mL/day		
Protective clothing	Gloves			
Transmission to skin	10	%		
Dermal exposure to formulation	0.08	mL/day		
DERMAL EXPOSURE DURING SPRAY APPLICATION				
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	100	spray/ha		
Volume of surface contamination	10	mL/h		
Distribution	Hands	Trunk	Legs	
	65%	10%	25%	
Clothing	Gloves	Permeable	Permeable	
Penetration	10%	5%	15%	
Dermal exposure	0.65	0.05	0.375	mL/h
Duration of exposure	6	h		
Total dermal exposure to spray	6.45	mL/day		
ABSORBED DERMAL DOSE				
	Mix/load		Application	
Dermal exposure	0.08	mL/day	6.45	mL/day

Concen. of a.s. product or spray	65	mg/mL	0.975	mg/mL
Dermal exposure to a.s.	5.2	mg/day	6.289	mg/day
Percent absorbed	25	%	75	%
Absorbed dose	1.3	mg/day	4.717	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.01	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	0.975	mg/mL		
Inhalation exposure to a.s.	0.059	mg/day		
Percent absorbed	100	%		
Absorbed dose	0.059	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	6.075	mg/day		
Operator body weight	60	kg		
Operator exposure	0.101	mg/kg bw/day		
Amount of AOEL	**77.9**	**%**		

A 3.1.2 Calculations for fluopyram

Table A 12: Input parameters considered for the estimation of operator exposure

Formulation type:	EC		**Application technique:**	Field Crop Tractor Mounted (FCTM)	
Application rate (AR):	0.0975	kg a.s./ha			
Area treated per day (A):	20	ha	**Dermal hands m/l ($D_{M(H)}$):**	2.4	mg/person/kg a.s.
Dermal absorption (DA):	25	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	0.38	mg/person/kg a.s.
	75	% (dilution)	**Dermal body appl. ($D_{A(B)}$):**	1.6	mg/person/kg a.s.
Inhalation absorption (IA):	100	%	**Dermal head appl. ($D_{A(C)}$):**	0.06	mg/person/kg a.s.
Body weight (BW):	70	kg/person	**Inhalation m/l (I_M):**	0.0006	mg/person/kg a.s.
AOEL	0.05	mg/kg bw/d	**Inhalation appl. (I_A):**	0.001	mg/person/kg a.s.

Table A 13: Estimation of operator exposure towards fluoryram using the German model

Without PPE			**With PPE[1)]**		
Operators: Systemic dermal exposure after application in Getreide-Arten					
Dermal exposure during mixing/loading					
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times DA) / BW$			$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times PPE^{1)} \times DA) / BW$		
(2.4 x 0.0975 x 20 x 25%) / 70			(2.4 x 0.0975 x 20 x 0.01 x 25%) / 70		
External dermal exposure	4.68	mg/person	External dermal exposure	0.0468	mg/person
External dermal exposure	0.066857	mg/kg bw/d	External dermal exposure	0.000669	mg/kg bw/d
Systemic dermal exposure	**0.016714**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000167**	**mg/kg bw/d**
Dermal exposure during application					
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times DA) / BW$			$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times PPE \times DA) / BW$		
(0.38 x 0.0975 x 20 x 75%) / 70			(0.38 x 0.0975 x 20 x 0.01 x 75%) / 70		
External dermal exposure	0.741	mg/person	External dermal exposure	0.00741	mg/person
External dermal exposure	0.010586	mg/kg bw/d	External dermal exposure	0.000106	mg/kg bw/d
Systemic dermal exposure	**0.007939**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000079**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times DA) / BW$			$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times PPE \times DA) / BW$		
(1.6 x 0.0975 x 20 x 75%) / 70			(1.6 x 0.0975 x 20 x 0.05 x 75%) / 70		
External dermal exposure	3.12	mg/person	External dermal exposure	0.156	mg/person
External dermal exposure	0.044571	mg/kg bw/d	External dermal exposure	0.002229	mg/kg bw/d
Systemic dermal exposure	**0.033429**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001671**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$			$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times PPE \times DA) / BW$		
(0.06 x 0.0975 x 20 x 75%) / 70			(0.06 x 0.0975 x 20 x 1 x 75%) / 70		
External dermal exposure	0.117	mg/person	External dermal exposure	0.117	mg/person
External dermal exposure	0.001671	mg/kg bw/d	External dermal exposure	0.001671	mg/kg bw/d

Systemic dermal exposure	**0.001254**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001254**	**mg/kg bw/d**
Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$			Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		
Total external dermal exposure	8.658	mg/person	Total external dermal exposure	0.32721	mg/person
Total external dermal exposure	0.123686	mg/kg bw/d	Total external dermal exposure	0.004674	mg/kg bw/d
Total systemic dermal exposure	**0.059336**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.003172**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in Getreide-Arten					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M \times AR \times A \times IA) / BW$			$SIE_{OM} = (I_M \times AR \times A \times PPE \times IA) / BW$		
(0.0006 x 0.0975 x 20 x 100%) / 70			(0.0006 x 0.0975 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.00117	mg/person	External inhalation exposure	0.00117	mg/person
External inhalation exposure	0.000017	mg/kg bw/d	External inhalation exposure	0.000017	mg/kg bw/d
Systemic inhalation exposure	**0.000017**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000017**	**mg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A \times AR \times A \times IA) / BW$			$SIE_{OA} = (I_A \times AR \times A \times PPE \times IA) / BW$		
(0.001 x 0.0975 x 20 x 100%) / 70			(0.001 x 0.0975 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.00195	mg/person	External inhalation exposure	0.00195	mg/person
External inhalation exposure	0.000028	mg/kg bw/d	External inhalation exposure	0.000028	mg/kg bw/d
Systemic inhalation exposure	**0.000028**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000028**	**mg/kg bw/d**
Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$			Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$		
Total external inhalation exposure	0.00312	mg/person	Total external inhalation exposure	0.00312	mg/person
Total external inhalation exposure	0.000045	mg/kg bw/d	Total external inhalation exposure	0.000045	mg/kg bw/d
Total systemic inhalation exposure	**0.000045**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.000045**	**mg/kg bw/d**
Total systemic exposure: $SE_O = SDE_O + SIE_O$			Total systemic exposure: $SE_O = SDE_O + SIE_O$		
Total systemic exposure	4.15662	mg/person	Total systemic exposure	0.225128	mg/person
Total systemic exposure	**0.05938**	**mg/kg bw/d**	**Total systemic exposure**	**0.003216**	**mg/kg bw/d**
% of AOEL	**118.8**	**%**	**% of AOEL**	**6.4**	**%**

1) reduction factor for gloves is 0.01 (professional appl.)

Table A 14: Estimation of operator exposure towards fluopyram using the UK-POEM-without PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)		
Active substance	**Fluopyram**	
Product	Ascra Xpro	
Formulation type	organic solvent-based	
Concentration of a.s.	65	mg/mL
Dose	1.5	L preparation/ha (0.098 kg a.s./ha)
Application volume	100	L/ha
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles	
Container	10 litres 45 mm closure	
Work rate/day	50	ha
Duration of spraying	6	h
PPE during mix./loading	None	
PPE during application	None	
Dermal absorption from product	25	%
Dermal absorption from spray	75	%
EXPOSURE DURING MIXING AND LOADING		
Container size	10	Litres
Hand contamination/operation	0,1	mL
Application dose	1.5	Litres product/ha
Work rate	50	ha/day
Number of operations	8	/day
Hand contamination	0.8	mL/day
Protective clothing	None	
Transmission to skin	100	%
Dermal exposure to formulation	0.8	mL/day

DERMAL EXPOSURE DURING SPRAY APPLICATION				
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	100	spray/ha		
Volume of surface contamination	10	mL/h		
Distribution	Hands	Trunk	Legs	
	65%	10%	25%	
Clothing	None	Permeable	Permeable	
Penetration	100%	5%	15%	
Dermal exposure	6.5	0.05	0.375	mL/h
Duration of exposure	6	h		
Total dermal exposure to spray	41.55	mL/day		
ABSORBED DERMAL DOSE				
	Mix/load		Application	
Dermal exposure	0.8	mL/day	41.55	mL/day
Concen. of a.s. product or spray	65	mg/mL	0.975	mg/mL
Dermal exposure to a.s.	52	mg/day	40.511	mg/day
Percent absorbed	25	%	75	%
Absorbed dose	13	mg/day	30.383	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.01	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	0.975	mg/mL		
Inhalation exposure to a.s.	0.059	mg/day		
Percent absorbed	100	%		
Absorbed dose	0.059	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	43.442	mg/day		
Operator body weight	60	kg		
Operator exposure	0.724	mg/kg bw/day		
Amount of AOEL	**1448.1**	**%**		

Table A 15: Estimation of operator exposure towards fluopyram using the UK-POEM-with PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)			
Active substance	**Fluopyram**		
Product	Ascra Xpro		
Formulation type	organic solvent-based		
Concentration of a.s.	65	mg/mL	
Dose	1.5	L preparation/ha	(0.098 kg a.s./ha)
Application volume	100	L/ha	
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Container	10 litres 45 mm closure		
Work rate/day	50	ha	
Duration of spraying	6	h	
PPE during mix./loading	Gloves		
PPE during application	Gloves		
Dermal absorption from product	25	%	
Dermal absorption from spray	75	%	
EXPOSURE DURING MIXING AND LOADING			
Container size	10	Litres	
Hand contamination/operation	0,1	mL	
Application dose	1.5	Litres product/ha	
Work rate	50	ha/day	
Number of operations	8	/day	
Hand contamination	0.8	mL/day	
Protective clothing	Gloves		
Transmission to skin	10	%	

Dermal exposure to formulation	0.08	mL/day		
DERMAL EXPOSURE DURING SPRAY APPLICATION				
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	100	spray/ha		
Volume of surface contamination	10	mL/h		
Distribution	Hands	Trunk	Legs	
	65%	10%	25%	
Clothing	Gloves	Permeable	Permeable	
Penetration	10%	5%	15%	
Dermal exposure	0.65	0.05	0.375	mL/h
Duration of exposure	6	h		
Total dermal exposure to spray	6.45	mL/day		
ABSORBED DERMAL DOSE				
	Mix/load		Application	
Dermal exposure	0.08	mL/day	6.45	mL/day
Concen. of a.s. product or spray	65	mg/mL	0.975	mg/mL
Dermal exposure to a.s.	5.2	mg/day	6.289	mg/day
Percent absorbed	25	%	75	%
Absorbed dose	1.3	mg/day	4.717	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.01	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	0.975	mg/mL		
Inhalation exposure to a.s.	0.059	mg/day		
Percent absorbed	100	%		
Absorbed dose	0.059	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	6.075	mg/day		
Operator body weight	60	kg		
Operator exposure	0.101	mg/kg bw/day		
Amount of AOEL	**202.5**	**%[1)]**		

1) Operator exposure amounts to 22.8 % AOEL when the EFSA calculator is applied according to the 'Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products' (EFSA Journal 2014; 12(10):3874) and provided that workwear and gloves are worn

A 3.1.3 Calculations for prothioconazole

Table A 16: Input parameters considered for the estimation of operator exposure

Formulation type:	EC		**Application technique:**	Field Crop Tractor Mounted (FCTM)	
Application rate (AR):	0.195	kg a.s./ha			
Area treated per day (A):	20	ha	**Dermal hands m/l ($D_{M(H)}$):**	2.4	mg/person/kg a.s.
Dermal absorption (DA):	25	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	0.38	mg/person/kg a.s.
	75	% (dilution)	**Dermal body appl. ($D_{A(B)}$):**	1.6	mg/person/kg a.s.
Inhalation absorption (IA):	100	%	**Dermal head appl. ($D_{A(C)}$):**	0.06	mg/person/kg a.s.
Body weight (BW):	70	kg/person	**Inhalation m/l (I_M):**	0.0006	mg/person/kg a.s.
AOEL	0.2	mg/kg bw/d	**Inhalation appl. (I_A):**	0.001	mg/person/kg a.s.

Table A 17: Estimation of operator exposure towards prothioconazole using the German model

Without PPE			**With PPE[1)]**		
Operators: Systemic dermal exposure after application in Getreide-Arten					
Dermal exposure during mixing/loading					
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times DA) / BW$			$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times PPE^{1)} \times DA) / BW$		
(2.4 x 0.195 x 20 x 25%) / 70			(2.4 x 0.195 x 20 x 0.01 x 25%) / 70		
External dermal exposure	9.36	mg/person	External dermal exposure	0.0936	mg/person

External dermal exposure	0.133714	mg/kg bw/d	External dermal exposure	0.001337	mg/kg bw/d
Systemic dermal exposure	**0.033429**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000334**	**mg/kg bw/d**
Dermal exposure during application					
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times DA) / BW$			$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times PPE \times DA) / BW$		
(0.38 x 0.195 x 20 x 75%) / 70			(0.38 x 0.195 x 20 x 0.01 x 75%) / 70		
External dermal exposure	1.482	mg/person	External dermal exposure	0.01482	mg/person
External dermal exposure	0.021171	mg/kg bw/d	External dermal exposure	0.000212	mg/kg bw/d
Systemic dermal exposure	**0.015879**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000159**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times DA) / BW$			$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times PPE \times DA) / BW$		
(1.6 x 0.195 x 20 x 75%) / 70			(1.6 x 0.195 x 20 x 0.05 x 75%) / 70		
External dermal exposure	6.24	mg/person	External dermal exposure	0.312	mg/person
External dermal exposure	0.089143	mg/kg bw/d	External dermal exposure	0.004457	mg/kg bw/d
Systemic dermal exposure	**0.066857**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.003343**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$			$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times PPE \times DA) / BW$		
(0.06 x 0.195 x 20 x 75%) / 70			(0.06 x 0.195 x 20 x 1 x 75%) / 70		
External dermal exposure	0.234	mg/person	External dermal exposure	0.234	mg/person
External dermal exposure	0.003343	mg/kg bw/d	External dermal exposure	0.003343	mg/kg bw/d
Systemic dermal exposure	**0.002507**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.002507**	**mg/kg bw/d**
Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$			Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		
Total external dermal exposure	17.316	mg/person	Total external dermal exposure	0.65442	mg/person
Total external dermal exposure	0.247371	mg/kg bw/d	Total external dermal exposure	0.009349	mg/kg bw/d
Total systemic dermal exposure	**0.118671**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.006343**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in Getreide-Arten					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M \times AR \times A \times IA) / BW$			$SIE_{OM} = (I_M \times AR \times A \times PPE \times IA) / BW$		
(0.0006 x 0.195 x 20 x 100%) / 70			(0.0006 x 0.195 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.00234	mg/person	External inhalation exposure	0.00234	mg/person
External inhalation exposure	0.000033	mg/kg bw/d	External inhalation exposure	0.000033	mg/kg bw/d
Systemic inhalation exposure	**0.000033**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000033**	**mg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A \times AR \times A \times IA) / BW$			$SIE_{OA} = (I_A \times AR \times A \times PPE \times IA) / BW$		
(0.001 x 0.195 x 20 x 100%) / 70			(0.001 x 0.195 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.0039	mg/person	External inhalation exposure	0.0039	mg/person
External inhalation exposure	0.000056	mg/kg bw/d	External inhalation exposure	0.000056	mg/kg bw/d
Systemic inhalation exposure	**0.000056**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000056**	**mg/kg bw/d**
Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$			Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$		
Total external inhalation exposure	0.00624	mg/person	Total external inhalation exposure	0.00624	mg/person
Total external inhalation exposure	0.000089	mg/kg bw/d	Total external inhalation exposure	0.000089	mg/kg bw/d
Total systemic inhalation exposure	**0.000089**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.000089**	**mg/kg bw/d**
Total systemic exposure: $SE_O = SDE_O + SIE_O$			Total systemic exposure: $SE_O = SDE_O + SIE_O$		
Total systemic exposure	8.31324	mg/person	Total systemic exposure	0.450255	mg/person
Total systemic exposure	**0.118761**	**mg/kg bw/d**	**Total systemic exposure**	**0.006432**	**mg/kg bw/d**
% of AOEL	**59.4**	**%**	**% of AOEL**	**3.2**	**%**

1) reduction factor for gloves is 0.01 (professional appl.)

Table A 18: Estimation of operator exposure towards prothioconazole using the UK-POEM-without PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)			
Active substance	**Prothioconazol**		
Product	Ascra Xpro		
Formulation type	organic solvent-based		
Concentration of a.s.	130	mg/mL	
Dose	1.5	L preparation/ha	(0.195 kg a.s./ha)

Application volume	100	L/ha		
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Container	10 litres 45 mm closure			
Work rate/day	50	ha		
Duration of spraying	6	h		
PPE during mix./loading	None			
PPE during application	None			
Dermal absorption from product	25	%		
Dermal absorption from spray	75	%		
EXPOSURE DURING MIXING AND LOADING				
Container size	10	Litres		
Hand contamination/operation	0,1	mL		
Application dose	1.5	Litres product/ha		
Work rate	50	ha/day		
Number of operations	8	/day		
Hand contamination	0.8	mL/day		
Protective clothing	None			
Transmission to skin	100	%		
Dermal exposure to formulation	0.8	mL/day		
DERMAL EXPOSURE DURING SPRAY APPLICATION				
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	100	spray/ha		
Volume of surface contamination	10	mL/h		
Distribution	Hands	Trunk	Legs	
	65%	10%	25%	
Clothing	None	Permeable	Permeable	
Penetration	100%	5%	15%	
Dermal exposure	6.5	0.05	0.375	mL/h
Duration of exposure	6	h		
Total dermal exposure to spray	41.55	mL/day		
ABSORBED DERMAL DOSE				
	Mix/load		Application	
Dermal exposure	0.8	mL/day	41.55	mL/day
Concen. of a.s. product or spray	130	mg/mL	1.95	mg/mL
Dermal exposure to a.s.	104	mg/day	81.023	mg/day
Percent absorbed	25	%	75	%
Absorbed dose	26	mg/day	60.767	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.01	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	1.95	mg/mL		
Inhalation exposure to a.s.	0.117	mg/day		
Percent absorbed	100	%		
Absorbed dose	0.117	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	86.884	mg/day		
Operator body weight	60	kg		
Operator exposure	1.448	mg/kg bw/day		
Amount of AOEL	**724**	**%**		

Table A 19: Estimation of operator exposure towards prothioconazole using the UK-POEM-with PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)		
Active substance	**Prothioconazol**	
Product	Ascra Xpro	
Formulation type	organic solvent-based	
Concentration of a.s.	130	mg/mL

Dose	1.5	L preparation/ha	(0.195 kg a.s./ha)	
Application volume	100	L/ha		
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Container	10 litres 45 mm closure			
Work rate/day	50	ha		
Duration of spraying	6	h		
PPE during mix./loading	Gloves			
PPE during application	Gloves			
Dermal absorption from product	25	%		
Dermal absorption from spray	75	%		
EXPOSURE DURING MIXING AND LOADING				
Container size	10	Litres		
Hand contamination/operation	0,1	mL		
Application dose	1.5	Litres product/ha		
Work rate	50	ha/day		
Number of operations	8	/day		
Hand contamination	0.8	mL/day		
Protective clothing	Gloves			
Transmission to skin	10	%		
Dermal exposure to formulation	0.08	mL/day		
DERMAL EXPOSURE DURING SPRAY APPLICATION				
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	100	spray/ha		
Volume of surface contamination	10	mL/h		
Distribution	Hands	Trunk	Legs	
	65%	10%	25%	
Clothing	Gloves	Permeable	Permeable	
Penetration	10%	5%	15%	
Dermal exposure	0.65	0.05	0.375	mL/h
Duration of exposure	6	h		
Total dermal exposure to spray	6.45	mL/day		
ABSORBED DERMAL DOSE				
	Mix/load		Application	
Dermal exposure	0.08	mL/day	6.45	mL/day
Concen. of a.s. product or spray	130	mg/mL	1.95	mg/mL
Dermal exposure to a.s.	10.4	mg/day	12.578	mg/day
Percent absorbed	25	%	75	%
Absorbed dose	2.6	mg/day	9.433	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.01	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	1.95	mg/mL		
Inhalation exposure to a.s.	0.117	mg/day		
Percent absorbed	100	%		
Absorbed dose	0.117	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	12.15	mg/day		
Operator body weight	60	kg		
Operator exposure	0.203	mg/kg bw/day		
Amount of AOEL	**101.3**	**%**		

A 3.1.4 Calculations for desthio-prothioconazole

Table A 20: Input parameters considered for the estimation of operator exposure

Formulation type:	EC			
Application rate (AR):	0.0975 or 0.195	kg a.s./ha[1)]	**Application technique:**	Field Crop Tractor Mounted (FCTM)

Area treated per day (A):	20	ha	**Dermal hands m/l ($D_{M(H)}$):**	2.4	mg/person/kg a.s.
Dermal absorption (DA):	25	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	0.38	mg/person/kg a.s.
	75	% (dilution)	**Dermal body appl. ($D_{A(B)}$):**	1.6	mg/person/kg a.s.
Inhalation absorption (IA):	100	%	**Dermal head appl. ($D_{A(C)}$):**	0.06	mg/person/kg a.s.
Body weight (BW):	70	kg/person	**Inhalation m/l (I_M):**	0.0006	mg/person/kg a.s.
AOEL	0.01	mg/kg bw/d	**Inhalation appl. (I_A):**	0.001	mg/person/kg a.s.

1) risk assessment based on an assumed conversion of prothioconazole to desthio-prothioconazole of 50 % in the case of dermal exposure and 100 % for inhalative exposure (see summary of field studies, Appendix 4).

Table A 21: Estimation of operator exposure towards desthio-prothioconazole using the German model

Without PPE			**With PPE[1), 2)]**		
Operators: Systemic dermal exposure after application in cereals					
Dermal exposure during mixing/loading					
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times DA) / BW$			$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times PPE^{1)} \times DA) / BW$		
(2.4 x 0.0975 x 20 x 25%) / 70			(2.4 x 0.0975 x 20 x 0.01 x 25%) / 70		
External dermal exposure	4.68	mg/person	External dermal exposure	0.0468	mg/person
External dermal exposure	0.066857	mg/kg bw/d	External dermal exposure	0.000669	mg/kg bw/d
Systemic dermal exposure	**0.016714**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000167**	**mg/kg bw/d**
Dermal exposure during application					
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times DA) / BW$			$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times PPE^{1)} \times DA) / BW$		
(0.38 x 0.0975 x 20 x 75%) / 70			(0.38 x 0.0975 x 20 x 0.01 x 75%) / 70		
External dermal exposure	0.741	mg/person	External dermal exposure	0.00741	mg/person
External dermal exposure	0.010586	mg/kg bw/d	External dermal exposure	0.000106	mg/kg bw/d
Systemic dermal exposure	**0.007939**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000079**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times DA) / BW$			$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times PPE^{2)} \times DA) / BW$		
(1.6 x 0.0975 x 20 x 75%) / 70			(1.6 x 0.0975 x 20 x 0.05 x 75%) / 70		
External dermal exposure	3.12	mg/person	External dermal exposure	0.156	mg/person
External dermal exposure	0.044571	mg/kg bw/d	External dermal exposure	0.002229	mg/kg bw/d
Systemic dermal exposure	**0.033429**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001671**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$			$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times PPE^{3)} \times DA) / BW$		
(0.06 x 0.0975 x 20 x 75%) / 70			(0.06 x 0.0975 x 20 x 1 x 75%) / 70		
External dermal exposure	0.117	mg/person	External dermal exposure	0.117	mg/person
External dermal exposure	0.001671	mg/kg bw/d	External dermal exposure	0.001671	mg/kg bw/d
Systemic dermal exposure	**0.001254**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001254**	**mg/kg bw/d**
Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$			Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		
Total external dermal exposure	8.658	mg/person	Total external dermal exposure	0.32721	mg/person
Total external dermal exposure	0.123686	mg/kg bw/d	Total external dermal exposure	0.004674	mg/kg bw/d
Total systemic dermal exposure	**0.059336**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.003172**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in cereals					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M \times AR \times A \times IA) / BW$			$SIE_{OM} = (I_M \times AR \times A \times PPE \times IA) / BW$		
(0.0006 x 0.195 x 20 x 100%) / 70			(0.0006 x 0.195 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.00234	mg/person	External inhalation exposure	0.00234	mg/person
External inhalation exposure	0.000033	mg/kg bw/d	External inhalation exposure	0.000033	mg/kg bw/d
Systemic inhalation exposure	**0.000033**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000033**	**mg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A \times AR \times A \times IA) / BW$			$SIE_{OA} = (I_A \times AR \times A \times PPE \times IA) / BW$		
(0.001 x 0.195 x 20 x 100%) / 70			(0.001 x 0.195 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.0039	mg/person	External inhalation exposure	0.0039	mg/person
External inhalation exposure	0.000056	mg/kg bw/d	External inhalation exposure	0	mg/kg bw/d
Systemic inhalation exposure	**0.000056**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000056**	**mg/kg bw/d**
Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$			Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$		
Total external inhalation	0.00624	mg/person	Total external inhalation	0.00624	mg/person

exposure			exposure		
Total external inhalation exposure	0.000089	mg/kg bw/d	Total external inhalation exposure	0.000033	mg/kg bw/d
Total systemic inhalation exposure	**0.000089**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.000089**	**mg/kg bw/d**
Total systemic exposure: $SE_O = SDE_O + SIE_O$			Total systemic exposure: $SE_O = SDE_O + SIE_O$		
Total systemic exposure	4.15974	mg/person	Total systemic exposure	0.228248	mg/person
Total systemic exposure	**0.059425**	**mg/kg bw/d**	**Total systemic exposure**	**0.003261**	**mg/kg bw/d**
% of AOEL	**594.2**	**%**	**% of AOEL**	**32.6**	**%**

1) reduction factor for gloves is 0.01 (professional appl.)

2) reduction factor for protective garment is 0.05 (professional appl.).

Table A 22: Estimation of operator exposure towards desthio-prothioconazole using the UK-POEM-without PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)					
Active substance	**Prothioconazol-desthio**				
Product	Ascra Xpro				
Formulation type	organic solvent-based				
Concentration of a.s.	65	mg/mL			
Dose	1.5	L preparation/ha	(0.098 or 0.195 kg a.s./ha[1)])		
Application volume	100	L/ha			
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Container	10 litres 45 mm closure				
Work rate/day	50	ha			
Duration of spraying	6	h			
PPE during mix./loading	None				
PPE during application	None				
Dermal absorption from product	25	%			
Dermal absorption from spray	75	%			
EXPOSURE DURING MIXING AND LOADING					
Container size	10	Litres			
Hand contamination/operation	0,1	mL			
Application dose	1.5	Litres product/ha			
Work rate	50	ha/day			
Number of operations	8	/day			
Hand contamination	0.8	mL/day			
Protective clothing	None				
Transmission to skin	100	%			
Dermal exposure to formulation	0.8	mL/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Application volume	100	spray/ha			
Volume of surface contamination	10	mL/h			
Distribution	Hands		Trunk	Legs	
	65%		10%	25%	
Clothing	None		Permeable	Permeable	
Penetration	100%		5%	15%	
Dermal exposure	6.5		0.05	0.375	mL/h
Duration of exposure	6	h			
Total dermal exposure to spray	41.55	mL/day			
ABSORBED DERMAL DOSE					
	Mix/load			Application	
Dermal exposure	0.8	mL/day		41.55	mL/day
Concen. of a.s. product or spray	65	mg/mL		0.975	mg/mL
Dermal exposure to a.s.	52	mg/day		40.511	mg/day
Percent absorbed	25	%		75	%
Absorbed dose	13	mg/day		30.383	mg/day

INHALATION EXPOSURE DURING SPRAYING		
Inhalation exposure	0.01	mL/h
Duration of exposure	6	h
Concentration of a.s. in spray	1.95	mg/mL
Inhalation exposure to a.s.	0.117	mg/day
Percent absorbed	100	%
Absorbed dose	0.117	mg/day
PREDICTED EXPOSURE		
Total absorbed dose	43.500	mg/day
Operator body weight	60	kg
Operator exposure	0.725	mg/kg bw/day
Amount of AOEL	**7250.0**	**%**

1) risk assessment based on an assumed conversion of prothioconazole to desthio-prothioconazole of 50 % in the case of dermal exposure and 100 % for inhalative exposure (see summary of field studies, Appendix 4).

Table A 23: Estimation of operator exposure towards desthio-prothioconazole using the UK-POEM-with PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)				
Active substance	**Prothioconazol-desthio**			
Product	Ascra Xpro			
Formulation type	organic solvent-based			
Concentration of a.s.	65	mg/mL		
Dose	1.5	L preparation/ha	(0.098 or 0.195 kg a.s./ha[1)])	
Application volume	100	L/ha		
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Container	10 litres 45 mm closure			
Work rate/day	50	ha		
Duration of spraying	6	h		
PPE during mix./loading	Gloves			
PPE during application	Gloves			
Dermal absorption from product	25	%		
Dermal absorption from spray	75	%		
EXPOSURE DURING MIXING AND LOADING				
Container size	10	Litres		
Hand contamination/operation	0,1	mL		
Application dose	1.5	Litres product/ha		
Work rate	50	ha/day		
Number of operations	8	/day		
Hand contamination	0.8	mL/day		
Protective clothing	Gloves			
Transmission to skin	10	%		
Dermal exposure to formulation	0.08	mL/day		
DERMAL EXPOSURE DURING SPRAY APPLICATION				
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	100	spray/ha		
Volume of surface contamination	10	mL/h		
Distribution	Hands	Trunk	Legs	
	65%	10%	25%	
Clothing	Gloves	Permeable	Permeable	
Penetration	10%	5%	15%	
Dermal exposure	0.65	0.05	0.375	mL/h
Duration of exposure	6	h		
Total dermal exposure to spray	6.45	mL/day		
ABSORBED DERMAL DOSE				
	Mix/load		Application	
Dermal exposure	0.08	mL/day	6.45	mL/day

Concen. of a.s. product or spray	65	mg/mL	0.975	mg/mL
Dermal exposure to a.s.	5.2	mg/day	6.289	mg/day
Percent absorbed	25	%	75	%
Absorbed dose	1.3	mg/day	4.717	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.01	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	1.95	mg/mL		
Inhalation exposure to a.s.	0.117	mg/day		
Percent absorbed	100	%		
Absorbed dose	0.117	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	6.134	mg/day		
Operator body weight	60	kg		
Operator exposure	0.102	mg/kg bw/day		
Amount of AOEL	**1022.3**	**%**		

1) risk assessment based on an assumed conversion of prothioconazole to desthio-prothioconazole of 50 % in the case of dermal exposure and 100 % for inhalative exposure (see summary of field studies, Appendix 4).

A 3.2 Worker exposure calculations (IIIA1 7.5.1)

A 3.2.1 Calculations for bixafen

Table A 24: Input parameters considered for the estimation of worker exposure

Intended use(s):	Cereals		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg a.s.
Application rate (AR):	0.0975	kg a.s./ha	**Transfer coefficient (TC):**	12500	cm²/person/h
Number of applications (NA):	2		**Work rate per day (WR):**	2	h/d
Body weight (BW):	60	kg/person	**PPE TC:**	1400	cm²/person/h
Dermal absorption (DA):	75	% ('worst case')			
AOEL	0.13	mg/kg bw/d			

Table A 25: Estimation of worker exposure towards bixafen using the German re-entry model

Without PPE [1]			**With PPE** [2]		
Worker (re-entry): Systemic dermal exposure after application in cereals					
SDE_W = (DFR x TC x WR x AR x NA x DA) / BW			SDE_W = (DFR x TC x WR x AR x NA x DA) / BW		
(1 x 12500 x 2 x 0.0975 x 2 x 75%) / 60			(1 x 1400 x 2 x 0.0975 x 2 x 75%) / 60		
External dermal exposure	4.875	mg/person	External dermal exposure	0.546	mg/person
External dermal exposure	0.08125	mg/kg bw/d	External dermal exposure	0.0091	mg/kg bw/d
Total systemic exposure	3.65625	mg/person	Total systemic exposure	0.4095	mg/person
Total systemic exposure	**0.060938**	**mg/kg bw/d**	**Total systemic exposure**	**0.006825**	**mg/kg bw/d**
% of AOEL	**46.9**	**%**	**% of AOEL**	**5.3**[3]	**%**

1) Potential exposure
2) With PPE: worker wearing work wear and sturdy footwear (e.g. rubber boots)
3) At 3 µg/cm²/kg a.s. DFR, exposure amounts to 15.9 % AOEL

A 3.2.2 Calculations for flupyram

Table A 26: Input parameters considered for the estimation of worker exposure

Intended use(s):	Cereals		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg a.s.
Application rate (AR):	0.0975	kg a.s./ha	**Transfer coefficient (TC):**	12500	cm²/person/h
Number of applications (NA):	2		**Work rate per day (WR):**	2	h/d
Body weight (BW):	60	kg/person	**PPE TC:**	1400	cm²/person/h

Dermal absorption (DA):	75	% ('worst case')	**DT50:**	30	days
AOEL	0.05	mg/kg bw/d	**Intervall:**	14	days

Table A 27: Estimation of worker exposure towards fluopyram using the German re-entry model (2 applications)

Without PPE [1)]			**With PPE** [2)]		
Worker (re-entry): Systemic dermal exposure after application in cereals					
SDE_W = (DFR x TC x WR x AR x NA x DA) / BW			SDE_W = (DFR x TC x WR x AR x NA x DA) / BW		
(1 x 12500 x 2 x 0.0975 x 2 x 75%) / 60			(1 x 1400 x 2 x 0.0975 x 2 x 75%) / 60		
External dermal exposure	4.875	mg/person	External dermal exposure	0.546	mg/person
External dermal exposure	0.08125	mg/kg bw/d	External dermal exposure	0.0091	mg/kg bw/d
Total systemic exposure	3.65625	mg/person	Total systemic exposure	0.4095	mg/person
Total systemic exposure	**0.060938**	**mg/kg bw/d**	**Total systemic exposure**	**0.006825**	**mg/kg bw/d**
% of AOEL	**121.9**	**%**	**% of AOEL**	**13.7**[3)]	**%**

1) Potential exposure
2) With PPE: worker wearing work wear and sturdy footwear (e.g. rubber boots)
3) At 3 µg/cm²/kg a.s. DFR, exposure amounts to 41.1 % AOEL

Table A 28: Estimation of worker exposure towards fluopyram using the German re-entry model (MAF of 1.5)

Without PPE [1)]			**With PPE** [2)]		
Worker (re-entry): Systemic dermal exposure after application in cereals					
SDE_W = (DFR x TC x WR x AR x NA x DA) / BW			SDE_W = (DFR x TC x WR x AR x NA x DA) / BW		
(1 x 12500 x 1.5 x 0.0975 x 2 x 75%) / 60			(1 x 1400 x 1.5 x 0.0975 x 2 x 75%) / 60		
External dermal exposure	3.65625	mg/person	External dermal exposure	0.182813	mg/person
External dermal exposure	0.060938	mg/kg bw/d	External dermal exposure	0.003047	mg/kg bw/d
Total systemic exposure	2.742188	mg/person	Total systemic exposure	0.137109	mg/person
Total systemic exposure	**0.045703**	**mg/kg bw/d**	**Total systemic exposure**	**0.002285**	**mg/kg bw/d**
% of AOEL	**91.4**[3)]	**%**	**% of AOEL**	**4.6**	**%**

1) Potential exposure
2) With PPE: worker wearing work wear and sturdy footwear (e.g. rubber boots)
3) At 3 µg/cm²/kg a.s. DFR, exposure amounts to 274 % AOEL

A 3.2.3 Calculations for prothioconazole

Table A 29: Input parameters considered for the estimation of worker exposure

Intended use(s):	Cereals		**Dislodgeable foliar residues (DFR):**	0.059	µg/cm²
Application rate (AR):	0.195	kg a.s./ha	**Transfer coefficient (TC):**	12500	cm²/person/h
Number of applications (NA):	2		**Work rate per day (WR):**	2	h/d
Body weight (BW):	60	kg/person	**PPE TC:**	1400	cm²/person/h
Dermal absorption (DA):	75	% ('worst case')			
AOEL	0.2	mg/kg bw/d			

Table A 30: Estimation of worker exposure towards prothioconazole using the German re-entry model

Without PPE [1)]			**With PPE** [2)]		
Worker (re-entry): Systemic dermal exposure after application in cereals					
SDE_W = (DFR x TC x WR x DA) / BW			SDE_W = (DFR x TC x WR x DA) / BW		
(0.059 x 12500 x 2 x 75%) / 60			(0.059 x 1400 x 2 x 75%) / 60		
External dermal exposure	1.475	mg/person	External dermal exposure	0.1652	mg/person
External dermal exposure	0.024583	mg/kg bw/d	External dermal exposure	0.002753	mg/kg bw/d
Total systemic exposure	1.10625	mg/person	Total systemic exposure	0.1239	mg/person
Total systemic exposure	**0.018438**	**mg/kg bw/d**	**Total systemic exposure**	**0.002065**	**mg/kg bw/d**
% of AOEL	**9.2**	**%**	**% of AOEL**	**1**	**%**

1) Potential exposure
2) With PPE: worker wearing work wear and sturdy footwear (e.g. rubber boots)

A 3.2.4 Calculations for desthio-prothioconazole

Table A 31: Input parameters considered for the estimation of worker exposure

Intended use(s):	Cereals		**Dislodgeable foliar residues (DFR):**	0.116	µg/cm²
Application rate (AR):	0.0975	kg a.s./ha	**DFR-value 3 days after application:**	0.012	µg/cm²
Number of applications (NA):	2		**Transfer coefficient (TC):**	12500	cm²/person/h
Body weight (BW):	60	kg/person	**Work rate per day (WR):**	2	h/d
Dermal absorption (DA):	75	% ('worst case')	**PPE TC:**	1400	cm²/person/h
AOEL	0.01	mg/kg bw/d			

Table A 32: Estimation of worker exposure towards desthio-prothioconazole using the German re-entry model

Without PPE 1)			**With PPE 2)**		
Worker (re-entry): Systemic dermal exposure after application in cereals					
SDE_W = (DFR x TC x WR x DA) / BW			SDE_W = (DFR x TC x WR x DA) / BW		
(0.116 x 12500 x 2 x 75%) / 60			(0.116 x 1400 x 2 x 75%) / 60		
External dermal exposure	2.9	mg/person	External dermal exposure	0.3248	mg/person
External dermal exposure	0.048333	mg/kg bw/d	External dermal exposure	0.005413	mg/kg bw/d
Total systemic exposure	2.175	mg/person	Total systemic exposure	0.2436	mg/person
Total systemic exposure	**0.03625**	**mg/kg bw/d**	**Total systemic exposure**	**0.00406**	**mg/kg bw/d**
% of AOEL	**362.5**	**%**	**% of AOEL**	**40.6**	**%**

1) Without PPE: worker wearing long sleeved shirt, long trousers ("permeable") but no gloves
2) Acceptable with PPE: worker wearing work wear and sturdy footwear (e.g. rubber boots)

Table A 33: Estimation of worker exposure towards desthio-prothioconazole using the German re-entry model, three days after application

Without PPE 1)			**With PPE 2)**		
Worker (re-entry): Systemic dermal exposure after application in cereals					
SDE_W = (DFR x TC x WR x DA) / BW			SDE_W = (DFR x TC x WR x DA) / BW		
(0.012 x 12500 x 2 x 75%) / 60			(0.012 x 1400 x 2 x 75%) / 60		
External dermal exposure	0.3	mg/person	External dermal exposure	0.0336	mg/person
External dermal exposure	0.005	mg/kg bw/d	External dermal exposure	0.00056	mg/kg bw/d
Total systemic exposure	0.225	mg/person	Total systemic exposure	0.0252	mg/person
Total systemic exposure	**0.00375**	**mg/kg bw/d**	**Total systemic exposure**	**0.00042**	**mg/kg bw/d**
% of AOEL	**37.5**	**%**	**% of AOEL**	**4.2**	**%**

1) Without PPE: worker wearing long sleeved shirt, long trousers ("permeable") but no gloves
2) Acceptable with PPE: worker wearing work wear and sturdy footwear (e.g. rubber boots)

A 3.3 Bystander and resident exposure calculations (IIIA1 7.4.1)

A 3.3.1 Calculations for bixafen

Table A 34: Input parameters considered for the estimation of bystander exposure

Intended use(s):	Cereals		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR):	0.0975	kg a.s./ha	**Exposed body surface area (BSA):**	1	m² (adults)
	9.75	mg/m²		0.21	m² (children)
Body weight (BW):	60	kg/person (adults)	**Specific Inhalation Exposure (I^*_A):**	0.001	mg/kg a.s. (6 hours, adults)
	16.15	kg/person (children)		0.000575	mg/kg a.s. (6 hours, children)
Dermal absorption (DA):	75	% ('worst case')	**Area Treated (A):**	20	ha/d (based on FCTM)

Inhalation absorption (IA):	100	%			
AOEL:	0.13	mg/kg bw/d	**Exposure duration (T):**	5	min

Table A 35: Estimation of bystander exposure towards bixafen

Adults			**Children**		
Bystander: Systemic dermal exposure during/after application (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(9.75 x 2.77% x 1 x 75%) / 60			(9.75 x 2.77% x 0.21 x 75%) / 16.15		
External dermal exposure	0.270075	mg/person	External dermal exposure	0.056716	mg/person
External dermal exposure	0.004501	mg/kg bw/d	External dermal exposure	0.003512	mg/kg bw/d
Systemic dermal exposure	**0.003376**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.002634**	**mg/kg bw/d**
Bystander: Systemic inhalation exposure during/after application (via spray drift)					
SIE_B = (I^*_A x AR x A x T x IA) / BW			SIE_B = (I^*_A x AR x A x T x IA) / BW		
(0.001 / 360 x 0.0975 x 20 x 5 x 100%) / 60			(0.000575 / 360 x 0.0975 x 20 x 5 x 100%) / 16.15		
External inhalation exposure	0.000027	mg/person	External inhalation exposure	0.000016	mg/person
External inhalation exposure	0	mg/kg bw/d	External inhalation exposure	0.000001	mg/kg bw/d
Systemic inhalation exposure	**0**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000001**	**mg/kg bw/d**
Total systemic exposure: $SE_B = SDE_B + SIE_B$			Total systemic exposure: $SE_B = SDE_B + SIE_B$		
Total systemic exposure	0.202583	mg/person	Total systemic exposure	0.042552	mg/person
Total systemic exposure	**0.003376**	**mg/kg bw/d**	**Total systemic exposure**	**0.002635**	**mg/kg bw/d**
% of AOEL	**2.6**	**%**	**% of AOEL**	**2.03**	**%**

Table A 36: Input parameters considered for the estimation of resident exposure

Intended use(s):	Cereals		**Drift (D):**	2.38	% (FC, 1 m)
Application rate (AR):	0.0975	kg a.s./ha	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
	0.000975	mg/cm^2		2600	cm^2/h (children)
Number of applications (NA):	2		**Turf Transferable Residues (TTR):**	5	%
Body weight (BW):	60	kg/person (adults)	**Exposure Duration (H):**	2	h
	16.15	kg/person (children)	**Airborne Concentration of Vapour (ACV):**	0	mg/m^3
Dermal absorption (DA):	75	% ('worst case')	**Inhalation Rate (IR):**	16.57	m^3/d (adults)
Inhalation absorption (IA):	100	%		8.31	m^3/d (children)
Oral absorption (OA):	100	%	**Saliva Extraction Factor (SE):**	50	%
AOEL:	0.13	mg/kg bw/d	**Surface Area of Hands (SA):**	20	cm^2
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm^2/d

Table A 37: Estimation of resident exposure towards bixafen

Adults			**Children**		
Residents: Systemic dermal exposure after application (via deposits caused by spray drift)					
SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW			SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW		
(0.000975 x 2 x 2.38% x 5% x 7300 x 2 x 75%) / 60			(0.000975 x 2 x 2.38% x 5% x 2600 x 2 x 75%) / 16.15		
External dermal exposure	0.033879	mg/person	External dermal exposure	0.012067	mg/person
External dermal exposure	0.000565	mg/kg bw/d	External dermal exposure	0.000747	mg/kg bw/d
Systemic dermal exposure	**0.000423**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.00056**	**mg/kg bw/d**
Residents: Systemic inhalation exposure after application (via vapour)					
SIE_R = (AC_V x IR x IA) / BW			SIE_R = (AC_V x IR x IA) / BW		
(0 x 16.57 x 100%) / 60			(0 x 8.31 x 100%) / 16.15		
External inhalation exposure		none	External inhalation exposure		none
Systemic inhalation exposure		**none**	**Systemic inhalation exposure**		**none**
			Residents: Systemic oral exposure (hand-to-mouth transfer)		
			$SOE_{R(H)}$ = (AR x NA x D x TTR x SE x SA x Freq x H x OA) / BW		
			(0.000975 x 2 x % x 5% x 50% x 20 x 20 x 2 x 100%) / 16.15		

			External oral exposure	0.000928	mg/person
			External oral exposure	0.000057	mg/kg bw/d
			Systemic oral exposure	**0.000057**	**mg/kg bw/d**
			Residents: Systemic oral exposure (object-to-mouth transfer)		
			$SOE_{R(O)}$ = (AR x NA x D x DFR x IgR x OA) / BW		
			(0.000975 x 2 x % x 20% x 25 x 100%) / 16.15		
			External oral exposure	0.000232	mg/person
			External oral exposure	0.000014	mg/kg bw/d
			Systemic oral exposure	**0.000014**	**mg/kg bw/d**
Total systemic exposure: $SE_R = SDE_R + SIE_R$			Total systemic exposure: $SE_R = SDE_R + SIE_R + SOE_{R(H)} + SOE_{R(O)}$		
Total systemic exposure	0.025409	mg/person	Total systemic exposure	0.01021	mg/person
Total systemic exposure	**0.000423**	**mg/kg bw/d**	**Total systemic exposure**	**0.000632**	**mg/kg bw/d**
% of AOEL	**0.33**	**%**	**% of AOEL**	**0.49**	**%**

A 3.3.2 Calculations for fluopyram

Table A 38: Input parameters considered for the estimation of bystander exposure

Intended use(s):	Cereals		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR):	0.0975	kg a.s./ha	**Exposed body surface area (BSA):**	1	m² (adults)
	9.75	mg/m²		0.21	m² (children)
Body weight (BW):	60	kg/person (adults)	**Specific Inhalation Exposure (I^*_A):**	0.001	mg/kg a.s. (6 hours, adults)
	16.15	kg/person (children)		0.000575	mg/kg a.s. (6 hours, children)
Dermal absorption (DA):	75	% ('worst case')	**Area Treated (A):**	20	ha/d (based on FCTM)
Inhalation absorption (IA):	100	%			
AOEL:	0.05	mg/kg bw/d	**Exposure duration (T):**	5	min

Table A 39: Estimation of bystander exposure towards fluopyram

Adults			**Children**		
Bystander: Systemic dermal exposure during/after application (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(9.75 x 2.77% x 1 x 75%) / 60			(9.75 x 2.77% x 0.21 x 75%) / 16.15		
External dermal exposure	0.270075	mg/person	External dermal exposure	0.056716	mg/person
External dermal exposure	0.004501	mg/kg bw/d	External dermal exposure	0.003512	mg/kg bw/d
Systemic dermal exposure	**0.003376**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.002634**	**mg/kg bw/d**
Bystander: Systemic inhalation exposure during/after application (via spray drift)					
SIE_B = (I^*_A x AR x A x T x IA) / BW			SIE_B = (I^*_A x AR x A x T x IA) / BW		
(0.001 / 360 x 0.0975 x 20 x 5 x 100%) / 60			(0.000575 / 360 x 0.0975 x 20 x 5 x 100%) / 16.15		
External inhalation exposure	0.000027	mg/person	External inhalation exposure	0.000016	mg/person
External inhalation exposure	0	mg/kg bw/d	External inhalation exposure	0.000001	mg/kg bw/d
Systemic inhalation exposure	**0**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000001**	**mg/kg bw/d**
Total systemic exposure: $SE_B = SDE_B + SIE_B$			Total systemic exposure: $SE_B = SDE_B + SIE_B$		
Total systemic exposure	0.202583	mg/person	Total systemic exposure	0.042552	mg/person
Total systemic exposure	**0.003376**	**mg/kg bw/d**	**Total systemic exposure**	**0.002635**	**mg/kg bw/d**
% of AOEL	**6.75**	**%**	**% of AOEL**	**5.27**	**%**

Table A 40: Input parameters considered for the estimation of resident exposure

Intended use(s):	Cereals		**Drift (D):**	2.38	% (FC, 1 m)
Application rate (AR):	0.0975	kg a.s./ha	**Transfer coefficient (TC):**	7300	cm²/h (adults)
	0.000975	mg/cm²		2600	cm²/h (children)
Number of applications (NA):	2		**Turf Transferable Residues (TTR):**	5	%
Body weight (BW):	60	kg/person (adults)	**Exposure Duration (H):**	2	h
	16.15	kg/person (children)	**Airborne Concentration of Vapour (ACV):**	0	mg/m³
Dermal absorption (DA):	75	% ('worst case')	**Inhalation Rate (IR):**	16.57	m³/d (adults)
Inhalation absorption (IA):	100	%		8.31	m³/d (children)

Oral absorption (OA):	100	%	**Saliva Extraction Factor (SE):**	50	%
AOEL:	0.05	mg/kg bw/d	**Surface Area of Hands (SA):**	20	cm^2
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm^2/d

Table A 41: Estimation of resident exposure towards fluopyram

Adults			**Children**		
Residents: Systemic dermal exposure after application (via deposits caused by spray drift)					
SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW			SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW		
(0.000975 x 2 x 2.38% x 5% x 7300 x 2 x 75%) / 60			(0.000975 x 2 x 2.38% x 5% x 2600 x 2 x 75%) / 16.15		
External dermal exposure	0.033879	mg/person	External dermal exposure	0.012067	mg/person
External dermal exposure	0.000565	mg/kg bw/d	External dermal exposure	0.000747	mg/kg bw/d
Systemic dermal exposure	**0.000423**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.00056**	**mg/kg bw/d**
Residents: Systemic inhalation exposure after application (via vapour)					
SIE_R = (AC_V x IR x IA) / BW			SIE_R = (AC_V x IR x IA) / BW		
(0 x 16.57 x 100%) / 60			(0 x 8.31 x 100%) / 16.15		
External inhalation exposure		none	External inhalation exposure		none
Systemic inhalation exposure		**none**	**Systemic inhalation exposure**		**none**
			Residents: Systemic oral exposure (hand-to-mouth transfer)		
			$SOE_{R(H)}$ = (AR x NA x D x TTR x SE x SA x Freq x H x OA) / BW		
			(0.000975 x 2 x % x 5% x 50% x 20 x 20 x 2 x 100%) / 16.15		
			External oral exposure	0.000928	mg/person
			External oral exposure	0.000057	mg/kg bw/d
			Systemic oral exposure	**0.000057**	**mg/kg bw/d**
			Residents: Systemic oral exposure (object-to-mouth transfer)		
			$SOE_{R(O)}$ = (AR x NA x D x DFR x IgR x OA) / BW		
			(0.000975 x 2 x % x 20% x 25 x 100%) / 16.15		
			External oral exposure	0.000232	mg/person
			External oral exposure	0.000014	mg/kg bw/d
			Systemic oral exposure	**0.000014**	**mg/kg bw/d**
Total systemic exposure: $SE_R = SDE_R + SIE_R$			Total systemic exposure: $SE_R = SDE_R + SIE_R + SOE_{R(H)} + SOE_{R(O)}$		
Total systemic exposure	0.025409	mg/person	Total systemic exposure	0.01021	mg/person
Total systemic exposure	**0.000423**	**mg/kg bw/d**	**Total systemic exposure**	**0.000632**	**mg/kg bw/d**
% of AOEL	**0.85**	**%**	**% of AOEL**	**1.26**	**%**

A 3.3.3 Calculations for prothioconazole

Table A 42: Input parameters considered for the estimation of bystander exposure

Intended use(s):	Cereals		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR):	0.195	kg a.s./ha	**Exposed body surface area (BSA):**	1	m² (adults)
	19.5	mg/m^2		0.21	m² (children)
Body weight (BW):	60	kg/person (adults)	**Specific Inhalation Exposure (I^*_A):**	0.001	mg/kg a.s. (6 hours, adults)
	16.15	kg/person (children)		0.000575	mg/kg a.s. (6 hours, children)
Dermal absorption (DA):	75	% ('worst case')	**Area Treated (A):**	20	ha/d (based on FCTM)
Inhalation absorption (IA):	100	%			
AOEL:	0.2	mg/kg bw/d	**Exposure duration (T):**	5	min

Table A 43: Estimation of bystander exposure towards prothioconazole

Adults	**Children**
Bystander: Systemic dermal exposure during/after application (via spray drift)	
SDE_B = (AR x D x BSA x DA) / BW	SDE_B = (AR x D x BSA x DA) / BW

(19.5 x 2.77% x 1 x 75%) / 60			(19.5 x 2.77% x 0.21 x 75%) / 16.15		
External dermal exposure	0.54015	mg/person	External dermal exposure	0.113432	mg/person
External dermal exposure	0.009003	mg/kg bw/d	External dermal exposure	0.007024	mg/kg bw/d
Systemic dermal exposure	**0.006752**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.005268**	**mg/kg bw/d**
Bystander: Systemic inhalation exposure during/after application (via spray drift)					
$SIE_B = (I^*_A$ x AR x A x T x IA) / BW			$SIE_B = (I^*_A$ x AR x A x T x IA) / BW		
(0.001 / 360 x 0.195 x 20 x 5 x 100%) / 60			(0.000575 / 360 x 0.195 x 20 x 5 x 100%) / 16.15		
External inhalation exposure	0.000054	mg/person	External inhalation exposure	0.000031	mg/person
External inhalation exposure	0.000001	mg/kg bw/d	External inhalation exposure	0.000002	mg/kg bw/d
Systemic inhalation exposure	**0.000001**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000002**	**mg/kg bw/d**
Total systemic exposure: $SE_B = SDE_B + SIE_B$			Total systemic exposure: $SE_B = SDE_B + SIE_B$		
Total systemic exposure	0.405167	mg/person	Total systemic exposure	0.085105	mg/person
Total systemic exposure	**0.006753**	**mg/kg bw/d**	**Total systemic exposure**	**0.00527**	**mg/kg bw/d**
% of AOEL	**3.38**	**%**	**% of AOEL**	**2.63**	**%**

Table A 44: Input parameters considered for the estimation of resident exposure

Intended use(s):	Cereals		**Drift (D):**	2.38	% (FC, 1 m)
Application rate (AR):	0.195	kg a.s./ha	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
	0.00195	mg/cm^2		2600	cm^2/h (children)
Number of applications (NA):	2		**Turf Transferable Residues (TTR):**	5	%
Body weight (BW):	60	kg/person (adults)	**Exposure Duration (H):**	2	h
	16.15	kg/person (children)	**Airborne Concentration of Vapour (ACV):**	0	mg/m^3
Dermal absorption (DA):	75	% ('worst case')	**Inhalation Rate (IR):**	16.57	m^3/d (adults)
Inhalation absorption (IA):	100	%		8.31	m^3/d (children)
Oral absorption (OA):	100	%	**Saliva Extraction Factor (SE):**	50	%
AOEL:	0.2	mg/kg bw/d	**Surface Area of Hands (SA):**	20	cm^2
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm^2/d

Table A 45: Estimation of resident exposure towards prothioconazole

Adults			**Children**		
Residents: Systemic dermal exposure after application (via deposits caused by spray drift)					
$SDE_R = (AR \times NA \times D \times TTR \times TC \times H \times DA) / BW$			$SDE_R = (AR \times NA \times D \times TTR \times TC \times H \times DA) / BW$		
(0.00195 x 2 x 2.38% x 5% x 7300 x 2 x 75%) / 60			(0.00195 x 2 x 2.38% x 5% x 2600 x 2 x 75%) / 16.15		
External dermal exposure	0.067759	mg/person	External dermal exposure	0.024133	mg/person
External dermal exposure	0.001129	mg/kg bw/d	External dermal exposure	0.001494	mg/kg bw/d
Systemic dermal exposure	**0.000847**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001121**	**mg/kg bw/d**
Residents: Systemic inhalation exposure after application (via vapour)					
$SIE_R = (AC_V$ x IR x IA) / BW			$SIE_R = (AC_V$ x IR x IA) / BW		
(0 x 16.57 x 100%) / 60			(0 x 8.31 x 100%) / 16.15		
External inhalation exposure		none	External inhalation exposure		none
Systemic inhalation exposure		**none**	**Systemic inhalation exposure**		**none**
			Residents: Systemic oral exposure (hand-to-mouth transfer)		
			$SOE_{R(H)} = (AR \times NA \times D \times TTR \times SE \times SA \times Freq \times H \times OA) / BW$		
			(0.00195 x 2 x % x 5% x 50% x 20 x 20 x 2 x 100%) / 16.15		
			External oral exposure	0.001856	mg/person
			External oral exposure	0.000115	mg/kg bw/d
			Systemic oral exposure	**0.000115**	**mg/kg bw/d**
			Residents: Systemic oral exposure (object-to-mouth transfer)		
			$SOE_{R(O)} = (AR \times NA \times D \times DFR \times IgR \times OA) / BW$		
			(0.00195 x 2 x % x 20% x 25 x 100%) / 16.15		
			External oral exposure	0.000464	mg/person
			External oral exposure	0.000029	mg/kg bw/d

			Systemic oral exposure	**0.000029**	**mg/kg bw/d**
Total systemic exposure: $SE_R = SDE_R + SIE_R$			Total systemic exposure: $SE_R = SDE_R + SIE_R + SOE_{R(H)} + SOE_{R(O)}$		
Total systemic exposure	0.050819	mg/person	Total systemic exposure	0.02042	mg/person
Total systemic exposure	**0.000847**	**mg/kg bw/d**	**Total systemic exposure**	**0.001264**	**mg/kg bw/d**
% of AOEL	**0.42**	**%**	**% of AOEL**	**0.63**	**%**

A 3.3.4 Calculations for desthio-prothioconazole

Table A 46: Input parameters considered for the estimation of bystander exposure

Intended use(s):	Cereals		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR)[1]:	0.0975 or 0.195	kg a.s./ha	**Exposed body surface area (BSA):**	1	m² (adults)
	9.75 or 19.5	mg/m²		0.21	m² (children)
Body weight (BW):	60	kg/person (adults)	**Specific Inhalation Exposure (I^*_A):**	0.001	mg/kg a.s. (6 hours, adults)
	16.15	kg/person (children)		0.000575	mg/kg a.s. (6 hours, children)
Dermal absorption (DA):	75	% ('worst case')	**Area Treated (A):**	20	ha/d (based on FCTM)
Inhalation absorption (IA):	100	%			
AOEL:	0.01	mg/kg bw/d	**Exposure duration (T):**	5	min

[1] risk assessment based on an assumed conversion of prothioconazole to desthio-prothioconazole of 50 % in the case of dermal exposure and 100 % for inhalative exposure (see summary of field studies, Appendix 4).

Table A 47: Estimation of bystander exposure towards desthio-prothioconazole

Adults			**Children**		
Bystander: Systemic dermal exposure during/after application (via spray drift)					
$SDE_B = (AR \times D \times BSA \times DA) / BW$			$SDE_B = (AR \times D \times BSA \times DA) / BW$		
(9.75 x 2.77% x 1 x 75%) / 60			(9.75 x 2.77% x 0.21 x 75%) / 16.15		
External dermal exposure	0.270075	mg/person	External dermal exposure	0.056716	mg/person
External dermal exposure	0.004501	mg/kg bw/d	External dermal exposure	0.003512	mg/kg bw/d
Systemic dermal exposure	**0.003376**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.002634**	**mg/kg bw/d**
Bystander: Systemic inhalation exposure during/after application (via spray drift)					
$SIE_B = (I^*_A \times AR \times A \times T \times IA) / BW$			$SIE_B = (I^*_A \times AR \times A \times T \times IA) / BW$		
(0.001 / 360 x 0.195 x 20 x 5 x 100%) / 60			(0.000575 / 360 x 0.195 x 20 x 5 x 100%) / 16.15		
External inhalation exposure	0.000054	mg/person	External inhalation exposure	0.000031	mg/person
External inhalation exposure	0.000001	mg/kg bw/d	External inhalation exposure	0.000002	mg/kg bw/d
Systemic inhalation exposure	**0.000001**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000002**	**mg/kg bw/d**
Total systemic exposure: $SE_B = SDE_B + SIE_B$			Total systemic exposure: $SE_B = SDE_B + SIE_B$		
Total systemic exposure	0.20261	mg/person	Total systemic exposure	0.042568	mg/person
Total systemic exposure	**0.003377**	**mg/kg bw/d**	**Total systemic exposure**	**0.002636**	**mg/kg bw/d**
% of AOEL	**33.77**	**%**	**% of AOEL**	**26.36**	**%**

Table A 48: Input parameters considered for the estimation of resident exposure

Intended use(s):	Cereals		**Drift (D):**	2.38	% (FC, 1 m)
Application rate (AR):	0.0975	kg a.s./ha	**Transfer coefficient (TC):**	7300	cm²/h (adults)
	0.000975	mg/cm²		2600	cm²/h (children)
Number of applications (NA):	2		**Turf Transferable Residues (TTR):**	5	%
Body weight (BW):	60	kg/person (adults)	**Exposure Duration (H):**	2	h
	16.15	kg/person (children)	**Airborne Concentration of Vapour (ACV):**	0	mg/m³
Dermal absorption (DA):	75	% ('worst case')	**Inhalation Rate (IR):**	16.57	m³/d (adults)
Inhalation absorption (IA):	100	%		8.31	m³/d (children)
Oral absorption (OA):	100	%	**Saliva Extraction Factor (SE):**	50	%
AOEL:	0.01	mg/kg bw/d	**Surface Area of Hands (SA):**	20	cm²
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%

			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm^2/d

Table A 49: Estimation of resident exposure towards desthio-prothioconazole

Adults			**Children**		
Residents: Systemic dermal exposure after application (via deposits caused by spray drift)					
SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW			SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW		
(0.000975 x 2 x 2.38% x 5% x 7300 x 2 x 75%) / 60			(0.000975 x 2 x 2.38% x 5% x 2600 x 2 x 75%) / 16.15		
External dermal exposure	0.033879	mg/person	External dermal exposure	0.012067	mg/person
External dermal exposure	0.000565	mg/kg bw/d	External dermal exposure	0.000747	mg/kg bw/d
Systemic dermal exposure	**0.000423**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.00056**	**mg/kg bw/d**
Residents: Systemic inhalation exposure after application (via vapour)					
SIE_R = (AC_V x IR x IA) / BW			SIE_R = (AC_V x IR x IA) / BW		
(0 x 16.57 x 100%) / 60			(0 x 8.31 x 100%) / 16.15		
External inhalation exposure		none	External inhalation exposure		none
Systemic inhalation exposure		**none**	**Systemic inhalation exposure**		**none**
			Residents: Systemic oral exposure (hand-to-mouth transfer)		
			$SOE_{R(H)}$ = (AR x NA x D x TTR x SE x SA x Freq x H x OA) / BW		
			(0.000975 x 2 x % x 5% x 50% x 20 x 20 x 2 x 100%) / 16.15		
			External oral exposure	0.000928	mg/person
			External oral exposure	0.000057	mg/kg bw/d
			Systemic oral exposure	**0.000057**	**mg/kg bw/d**
			Residents: Systemic oral exposure (object-to-mouth transfer)		
			$SOE_{R(O)}$ = (AR x NA x D x DFR x IgR x OA) / BW		
			(0.000975 x 2 x % x 20% x 25 x 100%) / 16.15		
			External oral exposure	0.000232	mg/person
			External oral exposure	0.000014	mg/kg bw/d
			Systemic oral exposure	**0.000014**	**mg/kg bw/d**
Total systemic exposure: $SE_R = SDE_R + SIE_R$			Total systemic exposure: $SE_R = SDE_R + SIE_R + SOE_{R(H)} + SOE_{R(O)}$		
Total systemic exposure	0.025409	mg/person	Total systemic exposure	0.01021	mg/person
Total systemic exposure	**0.000423**	**mg/kg bw/d**	**Total systemic exposure**	**0.000632**	**mg/kg bw/d**
% of AOEL	**4.23**	**%**	**% of AOEL**	**6.32**	**%**

Appendix 4 Detailed evaluation of exposure and DFR studies relied upon (IIIA1 7.3.3, IIIA1 7.7.1)

A 4.1 Measurement of operator exposure (IIIA1 7.3.3)

Comments of zRMS:	Acceptable; used in evaluation

Reference:	OECD IIIA1 7.3.3
Main report	Maasfeld, W., Sutor, P. & Hamacher, G., 2009, Operator exposure and safety to prothioconazole containing products in spray applications. ASB2010-11547
Report 1	Maasfeld, W., 2002; Determination of exposure to JAU 6476 and JAU 6476-desthio (SXX 0665) during mixing/loading and application of JAU 6476 in cereals. Report No & Document No: MR-036/02, M-040604-01-1.
Report 2	Maasfeld, W., Sutor, P., 2007; Determination of exposure during mixing/loading and application of Proline in cereals. Report No & Document No: MR-156/05, M-285798-01-1
Report 3	Maasfeld, W., 2007; Determination of exposure during mixing/loading and application of prothioconazole in cereals and canola. Report No & Document No: MR-244/07, M-286545-01-1
Guidelines:	OECD Series on testing and assessment no. 9 (1997): Guidance Document for the conduct of studies of occupational exposure to pesticides during agricultural application
GLP:	Yes (certified laboratory)
Acceptability:	The reports are considered to be acceptable.

Operator exposure to prothioconazole and its metabolite desthio-prothioconazole during spray application in cereals and canola was determined in three field studies. In total, twenty replicates – performed by fifteen operators – were monitored.
The first study – conducted in 2000 – was performed under confined conditions as the active substance was still under development. Therefore, the area treated was restricted to 20 ha, nevertheless different types of application equipment were used. Three Bayer employees were involved as operators. The second study was conducted in 2005 with five professional farmers applying on their own fields (19 ha to 49 ha). In the third study seven professional farmers applied prothioconazole on their fields (23 ha to 180 ha). All studies were designed as mixer/loader/applicator studies. The application rate in the studies ranged from 175 g to 200 g prothioconazole/ha diluted in 150 L/ha to 300 L/ha. All tractors were equipped with closed cabins.

Materials and methods

Dermal and inhalation exposure were measured by passive dosimetry. The body exposure was determined by analysing the outer garment (cotton shirt, trousers) and inner garment (long underwear, representing skin). Exposure to the head was determined by a cap in some cases. Hand exposure was determined via glove rinsing and hand washing. Inhalation exposure was measured via IOM-samplers equipped with glass fiber filters that were located in the breathing zone of the operator and connected to a pump.

Results

The normalized exposure figures from all studies are listed in the tables below. Normalization was performed with regard to the total amount of prothioconazole handled per day.
Figures in bold indicate that they consist of at least one sample analysis > LOQ. The LOQ per sample was 50 µg (outer garments), 10 µg (undergarments) and 5 µg (hand wash water) for prothioconazole and 20 µg, 2 µg and 2 µg for desthio-prothioconazole, respectively.

Table A 50: Normalized dermal exposure to prothioconazole (in mg/kg prothioconazole)

Study	Operator ID	Outer clothing mg/kg a.s.	Under-garments mg/kg a.s.	Cap (head) mg/kg a.s.	Glove rinse			Hand washing mg/kg a.s.
					Mix/load mg/kg a.s.	Appl. mg/kg a.s.	Total mg/kg a.s.	
01	A1	**0.069**	0.0038	0.0063	**0.422**	---	**0.422**	0.0006
01	B1	0.025	0.0037	0.0062	**1.23**	---	**1.23**	0.0006
01	C1	**0.032**	0.0037	0.0062	**0.878**	---	**0.878**	0.0006
01	B2	0.025	0.0037	0.0062	**0.407**	---	**0.407**	0.0006
01	C2	**0.115**	0.0037	0.0062	**3.55**	---	**3.55**	**0.0018**
01	A3	**0.102**	0.0037	0.0062	**2.66**	---	**2.66**	0.0012
01	C3	**0.039**	0.0037	0.0062	**5.27**	---	**5.27**	**0.0020**
01	B3	0.025	0.0037	0.0062	**3.42**	---	**3.42**	0.0012
02	A	**0.111**	0.0011	0.0018	**0.686**	<0.001	**0.686**	**0.0093**
02	B	**0.040**	0.0038	0.0063	**0.690**	**0.229**	**0.919**	0.0019
02	C	**0.285**	0.0043	0.0071	**0.999**	---	**0.999**	0.0014
02	D	**0.010**	0.0011	0.0019	**0.047**	**0.046**	**0.093**	0.0008
02	E	**0.031**	0.0028	0.0047	**0.285**	---	**0.285**	0.0014
03	A	**0.035**	**0.0063**	0.0054	**0.687**	**0.041**	**0.728**	**0.0031**
03	B	**0.025**	0.0012	0.0020	**0.606**	---	**0.606**	0.0012
03	C	**0.156**	**0.0007**	0.0008	**0.095**	---	**0.095**	**0.0004**
03	D	**0.012**	0.0013	0.0021	**0.040**	---	**0.040**	0.0004
03	E	**0.148**	0.0027	0.0045	**0.243**	**0.293**	**0.536**	**0.0017**
03	F	**0.042**	0.0021	0.0035	**0.834**	**0.002**	**0.836**	0.0011
03	H	**0.225**	**0.0017**	0.0017	**0.220**	---	**0.220**	0.0003

Table A 51: Normalized dermal exposure to desthio-prothioconazole (in mg/kg prothioconazole)

Study	Operator ID	Outher clothing mg/kg a.s.	Under-garments mg/kg a.s.	Cap (head) mg/kg a.s.	Glove rinse			Hand washing mg/kg a.s.
					Mix/load mg/kg a.s.	Appl. mg/kg a.s.	Total mg/kg a.s.	
01	A1	**0.019**	0.0008	0.0025	**0.003**	---	**0.003**	0.0003
01	B1	0.010	0.0007	0.0025	**0.008**	---	**0.008**	0.0002
01	C1	0.010	0.0007	0.0025	**0.007**	---	**0.007**	0.0002
01	B2	0.010	0.0007	0.0025	**0.021**	---	**0.021**	0.0002
01	C2	0.010	0.0007	0.0025	**0.050**	---	**0.050**	0.0002
01	A3	**0.018**	0.0007	0.0025	**0.112**	---	**0.112**	0.0005
01	C3	**0.013**	0.0007	0.0025	**0.185**	---	**0.185**	0.0005
01	B3	**0.012**	0.0007	0.0025	**0.151**	---	**0.151**	**0.0018**
02	A	**0.034**	**0.0003**	0.0007	**0.045**	<0.001	**0.045**	**0.0088**
02	B	**0.018**	0.0008	0.0025	**0.062**	**0.025**	**0.087**	**0.0011**
02	C	**0.029**	0.0009	0.0029	**0.073**	---	**0.073**	0.0006
02	D	**0.005**	0.0002	0.0008	**0.004**	**0.009**	**0.013**	0.0003
02	E	0.008	0.0006	0.0019	**0.016**	---	**0.016**	0.0006
03	A	**0.036**	0.0007	0.0022	**0.072**	**0.020**	**0.092**	0.0007
03	B	**0.006**	0.0002	0.0008	**0.014**	---	**0.014**	**0.0011**
03	C	**0.017**	**0.0003**	0.0003	**0.003**	---	**0.003**	**0.0006**
03	D	**0.005**	0.0003	0.0008	**0.006**	---	**0.006**	0.0002
03	E	**0.053**	**0.0010**	0.0018	**0.015**	**0.053**	**0.068**	**0.0013**
03	F	**0.010**	0.0004	0.0014	**0.041**	**0.004**	**0.045**	0.0004
03	H	**0.007**	0.0002	0.0007	**0.013**	---	**0.013**	**0.0004**

Though, 17 out of 20 replicates had measurable residues of prothioconazole on their outer clothing, only three operators showed measurable residues of prothioconazole on their undergarments. For desthio-prothioconazole in 15 out of 20 replicates measureable residues were found on the outer clothing but only

three operators had measured residues of both prothioconazole and desthio-prothiocoonazole concurrently on his undergarments.

Exposure to the head was determined for 15 replicates. In all cases – for prothioconazole as well as for desthio-prothioconazole – the results were below the LOQ. Hence, it is acceptable that these results can be extrapolated to the other five replicates to calculate a hypothetical head exposure.

The results of the protective gloves show higher exposure for the first study. The reason for this is mainly due to the fact that the operators in the other studies rinsed their gloves under water before taking them off (in accordance to good occupational hygiene practice).

The inhalation exposure to prothioconazole and desthio-prothioconazole is presented in Table A 41. Only prothioconazole was found and also only in a few replicates. The absolute residues of prothioconazole determined on the sampling devices were very low and did not exceed a level of four times the LOQ (0.1 µg/sample). Desthio-prothioconazole was not detected at all. Therefore, as a 'worst case' assumption, 100 % conversion of prothioconazole to desthio-prothioconazole is taken into account for estimation of inhalative exposure for risk assessment.

Table A 52: Normalized inhalation exposure to prothioconazole and desthio-prothioconazole (in µg/kg prothioconazole)

Study	Operator ID	Prothioconazole		Desthio-prothioconazole	
		Mix/load µg/kg a.s.	**Appl.** µg/kg a.s.	**Mix/load** µg/kg a.s.	**Appl.** µg/kg a.s.
01	A1	0.35	0.35	0.35	0.35
01	B1	**0.43**	0.35	0.35	0.35
01	C1	0.35	0.35	0.35	0.35
01	B2	**0.43**	0.35	0.35	0.35
01	C2	0.35	0.35	0.35	0.35
01	A3	0.17	0.17	0.17	0.17
01	C3	0.17	0.17	0.17	0.17
01	B3	0.17	0.17	0.17	0.17
02	A	**0.10**	**0.05**	0.03	0.03
02	B	0.09	0.09	0.09	0.09
02	C	0.10	0.06	0.10	0.06
02	D	0.03	0.03	0.03	0.03
02	E	0.07	0.07	0.07	0.07
03	A	0.15	0.15	0.15	0.15
03	B	0.05	**0.25**	0.05	0.05
03	C	0.02	0.02	0.02	0.02
03	D	0.06	0.06	0.06	0.06
03	E	0.13	**0.30**	0.13	0.13
03	F	0.10	**0.20**	0.10	0.10
03	H	0.05	0.05	0.05	0.05

For the risk assessment of prothioconazole the potential and actual body and hand exposure are calculated. The potential body exposure results from deposits on outer clothing, undergarments and cap while the actual body exposure results only from deposits on undergarment and cap. Potential hand exposure is calculated by adding up values for protective gloves and hand washings; actual hand exposure is represented by hand washings. The results (including inhalation) are given in Table A 53.

Table A 53: Specific exposure figures for prothioconazole during downward directed boom application

Type of exposure	Prothioconazole [mg/kg a.s.]	
	Geometric mean	75th percentile
Potential body exposure	0.060	0.116
Potential hand exposure	0.628	1.06
Actual body exposure	0.007	0.010
Actual hand exposure	0.001	0.002
Inhalation exposure (mix./load.)	0.00012	0.00022
Inhalation exposure (appl.)	0.00013	0.00031

For estimating potential dermal exposure to desthio-prothioconazole the highest single figures for outer clothing, undergarments, cap, protective gloves and hand washings are added up. For estimating actual dermal exposure the highest single figures for undergarments, cap and hand washings are added up. For estimating inhalation exposure the normalized values of 0.17 µg/kg a.s. for mixing/loading and application, each, are taken and added up (consistent with the use and analysis of one sampling device per task). The resulting figures are presented in the following table.

Table A 54: Specific exposure figures for desthio-prothioconazole during downward directed boom application

Type of exposure	Desthio-prothioconazole [mg/kg a.s.]
Potential dermal exposure	0.251
Actual dermal exposure	0.013
Inhalation exposure	0.00034

The conversion of prothioconazole to desthio-prothioconazole was found to be very variable in the studies ranging from 1 % to 60 % in study 1, from 3 % to 60 % in study 2 and from 2 % to 72 % in study 3 (90. percentile = 50 %).

A 4.2 Determination of dislodgeable foliar residues (IIIA1 7.7.1)

Comments of zRMS:	Acceptable; deviations but used in evaluation

Reference: OECD IIIA1 7.7.1

Report: Determination of the dislodgeable foliar residues (DFR) of prothioconazole in/on wheat after spray application of JAU 6476 & KWG 4168 EC 460 in the field in Germany
Stuke, S.; 2013
12-2901 ! RAAAN168 !, ASB2014-1765

Guidelines: US EPA OPPTS 875.2100 Foliar Dislodgeable Residue Dissipation (formerly US EPA Pesticide Assessment Guidelines Subdivision K: Reentry Protection, Series 132-1 (a))

Deviations: Due to the lack of addition of cysteine hydrochloride for stabilization to the field spike samples for prothioconazole, i.e. samples were not fortified, low field recoveries were obtained at the low and intermediate fortification level. All other samples were not affected, so that also the field samples were not. The average laboratory recoveries were within the acceptable range (94 – 99%) demonstrating the reliability of the method.

GLP: Yes (certified laboratory)

Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	JAU 6476 & KWG 4168 (EC 460), containing 160 g/L prothioconazole and 300 g/L spiroxamine
Culture treated and trial details	Wheat, 1 trial with 3 sub-plots of 324 m² in total, conducted in Germany during the season 2012

Application parameters						
Crop and situation (e.g. growth stage of crop)	**F/G or I [2)]**	**Application**		**Application rate**		
		Method / Kind (incl. application technique [3)])	**Number of applications (interval between)**	**Liters product/ha**	**Water L/ha**	**Kg a.s/ha a) one application b) two applications**
Wheat BBCH 47-61	F	Spraying FCTM	2 (14 days)	1.25	100 - 150	Prothioconazole: a) 0.2 b) 0.4 Spiroxamine: a) 0.375 b) 0.75

Sample material	Leaf punches from upper, middle and lower portions of crop taken after the spray had dried.(80 disks per sample, disk area for one side of leaf surface: 1.25 cm² each, i.e. 200 cm² total double-sided)
Controls	Leaf punches taken prior to first application
Dislodging of leaf samples	Washing with 0.01 % Aerosol OT solution in tap water, 2 successive washings à 10 min, Stabilisation of prothioconazole in pooled samples by cysteine-hydrochloride (250 g/L)
Analysed substances	Prothioconazole and desthio-prothioconazole
Storage period for samples	210 – 252 days, deep-frozen
Method/Principle of measurement	01354/HPLC-MS/MS
Limit of quantifiacation	5 µg/L / 0.005 µg/cm² for prothioconazole and desthio-prothioconazole
Recoveries	Prothioconazole field: low due to mistake (29 – 87%, see deviations) laboratory: 94 – 99% desthio-prothioconazole field: 81 – 97 % laboratory: 90 – 98 % No correction for field recovery was performed.

Results and discussions

Table A 55: Amounts of prothioconazole and desthio-prothioconazole two-sided dislodgeable foliar residues on wheat

Sampling		**Dislodgeable foliar residues [µg a.s./cm²]**	
Day after 1st application	**Day after 2nd application**	**Prothioconazole**	**Desthio-prothioconazole**
-0		<0.005	<0.005
0		0.059	0.096
1		0.006	0.083

3		<0.005	0.012
7		<0.005	<0.005
14	-0	<0.005	<0.005
14	**0**	0.042	0.116
15	1	<0.005	0.067
17	3	<0.005	0.008
22	8	<0.005	<0.005
27	13	<0.005	<0.005
35	21	<0.005	<0.005
42	28	<0.005	<0.005

" - " = before respective treatment
Figures in bold indicate day of treatment

Conclusion

The results show that there is a decline for both analytes, prothioconazole and desthio-prothioconazole, to DFR values <LOQ within 3 days after the first application for prothioconazole and within 7 days after application for desthio-prothioconazole. No increase or accumulation of residues on the leaf surface was observed with the second application. Measured maximum residues were found directly after applications and amounted to 0.059 µg/cm² for prothioconazole and to 0.116 µg/cm² for desthio-prothioconazole.

REGISTRATION REPORT
Part B

Section 4 Metabolism and Residues

Detailed summary of the risk assessment

Product name: Ascra Xpro

Active Substances: Bixafen 65 g/L
Fluopyram 65 g/L
Prothioconazole 130 g/L

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Applicant: Bayer CropScience

Date: 05/10/2017

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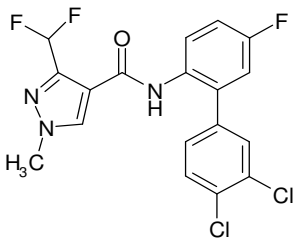
4 METABOLISM AND RESIDUES DATA

4.1 Evaluation of the active substances

4.1.1 Bixafen

Table 4.1-1: Identity of the active substance

Structural formula	
Common Name	Bixafen
CAS number	581809-46-3

4.1.1.1 Storage stability

A brief summary of the storage stability data on bixafen is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR (UK, 2011, ASB2011-11716, Addendum ASB2012-9669), EFSA's Conclusion on the peer review of bixafen (ASB2012-14631) and EFSA´s Reasoned Opinions on the setting of MRLs for bixafen (ASB2012-3256, ASB2012-3453).

Table 4.1-2: Stability of residues (Annex IIA, point 6.1)

Stability of bixafen, bixafen-desmethyl	The storage stability of bixafen and its metabolite bixafen-desmethyl was investigated in wheat (grain, straw and forage), potato tubers, lettuce and oilseed rape during freezer storage periods of 12 months (ASB2009-5839) and 24 months ASB2011-13507). All samples were fortified at a level of 0.1 mg/kg and stored in glass bottles at -18°C. Samples were analysed after 0, 30, 60, 90, 180, 360 (ASB2009-5839) and additionally after 540 and 720 days (ASB2011-13507). Both analytes remained stable during at least 12 or 24 months of storage.

4.1.1.2 Metabolism in plants and plant residue definition(s)

A brief summary of the metabolism of bixafen in plants is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR (UK, 2011, ASB2011-11716, Addendum ASB2012-9669), EFSA's Conclusion on the peer review of bixafen (ASB2012-14631) and EFSA´s Reasoned Opinions on the setting of MRLs for bixafen (ASB2012-3256, ASB2012-3453).

Table 4.1-3: Metabolism in plants (Annex IIA, point 6.2.1; 6.5.1, 6.5.2, 6.6.2 and 6.7.1)

Plant groups covered	Cereals (wheat), pulses/oilseeds (soya bean) – Wheat (ASB2009-5872): [pyrazole-5-^{14}C] label, two spray applications with 125 g/ha at BBCH 29-31 and 150 g/ha at BBCH 69, PHI 50 days – Wheat (ASB2009-5873): [dichlorophenyl-UL-^{14}C] label, two spray applications with 125 g/ha at BBCH 29-31 and 150 g/ha at BBCH 69, PHI 50 days In all commodities investigated (forage, hay, straw and grain) parent bixafen was the major residue with ≥90 % TRR. The main metabolic reaction was the demethylation of parent compound, though the main metabolite bixafen-desmethyl resulting therefrom was detected only in low amounts. – Soybean (ASB2009-5874): [pyrazole-5-^{14}C] label, three spray applications with 60 g/ha each (BBCH 60, BBCH 69 and BBCH 88), forage and hay already harvested after the 2nd application, seeds and straw harvested 26 days after the 3rd application – Soybean (ASB2009-5875): [dichlorophenyl-UL-^{14}C] label, three spray applications with 60 g/ha each (BBCH 60, BBCH 69 and BBCH 88), forage and hay already harvested after the 2nd application, seeds and straw harvested 26 days after the 3rd application In soybean matrices bixafen was the major residue with ≥90 % TRR in forage, straw and hay and up to 30 % in seeds. Metabolites were only found in minor amounts (bixafen-desmethyl and desmethyl-pyrazole-4-carboxylic acid). Main metabolic reaction was demethylation of parent compound.
Rotational crops	– Confined study (ASB2009-5955): [pyrazole-5-^{14}C], spray application of 0.785 kg/ha to bare soil, rotational crops wheat, turnips and Swiss chard planted/sewn at PBI 30, 138 and 285 days – Confined study (ASB2009-5956): [dichlorophenyl-UL-^{14}C] label, spray application of 0.847 kg/ha to bare soil, rotational crops wheat, turnips and Swiss chard planted/sewn at PBI 30, 138 and 285 days In rotational crops, TRR levels up to 0.492 mg as-eq/kg occurred, highest residues being found in wheat straw and hay. Wheat forage, chard, turnips and grain contained radioactive residues at lower levels not exceeding 0.08 mg/kg. Bixafen and bixafen-desmethyl were the dominant residues (reaching both levels of more than 70% TRR).
Metabolism in rotational crops similar to metabolism in primary crops? (yes/no)	Yes, except for a more extensive degradation of bixafen into pyrazole derivated metabolites in rotated leafy crops (EFSA, ASB2012-14631).
Distribution of the residue in peel/ pulp	Not applicable

Processed commodities (nature of residue)	The effect of industrial processing on bixafen residues was investigated under typical processing conditions simulating pasteurisation, cooking and sterilisation (ASB2009-5953). Sterile buffer solutions were fortified at a level of 0.25 mg/L and incubated at pH 4 (90°C, 20 min), pH 5 (100°C, 60 min) and pH 6 (120°C, 20 min). In none of the samples a degradation or transformation of bixafen was observed.
Residue pattern in raw and processed commodities similar? (yes/no)	Yes
Plant residue definition for monitoring	Bixafen (Reg. (EC) No. 396/2005)
Plant residue definition for risk assessment	Sum of bixafen and bixafen-desmethyl, expressed as bixafen (EFSA, ASB2012-14631) Currently restricted to cereals and oilseeds.
Conversion factor(s) (monitoring to risk assessment)	None – parent accounts on average for 80% of the residue.

4.1.1.3 Metabolism in livestock and animal residue definition(s)

A brief summary of the metabolism of bixafen in livestock is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR (UK, 2011, ASB2011-11716, Addendum ASB2012-9669), EFSA's Conclusion on the peer review of bixafen (ASB2012-14631) and EFSA´s Reasoned Opinions on the setting of MRLs for bixafen (ASB2012-3256, ASB2012-3453).

Table 4.1-4: Metabolism in livestock (Annex IIA, point 6.2.2 to 6.2.5 and 6.7.1)

Animals covered	Lactating goats, laying hens – Lactating goats (ASB2009-5940): [pyrazole-5-^{14}C] label, 2 mg/kg bw (35 mg/kg feed), 5 days – Lactating goats (ASB2009-5941): [dichlorophenyl-UL-^{14}C] label, 2 mg/kg bw (46 mg/kg feed), 5 days – Laying hens (ASB2009-5876): [pyrazole-5-^{14}C], 2.04 mg/kg bw (25.75 mg/kg feed), 14 days – Laying hens (ASB2009-5877): [dichlorophenyl-UL-^{14}C] label, 2.03 mg/kg bw (32.42 mg/kg feed), 14 days The metabolic pattern in livestock animals was comparable to that in plants. Most of the radioactive residue was identified as bixafen (4.5-89.4% TRR) and bixafen-desmethyl (10.4-43.2% TRR). Except for poultry liver, bixafen was present in all samples at > 10 % of the TRR, qualifying the substance as a suitable marker for enforcement purposes. For risk assessment bixafen-desmethyl, which was present in relevant amounts and has comparable toxicological properties as the parent, should be taken into account additionally. Minor cleavage of bixafen was observed leading to the formation of pyrazole-4-metabolites. The cleavage of bixafen was also observed in rats. Like in plants, no bixafen-aniline was found.
Time needed to reach a plateau concentration in milk and eggs	Milk – 3 days (EFSA, ASB2012-14631) Eggs – 7 days (EFSA, ASB2012-14631)

Animal residue definition for monitoring	Commodities of animal origin (code 1000000 except 1040000): Sum of bixafen and bixafen-desmethyl, expressed as bixafen (Reg. (EC) No. 396/2005) Honey (code 1040000): Bixafen
Animal residue definition for risk assessment	Sum of bixafen and bixafen-desmethyl, expressed as bixafen (EFSA, ASB2012-14631)
Conversion factor(s) (monitoring to risk assessment)	None
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	Yes, log $P_{O/W}$ = 3.3 In view of a log pow of 3.3 and a ratio of residues in fat/muscle of ~10:1 in the goat and hen metabolism studies, the residue of bixafen is considered as fat soluble. Although in the 28 day-feeding study with dairy cattle the residues in muscle and fat were at a lower ratio of 2:1, bixafen and bixafen-desmethyl were predominant in cream (and not in skim milk), supporting the assumption of fat solubility. It has to be noted, that for MRL setting and in the ongoing procedure for the inclusion of bixafen in Annex I fat solubility was not yet considered. Germany has commented on this issue.

4.1.1.4 Residues in rotational crops

A brief summary of the field rotational crop studies on bixafen is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR (UK, 2011, ASB2011-11716) and EFSA's Conclusion on the peer review of bixafen (ASB2012-14631).

Table 4.1-5: Residues in rotational crops (Annex IIA, point 6.6.3)

Field studies	According to the EFSA Conclusion on bixafen (ASB2012-14631), the plateau concentration of 0.48 mg/kg was reached after 40 years application of 2 x 125 g/ha per annum in field studies (based on steady state concentration over 20 cm of 0.31 mg/kg plus annual loading over 5 cm of 0.167 mg/kg. Assuming yearly application of bixafen according to the critical GAP in Germany (2x 93.8 g/ha bixafen per annum) results in a lower steady state concentration equivalent to ca 0.7 kg/ha. The available field rotational crop studies were conducted at rates lower than the estimated soil plateau concentration: – ASB2009-5957: Germany; a) bixafen applied at 281 g/ha to bare soil, rotational crops turnip, lettuce and winter wheat planted at PBI 30 days; b) bixafen applied twice (156+125 g/ha) to winter barley at BBCH 47 and 69, turnip and lettuce planted at PBI 60 days, winter wheat planted at PBI 140 days, further rotation interval for all crops PBI 300-328 days – ASB2009-5958: N-France; a) bixafen applied at 281 g/ha to bare soil, rotational crops turnip, lettuce and winter wheat planted at PBI 30 days; b) bixafen applied twice (156+125 g/ha) to winter barley at BBCH 47 and 69, turnip and lettuce planted at PBI 60

	days, winter wheat planted at PBI 120 days, further rotation interval for all crops PBI 298-331 days – ASB2009-5959: Germany; a) bixafen applied at 281 g/ha to bare soil, rotational crops turnip, lettuce and winter wheat planted at PBI 30 days; b) bixafen applied twice (156+125 g/ha) to winter barley at BBCH 47 and 69, turnip and lettuce planted at PBI 60 days, winter wheat planted at PBI 136 days, further rotation interval for all crops PBI 304-331 days – ASB2009-5960: Spain; a) bixafen applied at 281 g/ha to bare soil, rotational crops carrots, lettuce and winter wheat planted at PBI 32 days; b) bixafen applied twice (156+125 g/ha) to winter barley at BBCH 49 and 71, carrots and lettuce planted at PBI 70 days, winter wheat planted at PBI 184 days, further rotation interval for all crops PBI 278-302 days Samples were analysed for residues of bixafen and bixafen-desmethyl (M21), which were mostly below the LOQ of 0.01 mg/kg, except for two single detects in wheat straw (0.03 mg/kg total residue) and lettuce (0.06 mg/kg total residue). Because field studies were underdosed, EFSA identified a data gap "to provide rotational crop field trials on cereals, leafy vegetables and root vegetables at a dose rate covering the calculated minimum plateau concentration of bixafen and to determine the residue levels of bixafen and metabolites M21, M43, M44 and M20" (ASB2012-14631). BfR believes, however, that the issue of residues in rotational crops has already been sufficiently elucidated with respect to the GAPs applied for in Germany. Since (i) the intended and authorized uses of bixafen in Germany are only on cereals and continuous cultivation and treatment with bixafen is unlikely, (ii) residues in rotational crops seen in the confined studies were only slightly above 0.01 mg/kg (when extrapolated to the soil steady state concentration) and consisted predominantly of bixafen and bixafen-desmethyl (M21), (iii) the experimental conditions in the confined study (bare soil application) and the plateau calculation parameters were very conservative, MRL compliance for rotational crops under realistic field conditions is assumed.

4.1.1.5 Residues in livestock

An actual calculation of the dietary burden (based on relevant cereal and oilseed uses evaluated in the EU for MRL setting which also cover the uses applied for in Germany) is provided in Table 4.1-6, for input values it is referred to EFSA´s RO on the setting of MRLs for bixafen in oilseed rape, linseed, mustard seed and poppy seed, EFSA Journal 2011;9(7):2286, ASB2012-3256) is provided in the following tables.

Table 4.1-6: Calculation of the maximum dietary burden

Feedstuff	% DM	Percent of daily livestock diet (dry feed basis)				Residue (mg/kg)	Intake (mg/kg, dry feed basis)			
		Chicken 1.9 kg bw daily max feed (DM) 120 g	Dairy cattle 550 kg bw daily max feed (DM) 20 kg	Beef cattle 350 kg bw daily max feed (DM) 15 kg	Pig 75 kg bw daily max feed (DM) 3 kg		Chicken	Dairy cattle	Beef cattle	Pig
Cereals (grain)	86	70	–	–	80	0.11 [a]	0.090	–	–	0.102
Bran	86	–	20	50	–	0.44 [b]	–	0.099	0.099	–
Cereals (straw)	86	–	20	50	–	11.5 [C]	–	2.674	6.686	–
Oilseed meal	86	10	30	30	20	0.04 [d]	0.005	0.014	0.014	0.009
Intake (mg/kg dry weight feed)							**0.094**	**2.787**	**6.799**	**0.112**
Intake (mg/kg bw/d)							**0.006**	**0.101**	**0.290**	**0.004**
Intake (mg/animal/d)							**0.011**	**55.745**	**101.983**	**0.335**

[a] STMR, based on the following cGAP: cereals, 2 x 0.125 kg as/ha, up to BBCH 69, PHI 35 days (ASB2011-11716)
[b] STMR-P, based on STMR (grain) of 0.11 x default PF of 4
[c] HR, based on the following cGAP : cereals, 2 x 0.125 kg as/ha, up to BBCH 69, PHI 35 days (ASB2011-11716)
[d] STMR-P, based on the following cGAP: oilseeds, 2 x 0.075 kg as/ha, up to BBCH 69, PHI 56 days, use of default PF of 2 (ASB2012-3256)

Table 4.1-7: Calculation of the mean dietary burden

Feedstuff	% DM	Percent of daily livestock diet (dry feed basis)				Residue (mg/kg)	Intake (mg/kg, dry feed basis)			
		Chicken 1.9 kg bw daily max feed (DM) 120 g	Dairy cattle 550 kg bw daily max feed (DM) 20 kg	Beef cattle 350 kg bw daily max feed (DM) 15 kg	Pig 75 kg bw daily max feed (DM) 3 kg		Chicken	Dairy cattle	Beef cattle	Pig
Cereals (grain)	86	70	–	–	80	0.11 [a]	0.090	–	–	0.102
Bran	86	–	20	50	–	0.44 [b]	–	0.099	0.099	–
Cereals (straw)	86	–	20	50	–	4.14 [C]	–	0.963	2.407	–
Oilseed meal	86	10	30	30	20	0.04 [d]	0.005	0.014	0.014	0.009
Intake (mg/kg dry weight feed)							**0.095**	**1.076**	**2.520**	**0.112**
Intake (mg/kg bw/d)							**0.006**	**0.039**	**0.108**	**0.004**
Intake (mg/animal/d)							**0.011**	**21.512**	**37.797**	**0.335**

[a] STMR, based on the following cGAP : cereals, 2 x 0.125 kg as/ha, up to BBCH 69, PHI 35 days (ASB2011-11716)
[b] STMR-P, based on STMR (grain) of 0.11 x default PF of 4
[c] STMR, based on the following cGAP: cereals, 2 x 0.125 kg as/ha, up to BBCH 69, PHI 35 days (ASB2011-11716)
[d] STMR-P, based on the following cGAP: oilseeds, 2 x 0.075 kg as/ha, up to BBCH 69, PHI 56 days, use of default PF of 2 (ASB2012-3256)

Table 4.1-8: Conditions of requirement of livestock feeding studies on bixafen

	Ruminant:	**Poultry:**	**Pig:**
Expected intakes by livestock ≥0.1 mg/kg diet (dry weight basis) (yes/no – If yes, specify the level)	Yes: 2.8 (dairy), 6.8 (beef)	No	No
Potential for accumulation (yes/no):	Yes	Yes	Yes
Metabolism studies indicate potential level of residues ≥0.01 mg/kg in edible tissues (yes/no)	Yes	No	No

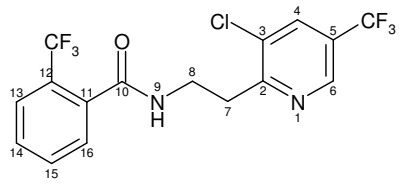
A brief summary of the available livestock feeding studies is given in the following table. Data, which has previously been evaluated at EU level is described in detail in the DAR (UK, 2011, ASB2011-11716) and in EFSA's Conclusion on the peer review of bixafen (ASB2012-14631).

Table 4.1-9: Results of livestock feeding studies (Annex IIA, point 6.4)

	Ruminant:	**Poultry:**	**Pig:**
Feeding levels (mg/kg feed dry matter) in feeding studies	Dairy cattle: 4, 12, 40 (0.15, 0.45, 1.5 mg/kg bw, ASB2009-5952)	Laying hens: 1.5, 4.5, 15 (0.09, 0.28, 1.01 mg/kg bw, ASB2009-5951)	See ruminant
Relevant dosing levels in feeding study:	4, 12	1.5	4 (ruminant)
	Expected residue levels (sum of bixafen and desmethyl-bixafen) in animal matrices (mg/kg):		
Muscle	Max = 0.14 Mean = 0.03 (MRL = 0.15)	<0.02* (MRL)	<0.02* (MRL)
Liver	Max = 1.0 Mean = 0.40 (MRL = 1.5)	<0.02* (MRL)	<0.02* (MRL)
Kidney	Max = 0.22 Mean = 0.10 (MRL = 0.3)	<0.02* (MRL)	<0.02* (MRL)
Fat	Max = 0.30 Mean = 0.10 (MRL = 0.4)	<0.02* (MRL)	<0.02* (MRL)
Milk	Max = 0.04 Mean = 0.02 (MRL = 0.04)	–	–
Eggs	–	<0.02* (MRL)	–

4.1.2 Fluopyram

Table 4.1-10: Identity of the active substance

Structural formula	
Common Name	fluopyram
CAS number	658066-35-4

4.1.2.1 Storage stability

A brief summary of the storage stability data on fluopyram and its metabolites is given in the following table. Most of the data (Interim Reports) were previously evaluated in a joint EU/NAFTA review project and are described in more detail in the DAR (ASB2011-9692), in EFSA's Reasoned Opinion "Setting of new MRLs and import tolerances for fluopyram in various crops" (EFSA 2011, ASB2011-10855) and in EFSA's Conclusion on the Peer Review of the pesticide risk assessment of the active substance fluopyram (EFSA 2013, ASB2013-5375). For the detailed evaluation of additional studies on storage stability (Final Reports) it is also referred to the revised DAR (RMS: Germany, 2012, ASB2012-13749).

Table 4.1-11: Stability of residues (Annex IIA, point 6.1)

Stability of fluopyram and its metabolites – fluopyram benzamide (M25, AE F148815), – PAA (M40, BCS-AA10139), – PCA (M43, AE C657188), – fluopyram-7-OH (M08, BCS-AA10065) and – fluopyram-methyl-sulfoxide (M45, AE 1344122)	Lettuce, wheat grain, dry peas, rape seed (ASB2008-5379: Interim Report 13 months, ASB2009-10166: Interim report 24 months, ASB2011-6939: final report 36 months): ≤-18°C, deep freeze storage Fluopyram, fluopyram benzamide and PAA were stable for 36 months in lettuce, wheat grain and dry peas and for 37 months in rape seed. PCA was stable for 36 months in dry peas and for 37 months in rape seed. Fluopyram-7-OH was stable for 36 months in lettuce and wheat grain. Orange (ASB2008-5380: Interim report 6 months, ASB2010-11139: interim report 24 months, ASB2011-6940: final report 36 months): ≤-18°C, deep freeze storage Fluopyram, fluopyram benzamide and PCA were stable for 36 months in oranges, PAA for only 6 months. Dry pea, rape seed and orange (ASB2011-6941): ≤-18°C, deep freeze storage Fluopyram-methyl-sulfoxide and fluopyram-7-OH were stable for 25 months in dry peas and oranges and for 24 months in rape seed.

4.1.2.2 Metabolism in plants and plant residue definition(s)

A brief summary of the metabolism of fluopyram in plants is given in the following table. The data were previously evaluated in a joint EU/NAFTA review project and are described in more detail in the DAR (ASB2011-9692), in EFSA's Reasoned Opinion "Setting of new MRLs and import tolerances for fluopyram in various crops" (EFSA 2011, ASB2011-10855) and in EFSA's Conclusion on the Peer Review of the pesticide risk assessment of the active substance fluopyram (EFSA 2013, ASB2013-5375).

Table 4.1-12: Metabolism in plants (Annex IIA, point 6.2.1; 6.5.1, 6.5.2, 6.6.2 and 6.7.1)

Plant groups covered	- Foliar spray: fruits (grapes, 1 + 2 applications, 100 + 200 g as/ha, sampling: 18-19 DALA, ASB2008-5383, ASB2008-5384), roots and tubers (potatoes, 3 x 167 g as/ha, sampling: 51 DALA, ASB2008-5385, ASB2008-5386), pulses and oilseeds (beans, 2 x 250 g as/ha, sampling: 4-29 DALA, ASB2008-5387, ASB2008-5388) - Drip irrigation, artificial substrate: fruiting vegetables (peppers, 1 x 5 and 20 mg/plant, sampling: 33-97 DALA, ASB2008-5389, ASB2008-5390) - Seed treatment (cereals): by means of bridging of confined rotational crop studies (ASB2008-5391, ASB2008-5392) All studies were conducted with both [phenyl-UL-^{14}C] and [pyridyl-2.6-^{14}C] labelled fluopyram. After foliar spray application, the parent compound made up the prominent part of the total residue. Fluopyram was moderately metabolised and hardly translocated within the plants. Significant metabolites identified in primary crops were: M25 (benzamide), M40 (PAA), M42 (PAA-conj.), M43 (PCA).

Rotational crops	Crops covered: Swiss chard, turnips and wheat Confined studies (ASB2008-5391, ASB2008-5392): [phenyl-UL-^{14}C] and [pyridyl-2,6-^{14}C] labelled fluopyram, application to bare soil at a nominal rate of 500 g as/ha at 30, 139 and 280 days prior to sowing of Swiss chard, turnips and wheat. Main residue components at all plant-back intervals (30, 139, 280 days) were parent fluopyram, methyl sulfoxide (M45), PCA (M43), 7-hydroxy and its conjugates (M08, M10, M11, M12) and phenol-glc (M06).
Metabolism in rotational crops similar to metabolism in primary crops? (yes/no)	yes
Distribution of the residue in peel/ pulp	not applicable
Processed commodities (nature of residue)	The behaviour of fluopyram (ASB2008-5419) and four of its metabolites (ASB2008-5420: fluopyram-benzamide (M25), ASB2008-5421: fluopyram-7-hydroxy (M08), ASB2008-5422: fluopyram-pyridyl-carboxylic acid (PCA; M43), ASB2008-5423: fluopyram-pyridyl-acetic acid (PAA; M40)) during hydrolysis was studied in buffer solutions (1.0 mg/L per analyte) simulating processing conditions. Fluopyram, M25, M08 and M43 were found to be stable against hydrolysis under conditions representative of pasteurization, baking, brewing, boiling and sterilization.
Residue pattern in raw and processed commodities similar? (yes/no)	yes
Plant residue definition for monitoring	Fluopyram (according to Reg. (EC) No 396/2005)
Plant residue definition for risk assessment	Sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram equivalents (according to EFSA Conclusion, ASB2013-5375) Note: JMPR proposed to limit the DoR to fluopyram also for risk assessment.
Conversion factors (monitoring to risk assessment)	Apples, peaches, grapes, strawberries, spring onions, lettuce, scarole, Chinese cabbage: 1.1 Beans/peas with pods, leek, rape seed, hops: 1.2 Beans/peas w/o pods: 1.5 Others: M25 not expected >LOQ, CF not proposed These factors were derived by EFSA (ASB2011-10855) and were updated in 2014 (ASB2014-11146).

4.1.2.3 Metabolism in livestock and animal residue definition(s)

A brief summary of the metabolism of fluopyram in livestock is given in the following table. The data were previously evaluated in a joint EU/NAFTA review project and are described in more detail in the DAR (ASB2011-9692), in EFSA's Reasoned Opinion "Setting of new MRLs and import tolerances for fluopyram in various crops" (EFSA 2011, ASB2011-10855) and in EFSA's Conclusion on the Peer Review of the pesticide risk assessment of the active substance fluopyram (EFSA 2013, ASB2013-5375).

Table 4.1-13: Metabolism in livestock (Annex IIA, point 6.2.2 to 6.2.5 and 6.7.1)

Animals covered	Laying hens (ASB2008-5394, ASB2008-5395), lactating goats (ASB2008-5396, ASB2008-5397) All studies were conducted with [phenyl-UL-^{14}C] and [pyridyl-2,6-^{14}C] labelled fluopyram, nominal rate was 2 mg/kg bw/day. Fluopyram was intensively metabolised in livestock. Main metabolites in goat and hen were benzamide (M25) and E- and Z-olefines (M02 and M03). Metabolites 7-OH-GA (M09; sum of isomers) and 8-OH-GA (M20b; isomer 2) exceeded 10 % of TRR in the goat only.
Time needed to reach a plateau concentration in milk and eggs	Milk: 8 days (feeding study with lactating cows) Eggs: 21 days (feeding study with laying hens).
Animal residue definition for monitoring	Sum of fluopyram and fluopyram-benzamide (M25), expr. as fluopyram equivalents (according to Reg. (EC) No 396/2005)
Animal residue definition for risk assessment	Sum of fluopyram, fluopyram-benzamide (M25), E-/Z-olefines (M02, M03), expressed as fluopyram equivalents Note: - The DoR is in line with the DoR proposed by JMPR. - RMS Germany originally proposed also to include 7-OH (M08), 7-OH-GA (M09; isomer 1 and 2) and 8-OH-GA (isomer 2; M20b), at least for ruminant matrices (for poultry matrices they were quantitatively not relevant). However, including these metabolites has not been considered necessary by EFSA in its Reasoned Opinion in the context of MRL setting (see EFSA, ASB2011-10855). RMS agreed.
Conversion factor(s) (monitoring to risk assessment)	fat: 1.5 Milk, liver and kidney: 1.1 muscle: 1 based on feeding studies conducted on cows and poultry (source: EFSA 2013, ASB2013-5375)
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	no

4.1.2.4 Residues in rotational crops

A brief summary of the field rotational crop studies on fluopyram is given in the following table. The data were previously evaluated in a joint EU/NAFTA review project and are described in more detail in the DAR (ASB2011-9692), in EFSA's Reasoned Opinion "Setting of new MRLs and import tolerances for fluopyram in various crops" (EFSA 2011, ASB2011-10855) and in EFSA's Conclusion on the Peer Review of the pesticide risk assessment of the active substance fluopyram (EFSA 2013, ASB2013-5375).

Table 4.1-14: Residues in rotational crops (Annex IIA, point 6.6.3)

Field studies	Five field rotational crop studies are available covering the EU and North America (ASB2008-5434, ASB2008-8222, ASB2008-8223, ASB2008-8224). The crop groups investigated were cereals, root crops, leafy crops and oilseeds. Plant back intervals were 30 days, 60-270 days

	and 270-365 days for EU studies and 14 days (alfalfa, cotton seed). Residues were analyzed for parent compound (EU, US trials) and metabolites M08, M25, M43 and M45 (EU trials only). The available data showed that after treatment according to the critical GAP, residues of the parent may occur in some human edible commodities obtained from rotated crops at levels not exceeding 0.10 mg/kg (highest residue detected in edible commodities, i.e. root crops: 0.05 mg/kg). Fluopyram residues in feed reached a maximum of 0.39 mg/kg in alfalfa forage and 0.28 mg/kg in wheat straw. Significant levels of metabolites M25 and M08 were found in wheat straw. Residues of parent and metabolites decreased with increasing plant-back intervals. Default MRLs have been proposed for root/tuber crops (0.1 mg/kg), leafy crops (0.1 mg/kg), cereals (0.01 mg/kg), oilseeds (0.01 mg/kg) and perennial crops (0.01 mg/kg) grown in rotation with fluopyram treated crops (EFSA 2013, ASB2013-5375).

4.1.2.5 Residues in livestock

An actual calculation of the dietary burden, based on all relevant uses authorized in the EU (according to EFSA's Reasoned Opinion "Setting of new MRLs and import tolerances for fluopyram in various crops" (EFSA 2011, ASB2011-10855) and additionally the uses for which authorization is sought, is provided in Table 4.1-15.

Table 4.1-15: Calculation of the dietary burden based on all relevant uses authorized in the EU (according to ASB2011-10855)

Feedstuff	% DM	Percent of daily livestock diet (dry feed basis)				Residue (mg/kg)	Intake (mg/kg, dry feed basis)			
		Chicken 1,9 kg bw daily maximum feed (DM) 120 g	Dairy cattle 550 kg bw daily maximum feed (DM) 20 kg	Beef cattle 350 kg bw daily maximum feed (DM) 15 kg	Pig 75 kg bw daily maximum feed (DM) 3 kg		Chicken	Dairy cattle	Beef cattle	Pig
Cabbage (leafy)	14	5	35	35	15	0.500 [a]	0.179	1.250	1.250	0.536
Citrus pomace	23	–	–	–	–	0.087 [b]	–	–	–	–
Apple pomace	23	–	–	–	–	0.475 [c]	–	–	–	–
Grains except Maize	86	70	–	–	–	0.429 [d]	0.349	–	–	–
Maize grain	86	–	–	–	–	0.011 [e]	–	–	–	–
Bran (Wheat and Rye)	89	–	20	20	20	0.572 [f]	–	0.129	0.129	0.129
Straw (Cereals)	86	–	15	–	–	0.330 [g]	–	0.058	–	–
Pulses	86	–	–	–	–	0.045 [h]	–	–	–	–
Potatoes	15	–	–	–	–	0.019 [i]	–	–	–	–
Swede/Turnip	10	20	30	45	60	0.055 [j]	0.110	0.165	0.248	0.330
Sugar beet	20	–	–	–	–	0.055 [k]	–	–	–	–
Oil seed	86	5	–	–	5	0.123 [l]	0.007	–	–	0.007

Feedstuff	% DM	Percent of daily livestock diet (dry feed basis)				Residue (mg/kg)	Intake (mg/kg, dry feed basis)			
		Chicken 1,9 kg bw daily maximum feed (DM) 120 g	Dairy cattle 550 kg bw daily maximum feed (DM) 20 kg	Beef cattle 350 kg bw daily maximum feed (DM) 15 kg	Pig 75 kg bw daily maximum feed (DM) 3 kg		Chicken	Dairy cattle	Beef cattle	Pig
					Intake (mg/kg dry weight feed)		**0.645**	**1.601**	**1.626**	**1.001**
					Intake (mg/kg bw/d)		**0.041**	**0.058**	**0.070**	**0.040**
					Intake (mg/animal/d)		**0.077**	**32.022**	**24.391**	**3.004**

[a] HR, based on the following cGAP: 2x 0.25 kg as/ha, PHI: 0 d
[b] STMR-P, based on the following cGAP: 2 x 0.25 kg as/ha, PHI: 7 d, STMR = 0.33, CF = 1.1, PF = 0.24
[c] STMR-P, based on the following cGAP: 2 x 0.25 kg as/ha, PHI: 0 d, STMR = 0.21 mg/kg, PF = 2.26
[d] STMR, based on the following cGAP: 2 x 0.25 kg as/ha, PHI: 14 d, STMR = 0.39 (sorghum), CF = 1.1
[e] STMR, based on the following cGAP: 2 x 0.25 kg as/ha, PHI: 14 d, STMR =0.01, CF = 1.1
[f] STMR-P, based on the following cGAP: 2 x 0.25 kg as/ha, PHI: 14 d, STMR = 0.20 (wheat), CF = 1.1, PF = 2.6
[g]HR, based on the following cGAP: 2x 0.25 kg as/ha, PHI: 14 d, HR = 0.33 (wheat)
[h] STMR, based on the following cGAP: 2 x 0.25 kg as/ha, PHI: 14 d, STMR = 0.03, CF =1.5
[i] HR, based on the following cGAP: 2x 0.25 kg as/ha, PHI: 7 d, HR = 0.05, CF = 1.1
[j] HR, based on rotational trials, HR = 0.05, CF = 1.1
[k] HR, based on the following cGAP: 2x 0.25 kg as/ha, PHI: 7 d, HR = 0.017, CF = 1.1
[l] STMR-P, based on the following cGAP: 2x 0.25 kg as/ha, PHI: 14 d, STMR = 0.14 (rape seed),CF = 1.2, PF = 0.73

Table 4.1-16: Conditions of requirement of livestock feeding studies (Annex IIA, point 6.4)

	Ruminant:	**Poultry:**	**Pig:**
Expected intakes by livestock ≥0.1 mg/kg diet (dry weight basis) (yes/no – If yes, specify the level)	yes 1.60 (dairy cattle) 1.63 (beef cattle)	yes 0.65	yes 1.0
Potential for accumulation (yes/no):	no	no	no
Metabolism studies indicate potential level of residues ≥0.01 mg/kg in edible tissues (yes/no)	yes	yes	yes

A brief summary of the available livestock feeding studies is given in the following table. The data, has been previously evaluated at EU level and is described in more detail in the DAR (ASB2011-9692), in EFSA's Reasoned Opinion "Setting of new MRLs and import tolerances for fluopyram in various crops" (EFSA 2011, ASB2011-10855) and in EFSA's Conclusion on the Peer Review of the pesticide risk assessment of the active substance fluopyram (EFSA 2013, ASB2013-5375).

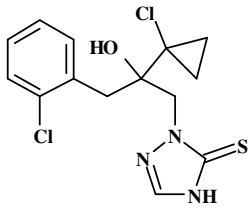
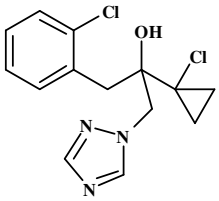
Table 4.1-17: Results of livestock feeding studies (Annex IIA, point 6.4)

	Ruminant:	**Poultry:**	**Pig:**
Feeding studies	Cows (ASB2008-5418):	Hens (ASB2008-5417)	Bridging from ruminants
Feeding levels in mg/kg feed DM	1, 10, 30, 100	0.05, 0.5, 1.5, 5	-
Feeding levels in mg/kg bw	0.04; 0.44; 1.21; 4.05	0.003; 0.035; 0.110; 0.320	-
Relevant dosing levels in feeding study:	1; 10	0.5; 1.5	1

	Ruminant:	**Poultry:**	**Pig:**
	Expected residue levels in animal matrices (mg/kg) of fluopyram equivalents (according to DoR for enforcement) / fluopyram equivalents (according to DoR for risk ass.):		
Muscle	0.06 / 0.08	0.06 / 0.06	0.03 / 0.05
Liver	0.50 / 0.52	0.20 / 0.20	0.03 / 0.05
Kidney	0.07 / 0.09	–	0.03 / 0.05
Fat	0.05 / 0.07	0.06 / 0.06	0.03 / 0.05
Milk	0.06 / 0.08	–	–
Eggs	–	0.12 / 0.12	–

4.1.3 Prothioconazole

Table 4.1-18: Identity of the active substance

Structural formula	
Common Name	Prothioconazole
CAS number	178928-70-6
Structural formula metabolite of concern	
Common Name main metabolite	Prothioconazole-desthio

4.1.3.1 Storage stability

A brief summary of the storage stability data on prothioconazole is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR (UK, 2004, ASB2010-10593), EFSA's Conclusion regarding the peer review of the pesticide risk assessment of prothioconazole (EFSA Scientific Report (2007) 106, 1-98, ASB2012-3641) and EFSA's Reasoned Opinion on the modification of the existing MRLs for prothioconazole according to Article 12 of Regulation (EC) No 396/2005 (EFSA Journal 2014;12(5):3689, ASB2014-5347).

Table 4.1-19: Stability of residues (Annex IIA, point 6.1)

Stability of prothioconazole, prothioconazole-desthio and a couple of further metabolites	The stability of prothioconazole and prothioconazole-desthio was tested in wheat matrices under deep-freezer conditions (-18°C) for 18 months (RIP2002-1036) and further for 36 months (ASB2010-11627). Prothioconazole was stable only for a limited period of time. A recovery of ≥ 70 % was achieved for storage intervals of up to 4 months (121 days) in forage, 6.5 months (197 days) in grain and 13 months (392 days) in

	straw. Residues of prothioconazole-desthio were stable in wheat forage, wheat grain and wheat straw under deep freezer for up to 540 days (18 months) or 1080 days (36 months). Residues of prothioconazole-desthio were stable in rape matrices (seed, pod, straw), spinach, sugar beets (roots and tops), tomatoes and dried peas for up to 24 months under deep freezer conditions (ASB2008-6522). In addition, residues of prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio and prothioconazole-6-hydroxy-desthio were stable under deep freezer conditions (-18°C) in tomatoes, potatoes, soybeans, oranges and oilseed rape for up to 24 months (ASB2012-5963).

4.1.3.2 Metabolism in plants and plant residue definition(s)

A brief summary of the metabolism of prothioconazole in plants is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR (UK, 2004, ASB2010-10593), EFSA's Conclusion regarding the peer review of the pesticide risk assessment of prothioconazole (EFSA Scientific Report (2007) 106, 1-98, ASB2012-3641) and EFSA's Reasoned Opinion on the modification of the existing MRLs for prothioconazole according to Article 12 of Regulation (EC) No 396/2005 (EFSA Journal 2014;12(5):3689, ASB2014-5347).

Table 4.1-20: Metabolism in plants (Annex IIA, point 6.2.1; 6.5.1, 6.5.2, 6.6.2 and 6.7.1)

Plant groups covered	Cereals, pulses/oilseeds, root/tuber – Wheat (RIP2002-1037): foliar application, 2x200 g/ha at BBCH 32 and 65, phenyl-^{14}C prothioconazole – Wheat (ASB2009-4276): 2 foliar applications at BBCH 32 and 65 (overall 470 g/ha), triazole-3,5-^{14}C prothioconazole Prothioconazole-desthio was the major metabolite in all plant parts and at all growth stages. It is further hydroxylated in the chlorophenyl ring forming various hydroxy-desthio isomers and dihydroxy-olefins. Cleavage of the triazole moiety was shown in the triazin labelled study resulting in various triazole metabolites (TDM). Triazolyl alanine and triazolyl acetic acid were intensively translocated into wheat grain (90 % of the TRR). – Wheat (RIP2002-1038): seed treatment with 20 g as/kg seed, phenyl-UL-^{14}C prothioconazole No significant differences in metabolism were found following seed treatment. – Wheat (RIP2002-1039): foliar application, 2x250 g/ha, triazole-3,5-^{14}C prothioconazole-desthio Prothioconazole-desthio remained widely unchanged with still 72% TRR occurring in straw at harvest (48 DALA). The major components of the TRR in grain were TA (60%) and TAA (32%) with unchanged prothioconazole-

	desthio accounting for only 3.2% TRR. – Peanuts (RIP2002-1042): 3 foliar applications (overall 800 g/ha), phenyl-UL-^{14}C prothioconazole – Peanuts (ASB2009-4296): 3 foliar applications (overall 800 g/ha), triazole-3,5-^{14}C prothioconazole Prothioconazole-desthio was the major metabolite except for nutmeat, where it was not found. The major metabolites in nutmeat were triazolyl alanine (48 % TRR) and triazolyl hydroxypropionic acid (25 % TRR). – Sugar beet (ASB2009-4272): 4 foliar applications (overall 1150 g/ha), phenyl-UL-^{14}C prothioconazole – Sugar beet (ASB2009-4274): 4 foliar applications (overall 1150 g/ha), triazole-3,5-^{14}C prothioconazole Prothioconazole-desthio was the major metabolite, also a couple of TDMs occurred.
Rotational crops	Confined study (RIP2002-1082): application of 660 g/ha to bare soil, [phenyl-UL-^{14}C] label, rotational crops wheat, swiss chard, turnips, PBIs 28, 146 and 269 days Only small amounts of parent were found (<1 % TRR). More than 20 metabolites were identified, most of them also seen in the primary metabolism studies. Prothioconazole-desthio was the main metabolite in all crops rotated at a PBI of 28 days. It was further hydroxylated and conjugated to glucosides (found in all rotations). Confined study (ASB2009-4303): 4x204 g/ha applied to bare soil, triazole labelled prothioconazole, rotational crops wheat, swiss chard, turnips, PBIs 30, 125 and 366 days Major compounds in all rotational crop matrices were triazolyl alanine (33-93 % of TRR), triazolyl hydroxypropionic acid (1-35 % of TRR) and triazolyl acetic acid (1-29 % of TRR). Only minor residues of prothioconazole-desthio were found in rotational crops (<1-4 % of TRR) and no prothioconazole was detected in any matrix after any of the PBIs.
Metabolism in rotational crops similar to metabolism in primary crops? (yes/no)	Yes
Distribution of the residue in peel/ pulp	Not applicable
Processed commodities (nature of residue)	A hydrolysis study (RIP2002-1081) simulating typical processing conditions (pasteurisation, baking, boiling, brewing and sterilisation) demonstrated that prothioconazole was degraded to prothioconazole-desthio to a limited extent with a maximum of 11 % at 120 °C/ pH 6. Another hydrolysis study (ASB2012-5968) demonstrated that the metabolite prothioconazole-desthio was stable under simulated processing conditions (pasteurisation, baking, boiling, brewing and sterilisation).
Residue pattern in raw and processed commodities	Yes

similar? (yes/no)	
Plant residue definition for monitoring	Prothioconazole-desthio (sum of isomers), according to Reg. (EC) No 396/2005 (Note:applicable from 16/08/2016)
Plant residue definition for risk assessment	Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA 2014, ASB2014-5347) This definition is provisional and will need to be reconsidered in the light of a scheduled EU risk assessment strategy for triazole metabolites.
Conversion factor(s) (monitoring to risk assessment)	cereal grain, pulses and oilseeds, leafy vegetables, root and tuber vegetables: 2 cereal straw: 3 (EFSA 2014, ASB2014-5347)

4.1.3.3 Metabolism in livestock and animal residue definition(s)

A brief summary of the metabolism of prothioconazole in livestock is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR (UK, 2004, ASB2010-10593), EFSA's Conclusion regarding the peer review of the pesticide risk assessment of prothioconazole (EFSA Scientific Report (2007) 106, 1-98, ASB2012-3641) and EFSA's Reasoned Opinion on the modification of the existing MRLs for prothioconazole according to Article 12 of Regulation (EC) No 396/2005 (EFSA Journal 2014;12(5):3689, ASB2014-5347).

Table 4.1-21: Metabolism in livestock (Annex IIA, point 6.2.2 to 6.2.5 and 6.7.1)

Animals covered (prothioconazole)	Lactating goat, laying hen Lactating goat (RIP2002-1044): [Phenyl-UL-^{14}C] label, 10 mg/kg bw, 3 days The kinetics of prothioconazole is characterised by a very fast onset and almost complete absorption, followed by a rapid distribution, a monaphasic elimination phase from the plasma with a very short half-life and an extensively urinary excretion. Due to the fast excretion, only traces of parent were found in milk. At sacrifice parent was found at 13%TRR each in liver, muscle and fat and at 19 % TRR in kidney. Prothioconazole-desthio exceeded 10 % TRR only in fat (19% TRR) and 4-hydroxy-prothioconazol only in liver (11 % TRR). Major metabolite was 3-hydroxy-desthio-glucuronid (10-34 % TRR). Lacting goat (ASB2009-4301): [Triazole-UL-^{14}C] label, 10 mg/kg bw, 3 days Fast urinary excretion resulted in only traces of parent occurring in milk. At sacrifice parent was found at 17%TRR in liver, 7 % TRR in muscle, 16 % TRR in fat and 20 % TRR in kidney. Main metabolite in milk and muscle was prothioconazole-thiocyanate (41 and 30 % TRR, respectively), which was specific for the triazole label. Laying hen (RIP2002-1054): [phenyl-UL-^{14}C] label, 10

	mg/kg bw, 3 days At sacrifice the excretion amounted on average to 78 % of the radioactivity totally administered. Only 0.01 % of the total dose (4 % of TRR) were determined in the eggs. Parent and its glucuronide and prothioconazole-desthio were the major residue compounds. Laying hen(ASB2009-4297): [Triazole-UL-^{14}C] label, 10 mg/kg bw, 3 days At sacrifice the excretion amounted on average to 66 % of the radioactivity totally administered. Only 0.01 % of the total dose (3 % of TRR) were determined in the eggs. Parent, its glucuronide (5-17 % TRR), prothioconazole-desthio (4-29 % TRR) and a couple of triazole metabolites (1,2,4-triazole, thiocyanate and prothioconazole-triazolyl-ethanol) occurred.
Animals covered (prothioconazole-desthio)	Lacting goat (RIP2002-1045, part 2: RIP2002-1046): [Phenyl-UL-^{14}C] labelled prothioconazole-desthio, 10 mg/kg bw, 3 days Prothioconazole-desthio was found as major constituent of the TRR in liver (31 % of TRR), fat (14 % of TRR), in lesser amount in muscle (2 % of TRR) and kidney (8 % of TRR). It was not found in milk. Its glucuronide conjugate was found in milk (6 % of TRR) and in higher amounts in kidney (24 % of TRR). Due to the labelling position in the metabolism study, no information is available concerning the triazole metabolites. Further metabolites were identified using acidic hydrolysis: – Prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio (RIP2002-1046) – Prothioconazole-3,4-dihydroxy-desthio, prothio-conazole-4,5-dihydroxy-desthio (ASB2009-4302) – The metabolic pathway consists of hydroxylation reactions at the chlorophenyl ring and partly further glucuronide and sulphate conjugation.
Time needed to reach a plateau concentration in milk and eggs	Milk (cow feeding study, desthio-metabolite): 1-2 days
Animal residue definition for monitoring	Prothioconazole-desthio (sum of isomers), according to Reg. (EC) No 396/2005 (Note:applicable from 16/08/2016)
Animal residue definition for risk assessment	Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA 2014, ASB2014-5347) This definition is provisional and will need to be reconsidered regarding the triazole metabolites (see plant residue definition).
Conversion factor(s) (monitoring to risk assessment)	Milk, muscle and fat: 1 liver: 2 kidney: 9 (EFSA 2014, ASB2014-5347)

Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	Indication as fat soluble ("F") in EU residue legislation (log Pow for prothioconazole-desthio 3.04 at 22 °C)

4.1.3.4 Residues in rotational crops

No field studies with succeeding crops were submitted or required, due to residues of parent and individual metabolites in rotational crops being below 0.1 mg/kg in the rotational crop metabolism study.

Table 4.1-22: Residues in rotational crops (Annex IIA, point 6.6.3)

Field studies	Field rotational crop studies were neither submitted nor required. In metabolism studies with rotational crops prothioconazole-desthio was present in edible parts of Swiss chard and turnip at a level of 0.01 mg/kg and in wheat grain below 0.01 mg/kg, when these plants were sown 28 and 146 days after application. The total amount of all metabolites containing the prothioconazole-desthio structural moiety was around 0.03 mg/kg for these PBIs. Therefore, under practical conditions of use, no residue above 0.01 mg/kg is expected for any of the metabolites in rotational crops.

4.1.3.5 Residues in livestock

An actual calculation of the dietary burden of prothioconazole-desthio based on all relevant uses authorized in the EU which are currently known (EFSA, 2014, ASB2014-5347) is provided in Table 4.1-23.

Table 4.1-23: Calculation of the dietary burden of prothioconazole-desthio (based on all relevant uses authorized in the EU which are currently known (EFSA, 2014, ASB2014-5347)

Feedstuff	% DM	Percent of daily livestock diet (dry feed basis)				Residue (mg/kg)	Intake (mg/kg, dry feed basis)			
		Chicken 1,9 kg bw daily maximum feed (DM) 120 g	Dairy cattle 550 kg bw daily maximum feed (DM) 20 kg	Beef cattle 350 kg bw daily maximum feed (DM) 15 kg	Pig 75 kg bw daily maximum feed (DM) 3 kg		Chicken	Dairy cattle	Beef cattle	Pig
Kale/Cabbage	14	5	35	–	15	0.120 [a]	0.043	0.300	–	0.129
Maize silage	20	–	–	–	–	0.01 [b]	–	–	–	–
Cereal grain	86	–	–	–	–	0.02 [c]	–	–	–	–
Maize grain	86	–	–	–	–	0.01 [b]	–	–	–	–
Bran (Wheat and Rye)	89	15	15	–	20	0.160 [c]	0.027	0.027	–	0.036
Straw (Cereals)	86	–	20	50	–	7.500 [d]	–	1.744	4.360	–
Pulses	86	30	–	–	–	0.020 [e]	0.007	–	–	–
Potatoes	15	–	–	–	–	0.010 [f]	–	–	–	–
Swede/Turnip	10	20	30	50	60	0.100 [g]	0.200	0.300	0.500	0.600
Oil seed	86	10	–	–	5	0.120 [h]	0.014	–	–	0.007
					Intake (mg/kg dry weight feed)		**0.291**	**2.371**	**4.860**	**0.772**
					Intake (mg/kg bw/d)		**0.018**	**0.086**	**0.208**	**0.031**
					Intake (mg/animal/d)		**0.035**	**47.423**	**72.907**	**2.315**

[a] HR x cf (2), based on the following cGAP: NEU, 3 x 192 g as/ha, BBCH 15-49, PHI: 21 Tage
[b] STMR (maize grain), HR (maize silage), based on the following cGAP: NEU/SEU, 1 x 27 g as/100 kg seed, PHI: F

[c] STMR x cf (2) (cereal grain), STMR-P (bran, x cf (2) x default PF (8), based on the following cGAP: NEU, 3 x 200 g as/ha, BBCH 30-69, PHI: 35 Tage
[d] HR x cf (3), based on the following cGAP: SEU, 2 x 200 g as/ha, BBCH 32-61, PHI 35 Tage
[e] STMR x cf (2), based on the following cGAP: NEU, 2 x 125 g as/ha, BBCH 61-69, PHI: 35 Tage
[f] HR, based on the following cGAP: NEU, 1 x 640 g as/100 kg seed, PHI F
[g] HR x cf (2), based on the following cGAP: NEU, 3 x 192 g as/ha, BBCH 19-49, PHI: 21 Tage
[h] STMR x cf (2), based on the following cGAP: NEU + SEU, 2 x 120 g as/ha, PHI: 28 Tage

Table 4.1-24: Conditions of requirement of livestock feeding studies

	Ruminant:	**Poultry:**	**Pig:**
Expected intakes by livestock ≥0.1 mg/kg diet (dry weight basis) (yes/no – If yes, specify the level)	Yes 2.37 (dairy) 4.86 (beef)	Yes 0.29	Yes 0.77
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥0.01 mg/kg in edible tissues (yes/no)	Yes	No	See ruminant

A brief summary of the available livestock feeding study is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR (UK, 2004, ASB2010-10593), EFSA's Conclusion regarding the peer review of the pesticide risk assessment of prothioconazole (EFSA Scientific Report (2007) 106, 1-98, ASB2012-3641) and EFSA's Reasoned Opinion on the modification of the existing MRLs for prothioconazole according to Article 12 of Regulation (EC) No 396/2005 (EFSA Journal 2014;12(5):3689, ASB2014-5347).

Table 4.1-25: Results of livestock feeding studies (Annex IIA, point 6.4)

	Ruminant:	**Poultry:**	**Pig:**
Feeding levels (mg/kg feed dry matter) in feeding studies	Cow feeding study with prothioconazole-desthio (RIP2002-1080): 4, 25, 100 (0.145; 0.909, 3.636 mg/kg bw/d)	No study was conducted or required.	No study was conducted or required.
Relevant dosing levels (mg/kg feed dry matter) in feeding studies:	4	--	4
	Expected residue levels in animal matrices at the calculated dietary burden (mg/kg):		
Muscle	<0.01 (MRL = 0.01)	<0.01 (MRL = 0.01)	<0.01 (MRL = 0.01)
Liver	0.042 (MRL = 0.5)	<0.01 (MRL = 0.01)	<0.01 (MRL = 0.5)
Kidney	0.012 (MRL = 0.5)	<0.01 (MRL = 0.01)	<0.01 (MRL = 0.5)
Fat	<0.01 (MRL = 0.01)	<0.01 (MRL = 0.01)	<0.01 (MRL = 0.01)
Milk	<0.005 (MRL = 0.01*)	–	–
Eggs	–	<0.01 (MRL = 0.01)	–

4.2 Evaluation of the intended uses

4.2.1 Selection of critical use and justification

The GAP reported for the central zone of the EU is presented in Table 4.2-1. It has been used for consumer intake and risk assessment.

Table 4.2-1: Critical Uses (worst case) used for consumer intake and risk assessment

1	2	3	4	5	6	7	8	9	10	11	12	13
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)** **(a)**	**F G or I** **(b)**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)** **(c)**	**Application**			**Application rate**			**PHI (days) (i)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures** **(j)**
					Method / Kind **(d-f)**	**Timing / Growth stage of crop & season** **(g)**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season** **(h)**	**L product / ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**g as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
1	DE, AT, BE, NL, PL, SI, UK	Barley (0500010)	F	stem break of cereals (*Pseudocercosporella herpotrichoides*), powdery mildew (*Erysiphe graminis*), leaf blotch of cereals (*Rhynchosporium secalis*), net blotch (*Pyrenophora teres*), brown rust of barley (*Puccinia hordei*), Ramularia leaf spot disease (*Ramularia collo-cygni*), decrease of non-parasitic leaf spots	spraying	BBCH 30-34 or BBCH 30-61, from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) bixafen: 78 g as/ha fluopyram: 78 g as/ha prothioconazole: 156 g as/ha	100-400	F	DE: 008, 009, 010, 011, 012, 013, 014
2	DE, AT, BE, NL, PL, SI, UK	Oats (0500050)	F	powdery mildew (*Erysiphe graminis*), crown rust of oats (*Puccinia coronata*),	spraying	BBCH 30-61, from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) bixafen: 78 g as/ha fluopyram: 78 g as/ha prothioconazole: 156 g as/ha	100-400	F	DE: 020, 021
3	DE, AT, BE, NL, PL, SI, UK	Rye (0500070)	F	leaf blotch of cereals (*Rhynchosporium secalis*), brown leaf rust of cereals (*Puccinia recondita*)	spraying	BBCH 30-61, from spring at beginning of infestation and/or when first symptoms become visible	a) 1-2 b) 2 (interval: 14-21 days)	a) 1.5 L/ha b) 3.0 L/ha	a) bixafen: 97.5 g as/ha fluopyram: 97.5 g as/ha prothioconazole: 195 g as/ha b) bixafen: 195 g as/ha fluopyram: 195 g as/ha prothioconazole: 390 g as/ha	100-400	F	DE: 015, 016, 029, 030

1	2	3	4	5	6	7	8	9	10	11	12	13
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)** **(a)**	**F G or I** **(b)**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)** **(c)**	**Application**			**Application rate**			**PHI (days) (i)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures** **(j)**
					Method / Kind **(d-f)**	**Timing / Growth stage of crop & season** **(g)**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season** **(h)**	**L product / ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**g as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
4	DE, AT, BE, NL, PL, SI, UK	Wheat, Triticale, Spelt (0500090)	F	stem break of cereals (*Pseudocercosporella herpotrichoides*), powdery mildew (*Erysiphe graminis*), leaf spot of wheat (*Septoria tritici*), tan spot of cereals (*Drechslera tritici-repentis*), brown leaf rust of cereals (*Puccinia recondita*), stripe rust of grasses (*Puccinia striiformis*), septoria leaf spot (*Septoria nodorum*)	spraying	BBCH 30-32 or BBCH 30-61, from spring at beginning of infestation and/or when first symptoms become visible	a) 1-2 b) 2 (interval: 14-21 days)	a) 1.5 L/ha b) 3.0 L/ha	a) bixafen: 97.5 g as/ha fluopyram: 97.5 g as/ha prothioconazole: 195 g as/ha b) bixafen: 195 g as/ha fluopyram: 195 g as/ha prothioconazole: 390 g as/ha	100-400	F	DE: 001, 002, 003, 004, 005, 006, 007, 017, 018, 019, 022, 023, 024, 025, 026, 027, 028, 031, 032, 033

Remarks:
(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) All abbreviations used must be explained
(e) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(f) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(g) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(h) The minimum and maximum number of application possible under practical conditions of use must be provided
(i) PHI - minimum pre-harvest interval
(j) Remarks may include: Extent of use/economic importance/restrictions

4.2.2 Barley, Oats

4.2.2.1 Residues in primary crops

Bixafen

The following table gives a brief overview of the supervised residue trials selected for the assessment of bixafen in barley. According to the agreed EU provisions of extrapolation (SANCO 7525/VI/95 rev.10.1, 01 December 2015) the results of residue trials performed on barley may be extrapolated to oats. Data has been previously evaluated at EU level and is described in detail in the DAR (UK, 2011, ASB2011-11716) and EFSA's Conclusion on the peer review of bixafen (ASB2012-14631). For the detailed evaluation of residue trials it is referred to Appendix 2.

Table 4.2-2: Overview of the selected supervised residue trials for bixafen in barley

Commodity	Region [a]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [b]	HR (mg/kg) [c]	Existing MRL (mg/kg)	Median CF [d]
			Enforcement (bixafen)	Risk assessment (sum of bixafen and bixafen-desmethyl, expressed as bixafen)*				
Barley grain ➔Oat grain	NEU	Outdoor	Trials with 1x 0.078 kg/ha: 0.011; 0.053; 0.079 Trials with 2x 0.13 kg/ha: 0.02, 3x 0.04, 0.07, 0.08, 2x 0.09, 0.10	Trials with 1x 0.078 kg/ha: 0.021; 0.063; 0.092 Trials with 2x 0.13 kg/ha: 0.03, 3x 0.05, 0.08, 3x 0.10, 0.11	0.0715	0.11	Barley/oat: 0.5	-
			Summary of available trials data: 0.011; 0.02, 3x 0.04, 0.053; 0.07, 0.079; 0.08, 2x 0.09, 0.10	Summary of available trials data: 0.021; 0.03, 3x 0.05, 0.063; 0.08, 0.092; 3x 0.10, 0.11				
Barley straw ➔Oat straw	NEU	Outdoor	Trials with 1x 0.078 kg/ha: 0.28; 0.59; 0.75 Trials with 2x 0.13 kg/ha: 0.64, 0.70, 0.77, 0.86; 1.1, 3.7, 4.8, 5.4, 10.0	Trials with 1x 0.078 kg/ha: 0.34; 0.63; 0.79 Trials with 2x 0.13 kg/ha: 0.73, 0.74, 0.84, 1.0; 1.2, 3.9, 5.2, 5.6, 12	0.92	12	-	-
			Summary of available trials data: 0.28; 0.59; 0.64, 0.70, 0.75; 0.77, 0.86; 1.1, 3.7, 4.8, 5.4, 10.0	Summary of available trials data: 0.34; 0.63; 0.73, 0.74, 0.79; 0.84, 1.0; 1.2, 3.9, 5.2, 5.6, 12				

* the values were calculated from individual results for bixafen and its metabolite in the trials
(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

It is noted that only 3 GAP compliant trials were available for bixafen on the major crop barley. However, on EU level a more critical GAP (2x 0.125 kg as/ha) was evaluated to derive the established MRLs from. This GAP was sufficiently covered by residue trials, which are described in more detail in the DAR (UK, 2011, ASB2011-11716) and EFSA's Conclusion on the peer review of bixafen (ASB2012-14631). These trials were also submitted with the current application. For this reason no further residue data is considered necessary.

Fluopyram

The following table gives a brief overview of the supervised residue trials selected for the assessment of fluopyram in barley. According to the agreed EU provisions of extrapolation (SANCO 7525/VI/95 rev.10.1, 01 December 2015) the results of residue trials performed on barley may be extrapolated to oats. For the evaluation of the residue trials it is referred to Appendix 2.

Table 4.2-3: Overview of the selected supervised residue trials for fluopyram

Commodity	Region [(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [(b)]	HR (mg/kg) [(c)]	Existing MRL (mg/kg)	Median CF [(d)]
			Enforcement (fluopyram)	Risk assessment (fluopyram and fluopyram-benzamide (M25), expressed as fluopyram equivalents)				
Barley grain ➔Oat grain	NEU	Outdoor	Trials with 1x 0.078 kg/ha: <0.01; 0.015; 0.025 Trials with 1x 0.13 kg/ha: 0.014; 0.016; 2x 0.018; 0.025; 0.026; 0.027; 0.033	Trials with 1 x 0.078 kg/ha: <0.02; 0.025; 0.035 Trials with 1 x 0.13 kg/ha: 0.024; 0.026; 2x 0.028; 0.035; 0.036; 0.037; 0.046	0.028	0.046	Barley/oat: 0.2	-
			Summary of available trials data: <0.01; 0.014; 0.015; 0.016; 2x 0.018; 2x 0.025; 0.026; 0.027; 0.033	Summary of available trials data: <0.02, 0.024; 0.025; 0.026; 2x 0.028; 2x 0.035; 0.036; 0.037; 0.046				
Barley straw ➔Oat straw	NEU	Outdoor	Trials with 1x 0.078 kg/ha: 0.024; 0.054; 0.058 Trials with 1x 0.13 kg/ha: 0.025; 0.057; 0.066; 0.081; 0.11; 0.13; 2x 0.14	Trials with 1x 0.078 kg/ha: 0.041; 0.064; 0.068 Trials with 1x 0.13 kg/ha: 0.035; 0.067; 0.076; 0.091; 0.139; 0.153; 0.16; 0.167	0.076	0.167	-	-
			Summary of available trials data: 0.024; 0.025; 0.054; 0.057; 0.058; 0.066; 0.081; 0.11; 0.13; 2x 0.14	Summary of available trials data: 0.035; 0.041; 0.064; 0.067; 0.068; 0.076; 0.091; 0.139; 0.153; 0.16; 0.167				

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

11 residue trials were available for fluopyram on the major crop barley, but only 3 of them were conducted in full compliance with the GAP. In the remaining trials the application rate was much higher (ca 2*N* treatment rate). Since residues found in mature grain were always below the MRL, the overdosed residue trials were also considered for the assessment.

Prothioconazole

The following table gives a brief overview of the supervised residue trials selected for the assessment of prothioconazole in barley. According to the agreed EU provisions of extrapolation (SANCO 7525/VI/95 rev.10.1, 01 December 2015) the results of residue trials performed on barley may be extrapolated to oats. For the evaluation of residue trials it is referred to Appendix 2.

Table 4.2-4: Overview of the selected supervised residue trials for prothioconazole in barley

Commodity	Region [a]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [b]	HR (mg/kg) [c]	Existing MRL (mg/kg)	Median CF [d]
			Enforcement (prothioconazole-desthio)	Risk assessment (Sum of prothio-conazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chloro-phenyl)-2-hydroxy-propyl-2H-1,2,4-triazole moiety, expr. as prothio-conazole-desthio))				
Barley grain ➔Oat grain	NEU	Outdoor	Trials with 1x 0.13-0.16 kg/ha: 10x <0.01; 0.01	Trials with 1x 0.13-0.16 kg/ha: 10x <0.06; 0.06	0.06	0.06	Barley: 0.2[e] Oat: 0.05	-
Barley straw ➔Oat straw	NEU	Outdoor	Trials with 1x 0.13-0.16 kg/ha: <0.01; 0.020;0.024; 0.025; 0.026; 0.031; 0.042; 0.044; 2 x 0.048; 0.069	Trials with 1x 0.13-0.16 kg/ha: <0.06; 0.07; 0.074; 0.075; 0.076; 0.084; 0.098; 0.126; 0.157; 0.179; 0.181	0.084	0.181	-	-

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.
(e): MRL of 0.2 mg/kg applicable from 16/08/2016; currently set: 0.3 mg/kg

11 GAP compliant trials were available for prothioconazole on the major crop barley.

4.2.2.2 Distribution of the residue in peel/pulp

Not relevant.

4.2.2.3 Residues in processed commodities

Not relevant. Due to low residues at harvest, no processing studies are required.

4.2.2.4 Proposed pre-harvest intervals, withholding periods

The pre-harvest interval (PHI) is covered by the time elapsing between application and commercial harvest. Setting of a specific PHI in days is not required.

4.2.3 Wheat, Triticale, Rye

4.2.3.1 Residues in primary crops

Bixafen
The following table gives a brief overview of the supervised residue trials selected for the assessment of bixafen in wheat. According to the agreed EU provisions of extrapolation (SANCO 7525/VI/95 rev.10.1, 01 December 2015) the results of residue trials performed on wheat may be extrapolated to rye, triticale and spelt. Data has been previously evaluated at EU level and is described in detail in the DAR (UK, 2011, ASB2011-11716) and EFSA's Conclusion on the peer review of bixafen (ASB2012-14631). For the detailed evaluation of residue trials it is referred to Appendix 2.

Table 4.2-5: Overview of the selected supervised residue trials for bixafen in wheat

Commodity	Region [(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [(b)]	HR (mg/kg) [(c)]	Existing MRL (mg/kg)	Median CF [(d)]
			Enforcement (bixafen)	(Risk assessment (sum of bixafen and bixafen-desmethyl, expressed as bixafen)*				
Wheat grain ➔Rye grain, triticale grain, spelt grain	NEU	Outdoor	Trials with 2x 0.098 kg/ha: 4x <0.01 Trials with 2x 0.13 kg/ha: 6x <0.01; 2x 0.01; 2x 0.03	Trials with 2x 0.098 kg/ha: 4x <0.02 Trials with 2x 0.13 kg/ha: 6x <0.02; 2x 0.02; 2x 0.04	0.02	0.04	Rye/ Wheat/ Triticale/ Spelt: 0.05	-
			Summary of available trials data: 10x <0.01; 2x 0.01; 2x 0.03	Summary of available trials data: 10x <0.02; 2x 0.02; 2x 0.04				
Wheat straw ➔Rye straw, triticale straw, spelt straw	NEU	Outdoor	Trials with 2x 0.098 kg/ha: 0.16; 0.38; 0.45; 0.47 Trials with 2x 0.13 kg/ha: 0.52; 0.93; 0.95; 1.3; 1.8; 1.9; 3.6; 4.1; 8.4; 10	Trials with 2x 0.098 kg/ha: 0.28; 0.56; 0.74; 0.82 Trials with 2x 0.13 kg/ha: 0.78; 1.2; 1.3; 1.5; 2.1; 2.5; 3.8; 4.4; 9.7; 11	1.4	11	-	-
			Summary of available trials data: 0.16; 0.38; 0.45; 0.47; 0.52, 0.93, 0.95; 1.3; 1.8; 1.9; 3.6; 4.1; 8.4; 10	Summary of available trials data: 0.28; 0.56; 0.74; 0.78; 0.82; 1.2; 1.3; 1.5; 2.1; 2.5; 3.8; 4.4; 9.7; 11				

* the values were calculated from individual results for bixafen and its metabolite in the trials
(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

It is noted that only 4 GAP compliant trials were available for bixafen on the major crop wheat. Nonetheless, since no residues were found in mature grain, the number of trials is deemed sufficient for the residue assessment. Moreover, 10 overdosed trials were available confirming these results. They belong to a more critical GAP (2x 0.125 kg as/ha) evaluated at EU level to derive the established MRLs from. This GAP was sufficiently covered by residue trials, which are described in more detail in the DAR (UK, 2011, ASB2011-11716) and EFSA's Conclusion on the peer review of bixafen (ASB2012-14631).

Fluopyram
The following table gives a brief overview of the supervised residue trials selected for the assessment of fluopyram in wheat. According to the agreed EU provisions of extrapolation (SANCO 7525/VI/95 rev.10.1, 01 December 2015) the results of residue trials performed on wheat may be extrapolated to rye, triticale and spelt. For the detailed evaluation of the residue trials, it is referred to Appendix 2.

Table 4.2-6: Overview of the selected supervised residue trials for fluopyram

Commodity	Region [a]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [b]	HR (mg/kg) [c]	Existing MRL (mg/kg)	Median CF [d]
			Enforcement (fluopyram)	Risk assessment (fluopyram and fluopyram-benzamide (M25), expressed as fluopyram equivalents)				
Wheat grain ➔Rye grain, triticale grain, spelt grain	NEU	Outdoor	7 x <0.01; 0.01; 0.011; 0.012; 0.014; 0.022	7 x <0.02; 0.02; 0.021; 0.022; 0.024; 0.032	0.02	0.032	Rye/ Wheat/ Triticale/ Spelt: 0.8	-
Wheat straw ➔Rye straw, triticale straw, spelt straw	NEU	Outdoor	0.057; 0.091; 3x 0.11, 0.13; 0.16; 0.20; 0.21; 0.26; 0.28; 0.35	0.068; 0.115; 0.131; 0.148; 0.15; 0.162; 0.17; 0.256; 0.262; 0.287; 0.348; 0.378	0.166	0.378	-	-

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

12 GAP-compliant residue trials were available for fluopyram on the major crop wheat.

Prothioconazole

The following table gives a brief overview of the supervised residue trials selected for the assessment of prothioconazole in wheat. According to the agreed EU provisions of extrapolation (SANCO 7525/VI/95 rev.10.1, 01 December 2015) the results of residue trials performed on wheat may be extrapolated to rye, triticale and spelt. Data, which has been previously evaluated at EU level is described in detail in the DAR (UK, 2004, ASB2010-10593) and EFSA's Conclusion regarding the peer review of the pesticide risk assessment of prothioconazole (EFSA Scientific Report (2007) 106, 1-98, ASB2012-3641). For the detailed evaluation of residue trials it is referred to Appendix 2.

Table 4.2-7: Overview of the selected supervised residue trials for prothioconazole in wheat

Commodity	Region [a]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [b]	HR (mg/kg) [c]	Existing MRL (mg/kg)	Median CF [d]
			Enforcement (prothiocaonzole-desthio)	Risk assessment (Sum of prothio-conazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chloro-phenyl)-2-hydroxy-propyl-2H-1,2,4-triazole moiety, expr. as prothio-conazole-desthio)*)				
Wheat grain ➔ Rye grain, triticale grain, spelt grain	NEU	Outdoor	Trials with 2x 0.2 kg/ha: 4x <0.01	Trials with 2x 0.2 kg/ha: 4x <0.06	0.02	0.06	Wheat/ Triticale/ Spelt: 0.1 Rye: 0.05	-
			Trials with 3x 0.2 kg/ha: 11x <0.01	Trials with 3x 0.2 kg/ha: 11x <0.02				2
			Summary of available trials data:	Summary of available trials data:				- / 2

Commodity	Region [a]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [b]	HR (mg/kg) [c]	Existing MRL (mg/kg)	Median CF [d]
			Enforcement (prothiocaonzole-desthio)	**Risk assessment (Sum of prothio-conazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chloro-phenyl)-2-hydroxy-propyl-2H-1,2,4-triazole moiety, expr. as prothio-conazole-desthio)*)**				
			15x <0.01	11x <0.02; 4x <0.06				
Wheat straw ➔ Rye straw, triticale straw, spelt straw	NEU	Outdoor	Trials with 2x 0.2 kg/ha: 0.021; 0.046; 0.078; 0.094	Trials with 2x 0.2 kg/ha: 0.2; 0.202; 0.318; 1.052	0.45	2.16	n/a	-
			Trials with 3x 0.2 kg/ha: 0.08; 0.09; 0.11, 0.14, 0.15 , 0.19, 0.20, 0.27, 0.31, 0.66, 0.72	Trials with 3x 0.2 kg/ha: 0.24; 0.27, 0.33, 0.42, 0.45 , 0.57, 0.60, 0.81, 0.93, 1.98, 2.16				3
			Summary of available trials data: 0.021; 0.046; 0.078; 0.08; 0.09; 0.094; 0.11, 0.14, 0.15 , 0.19, 0.20, 0.27, 0.31, 0.66, 0.72	Summary of available trials data: 0.20; 0.202; 0.24; 0.27, 0.318; 0.33, 0.42, 0.45 , 0.57, 0.60, 0.81, 0.93, 1.052; 1.98, 2.16				- / 3

* the values were calculated by using the CFs indicated
(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

It is noted that only 4 GAP-compliant trials were available for prothioconazole on the major crop wheat. However, on EU level a more critical GAP (3x 0.2 kg as/ha; up to BBCH 69) was evaluated to derive the established MRLs from. This GAP was sufficiently covered by residue trials, which are described in more detail in the DAR (UK, 2004, ASB2010-10593) and EFSA's Conclusion regarding the peer review of the pesticide risk assessment of prothioconazole (EFSA Scientific Report (2007) 106, 1-98, ASB2012-3641). These trials were also submitted with the current application. For this reason no further residue data is considered necessary.

4.2.3.2 Distribution of the residue in peel/pulp

Not relevant.

4.2.3.3 Residues in processed commodities

Not relevant. Due to low residues at harvest, no processing studies are required.

4.2.3.4 Proposed pre-harvest intervals, withholding periods

The pre-harvest interval (PHI) is covered by the time elapsing between application and commercial harvest. Setting of a specific PHI in days is not required.

4.3 Consumer intake and risk assessment

4.3.1 Bixafen

The key data for consumer intake assessment, which have been derived from residue studies for the intended uses, are summarized in Table 4.3-1.

Table 4.3-1: Key data for consumer intake assessment derived for the intended uses

Commodity	Long-term intake		Short-term intake	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Barley, oat	0.07	STMR	0.07	STMR
Wheat, rye, triticale	0.02	STMR	0.02	STMR

The toxicological reference values and all input values used for consumer risk assessment are stated in Table 4.3-2. To illustrate the results of the chronic risk assessment, a screenshot of the TMDI results obtained with EFSA PRIMO is displayed in Appendix 3.

Table 4.3-2: Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

Chronic risk assessment	
ADI	0.02 mg/kg bw/d
TMDI (% ADI) according to EFSA PRIMo	11% (based on NL children, mean body weight 17.1 kg)
NTMDI (% ADI) according to German NVS II	9% (based on DE children, individual consumption/body weight ratio)
IEDI (% ADI) according to EFSA PRIMo rev.2	Not required
NEDI (% ADI) according to German NVS II	Not required
Factors included in IEDI and NEDI	Not applicable
Acute risk assessment	
ARfD	0.2 mg/kg bw
IESTI (% ARfD) according to EFSA PRIMo rev.2	Barley: <1% (based on NL adults) Oats: <1% (based on DE children) Wheat: <1% (based on UK children aged 4-6 years) Rye: <1% (based on UK infants)
NESTI (% ARfD) according to German NVS II	Barley: <1% (based on DE general population, 14-80 yrs) Oat: <1% (based on DE children aged 2-4 years) Wheat: <1% (based on DE children aged 2-4 years) Rye: <1% (based on DE children aged 2-4 years)
Factors included in IESTI and NESTI	see table 4.3-1

4.3.2 Fluopyram

The key data for consumer intake assessment, which have been derived from residue studies for the intended uses, are summarized in Table 4.3-3.

Table 4.3-3: Key data for consumer intake assessment derived for the intended uses

Commodity	Long-term intake		Short-term intake	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Barley, oat	0.028	STMR	0.028	STMR
Wheat, rye, triticale	0.02	STMR	0.02	STMR

The toxicological reference values and all input values used for consumer risk assessment are stated in Table 4.3-4. To illustrate the results of the chronic risk assessment, a screenshot of the TMDI and IEDI results obtained with EFSA PRIMO is displayed in Appendix 3.

Table 4.3-4: Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

Chronic risk assessment	
ADI	0.012 mg/kg bw/d
TMDI (% ADI) according to EFSA PRIMo	327% (based on NL children, mean body weight)
NTMDI (% ADI) according to German NVS II	337% (based on DE children, individual consumption/body weight ratio)
IEDI (% ADI) according to EFSA PRIMo rev.2	73% (based on NL children, mean body weight)
NEDI (% ADI) according to German NVS II	89% (based on DE children, individual consumption/body weight ratio)
Factors included in IEDI and NEDI	see table 4.3-5
Acute risk assessment	
ARfD	0.5 mg/kg bw
IESTI (% ARfD) according to EFSA PRIMo rev.2	Barley: <1% (based on NL adults) Oat: <1% (based on DE children) Wheat: <1% (based on UK children aged 4-6 years) Rye: <1% (based on UK infants)
NESTI (% ARfD) according to German NVS II	Barley: <1% (based on DE general population, 14-80 yrs) Oat: <1% (based on DE children aged 2-4 years) Wheat: <1% (based on DE children aged 2-4 years) Rye: <1% (based on DE children aged 2-4 years)
Factors included in IESTI and NESTI	see table 4.3-3

Table 4.3-5: Factors included in IEDI and NEDI*

Commodity	Long-term intake	
	Input value (mg/kg)	Comment
Tree nuts	0.011	STMR (0.01) x CF (1.1)
Except coconut	0.01	STMR
Apples	0.23	STMR (0.21) x CF (1.1)
Other pome fruits	0.19	STMR
Apricots	0.22	STMR (Codex, JMPR 2015)
Peaches	0.26	STMR

Commodity	Long-term intake	
	Input value (mg/kg)	**Comment**
Cherries	0.63	STMR (0.57) x CF(1.1)
Plums	0.20	STMR
Table grapes	0.60	STMR
Wine grapes	0.07	STMR (0.44) x CF (1.17) x PF wine (0.18) x YF (0.7)
Strawberries	0.44	STMR (0.40) x CF (1.1)
Other small fruit and berries	0.83	STMR
Bananas	0.175	STMR
Potatoes	0.02	STMR
Other root and tuber vegetables	0.10	STMR
Except carrots	0.09	STMR
Spring onions	0.52	STMR
Tomatoes	0.20	STMR
Aubergines	0.20	STMR
Peppers	0.30	STMR
Cucurbits-edible peel	0.15	STMR
Cucurbits-inedible peel	0.01	STMR x PF (peeling)
Broccoli	0.06	STMR (Codex, JMPR 2015)
Flowering brassica	0.03	STMR
Brussels sprouts	0.05	STMR (Codex, JMPR 2015)
Head cabbage	0.03	STMR
Chinese cabbage	0.18	STMR
Lettuce and other salad plants	2.63	STMR
Except scarole	0.31	STMR
Spinach	0.09	STMR
Witloof	0.05	STMR
Beans with pods	0.21	STMR
Beans without pods	0.04	STMR
Peas with pods	0.15	STMR
Peas without pods	0.04	STMR
Globe artichokes	0.18	STMR
Leek	0.14	STMR
Pulses	0.045	STMR (0.03) x CF (1.5)
Linseed	0.12	STMR
Peanuts	0.01	STMR
Poppy seed	0.12	STMR

Commodity	Long-term intake	
	Input value (mg/kg)	**Comment**
Rape seed	0.33	STMR (Codex, JMPR 2015)
Soya beans	0.004	STMR (0.01) x CF (1.2) x PF oil (0.93) x YF (0.4)
Mustard seed	0.12	STMR
Gold of pleasure	0.12	STMR
Maize	0.011	STMR (0.01) x CF (1.1)
Rye, Wheat	0.22	STMR (0.20) x CF (1.1)
Sorghum	0.43	STMR (0.39) x CF (1.1)
Herbal infusions (roots)	0.64	STMR
Spices (roots or rhizome)	0.1	STMR
Hops	1.05	STMR
Sugar beet root	0.033	STMR (0.03) x CF (1.1)
Mammalian muscle	0.052	STMR
Mammalian fat	0.06	STMR
Mammalian liver	0.53	STMR
Mammalian kidney	0.06	STMR
Mammalian edible offal	0.37	STMR
Poultry muscle, fat	0.01	STMR
Poultry liver	0.02	STMR
Milk	0.05	STMR
Birds´ eggs	0.008	STMR
Other commodities of plant + animal origin	Variable	MRLs as laid down in Reg. (EU) 2017/626

*STMR, processing factors, conversion factors (CF) and yield factors (YF) were drawn from EFSA's Reasoned Opinion on the modification of the existing MRLs for Fluopyram in various crops (EFSA 2014, ASB2014-11146)

4.3.3 Prothioconazole

The key data for consumer intake assessment, which have been derived from residue studies for the intended uses, are summarized in Table 4.3-6.

Table 4.3-6: Key data for consumer intake assessment derived for the intended uses

Commodity	Long-term intake		Short-term intake	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Barley, oat	0.06	STMR	0.06	STMR
Wheat, rye, triticale	0.02	STMR	0.02	STMR

The toxicological reference values and all input values used for consumer risk assessment are stated in Table 4.3-7. To illustrate the results of the chronic risk assessment, a screenshot of the IEDI results

obtained with EFSA PRIMO is displayed in Appendix 3.

Table 4.3-7: Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

Chronic risk assessment	
ADI	0.01 mg/kg bw/d (prothioconazole-desthio)
TMDI (% ADI) according to EFSA PRIMo	Not calculated since residue definitions for monitoring and risk assessment differ
NTMDI (% ADI) according to German NVS II	Not calculated since residue definitions for monitoring and risk assessment differ
IEDI (% ADI) according to EFSA PRIMo rev.2	10% (based on WHO cluster diet B, mean body weight)
NEDI (% ADI) according to German NVS II	7.8% (based on 2-4 years old German children, individual consumption/body weight ratio)
Factors included in IEDI and NEDI	STMR figures and conversion factors as compiled in EFSA's RO on the review of existing MRLs according to article 12 of Reg. (EC) No 396/2005 (EFSA 2014, ASB2014-5347) and in EFSA's ROs on the modification of the MRL for prothioconazole in shallots (ASB2015-4819) and in sunflower seed (ASB2016-5505).
Acute risk assessment	
ARfD	0.01 mg/kg bw (prothioconazole-desthio)
IESTI (% ARfD) according to EFSA PRIMo rev.2	Barley:4% (based on NL adults) Oat: 2.4% (based on DE children) Rye: 1% (based on UK infants) Wheat: 3% (based on UK 4-6 years)
NESTI (% ARfD) according to German NVS II	Barley: 1% (based on DE general population, 14-80 yrs) Oat: 2% (based on DE children aged 2-4 years) Rye 1% (based on DE children aged 2-4 years) Wheat: 2% (based on DE children aged 2-4 years)
Factors included in IESTI and NESTI	see table 4.3-6

4.4 Combined exposure and risk assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised "scientific methods accepted by the Authority to assess such effects are available."
Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

The product is a mixture of three active substances and for all of them an acute reference dose has been allocated. Therefore, combined acute exposure can be considered.

4.4.1 Acute consumer risk assessment from combined exposure

In a first step, dose-addition of residues of the individual active substances is assumed by making use of the Hazard Index (HI) concept. The Hazard Quotient (HQ) is calculated for all active substances in the PPP that are acutely toxic by performing deterministic IESTI/NESTI calculations with the calculation models EFSA PRIMO (rev.2) and appropriate national models, if required, and dividing the individual exposure levels by the respective ARfD. Addition of the individual HQs irrespective of any considerations on phenomenological effects or mode(s)/mechanisms of action results in the HI. The results of the HQ/HI calculations are summarized in the following table.

Table 4.4-1: Acute consumer risk assessment from combined exposure

Crop	Active Ingredient	HQ (based on IESTI according to EFSA PRIMo)	HQ (based on NESTI according to German NVS II)
Barley	Bixafen	<0.01 (Dutch adults)	<0.01 (DE general)
	Fluopyram	<0.01 (Dutch adults)	<0.01 (DE general)
	Prothioconazole	<0.01 (Dutch adults)	<0.01 (DE general)
	Cumulative risk barley (HI)	**<0.03**	**<0.03**
Oats	Bixafen	<0.01 (DE children)	<0.01 (DE children)
	Fluopyram	<0.01 (DE children)	<0.01 (DE children))
	Prothioconazole	<0.01 (DE children)	<0.01 (DE children))
	Cumulative risk oats (HI)	**<0.03**	**<0.03**
Rye	Bixafen	<0.01 (UK infants)	<0.01 (DE children)
	Fluopyram	<0.01 (UK 4-6 yrs)	<0.01 (DE children)
	Prothioconazole	<0.01 (UK 4-6 yrs)	<0.01 (DE children)
	Cumulative risk rye (HI)	**<0.03**	**<0.03**
Wheat	Bixafen	<0.01 (UK 4-6 yrs)	<0.01 (DE children)
	Fluopyram	<0.01 (UK 4-6 yrs)	<0.01 (DE children)
	Prothioconazole	<0.01 (UK 4-6 yrs)	<0.01 (DE children)
	Cumulative risk wheat (HI)	**<0.03**	**<0.03**

The Hazard Index is <1. Thus combined exposure to all active substances in Ascra Xpro is not expected to present a consumer risk. No further refinement of the assessment is required.

4.4.2 Chronic consumer risk assessment from combined exposure

The uses under consideration provide only a minor contribution to the overall chronic exposure of consumers to pesticide residues. The issue requires a more universal consideration and possibly the generic usage of monitoring data. A harmonised approach is not yet available, and currently no specific consideration is warranted in the scope of this evaluation.

4.5 Proposed maximum residue levels (MRLs)

No new MRLs are required.

4.6 Conclusion

The data available is considered sufficient for risk assessment. It is noted however that EFSA identified a data gap for bixafen "to provide rotational crop field trials on cereals, leafy vegetables and root vegetables at a dose rate covering the calculated minimum plateau concentration of bixafen and to determine the residue levels of bixafen and metabolites M21, M43, M44 and M20" (ASB2012-14631). BfR believes that the issue of residues in rotational crops has already been sufficiently elucidated with respect to the GAPs applied for in Germany. Since (i) the intended and authorized uses of bixafen in Germany are only on cereals and continuous cultivation and treatment with bixafen is unlikely, (ii) residues in rotational crops seen in the confined studies were only slightly above 0.01 mg/kg and consisted predominantly of bixafen and bixafen-desmethyl (M21), (iii) the experimental conditions in the confined study (bare soil application) and the plateau calculation parameters were very conservative, MRL compliance for rotational crops under realistic field conditions is assumed.

An exceedance of the current MRLs in cereals (bixafen: 0.5 mg/kg for barley and oats, 0.05 mg/kg for wheat, rye, triticale and spelt; Fluopyram: 0.2 mg/kg for barley and oats; 0.8 mg/kg for wheat, rye, triticale and spelt; prothioconazole: 0.2 mg/kg for barley; 0.05 mg/kg for oats and rye, 0.1 mg/kg for wheat, triticale and spelt) as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intake of bixafen, fluopyram and prothioconazole residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, BfR/Germany agrees with the authorization of the intended uses.

Appendix 1 List of data submitted in support of the evaluation

Table A 1: List of data submitted in support of the evaluation

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
	Canada; Germany; USA;	2011	Fluopyram: Draft Assessment Report, Volume 1-3 ASB2011-9692			
	EFSA	2007	Conclusion regarding the peer review of the pesticide risk assessment of the active substance prothioconazole EFSA Scientific Report (2007) 106, 1-98 ASB2012-3641			
	EFSA	2009	Reasoned opinion: Setting of new MRLs for Bixafen in certain cereals and products of animal origin EFSA Journal 2009; 7(12):1440 ASB2012-3453			

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
	EFSA	2011	Reasoned opinion: Setting of MRLs for Bixafen in oil seed rape, linseed, mustard seed and poppy seed EFSA Journal 2011; 9(7):2286, 1-31 ASB2012-3256			
	EFSA	2011	Reasoned Opinion: Setting of new MRLs and import tolerances for Fluopyram in various crops EFSA Journal 2011;9(9):2388, 1-68 ASB2011-10855			
	EFSA	2012	Conclusion on the peer review of the pesticide risk assessment of the active substance Bixafen EFSA Journal 2012;10(11):2917 ASB2012-14631			
	EFSA	2012	Conclusion on the peer review of the pesticide risk assessment of the active substance Fluopyram EFSA Journal 2013;11(4):3052 ASB2013-5375			
	EFSA	2014	Reasoned opinion on the modification of the existing MRLs for Fluopyram in various crops EFSA Journal 2014;12(12):3947 ASB2014-11146			
	EFSA	2014	Reasoned opinion on the review of the existing maximum residue levels (MRLs) for Prothioconazole according to Article 12 of Regulation (EC) No 396/2005 EFSA Journal 2014;12(5):3689 ASB2014-5347			
	Germany	2012	Fluopyram: Draft Assessment Report, Volume 3, B.7 Residue data ASB2012-13749			
	United Kingdom	2004	Prothioconazole: (Draft Assessment Report) Vol. 1-4 GLP: Open Published: Yes ASB2010-10593			
	United Kingdom	2011	Bixafen: Draft Assessment Report (DAR) ASB2011-11716			
	United Kingdom	2012	Bixafen: Draft Assessment Report, Addendum B6-B7-B8-B9 ASB2012-9669			
KIIA 6.1.1	Billian, P.	2008	Storage stability of BYF 00587 and its metabolite BYF00587-desmethyl in/on wheat (grain, straw, green material), potato tuber, lettuce head and oil seed rape for 24 months (Storage period: 0 to 12 months) MR-06/141 ! P642064717 ! M-297081-01-1 GLP: Open Published: Open BVL-1994731, BVL-1994731, ASB2009-5839	Yes	Bayer CropScience	Y
KIIA 6.1.1	Billian, P.; Schöning, R.	2006	Storage stability of AE C638206 and its metabolites AE C657378 (3-OH-BAM), AE C653711 (BAM) and AE 1344122 (P1x) in/on cereals (rest of plant, grain, straw) for 25 months (incl. addendum No. 1 dated 2007-03-05) MR-178/04 ! P642034707 ! M-274729-01-1 ! M-274729-02-1 GLP: Open Published: Open BVL-1783054, ASB2008-5382	Yes	Bayer CropScience	N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 6.1.1	Cavaillé, C.; Portet, M.	2008	Storage stability of residues of AE C656948 and its metabolites (AE F148815, AE C657188, BCS-AA10139 and BCS-AA10065) in plants during deep freeze storage for up to 24 months MR-08/035 ! M-299461-01-2 ! 06-06 GLP: Open Published: Open BVL-1783048, ASB2008-5379	Yes	Bayer CropScience	Y
KIIA 6.1.1	Cavaillé, C.; Portet, M.	2008	Storage stability of residues of AE C656948 and its metabolites (AE F148815, AE C657188 and BCS-AA10139) in orange during deep freeze storage for up to 24 months MR-08/036 ! M-298687-01-2 ! 07-02 GLP: Open Published: Open BVL-1783050, ASB2008-5380	Yes	Bayer CropScience	Y
KIIA 6.1.1	Cavaillé, Ch.; Meilland-Berthier, I.	2010	Storage stability of residues of AE C656948 and its metabolites (AE F148815, AE C657188, BCS-AA10139 and BCS-AA10065) in plants during deep freeze storage for up to 36 months 06-06 ! M-299461-03-2 ! MR-10/044 GLP: Open Published: Open BVL-2603908, ASB2011-6939	Yes	Bayer CropScience	Y
KIIA 6.1.1	Cavaillé, Ch.; Meilland-Berthier, I.	2010	Storage stability of residues of AE C656948 and its metabolites (AE F148815, AE C657188 and BCS-AA10139) in orange during deep freeze storage for up to 36 months 07-02 ! M-356046-02-1 ! MR-08/036 GLP: Open Published: Open BVL-2300747, BVL-2603909, ASB2011-6940	Yes	Bayer CropScience	Y
KIIA 6.1.1	Cavaillé, Ch.; Meilland-Berthier, I.	2010	Storage stability of residues of AE C656948 metabolites (AE 1344122 and BCS-AA10065) in dry pea, rape and orange during deep freeze storage for up to 24 months 08-04 ! M-389465-01-1 ! MR-10/045 GLP: Open Published: Open BVL-2300762, BVL-2603910, ASB2011-6941	Yes	Bayer CropScience	Y
KIIA 6.1.1	Freitag, T.	2005	Storage stability of Prothioconazole-desthio in/on canola, spinach, sugar beet, tomato, and pea during freezer storage for 24 months (incl. amendment no. 001 dated 04.06.2007) MR-07/282 (new) ! MR-066/03 (old) ! P 642031802 ! M-258955-01-1 ! M-258955-02-1 GLP: Open Published: Open BVL-2614703, ASB2008-6522	Yes	Bayer CropScience	Y
KIIA 6.1.1	Freitag, T.	2011	Storage stability of prothioconazole-á-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, and prothioconazole-6-hydroxy-desthio in/on tomato fruit, potato tuber, soybean, orange fruit MR-08/024 ! M-405410-01-1 GLP: Open Published: Open BVL-2614704, ASB2012-5963	Yes	Bayer CropScience	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 6.1.1	Heinemann, O.	2001	18 months storage stability of residues of JAU6476 and JAU6476-desthio during frozen storage in/on wheat matrices MR-282/00 ! P64283007 ! MO-01-016846 GLP: Open Published: Open BVL-1982416, RIP2002-1036	Yes	Bayer CropScience	Y
KIIA 6.1.1	Heinemann, O.	2003	36 Months storage stability of residues of JAU6476 and JAU6476-desthio during frozen storage in/on wheat matrices MR-354/01 ! P64283007 ! M-081351-02-1 ! MO-03-005325 GLP: Open Published: Open BVL-2447673, ASB2010-11627	Yes	Bayer CropScience	Y
KIIA 6.1.1	Kneen, R.	2009	Submission of interim storage stability data for the active ingredient, fluopyram M-350230-01-1 GLP: Open Published: Open BVL-2082014, ASB2009-11821	Yes	Bayer CropScience	N
KIIA 6.1.1	Lakaschus, S.; Gizler, A.	2014	7 Days freezer storage stability study with different combinations of a total of 61 analytes (parent and metabolite molecules) and five matrix types (high water / acidic / starch / protein / oil) M-480441-01-1 ! S13-03307 GLP: Open Published: Open BVL-2614701, BVL-2614701, BVL-2614701, BVL-2614701, ASB2015-1733	Yes	Bayer CropScience	N
KIIA 6.1.1	Schöning, R.; Billian, P.	2009	Storage stability of BYF 00587 and its metabolite BYF00587-desmethyl in/on wheat (grain, straw, green material), potato tuber, lettuce head and oil seed rape for 24 months MR-08/206 ! M327638-01-1 GLP: Open Published: Open BVL-2447671, BVL-2447671, ASB2011-13507	Yes	Bayer CropScience	Y
KIIA 6.2.1	Beedle, E. C.; Ying, S. L.	2004	Prothioconazol: The metabolism of [phenyl-UL-14C] JAU6476 in sugar beets J6041602 ! M-001059-01-1 ! 200466 GLP: Open Published: Open BVL-1982395, ASB2009-4274	Yes	Bayer CropScience	Y
KIIA 6.2.1	Beedle, E. C.; Ying, S. L.	2004	The metabolism of [triazole-UL-14C] JAU6476 in sugar beets J6041603 ! M-001049-01-1 ! 200467 GLP: Open Published: Open BVL-1982413, ASB2009-4272	Yes	Bayer CropScience	Y
KIIA 6.2.1	Bongartz, R.	2007	Metabolism of [phenyl-UL-14C]AE C656948 in potatoes MEF-05/512 ! M1731466-8 ! M-286400-01-2 GLP: Open Published: Open BVL-1783064, ASB2008-5385	Yes	Bayer CropScience	Y
KIIA 6.2.1	Bongartz, R.	2007	Metabolism of [pyridyl-2,6-14C]AE C656948 in potatoes MEF-05/513 ! M1731467-9 ! M-286531-01-2 GLP: Open Published: Open BVL-1783066, ASB2008-5386	Yes	Bayer CropScience	Y
KIIA 6.2.1	Duah, F. K.; Lopez, R. T.	2004	Prothioconazol: The metabolism of [triazole-3,5-14C] JAU6476 in wheat J6041601 ! M-001524-01-1 ! 200733 ! MO-04-003190 GLP: Open Published: Open BVL-1982407, ASB2009-4276	Yes	Bayer CropScience	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 6.2.1	Haas, M.	2001	Prothioconazol: Metabolism of [phenyl-UL-14C]JAU6476 in peanuts MR-193/01 ! M-033059-01-2 ! M 1730984-2 ! MO-04-007565 GLP: Open Published: Open BVL-1982394, RIP2002-1042	Yes	Bayer CropScience	Y
KIIA 6.2.1	Haas, M.	2001	Prothioconazol: Metabolism of JAU 6476 in spring wheat after seed dressing MR-467/99 ! 110881 ! M1730885-2 ! MO-04-007892 ! MO-01-009932 GLP: Open Published: Open BVL-1982398, RIP2002-1038	Yes	Bayer CropScience	Y
KIIA 6.2.1	Haas, M.	2003	Prothioconazol: Metabolism of [triazole-UL-14C]JAU6476 in peanuts MR-194/02 ! M-103268-01-2 ! M1731145-2 ! MO-03-015499 ! MO-04-007894 GLP: Open Published: Open BVL-1982412, ASB2009-4296	Yes	Bayer CropScience	Y
KIIA 6.2.1	Haas, M.	2006	Metabolism of [phenyl-UL-14C]AE C656948 in beans after spray application MEF-06/005 ! M1731489-3 ! M-283161-01-2 GLP: Open Published: Open BVL-1783068, ASB2008-5387	Yes	Bayer CropScience	Y
KIIA 6.2.1	Haas, M.	2006	Metabolism of [pyridyl-2,6-14C]AE C656948 in grapes after spray application MEF-06/086 ! M1731504-1 ! M-282460-01-2 GLP: Open Published: Open BVL-1783062, ASB2008-5384	Yes	Bayer CropScience	Y
KIIA 6.2.1	Haas, M.	2006	Metabolism of [phenyl-UL-14C]AE C656948 in grapes after spray application MEF-06/087 ! M1731505-2 ! M-282177-01-2 GLP: Open Published: Open BVL-1783060, ASB2008-5383	Yes	Bayer CropScience	Y
KIIA 6.2.1	Haas, M.	2008	Degradation of [phenyl-UL-14C] and [pyridyl-2,6-14C]AE C656948 by plant suspension cell cultures MEF-05/142 ! M1711447-5 ! M-259283-01-2 GLP: Open Published: Open BVL-1783080, ASB2008-5393	Yes	Bayer CropScience	N
KIIA 6.2.1	Haas, M.; Bornatsch, W.	2000	Metabolism of JAU6476 in spring wheat (after foliar application) MR-198/99 ! MO-00-010357 ! M 1730851-5 GLP: Open Published: Open BVL-1982399, RIP2002-1037	Yes	Bayer CropScience	Y
KIIA 6.2.1	Haas, M.; Henk, F.; Weber, E.	2008	Metabolism of [pyridyl-2,6-14C]AE C656948 in beans after spray application MEF-06/004 ! M1731490-5 ! M-299067-01-2 GLP: Open Published: Open BVL-1783070, ASB2008-5388	Yes	Bayer CropScience	Y
KIIA 6.2.1	Henk, F.; Kuhnke, G.; Spiegel, K.	2008	Metabolism of [phenyl-UL-14C]AE C656948 in red pepper after drip application MEF-06/315 ! M1731535-5 ! M-298790-01-2 GLP: Open Published: Open BVL-1783072, ASB2008-5389	Yes	Bayer CropScience	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 6.2.1	Henk, F.; Spiegel, K.; Weber, E.	2008	Metabolism of [pyridyl-2,6-14C]AE C656948 in red pepper after drip application MEF-06/314 ! M1731534-4 ! M-298741-01-2 GLP: Open Published: Open BVL-1783074, ASB2008-5390	Yes	Bayer CropScience	Y
KIIA 6.2.1	Miebach, D.; Bongartz, R.	2007	Metabolism of [pyrazole-5-14C]BYF00587 in wheat after spray application MEF-06/347 ! M1731486-0 ! M-286756-01-1 GLP: Open Published: Open BVL-1994732, BVL-1994732, ASB2009-5872	Yes	Bayer CropScience	Y
KIIA 6.2.1	Miebach, D.; Bongartz, R.	2007	Metabolism of [dichlorophenyl-UL-14C]BYF00587 in wheat after spray application MEF-06/348 ! M1731485-9 ! M-290581-01-1 GLP: Open Published: Open BVL-1994733, BVL-1994733, ASB2009-5873	Yes	Bayer CropScience	Y
KIIA 6.2.1	Spiegel, K.	2007	Metabolism of [dichlorophenyl-UL-14C]BYF 00587 in soybeans after spray application MEF-07/068 ! M1731603-1 ! M-289680-01-1 GLP: Open Published: Open BVL-1994735, BVL-1994735, ASB2009-5875	Yes	Bayer CropScience	Y
KIIA 6.2.1	Spiegel, K.	2007	Metabolism of [pyrazole-5-14C]BYF 00587 in soybeans after spray application MEF-07/069 ! M1731604-2 ! M-289916-01-1 GLP: Open Published: Open BVL-1994734, BVL-1994734, ASB2009-5874	Yes	Bayer CropScience	Y
KIIA 6.2.1	Vogeler, K.; Sakamoto, H.; Brauner, A.	1993	Metabolism of SXX 0665 in summer wheat PF 3906 ! MO-99-003732 ! M 173 0 365-5 ! M 1730365-5 ! M-008633-01-1 GLP: Open Published: Open BVL-1982387, RIP2002-1039	Yes	Bayer CropScience	Y
KIIA 6.2.1, KIIA 6.6.2	Klempner, A.	2008	Metabolism of [phenyl-UL-14C]AE C656948 in confined rotational crops MEF-07/412 ! M1301460-5 ! M-297921-01-2 GLP: Open Published: Open BVL-1783076, BVL-1783160, ASB2008-5391	Yes	Bayer CropScience	Y
KIIA 6.2.1, KIIA 6.6.2	Klempner, A.	2008	Metabolism of [pyridyl-2,6-14C]AE C656948 in confined rotational crops MEF-07/413 ! M1301461-6 ! M-298035-01-2 GLP: Open Published: Open BVL-1783078, BVL-1783162, ASB2008-5392	Yes	Bayer CropScience	Y
KIIA 6.2.2	[redacted]	2008	Metabolism of [phenyl-UL-14C]AE C656948 in the laying hen MEF-06/329 ! M01819173 ! M-297093-01-2 GLP: Open Published: Open BVL-1783082, ASB2008-5394	Yes	Bayer CropScience	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 6.2.2	[redacted]	2008	Metabolism of [pyridyl-2,6-14C]AE C656948 in the laying hen MEF-06/405 ! M91819181 ! M-298190-01-2 GLP: Open Published: Open BVL-1783084, ASB2008-5395	Yes	Bayer CropScience	Y
KIIA 6.2.2	[redacted]	2007	Metabolism of [dichlorophenyl-UL-14C]BYF 00587 in the laying hen MEF-06/415 ! M61819179 ! M-290951-01-1 GLP: Open Published: Open BVL-1994737, BVL-1994737, ASB2009-5877	Yes	Bayer CropScience	Y
KIIA 6.2.2	[redacted]	2007	Metabolism of [pyrazole-5-14C]BYF 00587 in the laying hen MEF-06/460 ! M91819172 ! M-290845-01-1 GLP: Open Published: Open BVL-1994736, BVL-1994736, ASB2009-5876	Yes	Bayer CropScience	Y
KIIA 6.2.2	[redacted]	2003	[Triazole-UL-14C]JAU6476: Absorption, distribution, excretion, and metabolism in laying hens (incl. amendment No. 1 dated 2003-07-14) M91819118 ! MEF005/03 ! M-109936-02-1 ! MO-03-009641 GLP: Open Published: Open BVL-1982381, ASB2009-4297	Yes	Bayer CropScience	Y
KIIA 6.2.2	[redacted]	2001	[Phenyl-UL-14C]JAU6476: Absorption, distribution, excretion, and metabolism in laying hens MR 309/01 ! M81819090 ! MO-04-007569 GLP: Open Published: Open BVL-1982396, RIP2002-1054	Yes	Bayer CropScience	Y
KIIA 6.2.3	[redacted]	2007	Metabolism of [pyrazole-5-14C]BYF 00587 in the lactating goat MEF-06/316 ! M51819178 ! M-296034-01-1 GLP: Open Published: Open BVL-1994738, BVL-1994738, ASB2009-5940	Yes	Bayer CropScience	Y
KIIA 6.2.3	[redacted]	2007	Metabolism of [dichlorophenyl-UL-14C]BYF 00587 in the lactating goat (incl. amendment No. 1 dated 2007-09-25) MEF-06/288 ! M21819166 ! M-288615-02-1 GLP: Open Published: Open BVL-1994739, BVL-1994739, ASB2009-5941	Yes	Bayer CropScience	Y
KIIA 6.2.3	[redacted]	2006	Prothioconazol: [Phenyl-UL-14C]JAU6476-desthio: Absorption, distribution, excretion and metabolism in the lactating goat - Subsequent identification of metabolite hydrolysis products M-279178-01-1 ! MEF-06/469 GLP: Open Published: Open BVL-1982403, ASB2009-4302	Yes	Bayer CropScience	Y
KIIA 6.2.3	[redacted]	2008	Metabolism of [pyridyl-2,6-14C]AE C656948 in the lactating goat MEF-06/327 ! M31819176 ! M-297849-01-2 GLP: Open Published: Open BVL-1783088, ASB2008-5397	Yes	Bayer CropScience	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 6.2.3	[redacted]	2008	Metabolism of [phenyl-UL-14C]AE C656948 in the lactating goat MEF-06/519 ! M01819182 ! M-299111-01-2 GLP: Open Published: Open BVL-1783086, ASB2008-5396	Yes	Bayer CropScience	Y
KIIA 6.2.3	[redacted]	2003	[Triazole-UL-14C]JAU6476: Absorption, distribution, excretion, and metabolism in the lactating goat (incl. amendment No. 1 dated 2005-06-06) MR-448/02 ! M51819114 ! M-116219-02-1 ! MO-05-009171 GLP: Open Published: Open BVL-1982402, ASB2009-4301	Yes	Bayer CropScience	Y
KIIA 6.2.3	[redacted]	2001	[Phenyl-UL-14C]JAU6476: Absorption, distribution, excretion and metabolism in the lactating goat MR-092/01 ! M-034900-01-2 ! M 91819082 ! MO-04-007557 ! MO-02-002144 GLP: Open Published: Open BVL-1982382, RIP2002-1044	Yes	Bayer CropScience	Y
KIIA 6.2.3	[redacted]	2002	[Phenyl-UL-14C]JAU6476-desthio: Absorption, distribution, excretion, and metabolism in the lactating goat including the validation of the residue analytical method for the determination of JAU6476-desthio, JAU6476-3-hydroxy-desthio and JAU6476-4-hydroxy-desthio residues in animal matrices using aged radioactive residues MR-091/01 ! M-041101-01-2 ! M 91819091 ! MO-04-007555 ! MO-02-003680 GLP: Open Published: Open BVL-1982414, RIP2002-1045	Yes	Bayer CropScience	Y
KIIA 6.2.3	[redacted]	2002	[Phenyl-UL-14C]JAU6476-desthio: Absorption, distribution, excretion, and metabolism in the lactating goat including the validation of the residue analytical method for the determination of JAU6476-desthio, JAU6476-3-hydroxy-desthio and JAU6476-4-hydroxy-desthio residues in animal matrices using aged radioactive residues MR-091/01 ! Part 2 - MO-02-003998 ! M91819091 GLP: Open Published: Open BVL-1982415, RIP2002-1046	Yes	Bayer CropScience	Y
KIIA 6.2.5	[redacted]	2008	[Pyridyl-2,6-14C]- fluopyram bioconcentration and biotransformation in fish (Lepomis macrochirus) EBGMP116 ! E 244 3300 - 6 ! M-298506-01-2 GLP: Open Published: Open BVL-1783090, ASB2008-5398	Yes		N
KIIA 6.3	Arthur, E. L.; Mackie, S. J. W.	2008	AE C656948 500 SC: Magnitude of the residue on small fruit vine climbing subgroup 13F, except fuzzy kiwifruit (incl. amendment dated 11.04.2008) RAGMP043-1 ! M-299437-02-1 GLP: Open Published: Open BVL-1783104, ASB2008-5409	Yes	Bayer CropScience	N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 6.3	Ballesteros, C.	2008	Determination of the residues of AE C656948 in/on grape after low-volume spraying and spraying of AE C656948 (500 SC) in the field in Northern France and Germany RA-2500/07 ! M-298193-01-2 GLP: Open Published: Open BVL-1783098, ASB2008-5402	Yes	Bayer CropScience	N
KIIA 6.3	Ballesteros, C.	2008	Determination of the residues of AE C656948 in/on grape after low-volume spraying of AE C656948 (500 SC) in the field in Southern France RA-2501/07 ! M-298199-01-2 GLP: Open Published: Open BVL-1783100, ASB2008-5403	Yes	Bayer CropScience	N
KIIA 6.3	Ballesteros, C.	2008	Determination of the residues of AE C656948 in/on table grape after spraying of AE C656948 (500 SC) in the field in Spain, Portugal and Italy RA-2502/07 ! M-298633-01-2 GLP: Open Published: Open BVL-1783102, ASB2008-5404	Yes	Bayer CropScience	N
KIIA 6.3	Ballesteros, C.; Portet, M.	2008	Determination of the residues of AE C656948 in/on cherry tomato after spraying of AE C656948 (500 SC) in the greenhouse in Germany Spain and Italy RA-2591/07 ! M-297499-01-2 GLP: Open Published: Open BVL-1783122, ASB2008-5414	Yes	Bayer CropScience	N
KIIA 6.3	Billian, P.; Reineke, A.	2008	Determination of the residues of AE C656948 in/on strawberry after spraying of AE C656948 (500 SC) in the field in Northern France, Germany, the United Kingdom and the Netherlands RA-2503/07 ! M-298093-01-2 GLP: Open Published: Open BVL-1783112, ASB2008-5408	Yes	Bayer CropScience	N
KIIA 6.3	Billian, P.; Reineke, A.	2008	Determination of the residues of AE C656948 in/on strawberry after spraying of AE C656948 (500 SC) in the field in Southern France, Italy, Spain and Portugal RA-2504/07 ! M-298098-01-2 GLP: Open Published: Open BVL-1783114, ASB2008-5410	Yes	Bayer CropScience	N
KIIA 6.3	Billian, P.; Telscher, M.	2008	Determination of the residues of AE C656948 in/on tomato and cherry tomato after spraying of AE C656948 (500 SC) in the field in Spain, Italy and Portugal RA-2505/07 ! M-298074-01-2 GLP: Open Published: Open BVL-1783124, ASB2008-5415	Yes	Bayer CropScience	N
KIIA 6.3	Dallstream, K. A.; Fischer, D. R.	2008	AE C656948 500 SC: Magnitude of the residue in/on low growing berry (crop subgroup 13G) RAGMP084 ! M-300045-01-1 GLP: Open Published: Open BVL-1783116, ASB2008-5411	Yes	Bayer CropScience	N
KIIA 6.3	Diot, R.	2007	Determination of the residues of AE C656948 in/on tomato after spraying of AE C656948 (500 SC) in the greenhouse in (the) Southern France, Germany, Spain, Italy, Portugal, Greece and the Netherlands RA-2582/06 ! M-290788-01-2 GLP: Open Published: Open BVL-1783118, ASB2008-5412	Yes	Bayer CropScience	N

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KIIA 6.3	Glaubitz, J.	2014	Determination of the residues of AE C656948, BYF 00587 and Prothioconazole in/on spring wheat and winter wheat after spray application of bixafen & fluopyram & prothioconazole EC 260 in the field in northern france, the United Kingdom, Belgium and German - Amendment no. 2 - incl. amendment no. 1 dated 15.01.2014 - incl. report dated 10.12.2013 M-472538-03-1 ! 12-2131 GLP: Yes Published: No BVL-2629923, ASB2015-2164	Yes	Bayer CropScience	Y
KIIA 6.3	Glaubitz, J.	2014	Determination of the residues of AE C656948 and Prothioconazole in/on spring barley and winter barley after spray application of AE C656948 & JAU 6476 SE 250 in the field in Northern France, Germany, the Netherlands, Belgium and United Kingdom - Amendment no. 1 - incl. report dated 10.12.2013 M-472556-02-1 ! 12-2163 GLP: Yes Published: No BVL-2629920, ASB2015-2161	Yes	Bayer CropScience	Y
KIIA 6.3	Glaubitz, J.	2014	Determination of the residues of AE C656948 and Prothioconazole in/on spring wheat and winter wheat after spray application of AE C656948 & JAU 6476 SE 250 in the field in Northern France, Germany, the Netherlands, Belgium and the United Kingdom - incl. amendment no. 1 to analytical phase report dated 06.01.2014 M-474274-01-1 ! 12-2164 GLP: Yes Published: No BVL-2629922, ASB2015-2163	Yes	Bayer CropScience	Y
KIIA 6.3	Glaubitz, J.	2014	Determination of the residues of AE C656948, BYF 00587 and Prothioconazole in/on spring barley and winter barley after spray application of Bixafen & Fluopyram & Prothioconazole EC 260 in the field in Northern France, the United Kingdom, Belgium and Germany - Amendment no. 1 - incl. report dated 22.01.2014 M-475081-02-1 ! 12-2130 GLP: Yes Published: No BVL-2629921, ASB2015-2162	Yes	Bayer CropScience	Y
KIIA 6.3	Glaubitz, J.; Szeley, C.	2013	Determination of the residues of AE C656948 and Prothioconazole in/on barley, spring after spray application of AE C656948 & JAU 6476 SE 250 in Germany, Belgium and the Netherlands - incl. analytical phase report M-471216-01-1 ! 13-2950 GLP: Yes Published: No BVL-2669737, ASB2015-2165	Yes	Bayer CropScience	Y
KIIA 6.3	Heinemann, O.	2001	Determination of residues of JAU6476-Desthio on spring wheat and winter wheat following seed treatment of JAU6476 200 FS and spray application of JAU6476 250 EC in Germany, Northern France, and Great Britain RA-2003/99 ! MO-01-017905 GLP: Open Published: Open BVL-1982391, RIP2002-1057	Yes	Bayer CropScience	N

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KIIA 6.3	Heinemann, O.	2001	Determination of residues of JAU6476-Desthio on spring wheat following seed treatment of JAU6476 200 FS in Great Britain, Germany and France RA-2010/99 ! MO-01-017228 GLP: Open Published: Open BVL-1982384, RIP2002-1053	Yes	Bayer CropScience	N
KIIA 6.3	Heinemann, O.	2001	Determination of residues of JAU6476-Desthio on spring barley following seed treatment of JAU6476 200 FS and spray application of JAU6476 250 EC in Southern France RA-2079/98 ! MO-01-017824 GLP: Open Published: Open BVL-1982418, RIP2002-1070	Yes	Bayer CropScience	N
KIIA 6.3	Heinemann, O.	2001	Determination of residues of JAU6476-Desthio on rape after spray application of JAU6476 250 EC in Southern France RA-2089/00 ! MO-01-017797 GLP: Open Published: Open BVL-1982390, RIP2002-1076	Yes	Bayer CropScience	N
KIIA 6.3	Heinemann, O.	2001	Determination of residues of JAU6476-Desthio in/on spring wheat following seed treatment of JAU6476 200 FS in Italy and France RA-2090/00 ! MO-01-017028 GLP: Open Published: Open BVL-1982385, RIP2002-1052	Yes	Bayer CropScience	N
KIIA 6.3	Heinemann, O.	2001	Determination of residues of JAU6476-desthio on spring wheat following seed treatment of JAU6476 200 FS in Germany and France RA-2091/00 ! MO-01-017830 GLP: Open Published: Open BVL-1982383, RIP2002-1055	Yes	Bayer CropScience	N
KIIA 6.3	Heinemann, O.	2001	Determination of residues of JAU6476-Desthio on spring barley after spray application of JAU6476 250 EC in Sweden, Germany, Northern France and Great Britain RA-2101/00 ! MO-01-021173 GLP: Open Published: Open BVL-1982417, RIP2002-1069	Yes	Bayer CropScience	N
KIIA 6.3	Heinemann, O.	2001	Determination of residues of JAU6476-desthio in/on spring barley after spray application of JAU6476 250 EC in Spain, Italy and Southern France RA-2103/00 ! MO-01-021256 GLP: Open Published: Open BVL-1982411, RIP2002-1073	Yes	Bayer CropScience	N
KIIA 6.3	Heinemann, O.	2001	Determination of residues of JAU6476-Desthio on spring wheat after spray application of JAU6476 250 EC in Sweden, Germany, Northern France and Great Britain RA-2104/00 ! MO-01-022077 GLP: Open Published: Open BVL-1982405, RIP2002-1058	Yes	Bayer CropScience	N
KIIA 6.3	Heinemann, O.	2001	Determination of residues of JAU6476-Desthio in/on wheat and triticale after spray application of JAU6476 250 EC in Spain and France RA-2105/00 ! MO-01-022201 GLP: Open Published: Open BVL-1982397, RIP2002-1061	Yes	Bayer CropScience	N

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KIIA 6.3	Heinemann, O.	2001	Determination of residues of JAU6476-desthio on spring barley following seed treatment of JAU6476 200 FS and spray application of JAU6476 250 EC in Germany (incl. amendment No. 1 dated 2001-09-24) RA-2150/98 ! MO-01-017508 GLP: Open Published: Open BVL-1982389, RIP2002-1060	Yes	Bayer CropScience	N
KIIA 6.3	Heinemann, O.	2002	Determination of residues of JAU6476-Desthio on rape after spray application of JAU6476 250 EC in Germany, Sweden, Northern France and Great Britain RA-2088/00 ! MO-02-000664 GLP: Open Published: Open BVL-1982401, RIP2002-1074	Yes	Bayer CropScience	N
KIIA 6.3	Heinemann, O.	2002	Determination of residues of JAU6476-Desthio on rape after spray application of JAU6476 250 EC in Germany, Northern France and Great Britain RA-2178/01 ! MO-02-002329 GLP: Open Published: Open BVL-1982419, RIP2002-1077	Yes	Bayer CropScience	N
KIIA 6.3	Heinemann, O.	2002	Determination of residues of JAU6476-Desthio on rape after spray application of JAU6476 250 EC in Southern France RA-2179/01 ! MO-02-001543 GLP: Open Published: Open BVL-1982386, RIP2002-1079	Yes	Bayer CropScience	N
KIIA 6.3	Heinemann, O.; Elke, K.	2001	Determination of residues of JAU6476-desthio on spring barley following seed treatment of JAU6476 200 FS and spray application of JAU6476 250 EC in Germany, France and Great Britain (incl. amendment No. 1 dated 2001-09-24) RA-2140/98 ! MO-01-017515 GLP: Open Published: Open BVL-1982392, RIP2002-1068	Yes	Bayer CropScience	N
KIIA 6.3	Heinemann, O.; Elke, K.	2001	Determination of residues of JAU6476-desthio in/on winter barley after spray application of JAU6476 250 EC in France, Italy and Portugal (incl. amendment No. 1 dated 2001-09-24) RA-2144/98 ! MO-01-017514 GLP: Open Published: Open BVL-1982406, RIP2002-1071	Yes	Bayer CropScience	N
KIIA 6.3	Heinemann, O.; Elke, K.	2001	Determination of residues of JAU6476-Desthio on winter wheat following seed treatment of JAU6476 200 FS and spray application of JAU6476 250 EC in France, Spain and Italy RA-2149/98 ! MO-01-020726 GLP: Open Published: Open BVL-1982409, RIP2002-1059	Yes	Bayer CropScience	N
KIIA 6.3	Schöning, R.; Erler, S.	2007	Determination of the residues of AE C656948 in/on tomato after spraying of AE C656948 (500 SC) in the field in Portugal, Italy, Spain and Southern France RA-2599/06 ! M-295816-01-2 GLP: Open Published: Open BVL-1783120, ASB2008-5413	Yes	Bayer CropScience	N

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KIIA 6.3	Schöning, R.; Räcker, T.	2007	Determination of the residues of BYF 00587 in/on spring barley and winter barley after spraying of BYF 00587 (125 EC) in the field in Northern France, Sweden, the United Kingdom and Germany RA-2322/06 ! M-292772-01-1 GLP: Open Published: Open BVL-1994744, BVL-1994744, ASB2009-5946	Yes	Bayer CropScience	Y
KIIA 6.3	Schöning, R.; Räcker, T.; Erler, S.	2007	Determination of the residues of BYF 00587 in/on spring wheat and winter wheat after spraying of BYF 00587 (125 EC) in the field in Northern France, Sweden, the United Kingdom and Germany RA-2320/06 ! M-293308-01-1 GLP: Open Published: Open BVL-1994740, BVL-1994740, ASB2009-5942	Yes	Bayer CropScience	Y
KIIA 6.3	Schöning, R.; Räcker, T.; Erler, S.	2007	Determination of the residues of BYF 00587 in/on spring barley and winter barley after spraying of BYF 00587 (125 EC) in the field in Southern France, Italy, Spain and Portugal RA-2323/06 ! M-293305-01-1 GLP: Open Published: Open BVL-1994747, BVL-1994747, ASB2009-5949	Yes	Bayer CropScience	N
KIIA 6.3	Schöning, R.; Räcker, T.; Lorenz, S.	2007	Determination of the residues of BYF 00587 in/on winter wheat, wheat, durum and spring wheat after spraying of BYF 00587 (125 EC) in the field in Greece, Italy, Southern France and Spain RA-2321/06 ! M-292764-01-1 GLP: Open Published: Open BVL-1994742, BVL-1994742, ASB2009-5944	Yes	Bayer CropScience	N
KIIA 6.3	Schöning, R.; Räcker, T.; Telscher, M.	2007	Determination of the residues of AE C656948 in/on strawberry after spraying of AE C656948 (500 SC) in the field in Southern France, Italy, Spain, and Greece RA-2601/06 ! M-295419-01-2 GLP: Open Published: Open BVL-1783110, ASB2008-5407	Yes	Bayer CropScience	N
KIIA 6.3	Schöning, R.; Reineke, A.	2007	Determination of the residues of BYF 00587 in/on spring barley and winter barley after spraying of BYF 00587 (125 EC) in the field in Southern France, Italy and Spain (incl. amendment No. 1 dated 2008-01-25) RA-2004/07 ! M-295811-01-1 ! M-295811-02-1 GLP: Open Published: Open BVL-1994748, BVL-1994748, ASB2009-5950	Yes	Bayer CropScience	N
KIIA 6.3	Schöning, R.; Reineke, A.	2008	Determination of the residues of BYF 00587 in/on spring barley after spraying of BYF 00587 (125 EC) in the field in Northern France, Germany, the United Kingdom and Belgium RA-2003/07 ! M-296368-01-1 GLP: Open Published: Open BVL-1994745, BVL-1994745, ASB2009-5947	Yes	Bayer CropScience	Y

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KIIA 6.3	Schöning, R.; Reineke, A.	2008	Determination of the residues of BYF 00587 in/on spring wheat, wheat, durum and winter wheat after spraying of BYF 00587 (125 EC) in the field in Southern France, Italy, Spain and Portugal RA-2005/07 ! M-296364-01-1 GLP: Open Published: Open BVL-1994743, BVL-1994743, ASB2009-5945	Yes	Bayer CropScience	N
KIIA 6.3	Schöning, R.; Reineke, A.	2008	Determination of the residues of BYF 00587 in/on winter wheat and spring wheat after spraying of BYF 00587 (125 EC) in the field in Northern France, the United Kingdom, Sweden and Germany RA-2006/07 ! M-296300-01-1 GLP: Open Published: Open BVL-1994741, BVL-1994741, ASB2009-5943	Yes	Bayer CropScience	Y
KIIA 6.3	Schöning, R.; Telscher, M.	2007	Determination of the residues of AE C656948 in/on strawberry after spraying of AE C656948 (500 SC) in the greenhouse in Northern France, Italy, Spain, Belgium, the Netherlands, the United Kingdom, and Germany RA-2585/06 ! M-295155-01-2 GLP: Open Published: Open BVL-1783106, ASB2008-5405	Yes	Bayer CropScience	N
KIIA 6.3	Schöning, R.; Telscher, M.	2007	Determination of the residues of AE C656948 in/on strawberry after spraying of AE C656948 (500 SC) in the field in Northern France, Germany, Belgium, the Netherlands and the United Kingdom RA-2600/06 ! M-295412-01-2 GLP: Open Published: Open BVL-1783108, ASB2008-5406	Yes	Bayer CropScience	N
KIIA 6.3	Schöning, R.; Wolters, A.	2007	Determination of the residues of BYF 00587 in/on spring barley after spraying of BYF 00587 (125 EC) in the field in Sweden, Germany, and Northern France RA-2324/06 ! M-293318-01-1 GLP: Open Published: Open BVL-1994746, BVL-1994746, ASB2009-5948	Yes	Bayer CropScience	N
KIIA 6.3	Schöning, R.; Wolters, A.	2008	Determination of the residues of AE C656948 in/on grape after spraying of AE C656948 (500 SC) in the field in Northern France and Germany RA-2611/06 ! M-296837-01-2 GLP: Open Published: Open BVL-1783092, ASB2008-5399	Yes	Bayer CropScience	N
KIIA 6.3	Schöning, R.; Wolters, A.	2008	Determination of the residues of AE C656948 in/on table grape after spraying of AE C656948 (500 SC) in the field in Spain, Portugal, Italy and Greece RA-2612/06 ! M-296514-01-2 GLP: Open Published: Open BVL-1783096, ASB2008-5401	Yes	Bayer CropScience	N
KIIA 6.3	Schöning, R.; Wolters, A.	2008	Determination of the residues of AE C656948 in/on grape after low-volume spraying of AE C656948 (500 SC) in the field in Southern France RA-2647/06 ! M-296564-01-2 GLP: Open Published: Open BVL-1783094, ASB2008-5400	Yes	Bayer CropScience	N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 6.4.1	[redacted]	2008	Fluopyram: Feeding study laying hens (Gallus gallus domesticus) MR-07/234 ! M-297674-01-2 ! P673070608 GLP: Open Published: Open BVL-1783128, ASB2008-5417	Yes	Bayer CropScience	Y
KIIA 6.4.1	[redacted]	2007	Bixafen: Feeding study laying hens (Gallus gallus domesticus) (incl. amendment No. 1 dated 2008-01-18) MR-07/220 ! P673070604 ! M-295887-01-1 ! M-295887-02-1 GLP: Open Published: Open BVL-1994749, BVL-1994749, ASB2009-5951	Yes	Bayer CropScience	Y
KIIA 6.4.2	[redacted]	2001	JAU6476-desthio - Dairy cattle feeding study MR-535/00 ! P 673003007 ! MO-01-019272 GLP: Open Published: Open BVL-1982400, RIP2002-1080	Yes	Bayer CropScience	Y
KIIA 6.4.2	[redacted]	2008	Bixafen: Feeding study with dairy cows MR-07/340 ! P673074704 ! M-296420-01-1 GLP: Open Published: Open BVL-1994750, BVL-1994750, ASB2009-5952	Yes	Bayer CropScience	Y
KIIA 6.4.2	[redacted]	2008	Fluopyram: Feeding study with dairy cows MR-07/367 ! M-298635-01-2 ! P673074725 GLP: Open Published: Open BVL-1783130, ASB2008-5418	Yes	Bayer CropScience	Y
KIIA 6.5.1	Gilges, M.	2001	Hydrolysis of JAU 6476-desthio under conditions of processing MR-106/00 ! MO-01-001956 GLP: Open Published: Open BVL-2614707, ASB2012-5968	Yes	Bayer CropScience	Y
KIIA 6.5.1	Gilges, M.	2001	Hydrolysis of JAU6476 under conditions of processing MR-166/00 ! M1771021-9 ! MO-01-001955 GLP: Open Published: Open BVL-1982388, RIP2002-1081	Yes	Bayer CropScience	Y
KIIA 6.5.1	Heinemann, O.	2006	[Pyridine-2,6-14C]AE C656948-7-hydroxy: Aqueous hydrolysis under conditions of processing studies MEF-06/349 ! M-278554-01-1 ! M1771623-7 GLP: Open Published: Open BVL-1783136, ASB2008-5421	Yes	Bayer CropScience	Y
KIIA 6.5.1	Heinemann, O.	2006	[Pyridine-2,6-14C]AE C656948-pyridyl-acetic acid: Aqueous hydrolysis under conditions of processing studies MEF-06/354 ! M-278760-01-1 ! M1771622-6 GLP: Open Published: Open BVL-1783140, ASB2008-5423	Yes	Bayer CropScience	Y
KIIA 6.5.1	Justus, K.; Kuhnke, G.	2008	BYF 00587: Aqueous hydrolysis under conditions of processing studies MEF-07/437 ! M 1771594-4 ! M-296836-01-1 GLP: Open Published: Open BVL-1994751, BVL-1994751, ASB2009-5953	Yes	Bayer CropScience	Y

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KIIA 6.5.1	Koenig, H.	2006	[Phenyl-UL-14C]AE C656948 and [Pyridyl-2,6-14C]AE C656948: Aqueous hydrolyses under conditions of processing studies MEF-06/170 ! M-278527-01-1 GLP: Open Published: Open BVL-1783132, ASB2008-5419	Yes	Bayer CropScience	Y
KIIA 6.5.1	Menke, U.	2006	[Phenyl-UL-14C]AE C656948-benzamide: Aqueous hydrolysis under conditions of processing studies MEF-06/273 ! M177 1605-7 ! M-278640-01-1 GLP: Open Published: Open BVL-1783134, ASB2008-5420	Yes	Bayer CropScience	Y
KIIA 6.5.1	Menke, U.	2006	[Pyridyl-2,6-14C]AE C656948-pyridyl-carboxylic acid: Aqueous hydrolysis under conditions of processing studies, Amended:06.11.2006 MEF-06/358 ! M-278803-02-1 ! M177 1606-8 GLP: Open Published: Open BVL-1783138, ASB2008-5422	Yes	Bayer CropScience	Y
KIIA 6.5.3	Billian, P.; Telscher, M.	2008	Determination of the residues of AE C656948 in/on tomato fruit and the processed fractions (raw juice; washings; fruit, washed; juice; peel; preserve; fruit, peeled; peeling water; puree; raw puree; strain rest) after spraying of AE C656 (500 SC) in the field in Italy RA-3505/07 ! M-298072-01-2 GLP: Open Published: Open BVL-1783156, ASB2008-5431	Yes	Bayer CropScience	N
KIIA 6.5.3	Lenz, C. A.; Harbin, A. M.	2008	AE C656948 500 SC: Magnitude of the residue in/on tomato processed commodities RAGMP058 ! M-299429-01-1 GLP: Open Published: Open BVL-1783158, ASB2008-5432	Yes	Bayer CropScience	N
KIIA 6.5.3	Mackie, S. J. W.	2008	AE C656948 500 SC: Magnitude of the residue on grape processed commodities RAGMP042 ! M-298571-01-1 GLP: Open Published: Open BVL-1783148, ASB2008-5427	Yes	Bayer CropScience	N
KIIA 6.5.3	Schöning, R.; Billian, P.; Raecker, T.; Telscher, M.	2007	Determination of the residues of AE C656948 in/on strawberry fruit and the processed fractions (fruit, washed; preserve; washings; jam) after spraying of AE C656948 (500 SC) in the field in Southern France and Spain RA-3601/06 ! M-295517-01-2 GLP: Open Published: Open BVL-1783150, ASB2008-5428	Yes	Bayer CropScience	N
KIIA 6.5.3	Schöning, R.; Billian, P.; Telscher, M.	2007	Determination of the residues of AE C656948 in/on strawberry fruit and the processed fractions (fruit, washed; preserve; washings; jam) after spraying of AE C656948 (500 SC) in the field in Northern France and Belgium RA-3600/06 ! M-295535-01-2 GLP: Open Published: Open BVL-1783152, ASB2008-5429	Yes	Bayer CropScience	N

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KIIA 6.5.3	Schöning, R.; Billian, P.; Wolters, A.	2007	Determination of the residues of BYF 00587 in/on spring barley grain and the processed fractions (brewers's malt; malt culms; beer; brewers's yeast; brewers's grain; hops draff; pearl barley; pearl barley rub off) after spraying of BYF 00587 (125 EC) in the field in Sweden, Germany and Northern France RA-3324/06 ! M-293322-01-1 GLP: Open Published: Open BVL-1994752, BVL-1994752, ASB2009-5954	Yes	Bayer CropScience	N
KIIA 6.5.3	Schöning, R.; Billian, P.; Wolters, A.	2008	Determination of the residues of AE C656948 in/on grape (bunch of grapes) and bunch of grapes for wine proc. and the processed fractions (juice; raw juice; washings; pomace, dried; pomace, wet; berry, washed; retentate; pomace, grape; must; wine at 1st taste test; wine) after low-volume spraying of AE C656948 (500 SC) in the field in Northern France RA-3611/06 ! M-296826-01-2 GLP: Open Published: Open BVL-1783142, ASB2008-5424	Yes	Bayer CropScience	N
KIIA 6.5.3	Schöning, R.; Billian, P.; Wolters, A.	2008	Determination of the residues of AE C656948 in/on table grape (bunch of grapes) and the processed fractions (raisin; raisin waste; washings) after spraying of AE C656948 (500 SC) in the field in Spain, Portugal, Italy and Greece RA-3612/06 ! M-296512-01 GLP: Open Published: Open BVL-1783146, ASB2008-5426	Yes	Bayer CropScience	N
KIIA 6.5.3	Schöning, R.; Billian, P.; Wolters, A.	2008	Determination of the residues of AE C656948 in/on grape (bunch of grapes) and bunch of grapes for wine proc. and the processed fractions (juice; raw juice; washings; pomace, dried; pomace, wet; berry, washed; retentate; pomace, grape; must; wine at 1st taste test; wine) after low-volume spraying of AE C656948 (500 SC) in the field in Southern France RA-3647/06 ! M-296549-01-2 GLP: Open Published: Open BVL-1783144, ASB2008-5425	Yes	Bayer CropScience	N
KIIA 6.5.3	Schöning, R.; Erler, S.	2007	Determination of the residues of AE C656948 in/on tomato fruit and the processed fractions (raw juice; washings; fruit, washed; juice; peel; preserve; fruit, peeled; peeling water; puree; raw puree; strain rest) after spraying of AE C656948 (500 SC) in the field in Portugal, Italy and Southern France - Amendment dated: 03.03.2008 RA-3599/06 ! M-295818-02-2 GLP: Open Published: Open BVL-1783154, ASB2008-5430	Yes	Bayer CropScience	N
KIIA 6.6.2	Duah, F. K.; Kraai, M. J.	2004	The accumulation of [triazole-3,5-14C] JAU6476 in confined rotational crops 200623 ! J6051601 ! M-000784-01-1 GLP: Open Published: Open BVL-1982408, ASB2009-4303	Yes	Bayer CropScience	Y
KIIA 6.6.2	Haas, M.	2001	Confined rotational crop study with JAU6476 MR-159/00 ! M1300891-2 ! MO-01-011374 GLP: Open Published: Open BVL-1982410, RIP2002-1082	Yes	Bayer CropScience	Y

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KIIA 6.6.2	Kuhnke, G.; Weber, E.; Koehn, D.	2007	Metabolism of [dichlorophenyl-UL-14C]BYF 00587 in confined rotational crops (incl. amendment No. 1 dated 2008-01-28) MEF-07/070 ! M1301474-0 ! M-295889-02-1 GLP: Open Published: Open BVL-1994754, BVL-1994754, ASB2009-5956	Yes	Bayer CropScience	Y
KIIA 6.6.2	Weber, E.; Spiegel, K.; Koehn, D.	2007	Metabolism of [pyrazole-5-14C]BYF 00587 in confined rotational crops MEF-07/071 ! M1301475-1 ! M-295793-01-1 GLP: Open Published: Open BVL-1994753, BVL-1994753, ASB2009-5955	Yes	Bayer CropScience	Y
KIIA 6.6.3	Noss, G.; Erler, S.	2008	Determination of the residues of AE C656948 in/on the field rotational crops turnip, lettuce and winter wheat after spraying of AE C656948 (500 SC) in the field in Germany RA-2648/06 ! RAGMX050 ! M-296625-02-1 GLP: Open Published: Open BVL-1861448, ASB2008-8222	Yes	Bayer CropScience	Y
KIIA 6.6.3	Noss, G.; Erler, S.	2008	Determination of the residues of AE C656948 in/on the field rotational crops turnip, lettuce and winter wheat after spraying of AE C656948 (500 SC) in the field in Northern France RA-2649/06 ! M-296608-01-2 GLP: Open Published: Open BVL-1783164, ASB2008-5434	Yes	Bayer CropScience	Y
KIIA 6.6.3	Noss, G.; Erler, S.	2008	Determination of the residues of AE C656948 in/on the field rotational crops carrot, lettuce and winter wheat after spraying of AE C656948 (500 SC) in the field in Italy RA-2650/06 ! RAGMX052 ! M-296652-02-1 GLP: Open Published: Open BVL-1861450, ASB2008-8223	Yes	Bayer CropScience	Y
KIIA 6.6.3	Noss, G.; Erler, S.	2008	Determination of the residues of AE C656948 in/on the field rotational crops carrot, lettuce and winter wheat after spraying of AE C656948 (500 SC) in the field in Spain RA-2651/06 ! RAGMX053 ! M-296671-02-1 GLP: Open Published: Open BVL-1861452, ASB2008-8224	Yes	Bayer CropScience	Y
KIIA 6.6.3	Schöning, R.; Erler, S.	2008	Determination of the residues of BYF 00587 in/on the field rotational crops turnip, lettuce, winter wheat and spring wheat after spraying of BYF 00587 (125 EC) in the field in Germany (incl. amendment No. 1 dated 2008-02-11) RA-2139/06 ! M-296357-01-1 ! M-296357-02-1 GLP: Open Published: Open BVL-1994755, BVL-1994755, ASB2009-5957	Yes	Bayer CropScience	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 6.6.3	Schöning, R.; Erler, S.	2008	Determination of the residues of BYF 00587 in/on the field rotational crops turnip, lettuce, winter wheat and spring wheat after spraying of BYF 00587 (125 EC) in the field in Northern France (incl. amendment No. 1 dated 2008-02-25) RA-2143/06 ! M-296525-01-1 ! M-296525-02-1 GLP: Open Published: Open BVL-1994756, BVL-1994756, ASB2009-5958	Yes	Bayer CropScience	Y
KIIA 6.6.3	Schöning, R.; Erler, S.	2008	Determination of the residues of BYF 00587 in/on the field rotational crops turnip, lettuce, winter wheat and spring wheat after spraying of BYF 00587 (125 EC) in the field in Germany (incl. amendment No. 1 dated 2008-02-15) RA-2144/06 ! M-296536-01-1 ! M-296536-02-1 GLP: Open Published: Open BVL-1994757, BVL-1994757, ASB2009-5959	Yes	Bayer CropScience	Y
KIIA 6.6.3	Schöning, R.; Erler, S.	2008	Determination of the residues of BYF 00587 in/on the field rotational crops carrot, lettuce and winter wheat after spraying of BYF 00587 (125 EC) in the field in Spain RA-2145/06 ! M-296409-01-1 GLP: Open Published: Open BVL-1994758, BVL-1994758, ASB2009-5960	Yes	Bayer CropScience	Y

* Y: Yes, relied on
N: No, not relied on
Add: Relied on, study not submitted by applicant but necessary for evaluation

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Storage stability

No further study on storage stability submitted/needed.

A 2.2 Residues in primary crops

A 2.2.1 Nature of residues

No further study on nature of residues submitted/needed.

A 2.2.2 Magnitude of residues in barley

Reference:	OECD KIIA 6.3
Report	see authority registration numbers cited in the remarks columns of the tables below (and study identification as laid down in the reference list)
Guideline(s):	in accordance with agreed guidance unless stated otherwise in the commenting box
Deviations:	no relevant deviations unless stated otherwise in the commenting box
GLP:	see reference list
Acceptability:	acceptable unless stated otherwise in the commenting box

Table A 2: Residues of bixafen in barley

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 65 g/L
Formulation (e.g. WP) : EC (emulsifiable concentrate)
Commercial product (name) : Ascra Xpro

Applicant : Bayer CropScience Registrierung & PGA

Active ingredient : Bixafen
Crop / crop group : Spring barley

Submission date : 2015-02-18

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) : 65 g/L Fluopyram
130 g/L Prothioconazole

Residues calculated as : 8.1 Bixafen
8.2 Bixafen-desmethyl, calculated as bixafen
8.3 Sum of bixafen and bixafen-desmethyl

1	2	3	4			5	6	7	8.1	8.2	8.3	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl								
	(a)	(b)				(c)		(a)				(d)	(e)
study 12-2130, trial 12-2130-02 Belgium (BE) 1495 Marbais 2014-03-31	Quench	1) 2012-03-15 (sowing) 2) 2012-06-22 - 2012-06-26 3) 2012-08-08 - 2012-08-17	0.078	250	0.031	2012-06-22[4)]	BBCH 61	forage grain straw	1.4 0.053 0.59	<0.010 <0.010 0.038	1.4 0.063 0.63	0 47 47	4) spraying analytical method: 01013 (HPLC-MS/MS), LOQ(s): 8.1/8.2: 0.01 mg/kg, 8.3: 0.02 mg/kg max. sample storage time in month(s): 8 ASB2015-2162

1	2	3	4			5	6	7	8.1	8.2	8.3	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl								
	(a)	(b)				(c)		(a)				(d)	(e)
study 12-2130, trial 12-2130-04 Germany (DE) 51399 Burscheid 2014-03-31	Simba	1) 2012-03-16 (sowing) 2) 2012-06-05 - 2012-06-11 3) 2012-08-10 - 2012-08-24	0.078	300	0.026	2012-06-05[4)]	BBCH 61	forage grain straw	1.8 0.011 0.28	<0.010 <0.010 0.063	1.8 0.021 0.34	0 69 69	4) spraying analytical method: 01013 (HPLC-MS/MS), LOQ(s): 8.1/8.2: 0.01 mg/kg, 8.3: 0.02 mg/kg max. sample storage time in month(s): 8 ASB2015-2162

Comments of zRMS:	Acceptable. GAP-compliant.

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 65 g/L
Formulation (e.g. WP) : EC (emulsifiable concentrate)
Commercial product (name) : Ascra Xpro

Applicant : Bayer CropScience Registrierung & PGA

Active ingredient : Bixafen
Crop / crop group : Winter barley

Submission date : 2015-02-18

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) : 65 g/L Fluopyram
130 g/L Prothioconazole

Residues calculated as : 8.1 Bixafen
8.2 Bixafen-desmethyl, calculated as bixafen
8.3 Sum of bixafen and bixafen-desmethyl

1	2	3	4			5	6	7	8.1	8.2	8.3	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl								
	(a)	(b)				(c)		(a)				(d)	(e)
study 12-2130, trial 12-2130-01 France (FR) 95710 Chaussy 2014-03-31	Volume	1) 2011-10-04 (sowing) 2) 2012-05-14 - 2012-05-25 3) 2012-07-17 - 2012-07-20	0.078	300	0.026	2012-05-14[4)]	BBCH 61	forage grain straw	1.2 0.47 0.42 0.17 0.079 0.75	<0.010 <0.010 0.021 0.021 0.013 0.042	1.2 0.48 0.44 0.19 0.092 0.79	0 7 14 28 64 64	4) spraying analytical method: 01013 (HPLC-MS/MS), LOQ(s): 8.1/8.2: 0.01 mg/kg, 8.3: 0.02 mg/kg max. sample storage time in month(s): 9 ASB2015-2162
study 12-2130, trial 12-2130-03 United Kingdom (UK) CB22 5EU Cambridge 2014-03-31	Carrat	1) 2011-09-07 (sowing) 2) 2012-05-21 3) 2012-07-15 - 2012-08-10	0.078	200	0.039	2012-05-23[4)]	BBCH 61	forage	1.8 1.1 0.60 0.26	<0.010 0.096 0.082 0.066	1.8 1.2 0.68 0.33	0 7 14 27	4) spraying analytical method: 01013 (HPLC-MS/MS), LOQ(s): 8.1/8.2: 0.01 mg/kg, 8.3: 0.02 mg/kg max. sample storage time in month(s): 8 ASB2015-2162

Comments of zRMS:	Acceptable. GAP-compliant.

Table A 3: Residues of fluopyram in barley

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 125 g/L
Formulation (e.g. WP) : SE (suspo-emulsion)
Commercial product (name) : Propulse
Applicant : Bayer CropScience Registrierung & PGA

Active ingredient : Fluopyram
Crop / crop group : Spring barley

Submission date : 2015-02-18

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) : 125 g/L Prothioconazole
Residues calculated as : 8.1 Fluopyram
8.2 Fluopyram-benzamide (M25), expressed as fluopyram

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl							
	(a)	(b)				(c)		(a)			(d)	(e)
study 12-2163, trial 12-2163-05 France (FR) 37310 Chambourg sur Indre 2014-01-09	Sebastian	1) 2012-03-02 (sowing) 2) 2012-06-01 - 2012-06-08 3) 2012-07-20 - 2012-07-25	0.13	300	0.043	2012-06-01[4)]	BBCH 61	forage grain straw	1.9 0.018 0.14	<0.010 <0.010 0.020	0 53 53	4) spraying analytical method: 00984/M003 (MR12/036) (HPLC-MS/MS), LOQ(s): 0.01 mg/kg, max. sample storage time in month(s): 11 ASB2015-2161
study 12-2163, trial 12-2163-06 Belgium (BE) 1495 Marbais 2014-01-09	Quench	1) 2012-03-15 (sowing) 2) 2012-06-22 - 2012-06-26 3) 2012-08-08 - 2012-08-17	0.13	200	0.065	2012-06-22[4)]	BBCH 61	forage grain straw	2.2 0.026 0.081	<0.010 <0.010 <0.010	0 47 47	4) spraying analytical method: 00984/M003 (MR12/036) (HPLC-MS/MS), LOQ(s): 0.01 mg/kg, max. sample storage time in month(s): 11 ASB2015-2161
study 12-2163, trial 12-2163-07 United Kingdom (UK) CB22 5EU Little Shelford Farm 2014-01-09	Propino	1) 2012-03-23 (sowing) 2) 2012-06-25 - 2012-07-09 3) 2012-08-06 - 2012-08-20	0.13	200	0.065	2012-06-25[4)]	BBCH 61	forage grain straw	2.4 0.033 0.13	<0.010 0.013 0.037	0 46 46	4) spraying analytical method: 00984/M003 (MR12/036) (HPLC-MS/MS), LOQ(s): 0.01 mg/kg, max. sample storage time in month(s): 11 ASB2015-2161

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl							
	(a)	(b)				(c)		(a)			(d)	(e)
study 12-2163, trial 12-2163-08 Germany (DE) 51399 Burscheid 2014-01-09	Simba	1) 2012-03-16 (sowing) 2) 2012-06-05 - 2012-06-11 3) 2012-08-10 - 2012-08-24	0.13	300	0.043	2012-06-05[4)]	BBCH 61	forage grain straw	2.6 0.016 0.11	<0.010 <0.010 0.029	0 69 69	4) spraying analytical method: 00984/M003 (MR12/036) (HPLC-MS/MS), LOQ(s): 0.01 mg/kg, max. sample storage time in month(s): 11 ASB2015-2161
study 13-2950, trial 13-2950-01 Germany (DE) 51399 Burscheid 2013-11-25	Conchita	1) 2013-03-28 (sowing) 2) 3)	0.13	300	0.043	2013-05-14[4)]	BBCH 30	forage	8.6 6.8 5.0 2.3 1.5 0.53 0.24		0 1 2 3 5 7 10	4) spraying analytical method: 00984/M003 (MR12/036) (HPLC-MS/MS), LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 4 ASB2015-2165
study 13-2950, trial 13-2950-02 Germany (DE) 49377 Langförden 2013-11-25	Grace	1) 2013-04-09 (sowing) 2) 3)	0.13	300	0.043	2013-05-21[4)]	BBCH 31	forage	4.5 0.96 0.83 0.75 0.61 0.44 0.25		0 1 2 3 5 7 10	4) spraying analytical method: 00984/M003 (MR12/036) (HPLC-MS/MS), LOQ(s):: 0.01 mg/kg max. sample storage time in month(s): 4 ASB2015-2165
study 13-2950, trial 13-2950-03 Belgium (BE) 6221 Saint-Amand 2013-11-25	Quench	1) 2013-03-06 (sowing) 2) 2013-06-29 - 2013-07-04 3) 2013-08-10 - 2013-08-21	0.13	300	0.043	2013-05-15[4)]	BBCH 30	forage	7.3 1.4 1.2 1.0 0.54 0.30 0.20		0 1 2 3 5 7 10	4) spraying analytical method: 00984/M003 (MR12/036) (HPLC-MS/MS), LOQ(s):: 0.01 mg/kg max. sample storage time in month(s): 4 ASB2015-2165

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl							
	(a)	(b)				(c)		(a)			(d)	(e)
study 13-2950, trial 13-2950-04 Netherlands (NL) 1775 PN Middenmeer 2013-11-25	Tipple	1) 2013-04-07 (sowing) 2) 2013-06-15 - 2013-06-30 3) 2013-08-10 - 2013-08-20	0.13	300	0.043	2013-05-24[4)]	BBCH 30	forage	8.0 6.3 1.5 1.4 0.67 0.41 0.20		0 1 2 3 5 7 10	4) spraying analytical method: 00984/M003 (MR12/036) (HPLC-MS/MS), LOQ(s):: 0.01 mg/kg max. sample storage time in month(s): 4 ASB2015-2165

Comments of zRMS:	Acceptable. Overcritical use pattern in terms of application rate (0.13 kg as/ha instead of 0.078 kg as/ha).

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 65 g/L
Formulation (e.g. WP) : EC (emulsifiable concentrate)
Commercial product (name) : Ascra Xpro

Applicant : Bayer CropScience Registrierung & PGA

Active ingredient : Fluopyram
Crop / crop group : Spring barley

Submission date : 2015-02-18

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) : 65 g/L Bixafen
130 g/L Prothioconazole

Residues calculated as : 8.1 Fluopyram
8.2 Fluopyram-benzamide (M25), expressed as fluopyram

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl							
	(a)	(b)				(c)		(a)			(d)	(e)
study 12-2130, trial 12-2130-02 Belgium (BE) 1495 Marbais 2014-03-31	Quench	1) 2012-03-15 (sowing) 2) 2012-06-22 - 2012-06-26 3) 2012-08-08 - 2012-08-17	0.079	250	0.032	2012-06-22[4)]	BBCH 61	forage grain straw	1.3 0.025 0.058	<0.010 <0.010 <0.010	0 47 47	4) spraying analytical method: 00984/M003 (MR12/036) (LC-MS/MS), LOQ(s): 0.01 mg/kg, max. sample storage time in month(s): 14 ASB2015-2162
study 12-2130, trial 12-2130-04 Germany (DE) 51399 Burscheid 2014-03-31	Simba	1) 2012-03-16 (sowing) 2) 2012-06-05 - 2012-06-11 3) 2012-08-10 - 2012-08-24	0.079	300	0.026	2012-06-05[4)]	BBCH 61	forage grain straw	1.8 <0.010 0.024	<0.010 <0.010 0.017	0 69 69	4) spraying analytical method: 00984/M003 (MR12/036) (LC-MS/MS), LOQ(s): 0.01 mg/kg, max. sample storage time in month(s): 14 ASB2015-2162

Comments of zRMS:	Acceptable. GAP-compliant.

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 125 g/L
Formulation (e.g. WP) : SE (suspo-emulsion)
Commercial product (name) : Propulse
Applicant : Bayer CropScience Registrierung & PGA

Active ingredient : Fluopyram
Crop / crop group : Winter barley

Submission date : 2015-02-18

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) : 125 g/L Prothioconazole
Residues calculated as : 8.1 Fluopyram
8.2 Fluopyram-benzamide (M25), expressed as fluopyram

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl							
	(a)	(b)				(c)		(a)			(d)	(e)
study 12-2163, trial 12-2163-01 France (FR) 95710 Chaussy 2014-01-09	Volume	1) 2011-10-04 (sowing) 2) 2012-05-14 - 2012-05-25 3) 2012-07-16 - 2012-07-19	0.13	300	0.043	2012-05-14[4)]	BBCH 61	forage grain straw	1.8 0.26 0.19 0.043 0.018 0.14	<0.010 <0.010 <0.010 <0.010 <0.010 0.013	0 7 14 28 64 64	4) spraying analytical method: 00984/M003 (MR12/036) (LC-MS/MS), LOQ(s): 0.01 mg/kg, max. sample storage time in month(s): 12 ASB2015-2161
study 12-2163, trial 12-2163-02 Germany (DE) 49377 Vechta-Langförden 2014-01-09	Meridian multiline	1) 2011-09-30 (sowing) 2) 2012-05-21 - 2012-06-04 3) 2012-07-05 - 2012-07-25	0.13	300	0.043	2012-05-22[4)]	BBCH 61	forage grain straw	1.8 0.95 0.31 0.14 0.025 0.066	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0 7 14 28 62 62	4) spraying analytical method: 00984/M003 (MR12/036) (LC-MS/MS), LOQ(s): 0.01 mg/kg, max. sample storage time in month(s): 11 ASB2015-2161
study 12-2163, trial 12-2163-03 Netherlands (NL) 1774 Slootdorp 2014-01-09	Winter Malt	1) 2011-10-14 (sowing) 2) 2012-06-01 - 2012-06-15 3) 2012-07-22 - 2012-08-02	0.13	300	0.043	2012-06-01[4)]	BBCH 61	forage grain straw	2.6 0.62 0.30 0.062 0.027 0.057	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0 7 14 28 54 54	4) spraying analytical method: 00984/M003 (MR12/036) (LC-MS/MS), LOQ(s): 0.01 mg/kg, max. sample storage time in month(s): 11 ASB2015-2161

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment kg a.i./ha	Water l/ha	kg a.i./hl	Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)			(d)	(e)
study 12-2163, trial 12-2163-04 Netherlands 9076 PP Sint Annaparochie 2014-01-09	Winter Malt	1) 2011-10-10 (sowing) 2) 2012-05-30 - 2012-06-18 3) 2012-07-15 - 2012-08-01	0.13	300	0.043	2012-05-30[4)]	BBCH 61	forage grain straw	2.1 0.25 0.088 0.030 0.014 0.025	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0 7 14 28 56 56	4) spraying analytical method: 00984/M003 (MR12/036) (LC-MS/MS), LOQ(s): 0.01 mg/kg, max. sample storage time in month(s): 11 ASB2015-2161

Comments of zRMS:	Acceptable. Overcritical use pattern in terms of application rate (0.13 kg as/ha instead of 00.78 kg as/ha).

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 65 g/L
Formulation (e.g. WP) : EC (emulsifiable concentrate)
Commercial product (name) : Ascra Xpro

Applicant : Bayer CropScience Registrierung & PGA

Active ingredient : Fluopyram
Crop / crop group : Winter barley

Submission date : 2015-02-18

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) : 65 g/L Bixafen
130 g/L Prothioconazole

Residues calculated as : 8.1 Fluopyram
8.2 Fluopyram-benzamide (M25), expressed as fluopyram

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl							
	(a)	(b)				(c)		(a)			(d)	(e)
study 12-2130, trial 12-2130-01 France (FR) 95710 Chaussy 2014-03-31	Volume	1) 2011-10-04 (sowing) 2) 2012-05-14 - 2012-05-25 3) 2012-07-17 - 2012-07-20	0.079	300	0.026	2012-05-14[4)]	BBCH 61	forage grain straw	1.0 0.23 0.16 0.035 0.015 0.054	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0 7 14 28 64 64	4) spraying analytical method: 00984/M003 (MR12/036) (LC-MS/MS), LOQ(s): 0.01 mg/kg, max. sample storage time in month(s): 15 ASB2015-2162
study 12-2130, trial 12-2130-03 United Kingdom CB22 5EU Cambridge 2014-03-31	Carrat	1) 2011-09-07 (sowing) 2) 2012-05-21 3) 2012-07-15 - 2012-08-10	0.079	200	0.040	2012-05-23[4)]	BBCH 61	forage	1.7 0.86 0.28 0.080	<0.010 0.029 0.016 <0.010	0 7 14 27	4) spraying analytical method: 00984/M003 (MR12/036) (LC-MS/MS), LOQ(s): 0.01 mg/kg, max. sample storage time in month(s): 15 ASB2015-2162

Comments of zRMS:	Acceptable. GAP-compliant.

Table A 4: Residues of prothioconazole in barley

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 125 g/L
Formulation (e.g. WP) : SE (suspo-emulsion)
Commercial product (name) : Propulse
Applicant : Bayer CropScience Registrierung & PGA

Active ingredient : Prothioconazole
Crop / crop group : Spring barley

Submission date : 2015-02-18

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) : 125 g/L Fluopyram
Residues calculated as : 8.1 JAU 6476-3-hydroxy-desthio
8.2 JAU 6476-4-hydroxy-desthio
8.3 JAU 6476-5-hydroxy-desthio
8.4 JAU 6476-6-hydroxy-desthio
8.5 JAU 6476-alpha-hydroxy-desthio
8.6 protioconazole-desthio

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	8.5	8.6	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl											
	(a)	(b)				(c)		(a)							(d)	(e)
study 12-2163, trial 12-2163-05 France (FR) 37310 Chambourg sur Indre 2014-01-09	Sebastian	1) 2012-03-02 (sowing) 2) 2012-06-01 - 2012-06-08 3) 2012-07-20 - 2012-07-25	0.13	300	0.043	2012-06-01 4)	BBCH 61	forage grain straw	<0.010 <0.010 0.038	<0.010 <0.010 0.013	<0.010 <0.010 0.017	<0.010 <0.010 <0.010	<0.010 <0.010 <0.010	0.50 <0.010 0.069	0 53 53	4) spraying analytical methods: (HPLC-MS/MS), LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 13 ASB2015-2161
study 12-2163, trial 12-2163-06 Belgium 1495 Marbais 2014-01-09	Quench	1) 2012-03-15 (sowing) 2) 2012-06-22 - 2012-06-26 3) 2012-08-08 - 2012-08-17	0.13	200	0.065	2012-06-22 4)	BBCH 61	forage grain straw	<0.010 <0.010 0.025	<0.010 <0.010 0.025	<0.010 <0.010 0.014	<0.010 <0.010 <0.010	<0.010 <0.010 <0.010	0.40 <0.010 0.042	0 47 47	4) spraying analytical methods: (HPLC-MS/MS), LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 13 ASB2015-2161

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	8.5	8.6	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl											
	(a)	(b)				(c)		(a)							(d)	(e)
study 12-2163, trial 12-2163-07 United Kingdom CB22 5EU Little Shelford Farm 2014-01-09	Propino	1) 2012-03-23 (sowing) 2) 2012-06-25 - 2012-07-09 3) 2012-08-06 - 2012-08-20	0.13	200	0.065	2012-06-25[4)]	BBCH 61	forage grain straw	<0.010 <u><0.010</u> <u><0.010</u>	<0.010 <u><0.010</u> <u><0.010</u>	<0.010 <u><0.010</u> <u><0.010</u>	<0.010 <u><0.010</u> <u><0.010</u>	<0.010 <u><0.010</u> <u><0.010</u>	0.63 <u><0.010</u> <u>0.048</u>	0 46 46	4) spraying analytical methods: (HPLC-MS/MS), LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 13 ASB2015-2161
study 12-2163, trial 12-2163-08 Germany 51399 Burscheid 2014-01-09	Simba	1) 2012-03-16 (sowing) 2) 2012-06-05 - 2012-06-11 3) 2012-08-10 - 2012-08-24	0.13	300	0.043	2012-06-05[4)]	BBCH 61	forage grain straw	<0.010 <u><0.010</u> <u><0.010</u>	<0.010 <u><0.010</u> <u><0.010</u>	<0.010 <u><0.010</u> <u><0.010</u>	<0.010 <u><0.010</u> <u><0.010</u>	<0.010 <u><0.010</u> <u><0.010</u>	0.56 <u><0.010</u> <u>0.020</u>	0 69 69	4) spraying analytical methods: (HPLC-MS/MS), LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 13 ASB2015-2161

Comments of zRMS:	Acceptable. GAP-compliant (within 25 % rule).

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 130 g/L
Formulation (e.g. WP) : EC (emulsifiable concentrate)
Commercial product (name) : Ascra Xpro

Applicant : Bayer CropScience Registrierung & PGA

Active ingredient : Prothioconazole
Crop / crop group : Spring barley

Submission date : 2015-02-18

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) : 65 g/L Bixafen
65 g/L Fluopyram

Residues calculated as : 8.1 JAU 6476-3-hydroxy-desthio
8.2 JAU 6476-4-hydroxy-desthio
8.3 JAU 6476-5-hydroxy-desthio
8.4 JAU 6476-6-hydroxy-desthio
8.5 JAU 6476-alpha-hydroxy-desthio
8.6 Prothioconazole-desthio

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	8.5	8.6	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl											
	(a)	(b)				(c)		(a)							(d)	(e)
study 12-2130, trial 12-2130-02 Belgium 1495 Marbais 2014-03-31	Quench	1) 2012-03-15 (sowing) 2) 2012-06-22 - 2012-06-26 3) 2012-08-08 - 2012-08-17	0.16	250	0.064	2012-06-22[4)]	BBCH 61	forage grain straw	<0.010 <0.010 0.036	<0.010 <0.010 0.052	<0.010 <0.010 0.023	<0.010 <0.010 <0.010	<0.010 <0.010 <0.010	0.89 <0.010 0.048	0 47 47	4) spraying analytical methods: (HPLC-MS/MS), LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 8 ASB2015-2162
study 12-2130, trial 12-2130-04 Germany 51399 Burscheid 2014-03-31	Simba	1) 2012-03-16 (sowing) 2) 2012-06-05 - 2012-06-11 3) 2012-08-10 - 2012-08-24	0.16	300	0.053	2012-06-05[4)]	BBCH 61	forage grain straw	<0.010 <0.010 <0.010	<0.010 <0.010 <0.010	<0.010 <0.010 <0.010	<0.010 <0.010 <0.010	<0.010 <0.010 <0.010	1.1 <0.010 0.026	0 69 69	4) spraying analytical methods: (HPLC-MS/MS), LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 8 ASB2015-2162

Comments of zRMS:	Acceptable. GAP-compliant.

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 125 g/L
Formulation (e.g. WP) : SE (suspo-emulsion)
Commercial product (name) : Propulse
Applicant : Bayer CropScience Registrierung & PGA

Active ingredient : Prothioconazole
Crop / crop group : Winter barley

Submission date : 2015-02-18

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) : 125 g/L Fluopyram
Residues calculated as : 8.1 JAU 6476-3-hydroxy-desthio
8.2 JAU 6476-4-hydroxy-desthio
8.3 JAU 6476-5-hydroxy-desthio
8.4 JAU 6476-6-hydroxy-desthio
8.5 JAU 6476-alpha-hydroxy-desthio
8.6 Prothioconazole-desthio

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	8.5	8.6	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl											
	(a)	(b)				(c)		(a)							(d)	(e)
study 12-2163, trial 12-2163-01 France (FR) 95710 Chaussy 2014-01-09	Volume	1) 2011-10-04 (sowing) 2) 2012-05-14 - 2012-05-25 3) 2012-07-16 - 2012-07-19	0.13	300	0.043	2012-05-14[4)]	BBCH 61	forage grain straw controls > LOQ forage	<0.010 0.010 0.018 0.021 <u><0.010</u> <u><0.010</u>	<0.010 0.014 0.022 0.024 <u><0.010</u> <u><0.010</u>	<0.010 0.011 0.019 0.019 <u><0.010</u> <u>0.013</u>	<0.010 <0.010 <0.010 <0.010 <u><0.010</u> <u><0.010</u>	<0.010 <0.010 <0.010 <0.010 <u><0.010</u> <u><0.010</u>	0.52 0.18 0.082 0.012 <u><0.010</u> <u>0.031</u> 0.017	0 7 14 28 64 64 0	4) spraying analytical methods: (HPLC-MS/MS), LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 13 <u>ASB2015-2161</u>
study 12-2163, trial 12-2163-02 Germany 49377 Vechta-Langförden 2014-01-09	Meridian multiline	1) 2011-09-30 (sowing) 2) 2012-05-21 - 2012-06-04 3) 2012-07-05 - 2012-07-25	0.13	300	0.043	2012-05-22[4)]	BBCH 61	forage grain straw	<0.010 0.032 0.033 0.034 <u><0.010</u> <u><0.010</u>	<0.010 0.051 0.052 0.045 <u><0.010</u> <u><0.010</u>	<0.010 0.029 0.031 0.024 <u><0.010</u> <u><0.010</u>	<0.010 <0.010 <0.010 <0.010 <u><0.010</u> <u><0.010</u>	<0.010 <0.010 <0.010 <0.010 <u><0.010</u> <u><0.010</u>	0.41 0.26 0.11 0.047 <u><0.010</u> <u>0.024</u>	0 7 14 28 62 62	4) spraying analytical methods: (HPLC-MS/MS), LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 13 <u>ASB2015-2161</u>
study 12-2163, trial 12-2163-03 Netherlands 1774 Slootdorp 2014-01-09	Winter Malt	1) 2011-10-14 (sowing) 2) 2012-06-01 - 2012-06-15 3) 2012-07-22 - 2012-08-02	0.13	300	0.043	2012-06-01[4)]	BBCH 61	forage grain straw	<0.010 0.021 0.027 0.019 <u><0.010</u> <u><0.010</u>	<0.010 0.037 0.043 0.016 <u><0.010</u> <u><0.010</u>	<0.010 0.025 0.031 0.020 <u><0.010</u> <u><0.010</u>	<0.010 0.010 <0.010 <0.010 <u><0.010</u> <u><0.010</u>	<0.010 <0.010 <0.010 <0.010 <u><0.010</u> <u><0.010</u>	0.83 0.43 0.17 0.029 <u><0.010</u> <u>0.025</u>	0 7 14 28 54 54	4) spraying analytical methods: (HPLC-MS/MS), LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 13 <u>ASB2015-2161</u>

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	8.5	8.6	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl											
	(a)	(b)				(c)		(a)							(d)	(e)
study 12-2163, trial 12-2163-04 Netherlands 9076 PP Sint Annaparochie 2014-01-09	Winter Malt	1) 2011-10-10 (sowing) 2) 2012-05-30 - 2012-06-18 3) 2012-07-15 - 2012-08-01	0.13	300	0.043	2012-05-30[4)]	BBCH 61	forage grain straw	<0.010 0.011 0.016 0.013 <0.010 <0.010	<0.010 0.018 0.023 0.018 <0.010 <0.010	<0.010 0.013 0.019 0.012 <0.010 <0.010	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.45 0.16 0.055 0.010 <0.010 <0.010	0 7 14 28 56 56	4) spraying analytical methods: (HPLC-MS/MS), LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 13 ASB2015-2161

Comments of zRMS:	Acceptable. GAP-compliant (within 25 % rule).

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 130 g/L
Formulation (e.g. WP) : EC (emulsifiable concentrate)
Commercial product (name) : Ascra Xpro

Applicant : Bayer CropScience Registrierung & PGA

Active ingredient : Prothioconazole
Crop / crop group : Winter barley

Submission date : 2015-02-18

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) : 65 g/L Bixafen
65 g/L Fluopyram

Residues calculated as : 8.1 JAU 6476-3-hydroxy-desthio
8.2 JAU 6476-4-hydroxy-desthio
8.3 JAU 6476-5-hydroxy-desthio
8.4 JAU 6476-6-hydroxy-desthio
8.5 JAU 6476-alpha-hydroxy-desthio
8.6 Prothioconazole-desthio

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	8.5	8.6	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl											
	(a)	(b)				(c)		(a)							(d)	(e)
study 12-2130, trial 12-2130-01 France (FR) 95710 Chaussy 2014-03-31	Volume	1) 2011-10-04 (sowing) 2) 2012-05-14 - 2012-05-25 3) 2012-07-17 - 2012-07-20	0.16	300	0.053	2012-05-14[4)]	BBCH 61	forage	<0.010 0.014 0.032 0.030	<0.010 0.018 0.040 0.033	<0.010 0.017 0.033 0.027	<0.010 <0.010 <0.010 <0.010	<0.010 <0.010 <0.010 <0.010	0.76 0.26 0.13 0.021	0 7 14 28	4) spraying analytical methods: (HPLC-MS/MS), LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 9 ASB2015-2162
								grain	<0.010	<0.010	<0.010	<0.010	<0.010	0.010	64	
								straw	0.029	0.045	0.043	<0.010	<0.010	0.044	64	
								controls > LOQ forage						0.016	0	
study 12-2130, trial 12-2130-03 United Kingdom CB22 5EU Cambridge 2014-03-31	Carrat	1) 2011-09-07 (sowing) 2) 2012-05-21 3) 2012-07-15 - 2012-08-10	0.16	200	0.080	2012-05-23[4)]	BBCH 61	forage	<0.010 0.082 0.10 0.089	<0.010 0.083 0.10 0.080	<0.010 0.063 0.076 0.054	<0.010 0.010 0.010 0.010	<0.010 0.014 0.010 <0.010	0.83 0.78 0.18 0.050	0 7 14 27	4) spraying analytical methods: (HPLC-MS/MS), LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 9 ASB2015-2162
								controls > LOQ forage						0.016	0	

Comments of zRMS:	Acceptable. GAP-compliant.

A 2.2.3 Magnitude of residues in wheat

Table A 5: Residues of bixafen in wheat

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 65 g/L
Formulation (e.g. WP) : EC (emulsifiable concentrate)
Commercial product (name) : Ascra Xpro

Applicant : Bayer CropScience Registrierung & PGA

Active ingredient : Bixafen
Crop / crop group : Spring soft wheat

Submission date : 2015-02-18

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) : 65 g/L Fluopyram
130 g/L Prothioconazole
Residues : 8.1 Bixafen
8.2 Bixafen-desmethyl, calculated as bixafen
8.3 Sum of bixafen and bixafen-desmethyl

1	2	3	4			5	6	7	8.1	8.2	8.3	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl								
	(a)	(b)				(c)		(a)				(d)	(e)
study 12-2131, trial 12-2131-02 United Kingdom CB2 5EU Little Shelford, Cambridge 2014-01-22	Tybalt	1) 2012-03-22 (sowing) 2) 2012-06-25 - 2012-07-09 3) 2012-08-03 - 2012-08-23	0.098 0.098	200 200	0.049 0.049	2012-06-07[4)] 2012-06-26[4)]	BBCH 61	forage grain straw	1.7 <0.010 0.45	0.030 <0.010 0.28	1.7 <0.020 0.74	0 64 64	4) spraying analytical method: 01013 (HPLC-MS/MS), LOQ(s): 8.1/8.2: 0.01 mg/kg, 8.3: 0.02 mg/kg, max. sample storage time in month(s): 8 ASB2015-2164
study 12-2131, trial 12-2131-04 Germany (DE) 51399 Burscheid 2014-01-22	Thasos	1) 2012-03-16 (sowing) 2) 2012-06-18 - 2012-06-25 3) 2012-08-10 - 2012-08-20	0.098 0.098	300 300	0.033 0.033	2012-05-31[4)] 2012-06-18[4)]	BBCH 61	forage grain straw	2.9 <0.010 0.38	0.053 <0.010 0.18	2.9 <0.020 0.56	0 56 56	4) spraying analytical method: 01013 (HPLC-MS/MS), LOQ(s): 8.1/8.2: 0.01 mg/kg, 8.3: 0.02 mg/kg, max. sample storage time in month(s): 8 ASB2015-2164

Comments of zRMS:	Acceptable. GAP-compliant.

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 65 g/L
Formulation (e.g. WP) : EC (emulsifiable concentrate)
Commercial product (name) : Ascra Xpro

Applicant : Bayer CropScience Registrierung & PGA

Active ingredient : Bixafen
Crop / crop group : Winter soft wheat

Submission date : 2015-02-18

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) : 65 g/L Fluopyram
130 g/L Prothioconazole

Residues calculated as : 8.1 Bixafen
8.2 Bixafen-desmethyl, calculated as bixafen
8.3 Sum of bixafen and bixafen-desmethyl

1	2	3	4			5	6	7	8.1	8.2	8.3	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl								
	(a)	(b)				(c)		(a)				(d)	(e)
study 12-2131, trial 12-2131-01 France (FR) 95710 Chaussy 2014-01-22	Altigo	1) 2011-10-15 (sowing) 2) 2012-05-28 - 2012-06-09 3) 2012-07-26 - 2012-07-30	0.098 0.098	300 300	0.033 0.033	2012-05-12[4)] 2012-05-29[4)]	BBCH 61	forage grain straw	0.24 1.9 1.0 0.48 0.18 <u><0.010</u> <u>0.47</u>	0.041 0.048 0.12 0.12 0.12 <u><0.010</u> <u>0.35</u>	0.28 1.9 1.2 0.60 0.30 <u><0.020</u> <u>0.82</u>	0[5)] 0 7 14 28 58 58	4) spraying 5) before last treatment analytical method: 01013 (HPLC-MS/MS), LOQ(s): 8.1/8.2: 0.01 mg/kg, 8.3: 0.02 mg/kg, max. sample storage time in month(s): 8 ASB2015-2164
study 12-2131, trial 12-2131-03 Belgium (BE) 5140 Vieille maison 2014-01-22	Ketchum	1) 2011-10-15 (sowing) 2) 2012-06-04 - 2012-06-19 3) 2012-07-25 - 2012-07-31	0.098 0.098	250 270	0.039 0.037	2012-05-29[4)] 2012-06-05[4)]	BBCH 61	forage grain straw	0.27 1.8 0.35 0.20 0.15 <u><0.010</u> <u>0.16</u>	0.025 0.024 0.059 0.069 0.081 <u><0.010</u> <u>0.12</u>	0.29 1.8 0.41 0.27 0.23 <u><0.020</u> <u>0.28</u>	0[5)] 0 7 14 28 51 51	4) spraying 5) before last treatment analytical method: 01013 (HPLC-MS/MS), LOQ(s): 8.1/8.2: 0.01 mg/kg, 8.3: 0.02 mg/kg, max. sample storage time in month(s): 8 ASB2015-2164

Comments of zRMS:	Acceptable. GAP-compliant.

Table A 6: Residues of fluopyram in wheat

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 65 g/L
Formulation (e.g. WP) : EC (emulsifiable concentrate)
Commercial product (name) : Ascra Xpro

Applicant : Bayer CropScience

Active ingredient : Fluopyram
Crop / crop group : Spring Soft Wheat

Submission date : 2015-02-18

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) : 65 g/L Bixafen
130 g/L Prothioconazole

Residues calculated as : 8.1 Fluopyram
8.2 Fluopyram-benzamide (M25), expressed as fluopyram

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl							
	(a)	(b)				(c)		(a)			(d)	(e)
study 12-2131, trial 12-2131-02 United Kingdom CB2 5EU Little Shelford, Cambridge 2014-01-22	Tybalt	1) 2012-03-22 (sowing) 2) 2012-06-25 - 2012-07-09 3) 2012-08-03 - 2012-08-23	0.099 0.099	200 200	0.050 0.050	2012-06-07[4)] 2012-06-26[4)]	BBCH 61	forage grain straw	1.6 <0.010 0.11	<0.010 <0.010 0.052	0 64 64	4) spraying analytical method: 00984/M003 (LC-MS/MS), LOQ(s): 0.01 mg/kg, max. sample storage time in month(s): 14 ASB2015-2164
study 12-2131, trial 12-2131-04 Germany (DE) 51399 Burscheid 2014-01-22	Thasos	1) 2012-03-16 (sowing) 2) 2012-06-18 - 2012-06-25 3) 2012-08-10 - 2012-08-20	0.099 0.099	300 300	0.033 0.033	2012-05-31[4)] 2012-06-18[4)]	BBCH 61	forage grain straw	2.7 <0.010 0.11	<0.010 <0.010 0.040	0 56 56	4) spraying analytical method: 00984/M003 (LC-MS/MS), LOQ(s): 0.01 mg/kg, max. sample storage time in month(s): 14 ASB2015-2164

Comments of zRMS:	Acceptable. GAP-compliant.

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Fluopyram
Crop / crop group : Winter Soft Wheat

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2015-02-18

Content of a.i. (g/kg or g/l) : 65 g/L
Formulation (e.g. WP) : EC (emulsifiable concentrate)
Commercial product (name) : Ascra Xpro

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) : 65 g/L Bixafen
130 g/L prothioconazole

Applicant : Bayer CropScience

Residues calculated as : 8.1 Fluopyram
8.2 Fluopyram-benzamide (M25), expressed as fluopyram

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl							
	(a)	(b)				(c)		(a)			(d)	(e)
study 12-2131, trial 12-2131-01, decline trial France (FR) 95710 Chaussy 2014-01-22	Altigo	1) 2011-10-15 (sowing) 2) 2012-05-28 - 2012-06-09 3) 2012-07-26 - 2012-07-30	0.099 0.099	300 300	0.033 0.033	2012-05-12[4)] 2012-05-29[4)]	BBCH 61	forage grain straw	0.21 1.7 0.96 0.46 0.13 0.012 0.21	<0.010 <0.010 0.016 0.011 <0.010 <0.010 0.052	0[5)] 0 7 14 28 58 58	4) spraying 5) before last treatment analytical method: 00984/M003 (LC-MS/MS), LOQ(s): 0.01 mg/kg, max. sample storage time in month(s): 14 ASB2015-2164
study 12-2131, trial 12-2131-03, decline trial Belgium (BE) 5140 Vieille maison 2014-01-22	Ketchum	1) 2011-10-15 (sowing) 2) 2012-06-04 - 2012-06-19 3) 2012-07-25 - 2012-07-31	0.099 0.099	250 270	0.040 0.037	2012-05-29[4)] 2012-06-05[4)]	BBCH 61	forage grain straw	0.24 1.8 0.29 0.16 0.092 <0.010 0.091	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 0.024	0[5)] 0 7 14 28 51 51	4) spraying 5) before last treatment analytical method: 00984/M003 (LC-MS/MS), LOQ(s): 0.01 mg/kg, max. sample storage time in month(s): 14 ASB2015-2164

Comments of zRMS:	Acceptable. GAP-compliant.

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Fluopyram
Crop / crop group : Spring Soft Wheat

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2015-02-18

Content of a.i. (g/kg or g/l) : 125 g/L
Formulation (e.g. WP) : SE (suspo-emulsion)
Commercial product (name) : Propulse
Applicant : Bayer CropScience

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) : 125 g/L Prothioconazole
Residues calculated as : 8.1 Fluopyram
8.2 Fluopyram-benzamide (M25), expressed as fluopyram

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl							
	(a)	(b)				(c)		(a)			(d)	(e)
study 12-2164, trial 12-2164-05, harvest trial Netherlands 1175 KD Lijnden 2014-01-07	Tibalt	1) 2012-03-30 (sowing) 2) 2012-06-20 - 2012-06-30 3) 2012-08-15 - 2012-08-25	0.13 0.13	300 300	0.043 0.043	2012-05-29[4)] 2012-06-26[4)]	BBCH 61	forage grain straw	2.3 0.022 0.26	<0.010 <0.010 0.027	0 55 55	4) spraying analytical method: 00984/M003 (HPLC-MS/MS), LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 14 ASB2015-2163
study 12-2164, trial 12-2164-06, harvest trial Belgium (BE) 1495 Marbais 2014-01-07	Granny	1) 2012-03-15 (sowing) 2) 2012-06-13 - 2012-06-20 3) 2012-08-16 - 2012-08-17	0.13 0.13	250 250	0.052 0.052	2012-06-01[4)] 2012-06-14[4)]	BBCH 61	forage grain straw	2.0 <0.010 0.057	<0.010 <0.010 0.011	0 64 64	4) spraying analytical method: 00984/M003 (HPLC-MS/MS), LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 14 ASB2015-2163
study 12-2164, trial 12-2164-07, harvest trial United Kingdom (UK) CB2 5EU Little Shelford, Cambridge 2014-01-07	Tybalt	1) 2012-03-22 (sowing) 2) 2012-06-25 - 2012-07-09 3) 2012-08-03 - 2012-08-23	0.13 0.13	200 200	0.065 0.065	2012-06-07[4)] 2012-06-26[4)]	BBCH 61	forage grain straw	2.1 <0.010 0.20	<0.010 <0.010 0.056	0 64 64	4) spraying analytical method: 00984/M003 (HPLC-MS/MS), LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 14 ASB2015-2163

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl							
	(a)	(b)				(c)		(a)			(d)	(e)
study 12-2164, trial 12-2164-08, harvest trial Germany (DE) 51399 Burscheid 2014-01-07	Thasos	1) 2012-03-16 (sowing) 2) 2012-06-18 - 2012-06-25 3) 2012-08-10 - 2012-08-20	0.13 0.13	300 300	0.043 0.043	2012-05-31[4)] 2012-06-18[4)]	BBCH 61	forage grain straw	2.8 <0.010 0.11	<0.010 <0.010 0.021	0 56 56	4) spraying analytical method: 00984/M003 (HPLC-MS/MS), LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 14 ASB2015-2163

Comments of zRMS:	Acceptable. GAP-compliant (within 25% rule).

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Fuopyram
Crop / crop group : Winter Soft Wheat

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2015-02-18

Content of a.i. (g/kg or g/l) : 125 g/L
Formulation (e.g. WP) : SE (suspo-emulsion)
Commercial product (name) : Propulse
Applicant : Bayer CropScience Registrierung & PGA

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) : 125 g/L Prothioconazole
Residues calculated as : 8.1 Fluopyram
8.2 Fluopyram-benzamide (M25), expressed as fluopyram

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl							
	(a)	(b)				(c)		(a)			(d)	(e)
study 12-2164, trial 12-2164-01, decline trial France (FR) 95710 Chaussy 2014-01-07	Altigo	1) 2011-10-15 (sowing) 2) 2012-05-28 -2012-06-09 3) 2012-07-26 -2012-07-30	0.13 0.13	300 300	0.043 0.043	2012-05-12[4)] 2012-05-29[4)]	BBCH 61	forage grain straw	0.22 1.5 0.75 0.44 0.12 0.014 0.28	<0.010 <0.010 <0.010 0.011 <0.010 <0.010 0.068	0[5)] 0 7 14 28 58 58	4) spraying 5) before last treatment analytical method: 00984/M003 (HPLC-MS/MS), LOQ(s): 0.01 mg/kg, max. sample storage time in month(s):14 ASB2015-2163
study 12-2164, trial 12-2164-02, decline trial Germany (DE) 59457 Werl-Niederbergstraße 2014-01-07	Akteur	1) 2011-11-06 (sowing) 2) 2012-06-04 -2012-06-11 3) 2012-07-15 -2012-08-20	0.13 0.13	300 300	0.043 0.043	2012-05-21[4)] 2012-06-05[4)]	BBCH 61	forage grain straw	0.37 2.1 0.56 0.49 0.22 <0.010 0.35	<0.010 <0.010 <0.010 0.012 <0.010 <0.010 0.028	0[5)] 0 7 14 28 59 59	4) spraying 5) before last treatment analytical method: 00984/M003 (HPLC-MS/MS), LOQ(s): 0.01 mg/kg, max. sample storage time in month(s):14 ASB2015-2163
study 12-2164, trial 12-2164-03, decline trial Netherlands 1774 Slootdorp 2014-01-07	Taureq	1) 2011-11-10 (sowing) 2) 2012-06-17 -2012-07-02 3) 2012-08-06 -2012-08-18	0.13 0.13	300 300	0.043 0.043	2012-06-01[4)] 2012-06-18[4)]	BBCH 61	forage grain straw	0.12 2.0 0.59 0.34 0.12 0.010 0.16	<0.010 <0.010 <0.010 0.011 <0.010 <0.010 0.010	0[5)] 0 7 14 28 53 53	4) spraying 5) before last treatment analytical method: 00984/M003 (HPLC-MS/MS), LOQ(s): 0.01 mg/kg, max. sample storage time in month(s):14 ASB2015-2163

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment kg a.i./ha	Water l/ha	kg a.i./hl	Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)			(d)	(e)
study 12-2164, trial 12-2164-04, decline trial Netherlands 9076 Sint Jacobieparochie 2014-01-07	Tataros	1) 2011-12-15 (sowing) 2) 2012-06-20 -2012-07-05 3) 2012-08-10 -2012-08-25	0.13 0.13	300 300	0.043 0.043	2012-05-30[4)] 2012-06-20[4)]	BBCH 61	forage grain straw	2.2 0.072 0.31 0.20 0.061 0.011 0.13	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 0.018	0[5)] 0 7 14 28 56 56	4) spraying 5) before last treatment analytical method: 00984/M003 (HPLC-MS/MS), LOQ(s): 0.01 mg/kg, max. sample storage time in month(s):14 ASB2015-2163

Comments of zRMS:	Acceptable. GAP-compliant (within 25% rule).

Table A 7: Residues of prothioconazole in wheat

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 130 g/L
Formulation (e.g. WP) : EC (emulsifiable concentrate)
Commercial product (name) : Ascra Xpro

Applicant : Bayer CropScience

Active ingredient : Prothioconazole
Crop / crop group : Spring Soft Wheat

Submission date : 2015-02-18

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) : 65 g/L Bixafen
65 g/L Fluopyram

Residues calculated as : 8.1 JAU 6476-3-hydroxy-desthio
8.2 JAU 6476-4-hydroxy-desthio
8.3 JAU 6476-5-hydroxy-desthio
8.4 JAU 6476-6-hydroxy-desthio
8.5 JAU 6476-alpha-hydroxy-desthio
8.6 Prothioconazole-desthio (SXX 0665)

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	8.5	8.6	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment kg a.i./ha	Water l/ha	kg a.i./hl	Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)							(d)	(e)
study 12-2131, trial 12-2131-02 UK CB2 5EU Little Shelford, Cambridge 2014-01-22	Tybalt	1) 2012-03-22 (sowing) 2) 2012-06-25 - 2012-07-09 3) 2012-08-03 - 2012-08-23	0.20 0.20	200 200	0.10 0.10	2012-06-07[4)] 2012-06-26[4)]	BBCH 61	forage grain straw	0.033 <0.010 0.062	0.021 <0.010 0.072	0.014 <0.010 0.057	<0.010 <0.010 0.011	0.013 <0.010 0.038	0.67 <0.010 0.078	0 64 64	4) spraying analytical methods: (HPLC-MS/MS), LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 8 ASB2015-2164
study 12-2131, trial 12-2131-04 Germany 51399 Burscheid 2014-01-22	Thasos	1) 2012-03-16 (sowing) 2) 2012-06-18 - 2012-06-25 3) 2012-08-10 - 2012-08-20	0.20 0.20	300 300	0.067 0.067	2012-05-31[4)] 2012-06-18[4)]	BBCH 61	forage grain straw	0.060 <0.010 0.047	0.045 <0.010 0.035	0.034 <0.010 0.036	0.010 <0.010 <0.010	0.041 <0.010 0.026	1.3 <0.010 0.046	0 56 56	4) spraying analytical methods: (HPLC-MS/MS), LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 8 ASB2015-2164

Comments of zRMS:	Acceptable. GAP-compliant.

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 130 g/L
Formulation (e.g. WP) : EC (emulsifiable concentrate)
Commercial product (name) : Ascra Xpro

Applicant : Bayer CropScience

Active ingredient : Prothioconazole
Crop / crop group : Winter Soft Wheat

Submission date : 2015-02-18

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) : 65 g/L Bixafen
65 g/L Fluopyram

Residues calculated as : 8.1 JAU 6476-3-hydroxy-desthio
8.2 JAU 6476-4-hydroxy-desthio
8.3 JAU 6476-5-hydroxy-desthio
8.4 JAU 6476-6-hydroxy-desthio
8.5 JAU 6476-alpha-hydroxy-desthio
8.6 prothioconazole-desthio (SXX 0665)

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	8.5	8.6	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl											
	(a)	(b)				(c)		(a)							(d)	(e)
study 12-2131, trial 12-2131-01 France (FR) 95710 Chaussy 2014-01-22	Altigo	1) 2011-10-15 (sowing) 2) 2012-05-28 - 2012-06-09 3) 2012-07-26 - 2012-07-30	0.20 0.20	300 300	0.067 0.067	2012-05-12[4)] 2012-05-29[4)]	BBCH 61	forage grain straw	0.085 0.081 0.15 0.17 0.16 <0.010 0.39	0.067 0.063 0.12 0.13 0.12 <0.010 0.30	0.048 0.043 0.082 0.092 0.083 <0.010 0.21	<0.010 <0.010 0.011 0.011 <0.010 <0.010 0.028	<0.010 <0.010 0.020 0.020 0.014 <0.010 0.030	0.15 1.0 0.83 0.33 0.058 <0.010 0.094	0[5)] 0 7 14 28 58 58	4) spraying 5) before last treatment analytical methods: (HPLC-MS/MS), LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 8 ASB2015-2164
study 12-2131, trial 12-2131-03 Belgium 5140 Vieille maison 2014-01-22	Ketchum	1) 2011-10-15 (sowing) 2) 2012-06-04 - 2012-06-19 3) 2012-07-25 - 2012-07-31	0.20 0.20	250 270	0.080 0.075	2012-05-29[4)] 2012-06-05[4)]	BBCH 61	forage grain straw controls > LOQ forage	0.028 0.028 0.047 0.061 0.058 <0.010 0.056	0.029 0.030 0.053 0.055 0.060 <0.010 0.059	0.020 0.020 0.033 0.040 0.037 <0.010 0.040	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	<0.010 <0.010 0.021 0.014 0.016 <0.010 0.016	0.20 1.1 0.19 0.071 0.023 <0.010 0.021 0.013 0.020 0.012	0[5)] 0 7 14 28 51 51 0 14 28	4) spraying 5) before last treatment analytical methods: (HPLC-MS/MS), LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 8 ASB2015-2164

Comments of zRMS:	Acceptable. GAP-compliant.

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 125 g/L
Formulation (e.g. WP) : SE (suspo-emulsion)
Commercial product (name) : Propulse
Applicant : Bayer CropScience

Active ingredient : Prothioconazole
Crop / crop group : Spring Soft Wheat

Submission date : 2015-02-18

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) : 125 g/L Fluopyram
Residues calculated as : 8.1 JAU 6476-3-hydroxy-desthio
8.2 JAU 6476-4-hydroxy-desthio
8.3 JAU 6476-5-hydroxy-desthio
8.4 JAU 6476-6-hydroxy-desthio
8.5 JAU 6476-alpha-hydroxy-desthio
8.6 protioconazole-desthio (SXX 0665)

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	8.5	8.6	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl											
	(a)	(b)				(c)		(a)							(d)	(e)
study 12-2164, trial 12-2164-05 Netherlands 1175 KD Lijnden 2014-01-07	Tibalt	1) 2012-03-30 (sowing) 2) 2012-06-20 - 2012-06-30 3) 2012-08-15 - 2012-08-25	0.13 0.13	300 300	0.043 0.043	2012-05-29[4)] 2012-06-26[4)]	BBCH 61	forage grain straw controls > LOQ straw	0.042 <0.010 0.038	0.023 <0.010 0.031	0.024 <0.010 0.027	<0.010 <0.010 0.010	<0.010 <0.010 0.011	0.60 <0.010 0.070 0.032	0 55 55 55	4) spraying analytical methods: (HPLC-MS/MS, LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 10 ASB2015-2163
study 12-2164, trial 12-2164-06 Belgium 1495 Marbais 2014-01-07	Granny	1) 2012-03-15 (sowing) 2) 2012-06-13 - 2012-06-20 3) 2012-08-16 - 2012-08-17	0.13 0.13	250 250	0.052 0.052	2012-06-01[4)] 2012-06-14[4)]	BBCH 61	forage grain straw	0.025 <0.010 0.016	0.015 <0.010 0.015	0.014 <0.010 0.014	<0.010 <0.010 <0.010	0.014 <0.010 <0.010	0.41 <0.010 0.017	0 64 64	4) spraying analytical methods: (HPLC-MS/MS, LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 10 ASB2015-2163

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	8.5	8.6	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl											
	(a)	(b)				(c)		(a)							(d)	(e)
study 12-2164, trial 12-2164-07 United Kingdom CB2 5EU Little Shelford, Cambridge 2014-01-07	Tybalt	1) 2012-03-22 (sowing) 2) 2012-06-25 - 2012-07-09 3) 2012-08-03 - 2012-08-23	0.13 0.13	200 200	0.065 0.065	2012-06-07[4)] 2012-06-26[4)]	BBCH 61	forage grain straw	0.023 <0.010 0.017	0.013 <0.010 0.027	0.010 <0.010 0.015	<0.010 <0.010 <0.010	0.012 <0.010 0.021	0.41 <0.010 0.054	0 64 64	4) spraying analytical methods: (HPLC-MS/MS, LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 10 ASB2015-2163
study 12-2164, trial 12-2164-08, harvest trial Germany 51399 Burscheid 2014-01-07	Thasos	1) 2012-03-16 (sowing) 2) 2012-06-18 - 2012-06-25 3) 2012-08-10 - 2012-08-20	0.13 0.13	300 300	0.043 0.043	2012-05-31[4)] 2012-06-18[4)]	BBCH 61	forage grain straw	0.035 <0.010 0.017	0.021 <0.010 0.012	0.018 <0.010 0.013	<0.010 <0.010 <0.010	0.020 <0.010 <0.010	0.57 <0.010 0.022	0 56 56	4) spraying analytical methods: (HPLC-MS/MS, LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 10 ASB2015-2163

Comments of zRMS:	Study acceptable as such, but not GAP-compliant.

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 125 g/L
Formulation (e.g. WP) : SE (suspo-emulsion)
Commercial product (name) : Propulse
Applicant : Bayer CropScience

Active ingredient : Prothioconazole
Crop / crop group : Winter Soft Wheat

Submission date : 2015-02-18

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) : 125 g/L fluopyram
Residues calculated as : 8.1 JAU 6476-3-hydroxy-desthio
8.2 JAU 6476-4-hydroxy-desthio
8.3 JAU 6476-5-hydroxy-desthio
8.4 JAU 6476-6-hydroxy-desthio
8.5 JAU 6476-alpha-hydroxy-desthio
8.6 protioconazole-desthio (SXX 0665)

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	8.5	8.6	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl											
	(a)	(b)				(c)		(a)							(d)	(e)
study 12-2164, trial 12-2164-01 France (FR) 95710 Chaussy 2014-01-07	Altigo	1) 2011-10-15 (sowing) 2) 2012-05-28 - 2012-06-09 3) 2012-07-26 - 2012-07-30	0.13 0.13	300 300	0.043 0.043	2012-05-12[4)] 2012-05-29[4)]	BBCH 61	forage grain straw	0.067 0.072 0.14 0.15 0.11 <0.010 0.13	0.048 0.055 0.11 0.11 0.083 <0.010 0.10	0.029 0.033 0.065 0.071 0.052 <0.010 0.072	<0.010 <0.010 0.013 0.012 <0.010 <0.010 0.014	<0.010 <0.010 0.019 0.020 0.011 <0.010 0.011	0.083 0.49 0.40 0.16 0.035 <0.010 0.059	0[5)] 0 7 14 28 58 58	4) spraying 5) before last treatment analytical methods: (HPLC-MS/MS, LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 10 ASB2015-2163
study 12-2164, trial 12-2164-02 Germany 59457 Werl-Niederbergstraße 2014-01-07	Akteur	1) 2011-11-06 (sowing) 2) 2012-06-04 - 2012-06-11 3) 2012-07-15 - 2012-08-20	0.13 0.13	300 300	0.043 0.043	2012-05-21[4)] 2012-06-05[4)]	BBCH 61	forage grain straw	0.093 0.097 0.11 0.11 0.091 <0.010 0.11	0.061 0.068 0.074 0.070 0.059 <0.010 0.077	0.086 0.090 0.093 0.097 0.075 <0.010 0.087	<0.010 0.011 0.010 0.011 0.010 <0.010 0.020	0.020 0.023 0.032 0.034 0.016 <0.010 0.012	0.10 0.38 0.19 0.077 0.023 <0.010 0.046	0[5)] 0 7 14 28 59 59	4) spraying 5) before last treatment analytical methods: (HPLC-MS/MS, LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 10 ASB2015-2163

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	8.5	8.6	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl											
	(a)	(b)				(c)		(a)							(d)	(e)
study 12-2164, trial 12-2164-03 Netherlands 1774 Slootdorp 2014-01-07	Taureq	1) 2011-11-10 (sowing) 2) 2012-06-17 - 2012-07-02 3) 2012-08-06 - 2012-08-18	0.13 0.13	300 300	0.043 0.043	2012-06-01[4)] 2012-06-18[4)]	BBCH 61	forage grain straw	0.038 0.048 0.078 0.074 0.070 <0.010 0.063	0.032 0.040 0.065 0.053 0.048 <0.010 0.054	0.032 0.040 0.059 0.058 0.049 <0.010 0.058	<0.010 <0.010 <0.010 0.012 <0.010 <0.010 0.011	0.019 0.022 0.057 0.057 0.028 <0.010 0.023	0.039 0.51 0.35 0.13 0.034 <0.010 0.061	0[5)] 0 7 14 28 53 53	4) spraying 5) before last treatment analytical methods: (HPLC-MS/MS, LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 10 ASB2015-2163
study 12-2164, trial 12-2164-04 Netherlands 9076 Sint Jacobieparochie 2014-01-07	Tataros	1) 2011-12-15 (sowing) 2) 2012-06-20 - 2012-07-05 3) 2012-08-10 - 2012-08-25	0.13 0.13	300 300	0.043 0.043	2012-05-30[4)] 2012-06-20[4)]	BBCH 61	forage grain straw	0.030 0.028 0.052 0.061 0.048 <0.010 0.034	0.022 0.018 0.042 0.043 0.035 <0.010 0.027	0.021 0.018 0.038 0.040 0.031 <0.010 0.022	<0.010 <0.010 0.010 <0.010 <0.010 <0.010 <0.010	0.010 <0.010 0.028 0.041 0.012 <0.010 <0.010	0.017 0.55 0.23 0.075 0.018 <0.010 0.052	0[5)] 0 7 14 28 56 56	4) spraying 5) before last treatment analytical methods: (HPLC-MS/MS, LOQ(s): 0.01 mg/kg max. sample storage time in month(s): 10 ASB2015-2163

Comments of zRMS:	Study acceptable as such, but not GAP-compliant.

A 2.3 Residues in processed commodities

No new study on residues in processed commodities has been submitted and none is needed due to low residues at harvest.

A 2.4 Residues in rotational crops

No new study on residues in rotational crops has been submitted.

A 2.5 Residues in livestock

No new study on residues in livestock has been submitted.

A 2.6 Other studies/information

None

Appendix 3 Pesticide Residue Intake Model (PRIMo rev.2)

A 3.1 TMDI calculation for bixafen

Bixafen (R)			
Status of the active substance:		Code no.	1151
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0,02	ARfD (mg/kg bw):	0,2
Source of ADI:	EU Comm.	Source of ARfD:	EU Comm.
Year of evaluation:	2013	Year of evaluation:	2013

Explain choice of toxicological reference values.

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment

TMDI (range) in % of ADI minimum - maximum	
1	11
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
10,7	NL child	5,9	Milk and milk products: Cattle	1,2	Wheat	0,9	Bovine: Meat	
8,4	IE adult	3,1	Barley	1,7	Sheep: Liver	0,6	Wheat	
7,7	FR infant	5,1	Milk and milk products: Cattle	1,0	VEGETABLES	0,8	FRUIT (FRESH OR FROZEN)	
6,9	WHO Cluster diet B	2,1	Wheat	0,7	VEGETABLES	0,7	Barley	
6,7	DE child	2,9	Milk and milk products: Cattle	1,2	FRUIT (FRESH OR FROZEN)	1,0	Wheat	
6,1	WHO cluster diet E	2,0	Barley	1,0	Wheat	0,6	Milk and milk products: Cattle	
6,0	ES child	2,5	Milk and milk products: Cattle	1,1	Wheat	1,1	Bovine: Meat	
5,6	WHO Cluster diet F	1,5	Barley	0,9	Wheat	0,8	Milk and milk products: Cattle	
5,4	DK child	1,4	Wheat	1,1	Rye	1,0	Oats	
5,0	WHO cluster diet D	1,6	Wheat	0,9	Milk and milk products: Cattle	0,6	Barley	
4,7	WHO regional European diet	1,0	Milk and milk products: Cattle	0,8	Barley	0,8	Bovine: Meat	
4,3	NL general	1,3	Milk and milk products: Cattle	0,9	Barley	0,5	Bovine: Meat	
4,3	SE general population 90th percentile	2,5	Milk and milk products: Cattle	0,8	Wheat	0,5	VEGETABLES	
4,2	ES adult	1,2	Barley	1,0	Milk and milk products: Cattle	0,6	Wheat	
3,4	UK Infant	0,7	Bovine: Liver	0,7	Wheat	0,6	Oats	
3,4	FR toddler	1,0	Bovine: Meat	0,9	VEGETABLES	0,7	Wheat	
3,3	UK Toddler	1,1	SUGAR PLANTS	1,0	Wheat	0,3	FRUIT (FRESH OR FROZEN)	
2,6	LT adult	0,8	Milk and milk products: Cattle	0,3	Rye	0,3	Wheat	
2,4	FR all population	0,8	Wheat	0,5	Milk and milk products: Cattle	0,4	Bovine: Meat	
2,3	DK adult	0,5	Wheat	0,4	Bovine: Meat	0,4	Bovine: Liver	
2,2	IT kids/toddler	1,7	Wheat	0,2	VEGETABLES	0,2	FRUIT (FRESH OR FROZEN)	
1,9	PT General population	1,0	Wheat	0,3	FRUIT (FRESH OR FROZEN)	0,3	VEGETABLES	
1,5	IT adult	1,0	Wheat	0,2	VEGETABLES	0,1	FRUIT (FRESH OR FROZEN)	
1,3	UK vegetarian	0,5	Wheat	0,2	SUGAR PLANTS	0,2	VEGETABLES	
1,2	UK Adult	0,4	Wheat	0,2	SUGAR PLANTS	0,2	VEGETABLES	
1,1	FI adult	0,2	Wheat	0,2	Oats	0,2	Rye	
0,5	PL general population	0,3	VEGETABLES	0,2	FRUIT (FRESH OR FROZEN)	0,0	PULSES, DRY	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Bixafen (R) is unlikely to present a public health concern.

A 3.2 TMDI calculation for fluopyram

Fluopyram (R)			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0,012	ARfD (mg/kg bw):	0,5
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2013	Year of evaluation:	2013

Prepare workbook for refined calculations

Undo refined calculations

Explain choice of toxicological reference values.
The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment

TMDI (range) in % of ADI minimum - maximum	
39	327
No of diets exceeding ADI:	20

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
326,9	NL child	146,6	Milk and cream,	31,7	Apples	31,6	Wheat	
317,8	FR toddler	198,1	Milk and cream,	17,5	Wheat	13,1	Apples	
278,6	UK Infant	193,6	Milk and cream,	17,5	Wheat	11,2	Birds' eggs	
276,4	DE child	71,5	Milk and cream,	60,3	Apples	27,4	Wheat	
260,3	WHO Cluster diet B	56,9	Wheat	44,8	Lettuce	26,8	Table and wine grapes	
217,8	ES child	62,6	Milk and cream,	52,2	Lettuce	29,6	Wheat	
211,6	DK child	63,2	Milk and cream,	36,7	Wheat	29,5	Rye	
206,1	UK Toddler	103,3	Milk and cream,	26,1	Wheat	19,1	Sugar beet (root)	
204,1	FR infant	128,7	Milk and cream,	12,5	Apples	8,8	Carrots	
170,5	WHO regional European diet	47,1	Lettuce	24,1	Milk and cream,	19,8	Wheat	
161,6	ES adult	67,0	Lettuce	24,8	Milk and cream,	15,7	Wheat	
156,8	IE adult	15,3	Wheat	14,6	Table and wine grapes	13,9	Milk and cream,	
155,7	FR all population	51,4	Table and wine grapes	23,8	Other lettuce and other salad plants	21,9	Wheat	
152,8	WHO cluster diet E	26,3	Wheat	22,4	Table and wine grapes	15,0	Milk and cream,	
152,5	WHO Cluster diet F	37,5	Lettuce	24,0	Wheat	19,8	Milk and cream,	
149,9	SE general population 90th percentile	61,9	Milk and cream,	21,3	Wheat	12,0	Bananas	
135,1	IT kids/toddler	44,3	Wheat	36,3	Lettuce	13,8	Other lettuce and other salad	
134,7	WHO cluster diet D	43,4	Wheat	25,2	Milk and cream,	7,6	Tomatoes	
130,0	IT adult	47,2	Lettuce	27,6	Wheat	19,7	Other lettuce and other salad	
121,0	NL general	32,8	Milk and cream,	15,0	Lettuce	13,8	Wheat	
97,3	PT General population	34,6	Table and wine grapes	26,1	Wheat	6,7	Tomatoes	
92,6	DK adult	26,8	Milk and cream,	18,4	Table and wine grapes	13,4	Wheat	
87,7	UK vegetarian	17,6	Lettuce	16,3	Milk and cream,	13,7	Wheat	
80,9	LT adult	19,8	Milk and cream,	9,3	Apples	7,9	Lettuce	
77,6	UK Adult	15,0	Milk and cream,	14,6	Lettuce	14,2	Table and wine grapes	
73,5	FI adult	28,4	Milk and cream,	9,8	Lettuce	6,6	Wheat	
38,6	PL general population	10,2	Apples	6,6	Tomatoes	4,0	Table and wine grapes	

Conclusion:
The estimated Theoretical Maximum Daily Intakes based on MS and WHO diets and pTMRLs were in the range of 38,6 % to 327 % of the ADI.
For 20 diets the ADI is exceeded. Further refinements of the dietary intake estimates have not been performed. A public health risk can not be excluded at the moment.

A 3.3 IEDI calculation for fluopyram

Fluopyram ®			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0,012	ARfD (mg/kg bw):	0,5
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2013	Year of evaluation:	2013

Prepare workbook for refined calculations

Undo refined calculations

Explain choice of toxicological reference values.
The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
12	73
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
72,8	NL child	12,2	Milk and cream,	12,1	Apples	10,4	Swine: Meat	
70,1	DE child	23,1	Apples	7,5	Wheat	6,3	Table grapes	
61,2	WHO Cluster diet B	15,6	Wheat	7,9	Lettuce	5,2	Swine: Meat	
45,6	FR toddler	16,5	Milk and cream,	5,0	Apples	4,8	Wheat	
45,1	ES child	9,1	Lettuce	8,2	Swine: Meat	8,1	Wheat	
43,5	IE adult	4,2	Wheat	3,4	Other cane fruit	3,0	Sweet potatoes	
41,8	DK child	10,1	Wheat	8,1	Rye	5,3	Milk and cream,	
40,8	WHO regional European diet	8,4	Swine: Meat	8,3	Lettuce	5,4	Wheat	
39,8	WHO cluster diet E	7,2	Wheat	5,0	Rape seed	3,9	Swine: Meat	
37,7	UK Toddler	8,6	Milk and cream,	7,2	Wheat	6,3	Sugar beet (root)	
37,4	WHO Cluster diet F	7,7	Swine: Meat	6,6	Wheat	6,6	Lettuce	
36,1	UK Infant	16,1	Milk and cream,	4,8	Wheat	3,0	Apples	
34,2	WHO cluster diet D	11,9	Wheat	4,4	Herbs	2,1	Milk and cream,	
33,6	IT kids/toddler	12,2	Wheat	6,4	Lettuce	2,4	Other lettuce and other salad	
32,5	ES adult	11,7	Lettuce	4,8	Swine: Meat	4,3	Wheat	
30,2	IT adult	8,3	Lettuce	7,6	Wheat	3,5	Other lettuce and other salad	
28,8	FR infant	10,7	Milk and cream,	4,8	Apples	2,0	Carrots	
27,6	NL general	6,2	Swine: Meat	3,8	Wheat	2,7	Milk and cream,	
27,0	SE general population 90th percentile	5,9	Wheat	5,2	Milk and cream,	2,6	Bananas	
25,1	FR all population	6,0	Wheat	4,2	Other lettuce and other salad plants	2,3	Wine grapes	
22,9	LT adult	6,4	Swine: Meat	3,6	Apples	2,0	Rye	
19,8	PT General population	7,2	Wheat	2,0	Apples	1,5	Tomatoes	
16,3	UK vegetarian	3,8	Wheat	3,1	Lettuce	1,4	Milk and cream,	
14,3	DK adult	3,7	Wheat	2,2	Milk and cream,	1,5	Apples	
13,3	UK Adult	3,1	Wheat	2,6	Lettuce	1,2	Milk and cream,	
12,5	FI adult	2,4	Milk and cream,	1,8	Wheat	1,7	Lettuce	
12,2	PL general population	3,9	Apples	1,6	Table grapes	1,5	Tomatoes	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Fluopyram ® is unlikely to present a public health concern.

A 3.4 IEDI calculation for prothioconazole

Prothioconazole: prothioconazole-desthio (sum of isomers) (F)			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,01**	ARfD (mg/kg bw):	**0,01**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2007**	Year of evaluation:	**2007**

Prepare workbook for refined calculations

Undo refined calculations

Explain choice of toxicological reference values.

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).

The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	1 10
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
10,0	WHO Cluster diet B	3,4	Wheat	1,2	Soya bean	0,4	Beetroot	
7,8	NL child	1,9	Wheat	1,5	Milk and cream,	0,6	Apples	
7,2	FR toddler	2,0	Milk and cream,	1,5	Carrots	1,0	Wheat	
7,0	UK Toddler	2,3	Sugar beet (root)	1,6	Wheat	1,0	Milk and cream,	
6,9	IE adult	1,0	Barley	0,9	Wheat	0,4	Parsnips	
6,9	DE child	1,6	Wheat	1,2	Apples	0,7	Milk and cream,	
6,8	WHO cluster diet E	1,6	Wheat	1,2	Soya bean	0,6	Barley	
6,8	UK Infant	1,9	Milk and cream,	1,0	Wheat	1,0	Sugar beet (root)	
6,2	WHO Cluster diet F	1,4	Wheat	1,3	Soya bean	0,5	Barley	
6,1	DK child	2,2	Wheat	0,9	Rye	0,8	Carrots	
6,0	WHO cluster diet D	2,6	Wheat	0,7	Soya bean	0,4	Potatoes	
5,2	ES child	1,8	Wheat	0,6	Milk and cream,	0,3	Cocoa (fermented beans)	
5,0	FR infant	1,6	Carrots	1,3	Milk and cream,	0,4	Potatoes	
4,5	WHO regional European diet	1,2	Wheat	0,4	Potatoes	0,3	Barley	
4,4	SE general population 90th percentile	1,3	Wheat	0,6	Milk and cream,	0,5	Carrots	
4,3	PT General population	1,6	Wheat	0,6	Soya bean	0,5	Potatoes	
3,8	IT kids/toddler	2,7	Wheat	0,2	Other cereal	0,1	Tomatoes	
3,5	NL general	0,8	Wheat	0,3	Milk and cream,	0,3	Barley	
3,3	ES adult	0,9	Wheat	0,4	Barley	0,2	Milk and cream,	
3,1	FR all population	1,3	Wheat	0,4	Wine grapes	0,2	Carrots	
2,6	IT adult	1,7	Wheat	0,1	Tomatoes	0,1	Carrots	
2,6	UK vegetarian	0,8	Wheat	0,4	Sugar beet (root)	0,2	Milk and cream,	
2,4	DK adult	0,8	Wheat	0,3	Milk and cream,	0,3	Carrots	
2,3	UK Adult	0,7	Wheat	0,4	Sugar beet (root)	0,1	Milk and cream,	
2,2	LT adult	0,4	Wheat	0,3	Potatoes	0,2	Rye	
1,7	FI adult	0,4	Wheat	0,3	Milk and cream,	0,1	Rye	
1,4	PL general population	0,3	Potatoes	0,2	Apples	0,2	Carrots	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.

A long-term intake of residues of Prothioconazole: prothioconazole-desthio (sum of isomers) (F) is unlikely to present a public health concern.

REGISTRATION REPORT
Part B

Section 5 Environmental Fate

Detailed summary of the risk assessment

Product code:	**Ascra Xpro / 102000027828**		
Active Substances:	**Bixafen**	**65**	**g/L**
	Fluopyram	**65**	**g/L**
	Prothioconazole	**130**	**g/L**

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: **Bayer CropScience**
Submission date: **14.05.2014**
MS Finalisation date: November 2017

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FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)

This document comprises the risk assessment for groundwater and the exposure assessment of surface water and soil for the plant protection product Ascra Xpro containing Bixafen, Fluopyram and Prothioconazole in its intended uses in cereals according to Appendix 3/Part B, Section 1, Appendix 2.

National Addenda are included containing country specific assessments for some annex points.

5.1 General Information on the formulation

Table 5.1-1: General information on the formulation Ascra Xpro

Code	102000027828		
Plant protection product	Ascra Xpro		
Applicant	Bayer CropScience		
Date of application	14/05/2014		
Formulation type (WP, EC, SC, …; density)	EC		
Active substances (as)	Bixafen	Fluopyram	Prothioconazole
Concentration of as (g/L)	65	65	130

5.2 Proposed use pattern

The critical GAPs used for exposure assessment is presented in Table 5.2-1. It has been selected from the individual GAPs in the central zone for Ascra Xpro. A list of all intended uses within the zone is given in Appendix 3 /Part B, Section 1, Appendix 2.

Table 5.2-1: Critical use pattern of Ascra Xpro

Group*	**Crop/ growth stage**	**Application method / Drift scenario**	**Number of applications, Minimum application interval, interception, application time**	**Application rate, cumulative (g as/ha)**	**Soil effective application rate (g as/ha)**
A	cereals (wheat, rye, triticale, spelt) BBCH 30-61	spraying / field crops	2 x, 14 d, 19.04. 1. 70 % 2. 70 %	Bixafen 2 x 97.5 = 195 Fluopyram 2 x 97.5 = 195 Prothioconazole 2 x 195 = 390	Bixafen 1. 29.25 2. 29.25 = 58.5 Fluopyram 1. 29.25 2. 29.25 = 58.5 Prothioconazole 1. 58.5 2. 58.5 = 117
B	cereals (barley, oats) BBCH 30-61	spraying / field crops	1 x, 19.04. 70 %	Bixafen 78 Fluopyram 78 Prothioconazole 156	Bixafen 23.4 Fluopyram 23.4 Prothioconazole 46.8

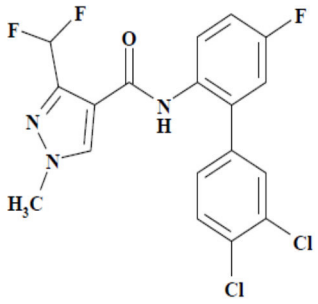
* Group A covers all intended uses in cereals in the central zone.

5.3 Information on the active substances

5.3.1 Bixafen

5.3.1.1 Identity, further information of Bixafen

Table 5.3-1: Identity, further information on Bixafen

Active substance (ISO common name)	Bixafen
IUPAC	N-(3′,4′-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide
Function (e.g. fungicide)	fungicide
Status under Reg. (EC) No 1107/2009	approval
Date of approval	01/10/2013
Conditions of approval	In this overall assessment Member States shall pay particular attention to: (a) the residues of bixafen and of its metabolites in rotational crops; (b) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; (c) the risk to aquatic organisms; (d) the risk to soil and sediment-dwelling organisms. Conditions of use shall include risk mitigation measures, where appropriate.
Confirmatory data	-
RMS	UK
Minimum purity of the active substance as manufactured (g/kg)	950
Molecular formula	$C_{18}H_{12}Cl_2F_3N_3O$
Molecular mass (g/mol)	414.21 g/mol
Structural formula	

5.3.1.2 Physical and chemical properties of Bixafen

Physical and chemical properties of Bixafen as agreed at EU level (see EFSA Journal 2012; (11):2917) and considered relevant for the exposure assessment are listed in Table 5.3-2.

Table 5.3-2: EU agreed physical chemical properties of Bixafen relevant for exposure assessment

	Value	**Reference**
Vapour pressure (at 20 °C) (Pa)	4.6 x 10-8 Pa at 20C (98.8%)	EFSA Journal 2012; (11):2917
Henry's law constant (Pa × m³ × mol^{-1})	3.89 x 10-5 Pa m3 mol-1	EFSA Journal 2012; (11):2917
Solubility in water (at 25 °C in mg/L)	0.00049 g/l at 20°C (5-9 pH) (99.2%)	EFSA Journal 2012; (11):2917
Partition co-efficient (at 25 °), log Pow	Log Pow = 3.3 at 40C	EFSA Journal 2012; (11):2917
Dissociation constant, pKa	No dissociation constant was found in the pH range 1 to12	EFSA Journal 2012; (11):2917
Hydrolytic degradation	pH 4: hydrolytically stable at 50ºC (96.5% remaining after 5 d). No further testing performed. No major metabolites.	EFSA Journal 2012; (11):2917
Photolytic degradation	DT50 : 82 experimental days No major (>10%) metabolites	EFSA Journal 2012; (11):2917
Quantum yield of direct phototransformation in water > 290 nm	Φ = 0.0000218	EFSA Journal 2012; (11):2917
Photochemical oxidative degradation in air (calculation according to Atkinson)	DT_{50} =10.4 h (AOP version: 1.91, 1.5 × 10^6 radicals/cm³, 12 h day)	EFSA Journal 2012; (11):2917

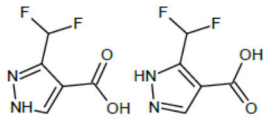
5.3.1.3 Metabolites of Bixafen

Environmental occurring metabolites of Bixafen requiring further assessment according to the results of the assessment of Bixafen for EU approval are summarized in Table 5.3-3.

No new study on the fate and behaviour of Bixafen or Ascra Xpro has been performed. Hence no potentially new metabolites need to be considered.

The leaching potential into groundwater of the soil metabolites M44 will be assessed for the application of the plant protection product and its intended uses.

Table 5.3-3: Metabolites of Bixafen potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of as and maximum of formation not yet reached at the end of the study)

Metabolite	Structural formula/Molecular formula	occurrence in compartments (Max. at day)	Status of Relevance
M44		Soil Max. 2.9 % at the end of study	No data were available in the DAR of bixafen (EFSA Journal 2012;10(11):2917), Data from EFSA Journal 2012;10(1):2522 European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance fluxapyroxad (BAS 700 F) (EFSA 2012): LC50/EC50 on fish, daphnia: >100 mg/L, EC50 on algae 22.44- 26.52 mg/L Groundwater[1)]: risk assessed as low to the aquatic environment

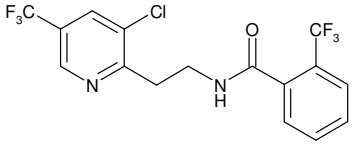
[1)] According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

5.3.2 Fluopyram

5.3.2.1 Identity, further information of Fluopyram

Table 5.3-4: Identity, further information on Fluopyram

Active substance (ISO common name)	Fluopyram
IUPAC	*N*-[2-[3-chloro-5-(trifluoromethyl)-2-pyridyl]ethyl]-α,α,α-trifluoro-ortho-toluamide
Function (e.g. fungicide)	fungicide
Status under Reg. (EC) No 1107/2009	approved
Date of approval	01/02/2014
Conditions of approval	Member States shall pay particular attention to the risk to birds and aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate.
Confirmatory data	Further studies were identified which were at this stage considered necessary in relation to the approval of fluopyram under the current approval conditions. This is particularly the case for information regarding: (1) the long term risk to insectivorous birds; (2) the potential for causing endocrine disrupting effects in non-target vertebrates other than mammals.

	The applicant shall submit to the Commission, Member States and the Authority the information set out in point 1 by 1 February 2016 and the information set out in point 2 two years after adoption of the corresponding OECD test guidelines on endocrine disruption.
RMS	Germany
Minimum purity of the active substance as manufactured (g/kg)	960
Molecular formula	$C_{16}H_{11}ClF_6N_2O$
Molecular mass (g/mol)	396.72
Structural formula	

5.3.2.2 Physical and chemical properties of Fluopyram

Physical and chemical properties of Fluopyram as agreed at EU level (see SANCO/11456/2013 rev 2 – 16/07/2013) and considered relevant for the exposure assessment are listed in Table 5.3-5.

Table 5.3-5: EU agreed physical chemical properties of Fluopyram relevant for exposure assessment

	Value	**Reference**
Vapour pressure (at 20 °C) (Pa)	1.2 x 10^{-6}	EFSA Journal 2013;11(4):3052
Henry's law constant (Pa × m³ × mol^{-1})	2.98 x 10^{-5}	
Solubility in water (at 25 °C in mg/L)	pH 4 → 15 mg/L pH 7 → 16 mg/L pH 9 → 15 mg/L	
Partition co-efficient (at 25 °), log POW	3.3	
Dissociation constant, pKa	non-dissociating	
Hydrolytic degradation	stable	
Photolytic degradation	stable	
Quantum yield of direct phototransformation in water > 290 nm	no significant adsorption at λ > 290 nm	
Photochemical oxidative degradation in air (calculation according to Atkinson)	DT_{50} = 20.78 h (AOP version: 1.91, 1.5 × 10^6 radicals/cm³, 12 h day)	

5.3.2.3 Metabolites of Fluopyram

Environmental occurring metabolites of Fluopyram requiring further assessment according to the results of the assessment of Fluopyram for EU approval are summarized in Table 5.3-6.

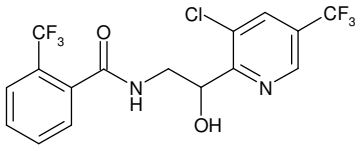
No new study on the fate and behaviour of Fluopyram or Ascra Xpro has been performed. Hence no potentially new metabolites need to be considered.

The risk assessment for these metabolites has already been performed for EU approval (see SANCO/11456/2013 rev 2 – 16/07/2013). Therefore no new risk assessment hence no exposure assessment for these metabolites is necessary.

Potential ground water contamination by the soil metabolite M08 was evaluated for EU approval of Fluopyram. PECgw modelled with FOCUS PELMO 4.4.3 was less than 0.1 µg/L for the metabolite in all scenarios based on an application of 250 g as/ha in tomatoes, strawberries and vines.

However, the leaching potential into groundwater of the soil metabolite M08 will be assessed for the application of the plant protection product and its intended uses in cereals.

Table 5.3-6: Metabolites of Fluopyram potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of as and maximum of formation not yet reached at the end of the study)

Metabolite	Structural formula/ Molecular formula	occurrence in compartments (Max. at day)	Status of Relevance (SANCO/11456/2013 rev 2 – 16/07/2013)
M08 AE C656948-7-hydroxy	 $C_{16}H_{11}ClF_6N_2O_2$ 412.72 g/mol	Soil: < 5% (4.2% at 62 d)	Aquatic organisms: Water: not applicable Sediment: not applicable Terrestrial organisms: not applicable Groundwater: not relevant (Step 2)[1)]

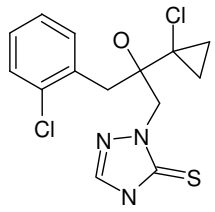
[1)] According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

5.3.3 Prothioconazole

5.3.3.1 Identity, further information of Prothioconazole

Table 5.3-7: Identity, further information on Prothioconazole

Active substance (ISO common name)	Prothioconazole
IUPAC	(RS)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-thione
Function (e.g. fungicide)	fungicide
Status under Reg. (EC) No 1107/2009	approved
Date of approval	01/08/2008
Conditions of approval	In this overall assessment Member States must pay particular attention to: - The operator safety in spray applications. Conditions of use should include adequate protective measures. - The protection of aquatic organisms. Risk mitigation measures such as buffer zones should be applied, where appropriate. - The protection of birds and small mammals. Risk mitigation measures should be applied, where appropriate.
Confirmatory data	The concerned Member States shall request the submission of: - Information to allow the assessment of consumer exposure to triazole metabolite derivatives in primary crops, rotational crops, and products of animal origin; - a comparison of the mode of action of prothioconazole and the triazole metabolite derivatives to allow the assessment of the

	toxicity resulting from the combined exposure to these compounds; - information to further address the long-term risk to granivorous birds and mammals arising from the use of prothioconazole as a seed treatment.
RMS	UK
Minimum purity of the active substance as manufactured (g/kg)	≥ 970 g/kg
Molecular formula	C_{14} H_{15} Cl_2 N_3 O S
Molecular mass (g/mol)	344.26
Structural formula	

5.3.3.2 Physical and chemical properties of Prothioconazole

Physical and chemical properties of Prothioconazole as agreed at EU level (see SANCO/3923/07 – 10/12/2007) and considered relevant for the exposure assessment are listed in Table 5.3-8.

Table 5.3-8: EU agreed physical chemical properties of Prothioconazole relevant for exposure assessment

	Value	**Reference**
Vapour pressure (at 20 °C) (Pa)	<< 4 x 10^{-7}	EFSA Scientific Report (2007) 106
Henry's law constant (Pa × m³ × mol^{-1})	<< 3 x 10^{-5}	
Solubility in water (at 25 °C in mg/L)	pH 4: 5 mg/L at 20 °C pH 8: 300 mg/L at 20 °C pH 9: 2000 mg/L at 20 °C	
Partition co-efficient (at 25 °), log P_{OW}	unbuffered: 4.05 at 20 °C pH 4: 4.16 at 20 °C pH 7: 3.82 at 20 °C pH 9: 2.00 at 20 °C	
Dissociation constant, pKa	6.9	
Hydrolytic degradation	50°C, pH 9, 7: > 1 year 50°C, pH 4: 120 days 25°C, pH 9, 7, 4: > 1 year	
Photolytic degradation	DT_{50} at pH 7 (sterile aqueous phosphate buffer), exposed to simulated sunlight (Suntest®) at 25°C: experimental half-life: 47.7 hours (n=2), corresponding to a predicted environmental half-life under solar summer conditions (June) of Phoenix, AZ, USA of 7.1 days and 11 days at Athens Main degradation products: [Phenyl-UL-^{14}C]-JAU 6476:	

	- max. 55% JAU 6476-desthio (M04) after 18 d - max. 14% JAU 6476-thiazocine (M12) after 5 d [Triazol-3,5-^{14}C]-JAU 6476: - max. 56% JAU 6476-desthio (M04) after 11 d - max. 9.5% JAU 6476-thiazocine (M12) after 11 d - max. 12% 1,2,3- triazole (M13) after 18 d	
Quantum yield of direct phototransformation in water > 290 nm	Φ = 0.0638 (pH 4) Φ = 0.0047 (pH 9)	
Photochemical oxidative degradation in air (calculation according to Atkinson)	DT_{50} = 1.1 h (AOP version: 1.87, 1.5 × 10^6 radicals/cm³, 12 h day)	
Direct Phototransformation Calculated by ABIWAS 2.0 for Central Europe (55°N) regarding radiation data. Calculation is based on UV/VIS Spectrum and quantum yield. Adsorption of the water body is not considered.	Φ = 0.0683 (pH 4) GC-Solar (50° N): DT_{50}= 88 d (summer) to > 1 y (autumn, winter) Frank & Klöpffer (50° N): DT_{50}= 73 d (June) to > 1 y (Oct. – March) Φ = 0.0047 (pH 9) GC-Solar (50° N): DT_{50} = 7.5 d (summer) to 53 d (winter) Frank & Klöpffer (50° N): DT_{50}= 7.2 d (June) to 270 d (February)	

5.3.3.3 Metabolites of Prothioconazole

Environmental occurring metabolites of Prothioconazole requiring further assessment according to the results of the assessment of Prothioconazole for EU approval are summarized in Table 5.3-9.

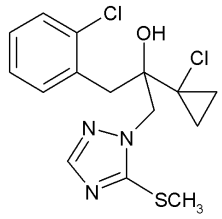
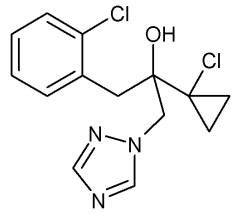
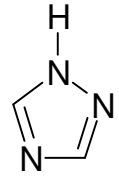
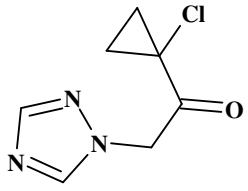
No new study on the fate and behaviour of Prothioconazole or Ascra Xpro has been performed. Hence no potentially new metabolites need to be considered.

The risk assessment for these metabolites has already been performed for EU approval (see SANCO/3923/07 – 10/12/2007). Therefore no new risk assessment hence no exposure assessment for these metabolites is necessary.

Potential ground water contamination by the soil metabolites JAU6476-S-methyl (M01) and JAU 6476-desthio (M04) was evaluated for EU approval of Prothioconazole. PECgw modelled with FOCUS PELMO (version 1.1.1) was less than 0.001 µg/L for the metabolites in all of nine scenarios based on an application of 3 times 200 g as/ha in wheat.

However, the leaching potential into groundwater of the soil metabolites JAU6476-S-methyl (M01) and JAU 6476-desthio (M04) will be assessed for the application of the plant protection product and its intended uses.

Table 5.3-9: Metabolites of Prothioconazole potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of as and maximum of formation not yet reached at the end of the study)

Metabolite	Structural formula/ Molecular formula	occurence in compartements (Max. at day/ 2 x > 5%)	Satus of Relevance (EFSA Scientific Report (2007) 106)
M01 JAU6476-S-methyl WAK7861	 C_{15} H_{17} Cl_2 N_3OS 358.3 g/mol	Soil: Max. 14.6 % at day 7 Sediment: Max. 9.6 % at day 7 (2x >5%)	Aquatic organism: not relevant Terrestrial organism: not relevant Groundwater: not relevant (Step 2)[1)]
M04 JAU 6476-desthio SXX 0665	 C_{14} H_{15} Cl_2 N_3O 312.2 g/mol	Soil: Max. 49.4 % at day 4 (lab) Max. 57 % (field studies) Water: Max. 32.3 % at day 7 Sediment: Max. 26.9 % at day 14 Photolysis: Max. 55.7 %	Aquatic organism: ecotoxicologically relevant Terrestrial organism: not relevant Groundwater: toxicologically relevant ecotoxicologically relevant (Step 2)[1)]
M13 1,2,4-Triazole CGA 71019	 $C_2H_3N_3$ 69.1 g/mol	Water: Max. 37.2 % at day 121 Sediment: Max. 6.1 % at day 121 Photolysis: Max. 11.9 %	Aquatic organism: not relevant
M42, M6a JAU 6476-triazolylketone WAK4995	 C_7 H_8 Cl N_3O 185.6 g/mol	Water: Max. 8 % at day 56, 5.6 % at day 121 (subsequent) Sediment: Max. 5.8 % at day 121	

[1)] According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

5.4 Summary on input parameters for environmental exposure assessment

5.4.1 Rate of degradation in soil

5.4.1.1 Laboratory studies

Bixafen

No new studies have been submitted regarding route and rate of degradation in soil of Bixafen. The environmental exposure assessment is based on the EU agreed DT_{50} values from the laboratory as summarized in Table 5.4-1.

Table 5.4-1: Summary of aerobic degradation rates for Bixafen - laboratory studies

Soil type		**pH**	**DT_{50} (d) 20 °C pF2/10 kPa**	**Method of calculation, Fit**	**Reference**
Sandy loam		6.0	>1y	Decline <10% over 120 d	EFSA Journal 2012; (11):2917
Silt loam		6.4	>1y	Decline <10% over 120 d	EFSA Journal 2012; (11):2917
Loam		5.4	>1y	Decline <10% over 120 d	EFSA Journal 2012; (11):2917
Silt loam		6.1	>1y	Decline <10% over 120 d	EFSA Journal 2012; (11):2917
Aggregated DT_{50} (n=4)	**Coefficient of variation (%)**				
	Geometric mean (d)		>1y		

5.4-2: Summary of aerobic degradation rates for metabolite M44 - laboratory studies

Soil type	**pH (H_2O)**	**T (°C)**	**Moisture**	**DT_{50}/ DT_{90} (d)**	**f.f.**	**DT_{50} (d) 20 °C pF2/10kPa**	**Method of calculation, Fit**	**Reference**
Li10 – Loamy sand – pyrazole label	6.3	20	40% MWHC	152/ 567 – overall; 0.968 DT50 fast; 178 DT50 slow		123 overall; 0.786 fast; 145 slow	DFOP, 0.4	EFSA Journal 2012; (11):2917
LUFA 2.2 – Sand – pyrazole label	5.9	20	40% MWHC	147/ >1000		147	FOMC, 1.9	EFSA Journal 2012; (11):2917

				120/ 567 overall; 4.86 DT50 fast; 193 DT50 slow		120 overall; 4.86 fast; 193 slow	DFOP, 2.1	EFSA Journal 2012; (11):2917
Wisconsin – Loamy sand – pyrazole label	5.9	20	40% MWHC	76.6/ >1000		70.4	FOMC, 2.2	EFSA Journal 2012; (11):2917
				83.1/ 454 – overall; 5.06 DT50 fast; 161 DT50 slow		76.3 overall; 4.65 fast; 148 slow	DFOP, 2.5	EFSA Journal 2012; (11):2917
Bruch West – Sandy loam – pyrazole label	7.4	20	40% MWHC	197/ >1000		134	FOMC, 2.0	EFSA Journal 2012; (11):2917
				158/ 636 – overall; 9.94 DT50 fast; 204 DT50 slow		- 108 overall; 6.78 fast; 139 slow	DFOP; 2.2	EFSA Journal 2012; (11):2917
Aggregated DT_{50} (n=4)		**Coefficient of variation (%)**				16		
		Geomean (d)				168.1		
		90th percentile				193		

Fluopyram

No new studies have been submitted regarding route and rate of degradation in soil of Fluopyram. The DT_{50} values from the laboratory are summarized in Table 5.4-3.

Table 5.4-3: Summary of aerobic degradation rates for Fluopyram - laboratory studies

Fluopyram	Aerobic conditions					
Soil type	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	Ch^2 (%)	Method of calculation
[pyridyl-2,6-^{14}C]AE C656948						
Hoefchen a. Hohenseh, silt loam	6.7	20°C/ 55% MWHC	210/ 697	160	0.64	SFO
Laacherhof AXXa, sandy loam	6.2	20°C/ 55% MWHC	464/ >1000	391	1	SFO
Laacherhof Wurmwiese, sandy loam	5.2	20°C/ 55% MWHC	250/ 829	211	0.74	SFO
Dollendorf, clay loam	7.3	20°C/ 55% MWHC	162/ 538	117	1.6	SFO
Porterville, US, sandy loam	7.9	25°C / 75% of 1/3 bar	561/ >1000	596 [b]	3.4	SFO
Springfield, US, silty clay loam	6.5	25°C / 75% of 1/3 bar	583/ >1000 (slow DT_{50} 765, k1=0.112 k2=0.000907g= 0.152)	711 [b] (941) [b]	2.9	DFOP (slow DT_{50} DFOP)
Geometric mean/median				309 / 301 [a]		
[phenyl-UL-^{14}C]AE C656948						
Hoefchen a. Hohenseh, silt loam	6.7	20°C/ 55% MWHC	221/735	168	1.1	SFO
Laacherhof AXXa, sandy loam	6.2	20°C/ 55% MWHC	231/761	195	1.3	SFO
Laacherhof Wurmwiese, sandy loam	5.2	20°C/ 55% MWHC	339/>1000	285	1.8	SFO
Laacherhof AIIIa, loam	7.3	20°C/ 55% MWHC	165/549	119	0.73	SFO
Porterville, US, sandy loam	7.9	25°C / 75% of 1/3 bar	746/>1000	795 [b]	2.4	SFO
Springfield, US, silty clay loam	6.5	25°C / 75% of 1/3 bar	654/>1000 (slow DT_{50} 990, k1=0.0924, k2=7e-4 g=0.2098)	805 [b] (1219) [b]	2.9	DFOP (slow DT_{50} DFOP)
Geometric mean/median				320 / 240 [a]		

[a] for DFOP kinetic the slow DT_{50} is used
[b] for t-normalisation Q10 = 2.58 is used

Table 5.4-4: Summary of aerobic degradation rates for metabolite M08 - laboratory studies

M08-7-hydroxy	Aerobic conditions							
Soil type	X[1]	pH ($CaCl_2$)	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	Ch^2 (%)	Method of calculation
Höfchen, silt loam, phenyl-labelled,		6.6	20°C/ 55%	13.2 /43.7	0.6327	10.0	9.3	SFO
Höfchen, silt loam, pyridyl- labelled		6.7	20°C/ 55%	5.9 /19.5	0.9406	4.5	9.7	SFO
Geo.mean				13.2	0.7867	6.7		
Laacher Hof AXXa, sandy loam phenyl-labelled		6.6	20°C/ 55%	17.3/57.6	0.6727	14.6	6.3	SFO
Laacher Hof AXXa, sandy loam pyridyl-labelled		6.2	20°C/ 55%	10.8/35.9	1	9.1	15.7	SFO
Geo.mean				13.7	0.8364	11.5		
Laacher Hof Wurmwiese, loam, phenyl-labelled		5.5	20°C/ 55%	14.1/46.8	1	10.8	7.1	SFO
Laacher Hof Wurmwiese, sandy loam, pyridyl-labelled		5.2	20°C/ 55%	8.5/28.2	1	5.9	27.7	SFO
Geo.mean				10.9	1	7.96		
Laacherhof AIIIa, clay loam, phenyl-labelled		6.6	20°C/ 55%	17.7/ 58.7	0.5459	13.5	9.0	SFO
Dollendorf II, clay loam (Laacherhof AIIIa) pyridyl-labelled		7.3	20°C/ 55%	5.8/19.3	1	4.2	24.5	SFO
Coefficient of variation (%)						43		
Geometric mean/median (n=5)						8.1/8.0		
Arithmetic mean (n=5)					0.8338			

Prothioconazole

No new studies have been submitted regarding route and rate of degradation in soil of Prothioconazole. The DT_{50} values from the laboratory studies are summarized in Table 5.4-5.

Table 5.4-5: Summary of aerobic degradation rates for Prothioconazole - laboratory studies

Soil type		pH	DT_{50} (d) 20 °C pF2/10 kPa	Fit	Kinetic	Reference
Laacher Hof, sandy loam		7.2	1.4* (0.1)	n.a. (1.0)	SFO (FOMC)	Gilges and Babczinski (2001)
Stanley, silty clay loam		5.9	21.9* (0.4)	n.a. (0.989)	SFO (FOMC)	Gilges and Babczinski (2001)
Höfchen, silt		7.1	0.3	0.990	SFO	Hellpointer (2001b)
Byromville, loamy sand		6.8	1.1	0.981	SFO	Hellpointer (2001b)
*calculated as $DT_{50SFO} = DT_{90FOMC}/3.32$						
Aggregated DT_{50} (n=4)	**Coefficient of variation (%)**		**170**			
	Geometric mean (d)		**1.8**			
	Median (d)		**1.3**			
	90th percentile (d)		**15.8**			

The DT_{50} values of Prothioconazole do not show any pH dependency.

Table 5.4-6: Summary of aerobic degradation rates for metabolite JAU6476-S-methyl (M01) - laboratory studies

Soil type	pH	T (°C)	Moisture	DT_{50}/ DT_{90} (d)	f.f.	DT_{50} (d) 20 °C pF2/10kPa	Fit	Kinetic	Refer-ence
Höfchen, silt	7.3	20	40% MWHC	5.9 / 19.6	-	3.4	0.97	SFO	Gilges (2001a)
Laacher Hof III, silt loam	7.9	20	40% MWHC	27.2 / 90.2	-	16.6	0.955	SFO	Gilges (2001a)
Laacher Hof XXa, sandy loam	7.2	20	40% MWHC	8.2 / 27.2	-	5.5	0.959	SFO	Gilges (2001a)
Stanley, silty clay	6.3	20	40% MWHC	46.0 / 153	-	25.9	0.965	SFO	Gilges (2001a)
Aggregated DT_{50} (n=4)		**Coefficient of variation (%)**				**81**	LoEP: DT_{50} of 15.7 d (geometric mean) is based on original study carried out at 20°C.		
		Geomean (d)				**9.5**			
		Median (d)				**11.1**			
		90th percentile (d)				**23.1**			
Formation Fraction from ai → M01 (n=4)		**Arithmetic mean**		**0.08**		formation fration refers to Schad (2001, based on Gilges and Babczinski, 2001 and Hellpointer, 2001)			
		Maximum		**0.14**					

Table 5.4-7: Summary of aerobic degradation rates for metabolite JAU 6476-desthio (M04) - laboratory studies

Soil type	pH	T (°C)	Moisture	DT_{50}/ DT_{90} (d)	f.f.	DT_{50} (d) 20 °C pF2/10kPa	Fit	Kinetic	Refer-ence
Höfchen, loamy silt	7.3	20	40% MWHC	34.0/ 113.0	-	26.1	0.820	SFO	Gilges (2001b)
Laacher Hof III, loamy silt	7.9	20	40% MWHC	29.6 / 59.2	-	18.0	0.987	SFO	Gilges (2001b)
Laacher Hof XXa, sandy loam	7.2	20	40% MWHC	7.0 / 23.2	-	4.7	0.985	SFO	Gilges (2001b)
Stanley, silty clay	6.3	20	40% MWHC	18.6 / 61.9	-	10.5	0.979	SFO	Gilges (2001b)
Aggregated DT_{50} (n=4)		**Coefficient of variation (%)**				**63**			
		Geomean (d)				**12.3**			
		Median (d)				**14.3**			
		90th percentile (d)				**23.7**			
Formation Fraction from ai → M04 (n=4)		**Arithmetic mean**		**0.31**		formation fration refers to Schad (2001, based on Gilges and Babczinski, 2001 and Hellpointer, 2001)			
		Maximum		**0.42**					

5.4.1.2 Field studies

Bixafen

The field dissipation rates of Bixafen were evaluated during EU assessment. No additional studies have been performed. The DT_{50} values are summarized in **Fehler! Verweisquelle konnte nicht gefunden werden.**.

At some locations field dissipation studies are fulfilling ctgb criteria, so that DT_{50} values can be used for PEC_{GW} modeling. The DT_{50} values are summarized in **Fehler! Verweisquelle konnte nicht gefunden werden.**.

Table 5.4-8: Field degradation studies of Bixafen fulfilling ctgb criteria (applicable for PEC_{GW})

Soil / location	pH	Depth (cm)	DT_{50} (d)	DT_{90} (d)	Method of calculation, Fit	DT_{50} (d) 20 °C, pF2	Method of calculation, Fit	Reference
Silt loam Germany	6.3	0-30	**>1235**	>1000	HS	320.1	SFO	EFSA Journal 2012; (11):2917
Sandy loam UK	7.4		316	>1000	HS	196.8	SFO	EFSA Journal 2012; (11):2917
Silt loam Sweden	7.4		541	>1000	HS	247.8	SFO	EFSA Journal 2012; (11):2917
Silt loam N. France	6.7		395	>1000	HS	231.4	SFO	EFSA Journal 2012; (11):2917

Loam Spain	6.1		105	>1000	HS	145.6	SFO	EFSA Journal 2012; (11):2917
Silt loam Italy	8.3		30.6	>1000	HS	122.4	SFO	EFSA Journal 2012; (11):2917
Silt loam Germany	6.3		>1000	>1000	HS	320.1	SFO	EFSA Journal 2012; (11):2917
Geometric Mean						**200.2**		

Table 5.4-9: Field degradation studies of M44

soil / location	**pH**	**depth (cm)**	**DT_{50} (d)**	**DT_{90} (d)**	**Fit, Kinetic, Parameters**	**DT_{50} (d) 20 °C, pF2**	**Fit, Kinetic**	**Reference**
Loamy sand – bare soil	5.8	0 - 40				17.9	SFO	EFSA Journal 2012; (11):2917
Silt Loam – bare soil	6.4	0 - 40				23.1	SFO	EFSA Journal 2012; (11):2917
Silt Loam – bare soil	7.7	0 - 70				44.1	SFO	EFSA Journal 2012; (11):2917
Loam – bare soil	5.5	0 - 60				24.6	SFO	EFSA Journal 2012; (11):2917
Geom. mean						**25.9**		

Fluopyram

The field dissipation rates of Fluopyram were evaluated during EU assessment. No additional studies have been performed. The DT_{50} values are summarized in Table 5.4-10.

Table 5.4-10: Field degradation studies of Fluopyram fulfilling ctgb criteria (applicable for PEC_{GW})

Soil / location	**pH** (H_2O)	**DT_{50}** (d)	**DT_{90}** (d)	**Kinetic**	**DT_{50} (d) 20 °C, pF2**	**Kinetic**	**Ch^2 (%)**	**Reference [3]**
Hoefchen, Germany, silt loam	6.9	145	> 1000	DFOP	92.8	SFO	6.8	Heinemann et. al. (2007), Kley et. al. (2008) kinetic evaluation: Sur (2010)
Little Shelford, UK, sandy loam	8.1	164	> 1000	DFOP	123.1	SFO	12.2	
Staffanstorp, Sweden, loam	8.1	179	> 1000	DFOP	100.0	SFO	12.3	
Vatteville, France, silt loam	7.3	347	> 1000	DFOP	124.4	SFO	9.9	
Vilobí d' Onyar, Spain, loam	6.7	147	487	SFO	87.4	SFO	19.0	
Alboro, Italy,	8.2	21.2	512	DFOP	115.5 [1]	DFOP	6.0	

silt loam								
median (EU trials) (d)					*107.8*			
geometric mean (EU trials) (d)					*106.2*			
CV (coefficient of variation) (EU trials) (%)					*15*			
New York, USA, loamy sand	6.2	539	>1000	SFO	228.4	SFO	13.5	Xu (2008)
North Dakota, USA, loam	7.0	83	>1000	DFOP	744.0 [1]	DFOP	7.1	
Washington, USA, sandy loam	8.1	163	>1000	DFOP	257.5 [1]	DFOP	3.0	
median (all trials) (d)					**123.1[2]**			
geometric mean (all trials) (d)					158.4			
CV (coefficient of variation) (all trials) (%)					101			

[1] DT_{50} for modelling: DFOP from rate k_{slow} of second phase

[2] Concluded to use the median DT_{50} of the 9 European and US field trials for PECsw, PECsed and PECgw calculations due to the increased number of DT_{50} values available (according to FOCUS, 2011)

[3] EFSA Journal 2013;11(4):3052

The DT_{50} values of Fluopyram do not show any pH dependency.

Prothioconazole

No new studies have been submitted on the soil dissipation of Prothioconazole under field conditions. However, DT_{50} values from these studies that were evaluated during EU assessment were recalculate according to FOCUS Degradation Kinetics, 2006 and taking the new Q_{10} of 2.58 into account. The recalculated and normalized DT_{50} values for Prothioconazole and its metabolite JAU 6476-desthio (M04) are summarized in Table 5.4-11 and Table 5.4-12.

Table 5.4-11: Field degradation studies of Prothioconazole fulfilling ctgb criteria (applicable for PEC_{GW})

soil / location	**pH ($CaCl_2$)**	**depth (cm)**	**DT_{50} (d)**	**DT_{90} (d)**	**Fit χ^2**	**DT_{50} (d) 20 °C, pF2**	**Fit χ^2**	**Kinetic**	**Reference**
D-Burscheid, silt loam	6.25	0-10	2.0	6.6	1.47	1.32	1.2	SFO	Schad and Zerbe (2008), Hardy (2012)
UK-Thurston, sandy clay loam	7.56	0-10	1.8	6.1	1.70	1.09	26.8	SFO	Schad and Zerbe (2008), Hardy (2012)
F(North)-Fresne, silt	6.42	0-10	1.5	4.9	3.87	0.75	4.5	SFO	Schad and Zerbe (2008), Hardy (2012)
UK-Thurston, sandy clay loam	7.56	0-10	2.4	7.9	2.08	1.38	32.2	SFO	Schad and Zerbe (2008), Hardy (2012)
F(North)-Fresne, silt	6.42	0-10	1.5	5.0	1.51	0.73	1.1	SFO	Schad and Zerbe (2008), Hardy (2012)

F(South)-St. Etienne, silt loam	7.61	0-10	1.9	6.3	2.68	0.70	2.0	SFO	Schad and Zerbe (2008), Hardy (2012)
I- Nogarole, sandy loam	7.56	0-10	1.5	5.1	2.57	0.97	2.1	SFO	Schad and Zerbe (2008), Hardy (2012)
D-Monheim, sandy loam	6.32	0-10	1.7	5.6	1.40	0.82	2.0	SFO	Schad and Zerbe (2008), Hardy (2012)
Aggregated DT_{50} (n=8)			**Coefficient of variation (%)**			**28**			
			Geometic mean (d)			**0.94**			

The DT_{50} values of Prothioconazole do not show any pH dependency.

Table 5.4-12: Field degradation studies of metabolite JAU 6476-desthio (M04) fulfilling ctgb criteria (applicable for PEC_{GW})

soil / location	pH ($CaCl_2$)	depth (cm)	DT_{50} (d)	DT_{90} (d)	Fit χ^2	DT_{50} (d) 20 °C, pF2	f.f.	Fit χ^2	Kinetic	Reference
D-Burscheid, silt loam	6.25	0-10	17.1	56.8	9.5	9.0	0.72	7.9	SFO	Schad and Zerbe (2008), Hardy (2012)
UK-Thurston, sandy clay loam	7.56	0-10	57.0	189	10.1	23.5	0.67	4.8	SFO	Schad and Zerbe (2008), Hardy (2012)
F(North)-Fresne, silt	6.42	0-10	49.8	165	12.7	29.5	0.42	13.5	SFO	Schad and Zerbe (2008), Hardy (2012)
UK-Thurston, sandy clay loam	7.56	0-10	50.8	169	13.4	19.8	0.76	9.8	SFO	Schad and Zerbe (2008), Hardy (2012)
F(North)-Fresne, silt	6.42	0-10	35.2	117	13.7	24.0	0.39	6.6	SFO	Schad and Zerbe (2008), Hardy (2012)
F(South)-St. Etienne, silt loam	7.61	0-10	50.8	169	10.1	36.4	0.65	10.1	SFO	Schad and Zerbe (2008), Hardy (2012)
I- Nogarole, sandy loam	7.56	0-10	31.7	105	6.2	26.7	0.48	6.5	SFO	Schad and Zerbe (2008), Hardy (2012)
D-Monheim, sandy loam	6.32	0-10	28.7	95.2	7.7	17.8	0.74	5.4	SFO	Schad and Zerbe (2008), Hardy (2012)
Aggregated DT_{50} (n=8)			**Coefficient of variation (%)**			**35**				
			Geometic mean (d)			**21.8**				
Formation Fraction from ai → M04 (n=8)			**Arithmetic mean**				**0.60**			

5.4.2 Adsorption/desorption

Bixafen

No new studies have been submitted regarding adsorption/desorption in soil of Bixafen. The exposure modeling is based on the EU K_{Foc} values as summarized in Table 5.4-13.

Table 5.4-13: K_F, K_{Foc} and 1/n (Freundlich exponent) values for Bixafen

Soil Type	OC (%)	pH (-)	K_F (mL g^{-1})	K_{Foc} (mL g^{-1})	1/n (-)	Reference
Sandy loam	1.3	6.5	42.8	3290	0.857	LoEP, Juni 2012
Silt loam	2.62	6.8	102.7	3920	0.876	
Loam	2.07	6	72	3477	0.883	
Loamy sand	1.1	5.4	40.5	3682	0.885	
Clay loam	1.1	6.3	54.7	4974	0.882	
Arithmetic mean				**3869**	**0.877**	

Table 5.4-14: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite M44

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
LUFA 2.1, Sand	0.52	5.2	0.07	13.1	0.969	EFSA Conclusion, 2012
Li 10, Loamy Sand	0.88	5.9	0.04	4.8	0.842	
New Jersey, Silt Loam	0.90	6.3	0.13	14.1	1.165	
Nierswalde, Silt Loam	1.63	6.5	0.15	9	0.937	
LUFA 2.3,Sandy Loam	1.09	6.9	0.06	5.6	1.078	
La Gironda, Silty Clay Loam	3.84	7.5	0.04	1	0.99	
California, Sandy Loam	0.41	7.6	0.02	5.6	0.764	
Arithmetic mean				**7.6**	**0.964**	

Fluopyram

No new studies have been submitted regarding adsorption/desorption in soil of Fluopyram. The exposure modeling is based on the EU K_{Foc} values as summarized in Table 5.4-15.

Table 5.4-15: K_F, K_{Foc} and 1/n (Freundlich exponent) values for Fluopyram

Soil Type	OC (%)	pH $_{H2O}$ (-)	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
Laacherhof AXXa, sandy loam	1.3	6.6	3.031	233.2	0.765	Henk and Haas (2005)
Hoefchen am Hohenseh, silt loam	2.6	6.7	6.825	260.5	0.838	
Laacherhof Wurmwiese, loam	2.1	6.0	4.839	233.7	0.849	
Pikeville, loamy sand	1.1	5.6	2.941	267.3	0.846	
Stilwell, clay loam	1.1	7.0	4.396	399.7	0.837	
Arithmetic mean (n=5)				**278.9**	**0.827**	

The K_{Foc}/K_F values of Fluopyram do not show any pH dependency.

Table 5.4-16: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite M08 -7-hydroxy

Soil Type	OC (%)	pH (water)	K_d (mL/g)	K_{oc} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/n	Reference
Loam	1.1	6.7			0.991	90.1	0.9241	Heinemann and Dehner (2007)
Sandy loam	1.5	6.4			1.321	88.1	0.9391	
Silt loam	1.6	7.0			2.390	149.4	0.9104	
Sandy loam	1.6	5.3			1.362	85.1	0.9432	
Arithmetic mean (n=4)					**1.516**	**103.2**	**0.9292**	
pH dependence					no			

Prothioconazole

No new studies have been submitted regarding adsorption/desorption in soil of Prothioconazole.

K_d and K_{oc} values of Prothioconazole could not be determined in standard batch equilibrium studies due to the instability of the compound in these systems. Therefore, a parent column leaching and an aged residue column leaching study were performed.

K_d : 15.2 mL/g

K_{oc} : 1765 mL/g

1/n : 1.0 (default)

For the metabolite JAU6476-S-methyl (M01) and JAU 6476-desthio (M04) the K_{foc} values are summarized in Table 5.4-17 and Table 5.4-18.

Table 5.4-17: K_F, K_{Foc} and 1/n (Freundlich exponent) values for metabolite JAU6476-S-methyl (M01) of Prothioconazole

Soil Type	OC (%)	pH (H_2O)	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
Sandy loam	2.02	7.2	56.0	2772	0.87	Hein (1999)
Silt	2.14	7.1	64.1	2995	0.88	Hein (1999)
Silty clay loam	1.66	5.9	41.2	2482	0.91	Hein (1999)
Loamy sand	0.79	6.8	15.6	1975	0.85	Hein (1999)
Arithmetic mean (n=4)				**2556**	**0.88**	

Table 5.4-18: K_F, K_{Foc} and 1/n (Freundlich exponent) values for metabolite JAU 6476-desthio (M04) of Prothioconazole

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
Sandy loam	2.02	7.2	12.46	617	0.79	Fent (1998)
Silt	2.14	7.1	13.38	625	0.83	Fent (1998)
Silty clay loam	1.66	5.9	8.9	536	0.83	Fent (1998)
Loamy sand	0.79	6.8	4.13	523	0.80	Fent (1998)
Arithmetic mean (n=4)				**575**	**0.81**	

The K_{Foc}/K_F values of the metabolites JAU6476-S-methyl (M01) and JAU 6476-desthio (M04) of Prothioconazole do not show any pH dependency.

5.4.3 Rate of degradation in water and sediment

Bixafen

No new water/sediment study has been submitted. The exposure modeling is based on the results of the water/sediment study of Bixafen reviewed in the DAR/AR/Addendum. The DT_{50} values of the water/sediment study are summarized in Table 5.4-19.

Table 5.4-19: Degradation in water/sediment of Bixafen

Water/sediment system	$DegT_{50}$ / $DegT_{90}$ whole system	Method of calculation, Fit	$DissT_{50}$/ $DissT_{90}$ water	Method of calculation, Fit	$DissT_{50}$/ $DissT_{90}$ sed.	Method of calculation, Fit	Reference
clay	1000		27.4	SFO, 9.1	1000		LoEP, Juni 2012
sand	1000		25.5	SFO, 12.2	1000		

Because of the $DegT_{50}$ of over 1000 days the accumulation of Bixafen in the sediment has to be considered.

Fluopyram

No new water/sediment study has been submitted. The exposure modeling is based on the results of the water/sediment study of Fluopyram (Allan and Shepherd, 2007; Kley, 2008) reviewed in the DAR.

The DT_{50} values of the water/sediment study are summarized in Table 5.4-20.

Table 5.4-20: Degradation in water/sediment of Fluopyram

Water / sediment system		pH water phase	pH sed	t. °C	DT_{50} / DT_{90} whole system	St. (r^2)	DT_{50} / DT_{90} water	St. (r^2)	DT_{50}/ DT_{90} Sed.	St. (r^2)	Method of calculation
Angler-weiher, Leverkusen, Germany	[phenyl^{14}C]-labelled	6.8	5.6	24	1190 / 3960	0.8	25 / 284	2.1	n.c.	-	SFO (whole system); DFOP (water phase)
	[pyridyl^{14}C]-labelled	6.8	5.6	24	1470 / 4900	1.3	26 / 293	1.8	n.c.	-	
	Geometric mean (Anglerweiher)				*1323 / 4405*		*25 / 288*				
Lawrence, Jefferson County, Kansas, USA	[phenyl^{14}C]-labelled:	7.3	5.3	n.m.	1000 / 3330	0.9	14/ 215	1.5	n.c.	-	SFO (whole system); DFOP (water phase)
	[pyridyl^{14}C]-labelled				648 / 2150	1.7	17 / 221	4.8	n.c.	-	
	Geometric mean (Lawrence)				*805 / 2676*		*15 /218*				
Geometric mean (all)					**1032 / 3433**		**20 / 251**				

Prothioconazole

No new water/sediment study has been submitted. The exposure modeling is based on the results of the water/sediment study of Prothioconazole (Brumhard, 2001) reviewed in the DAR.

The DT_{50} values of the water/sediment study are summarized in Table 5.4-21.

Table 5.4-21: Degradation in water/sediment of Prothioconazole

Water/sediment system	$DegT_{50}$ / $DegT_{90}$ whole system	Kinetic, Fit	$DissT_{50}$/ $DegT_{50}$ water	Kinetic, Fit	$DissT_{50}$/ $DegT_{50}$ sed.	Kinetic, Fit	Reference
I - Hönninger Weiher	24.1 d / n.a.	SFO	0.8 d / n.a.	SFO, 0.947	n.a.		Brumhard (2001), Schad (2001)
II - Anglerweiher	1.8 d / n.a.	SFO	1.0 d / n.a.	SFO, 0.999	n.a.		Brumhard (2001), Schad (2001)
Metabolit JAU6476-S-methyl (M01)							
I - Hönninger Weiher	18.5 d / n.a.	SFO					Brumhard (2001), Schad (2001)
II - Anglerweiher	40.2 d / n.a.	SFO					Brumhard (2001), Schad (2001)
Metabolit JAU6476-desthio (M04)							
I - Hönninger Weiher	49.9 d / n.a.	SFO					Brumhard (2001), Schad (2001)
II - Anglerweiher	39.2 d / n.a.	SFO					Brumhard (2001), Schad (2001)

The degradation behaviour of Prothioconazole in two different water/sediment systems was investigated under aerobic conditions. Prothioconazole rapidly dissipated in both systems. The DT_{50} values of Prothioconazole were calculated to be ca. 2 –24 days referring to the entire system including surface water and sediment. The evolution of $^{14}CO2$ increased continuously until termination of the experiment. On the other hand, mineralization of the Triazole-label was much slower than of the phenyl-label. More than 12 metabolites were formed and five of them were identified. The metabolites exceeding 10% of the applied radioactivity in the entire system were identified as JAU 6476-S-methyl (M01), JAU 6476-desthio (M04) and 1,2,4-triazole (M13). Among these metabolites, JAU 6476-desthio (M04) and 1,2,4-triazole (M13) were detected in the water layer at > 10% of the applied radioactivity. In the sediment extracts JAU 6476-desthio (M04) was the only major metabolite.

5.5 Estimation of concentrations in soil (PEC_{soil}) (KIIIA1 9.4)

PEC_{soil} calculations are based on the recommendations of the FOCUS workgroup on degradation kinetics. A soil bulk density of 1.5 g/cm^3, a soil depth of 5 cm and a tillage depth of 20 cm (arable crop)/5 cm (permanent crops) were assumed. The PEC_{soil} calculations were performed with ESCAPE 2.0 based on the input parameters as presented in tables below.

Table 5.5-1: Application related input parameters for PEC_{Soil} calculations

Plant protection product	Ascra Xpro
Use No.:	A
Crop:	cereals
Application rate (g a.s./ha):	Bixafen: 2 x 97.5 = 195 Fluopyram: 2 x 97.5 = 195 Prothioconazole: 2 x 195 = 390 Ascra Xpro: 2 x 1515 = 3030*
Number of applications/interval:	2 x/ 14 d
Crop interception:	2 x 70%

* Ascra Xpro-density: 1.010 g/ml, 1.5 L/ha applied

Table 5.5-2: Substance related input parameters for PEC_{soil} calculation

Active substance	**DT_{50}**	**value in accordance to EU endpoint**
Bixafen	1235 d HS-Model, Maximum, Field studies non normalised, see Table 5.4-8	yes
Fluopyram	Fast phase: DT_{50}= 20.33 d Slow phase: DT_{50}= 495.1 d g= 0.1804 (DFOP, real. worst case, field studies, Vatteville, France)	yes
Prothioconazole	2.4 d (SFO, Maximum field studies, non-normalised)	no
Metabolite JAU6476-S-methyl (M01)	25.9 d (SFO, Maximum laboratory studies, 20 °C, pF2)	no
Metabolite JAU6476-desthio (M04)	57 d (SFO, Maximum field studies, non-normalised)	no

Table 5.5-3: Substance related input parameters for metabolites for PEC_{soil} calculation

Metabolite	**Molecular weight [g/mol]**	**Molar correction factor [-]**	**Maximum occurrence in soil [%]**
JAU6476-S-methyl (M01)	358.3	1.041	14.2
JAU6476-desthio (M04)	312.2	0.907	57.1

Due to the slow degradation of Bixafen in soil (DT_{90} > 365 d, field data) the accumulation potential of Bixafen needs to be considered. Therefore PEC_{soil} used for risk assessment comprises background concentration in soil (PEC_{accu}) deducated from the soil accumulation study (Heinemann, Weuthen 2013) given for a depth of 10 cm and the maximum annual soil concentration PEC_{act} considering the relevant soil depth of 5.0 cm.

A factor of 3.7 between the concentration resulting from one application and the background concentration is derived from the soil accumulation study by Heinemann, Weuthen (2013).

As no plateau was not reached during the 8 years of the study, an extrapolation of the background concentration was performed by ZRMS. The measured background concentration after 8 years for a substance with a DT_{50} of 1235 days represents only 80% of the calculated background concentration for a substance with such a long DT_{50} value. Further, as no plateau was reached, we used additionally an uncertainty factor of 10 for the low background concentration .

Based on all informations about the degradation in soil of Bixafen coming from laboratory studies, field studies, and the soil accumulation study, Bixafen is very persistent. In this respect, the behaviour of Bixafen in soil is source of great concern.

Finally, this revised background concentration was added to the the maximum annual soil concentration PEC_{act} in a soil depth of 5 cm.

Due to the slow degradation of Fluopyram in soil (DT_{90} > 365 d, field data) the accumulation potential of Fluopyram needs to be considered. Therefore an accumulated soil concentration (PEC_{accu}) is used for risk assessment that comprises background concentration in soil (PEC_{bkgd}) considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops) and the maximum annual soil concentration PEC_{act} for a soil depth of 5 cm.

Due to the fast degradation of Prothioconazole in soil (DT_{90} < 365 d, field data) the accumulation potential of Prothioconazole does not need to be considered.

Table 5.5-4: Results of PEC_{soil} calculation for application of Ascra Xpro in cereals (soil bulk density 1.5 g/cm^{-3}, soil depth 5 cm) according to use No A

active substance/ preparation	soil relevant application rate (g/ha)	PEC_{act} (mg/kg)	PEC_{twa} 21 d (mg/kg)	tillage depth (cm)	PEC_{bkgd} (mg/kg)	PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)
Ascra Xpro	2 x 455	1.2133	-	-	-	-
Bixafen	2 x 29.25	0.0777	-	20	0.7566	0.8343
Fluopyram	2 x 29.25	0.0747 (d 14)	-	20	0.0235	0.0983
Prothioconazole	2 x 58.5	0.0798 (d 14)	-	-	-	-
JAU6476-S-methyl (M01)	2 x 8.6	0.0194 (d 14)	-	-	-	-
JAU6476-desthio (M04)	2 x 30.3	0.0745 (d 14)	-	-	-	-

Table 5.5-5: Results of PECaccu $_{soil}$ calculation for Bixafen

active substance/ formulation	**soil relevant application rate (g/ha)**	**soil depth$_{act}$ (cm)**	**PEC$_{act}$ (mg/kg)**	**Factor accumulation in soil after 8 years**	**PEC$_{bkgd}$ (mg/kg)**	**PEC$_{bkgd}$ after 8 years +20%**
Bixafen	2 x 29.25	5	***0.0777***			
		20	0.0194	3.7	0.07178	0.07566
active substance/ formulation	**soil relevant application rate (g/ha)**	**soil depth$_{act}$ (cm)**	**Factor for uncertainty**	**PECbkgd after 8 years +20% x 10 (mg/kg)**		**PEC$_{accu}$ = PEC$_{act}$ + PEC$_{bkgd}$ (mg/kg**
Bixafen	2 x 29.25	5				
		20	10	***0.7566***		**0.8343**

5.6 Estimation of concentrations in surface water and sediment (PECsw/PECsed) (KIIIA1 9.7)

PEC_{sw} and PEC_{sed} calculations are provided according to the recommendations of the FOCUS working group on surface water scenarios in a stepwise approach considering the pathways drainage and runoff.

The FOCUS calculations for Bixafen was performed by applicant (Scherr, Ellerich, 2013). The FOCUS calculations for Fluopyram was performed by applicant (Kley and Bolekhan, 2013). The FOCUS calculations for Prothioconazole was performed by applicant (Chapple and Ghafoor, 2014).

The relevant input parameters used for PEC calculation are summarized in the tables below.

Table 5.6-1: Input parameters for Bixafen for $PEC_{sw/sed}$ calculations

Parameter	Endpoint used for $PEC_{sw/sed}$ calculation	Values in accordance to EU endpoint in LoEP	Remarks
Active substance	Bixafen		
Molecular weight (g/mol)	414.21	yes	
Saturated vapour pressure (Pa)	$4.6x10^{-8}$	yes	
Water solubility (mg/L)	0.49		
Diffusion coefficient in water (m^2/d)	not required for Step 1+2/ 4.3 x 10^{-5}	--	default
Diffusion coefficient in air (m^2/d)	not required for Step 1+2/0.43	--	default
K_{Foc} (mL g^{-1})	3869		Arithmetic mean (see Table 5.4-13)
Freundlich Exponent 1/n	Not required for Step 1+2 0.88		Arithmetic mean (see Table 5.4-13)
Plant Uptake	not required for Step 1+2 0	-	default
Wash-Off factor from Crop	not required for Step 1+2/ 0.05 mm^{-1} (MACRO) 0.50 cm^{-1}(PRZM)	-	default
DT_{50},soil (d)	200.2	yes	Geomean (1st order, pF2,20°C) field data (see Table 5.4-8)
DT_{50},water (d)	1000		Geomean of whole system (1st order, 20°C) - Default value (see Table 5.4-19)
DT_{50},sed (d)	1000		Geomean of whole system (1st order, 20°C) - Default value (see Table 5.4-19)
DT_{50},whole system (d)	1000		Geomean of whole system (1st order, 20°C) - Default value (see Table 5.4-19)

Due to the slow degradation of bixafen in the water/sediment studies, it is not possible to exclude the potential of accumulation in sediment. For bixafen, an accumulation factor for the sediment of 4.47 was calculated with the following equation assuming a default DT_{50} of 1000 d and a time interval (Δt) of 365 d:

Accumulation factor = 1/(1-EXP(-k*Δt))

To also allow a comparison of the accumulated PECsed values with the water-spiked Chironomus study, the PECsed,accu values were converted to an equivalent water phase concentration PECsw,eq,accu using ratio of sediment to water in water-spiked Chironomus study, i.e. assuming as a worst case that 100% of residues bound to sediment are released to overlying water. This study was performed in the presence of 0.14 kg (wet weight) of sediment with a stated water content of 30.7% giving 0.097 kg (dry weight) of sediment and 0.38 L of water.

The following equation was used to convert sediment concentration to water:

PECsw,eq,accu = PECsed,accu * mass of sediment (dry weight) (kg) / volume of water (L)

However, it should be noted, that the degradation of Bixafen might take considerably longer than DT_{50} of 1000 d that were used for deriving the accumulation factor. This could result in higher PECsed,accu as calculated here.

Table 5.6-2: Input parameters for Fluopyram for $PEC_{sw/sed}$ calculations

Parameter	Endpoint used for $PEC_{sw/sed}$ calculation	Values in accordance to EU endpoint in LoEP	Remarks
Active substance	**Fluopyram**		
Molecular weight (g/mol)	396.72	yes	
Saturated vapour pressure (Pa)	not required for Step 1+2/ 1.2×10^{-6}	yes	
Water solubility (mg/L)	16 (at pH7)	yes	
Diffusion coefficient in water (m^2/d)	not required for Step 1+2/ 4.3×10^{-5}	--	default
Diffusion coefficient in air (m^2/d)	not required for Step 1+2/0.43	--	default
K_{Foc} (mL g^{-1})	278.9	yes	Arithmetic mean (see Table 5.4-15)
Freundlich Exponent 1/n	not required for Step 1+2/ 0.827	yes	Arithmetic mean (see Table 5.4-15)
Plant Uptake	not required for Step 1+2/ 0	-	default
Wash-Off factor from Crop	not required for Step 1+2/ 0.05 mm^{-1} (MACRO) 0.50 cm^{-1}(PRZM)	-	default
DT_{50},soil (d)	123.05	yes	Geomean (1st order, pF2, 20°C), field data (see Table 5.4-10)
DT_{50},water (d)	(1032) 1000[1]	yes	Geomean of whole system (1st order, 20°C) - Default value (see Table 5.4-20)

DT_{50},sed (d)	1000	yes	Default value (see Table 5.4-20)
DT_{50},whole system (d)	1032	yes	Geomean of whole system (1st order, 20°C, see Table 5.4-20)
Max. occurrence water/sediment	100 %	yes	
Max. occurrence soil	100 %	yes	

[1] The step 3 software SWASH does not accept half-lives greater than 1000 d, which was used then for water.

Table 5.6-3: Input parameters for Prothioconazole for $PEC_{sw/sed}$ calculations

Parameter	Endpoint used for $PEC_{sw/sed}$ calculation	Values in accordance to EU endpoint in LoEP	Remarks
Active substance	**Prothioconazole**		
Molecular weight (g/mol)	344.3	yes	
Saturated vapour pressure (Pa)	not required for Step 1+2/ 1 x 10^{-10}	no	
Water solubility (mg/L)	300 (at pH 8)	yes	
Diffusion coefficient in water (m^2/d)	not required for Step 1+2/ 4.3 x 10^{-5}	--	default
Diffusion coefficient in air (m^2/d)	not required for Step 1+2/ 0.43	--	default
K_{Foc} (mL g^{-1})	1765	yes	based on aged soil column leaching study
Freundlich Exponent 1/n	not required for Step 1+2/ 1.0		default
Plant Uptake	0	-	default
Wash-Off factor from Crop	not required for Step 1+2/ 0.05 mm^{-1} (MACRO) 0.50 cm^{-1}(PRZM)	-	default
DT_{50},soil (d)	1.77 for Step 1+2/ 0.94 for Step 3	no	geomean, field data (see Table 5.4-11), non-normalised for Step 1+2/ normalised for Step 3
DT_{50},water (d)	24.1	no	Maximum of whole system
DT_{50},sed (d)	24.1 for Step 1+2/ 1000 for Step 3	not stated	Maximum of whole system / default value
DT_{50},whole system (d)	24.1	no	Maximum (see Table 5.4-21)
Max. occurrence water/sediment	100 %	no	default
Max. occurrence soil	100 %	no	default

Table 5.6-4: Input parameters for metabolite JAU6476-S-methyl (M01) of Prothioconazole for $PEC_{sw/sed}$ calculations

Parameter	Endpoint used for $PEC_{sw/sed}$ calculation	Values in accordance to EU endpoint in LoEP	Remarks
Metabolite	**JAU6476-S-methyl (M01)**		
Molecular weight (g/mol)	358.3	yes	
Saturated vapour pressure (Pa)	not required for Step 1+2/ $2.9x10^{-8}$	not stated	calculated
Water solubility (mg/L)	1.5	not stated	calculated
Diffusion coefficient in water (m^2/d)	not required for Step 1+2/ 4.3 x 10^{-5}	-	default
Diffusion coefficient in air (m^2/d)	not required for Step 1+2/ 0.43	-	default
K_{Foc} (mL g^{-1})	2556.3	yes	Arithmetic mean (see Table 5.4-17)
Freundlich Exponent 1/n	not required for Step 1+2	-	
Plant Uptake	not required for Step 1+2	-	default
Wash-Off factor from Crop	not required for Step 1+2/ 0.05 mm^{-1} (MACRO) 0.50 cm^{-1}(PRZM)	-	default
DT_{50},soil (d)	15.7	yes	Geomean, Laboratory data
DT_{50},water (d)	40.2	not stated	Maximum of whole system
DT_{50},sed (d)	40.2	not stated	Maximum of whole system
DT_{50},whole system (d)	40.2	not stated	Maximum (see Table 5.4-21)
Max. occurrence water/sediment	12.7 %	not stated	
Max. occurrence soil	14.2 %	no	

Table 5.6-5: Input parameters for metabolite JAU6476-desthio (M04) of Prothioconazole for $PEC_{sw/sed}$ calculations

Parameter	Endpoint used for $PEC_{sw/sed}$ calculation	Values in accordance to EU endpoint in LoEP	Remarks
Metabolite	**JAU 6476-desthio (M04)**		
Molecular weight (g/mol)	312.2	yes	
Saturated vapour pressure (Pa)	not required for Step 1+2/ $1.0x10^{-10}$	not stated	
Water solubility (mg/L)	50.6	not stated	
Diffusion coefficient in water (m^2/d)	not required for Step 1+2/ 4.3×10^{-5}	-	default
Diffusion coefficient in air (m^2/d)	not required for Step 1+2/ 0.43	-	default
K_{Foc} (mL g^{-1})	575.4	yes	Arithmetic mean (see Table 5.4-18)
Freundlich Exponent 1/n	not required for Step 1+2/ 0.81	-	Arithmetic mean (see Table 5.4-18)
Plant Uptake	not required for Step 1+2/ 0	-	default
Wash-Off factor from Crop	not required for Step 1+2/ 0.05 mm^{-1} (MACRO) 0.50 cm^{-1}(PRZM)	-	default
DT_{50},soil (d)	37.6 for Step 1+2/ 21.8 for Step 3+4	yes	Geomean, field data
DT_{50},water (d)	49.9	not stated	Maximum of whole system
DT_{50},sed (d)	49.9 for Step 1+2/ 1000 for Step 3+4	not stated	Maximum of whole system/ default
DT_{50},whole system (d)	49.9	not stated	Maximum (see Table 5.4-21)
Max. occurrence water/sediment	54.4 %	not stated	
Max. occurrence soil	57.1 %	yes	

Table 5.6-6: Input parameters for metabolite 1,2,4-triazole of Prothioconazole for $PEC_{sw/sed}$ calculations

Parameter	Endpoint used for $PEC_{sw/sed}$ calculation	Values in accordance to EU endpoint in LoEP	Remarks
Metabolite	**1,2,4-triazole**		
Molecular weight (g/mol)	69.1	yes	
Saturated vapour pressure (Pa)	not required for Step 1+2	not stated	
Water solubility (mg/L)	700000	not stated	
Diffusion coefficient in water (m^2/d)	not required for Step 1+2	-	
Diffusion coefficient in air (m^2/d)	not required for Step 1+2	-	
K_{Foc} (mL g^{-1})	89	yes	Arithmetic mean
Freundlich Exponent 1/n	not required for Step 1+2	-	
Plant Uptake	not required for Step 1+2	-	
Wash-Off factor from Crop	not required for Step 1+2	-	
DT_{50},soil (d)	0.0001 for Step 1+2	not stated	default
DT_{50},water (d)	1000	not stated	default
DT_{50},sed (d)	1000	not stated	default
DT_{50},whole system (d)	1000	not stated	default
Max. occurrence water/sediment	41.8 %	not stated	
Max. occurrence soil	0.00001 %	not stated	

Table 5.6-7: Input parameters related to application for $PEC_{sw/sed}$ calculations

Plant protection product	Ascra Xpro
Use No.	A
Crop	cereals
Application rate (g as/ha)	Bixafen: 2 x 97.5 = 195 Fluopyram: 2 x 97.5 = 195 Prothioconazole: 2 x 195 = 390
Number of applications/interval	2 x / 14 d
Season of application (step 2)	Mar.-May (winter cereals), June-Sep. (spring cereals)
Crop interception (step 2)	average crop cover
Application method (step 3)	ground spray (CAM 2)
Models used for calculation	FOCUS STEPS 1+2 version 2.1 *Fluopyram:* FOCUS SWASH 3.1, including FOCUS PRZM 1.5.6 FOCUS MACRO 4.4.2 FOCUS TOXSWA 3.3.1 SWAN 1.1.4. *Prothioconazole:* FOCUS SWASH 3.1, including FOCUS PRZM 3.21.b connected to PRZM in FOCUS 2.6 FOCUS MACRO 4.4.2 FOCUS TOXWA 2.6

Table 5.6-8: FOCUS Step 3 Scenario related input parameters for $PEC_{SW/sed}$ calculations for the application of Ascra Xpro

Parameter	Spring cereals		Winter cereals	
PAT start date Rel./absolute Appl method (type) No of appl. PAT window range Appl. interval Crop	Absolute ground spray (CAM 2) 2 44 14 Spring cereals		Absolute ground spray (CAM 2) 2 58 14 Winter cereals	
Application details	**PAT start date (Julian Day)**	**Appl. date**	**PAT start date (Julian Day)**	**Appl. date**
D1	08-Jun (159)	17 Jun 02 Jul	30-Mar (89)	30 Mar 25 Apr
D2	-	-	03-Apr (93)	03 Apr 07 May
D3	11 May (131)	14 May 28 May	19-Apr (109)	20 Apr 04 May
D4	30 May (150)	30 May 04 Jul	27-Mar (86)	18 Apr 05 May
D5	20 Apr (110)	22 Apr 11 May	28-Mar (87)	08 Apr 22 Apr
D6	-	-	28-Mar (87)	09 Apr 23 Apr
R1	-	-	07-Apr (97)	07 Apr 26 Apr
R3	-	-	29-Mar (88)	29 Mar 12 Apr
R4	20 Apr (110)	04 May 27 May	28-Mar (87)	04 May 20 May

Results of FOCUS SW calculations for the worst-case application scenario of Ascra Xpro are summarized in the tables below.

Table 5.6-9: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of Bixafen for the application of Ascra Xpro in winter cereals according to use NoA (single application / multiple applications)

Bixafen/ winter cereals	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/kg)**
		12.41	410.4
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/kg)**
	North Europe (Multi)	1.892	69.17
	South Europe (Multi)	3.424	128.4
	North Europe (Single)	0.991	35.98
	South Europe (Single)	1.776	66.32

Table 5.6-10: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of Fluopyram for the application of Ascra Xpro in winter cereals according to use No A (single application / multiple applications)

Fluopyram/ winter cereals	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/kg)**
		49.17	132.1
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/kg)**
	North Europe (Multi)	5.717	15.62
	South Europe (Multi)	10.17	28.04
	North Europe (Single)	3.033	8.272
	South Europe (Single)	5.349	14.73

The resulting PECsed,accu and PECsw,eq,accu for FOCUS STEP 2 values are presented in the table below.

Table 5.6-11: PECsed,accu and PECsw,eq,accu values for Bixafen

Parameter	**FOCUS STEP 2** Scenario	
	North Europe, Mar.-May	**South Europe, Mar.-May**
PECsed (µg /kg)	69.17	128.4
Accumulation factor for Bixafen	4.47	
PECsed,accu (µg/kg)	309.2	574
Mass of sediment (dry weight)/ volume of water in spiked sediment study (kg/L)	0.255	
PECsw, eq, accu (µg/L)	78.8	146.4

Table 5.6-12: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of Fluopyram for the application of Ascra Xpro in spring cereals according to use No A (single application / multiple applications)

Fluopyram/ spring cereals	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/kg)**
		49.17	132.1
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/kg)**
	North Europe (Multi)	5.717	15.62
	South Europe (Multi)	7.946	21.83
	North Europe (Single)	3.033	8.272
	South Europe (Single)	4.191	11.50

Table 5.6-13: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of Prothioconazole for the application of Ascra Xpro in winter cereals according to use No A (single application / multiple applications)

Prothioconazole/ winter cereals	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/kg)**
		42.35	684.2
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/kg)**
	North Europe (Multi)	1.997	19.02
	South Europe (Multi)	1.997	25.99
	North Europe (Single)	1.793	15.12
	South Europe (Single)	1.793	22.06

Table 5.6-14: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of Prothioconazole for the application of Ascra Xpro in spring cereals according to use No A (single application / multiple applications)

Prothioconazole/ spring cereals	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/kg)**
		42.35	684.2
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/kg)**
	North Europe (Multi)	1.997	19.02
	South Europe (Multi)	1.997	22.51
	North Europe (Single)	1.793	15.12
	South Europe (Single)	1.793	18.59

Table 5.6-15: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} for metabolite JAU6476-S-methyl (M01) of Prothioconazole for the application of Ascra Xpro in winter cereals according to use No A (single application / multiple applications)

metabolite JAU6476-S-methyl (M01)/ winter cereals	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/kg)**
		4.832	111.4
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/kg)**
	North Europe (Multi)	0.388	9.051
	South Europe (Multi)	0.669	16.18
	North Europe (Single)	0.251	5.849
	South Europe (Single)	0.434	10.48

Table 5.6-16: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} for metabolite JAU6476-S-methyl (M01) of Prothioconazole for the application of Ascra Xpro in spring cereals according to use No A (single application / multiple applications)

metabolite JAU6476-S-methyl (M01)/ spring cereals	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/kg)**
		4.832	111.4
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/kg)**
	North Europe (Multi)	0.388	9.051
	South Europe (Multi)	0.529	12.59
	North Europe (Single)	0.251	5.849
	South Europe (Single)	0.342	8.149

Table 5.6-17: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} for metabolite JAU 6476-desthio (M04) of Prothioconazole for the application of Ascra Xpro in winter cereals according to use No A (single application / multiple applications)

metabolite JAU6476-desthio (M04)/ winter cereals	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/kg)**
		39.86	219.2
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/kg)**
	North Europe (Multi)	4.028	22.12
	South Europe (Multi)	7.163	39.92
	North Europe (Single)	2.323	12.73
	South Europe (Single)	4.092	22.76

Table 5.6-18: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} for metabolite JAU 6476-desthio (M04) of Prothioconazole for the application of Ascra Xpro in spring cereals according to use No A (single application / multiple applications)

metabolite JAU6476-desthio (M04)/ spring cereals	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/kg)**
		39.86	219.2
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/kg)**
	North Europe (Multi)	4.028	22.12
	South Europe (Multi)	5.596	31.02
	North Europe (Single)	2.323	12.73
	South Europe (Single)	3.207	17.75

Table 5.6-19: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} for metabolite 1,2,4-triazole of Prothioconazole for the application of Ascra Xpro in winter cereals according to use No A (single application / multiple applications)

metabolite 1,2,4-triazole/ winter cereals	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/kg)**
		0.301	< 0.001
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/kg)**
	North Europe (Multi)	0.255	0.145
	South Europe (Multi)	0.255	0.145
	North Europe (Single)	0.150	0.083
	South Europe (Single)	0.150	0.083

Table 5.6-20: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} for metabolite 1,2,4-triazole of Prothioconazole for the application of Ascra Xpro in spring cereals according to use No A (single application / multiple applications)

metabolite 1,2,4-triazole/ spring cereals	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/kg)**
		0.301	< 0.001
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/kg)**
	North Europe (Multi)	0.255	0.145
	South Europe (Multi)	0.255	0.145
	North Europe (Single)	0.150	0.083
	South Europe (Single)	0.150	0.083

Table 5.6-21: Global maximum FOCUS Step 3 PEC_{sw} and PEC_{sed} values for Bixafen for the application of Ascra Xpro in spring cereals according to use No. A (single application / multiple applications)

Scenario	**Single**		**Multiple**	
	PEC_{sw} [µg/L]	**PEC_{sed} [µg/kg]**	**PEC_{sw} [µg/L]**	**PEC_{sed} [µg/kg]**
D1 (ditch)	0.626	3.100	0.764	5.431
D1 (stream)	0.546	0.398	0.473	0.643
D2 (ditch)	-	-	-	-
D2 (stream)	-	-	-	-
D3 (ditch)	0.617	0.435	0.541	0.713
D4 (pond)	0.021	0.299	0.026	0.511
D4 (stream)	0.511	0.043	0.460	0.110
D5 (pond)	0.021	0.270	0.028	0.441
D5 (stream)	0.529	0.028	0.465	0.044
D6 (ditch)	-	-	-	-
R1 (pond)	-	-	-	-
R1 (stream)	-	-	-	-
R3 (stream)	-	-	-	-
R4 (stream)	0.408	5.020	0.353	12.57

Table 5.6-22: Global maximum FOCUS Step 3 PEC_{sw} and PEC_{sed} values for Bixafen for the application of Ascra Xpro in winter cereals according to use No. A (single application / multiple applications)

Scenario	Single		Multiple	
	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]
D1 (ditch)	0.621	0.670	0.555	2.504
D1 (stream)	0.476	0.171	0.462	0.582
D2 (ditch)	0.624	1.149	0.561	2.541
D2 (stream)	0.513	0.259	0.485	1.772
D3 (ditch)	0.616	0.432	0.540	0.629
D4 (pond)	0.021	0.283	0.028	0.502
D4 (stream)	0.489	0.028	0.428	0.068
D5 (pond)	0.021	0.270	0.029	0.442
D5 (stream)	0.496	0.016	0.468	0.042
D6 (ditch)	0.622	1.756	0.582	2.761
R1 (pond)	0.029	0.869	0.064	1.812
R1 (stream)	0.406	2.076	0.351	4.074
R3 (stream)	0.571	2.266	0.496	4.057
R4 (stream)	0.408	4.121	0.453	10.82

Table 5.6-23: Global maximum FOCUS Step 3 PEC_{sw} and PEC_{sed} values for Fluopyram for the application of Ascra Xpro in spring cereals according to use No A (single application / multiple applications)

Scenario	Single			Multiple		
	Entry route	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	Entry route	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]
D1 (ditch)	D	1.891	13.22	D	3.183	20.19
D1 (stream)	D	1.180	7.375	D	1.986	11.2
D2 (ditch)	-	-	-	-	-	-
D2 (stream)	-	-	-	-	-	-
D3 (ditch)	S	0.617	0.293	S	0.541	0.380
D4 (pond)	D	0.29	2.016	D	0.595	3.856
D4 (stream)	S	0.514	0.723	D	0.702	1.391
D5 (pond)	D	0.126	1.245	D	0.254	2.35
D5 (stream)	S	0.537	0.271	S	0.480	0.527
D6 (ditch)	-	-	-	-	-	-
R1 (pond)	-	-	-	-	-	-
R1 (stream)	-	-	-	-	-	-
R3 (stream)	-	-	-	-	-	-
R4 (stream)	R	1.330	0.943	R	1.330	0.942

S, D, R: dominant entry path spray drift, drainage, runoff

Table 5.6-24: Global maximum FOCUS Step 3 PEC_{sw} and PEC_{sed} values for Fluopyram for the application of Ascra Xpro in winter cereals according to use No A (single application / multiple applications)

Scenario	Single			Multiple		
	Entry route	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	Entry route	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]
D1 (ditch)	D	2.345	13.59	D	4.726	25.96
D1 (stream)	D	1.466	7.756	D	2.953	14.77
D2 (ditch)	D	2.039	9.366	D	4.257	18.39

D2 (stream)	D	1.281	5.306	D	2.658	10.45
D3 (ditch)	S	0.617	0.291	S	0.54	0.341
D4 (pond)	D	0.324	2.226	D	0.673	4.351
D4 (stream)	S	0.496	0.834	D	0.842	1.619
D5 (pond)	D	0.144	1.411	D	0.326	2.911
D5 (stream)	S	0.510	0.31	S	0.491	0.667
D6 (ditch)	S	0.624	0.866	S	0.588	1.250
R1 (pond)	R	0.075	0.507	R	0.139	0.875
R1 (stream)	R	0.719	0.33	R	1.457	0.629
R3 (stream)	R	1.072	0.64	R	2.487	1.527
R4 (stream)	R	1.230	0.579	R	2.204	1.586

S, D, R: dominant entry path spray drift, drainage, runoff

Table 5.6-25: Global maximum FOCUS Step 3 PEC_{sw} and PEC_{sed} values for Prothioconazole for the application of Ascra Xpro in spring cereals according to use No A (single application / multiple applications)

Scenario	Single			Multiple		
	Entry route	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	Entry route	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]
D1 (ditch)	S	1.249	2.963	S	1.654	4.877
D1 (stream)	S	1.093	0.532	S	0.945	0.564
D2 (ditch)	-	-		-	-	
D2 (stream)	-	-		-	-	
D3 (ditch)	S	1.234	0.638	S	1.082	0.822
D4 (pond)	S	0.043	0.133	S	0.049	0.201
D4 (stream)	S	1.023	0.081	S	0.922	0.175
D5 (pond)	S	0.043	0.141	S	0.057	0.224
D5 (stream)	S	1.059	0.054	S	0.932	0.065
D6 (ditch)	-	-	-	-	-	-
R1 (pond)	-	-	-	-	-	-
R1 (stream)	-	-	-	-	-	-
R3 (stream)	-	-	-	-	-	-
R4 (stream)	S	0.817	0.585	S	0.707	0.582

S, D, R: dominant entry path spray drift, drainage, runoff

Table 5.6-26: Global maximum FOCUS Step 3 PEC_{sw} and PEC_{sed} values for Prothioconazole for the application of Ascra Xpro in winter cereals according to use No A (single application / multiple applications)

Scenario	Single			Multiple		
	Entry route	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	Entry route	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]
D1 (ditch)	S	1.237	0.837	S	1.090	2.393
D1 (stream)	S	0.950	0.035	S	0.916	0.147
D2 (ditch)	S	1.243	1.330	S	1.097	2.220
D2 (stream)	S	1.025	0.084	S	0.962	1.758
D3 (ditch)	S	1.234	0.637	S	1.080	0.729
D4 (pond)	S	0.043	0.154	S	0.059	0.242
D4 (stream)	S	0.979	0.047	S	0.856	0.052
D5 (pond)	S	0.043	0.150	S	0.060	0.240
D5 (stream)	S	0.994	0.030	S	0.937	0.067
D6 (ditch)	S	1.244	1.859	S	1.169	2.640
R1 (pond)	S	0.043	0.141	S	0.057	0.233
R1 (stream)	S	0.813	0.106	S	0.703	0.109
R3 (stream)	S	1.142	0.213	S	0.994	0.842
R4 (stream)	S	0.813	0.106	R	0.803	1.007

S, D, R: dominant entry path spray drift, drainage, runoff

Aquatic metabolites

For the reason that it is not a standard approach, in the following chapter the approach for the Step 3/4 calculations for the metabolite JAU6476-desthio (M04) conducted by the applicant (Chapple and Ghafoor, 2014) is presented. The approach is not validated by zRMS because of less experience with Step 3 level modeling for metabolites.

TOXSWA in SWASH cannot simulate the formation of aquatic metabolites in surface water bodies after entry of the parent compound by spray drift, runoff/erosion, or drainage. Therefore, workarounds were applied on the basis of recommendations given in FOCUS (2003, 2007).

Step 3

When dealing with aquatic metabolites it has to be differentiated between metabolites formed only in the water/sediment system but not in soil (pure aquatic metabolites) and metabolites formed in both compartments (soil and aquatic metabolite). The data for pure aquatic metabolites are also entered in SWASH and runoff/erosion/drainage loadings are eliminated by selecting an extremely short soil DT50 (0.01 d) to generate p2t/m2t-files without metabolite mass fluxes, that only serve to describe the hydrology correctly when the below mentioned procedures are applied.

First, it is checked whether the time to maximum occurrence of the respective metabolite (t_{form}) in the water/sediment study with the parent is greater than the monthly averaged hydraulic residence time τ of the FOCUS surface water bodies FOCUS (2003). In case of varying residence times τ within a month, the longest (worst-case) was selected. The respective month is chosen based on the time point, when $PEC_{sw\ max}$ of the parent compound has occurred. Two cases can be differentiated:

1) $t_{form} > \tau$

In this case the parent has flowed out of the water body before significant amounts of the metabolite could have been formed in the surface water body. This is mainly the case when considering streams and ditches.

2) $t_{form} < \tau$

This is mostly the case for pond scenarios and only occasionally for ditch and stream scenarios. Depending on the entry path, one of the two procedures described in the following is followed.

Spray-drift dominated parent maximum peak

Pseudo spray-drift loadings of the metabolite are calculated from the parent drift deposition by correction for molar mass ratio and maximum occurrence in total water/sediment system. The "txw"-file is combined with the "p2t/m2t"-file of the metabolite, where the application dates of the metabolite are defined to occur at time $t_{max\ parent} + t_{form}$.

Runoff/erosion/drainage dominated parent maximum peak

Pseudo spray-drift loadings of the metabolite are calculated from the parent drift deposition by correction for molar mass ratio and maximum occurrence in total water/sediment system.

The "p2t/m2t"-file of the parent is converted into a metabolite loading file as follows:

For every parent mass flux an equivalent mass of metabolite is calculated by applying corrections for molar mass ratio and maximum occurrence in total water/sediment system. The recalculated metabolite loadings are then shifted in time by t_{form} and added to the metabolite "p2t/m2t"-file to create a new "synthetic" "p2t/m2t"-file. The pseudo application dates of the metabolite are defined in the new "p2t/m2t"-files to occur at time $t_{max\ parent} + t_{form}$.

The parameters of the aquatic metabolite desthio are given in Table 5.6-27.

Table 5.6-27: Substance parameters used for the assessment of the aquatic metabolite JAU6476-desthio (M04) at Step 3/4 level

Molar Mass Corr. Factor	0.90677
Max Occ.	54.4%
Tot. Corr. Factor	0.49328
Max Occ. at Day	7

The scenario data used for the evaluation of the aquatic metabolite JAU6476-desthio (M04) are summarised in Table 5.6-28 and Table 5.6-29.

Table 5.6-28: Parameters used for the assessment of the aquatic metabolite JAU6476-desthio (M04) at Step 3/4 level (single application)

Scenario	Winter cereals		Spring cereals	
	Month	τ [days]	Month	τ [days]
D1 (ditch, 1st)	Mar	2.6	Jun	45.5
D1 (stream)	Mar	0.017	Jun	0.927
D2 (ditch)	Apr	1.29	-	-
D2 (stream)	Apr	0.039	-	-
D3 (ditch)	Apr	1.78	May	1.71
D4 (pond)	Apr	230	May	217
D4 (stream)	Apr	0.05	May	0.103
D5 (pond)	Apr	218	Apr	218
D5 (stream)	Apr	0.064	Apr	0.064
D6 (ditch)	Apr	7.31	-	-
R1 (pond)	Apr	136	-	-
R1 (stream)	Apr	0.108	-	-
R3 (stream)	Mar	0.149	-	-
R4 (stream)	Mar	0.15	May	0.212

Table 5.6-29: Parameters used for the assessment of the aquatic metabolite JAU6476-desthio (M04) at Step 3/4 level (multiple application)

Scenario	Winter cereals		Spring cereals	
	Month	τ [days]	Month	τ [days]
D1 (ditch, 1st)	Apr	3.07	Jul	45.5
D1 (stream)	Apr	0.037	Jul	0.927
D2 (ditch)	May	2.38	-	-
D2 (stream)	May	0.066	-	-
D3 (ditch)	May	1.71	May	1.71
D4 (pond)	May	217	Jul	283
D4 (stream)	May	0.103	Jul	0.294
D5 (pond)	Apr	218	May	387
D5 (stream)	Apr	0.064	May	0.306
D6 (ditch)	Apr	7.31	-	-
R1 (pond)	Apr	136	-	-
R1 (stream)	Apr	0.108	-	-
R3 (stream)	Apr	0.381	-	-
R4 (stream)	May	0.212	May	0.212

Step 4

Based on the desired mitigation options the SWAN tool (Goerlitz et. al., 2007) modifies the m2t/p2t- and txw-files of parent compound and soil metabolite obtained on Step 3 before starting the Step 4 calculations with TOXSWA.

The aquatic metabolites in Step 4 are calculated on the basis of the SWAN-modified TOXSWA input files according to the same procedure as outlined for Step 3.

Table 5.6-30: Global maximum FOCUS Step 3 PEC_{sw} and PEC_{sed} values for metabolite JAU6476-desthio (M04) of Prothioconazole for the application of Ascra Xpro in spring cereals according to use No A (single application / multiple applications)

Scenario	Single		Multiple	
	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]
D1 (ditch)	0.616	1.891	0.810	3.126
D1 (stream)	< 0.001	0.015	0.002	0.036
D2 (ditch)	-		-	
D2 (stream)	-		-	
D3 (ditch)	< 0.001	< 0.001	< 0.001	< 0.001
D4 (pond)	0.021	0.128	0.025	0.199
D4 (stream)	0.002	0.002	0.004	0.005
D5 (pond)	0.021	0.134	0.028	0.21
D5 (stream)	< 0.001	< 0.001	< 0.001	< 0.001
D6 (ditch)	-	-	-	-
R1 (pond)	-	-	-	-
R1 (stream)	-	-	-	-
R3 (stream)	-	-	-	-
R4 (stream)	0.573	0.867	0.574	0.867

Table 5.6-31: Global maximum FOCUS Step 3 PEC_{sw} and PEC_{sed} values for metabolite JAU6476-desthio (M04) of Prothioconazole for the application of Ascra Xpro in winter cereals according to use No A (single application / multiple applications)

Scenario	Single		Multiple	
	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]
D1 (ditch)	< 0.001	0.011	0.002	0.045
D1 (stream)	< 0.001	0.006	0.001	0.026
D2 (ditch)	0.002	0.008	0.008	0.028
D2 (stream)	0.002	0.004	0.005	0.014
D3 (ditch)	< 0.001	< 0.001	< 0.001	< 0.001
D4 (pond)	0.021	0.138	0.029	0.215
D4 (stream)	0.002	0.001	0.004	0.003
D5 (pond)	0.021	0.140	0.030	0.218
D5 (stream)	< 0.001	< 0.001	< 0.001	< 0.001
D6 (ditch)	0.614	1.195	0.585	1.687
R1 (pond)	0.045	0.377	0.087	0.690
R1 (stream)	0.366	0.386	0.776	0.662
R3 (stream)	0.461	0.552	0.894	1.051
R4 (stream)	0.506	0.587	1.062	1.164

Step 4

Bixafen

FOCUS Step 4 PEC_{SW} and PEC_{sed} have been provided for the MS in the specific National Addenda. According to the applicant, for the MS in particular the following scenarios are relevant:

Table 5.6-32: Scenarios to consider for the supported crops

Belgium

Scenario	D1	D2	**D3**	**D4**	D5	D6	**R1**	R2	R3	R4
Cereals, spring	X	-	**X**	**X**	X	-	**-**	-	-	X
Cereals, winter	X	X	**X**	**X**	X	X	**X**	-	X	X

Austria

Scenario	D1	D2	D3	**D4**	**D5**	D6	**R1**	R2	**R3**	R4
Cereals, spring	X	-	X	**X**	**X**	-	**-**	-	**-**	X
Cereals, winter	X	X	X	**X**	**X**	X	**X**	-	**X**	X

Poland

Scenario	D1	D2	**D3**	**D4**	D5	D6	**R1**	R2	R3	R4
Cereals, spring	X	-	**X**	**X**	X	-	**-**	-	-	X
Cereals, winter	X	X	**X**	**X**	X	X	**X**	-	X	X

Slovenia

Scenario	D1	D2	D3	**D4**	**D5**	**D6**	R1	R2	R3	R4
Cereals, spring	X	-	X	**X**	**X**	**-**	-	-	-	X
Cereals, winter	X	X	X	**X**	**X**	**X**	X	-	X	X

Conclusion: The scenarios D3, D4, D5, D6, R1 and R3 are refined with FOCUS Step 4 calculations if required.

The MS The Netherlands, Germany and United Kingdom base their decisions for risk mitigation measures on specific calculations methods that are not presented here.

Table 5.6-33: FOCUS Step 4 PEC_{sw} values for Bixafen for the application of Ascra Xpro in winter cereals according to use No A (single application 1 × 98 g a.s./ha) with mitigation options according to FOCUS SW Step 4; SD = spray drift buffer, RO = runoff buffer)

Scenario	PEC_{sw} [µg/L] Drift Reduction				PEC_{sed} [µg/kg] Drift Reduction			
	0%	50%	75%	90%	0%	50%	75%	90%
5 m buffer zone (SD)								
D3 (ditch, 1st)	0.167	0.083	0.042	0.017	0.118	0.059	0.03	0.012
D4 (pond, 1st)	0.018	0.009	0.005	0.004	0.253	0.155	0.107	0.079
D4 (stream, 1st)	0.178	0.089	0.045	0.027	0.026	0.026	0.025	0.025
D5 (pond, 1st)	0.019	0.009	0.005	0.002	0.236	0.122	0.064	0.033
D5 (stream 1st)	0.181	0.090	0.045	0.018	0.006	0.003	0.002	0.002
R1 (pond, 1st)	0.028	0.026	0.025	0.025	0.846	0.772	0.734	0.713
R1 (stream, 1st)	0.148	0.137	0.137	0.137	2.071	2.070	2.069	2.068
R3 (stream 1st)	0.208	0.148	0.148	0.148	2.258	2.256	2.254	2.254
10 m buffer zone (SD, RO)								
D3 (ditch, 1st)	0.089	0.044	0.022	0.009	0.063	0.032	0.016	0.006
D4 (pond, 1st)	0.013	0.007	0.004	0.004	0.198	0.128	0.094	0.073
D4 (stream, 1st)	0.095	0.047	0.027	0.027	0.026	0.025	0.025	0.025
D5 (pond, 1st)	0.013	0.007	0.003	0.001	0.172	0.090	0.049	0.026
D5 (stream 1st)	0.096	0.048	0.024	0.010	0.003	0.002	0.002	0.002
R1 (pond, 1st)	0.013	0.011	0.011	0.010	0.391	0.334	0.306	0.289
R1 (stream, 1st)	0.079	0.062	0.062	0.062	0.376	0.375	0.375	0.374
R3 (stream 1st)	0.110	0.067	0.067	0.067	0.392	0.391	0.390	0.390
15 m buffer zone (SD, RO)								
D3 (ditch, 1st)	0.060	0.030	0.015	0.006	0.043	0.022	0.011	0.004
D4 (pond, 1st)	0.011	0.005	0.004	0.004	0.169	0.114	0.087	0.071
D4 (stream, 1st)	0.065	0.032	0.027	0.027	0.025	0.025	0.025	0.025
D5 (pond, 1st)	0.011	0.005	0.003	0.001	0.138	0.072	0.042	0.024
D5 (stream 1st)	0.066	0.033	0.017	0.006	0.002	0.002	0.002	0.002
R1 (pond, 1st)	0.012	0.011	0.010	0.010	0.367	0.323	0.300	0.287
R1 (stream, 1st)	0.062	0.062	0.062	0.062	0.375	0.375	0.374	0.374
R3 (stream 1st)	0.076	0.067	0.067	0.067	0.391	0.390	0.390	0.390
20 m buffer zone (SD, RO)								
D3 (ditch, 1st)	0.046	0.023	0.011	0.005	0.033	0.017	0.008	0.003
D4 (pond, 1st)	0.009	0.005	0.004	0.004	0.151	0.106	0.082	0.069
D4 (stream, 1st)	0.049	0.027	0.027	0.027	0.025	0.025	0.025	0.025
D5 (pond, 1st)	0.009	0.005	0.002	<0.001	0.117	0.063	0.036	0.021
D5 (stream 1st)	0.050	0.025	0.012	0.005	0.002	0.002	0.002	0.002
R1 (pond, 1st)	0.009	0.006	0.005	0.005	0.219	0.181	0.161	0.144
R1 (stream, 1st)	0.041	0.033	0.033	0.033	0.144	0.144	0.144	0.144
R3 (stream 1st)	0.057	0.035	0.035	0.035	0.146	0.146	0.145	0.145

Table 5.6-34: PEC_{sw} and PEC_{sed} values of bixafen applied in spring cereals (single application, 1 × 98 g a.s./ha) with mitigation options according to FOCUS SW Step 4; SD = spray drift buffer, RO = runoff buffer

Scenario	PEC_{sw} [µg/L] Drift Reduction				PEC_{sed} [µg/kg] Drift Reduction			
	0%	50%	75%	90%	0%	50%	75%	90%
5 m buffer zone (SD)								
D3 (ditch, 1st)	0.167	0.083	0.042	0.017	0.119	0.060	0.030	0.012
D4 (pond, 1st)	0.018	0.009	0.006	0.006	0.269	0.170	0.122	0.094
D4 (stream, 1st)	0.186	0.093	0.047	0.021	0.033	0.032	0.031	0.031
D5 (pond, 1st)	0.018	0.009	0.005	0.002	0.235	0.121	0.063	0.031
D5 (stream 1st)	0.193	0.096	0.048	0.019	0.010	0.005	0.003	0.001
10 m buffer zone (SD, RO)								
D3 (ditch, 1st)	0.089	0.044	0.022	0.009	0.064	0.032	0.016	0.006
D4 (pond, 1st)	0.013	0.007	0.006	0.006	0.214	0.143	0.108	0.088
D4 (stream, 1st)	0.099	0.049	0.025	0.021	0.032	0.031	0.031	0.030
D5 (pond, 1st)	0.013	0.007	0.003	0.001	0.172	0.089	0.047	0.024
D5 (stream 1st)	0.102	0.051	0.025	0.010	0.006	0.003	0.002	0.001
15 m buffer zone (SD, RO)								
D3 (ditch, 1st)	0.060	0.030	0.015	0.006	0.043	0.022	0.011	0.005
D4 (pond, 1st)	0.011	0.006	0.006	0.006	0.184	0.129	0.102	0.086
D4 (stream, 1st)	0.068	0.034	0.021	0.021	0.031	0.031	0.030	0.030
D5 (pond, 1st)	0.011	0.005	0.003	0.001	0.137	0.072	0.040	0.022
D5 (stream 1st)	0.070	0.035	0.018	0.007	0.004	0.002	0.001	0.001
20 m buffer zone (SD, RO)								
D3 (ditch, 1st)	0.046	0.023	0.011	0.005	0.033	0.017	0.008	0.003
D4 (pond, 1st)	0.009	0.006	0.006	0.006	0.166	0.121	0.097	0.084
D4 (stream, 1st)	0.051	0.026	0.021	0.021	0.031	0.031	0.030	0.030
D5 (pond, 1st)	0.009	0.005	0.002	<0.001	0.116	0.062	0.035	0.020
D5 (stream 1st)	0.053	0.027	0.013	0.005	0.003	0.002	0.001	0.001

Table 5.6-35: FOCUS Step 4 PEC_{sw} values for Bixafen for the application of Ascra Xpro in sping cereals according to use No A (mulitple application 2 × 98 g a.s./ha) with mitigation options according to FOCUS SW Step 4; SD = spray drift buffer, RO = runoff buffer)

Scenario	PEC_{sw} [µg/L] Drift Reduction				PEC_{sed} [µg/kg] Drift Reduction			
	0%	50%	75%	90%	0%	50%	75%	90%
5 m buffer zone (SD)								
D3 (ditch, 1st)	0.140	0.070	0.035	0.014	0.191	0.097	0.049	0.020
D4 (pond, 1st)	0.023	0.014	0.013	0.012	0.460	0.305	0.229	0.183
D4 (stream, 1st)	0.162	0.081	0.043	0.043	0.070	0.066	0.064	0.062
D5 (pond, 1st)	0.024	0.012	0.006	0.003	0.382	0.199	0.105	0.053
D5 (stream 1st)	0.164	0.082	0.041	0.016	0.016	0.008	0.004	0.003
10 m buffer zone (SD, RO)								
D3 (ditch, 1st)	0.073	0.036	0.018	0.007	0.101	0.051	0.026	0.011
D4 (pond, 1st)	0.016	0.013	0.012	0.012	0.369	0.261	0.207	0.175
D4 (stream, 1st)	0.084	0.043	0.043	0.043	0.066	0.064	0.063	0.062
D5 (pond, 1st)	0.017	0.009	0.004	0.002	0.275	0.145	0.080	0.043
D5 (stream 1st)	0.085	0.042	0.021	0.009	0.009	0.005	0.003	0.003
15 m buffer zone (SD, RO)								
D3 (ditch, 1st)	0.049	0.025	0.012	0.005	0.069	0.035	0.018	0.007
D4 (pond, 1st)	0.014	0.013	0.012	0.011	0.323	0.237	0.195	0.169
D4 (stream, 1st)	0.057	0.043	0.043	0.043	0.065	0.063	0.062	0.062
D5 (pond, 1st)	0.014	0.007	0.003	0.001	0.221	0.115	0.066	0.037
D5 (stream 1st)	0.057	0.029	0.014	0.008	0.006	0.003	0.003	0.003
20 m buffer zone (SD, RO)								
D3 (ditch, 1st)	0.037	0.019	0.009	0.004	0.052	0.027	0.013	0.005
D4 (pond, 1st)	0.014	0.012	0.012	0.011	0.293	0.223	0.189	0.167
D4 (stream, 1st)	0.043	0.043	0.043	0.043	0.064	0.063	0.062	0.062
D5 (pond, 1st)	0.011	0.006	0.003	0.001	0.184	0.098	0.059	0.034
D5 (stream 1st)	0.043	0.022	0.011	0.008	0.005	0.003	0.003	0.003

Table 5.6-36: PEC_{sw} and PEC_{sed} values of bixafen applied in winter cereals (multiple applications, 2 × 98 g a.s./ha) with mitigation options according to FOCUS SW Step 4; SD = spray drift buffer, RO = runoff buffer

Scenario	PEC_{sw} [µg/L] Drift Reduction				PEC_{sed} [µg/kg] Drift Reduction			
	0%	50%	75%	90%	0%	50%	75%	90%
5 m buffer zone (SD)								
D3 (ditch, 1st)	0.140	0.070	0.035	0.014	0.169	0.086	0.044	0.018
D4 (pond, 1st)	0.024	0.012	0.011	0.010	0.451	0.299	0.224	0.178
D4 (stream, 1st)	0.151	0.075	0.064	0.064	0.064	0.063	0.063	0.062
D5 (pond, 1st)	0.025	0.013	0.006	0.003	0.383	0.201	0.110	0.057
D5 (stream 1st)	0.165	0.083	0.041	0.016	0.015	0.008	0.004	0.004
R1 (pond, 1st)	0.063	0.060	0.059	0.058	1.774	1.659	1.600	1.565
R1 (stream, 1st)	0.324	0.324	0.324	0.324	4.065	4.063	4.062	4.061
R3 (stream 1st)	0.307	0.307	0.307	0.307	4.042	4.038	4.036	4.035
10 m buffer zone (SD, RO)								
D3 (ditch, 1st)	0.073	0.036	0.018	0.007	0.089	0.045	0.023	0.009
D4 (pond, 1st)	0.017	0.011	0.010	0.010	0.362	0.256	0.202	0.170
D4 (stream, 1st)	0.078	0.064	0.064	0.064	0.063	0.063	0.062	0.062
D5 (pond, 1st)	0.018	0.009	0.005	0.002	0.276	0.146	0.085	0.048
D5 (stream 1st)	0.086	0.043	0.022	0.010	0.008	0.004	0.004	0.003
R1 (pond, 1st)	0.027	0.025	0.024	0.024	0.794	0.707	0.663	0.637
R1 (stream, 1st)	0.147	0.147	0.147	0.147	0.754	0.753	0.752	0.752
R3 (stream 1st)	0.140	0.140	0.140	0.140	0.716	0.713	0.712	0.711
15 m buffer zone (SD, RO)								
D3 (ditch, 1st)	0.049	0.024	0.012	0.005	0.061	0.031	0.016	0.006
D4 (pond, 1st)	0.014	0.011	0.010	0.010	0.317	0.232	0.190	0.164
D4 (stream, 1st)	0.064	0.064	0.064	0.064	0.063	0.062	0.062	0.062
D5 (pond, 1st)	0.014	0.007	0.004	0.002	0.223	0.119	0.071	0.041
D5 (stream 1st)	0.058	0.029	0.014	0.010	0.006	0.004	0.003	0.003
R1 (pond, 1st)	0.026	0.025	0.024	0.023	0.758	0.688	0.653	0.632
R1 (stream, 1st)	0.147	0.147	0.147	0.147	0.753	0.752	0.752	0.751
R3 (stream 1st)	0.140	0.140	0.140	0.140	0.714	0.712	0.712	0.711
20 m buffer zone (SD, RO)								
D3 (ditch, 1st)	0.037	0.019	0.009	0.004	0.046	0.024	0.012	0.005
D4 (pond, 1st)	0.012	0.011	0.010	0.010	0.288	0.218	0.184	0.162
D4 (stream, 1st)	0.064	0.064	0.064	0.064	0.063	0.062	0.062	0.062
D5 (pond, 1st)	0.012	0.006	0.003	0.001	0.186	0.103	0.064	0.039
D5 (stream 1st)	0.044	0.022	0.011	0.010	0.005	0.004	0.003	0.003
R1 (pond, 1st)	0.015	0.013	0.012	0.012	0.434	0.375	0.347	0.328
R1 (stream, 1st)	0.077	0.077	0.077	0.077	0.294	0.293	0.293	0.292
R3 (stream 1st)	0.074	0.074	0.074	0.074	0.271	0.269	0.269	0.268

Table 5.6-37: FOCUS Step 4 PEC_{sw} values for Fluopyram for the application of Ascra Xpro in winter cereals according to use No A (single application / multiple applications)

Buffer Width & Type	Scenario	PECsw [µg/L] (single) Drift Reduction				PECsw [µg/L] (multiple) Drift Reduction			
		0%	50%	75%	90%	0%	50%	75%	90%
	D1 (ditch, 1st)	2.345	2.345	2.345	2.345	**4.726**	4.726	4.726	4.726
	D1 (stream, 1st)	1.466	1.466	1.466	1.466	2.953	2.953	2.953	2.953
	D2 (ditch, 1st)	2.039	2.039	2.039	2.039	4.257	4.257	4.257	4.257
	D2 (stream, 1st)	1.281	1.281	1.281	1.281	2.658	2.658	2.658	2.658
	D3 (ditch, 1st)	0.617	0.309	0.154	0.062	0.540	0.270	0.135	0.054
	D4 (pond, 1st)	0.324	0.322	0.321	0.320	0.673	0.670	0.668	0.667
0m	D4 (stream, 1st)	0.496	0.416	0.416	0.416	0.842	0.842	0.842	0.842
SD	D5 (pond, 1st)	0.144	0.143	0.142	0.141	0.326	0.323	0.321	0.321
	D5 (stream, 1st)	0.510	0.262	0.158	0.158	0.491	0.330	0.330	0.330
	D6 (ditch, 1st)	0.624	0.312	0.193	0.193	0.588	0.356	0.356	0.356
	R1 (pond, 1st)	0.075	0.069	0.066	0.065	0.139	0.129	0.123	0.120
	R1 (stream, 1st)	0.719	0.719	0.719	0.719	1.457	1.457	1.457	1.457
	R3 (stream, 1st)	1.072	1.072	1.072	1.072	2.487	2.487	2.487	2.487
	R4 (stream, 1st)	1.230	1.230	1.230	1.230	2.204	2.204	2.204	2.204

Buffer Width & Type	Scenario	PECsw [µg/L] (single) Drift Reduction				PECsw [µg/L] (multiple) Drift Reduction			
		0%	50%	75%	90%	0%	50%	75%	90%
5m SD	D1 (ditch, 1st)	2.345	2.345	2.345	2.345	4.726	4.726	4.726	4.726
	D1 (stream, 1st)	1.466	1.466	1.466	1.466	2.953	2.953	2.953	2.953
	D2 (ditch, 1st)	2.039	2.039	2.039	2.039	4.257	4.257	4.257	4.257
	D2 (stream, 1st)	1.281	1.281	1.281	1.281	2.658	2.658	2.658	2.658
	D3 (ditch, 1st)	0.167	0.084	0.042	0.017	0.140	0.070	0.035	0.014
	D4 (pond, 1st)	0.323	0.322	0.321	0.320	0.672	0.669	0.668	0.667
	D4 (stream, 1st)	0.416	0.416	0.416	0.416	0.842	0.842	0.842	0.842
	D5 (pond, 1st)	0.144	0.142	0.142	0.141	0.325	0.322	0.321	0.320
	D5 (stream, 1st)	0.194	0.158	0.158	0.158	0.330	0.330	0.330	0.330
	D6 (ditch, 1st)	0.193	0.193	0.193	0.193	0.356	0.356	0.356	0.356
	R1 (pond, 1st)	0.073	0.068	0.066	0.064	0.136	0.127	0.123	0.120
	R1 (stream, 1st)	0.719	0.719	0.719	0.719	1.457	1.457	1.457	1.457
	R3 (stream, 1st)	1.072	1.072	1.072	1.072	2.487	2.487	2.487	2.487
	R4 (stream, 1st)	1.230	1.230	1.230	1.230	2.204	2.204	2.204	2.204
10m SD & RO	D1 (ditch, 1st)	2.345	2.345	2.345	2.345	4.726	4.726	4.726	4.726
	D1 (stream, 1st)	1.466	1.466	1.466	1.466	2.953	2.953	2.953	2.953
	D2 (ditch, 1st)	2.039	2.039	2.039	2.039	4.257	4.257	4.257	4.257
	D2 (stream, 1st)	1.281	1.281	1.281	1.281	2.658	2.658	2.658	2.658
	D3 (ditch, 1st)	0.089	0.044	0.022	0.009	0.073	0.037	0.018	0.007
	D4 (pond, 1st)	0.322	0.321	0.321	0.320	0.671	0.668	0.667	0.667
	D4 (stream, 1st)	0.416	0.416	0.416	0.416	0.842	0.842	0.842	0.842
	D5 (pond, 1st)	0.143	0.142	0.141	0.141	0.323	0.322	0.321	0.320
	D5 (stream, 1st)	0.158	0.158	0.158	0.158	0.330	0.330	0.330	0.330
	D6 (ditch, 1st)	0.193	0.193	0.193	0.193	0.356	0.356	0.356	0.356
	R1 (pond, 1st)	0.033	0.029	0.027	0.026	0.060	0.054	0.051	0.049
	R1 (stream, 1st)	0.327	0.327	0.327	0.327	0.663	0.663	0.663	0.663
	R3 (stream, 1st)	0.490	0.490	0.490	0.490	1.136	1.136	1.136	1.136
	R4 (stream, 1st)	0.556	0.556	0.556	0.556	0.991	0.991	0.991	0.991
20m SD & RO	D1 (ditch, 1st)	2.345	2.345	2.345	2.345	4.726	4.726	4.726	4.726
	D1 (stream, 1st)	1.466	1.466	1.466	1.466	2.953	2.953	2.953	2.953
	D2 (ditch, 1st)	2.039	2.039	2.039	2.039	4.257	4.257	4.257	4.257
	D2 (stream, 1st)	1.281	1.281	1.281	1.281	2.658	2.658	2.658	2.658
	D3 (ditch, 1st)	0.046	0.023	0.012	0.005	0.037	0.018	0.009	0.004
	D4 (pond, 1st)	0.322	0.321	0.320	0.320	0.669	0.668	0.667	0.667
	D4 (stream, 1st)	0.416	0.416	0.416	0.416	0.842	0.842	0.842	0.842
	D5 (pond, 1st)	0.142	0.142	0.141	0.141	0.322	0.321	0.321	0.320
	D5 (stream, 1st)	0.158	0.158	0.158	0.158	0.330	0.330	0.330	0.330
	D6 (ditch, 1st)	0.193	0.193	0.193	0.193	0.356	0.356	0.356	0.356
	R1 (pond, 1st)	0.018	0.015	0.014	0.013	0.032	0.028	0.026	0.025
	R1 (stream, 1st)	0.171	0.171	0.171	0.171	0.347	0.347	0.347	0.347
	R3 (stream, 1st)	0.257	0.257	0.257	0.257	0.596	0.596	0.596	0.596
	R4 (stream, 1st)	0.291	0.291	0.291	0.291	0.517	0.517	0.517	0.517

SD, RO: spray drift or runoff buffer used

Table 5.6-38: FOCUS Step 4 PEC_{sw} values for Fluopyram for the application of Ascra Xpro in spring cereals according to use No A (single application / multiple applications)

Buffer Width & Type	Scenario	PECsw [µg/L] (single) Drift Reduction				PECsw [µg/L] (multiple) Drift Reduction			
		0%	50%	75%	90%	0%	50%	75%	90%
0m SD	D1 (ditch, 1st)	1.891	1.891	1.891	1.891	3.183	3.183	3.183	3.183
	D1 (stream, 1st)	1.180	1.180	1.180	1.180	1.986	1.986	1.986	1.986
	D3 (ditch, 1st)	0.617	0.309	0.154	0.062	0.541	0.271	0.135	0.054
	D4 (pond, 1st)	0.290	0.288	0.287	0.286	0.595	0.591	0.589	0.588
	D4 (stream, 1st)	0.514	0.358	0.358	0.358	0.702	0.702	0.702	0.702
	D5 (pond, 1st)	0.126	0.124	0.123	0.123	0.254	0.252	0.250	0.250
	D5 (stream, 1st)	0.537	0.272	0.142	0.142	0.480	0.266	0.266	0.266
	R4 (stream, 1st)	1.330	1.330	1.330	1.330	1.330	1.330	1.330	1.330
5m SD	D1 (ditch, 1st)	1.891	1.891	1.891	1.891	3.183	3.183	3.183	3.183
	D1 (stream, 1st)	1.180	1.180	1.180	1.180	1.986	1.986	1.986	1.986
	D3 (ditch, 1st)	0.167	0.084	0.042	0.017	0.140	0.070	0.035	0.014
	D4 (pond, 1st)	0.290	0.288	0.287	0.286	0.594	0.591	0.589	0.588
	D4 (stream, 1st)	0.358	0.358	0.358	0.358	0.702	0.702	0.702	0.702
	D5 (pond, 1st)	0.125	0.124	0.123	0.123	0.254	0.251	0.250	0.250
	D5 (stream, 1st)	0.201	0.142	0.142	0.142	0.266	0.266	0.266	0.266
	R4 (stream, 1st)	1.330	1.330	1.330	1.330	1.330	1.330	1.330	1.330
10m SD & RO	D1 (ditch, 1st)	1.891	1.891	1.891	1.891	3.183	3.183	3.183	3.183
	D1 (stream, 1st)	1.180	1.180	1.180	1.180	1.986	1.986	1.986	1.986
	D3 (ditch, 1st)	0.089	0.044	0.022	0.009	0.073	0.037	0.018	0.007
	D4 (pond, 1st)	0.289	0.287	0.287	0.286	0.592	0.590	0.589	0.588
	D4 (stream, 1st)	0.358	0.358	0.358	0.358	0.702	0.702	0.702	0.702
	D5 (pond, 1st)	0.125	0.124	0.123	0.123	0.252	0.251	0.250	0.249
	D5 (stream, 1st)	0.142	0.142	0.142	0.142	0.266	0.266	0.266	0.266
	R4 (stream, 1st)	0.601	0.601	0.601	0.601	0.601	0.601	0.601	0.601
20m SD & RO	D1 (ditch, 1st)	1.891	1.891	1.891	1.891	3.183	3.183	3.183	3.183
	D1 (stream, 1st)	1.180	1.180	1.180	1.180	1.986	1.986	1.986	1.986
	D3 (ditch, 1st)	0.046	0.023	0.012	0.005	0.037	0.019	0.009	0.004
	D4 (pond, 1st)	0.288	0.287	0.286	0.286	0.591	0.589	0.588	0.588
	D4 (stream, 1st)	0.358	0.358	0.358	0.358	0.702	0.702	0.702	0.702
	D5 (pond, 1st)	0.124	0.123	0.123	0.123	0.251	0.250	0.250	0.249
	D5 (stream, 1st)	0.142	0.142	0.142	0.142	0.266	0.266	0.266	0.266
	R4 (stream, 1st)	0.314	0.314	0.314	0.314	0.314	0.314	0.314	0.314

SD, RO: spray drift or runoff buffer used

Table 5.6-39: FOCUS Step 4 PEC_{sw} values for Prothioconazole for the application of Ascra Xpro in winter cereals according to use No A (single application/ multiple applications)

Buffer Width & Type	Scenario	PECsw [µg/L] (single) Drift Reduction				PECsw [µg/L] (multiple) Drift Reduction			
		0%	50%	75%	90%	0%	50%	75%	90%
5m SD	D1 (ditch, 1st)	0.335	0.168	0.084	0.034	0.283	0.141	0.071	0.028
	D1 (stream, 1st)	0.347	0.173	0.087	0.035	0.323	0.162	0.081	0.032
	D2 (ditch, 1st)	0.337	0.168	0.084	0.034	0.285	0.142	0.071	0.028
	D2 (stream, 1st)	0.375	0.187	0.094	0.037	0.340	0.170	0.085	0.034
	D3 (ditch, 1st)	0.334	0.167	0.084	0.034	0.280	0.140	0.070	0.028
	D4 (pond, 1st)	0.037	0.018	0.009	0.004	0.051	0.025	0.013	0.005
	D4 (stream, 1st)	0.358	0.179	0.090	0.036	0.302	0.151	0.076	0.030
	D5 (pond, 1st)	0.037	0.018	0.009	0.004	0.051	0.026	0.013	0.005
	D5 (stream, 1st)	0.363	0.181	0.091	0.036	0.331	0.165	0.083	0.033
	D6 (ditch, 1st)	0.337	0.168	0.084	0.034	0.303	0.152	0.076	0.030
	R1 (pond, 1st)	0.037	0.018	0.009	0.004	0.049	0.025	0.012	0.005
	R1 (stream, 1st)	0.297	0.148	0.074	0.053	0.248	0.124	0.074	0.074
	R3 (stream, 1st)	0.417	0.209	0.104	0.053	0.462	0.462	0.462	0.462
	R4 (stream, 1st)	0.297	0.148	0.096	0.096	0.803	0.803	0.803	0.803
10m SD & RO	D1 (ditch, 1st)	0.178	0.089	0.044	0.018	0.147	0.073	0.037	0.015
	D1 (stream, 1st)	0.184	0.092	0.046	0.018	0.168	0.084	0.042	0.017
	D2 (ditch, 1st)	0.179	0.089	0.045	0.018	0.148	0.074	0.037	0.015
	D2 (stream, 1st)	0.198	0.099	0.050	0.020	0.177	0.088	0.044	0.018
	D3 (ditch, 1st)	0.177	0.089	0.044	0.018	0.146	0.073	0.037	0.015
	D4 (pond, 1st)	0.027	0.013	0.007	0.003	0.036	0.018	0.009	0.004
	D4 (stream, 1st)	0.190	0.095	0.047	0.019	0.157	0.079	0.039	0.016
	D5 (pond, 1st)	0.027	0.013	0.007	0.003	0.037	0.018	0.009	0.004
	D5 (stream, 1st)	0.192	0.096	0.048	0.019	0.172	0.086	0.043	0.017
	D6 (ditch, 1st)	0.179	0.089	0.045	0.018	0.158	0.079	0.040	0.016
	R1 (pond, 1st)	0.027	0.013	0.007	0.003	0.035	0.018	0.009	0.003
	R1 (stream, 1st)	0.157	0.079	0.039	0.022	0.129	0.065	0.032	0.030
	R3 (stream, 1st)	0.221	0.111	0.055	0.024	0.211	0.211	0.211	0.211
	R4 (stream, 1st)	0.157	0.079	0.039	0.039	0.364	0.364	0.364	0.364
20m SD & RO	D1 (ditch, 1st)	0.093	0.046	0.023	0.009	0.075	0.038	0.019	0.008
	D1 (stream, 1st)	0.096	0.048	0.024	0.010	0.085	0.043	0.022	0.009
	D2 (ditch, 1st)	0.093	0.046	0.023	0.009	0.075	0.038	0.019	0.008
	D2 (stream, 1st)	0.103	0.052	0.026	0.010	0.090	0.045	0.023	0.009
	D3 (ditch, 1st)	0.092	0.046	0.023	0.009	0.074	0.037	0.018	0.008
	D4 (pond, 1st)	0.018	0.009	0.004	0.002	0.024	0.012	0.006	0.002
	D4 (stream, 1st)	0.099	0.049	0.025	0.010	0.080	0.040	0.020	0.008
	D5 (pond, 1st)	0.018	0.009	0.004	0.002	0.024	0.012	0.006	0.002
	D5 (stream, 1st)	0.100	0.050	0.025	0.010	0.087	0.044	0.022	0.009
	D6 (ditch, 1st)	0.093	0.046	0.023	0.009	0.080	0.040	0.020	0.008
	R1 (pond, 1st)	0.018	0.009	0.004	0.002	0.023	0.012	0.006	0.002
	R1 (stream, 1st)	0.082	0.041	0.020	0.011	0.066	0.033	0.017	0.015
	R3 (stream, 1st)	0.115	0.057	0.029	0.013	0.111	0.111	0.111	0.111
	R4 (stream, 1st)	0.082	0.041	0.020	0.020	0.190	0.190	0.190	0.190

SD, RO: spray drift or runoff buffer used

Table 5.6-40: FOCUS Step 4 PEC_{sw} values for Prothioconazole for the application of Ascra Xpro in spring cereals according to use No A (single application/ multiple applications)

Buffer Width & Type	Scenario	PECsw [µg/L] (single) Drift Reduction				PECsw [µg/L] (multiple) Drift Reduction			
		0%	50%	75%	90%	0%	50%	75%	90%
5m SD	D1 (ditch, 1st)	0.339	0.169	0.085	0.034	0.429	0.215	0.107	0.043
	D1 (stream, 1st)	0.399	0.199	0.100	0.040	0.334	0.167	0.084	0.033
	D3 (ditch, 1st)	0.335	0.167	0.084	0.034	0.281	0.140	0.070	0.028
	D4 (pond, 1st)	0.037	0.018	0.009	0.004	0.042	0.021	0.011	0.004
	D4 (stream, 1st)	0.374	0.187	0.094	0.037	0.325	0.163	0.082	0.033
	D5 (pond, 1st)	0.037	0.018	0.009	0.004	0.049	0.024	0.012	0.005
	D5 (stream, 1st)	0.387	0.193	0.097	0.039	0.329	0.164	0.082	0.033
	R4 (stream, 1st)	0.501	0.501	0.501	0.501	0.501	0.501	0.501	0.501
10m SD & RO	D1 (ditch, 1st)	0.179	0.090	0.045	0.018	0.223	0.111	0.056	0.022
	D1 (stream, 1st)	0.212	0.106	0.053	0.021	0.173	0.087	0.043	0.017
	D3 (ditch, 1st)	0.177	0.089	0.044	0.018	0.146	0.073	0.037	0.015
	D4 (pond, 1st)	0.027	0.013	0.007	0.003	0.030	0.015	0.007	0.003
	D4 (stream, 1st)	0.198	0.099	0.050	0.020	0.169	0.085	0.042	0.017
	D5 (pond, 1st)	0.027	0.013	0.007	0.003	0.035	0.017	0.009	0.003
	D5 (stream, 1st)	0.205	0.103	0.051	0.021	0.171	0.086	0.043	0.017
	R4 (stream, 1st)	0.227	0.227	0.227	0.227	0.227	0.227	0.227	0.227
20m SD & RO	D1 (ditch, 1st)	0.093	0.047	0.023	0.009	0.113	0.057	0.028	0.012
	D1 (stream, 1st)	0.110	0.055	0.027	0.011	0.088	0.044	0.022	0.009
	D3 (ditch, 1st)	0.092	0.046	0.023	0.009	0.074	0.037	0.018	0.008
	D4 (pond, 1st)	0.018	0.009	0.004	0.002	0.020	0.010	0.005	0.002
	D4 (stream, 1st)	0.103	0.051	0.026	0.010	0.086	0.043	0.022	0.009
	D5 (pond, 1st)	0.018	0.009	0.004	0.002	0.023	0.011	0.006	0.002
	D5 (stream, 1st)	0.107	0.053	0.027	0.011	0.087	0.043	0.022	0.009
	R4 (stream, 1st)	0.118	0.118	0.118	0.118	0.118	0.118	0.118	0.118

SD, RO: spray drift or runoff buffer used

Table 5.6-41: FOCUS Step 4 PEC_{sw} values for metabolite JAU6476-desthio (M04) of Prothioconazole for the application of Ascra Xpro in winter cereals according to use No A (single application/ multiple applications)

Buffer Width & Type	Scenario	PECsw [µg/L] (single) Drift Reduction				PECsw [µg/L] (multiple) Drift Reduction			
		0%	50%	75%	90%	0%	50%	75%	90%
5m SD	D1 (ditch, 1st)	<0.001	<0.001	<0.001	<0.001	0.002	0.002	0.002	0.002
	D1 (stream, 1st)	<0.001	<0.001	<0.001	<0.001	0.001	0.001	0.001	0.001
	D2 (ditch, 1st)	0.002	0.002	0.002	0.002	0.008	0.008	0.008	0.008
	D2 (stream, 1st)	0.002	0.002	0.002	0.002	0.005	0.005	0.005	0.005
	D3 (ditch, 1st)	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	D4 (pond, 1st)	0.018	0.009	0.005	0.002	0.025	0.012	0.006	0.002
	D4 (stream, 1st)	0.002	0.002	0.002	0.002	0.004	0.004	0.004	0.004
	D5 (pond, 1st)	0.018	0.009	0.005	0.002	0.025	0.013	0.006	0.002
	D5 (stream, 1st)	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	D6 (ditch, 1st)	0.166	0.083	0.042	0.017	0.152	0.076	0.038	0.015
	R1 (pond, 1st)	0.044	0.039	0.036	0.035	0.084	0.077	0.074	0.072
	R1 (stream, 1st)	0.366	0.366	0.366	0.366	0.776	0.776	0.776	0.776
	R3 (stream, 1st)	0.461	0.461	0.461	0.461	0.894	0.894	0.894	0.894
	R4 (stream, 1st)	0.506	0.506	0.506	0.506	1.062	1.062	1.062	1.062
10m SD & RO	D1 (ditch, 1st)	<0.001	<0.001	<0.001	<0.001	0.002	0.002	0.002	0.002
	D1 (stream, 1st)	<0.001	<0.001	<0.001	<0.001	0.001	0.001	0.001	0.001
	D2 (ditch, 1st)	0.002	0.002	0.002	0.002	0.008	0.008	0.008	0.008
	D2 (stream, 1st)	0.002	0.002	0.002	0.002	0.005	0.005	0.005	0.005
	D3 (ditch, 1st)	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	D4 (pond, 1st)	0.013	0.007	0.003	0.001	0.017	0.009	0.004	0.002
	D4 (stream, 1st)	0.002	0.002	0.002	0.002	0.004	0.004	0.004	0.004
	D5 (pond, 1st)	0.013	0.007	0.003	0.001	0.018	0.009	0.004	0.002
	D5 (stream, 1st)	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	D6 (ditch, 1st)	0.088	0.044	0.022	0.009	0.079	0.039	0.020	0.008
	R1 (pond, 1st)	0.021	0.017	0.015	0.014	0.038	0.033	0.031	0.029
	R1 (stream, 1st)	0.166	0.166	0.166	0.166	0.353	0.353	0.353	0.353
	R3 (stream, 1st)	0.211	0.211	0.211	0.211	0.408	0.408	0.408	0.408
	R4 (stream, 1st)	0.229	0.229	0.229	0.229	0.478	0.478	0.478	0.478
20m SD & RO	D1 (ditch, 1st)	<0.001	<0.001	<0.001	<0.001	0.002	0.002	0.002	0.002
	D1 (stream, 1st)	<0.001	<0.001	<0.001	<0.001	0.001	0.001	0.001	0.001
	D2 (ditch, 1st)	0.002	0.002	0.002	0.002	0.008	0.008	0.008	0.008
	D2 (stream, 1st)	0.002	0.002	0.002	0.002	0.005	0.005	0.005	0.005
	D3 (ditch, 1st)	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	D4 (pond, 1st)	0.009	0.004	0.002	<0.001	0.011	0.006	0.003	0.001
	D4 (stream, 1st)	0.002	0.002	0.002	0.002	0.004	0.004	0.004	0.004
	D5 (pond, 1st)	0.009	0.004	0.002	<0.001	0.012	0.006	0.003	0.001
	D5 (stream, 1st)	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	D6 (ditch, 1st)	0.046	0.023	0.011	0.005	0.040	0.020	0.010	0.004
	R1 (pond, 1st)	0.011	0.009	0.008	0.007	0.021	0.017	0.016	0.015
	R1 (stream, 1st)	0.087	0.087	0.087	0.087	0.185	0.185	0.185	0.185
	R3 (stream, 1st)	0.110	0.110	0.110	0.110	0.214	0.214	0.214	0.214
	R4 (stream, 1st)	0.119	0.119	0.119	0.119	0.249	0.249	0.249	0.249

SD, RO: spray drift or runoff buffer used

Table 5.6-42: FOCUS Step 4 PEC_{sw} values for metabolite JAU6476-desthio (M04) of Prothioconazole for the application of Ascra Xpro in spring cereals according to use No A (single application/ multiple applications)

Buffer Width & Type	Scenario	PECsw [µg/L] (single) Drift Reduction				PECsw [µg/L] (multiple) Drift Reduction			
		0%	50%	75%	90%	0%	50%	75%	90%
5m SD	D1 (ditch, 1st)	0.167	0.084	0.042	0.017	0.207	0.102	0.051	0.020
	D1 (stream, 1st)	<0.001	<0.001	<0.001	<0.001	0.002	0.002	0.002	0.002
	D3 (ditch, 1st)	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	D4 (pond, 1st)	0.018	0.009	0.005	0.002	0.022	0.011	0.005	0.002
	D4 (stream, 1st)	0.002	0.002	0.002	0.002	0.004	0.004	0.004	0.004
	D5 (pond, 1st)	0.018	0.009	0.005	0.002	0.024	0.012	0.006	0.002
	D5 (stream, 1st)	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	R4 (stream, 1st)	0.573	0.573	0.573	0.573	0.574	0.574	0.574	0.574
10m SD & RO	D1 (ditch, 1st)	0.089	0.045	0.022	0.009	0.107	0.053	0.027	0.011
	D1 (stream, 1st)	<0.001	<0.001	<0.001	<0.001	0.002	0.002	0.002	0.002
	D3 (ditch, 1st)	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	D4 (pond, 1st)	0.013	0.007	0.003	0.001	0.015	0.008	0.004	0.002
	D4 (stream, 1st)	0.002	0.002	0.002	0.002	0.004	0.004	0.004	0.004
	D5 (pond, 1st)	0.013	0.007	0.003	0.001	0.017	0.008	0.004	0.002
	D5 (stream, 1st)	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	R4 (stream, 1st)	0.261	0.261	0.261	0.261	0.261	0.261	0.261	0.261
20m SD & RO	D1 (ditch, 1st)	0.046	0.023	0.012	0.005	0.054	0.027	0.014	0.006
	D1 (stream, 1st)	<0.001	<0.001	<0.001	<0.001	0.002	0.002	0.002	0.002
	D3 (ditch, 1st)	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	D4 (pond, 1st)	0.009	0.004	0.002	<0.001	0.010	0.005	0.003	0.001
	D4 (stream, 1st)	0.002	0.002	0.002	0.002	0.004	0.004	0.004	0.004
	D5 (pond, 1st)	0.009	0.004	0.002	<0.001	0.011	0.006	0.003	0.001
	D5 (stream, 1st)	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	R4 (stream, 1st)	0.137	0.137	0.137	0.137	0.137	0.137	0.137	0.137

SD, RO: spray drift or runoff buffer used

5.7 Risk assessment ground water (KIIIA1 9.6)

5.7.1 Predicted environmental concentration in groundwater (PEC_{GW}) calculation for active substances and metabolites (Tier 1 and 2)

Groundwater contamination by direct leaching of the active substance and its metabolites, degradation or reaction products through soil is generally assessed by groundwater model calculations.

Table 5.7-1: Application related input parameters for PEC_{GW} modelling

Plant protection product	Ascra Xpro
Use No.	A
Application rate (g as/ha)	Bixafen: 2 x 97.5 = 195 Fluopyram: 2 x 97.5 = 195 Prothioconazole: 2 x 195 = 390
Crop (crop rotation)	cereals
Relative application date(s)	relative application dates used, 169 and 183 days after emergence, e.g. Hamburg scenario: 19.04. and 03.05.
Number of applications/interval:	2 x / 14 d
Interception (%)	2 x 70 %
Soil effective application rate (g as/ha)	Bixafen: 2 x 29.25 = 58.5 Fluopyram: 2 x 29.25 = 58.5 Prothioconazole: 2 x 58.5 = 117
Soil moisture	100 % FC
Q10-factor	2.58
Moisture exponent	0.7
Simulation period (years)	26

Bixafen

The PEC of Bixafen and its metabolite M44 in ground water have been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PELMO.

Table 5.7-2: Input parameters related to Bixafen for PEC_{GW} modelling

Parameter (PELOM/PEARL)	Endpoint used for PEC_{GW} calculation	Values in accordance to EU endpoint in LoEP	Remarks/Reference
Molecular weight (g/mol)	414.2	yes	
Solubility (mg/L)	0.489	yes	
Vapour pressure (Pa)	4.60×10^{-8}	yes	
DT_{50} in soil (d)	200.2	yes	
K_{Foc}	3869 (arithm mean)	yes	
Kom	2244	yes	
1/n	0.88	yes	
Plant uptake factor	0		

Walker Exponent	0.7		
Molar acitv. Energy (kJ/mol)	65.4		

Table 5.7-3: Input parameters related to metabolites of Bixafen for PEC_{GW} modelling

Parameter	Endpoint used for PEC_{GW} calculation	Values in accordance to EU endpoint in LoEP	Remarks/Reference
Metabolite 1	**M44**		
Molecular weight (g/mol)	162.1	yes	
Solubility (mg/L)	33200	yes	
Vapour pressure (Pa)	5.0×10^{-6}	yes	
Formation fraction PELOM	1		The formation fraction was set to 1
DT_{50} in soil (d)	25.9	yes	
K_{Foc}	7.7	yes	
Kom	4.4	yes	
1/n	0.964	yes	
Plant uptake factor	0		
Walker Exponent	0.7		

Table 5.7-4: PEC_{GW} at 1 m soil depth for Bixafen and its metabolites for the application of Ascra Xpro in cereals (based on geom. mean for DT_{50} value and arithm. mean for K_{Foc})

Crop/Group/ use No.	Scenario	80th percentile PEC_{GW} at 1 m soil depth (µg L^{-1}) groundwater model: FOCUS PELMO 5.5.3		
		Bixafen	**metabolite M44**	
A/ winter cereals	**Châteaudun**	<0.001	0.486	
	Hamburg	<0.001	1.652	
	Jokioinen	<0.001	2.158	
	Kremsmünster	<0.001	1.036	
	Okehampton	<0.001	1.115	
	Piacenza	<0.001	0.863	
	Porto	<0.001	0.808	
	Sevilla	<0.001	0.272	
	Thiva	<0.001	0.386	

Table 5.7-5: PEC_{GW} at 1 m soil depth for Bixafen and its metabolites for the application of Ascra Xpro in cereals (based on geom. mean for DT_{50} value and arithm. mean for K_{Foc})

Crop/Group/ use No.	Scenario	80th percentile PEC_{GW} at 1 m soil depth (µg L^{-1}) groundwater model: FOCUS PEARL 4.4.4		
		Bixafen	metabolite M44	
A/ winter cereals	Châteaudun	<0.001	0205	
	Hamburg	<0.001	0.641	
	Jokioinen	<0.001	0.809	
	Kremsmünster	<0.001	0.328	
	Okehampton	<0.001	0.371	
	Piacenza	<0.001	0.207	
	Porto	<0.001	0.218	
	Sevilla	<0.001	0.072	
	Thiva	<0.001	0.142	

According to the PEC_{GW} modelling with FOCUS PELOM 5.5.3/PEARL 4.4.4 a groundwater contamination of the active substance Bixafen at a concentration of ≥ 0.1 µg/L is not expected for the FOCUS groundwater scenarios.

For the metabolites M44 a groundwater concentration of ≥ 0.1 µg/L cannot be excluded in all FOCUS groundwater scenarios.

Fluopyram

The PEC of Fluopyram and its metabolite in ground water have been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PELMO. The FOCUS calculation was performed by zRMS.

Table 5.7-6: Input parameters related to Fluopyram for PEC_{GW} modelling

Parameter	Endpoint used for PEC_{GW} calculation	Values in accordance to EU endpoint in LoEP	Remarks/Reference
Molecular weight (g/mol)	396.72	yes	
DT_{50} in soil (d)	123.1	yes	Geometric mean
K_{Foc}	278.9	yes	Arithmetic mean
1/n	0.827	yes	Arithmetic mean
Plant uptake factor	0	yes	default

Table 5.7-7: Input parameters related to metabolite M08 of Fluopyram for PEC_{GW} modelling

Parameter	Endpoint used for PEC_{GW} calculation	Values in accordance to EU endpoint in LoEP	Remarks/Reference
Metabolite 1	**M08-7-hydroxy**		
Molecular weight (g/mol)	412.72	yes	
Formation fraction	0.8338	yes	Arithmetic mean
DT_{50} in soil (d)	8.1	yes	Geometric mean
K_{Foc}	103.2	yes	Arithmetic mean
1/n	0.9292	yes	Arithmetic mean
Plant uptake factor	0	yes	default

Table 5.7-8: PEC_{GW} at 1 m soil depth for Fluopyram and its metabolite for the application of Ascra Xpro in cereals

Crop/Group/ use No.	Scenario	80^{th} percentile PEC_{GW} at 1 m soil depth (µg L^{-1}) groundwater model: FOCUS PELMO 5.5.3		
		Fluopyram	Metabolite M08	
A/ winter cereals	**Châteaudun**	<0.001	<0.001	
	Hamburg	0.001	0.001	
	Jokioinen	<0.001	<0.001	
	Kremsmünster	<0.001	<0.001	
	Okehampton	0.002	0.002	
	Piacenza	0.001	0.001	
	Porto	<0.001	0.001	
	Sevilla	<0.001	<0.001	
	Thiva	<0.001	<0.001	

According to the PEC_{GW} modelling with FOCUS PELMO 5.5.3 a groundwater contamination of the active substance Fluopyram at a concentration of ≥ 0.1 µg/L is not expected for the FOCUS groundwater scenarios.

For the metabolite M08 a groundwater concentration of ≥ 0.1 µg/L can be excluded in the FOCUS groundwater scenarios.

Prothioconazole

The PEC of Prothioconazole and its metabolites JAU6476-S-methyl (M01) and JAU6476-desthio (M04) in ground water have been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PELMO. The FOCUS calculation was performed by zRMS.

Table 5.7-9: Input parameters related to Prothioconazole for PEC_{GW} modelling

Parameter	Endpoint used for PEC_{GW} calculation	Values in accordance to EU endpoint in LoEP	Remarks/Reference
Molecular weight (g/mol)	344.3	yes	
DT_{50} in soil (d)	0.94	no	geometric mean, field
K_{Foc}	1765	yes	based on aged soil column leaching study
1/n	1.0	no	default
Plant uptake factor	0	yes	default

Table 5.7-10: Input parameters related to metabolites of Prothioconazole for PEC_{GW} modelling

Parameter	Endpoint used for PEC_{GW} calculation	Values in accordance to EU endpoint in LoEP	Remarks/Reference
Metabolite 1	**JAU6476-S-methyl (M01)**		
Molecular weight (g/mol)	358.3	yes	
Formation fraction	a.i. → M01: 0.08 M01 → M04: 1.0	no	**refers to** Table 5.4-6
DT_{50} in soil (d)	9.5	no	geometric mean, lab
K_{Foc}	2556	yes	arithmetic mean
1/n	0.88	yes	arithmetic mean
Plant uptake factor	0	yes	default
Metabolite 2	**JAU6476-desthio (M04)**		
Molecular weight (g/mol)	312.2	yes	
Formation fraction	a.i. → M04: 0.60 M04 → sink: 1.0	no	refers to Table 5.4-12
DT_{50} in soil (d)	21.8	no	geometric mean, field
K_{Foc}	575	yes	arithmetic mean
1/n	0.81	yes	arithmetic mean
Plant uptake factor	0	yes	default

Table 5.7-11: PEC_{GW} at 1 m soil depth for Prothioconazole and its metabolites for the application of Ascra Xpro in cereals

Crop/Group/ use No.	Szenario	80th percentile PEC_{GW} at 1 m soil depth (µg L^{-1}) groundwater model: FOCUS PELMO 5.5.3		
		Prothioconazole	metabolite JAU6476-S-methyl (M01)	metabolite JAU 6476-desthio (M04)
A/ winter cereals	Châteaudun	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001
	Jokioinen	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001

According to the PEC_{GW} modelling with FOCUS PELMO 5.5.3 a groundwater contamination of the active substance Prothioconazole at a concentration of ≥ 0.1 µg/L is not expected for the FOCUS groundwater scenarios in cereals.

For the soil metabolites JAU6476-S-methyl (M01) and JAU 6476-desthio (M04) a groundwater concentration of ≥ 0.1 µg/L can be excluded in the FOCUS groundwater scenarios.

5.7.2 Higher tier leaching assessment (Tier 3)

Not required.

5.7.3 Summary of risk assessment for ground water

Results of modelling with FOCUS PELMO 5.5.3 show that the active substance Bixafen is not expected to penetrate into groundwater at concentrations of ≥ 0.1 µg/L in the intended uses in winter cereals.

For the metabolite M44 of Bixafen concentrations of ≥ 0.1 µg/L in groundwater cannot be excluded in all of the FOCUS groundwater scenarios in the intended uses.

Results of modelling show that the active substance Fluopyram is not expected to penetrate into groundwater at concentrations of ≥ 0.1 µg/L in the intended uses in cereals.

For the metabolite M08 of Fluopyram concentrations of ≥ 0.1 µg/L in groundwater can be excluded in all of the FOCUS groundwater scenarios in the intended uses.

Results of modelling show that the active substance Prothioconazole is not expected to penetrate into groundwater at concentrations of ≥ 0.1 µg/L in the intended uses in cereals.

For the metabolites JAU6476-S-methyl (M01) and JAU 6476-desthio (M04) of Prothioconazole concentrations of ≥ 0.1 µg/L in groundwater can be excluded in all FOCUS groundwater scenarios in the intended uses.

5.8 Potential of active substance for aerial transport

The vapour pressure at 20 °C of the active substance Bixafen is < 10^{-5} Pa. Hence the active substance Bixafen is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance Bixafen due to volatilization with subsequent deposition does not need to be considered.

The vapour pressure at 20 °C of the active substance Fluopyram is < 10^{-5} Pa. Hence the active substance Fluopyram is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance Fluopyram due to volatilization with subsequent deposition does not need to be considered.

The vapour pressure at 20 °C of the active substance Prothioconazole is < 10^{-5} Pa. Hence the active substance Prothioconazole is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance Prothioconazole due to volatilization with subsequent deposition does not need to be considered.

Appendix 1 List of data submitted in support of the evaluation

Table A 1: List of data submitted in support of the evaluation

Annex point/ reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not Authority registration No	Data protection claimed	Owner	How considered in dRR Study-Status/Usage*
OECD: KIIIA 9.2.1	Hardy, I.A.J.	2012	Kinetic modelling analysis of prothioconazole from field soil residue studies conducted in Europe normalised to 20ºC and pF2. M-429069-01-1 (VC/11/022) 2629932 // M-429069-01-1	Y	BAY	1)
OECD: KIIIA 9.2.1	Schad, T.; Zerbe, P.	2008	Dissipation of prothioconazole and JAU6476-desthio under field conditions in Europe. Kinetic evaluation and calculation of non-referenced DT50. M-298575-01-1 (MEF-08/114) 2629933 // M-298575-01-1	Y	BAY	1)
OECD: KIIIA 9.6.2	Kley and Sittig	2014	Fluopyram (FLU) and metabolite: PECgw FOCUS PEARL, PELMO EUR – Use in spring and winter cereals in Europe. M-477184-01-1 (EnSa-13-1068) 2629949//M-477184-01-1	Y	BAY	1)
OECD: KIIIA 9.7	Kley and Bolekhan	2013	Fluopyram (FLU): PECsw,sed FOCUS EUR- Use in winter and spring cereals in Europe. M-477192-01-1 (EnSa-13-1091) 2629953//M-477192-01-1	Y	BAY	1)
OECD: KIIIA 9.7	Chapple and Ghafoor	2014	Prothioconazole (PTZ) and metabolites: PECsw,sed FOCUS EUR - Use in winter and spring cereals in Europe. M-478500-01-1 (EnSa-13-0917) 2629954//M-478500-01-1	Y	BAY	1)
OECD: KIIIA 9.7	Scherr, F.; Ellerich, C.	2014	Predicted environmental concentrations in surface water (PECsw) and sediment (PECsed) for bixafen calculated with TOXSWA 1.2 - Use on cereals in the	Y	BAY	1)

			Netherlands M-477218-01-1			

*

1) accepted (study valid and considered for evaluation)
2) not accepted (study not valid and not considered for evaluation)
3) not considered (study not relevant for evaluation)
4) not submitted but necessary (study not submitted by applicant but necessary for evaluation)
5) supplemental (additional information, alone not sufficient to fulfil a data requirement, considered for evaluation)

Appendix 2 Detailed evaluation of studies relied upon

Report only studies, which have not previously been evaluated within a peer reviewed process at EU level (Annex I inclusion of active substance).

KIIIA1 9 Fate and Behaviour in the Environment – Plant protection product

KIIIA1 9.2.1 Hardy (2012)

Prothioconazole

Reference:	KIIIA 9.2.1
Author:	Hardy, I.A.J.
Report:	Kinetic modelling analysis of prothioconazole from field soil residue studies conducted in Europe normalised to 20ºC and pF2. M-429069-01-1 (VC/11/022) 2629932 // M-429069-01-1
Date:	11/04/2012
Guideline(s):	FOCUS (2006) "Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration" Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference SANCO/10058/2005 version 2.0
Deviations:	No
GLP:	No (calculation)
Acceptability:	Yes

Materials and methods

A kinetic modelling analysis of prothioconazole and JAU 6476-desthio (M04) soil residue data from European field dissipation studies was conducted in order to derive normalised DT_{50} values (20°C and pF2) of prothioconazole and its major metabolite JAU 6476-desthio in soil for use in subsequent risk assessments. Daily soil temperatures and moisture contents were used to normalise the data to reference conditions according to FOCUS groundwater assumptions (Q10 of 2.58 and Walker B factor moisture exponent of 0.7).

All datasets were evaluated with KinGUI2 in a stepwise procedure using simple first-order (SFO) kinetics with free optimisation of all parameters according to FOCUS kinetics guidance (FOCUS, 2006).

Evaluations with SFO kinetics resulted in acceptable fits both visually and statistically for prothioconazole and JAU 6476-desthio.

Findings

This evaluation led to the temperature and moisture normalised first-order DT_{50} values of prothioconazole and JAU 6476-desthio (M04) shown in Table A 2 and Table A 2. Referenced DT_{50} values of prothioconazole range from 0.7 to 1.38 days, with a geometric mean of 0.94 days, referenced DT_{50} values of JAU 6476-desthio range from 9.0 to 36.4 days, with a geometric mean of 21.8 days. The normalised kinetic parameters determined for the dissipation in soil under realistic field conditions are considered appropriate as input for modelling and environmental risk assessments.

Table A 2: FOCUS normalised field DT_{50} values of prothioconazole (referenced to 20°C and pF2, Q10: 2.58)

Study	Country	Location	DT_{50} [days]	Min Chi^2 error [%]
RA-2152/98[a)]	Germany	Burscheid	1.32	1.2
	Great Britain	Thurston	1.09	26.8
	France, North	La Fresne	0.75	4.5
	Great Britain	Thurston	1.38	32.2
	France, North	La Fresne	0.73	1.1
	France, South	St. Etienne	0.70	2.0
	Italy	Nogarole	0.97	2.1
	Germany	Monheim	0.82	2.0
geometric mean			*0.94*	

a) Schramel, O.: Dissipation of JAU6476 (250 EC) in soil under field conditions (France, Germany, Great Britain, Italy), Bayer CropScience AG, unpublished report no.: RA-2152/98, edition no.: M-049322-01-1, date: March 30, 2001 submitted in the basic EU dossier: IIA, 7.1.1.2.2 /01

Table A 3: FOCUS normalised field DT_{50} values of metabolite JAU 6476-desthio (M04) (referenced to 20°C and pF2, Q10: 2.58)

Study	Country	Location	DT_{50} [days]	Molar formation fraction (ffm)	Min Chi^2 error [%]
RA-2152/98[a)]	Germany	Burscheid	9.0	0.72	7.9
	Great Britain	Thurston	23.5	0.67	4.8
	France, North	La Fresne	29.5	0.42	13.5
	Great Britain	Thurston	19.8	0.76	9.8
	France, North	La Fresne	24.0	0.39	6.6
	France, South	St. Etienne	36.4	0.65	10.1
	Italy	Nogarole	26.7	0.48	6.5
	Germany	Monheim	17.8	0.74	5.4
geometric mean			*21.8*	-	
arithmetic mean			-	*0.60*	

a) Schramel, O.: Dissipation of JAU6476 (250 EC) in soil under field conditions (France, Germany, Great Britain, Italy), Bayer CropScience AG, unpublished report no.: RA-2152/98, edition no.: M-049322-01-1, date: March 30, 2001 submitted in the basic EU dossier: IIA, 7.1.1.2.2 /01

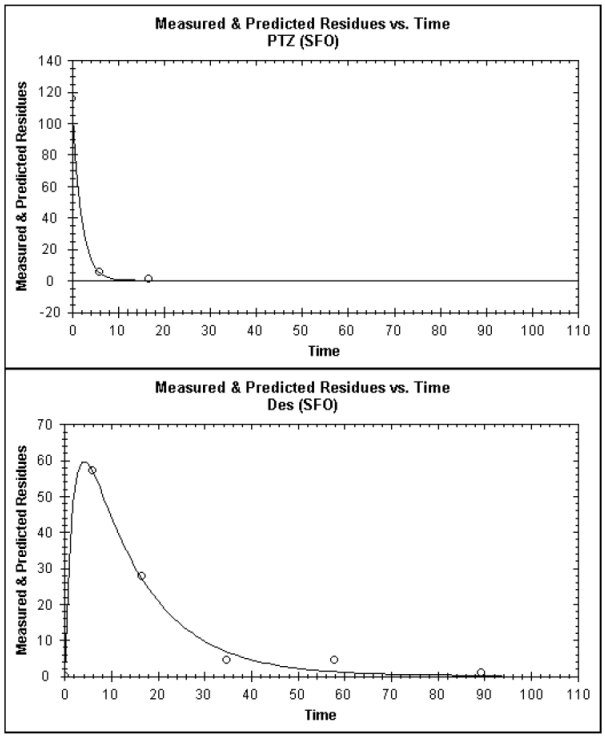


Figure A 1: SFO model fit for Germany (Burscheid)

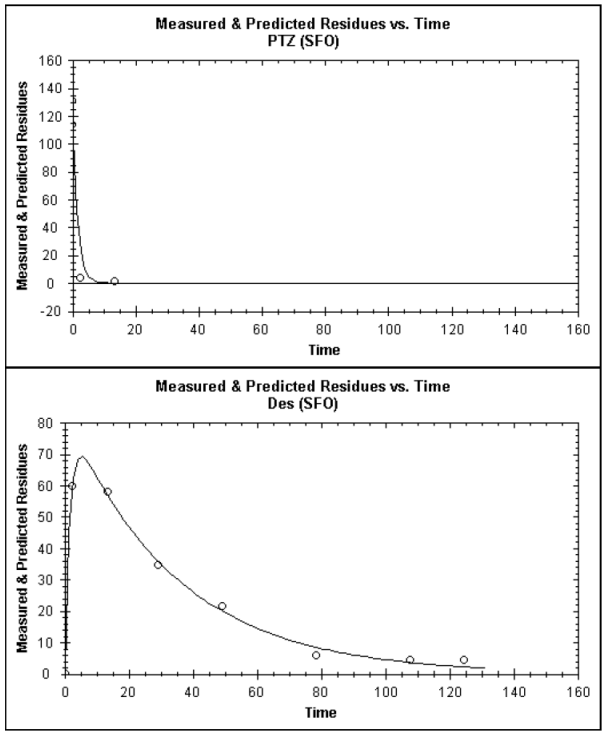


Figure A 2: SFO model fit for UK (Thurston)

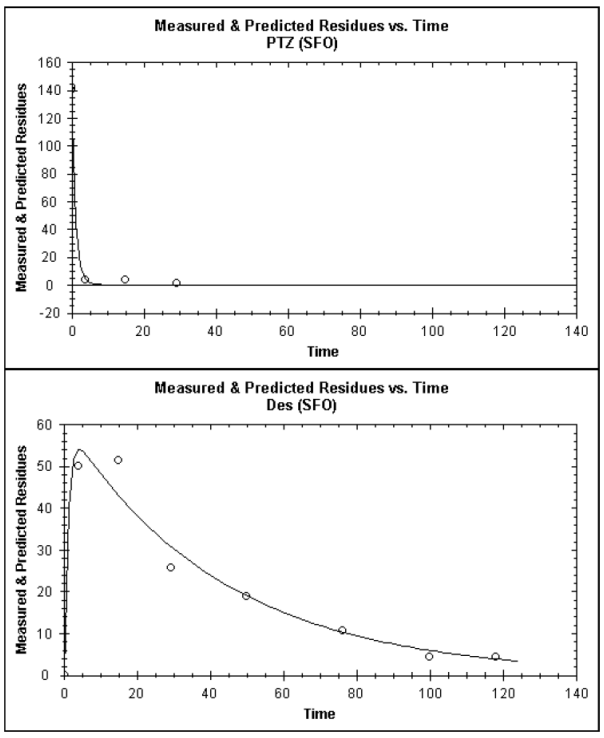


Figure A 3: SFO model fit for N-France (La Fresne)

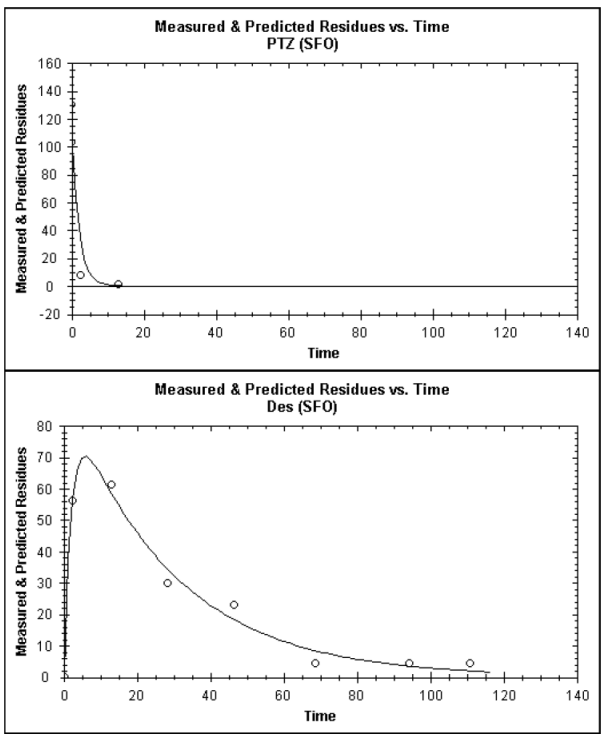


Figure A 4: SFO model fit for UK (Thurston)

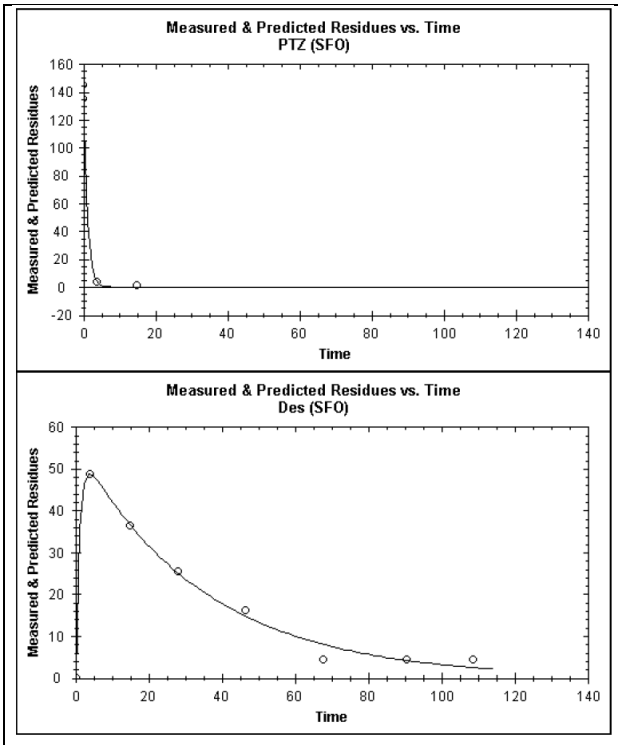


Figure A 5: SFO model fit for N-France (La Fresne)

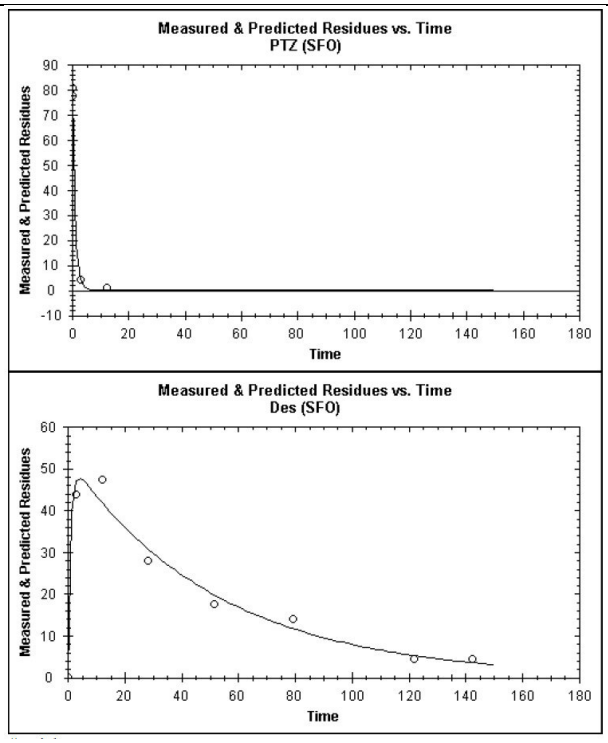


Figure A 6: SFO model fit for S-France (St. Etienne)

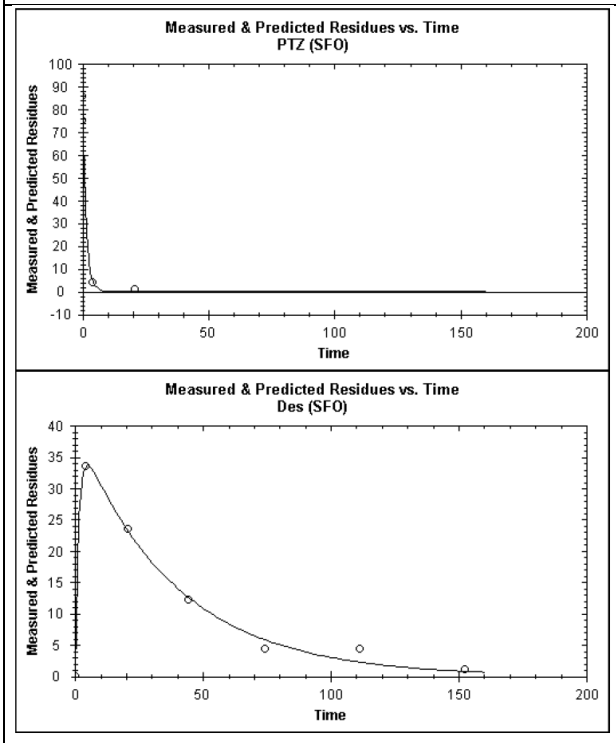


Figure A 7: SFO model fit for Italy (Nogarole)

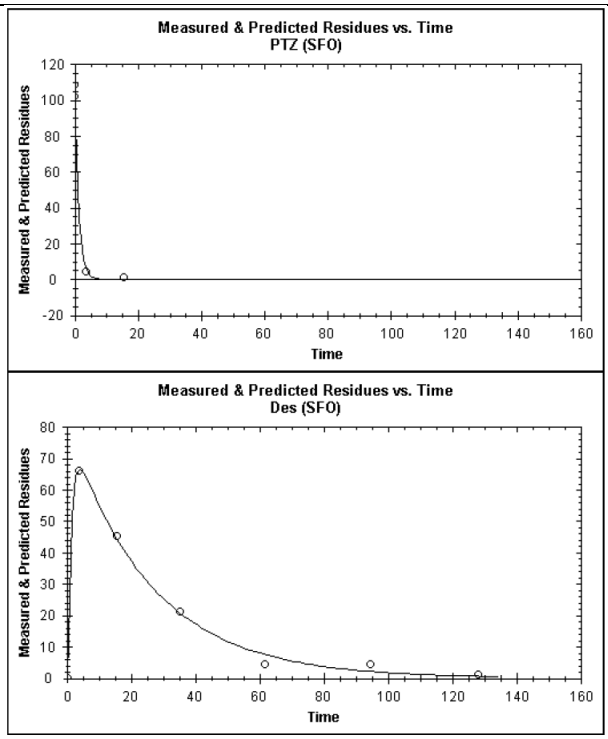


Figure A 8: SFO model fit for DE (Monheim)

Conclusion

Field normalised DT_{50} values for use in environmental modelling have been calculated. The geometric mean normalised DT_{50} values are 0.94 days for prothioconazole and 21.8 days for JAU 6476-desthio (M04), along with an average formation fraction of 0.60.

Comments of zRMS

The study is acceptable and considered for the exposure assessment.

KIIIA1 9.2.1 Schad; Zerbe (2008)

Reference:	KIIIA 9.2.1
Author:	Schad, T.; Zerbe, P.; 2008
Report:	Dissipation of prothioconazole and JAU6476-desthio under field conditions in Europe. Kinetic evaluation and calculation of non-referenced DT_{50}. M-298575-01-1 (MEF-08/114) 2629933 // M-298575-01-1
Date:	20/02/2008
Guideline(s):	Not applicable
Deviations:	No
GLP:	No (calculation)
Acceptability:	Yes

Materials and methods

A kinetic modelling analysis of prothioconazole and JAU 6476-desthio (M04) soil residue data from European field dissipation studies was conducted in order to derive non-referenced kinetic parameters on the dissipation of prothioconazole and its major metabolite JAU 6476-desthio in soil, suitable for comparison with regulatory trigger values and lower-tier environmental modelling.

The determination of the most appropriate kinetic model was based on a detailed statistical analysis including visual assessment, $\chi 2$ statistic, significance T-test, and correlation analysis. The Simple First Order (SFO) model and a biphasic model (First Order Multi Compartment, FOMC) were employed.

Findings

This evaluation led to non-referenced single first-order DT_{50} values of prothioconazole and JAU 6476-desthio (M04) shown in Table A 4 and Table A 5. Non-referenced DT_{50} of prothioconazole range from 1.5 to 2.4 days, with a geometric mean of 1.8 days. Non-referenced DT_{50} of the metabolite JAU 6476-desthio (M04) range from 17.1 to 57.0 days, geometric mean of 37.6 days.

Table A 4: Non-referenced DT_{50} values of prothioconazole under European field conditions using Single First-Order model (SFO)

Study	Country	Location	DT_{50} [days]	Chi^2 error [%]
RA-2152/98[a)]	Germany	Burscheid	2.0	1.5
	Great Britain	Thurston	1.8	1.7
	France, North	La Fresne	1.5	3.9
	Great Britain	Thurston	2.4	2.1
	France, North	La Fresne	1.5	1.5
	France, South	St. Etienne	1.9	2.7
	Italy	Nogarole	1.5	2.6
	Germany	Monheim	1.7	1.4
geometric mean			*1.8*	

a) Schramel, O.: Dissipation of JAU6476 (250 EC) in soil under field conditions (France, Germany, Great Britain, Italy), Bayer CropScience AG, unpublished report no.: RA-2152/98, edition no.: M-049322-01-1, date: March 30, 2001 submitted in the basic EU dossier: IIA, 7.1.1.2.2 /01

Table A 5: Non-referenced DT_{50} values of metabolite JAU 6476-desthio (M04) under European field conditions using Single First-Order model (SFO)

Study	Country	Location	DT_{50} [days]	Chi^2 error [%]
RA-2152/98[a)]	Germany	Burscheid	17.1	9.5
	Great Britain	Thurston	57.0	10.1
	France, North	La Fresne	49.8	12.7
	Great Britain	Thurston	50.8	13.4
	France, North	La Fresne	35.2	4.0
	France, South	St. Etienne	50.8	10.1
	Italy	Nogarole	31.7	6.2
	Germany	Monheim	28.7	7.7
geometric mean			*37.6*	

a) Schramel, O.: Dissipation of JAU6476 (250 EC) in soil under field conditions (France, Germany, Great Britain, Italy), Bayer CropScience AG, unpublished report no.: RA-2152/98, edition no.: M-049322-01-1, date: March 30, 2001 submitted in the basic EU dossier: IIA, 7.1.1.2.2 /01

Conclusion

The evaluation of the dissipation kinetics of prothioconazole and desthio in soil from field dissipation studies resulted in statistically significant non-referenced DT_{50} for all of the 8 investigated trials according to first-order kinetics. The resulting DT_{50} are considered appropriate for comparison with regulatory trigger values and as input for lower-tier environmental modelling.

Non-referenced DT_{50} of prothioconazole range from 1.5 to 2.4 days, with a geometric mean of 1.8 days. Non-referenced DT_{50} of the metabolite desthio range from 17.1 to 57.0 days, geometric mean of 37.6 days.

Comments of zRMS

The study is acceptable and considered for the exposure assessment.

KIIIA 9.6.1 and KIIIA 9.6.2 Scherr; Ellerich (2014)

Reference:	KIIIA 9.6.1and 9.6.2
Author:	Scherr, F.; Ellerich, C (2014)
Report:	a: KIIIA 9.6.1-Bixafen (BIX) and metabolite: PECgw FOCUS PEARL, PELMO EUR- Use in cereals in Europe and b: KIIIA 9.6.2- Bixafen (BIX) and metabolite: PECgw FOCUS PEARL, PELMO EUR- Use in cereals in Europe a, b: M-476538-01-1 (EnSa-13-1073)
Date:	2014
Guideline(s):	Not applicable
Deviations:	No
GLP:	No (calculation)
Acceptability:	Yes

Materials and methods
The predicted environmental concentrations in groundwater (PEC_{gw}) for bixafen were calculated using the simulation model FOCUS PEARL (version 4.4.4) and FOCUS PELMO (version 5.5.3). Detailed application data used for simulation of PEC_{gw} were compiled in the Table below

Comparison of simulated and actual use pattern

Individual Crop	FOCUS Crop Used for Interception	Application				Amount Reaching the Soil per Season application
		Rate per Season	Interval	Plant Interception	BBCH Stage	
		[g a.s. /ha]	[days]	[%]		[g a.s. /ha]
Winter and spring cereals - identical for GAP and simulation	Cereals, winter and spring (arable crops)	2 × 98	14	2 × 70	30 - 61	2 × 29.4

Application dates for the simulation runs were defined following the crop event dates of the respective crop and scenario as given by FOCUS (2009).

Application dates for the intended use in spring and winter cereals

Individual crop	Spring cereals	Winter cereals
Repeat interval for app. events	Every year	Every year
Application technique Absolute/relative to	Spray Absolute	Spray Absolute
Scenario	**1st app. date (Juilian day)**	
Châteaudun	21 Apr (111)	25 Mar (48)
Hamburg	15 May (135)	19 Apr (109)
Jokioinen	18 Jun (169)	28 Mar (87)
Kremsmuenster	17 May (137)	15 Apr (105)
Okehampton	13 May (133)	01 Apr (91)
Piacenza	-	02 Apr (92)
Porto	21 Apr (111)	06 Apr (96)
Sevilla	-	20 Mar (79)
Thiva	-	06 Apr (96)

Further input parameters for PEC_{gw} modelling of bixafen are summarised in the table below

Table 9.6.1- 1: Substance specific and model related input parameter for PEC_{gw} calculation of bixafen

Parameter	Unit	Bixafen	3-(difluoromethyl)-1H-pyrazole-4-carboxylic acid
Molar mass	[g/mol]	414.2	162.1
Water solubility	[mg/L]	0.5 (20°C)	33200 (20°C)
Vapour Pressure	[Pa]	4.6×10^{-8}	5×10^{-6} (20°C)
K_{oc}	[L/kg	3869	7.6
K_{om}	[L/kg]	2244	4.4
Freundlich Exponent	[-]	0.877	0.964
DT_{50}	[days]	200.2	26.6
Molar activ. energie	[kJ/mol]	65.4	65.4
Q_{10}	[-]	2.58	2.58
Plant uptake factor	[-]	0.0	0.0

Individual crop	Spring cereals	Winter cereals
Repeat interval for app. events	Every year	Every year
Application technique Absolute/relative to	Spray Absolute	Spray Absolute
Scenario	**1st app. date (Julian day)**	
Châteaudun	21 Apr (111)	25 Mar (48)
Hamburg	15 May (135)	19 Apr (109)
Jokioinen	18 Jun (169)	28 Mar (87)
Kremsmuenster	17 May (137)	15 Apr (105)
Okehampton	13 May (133)	01 Apr (91)
Piacenza	-	02 Apr (92)
Porto	21 Apr (111)	06 Apr (96)
Sevilla	-	20 Mar (79)
Thiva	-	06 Apr (96)

Findings
The 80th percentile concentrations of bixafen are given in the follow table

PEC_{GW} at 1 m soil depth for Bixafen and its metabolites for the application of Ascra Xpro in cereals (based on geom. mean for DT_{50} value and arithm. mean for K_{Foc})

Crop/Group/ use No.	Scenario	80th percentile PEC_{GW} at 1 m soil depth (µg L^{-1}) groundwater model: FOCUS PEARL 4.4.4		
		Bixafen	metabolite M44	
A/ winter cereals	Châteaudun	<0.001	0205	
	Hamburg	<0.001	0.641	
	Jokioinen	<0.001	0.809	
	Kremsmünster	<0.001	0.328	
	Okehampton	<0.001	0.371	
	Piacenza	<0.001	0.207	
	Porto	<0.001	0.218	
	Sevilla	<0.001	0.072	
	Thiva	<0.001	0.142	

Appendix 3 Table of Intended Uses justification and GAP tables

GAP rev. 01, date: 2014-05-07

PPP (product name/code)	**Ascra Xpro EC 260 / Spec No. 102000027828**	**Formulation type:**	**emulsifiable concentrate**
active substance 1	**bixafen**	**Conc. of as 1:**	**65 g/l**
active substance 2	**fluopyram**	**Conc. of as 2:**	**65 g/l**
active substance 3	**prothioconazole**	**Conc. of as 3:**	**130 g/l**
Applicant:	**Bayer CropScience**	**professional use**	☒
Zone(s):	**Central zone EU**	**non professional use**	☐

Verified by MS: northern/central/southern

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation (crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:**
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Central Zone												
1	Austria	wheat	F	PSDCHE, SEPTTR, LEPTNO, PUCCRT, PUCCST, ERYSGT PYRNTR , MONGNI, FUSASP	Overall spray	BBCH 30 - 61	2 (14 days)	a) 1.5 b) 3.0	a) 97.5+ 97.5+195 b) 195+195+ 390	100 - 400	*	
2	Belgium	Wheat	F	PSDCHE, SEPTTR, LEPTNO, PUCCRT, PUCCST, ERYSGT PYRNTR , MONGNI, FUSASP	Overall spray	BBCH 30 - 61	2 (14 days)	a) 1.5 b) 3.0	a) 97.5+ 97.5+195 b) 195+195+ 390	100 - 400	*	
4	Netherlands	Wheat	F	PSDCHE, SEPTTR, LEPTNO, PUCCRT, PUCCST, ERYSGT PYRNTR , MONGNI, FUSASP	Overall spray	BBCH 30 - 61	2 (14 days)	a) 1.5 b) 3.0	a) 97.5+ 97.5+195 b) 195+195+ 390	200 - 400	*	
5	Poland	Wheat	F	PSDCHE, SEPTTR, LEPTNO,	Overall	BBCH 30 - 61	2	a) 1.5	a) 97.5+ 97.5+195	200 - 400	*	1.0 – 1.5 L/ha

				PUCCRT, PUCCST, ERYSGT PYRNTR , MONGNI, FUSASP	spray		(14 days)	b) 3.0	b) 195+195+ 390			
6	Slovenia	Wheat	F	PSDCHE, SEPTTR, LEPTNO, PUCCRT, PUCCST, ERYSGT PYRNTR , MONGNI, FUSASP	Overall spray	BBCH 30 - 61	2 (14 days)	a) 1.5 b) 3.0	a) 97.5+ 97.5+195 b) 195+195+ 390	100 - 400	*	
7	United Kingdom	Wheat	F	PSDCHE, SEPTTR, LEPTNO, PUCCRT, PUCCST, ERYSGT PYRNTR , MONGNI, FUSASP	Overall spray	BBCH 30 - 61	2 (14 days)	a) 1.5 b) 3.0	a) 97.5+ 97.5+195 b) 195+195+ 390	100 - 400	*	
8	Austria	Rye	F	ERYSGS, RHYNSE, PUCCRR, PSDCHE	Overall spray	BBCH 30 - 61	2 (14 days)	a) 1.5 b) 3.0	a) 97.5+ 97.5+195 b) 195+195+ 390	100 - 400	*	
9	Belgium	Rye	F	ERYSGS, RHYNSE, PUCCRR, PSDCHE	Overall spray	BBCH 30 - 61	2 (14 days)	a) 1.5 b) 3.0	a) 97.5+ 97.5+195 b) 195+195+ 390	100 - 400	*	
11	Netherlands	Rye	F	ERYSGS, RHYNSE, PUCCRR, PSDCHE	Overall spray	BBCH 30 - 61	2 (14 days)	a) 1.5 b) 3.0	a) 97.5+ 97.5+195 b) 195+195+ 390	200 - 400	*	
12	Poland	Rye	F	ERYSGS, RHYNSE, PUCCRR, PSDCHE	Overall spray	BBCH 30 - 61	2 (14 days)	a) 1.5 b) 3.0	a) 97.5+ 97.5+195 b) 195+195+ 390	200 - 400	*	0.8 – 1.5 L/ha
13	Slovenia	Rye	F	ERYSGS, RHYNSE, PUCCRR, PSDCHE	Overall spray	BBCH 30 - 61	2 (14 days)	a) 1.5 b) 3.0	a) 97.5+ 97.5+195 b) 195+195+ 390	100 - 400	*	
14	United Kingdom	Rye	F	ERYSGS, RHYNSE, PUCCRR, PSDCHE	Overall spray	BBCH 30 - 61	2 (14 days)	a) 1.5 b) 3.0	a) 97.5+ 97.5+195 b) 195+195+ 390	100 - 400	*	
15	Austria	Triticale	F	PSDCHE, SEPTTR, LEPTNO, PUCCRT, PUCCST, ERYSGT PYRNTR	Overall spray	BBCH 30 - 61	2 (14 days)	a) 1.5 b) 3.0	a) 97.5+ 97.5+195 b) 195+195+ 390	100 - 400	*	
16	Belgium	Triticale	F	PSDCHE, SEPTTR, LEPTNO, PUCCRT, PUCCST, ERYSGT PYRNTR	Overall spray	BBCH 30 - 61	2 (14 days)	a) 1.5 b) 3.0	a) 97.5+ 97.5+195 b) 195+195+ 390	100 - 400	*	
18	Netherlands	Triticale	F	PSDCHE, SEPTTR, LEPTNO, PUCCRT, PUCCST, ERYSGT PYRNTR	Overall spray	BBCH 30 - 61	2 (14 days)	a) 1.5 b) 3.0	a) 97.5+ 97.5+195 b) 195+195+ 390	200 - 400	*	
19	Poland	Triticale	F	PSDCHE, SEPTTR, LEPTNO, PUCCRT, PUCCST, ERYSGT PYRNTR	Overall spray	BBCH 30 - 61	2 (14 days)	a) 1.5 b) 3.0	a) 97.5+ 97.5+195 b) 195+195+ 390	200 - 400	*	0.8 – 1.5 L/ha

20	Slovenia	Triticale	F	PSDCHE, SEPTTR, LEPTNO, PUCCRT, PUCCST, ERYSGT PYRNTR	Overall spray	BBCH 30 - 61	2 (14 days)	a) 1.5 b) 3.0	a) 97.5+ 97.5+195 b) 195+195+ 390	100 - 400	*	
21	United Kingdom	Triticale	F	PSDCHE, SEPTTR, LEPTNO, PUCCRT, PUCCST, ERYSGT PYRNTR	Overall spray	BBCH 30 - 61	2 (14 days)	a) 1.5 b) 3.0	a) 97.5+ 97.5+195 b) 195+195+ 390	100 - 400	*	
22	Austria	Spelt	F	PSDCHE, SEPTTR, LEPTNO, PUCCRT, PUCCST, ERYSGT PYRNTR	Overall spray	BBCH 30 - 61	2 (14 days)	a) 1.5 b) 3.0	a) 97.5+ 97.5+195 b) 195+195+ 390	100 - 400	*	
23	Belgium	Spelt	F	PSDCHE, SEPTTR, LEPTNO, PUCCRT, PUCCST, ERYSGT PYRNTR	Overall spray	BBCH 30 - 61	2 (14 days)	a) 1.5 b) 3.0	a) 97.5+ 97.5+195 b) 195+195+ 390	100 - 400	*	
24	Netherlands	Spelt	F	PSDCHE, SEPTTR, LEPTNO, PUCCRT, PUCCST, ERYSGT PYRNTR	Overall spray	BBCH 30 - 61	2 (14 days)	a) 1.5 b) 3.0	a) 97.5+ 97.5+195 b) 195+195+ 390	200 - 400	*	
25	Austria	Barley	F	ERYSGH, RHYNSE, PYRNTE PUCCHD, PSDCHE, RAMUCC, PUCCST,	Overall spray	BBCH 30 - 61	1	a) 1.2 b) 1.2	a) 78+ 78+156 b) 78+ 78+156	100 - 400	*	
26	Belgium	Barley	F	ERYSGH, RHYNSE, PYRNTE PUCCHD, PSDCHE, RAMUCC, PUCCST,	Overall spray	BBCH 30 - 61	1	a) 1.2 b) 1.2	a) 78+ 78+156 b) 78+ 78+156	100 - 400	*	
28	Netherlands	Barley	F	ERYSGH, RHYNSE, PYRNTE PUCCHD, PSDCHE, RAMUCC, PUCCST,	Overall spray	BBCH 30 - 61	1	a) 1.2 b) 1.2	a) 78+ 78+156 b) 78+ 78+156	200 - 400	*	
29	Poland	Barley	F	ERYSGH, RHYNSE, PYRNTE PUCCHD, PSDCHE, RAMUCC, PUCCST,	Overall spray	BBCH 30 - 61	1	a) 1.2 b) 1.2	a) 78+ 78+156 b) 78+ 78+156	200 - 400	*	0.8 – 1.2 L/ha
30	Slovenia	Barley	F	ERYSGH, RHYNSE, PYRNTE PUCCHD, PSDCHE, RAMUCC, PUCCST,	Overall spray	BBCH 30 - 61	1	a) 1.2 b) 1.2	a) 78+ 78+156 b) 78+ 78+156	100 - 400	*	
31	United Kingdom	Barley	F	ERYSGH, RHYNSE, PYRNTE PUCCHD, PSDCHE, RAMUCC,	Overall spray	BBCH 30 - 61	1	a) 1.2 b) 1.2	a) 78+ 78+156 b) 78+ 78+156	100 - 400	*	

				PUCCST,								
32	Austria	Oats	F	ERYSGH, RHYNSE, PYRNTE PUCCHD, PSDCHE, RAMUCC, PUCCST,	Overall spray	BBCH 30 - 61	1	a) 1.2 b) 1.2	a) 78+ 78+156 b) 78+ 78+156	100 - 400	*	
33	Belgium	Oats	F	ERYSGR, PSDCHE, PUCCCA,	Overall spray	BBCH 30 - 61	1	a) 1.2 b) 1.2	a) 78+ 78+156 b) 78+ 78+156	100 - 400	*	
35	Netherlands	Oats	F	ERYSGR, PSDCHE, PUCCCA,	Overall spray	BBCH 30 - 61	1	a) 1.2 b) 1.2	a) 78+ 78+156 b) 78+ 78+156	200 - 400	*	
36	Poland	Oats	F	ERYSGR, PSDCHE, PUCCCA,	Overall spray	BBCH 30 - 61	1	a) 1.2 b) 1.2	a) 78+ 78+156 b) 78+ 78+156	200 - 400	*	0.6 – 1.2 L/ha
37	Slovenia	Oats	F	ERYSGR, PSDCHE, PUCCCA,	Overall spray	BBCH 30 - 61	1	a) 1.2 b) 1.2	a) 78+ 78+156 b) 78+ 78+156	100 - 400	*	
38	United Kingdom	Oats	F	ERYSGR, PSDCHE, PUCCCA,	Overall spray	BBCH 30 - 61	1	a) 1.2 b) 1.2	a) 78+ 78+156 b) 78+ 78+156	100 - 400	*	

* as per growth stage

REGISTRATION REPORT
Part B

Section 5 Environmental Fate
Detailed summary of the risk assessment

Product code:	**Ascra Xpro / 102000027828**		
Active Substances:	**Bixafen**	**65**	**g/L**
	Fluopyram	**65**	**g/L**
	Prothioconazole	**130**	**g/L**

Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ADDENDUM – Germany

Applicant: Bayer CropScience
Date of application: May 2014

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Sec 5 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)

The exposure assessment of the plant protection product Ascra Xpro in its intended uses in cereals is documented in detail in the core assessment of the plant protection product Ascra Xpro dated from May 2017 performed by Germany.

This document comprises the risk assessment for groundwater and the exposure assessment of surface water and soil for authorization of the plant protection product Ascra Xpro in Germany according to uses listed in Appendix 3.

Regarding PECgw relevant risk mitigation measures, if necessary, are documented in this document. PECsoil, PECsw are used for risk assessment to derive specific risk mitigation measures if necessary (see National Addendum Germany, part B, section 6 and part A).

5.1 General Information on the formulation

Table 5.1-1: General information on the formulation Ascra Xpro

Code	102000027828		
Plant protection product	Ascra Xpro		
Applicant	Bayer CropScience		
Date of application	14/05/2014		
Formulation type (WP, EC, SC, …; density)	EC		
Active substances (as)	Bixafen	Fluopyram	Prothioconazole
Concentration of as (g/L)	65	65	130

Data pool/task force	-
Letter of access/cross reference	-

5.2 Proposed use pattern

The intended uses in Germany classified according the soil effective application rate (cumulative, disregarding degradation in soil) is presented in Table 5.2-1. Full details of the proposed uses that will be assessed is included in Appendix 3.

The intended uses in Germany (use No. 00-001 to 00-033) are covered by the core assessment performed by Germany.

Table 5.2-1: Classification of intended uses in Germany for Ascra Xpro

Group*	Crop/ growth stage	Application method / Drift scenario	Number of applications, Minimum application interval, interception, application time	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
A/ 00-001 to 00-007; 00-015 to 00-019	cereals (wheat, rye, triticale) BBCH 30-61	spraying / field crops	2 x, 14 d, 19.04. 1. 70 % 2. 70 %	Bixafen 2 x 97.5 = 195 Fluopyram 2 x 97.5 = 195 Prothioconazole 2 x 195 = 390	Bixafen 1. 29.25 2. 29.25 = 58.5 Fluopyram 1. 29.25 2. 29.25 = 58.5 Prothioconazole 1. 58.5 2. 58.5 = 117
B/ 00-008 to 00-014; 00-020 to 00-021	cereals (barley, oats) BBCH 30-61	spraying / field crops	1 x, 19.04. 70 %	Bixafen 78 Fluopyram 78 Prothioconazole 156	Bixafen 23.4 Fluopyram 23.4 Prothioconazole 46.8
C/ 00-022 to 00-033	cereals (wheat, rye, triticale) BBCH 30-61	spraying / field crops	1 x, 19.04. 70 %	Bixafen 97.5 Fluopyram 97.5 Prothioconazole 195	Bixafen 29.25 Fluopyram 29.25 Prothioconazole 58.5

* For administrative purposes, each intended use of a plant protection product in Germany is assigned with an individual use number from the German Federal Office of Consumer Protection and Food Safety (BVL). A complete list of the individual GAPs in Germany together with their assigned use numbers is given in Appendix 3 of this Addendum.

5.3 Information on the active substances

5.3.1 Bixafen

Please refer to the core assessment (May 2017), part B, section 5, chapter 5.3.1.

5.3.2 Fluopyram

Please refer to the core assessment (May 2017), part B, section 5, chapter 5.3.2.

5.3.3 Prothioconazole

Please refer to the core assessment (May 2017), part B, section 5, chapter 5.3.3.

5.4 Summary on input parameters for environmental exposure assessment

5.4.1 Rate of degradation in soil

5.4.1.1 Laboratory studies

Bixafen

Please refer to the core assessment (May 2017), part B, section 5, chapter 5.4.1.1.

Fluopyram

Please refer to the core assessment (May 2017), part B, section 5, chapter 5.4.1.1.

Prothioconazole

Please refer to the core assessment (May 2017), part B, section 5, chapter 5.4.1.1.

5.4.1.2 Field studies

Bixafen

Please refer to the core assessment (May 2017), part B, section 5, chapter 5.4.1.2.

Fluopyram

Please refer to the core assessment (May 2017), part B, section 5, chapter 5.4.1.2.

Prothioconazole

Please refer to the core assessment (May 2017), part B, section 5, chapter 5.4.1.2.

5.4.2 Adsorption/desorption

Bixafen

Please refer to the core assessment (May 2017), part B, section 5, point 5.4.2.

The K_{Foc} values were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

Table 5.4-1: K_F, K_{Foc} and 1/n (Freundlich exponent) values for Bixafen

Soil Type	OC (%)	pH (-)	K_F (mL g^{-1})	K_{Foc} (mL g^{-1})	1/n (-)	Reference
Sandy loam	1.3	6.5	42.8	3290	0.857	LoEP, Juni 2012
Silt loam	2.62	6.8	102.7	3920	0.876	
loam	2.07	6	72	3477	0.883	
Loamy sand	1.1	5.4	40.5	3682	0.885	
Clay loam	1.1	6.3	54.7	4974	0.882	
Arithmetic mean				3869	0.877	

Table 5.4-2: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite M44

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
LUFA 2.1, Sand	0.52	5.2	0.07	13.1	0.969	EFSA Conclusion, 2012
Li 10, Loamy Sand	0.88	5.9	0.04	4.8	0.842	
New Jersey, Silt Loam	0.90	6.3	0.13	14.1	1.165	
Nierswalde, Silt Loam	1.63	6.5	0.15	9	0.937	
LUFA 2.3,Sandy Loam	1.09	6.9	0.06	5.6	1.078	
La Gironda, Silty Clay Loam	3.84	7.5	0.04	1	0.99	
California, Sandy Loam	0.41	7.6	0.02	5.6	0.764	
Arithmetic mean				7.6	0.964	

Fluopyram

The K_{Foc} values were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products

and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

Table 5.4-3: K_F, K_{Foc} and 1/n (Freundlich exponent) values for Fluopyram

Soil Type	OC (%)	pH $_{H2O}$ (-)	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
Laacherhof AXXa, sandy loam	1.3	6.6	3.031	233.2	0.765	Henk and Haas (2005)
Hoefchen am Hohenseh, silt loam	2.6	6.7	6.825	260.5	0.838	
Laacherhof Wurmwiese, loam	2.1	6.0	4.839	233.7	0.849	
Pikeville, loamy sand	1.1	5.6	2.941	267.3	0.846	
Stilwell, clay loam	1.1	7.0	4.396	399.7	0.837	
Arithmetic mean (n=5)				**278.9**	**0.827**	

Table 5.4-4: Statistical values according to INPUT DECISION 3.3 for Fluopyram for PEC_{GW} modelling

Does the active substance dissociate?	no	
Correlation K_F and oc	Kendall-τ: 0.738 p-value: 0.065	not positive significant (p-value > significance level)
Coefficient of variation K_{Foc}	25 %	sufficiently low (≤ 60%)
Correlation K_F and pH	Kendall-τ: 0.400 p-value: 0.462	not significant (p-value > significance level)
Correlation K_F and other soil parameters (clay, CEC)	-	not relevant
K_{Foc}/K_F for PEC_{GW}	278.9	arithmetic mean all soils, n= 5
1/n PEC_{GW}	0.827	arithmetic mean all soils, n= 5

Table 5.4-5: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite M08 -7-hydroxy

Soil Type	OC (%)	pH (water)	K_d (mL/g)	K_{oc} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/n	Reference
Loam	1.1	6.7			0.991	90.1	0.9241	Heinemann and Dehner (2007)
Sandy loam	1.5	6.4			1.321	88.1	0.9391	
Silt loam	1.6	7.0			2.390	149.4	0.9104	
Sandy loam	1.6	5.3			1.362	85.1	0.9432	
Arithmetic mean (n=4)					**1.516**	**103.2**	**0.9292**	

Table 5.4-6: Statistical values according to INPUT DECISION 3.3 for metabolite M08 of Fluopyram for PEC_{GW} modelling

Does the active substance dissociate?	no	
Correlation K_F and oc	Kendall-τ: 0.913 p-value: 0.074	not positive significant (p-value > significance level)
Coefficient of variation K_{Foc}	30 %	sufficiently low (≤ 60%)
Correlation K_F and pH	Kendall-τ: 0.000 p-value: 1.000	not significant (p-value > significance level)
Correlation K_F and other soil parameters (clay, CEC)	-	not relevant
K_{Foc}/K_F for PEC_{GW}	103.2	arithmetic mean all soils, n= 4
1/n PEC_{GW}	0.929	arithmetic mean all soils, n= 4

Prothioconazole

Please refer to the core assessment (May 2017), part B, section 5, point 5.4.2.

The K_{Foc} values were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

Table 5.4-7: K_F, K_{Foc} and 1/n (Freundlich exponent) values for metabolite JAU6476-S-methyl (M01) of Prothioconazole

Soil Type	**OC (%)**	**pH (H_2O)**	**K_f (mL g^{-1})**	**K_{foc} (mL g^{-1})**	**1/n (-)**	**Reference**
Sandy loam	2.02	7.2	56.0	2772	0.87	Hein (1999)
Silt	2.14	7.1	64.1	2995	0.88	Hein (1999)
Silty clay loam	1.66	5.9	41.2	2482	0.91	Hein (1999)
Loamy sand	0.79	6.8	15.6	1975	0.85	Hein (1999)
Arithmetic mean				**2556**	**0.88**	

Table 5.4-8: Statistical values according to INPUT DECISION 3.3 for metabolite JAU6476-S-methyl (M01) of Prothioconazole for PEC_{GW} modelling

Does the active substance dissociate?	no	
correlation K_F and oc	Kendall-τ: 1.000 p-value: 0.500	not positive significant (p-value > significance level)
Coefficient of variation K_{Foc}	17 %	sufficiently low (≤ 60%)
Correlation K_F and pH	Kendall-τ: 0.333 p-value: 1.000	not significant (p-value > significance level)
Correlation K_F and other soil parameters (clay, CEC)	-	not relevant
K_{Foc}/K_F for PEC_{GW}	2556	arithmetic mean all soils, n= 4
1/n PEC_{GW}	0.878	arithmetic mean all soils, n= 4

Table 5.4-9: K_F, K_{Foc} and 1/n (Freundlich exponent) values for metabolite JAU6476-desthio (M04) of Prothioconazole

Soil Type	**OC (%)**	**pH (-)**	**K_f (mL g^{-1})**	**K_{foc} (mL g^{-1})**	**1/n (-)**	**Reference**
Sandy loam	2.02	7.2	12.46	617	0.79	Fent (1998)
Silt	2.14	7.1	13.38	625	0.83	Fent (1998)
Silty clay loam	1.66	5.9	8.9	536	0.83	Fent (1998)
Loamy sand	0.79	6.8	4.13	523	0.80	Fent (1998)
Arithmetic mean				**575**	**0.81**	

Table 5.4-10: Statistical values according to INPUT DECISION 3.3 for metabolite JAU6476-desthio (M04) of Prothioconazole for PEC_{GW} modelling

Does the active substance dissociate?	no	
correlation K_F and oc	Kendall-τ: 1.000 p-value: 0.045	significantly positive (p-value < significance level)
Coefficient of variation K_{Foc}	9 %	sufficiently low (≤ 60%)
Correlation K_F and pH	Kendall-τ: 0.333 p-value: 0.734	not significant (p-value > significance level)
Correlation K_F and other soil parameters (clay, CEC)	-	not relevant
K_{Foc}/K_F for PEC_{GW}	575	arithmetic mean all soils, n= 4
1/n PEC_{GW}	0.813	arithmetic mean all soils, n= 4

5.4.3 Rate of degradation in water/sediment

Bixafen

Please refer to the core assessment (May 2017) part B, section 5, point 5.4.3.

Accumulation of active substance and relevant metabolites in the sediment

active substance	Bixafen
accumulation potential in sediment	yes ($DT_{90,whole\ system}$ >1 year, see core assessment, part B, section 5, chapter 5.4.3)
accumulation factor (SFO) $\mathbf{f_{accu} = e^{-kt}/(1 - e^{-kt})}$	3.47 based on $DT_{50,\ whole\ system}$ = 1000d (maximum, see core assessment, part B, section 5, chapter 5.4.3), t = 365 d

Fluopyram

Please refer to the core assessment (May 2017), part B, section 5, point 5.4.3.

Accumulation of active substance and relevant metabolites in the sediment

active substance	Fluopyram
accumulation potential in sediment	yes ($DT_{90,whole\ system}$ > 1 year, see core assessment, part B, section 5, chapter 5.4.3)
accumulation factor (SFO) $\mathbf{f_{accu} = e^{-kt}/(1 - e^{-kt})}$	4.745 based on $DT_{50,\ whole\ system}$ = 1323 d (maximum, see core assessment, part B, section 5, chapter 5.4.3), t = 365 d

Prothioconazole

Please refer to the core assessment (May 2017), part B, section 5, point 5.4.3.

Accumulation of active substance and relevant metabolites in the sediment

active substance	Prothioconazole
accumulation potential in sediment	no ($DT_{90,whole\ system}$ < 1 year, see core assessment, part B, section 5, chapter 5.4.3)
accumulation factor (SFO) $\mathbf{f_{accu} = e^{-kt}/(1 - e^{-kt})}$	-

5.5 Estimation of concentrations in soil (KIIIA1 9.4)

Results of PECsoil calculation for Ascra Xpro according to EU assessment considering 5 cm soil depth are given in the core assessment (May 2017), part B, section 5, chapter 5.5.

For German exposure assessment the applied soil depth is based on experimental data (Fent, Löffler, Kubiak: Ermittlung der Eindringtiefe und Konzentrationsverteilung gesprühter Pflanzenschutzmittel-wirkstoffe in den Boden zur Berechnung des PEC-Boden. Abschlussbericht zum Forschungsvorhaben FKZ 360 03 018, UBA, Berlin 1999). Generally for active substances with a $K_{Foc} < 500$ a soil depth of 2.5 cm is applied whereas for active substances with a $K_{Foc} > 500$ a soil depth of 1 cm is applied. As soil bulk density 1.5 g cm^{-3} is assumed.

Due to the slow degradation of the active substance Bixafen in soil (DT_{90} > 365 d, field data) the accumulation potential of Bixafen needs to be considered. Therefore PEC_{soil} used for risk assessment comprises background concentration in soil (PEC_{accu}) considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops) and the maximum annual soil concentration PEC_{act} considering the relevant soil depth of 2.5 cm or 1.0 cm, respectively.

Due to the slow degradation of the active substance Fluopyram in soil (DT_{90} > 365 d, field data) the accumulation potential of Fluopyram needs to be considered. Therefore PEC_{soil} used for risk assessment comprises background concentration in soil (PEC_{accu}) considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops) and the maximum annual soil concentration PEC_{act} considering the relevant soil depth of 2.5 cm or 1.0 cm, respectively.

Due to the fast degradation of the active substance Prothioconazole in soil (DT_{90} < 365 d, SFO, field data) the accumulation potential of Prothioconazole does not need to be considered.

The PEC_{soil} calculations were performed with ESCAPE 2.0 based on the input parameters as presented in Table 5.5-1.

Table 5.5-1: Input parameters for Ascra Xpro for PEC_{soil} calculation

Active substance	**DT_{50}**
Bixafen	1235 d HS-Model (worst case, non-normalised DT50 from field dissipation studies - German trial) DT50 (D): K1 = 0.00810; K2 = 0.00023 BREAKPOINT (TB) = 53 d (DT50 = 1235 d)
Fluopyram	Fast phase: DT_{50}= 20.33 d Slow phase: DT_{50}= 495.1 d g= 0.1804 (DFOP, real. worst case, field studies, Vatteville, France)
Prothioconazole	2.4 d (SFO, Maximum field studies, non-normalised)
Metabolite JAU6476-S-methyl (M01)	23.1 d (90^{th} percentile, laboratory studies, 20 °C, pF2)
Metabolite JAU6476-desthio (M04)	57 d (SFO, Maximum field studies, non-normalised)

Table 5.5-2: Substance related input parameters for metabolites for PEC_{soil} calculation

Metabolite	**Molecular weight [g/mol]**	**Molar correction factor [-]**	**Maximum occurrence in soil [%]**
JAU6476-S-methyl (M01)	358.3	1.041	14.2

JAU6476-desthio (M04)	312.2	0.907	57.1

Additional $PEC_{soil,act}$ was calculated for the formulation Ascra Xpro for a soil depth of 2.5 cm. No short-term and long-term PEC_{soil} were calculated since $PEC_{soil,act}$ is considered sufficient for German risk assessment.

The calculated PEC_{soil} used for German risk assessment for Bixafen, Fluopyram and Prothioconazole as well as for the formulation Ascra Xpro are summarized in Table 5.5-3.

Table 5.5-3: Results of PEC_{soil} calculation for the intended use in cereals used for German risk assessment

plant protection product:		Ascra Xpro				
Use group:		A				
Number of applications/intervall:		2 x/ 14 d				
application rate:		Bixafen: 2 x 97.5 = 195 Fluopyram: 2 x 97.5 = 195 Prothioconazole: 2 x 195 = 390 Ascra Xpro: 2 x 1515 = 3030*				
crop interception:		2 x 70%				
active substance/ formulation	**soil relevant application rate (g/ha)**	**soil $depth_{act}$ (cm)**	**PEC_{act} (mg/kg)**	**tillage depth (cm)**	**PEC_{bkgd} (mg/kg)**	**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)**
Ascra Xpro	2 x 455	1.0	6.0667	-	-	-
Ascra Xpro	2 x 455	2.5	2.4267	-	-	-
Bixafen**	2 x 29.25	1.0	0.3885	20	0.7566	1.1451
Fluopyram	2 x 29.25	2.5	0.1494	20	0.0235	0.1730
Prothioconazole	2 x 58.5	1.0	0.3968	-	-	-
JAU6476-S-methyl (M01)	2 x 8.6	1.0	0.0950	-	-	-
JAU6476-desthio (M04)	2 x 30.3	1.0	0.3724	-	-	-

* Ascra Xpro-density: 1.010 g/ml, 1.5 L/ha applied

**Calculation see table below

Table 5.5-4: Results of PECaccu $_{soil}$ calculation for Bixafen

active substance/ formulation	**soil relevant application rate (g/ha)**	**soil $depth_{act}$ (cm)**	**PEC_{act} (mg/kg)**	**Factor accumulation in soil after 8 years**	**PEC_{bkgd} (mg/kg)**	**PEC_{bkgd} after 8 years +20%**
Bixafen	2 x 29.25	1	***0.3885***			
		20	0.0194	3.7	0.07178	0.07566

active substance/ formulation	soil relevant application rate (g/ha)	soil $depth_{act}$ (cm)	Factor for uncertainty	PECbkgd after 8 years +20% x 10 (mg/kg)	PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg
Bixafen	2 x 29.25	5			
		20	10	***0.7566***	**1.1451**

5.6 Estimation of concentrations in surface water and sediment (KIIIA1 9.7)

Results of PECsw calculation of Bixafen, Fluopyram and Prothioconazole for the intended uses of Ascra Xpro in cereals using FOCUS Surface Water are given in the core assessment (May 2017), part B, section 5, chapter 5.6.

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilisation with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route.

Surface water exposure via spray drift and volatilization with subsequent deposition is estimated with the model EVA 2.1. Surface water exposure via surface run-off and drainage is estimated using the model EXPOSIT 3.0.

The German surface water exposure assessment is outlined in the following chapters.

5.6.1 PEC_{SW} after exposure by spraydrift and volatilization with subsequent deposition

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. The vapour pressure at 20 °C of the active substance Bixafen is < 10^{-5} Pa. Hence the active substance Bixafen is regarded as non-volatile. Therefore exposure of surface water by the active substance Bixafen due to volatilization with subsequent deposition does not need to be considered.

The vapour pressure at 20 °C of the active substance Fluopyram is < 10^{-5} Pa. Hence the active substance Fluopyram is regarded as non-volatile. Therefore exposure of surface water by the active substance Fluopyram due to volatilization with subsequent deposition does not need to be considered.

The vapour pressure at 20 °C of the active substance Prothioconazole is < 10^{-5} Pa. Hence the active substance Prothioconazole is regarded as non-volatile. Therefore exposure of surface water by the active substance Prothioconazole due to volatilization with subsequent deposition does not need to be considered.

The calculation of PECsw after exposure via spray drift and volatilization with subsequent deposition is performed using the model EVA 3. For a single application, the exposure assessment via spray drift is based on the application rate in conjunction with the 90th percentile of the drift values. For multiple applications, lower percentiles of the drift values for each application are applied, resulting in an overall 90th percentile of drift probabilities. Only one volatilization event following the last use of pesticide is generally considered.

The endpoints used for modelling of surface water exposure via spray drift and volatilization with subsequent deposition with EVA 3 are summarized below.

Table 5.6-1: Endpoints of Bixafen used for the PEC_{SW} calculations with EVA 3

Parameter	Bixafen	Reference
vapour pressure at 20°C (Pa)	not required since no v/d	See EU endpoint
Solubility in water at 20°C (mg/L)	not required since no v/d	
$DissT_{50}$ water (d)	27.4	SFO (worst case) see core assessment, section 5, chapter 5.4.3
$DegT_{50}$ water/sediment study, total system (d)	1000 (default)	SFO (worst case) see core assessment, section 5, chapter 5.4.3

Table 5.6-2: Endpoints of Fluopyram used for the PEC_{SW} calculations with EVA 3

Parameter	Fluopyram	Reference
Vapour pressure at 20 °C (Pa)	not required since no v/d	
Solubility in water at 20 °C (mg/L)	not required since no v/d	
$DissT_{50}$ water (d)	26	SFO (worst case), see core assessment, section 5, chapter 5.4.3
$DegT_{50}$ water/sediment study, total system (d)	1470	SFO (worst case), see core assessment, section 5, chapter 5.4.3

Table 5.6-3: Endpoints of Prothioconazole used for the PEC_{SW} calculations with EVA 3

Parameter	Prothioconazole	Reference
vapour pressure at 20 °C (Pa)	not required since no v/d	
Solubility in water at 20 °C (mg/L)	not required since no v/d	
$DissT_{50}$ water (d)	1.0	SFO (worst case), see core assessment, section 5, chapter 5.4.3
$DegT_{50}$ water/sediment study, total system (d)	24.1	SFO (worst case), see core assessment, section 5, chapter 5.4.3

The calculated PECsw values after exposure via spray drift for Bixafen, Fluopyram and Prothioconazole for the intended use of Ascra Xpro in cereals according to use No. A are presented in the National addendum Germany, part B, section 6, chapter 6.5 considering the following input parameters related to the application.

Table 5.6-4: Input parameters for Ascra Xpro used for PEC_{SW} calculations with EVA 3

Use No.:	A (worst case)
Number of applications/ interval:	2x, 14 d
Application rate (g a.s./ha)	Bixafen: 2 x 97.5 = 195 Fluopyram: 2 x 97.5 = 195 Prothioconazole: 2 x 195 = 390
Drift scenario:	Arable crops

5.6.2 PECsw after exposure by surface run-off and drainage

The concentration of the active substance Bixafen, Fluopyram and Prothioconazole in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.01.

The substance specific input parameters used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.01 are summarized in chapter 5.7.2 of this document.

The calculated PEC_{SW} in an adjacent ditch due to surface run-off and drainage for the active substances Bixafen, Fluopyram and Prothioconazole for the intended use of Ascra Xpro in cereals according to use No. A are presented in the National addendum Germany, part B, section 6, chapter 6.5 considering the following input parameters related to the application.

Table 5.6-5: Input parameters related to the application for PEC_{sw} calculations with Exposit 3.01

Use No.:	A (worst case)
Number of applications/ interval:	2x, 14 d
Application rate: **(g a.s./ha)**	Bixafen: 2 x 97.5 = 195 Fluopyram: 2 x 97.5 = 195 Prothioconazole: 2 x 195 = 390
Crop interception:	2 x 70%

5.7 Risk assessment for groundwater (KIIIA1 9.6)

Results of the PECgw calculation of Bixafen, Fluopyram and Prothioconazole for the intended uses of Ascra Xpro in cereals according to EU assessment using FOCUS PELMO are given in the core assessment (May 2017), part B, section 5, chapter 5.7.

For authorization in Germany, risk assessment for groundwater considers two pathways, (i) direct leaching of the active substance into the groundwater after soil passage and (ii) surface run-off and drainage of the active substance into an adjacent ditch with subsequent bank filtration into the groundwater.

Direct leaching after soil passage is assessed following the recommendations of the publication of Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011) for tier 1 and tier 2 risk assessment. According to Hold et al, 2011, endpoints for groundwater modelling are derived with the program INPUT DECISION 3.1 and subsequent simulations are performed for the groundwater scenarios "Hamburg" or with the scenarios "Hamburg" and "Kremsmünster" of FOCUS PELMO.

In tier 3 risk assessment, results of experimental studies (lysimeter studies and/or field leaching studies) can also be considered in German groundwater risk assessment.

Surface run-off and drainage into an adjacent ditch with subsequent bank filtration into the groundwater are estimated using the model EXPOSIT 3.

The German risk assessment for groundwater is given in the following chapters.

5.7.1 Direct leaching into groundwater

5.7.1.1 PEC_{GW} modelling

The worst case scenario used for PECgw modelling is summarized in Table 5.7-1. It covers the intended uses of Ascra Xpro in cereals according to Table 5.2-1 (see also Appendix 3).

Table 5.7-1: Input parameters related to application for PEC_{GW} modelling with FOCUS PELMO 5.5.3

Use evaluated	A
Application rate (kg as/ha)	Bixafen: 2 x 97.5 = 195 Fluopyram: 2 x 97.5 = 195 Prothioconazole: 2 x 195 = 390
Crop (crop rotation)	cereals
Date(s) of application(s)	relative application dates used, 169 and 183 days after emergence, Hamburg scenario: 19.04. and 03.05.
Number of applications/interval:	2 x / 14 d
Interception (%)	2 x 70 %
Soil effective application rate (g as/ha)	Bixafen: 2 x 29.25 = 58.5 Fluopyram: 2 x 29.25 = 58.5 Prothioconazole: 2 x 58.5 = 117
Soil moisture	100 % FC
Q10-factor	2.58
Moisture exponent	0.7

Plant uptake	0
Simulation period (years)	26

Bixafen

Please refer to the core assessment (May 2017), part B, section 5, chapter 5.7.1.

Fluopyram

Please refer to the core assessment (May 2017), part B, section 5, chapter 5.7.1.

Prothioconazole

Please refer to the core assessment (May 2017), part B, section 5, chapter 5.7.1.

5.7.1.2 Experimental data to the leaching behaviour

Bixafen

Not required.

Fluopyram

Not required.

Prothioconazole

Not required.

5.7.1.3 Summary on risk assessment for groundwater after direct leaching

Results of modelling with FOCUS PELMO 5.5.3 show that the active substance Bixafen is not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended of Ascra Xpro uses in cereals according to use No.A.

For the metabolite M44 concentrations of ≥ 0.1µg/L in groundwater cannot be excluded.

Results of modelling with FOCUS PELMO 5.5.3 show that the active substance Fluopyram is not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended of Ascra Xpro uses in cereals according to use group A.

For the metabolite M08 concentrations of ≥ 0.1µg/L in groundwater can be excluded.

Results of modelling with FOCUS PELMO 5.5.3 show that the active substance Prothioconazole is not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended of Ascra Xpro uses in cereals according to use group A.

For the metabolites JAU6476-S-methyl (M01) and JAU6476-desthio (M04) concentrations of ≥ 0.1µg/L in groundwater can be excluded.

Consequences for authorization:

-

5.7.2 Ground water contamination by bank filtration due to surface water exposure via run-off and drainage

Bixafen

The input parameters for Bixafen used for modelling surface water exposure via run-off and drainage in an adjacent ditch with subsequent bank filtration into the groundwater with EXPOSIT 3.01 are summarized in Table 5.7-2.

Table 5.7-2: Input parameters for Bixafen used for PEC_{GW} calculations with EXPOSIT 3.01

Parameter	Bixafen	Reference
$K_{Foc, Runoff}$	3869	arithm. mean (see core assessment, section 5, chapter 5.4.2)
$K_{Foc, mobility class}$	3869	arithm. mean (see core assessment, section 5, chapter 5.4.2)
DT_{50} soil (d)	1235	
Solubility in water (mg/L)	0.49	
Mobility class	1	
Reduction by bank filtration	100%	

As the reduction by bank filtration is assumed to be 100 % for Bixafen, no calculation is necessary.

Fluopyram

The input parameters for Fluopyram used for modelling surface water exposure via run-off and drainage in an adjacent ditch with subsequent bank filtration into the groundwater with EXPOSIT 3.01 are summarized in Table 5.7-3.

Table 5.7-3: Input parameters for Fluopyram used for PEC_{GW} calculations with EXPOSIT 3.01

Parameter	Fluopyram	Reference
$K_{Foc, Runoff}$	278.9	arithm. mean (see core assessment, section 5, chapter 5.4.2)
$K_{Foc, mobility class}$	278.9	arithm. mean (see core assessment, section 5, chapter 5.4.2)
DT_{50} soil (d)	495.1	slow phase DFOP, field studies, Vatteville, France
Solubility in water (mg/L)	16	Table 5.3-6 core assessment, pH7
Mobility class	2	default

Reduction by bank filtration	75%	default

The calculated PECgw for Fluopyram after surface run-off and drainage with subsequent bank filtration are summarized in Table 5.7-4.

Table 5.7-4: PEC_{gw} for Fluopyram after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Active substance		**Fluopyram**			
Use No.	**application rate interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**time of application**	**bank filtrate (µg/L)**
A/ cereals	2 x 97.5 g/ha, 2 x 70 %	0	0.010	spring/summer	0.004
		5	-		
		10	-	autumn/winter/ early spring	0.011
		20	-		
Required labelling		none			

According modelling with EXPOSIT 3.01, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance Fluopyram due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Metabolites of Fluopyram

No soil metabolites of Fluopyram are formed >10 % in soil. Therefore potential ground water contamination due to bank filtration via surface water exposure by run-off and drainage does not need to be assessed.

Prothioconazole

The input parameters for Prothioconazole used for modelling surface water exposure via run-off and drainage in an adjacent ditch with subsequent bank filtration into the groundwater with EXPOSIT 3.01 are summarized in Table 5.7-5.

Table 5.7-5: Input parameters for Prothioconazole used for PEC_{GW} calculations with EXPOSIT 3.01

Parameter	**Prothioconazole**	**Reference**
$K_{Foc, Runoff}$	1765	based on aged soil column leaching study (see core assessment, section 5, chapter 5.4.2)
$K_{Foc, mobility class}$	1765	based on aged soil column leaching study (see core assessment, section 5, chapter 5.4.2)
DT_{50} soil (d)	2.4	Maximum field studies (see core assessment, section 5, chapter 5.4.1.2)
Solubility in water (mg/L)	300	
Mobility class	1	
Reduction by bank filtration	100%	

As the reduction by bank filtration is assumed to be 100 % for Prothioconazole, no calculation is necessary.

According modelling with EXPOSIT 3.01, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance Prothioconazole due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Metabolites of Prothioconazole

The soil metabolites of Prothioconazole (see core assessment, part B, section 5, point 5.3.3.3) are formed >10 % in soil. Therefore potential ground water contamination due to bank filtration via surface water exposure by run-off and drainage needs to be assessed using EXPOSIT 3.01.

The input parameter for the model EXPOSIT 3.01 are summarized in Table 5.7-6 and Table 5.7-7.

Table 5.7-6: Input parameter for soil metabolite JAU6476-S-methyl (M01) of Prothioconazole for EXPOSIT 3.01

Parameter	Metabolite JAU6476-S-methyl (M01)	Reference
Molecular weight (g/mol)	358.3	
Correction factor molecular weight	1.041	
Maximum occurrence in soil (%)	14.2	
$K_{Foc, Runoff}$	2556	arithmetic mean
$K_{Foc, mobility\ class}$	2556	arithmetic mean
DT_{50} soil (d)	23.1	90th percentile, laboratory data
Solubility in water (mg/L)	1.5	
Mobility class	1	
Reduction by bank filtration	100 %	

As the reduction by bank filtration is assumed to be 100 % for metabolite JAU6476-S-methyl (M01), no calculation is necessary.

Table 5.7-7: Input parameter for soil metabolite JAU6476-desthio (M04) of Prothioconazole for EXPOSIT 3.01

Parameter	Metabolite JAU6476-desthio (M04)	Reference
Molecular weight (g/mol)	312.2	
Correction factor molecular weight	0.907	
Maximum occurrence in soil (%)	57.1	
$K_{Foc, Runoff}$	575	arithmetic mean
$K_{Foc, mobility\ class}$	575	arithmetic mean
DT_{50} soil (d)	57	Maximum field studies
Solubility in water (mg/L)	50.6	
Mobility class	1	
Reduction by bank filtration	100 %	

As the reduction by bank filtration is assumed to be 100 % for metabolite JAU6476-desthio (M04), no calculation is necessary.

According to modelling with EXPOSIT 3, groundwater contamination at concentrations ≥ 0.1 µg/L by the soil metabolites of Prothioconazole due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Consequences for authorization:

None.

Appendix 1 List of data submitted in support of the evaluation

No additional data for national assessment submitted.

Appendix 2 Detailed evaluation of studies relied upon

Report only studies, which have not previously been evaluated within a peer reviewed process at EU level (Annex I inclusion of active substance).

PECgw calculations were performed by Germany. The study by Scherr and Ellerich (2014) is used as information only.

Appendix 3 Table of Intended Uses in Germany (according to BVL 13.02.2015)

GAP rev. (2), date: 2015-02-13

PPP (product name/code)	**Ascra Xpro**	**Formulation type:**	**EC**
active substance 1	**Prothioconazole**	**Conc. of as 1:**	**130 g/L**
active substance 2	**Fluopyram**	**Conc. of as 2:**	**65 g/L**
active substance 3	**Bixafen**	**Conc. of as 3:**	**65 g/L**
Applicant:	**Bayer CropScience**	**professional use**	☒
Zone(s):	**central EU**	**non professional use**	☐

Verified by MS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	wheat TRZSS	F	stem break of cereals *Pseudocercosporella herpotrichoides* PSDCHE	spraying	BBCH 30 - 32 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 2	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F	
002	DE	wheat TRZSS	F	powdery mildew *Erysiphe graminis*	spraying	BBCH 30 - 61	a) 2 b) 2	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha	100 - 400	F	

				ERYSGR		from spring at beginning of infestation and/or when first symptoms become visible	(14 - 21 d)		as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha			
003	DE	wheat TRZSS	F	leaf spot of wheat *Septoria tritici* SEPTTR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F	
004	DE	wheat TRZSS	F	tan spot of cereals *Drechslera tritici-repentis* PYRNTR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F	
005	DE	wheat TRZSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha	100 - 400	F	

						when first symptoms become visible			as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha			
006	DE	wheat TRZSS	F	stripe rust of grasses *Puccinia striiformis* PUCCST	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F	
007	DE	wheat TRZSS	F	septoria leaf spot *Septoria nodorum* LEPTNO	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F	
008	DE	barley HORVX	F	stem break of cereals *Pseudocercosporella herpotrichoides* PSDCHE	spraying	BBCH 30 - 34 from spring at beginning of infestation and/or when first	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha	100 - 400	F	

						symptoms become visible			b)) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha			
009	DE	barley HORVX	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b)) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha	100 - 400	F	
010	DE	barley HORVX	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b)) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha	100 - 400	F	
011	DE	barley HORVX	F	net blotch *Pyrenophora teres* PYRNTE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b)) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha	100 - 400	F	
012	DE	barley HORVX	F	brown rust of barley *Puccinia hordei* PUCCHD	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b)) as1: 156 g as/ha	100 - 400	F	

									as2: 78 g as/ha as3: 78 g as/ha			
013	DE	barley HORVX	F	Ramularia leaf spot disease *Ramularia collo-cygni* RAMUCC	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b)) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha	100 - 400	F	
014	DE	barley HORVX	F	decrease of non-parasitic leaf spots YBFMI	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b)) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha	100 - 400	F	
015	DE	rye SECCE	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F	
016	DE	rye SECCE	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F	

						symptoms become visible			b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha			
017	DE	triticale TTLSS	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F	
018	DE	triticale TTLSS	F	septoria-species *Septoria spp.* SEPTSP	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F	
019	DE	triticale TTLSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha	100 - 400	F	

									as2: 195 g as/ha as3: 195 g as/ha			
020	DE	oat AVESS	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b)) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha	100 - 400	F	
021	DE	oat AVESS	F	crown rust of oats *Puccinia coraonata* PUCCCA	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b)) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha	100 - 400	F	
022	DE	wheat TRZSS	F	stem break of cereals *Pseudocercosporella herpotrichoides* PSDCHE	spraying	BBCH 30 - 32 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F	
023	DE	wheat TRZSS	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha	100 - 400	F	

						when first symptoms become visible			as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha			
024	DE	wheat TRZSS	F	leaf spot of wheat *Septoria tritici* SEPTTR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F	
025	DE	wheat TRZSS	F	tan spot of cereals *Drechslera tritici-repentis* PYRNTR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F	
026	DE	wheat TRZSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha	100 - 400	F	

						symptoms become visible			as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha			
027	DE	wheat TRZSS	F	stripe rust of grasses *Puccinia striiformis* PUCCST	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F	
028	DE	wheat TRZSS	F	septoria leaf spot *Septoria nodorum* LEPTNO	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F	
029	DE	rye SECCE	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha	100 - 400	F	

						symptoms become visible			as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha			
030	DE	rye SECCE	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F	
031	DE	triticale TTLSS	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F	
032	DE	triticale TTLSS	F	septoria-species *Septoria spp.* SEPTSP	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha	100 - 400	F	

						symptoms become visible			as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha			
033	DE	triticale TTLSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F	

Remarks:
(1) Numeration of uses in accordance with the application/as verified by MS
(2) Member State(s) or zone for which use is applied for
(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(4) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(5) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds, developmental stages
(6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(7) Growth stage of treatment(s) (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(8) The maximum number of applications possible under practical conditions of use for each single application and per year (permanent crops) or crop (annual crops) must be provided
(9) Min. interval between applications (days) were relevant
(10) The application rate of the product a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. kg or L product / ha)
(11) The application rate of the active substance a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. g or kg / ha)
(12) The range (min/max) of water volume under practical conditions of use must be given (L/ha)
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions/minor use etc.

DRAFT REGISTRATION REPORT
Part B

Section 6: Ecotoxicological studies
Detailed summary of the risk assessment

Product name: Ascra XPro
Product code: 102000027828 EC 260
Active Substances: Bixafen 65 g/L
Fluopyram 65 g/L
Prothioconazole 130 g/L

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Bayer Crop Science
Application Date: 14/05/2014

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Sec 6 ECOTOXICOLOGICAL STUDIES (MIIIA 10)

This document reviews the ecotoxicological studies for the product Ascra XPro containing the active substances bixafen and prothioconazole, which are currently approved under Reg. (EC) No 1107/2009 (repealing Directive 91/414/EEC) and fulfil the criteria according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2.

Ascra XPro was not the representative formulation considered in the EU review process as part of the approval of the active substances bixafen or prothioconazole.

The studies with the relevant endpoints for each non-target organism group were agreed during EU review process and are used for the risk assessment. Reference is made to the following documents, if not otherwise labelled with an asterisk:

Bixafen: EFSA Journal 2012;10(11):2917

Prothioconazole: EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of prothioconazole

Full details of toxicity studies are provided in the respective EU DAR. The applicant provides further studies with the formulation Ascra XPro and for relevant metabolites of the active substances. Detailed study summaries for the studies performed with the formulated product Ascra XPro and for other new studies are presented in Appendix 2.

6.1 GAP and overall conclusions

6.1.1 Table of intended uses

Table 6.1-1: GAP and overall conclusions

Intended use	F/G	Timing (months, BBCH)	Max number appl. (interval in days)	Application per treatment		Overall conclusions						
				a) g a.s./ha/ application b)g a.i./ crop or year	Rate/season a) L/ha / application b) L/ha/crop or year	Birds	Aquatic organisms	Mammals	Bees	Non-target arthropods	Soil organisms	Non-target plants
Zonal uses												
Wheat, Rye, Triticale, Spelt	F	30-61	2 (14 days)	a) 97.5+ 97.5+195 b) 195+195+ 390	a) 1.5 b) 3.0		20 m runoff buffer required				National fate and effect monitoring recommended	
Barley, Oats	F	30-61	1	a) 78+ 78+156 b) 78+ 78+156	a) 1.2 b) 1.2							
National uses (zRMS Germany)												
00-001, 00-022		30-32	1	a) 97.5+ 97.5+195 b) 97.5+ 97.5+195	a) 1.5 b) 1.5						National fate and effect monitoring required	

Intended use	F/G	Timing (months, BBCH)	Max number appl. (interval in days)	Application per treatment		Overall conclusions						
				a) g a.s./ha/ application b)g a.i./ crop or year	Rate/season a) L/ha / application b) L/ha/crop or year	Birds	Aquatic organisms	Mammals	Bees	Non-target arthropods	Soil organisms	Non-target plants
00-023, 00-024, 00-025, 00-026, 00-027, 00-028, 00-029, 00-030, 00-031, 00-032, 00-033		30-61	1	a) 97.5+ 97.5+195 b) 97.5+ 97.5+195	a) 1.5 b) 1.5						National fate and effect monitoring required	
00-002, 00-003, 00-004 00-005, 00-006 00-007, 00-015, 00-016, 00-017, 00-018, 00-019	F	30-61	2 (14 days)	a) 97.5+ 97.5+195 b) 195+195+ 390	a) 1.5 b) 3.0						National fate and effect monitoring required	
00-008, 00-009, 00-010, 00-011 00-012, 00-013, 00-014 00-020, 00-021	F	30-61	1	a) 78+ 78+156 b) 78+ 78+156	a) 1.2 b) 1.2						National fate and effect monitoring required	

F: Field use; G: Glasshouse use

Remarks:

Safe use identified

Further refinement and/or risk mitigation measures are needed

No safe use identified and considered possible

Explanations:

The colours in the Table 6-1 are intended to reflect the outcome of the assessments including the available and valid refinement steps and risk mitigations measures.

6.1.2 Overall conclusions

6.1.2.1 Fehler! Verweisquelle konnte nicht gefunden werden., Fehler! Verweisquelle konnte nicht gefunden werden., Fehler! Verweisquelle konnte nicht gefunden werden.

Based on the screening and tier 1 assessment step, the calculated TER values for the acute and long-term risk resulting from an exposure of birds and mammals to bixafen, fluopyram and prothioconazole (oral exposure from contaminated feed items) according to the GAP of the formulation Ascra XPro achieve the acceptability criteria TER ≥ 10 resp. TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for acute and chronic effects. A refined assessment was necessary for the long-term risk from the metabolite JAU 6476-desthio. Under consideration of its short half-life on cerals the calculated TER values met the required trigger of TER ≥ 5.

The results of the assessment indicate an acceptable acute and long-term risk for birds and mammals due to the intended use of Ascra XPro in cereals according to the label.

Regarding the exposure via drinking water, due to the characterisics of the active substances no specific risk assessment was required.

Based on the calculation of the risk arising from secondary poisoning , the calculated TER values for birds and mammals exposed to the active substances bixafen, fluopyram and prothioconazole as well as the prothioconazole-metabolites JAU 6476-desthio and JAU-6476-S-methyl according to the GAP of the formulation Ascra XPro achieve the acceptability criteria TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for long-term effects.

6.1.2.2 Fehler! Verweisquelle konnte nicht gefunden werden.

The risk for aquatic organisms was assessed based on the active substances bixafen, fluopyram and prothioconazole. The chronic risk from bixafen and the prothioconazole-metabolite JAU 6476-desthio (M04) were key drivers of the risk from the use of the formulation Ascra XPro, as the TER triggers were met only with FOCUS Step 4 calculations. Risk mitigation measures have to be implemented.

TER calculations lead to the following risk mitigation requirements

- multiple use in winter cereals (use group A): 20 m buffer zone
- single use in winter cereals, single and multiple use in spring cereals (use group B): 10 m buffer zone

6.1.2.3 Fehler! Verweisquelle konnte nicht gefunden werden.

6.1.2.4 Fehler! Verweisquelle konnte nicht gefunden werden.

In-field

Based on the calculated rates of Ascra XPro in-field, the comparison between experimental effect values and predicted exposure concentrations indicate a risk to sensitive non-target arthropod species. The applicant provided an extrapolation based on conservative estimations that a recolonization of treated areas can be possible two weeks after the second treatment with the formulation Ascra XPro. The applicant furthermore provided higher tier studies with a similar formulation that resulted in effects < 50 % at higher predicted exposure concentrations than expected from the use of Ascra XPro according to the GAP. Therefore, an acceptable in-field risk to non-target arthropods can be concluded.

However, specific environmental conditions in some MS may require risk mitigation measures to ensure the protection goals are met.

Off-field

Based on the calculated rates of Ascra XPro in off-field areas, the calculated HQ and TER values describing the risk resulting from an exposure of non-target arthropods to Ascra XPro according to the GAP of the formulation Ascra XPro achieve the acceptability criteria HQ ≤ 2 (Tier 1)/ of less than 50% effects at calculated drift rates (higher Tier) and of TER ≥ 10 (Tier 1), according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target arthropods due to the intended use of Ascra XPro in cereals according to the label.

6.1.2.5 Fehler! Verweisquelle konnte nicht gefunden werden., Fehler! Verweisquelle konnte nicht gefunden werden.

Based on standard assumptions for calculating the predicted concentrations of the active substances, their metabolites as well as the product Ascra XPro in soil, all TER values meet the required trigger of ≥ 10 and 5, respectively, and an acceptable risk can be concluded.

However, it has to be pointed out that due to the uncertainties regarding the fate studies of bixafen in soils, an additional safety factor has been included in the PEC calculations addressing the high persistency of the active substance. If the safety factor is included in the calculation of the predicted concentrations in soil, a high risk to soil macro-organisms from bixafen is indicated. In oder to address these uncertainties monitoring studies are recommended on national level regarding the fate and ecotoxicologal impacts of the formulation.

6.1.2.6 Fehler! Verweisquelle konnte nicht gefunden werden.

Based on the predicted rates of Ascra XPro in off-field areas, the TER values describing the risk for non-target plants following exposure to Ascra XPro according to the GAP of the formulation achieve the acceptability criteria TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of Ascra XPro in cereals according to the label.

6.1.2.7 Fehler! Verweisquelle konnte nicht gefunden werden.

No information. Not required.

6.1.3 Grouping of intended uses for risk assessment

The following table lists the grouping of the intended uses in order to perform a risk envelope approach.

Table 6.1-2: Critical use pattern of Ascra XPro

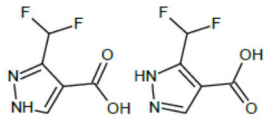
Group/use No.	Crop/growth stage/interception	Application method/drift scenario	Application rate, cumulative (g a.s./ha)
A: 2 x 1.5 L/ha	cereals (wheat, rye, triticale, spelt) BBCH 30-61	spraying / field crops	2 x, 14 d, 19.04. 1. 70 % 2. 70 %
B: 1 x 1.2 L/ha	cereals (barley, oats) BBCH 30-61	spraying / field crops	1 x, 19.04. 70 %
C 1 x 1.5 L	Cereals (wheat, rye, triticale) BBCH 30 - 61	spraying / field crops	1 x, 19.04. 70 %

6.1.4 Consideration of metabolites

The metabolites which require an ecotoxicological assessment according to the endpoint list are given below.

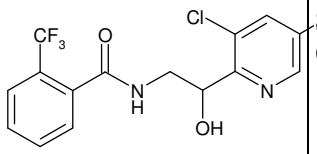
Table 6.1-3: Metabolites of bixafen potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of a.s. and maximum of formation not yet reached at the end of the study)

Metabolite	Structural formula/Molecular formula	occurrence in compartments (Max. at day/	Status of Relevance

M44		Soil Max. 2.9 % at the end of study	No data were available in the DAR of bixafen (EFSA Journal 2012;10(11):2917), Data from EFSA Journal 2012;10(1):2522 European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance fluxapyroxad (BAS 700 F) (EFSA 2012): LC50/EC50 on fish, daphnia: >100 mg/L, EC50 on algae 22.44- 26.52 mg/L Groundwater[1)]: risk assessed as low to the aquatic environment

[1)] According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

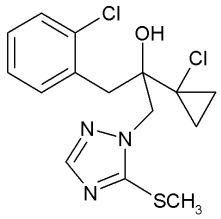
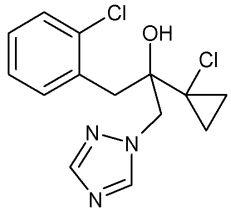
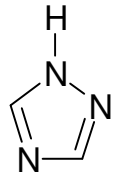
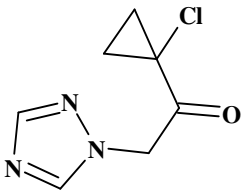
Table 6.1-4: Metabolites of fluopyram potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of a.s. and maximum of formation not yet reached at the end of the study)

Metabolite	Structural formula/Molecular formula	occurrence in compartments (Max. at day/	Status of Relevance (SANCO/11456/2013 rev 2 – 16/07/2013)
M08 AE C656948-7-hydroxy	 $C_{16}H_{11}ClF_6N_2O_2$ 412.72 g/mol	Soil: < 5% (4.2% at 62 d)	Aquatic organisms: Water: not applicable Sediment: not applicable Terrestrial organisms: not applicable Groundwater: not relevant (Step 2)[1)]

1) According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

Table 6.1-5: Metabolites of prothioconazole potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of a.s. and maximum of formation not yet reached at the end of the study)

Metabolite	Structural formula/Molecular formula	occurrence in compartments (Max. at day/	Status of Relevance (EFSA Scientific Report (2007) 106)

M01 JAU6476-S-methyl WAK7861	 C_{15} H_{17} Cl_2 N_3OS 358.3 g/mol	Soil: Max. 14.6 % at day 7 Sediment: Max. 9.6 % at day 7 (2x >5%)	Aquatic organisms: not relevant Terrestrial organisms: not relevant Groundwater: not relevant (Step 2)[1)]
M04 JAU 6476-desthio SXX 0665	 C_{14} H_{15} Cl_2 N_3O 312.2 g/mol	Soil: Max. 49.4 % at day 4 (lab) Max. 57 % (field studies) Water: Max. 32.3 % at day 7 Sediment: Max. 26.9 % at day 14 Photolysis: Max. 55.7 %	Aquatic organisms: ecotoxicological relevant Terrestrial organisms: not relevant Groundwater: toxicological relevant ecotoxicological relevant (Step 2)[1)]
M13 1,2,4-Triazole CGA 71019	 $C_2H_3N_3$ 69.1 g/mol	Water: Max. 37.2 % at day 121 Sediment: Max. 6.1 % at day 121 Photolysis: Max. 11.9 %	Aquatic organisms: not relevant
M42, M6a JAU 6476-triazolylketone WAK4995	 C_7 H_8 Cl N_3O 185.6 g/mol	Water: Max. 8 % at day 56, 5.6 % at day 121 (subsequent) Sediment: Max. 5.8 % at day 121	

[1)] According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

6.2 Effects on birds (MIIIA 10.1, KPC 10.1, KPC 10.1.1)

Table 6.2-1: Endpoints used for risk assessment for birds

Species	Substance	Exposure System	Results	Reference	Internal code
Colinus virginianus	Bixafen	Acute toxicity	LD_{50} > 2000 mg/kg bw	XXX 20.12.2005 E 204 2937-7	69475
Colinus virginianus	Bixafen	Short-term	LD_{50} > 1159 mg/kg bw	XXX 25.01.2006 E 206 2934-6	69622
Colinus virginianus	Bixafen	Reproductive toxicity	NOEC = 24.5 mg/kg bw/d	XXX 23.02.2007 E 205 3014-5	69623
Colinus virginianus	Bixafen	Reproductive toxicity	NOEC = 30.0 mg/kg bw/d	XXX 17.06.2009 EBDRL003	75490
Colinus virginianus	Fluopyram	Acute toxicity	LD_{50} > 2000 mg/kg bw	XXX 20.12.2005 BAR/LD 074	68477
Anas platyrhynchos	Fluopyram	Short-term	LD_{50} >1643 nom mg/kg bw/d	XXX 19.12.2005 BAR/LC 020	68480
Colinus virginianus	Fluopyram	Reproductive toxicity	NOEL 4.5 mg/kg bw/d (corresponding to 50 mg/kg feed)	XXX 05.03.2008 EBGMP152	68494
Colinus virginianus	Prothioconazole (JAU-6476)	1d, acute toxicity	LD_{50} > 2000 mg/kg bw	XXX 17.06.1999 BAR/LD028	46062
Colinus virginianus	Prothioconazole-Desthio (JAU-6476-Desthio, SXX 0665)	1d, acute toxicity	LD_{50} > 2000 mg/kg bw	XXX 30.11.1990 VB-009	46070
Colinus virginianus	Prothioconazole (JAU-6476)	5d, dietary	LD_{50}>1413 mg/kg bw/d	XXX 18.04.2001 BAR/LC005	46064
Colinus virginianus	Prothioconazole-Desthio (JAU-6476-Desthio, SXX 0665)	5d, dietary	LD_{50} >297 mg/kg bw/d	XXX 19.04.2001 BAR/LC011	46103
Anas platyrhynchos	Prothioconazole (JAU 6476)	147 d, reproduction	NOEC = 78 mg/kg bw/d	XXX 07.11.2000 259919	46105
Colinus virginianus	Prothioconazole-Desthio (JAU 6476-Desthio, SXX 0665)	154 d, reproduction	NOEC = 14.8 mg/kg bw/d	XXX 07.01.2002 BAR/REP006	46106

* Endpoint differing from LoEP/New study submitted

6.2.1 Justification for new endpoints

Not necessary.

6.2.2 Risk assessment (MIIIA 10.1.1, MIIIA 10.1.2) for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438).

For risk assessment purposes, a risk envelope approach was used. Hence, intended use group A covers the risk for birds from intended use group B (see Table 6.1-2).

Exposure to standard generic focal species was estimated according to the Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12): 1438)

$$DDD = \sum_i \frac{PD_i \times FIR_{total}}{bw} \times RUD \times AR \times PT$$

$$= \sum_i \frac{FIR_i}{bw} \times RUD \times AR \times PT$$

where:

DDD = Daily dietary dose (mg/kg bw/day)
PDi = composition of diet obtained from treated area
FIRi = Food intake rate of indicator species i (g fresh weight/d)
bw = Body weight (g)
RUD = Residue per unit dose, bases on an application rate of 1 kg a.s./ha and assuming broadcast seedling
AR = Application rate (kg/ha)
PT = Proportion of diet obtained in the treated area (0…1)

In a first approach, it is assumed that birds do not avoid contaminated food items, that they feed exclusively in the treated area and on a single food type. Factors PT and PD are therefore equal to 1.

The risk assessment procedure follows a stepwise approach. A first screening step involves standard scenarios and default values for the exposure estimate, representing a “reasonable worst case”. If a risk is indicated in the screening step, then one or several refinement steps (Tier 1, Tier2) may follow. According to the Guidance Document, no further assessment is required if all uses are safe in the screening step.

Mixture toxicity

According to Appendix B to the Guidance Document on the Risk assessment for birds and mammals (EFSA, 1438/2009), the basic concept of the risk assessment is that animals are exposed to residues of the active substances in the environment. Thus, the assessment for Ascra XPro does not evaluate the formulation toxicity as such, but the effects of an exposure to a mixture of active substances in the environment, resulting from the use of the formulation. Toxicity studies for birds with formulated products

are typically not available. For the assessment of acute effects, a surrogate LD_{50} is calculated. Sublethal effects and effects on reproduction are assessed on a case-by-case basis. A model often used to estimate the toxicity of mixtures is the assumption of dose/concentration additivity of toxicity (Finney approach of concentration additivity of toxicity; Finney 1948 and 1971).

The following formula is used to derive a surrogate LD_{50} for the mixture of active substances with known toxicity assuming dose additivity:

$$LD_{50}(mix) = \left(\sum_i \frac{X(a.s._i)}{LC_{50}(a.s._i)} \right)^{-1}$$

where:

X(a.s. *i*)= fraction of active substance (i) in the mixture expressed as e.g.:

X(<active substance>) = xy g active substance /kg / (xy g active substance1 /kg + xy g active substance /kg)

X(<active substance>) = xy g active substance /kg / (xy g active substance1 /kg +xy g active substance/kg)

LD_{50}(a.s. *i*) = acute toxicity value for active substance (*i*)

Because of the direct proportionality of the calculated TER to the LD_{50}, it is possible to calculate a TER(mix) with the following formula:

$$\text{TER(mix)} = \left(\sum_i \frac{1}{\text{TER(a.s.}_i\text{)}} \right)^{-1}$$

where:

$TER_{(a.s.i)}$= calculated TER for the active substance *i*

6.2.2.1 Screening assessment

In the screening step, the risk to indicator bird species from an exposure to Ascra XPro is assessed. These indicators are considered to have highest exposure in a specific crop at a particular time due to their size and feeding habits and represent a worst case scenario.

To estimate the daily dietary doses, following equations were used:

Daily dietary dose (DDD):

$DDD_{single\ application}$ = application rate [kg a.s./ha] × shortcut value[1]

[1] see section 4.1 of EFSA/2009/1438

In case of multiple applications, the daily dietary dose for a single application is multiplied with an appropriate multiple application factor for 90th percentile residue data (MAF_{90}; see Table 7 of EFSA/2009/1438).A specific MAF_{90} may be calculated according to Appendix H of EFSA/2009/1438 for non-standard application intervals.

$$DDD_{multiple\ application} = DDD_{single\ application} \times MAF_{90}{}^{1}$$

Toxicity exposure ratio (acute):

$$TER_A = \frac{LD_{50}\ (mg/kg\,bw/day)}{Acute DDD (mg/kg\,bw/day)}$$

The results of the acute screening risk assessment are summarized in the following table.

The risk assessment has been performed for cereals for an application rate of 1.0 L product/ha corresponding to 0.060 kg/ha bixafen and 0.200 kg/ha prothioconazole, 2 applications and a minimum application interval of 14 days.

Table 6.2-2: Acute screening assessment for birds

Intended use [g/ha]	Indicator species	Endpoint [mg/kg bw]	SV	MAF_{90}	DDD	TER
Ascra XPro/Combined toxicity						
Group A (2 x 1.5 L prod./ha - = 97.5 g bixafen + 97.5 g fluopyram + 195 g prothioconazole) = 2 x 390 g a.i./ha	Small omnivorous bird	$LD_{50\ mix}$ = 2000	158.8	1.2	74.32	27
Group B (1.2 L prod./ha = 78 g bixafen + 78 g fluopyram + 156 g prothioconazole) = 2 x 312 g a.i./ha	Small omnivorous bird	$LD_{50\ mix}$ = 2000	158.8	-	49.55	40
Bixafen						
Group A (2 x 97.5 g a.s./ha)	Small omnivorous bird	> 2000	158.8	1.2	18.58	> 108
Group B (78 g a.s./ha)	Small omnivorous bird	> 2000	158.8	---	12.38	> 161
Fluopyram						
Group A (2 x 97.5 g a.s./ha)	Small omnivorous bird	> 2000	158.8	1.2	18.58	> 108
Group B (78 g a.s./ha)	Small omnivorous bird	> 2000	158.8	---	12.38	> 161
Prothioconazole						
Group A (2 x 195 g a.s./ha)	Small omnivorous bird	> 2000	158.8	1.2	37.16	> 54
Group B (156 g a.s./ha)	Small omnivorous bird	> 2000	158.8	---	24.77	> 81

SV: shortcut value; MAF_{90}: multiple application factor (90th percentile); DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The acute risk of the prothioconazole metabolite JAU 6476-desthio is covered by the risk assessment for the parent as the toxicity endpoint used for risk assessment is identical (LD_{50} > 2000 mg/kg bw for metabolite and parent) and the exposure to the metabolite is not higher than to the parent.

In the reproductive risk assessment zRMS proceeded directly to the tier 1 assessment step.

6.2.2.2 Tier 1 risk assessment

In the Tier 1 risk assessment step, the defined daily dietary doses and TER values were calculated for so-called generic focal species (see EFSA 1438/2009, Annex I). As for the indicator species, the generic focal species are considered to be representative for all species potentially at risk. In the Tier 1 assessment, a mixed diet approach is followed when appropriate and interception of the spray by the crop is taken into account for the calculation of residue levels for different food types.

If more than one generic focal species is relevant for the crop, the one that is relevant in terms of time of application or growth stage should be selected. If more than one generic focal species is relevant in terms of application time and growth stage, then the risk should be assessed for all relevant generic focal species. If the same generic focal species is relevant for several application times according to the BBCH growth stages, the risk assessment for this generic focal species is conducted once using the highest mean short-cut value, since this mirrors a realistic worst case scenario.

The results of the acute and reproductive Tier 1 risk assessments are summarized in the following table. For omnivorous birds only mixed diet scenarios are presented. The metabolites JAU 6476-desthio and JAU 6476-S-methyl are considered as they can cause relevant effects on reproduction.

Table 6.2-3: Reproductive tier 1 risk assessment for birds: active substances and combined risk, Use group A (2 x 1.5 L pro./ha, 14 d interval)

Intended use	Generic focal species	Generic diet composition	Endpoint [mg/kg bw/d]	SV	MAF_{mean} x twa	DDD_A [mg/kg bw/d]	TER
Bixafen (2 x 97.5 g a.s./ha)							
BBCH 30 - 39	Small omnivorous bird – "lark"	25% crop leaves 25% weed seeds 50% ground arthropods	30.0	5.4	0.742	0.391	77
BBCH ≥ 40				3.3		0.239	126
Fluopyram (2 x 97.5 g a.s./ha)							
BBCH 30 - 39		25% crop leaves	4.5	5.4	0.742	0.391	12

BBCH ≥ 40	Small omnivorous bird – "lark"	25% weed seeds 50% ground arthropods		3.3		0.239	19
Prothioconazole (2 x 195 g a.s./ha)							
BBCH 30 - 39	Small omnivorous bird – "lark"	25% crop leaves 25% weed seeds 50% ground arthropods	78	5.4	0.742	0.781	100
BBCH ≥ 40				3.3		0.477	163
JAU 6476-desthio (2 x 195 g a.s./ha)[1]							
BBCH 30 - 39	Small omnivorous bird – "lark"	25% crop leaves 25% weed seeds 50% ground arthropods	14.8	5.4	0.742	0.781	19
BBCH ≥ 40				3.3		0.477	31
JAU 6476-S-methyl (2 x 195 g a.s./ha)[1]							
BBCH 30 - 39	Small omnivorous bird – "lark"	25% crop leaves 25% weed seeds 50% ground arthropods	7.8 [2]	5.4	0.742	0.781	10
BBCH ≥ 40				3.3		0.477	16
TERmix (calculated as mixture toxicity for bixafen+fluopyram+prothioconazole):							6 [3]
TERmix (alternatively calculated as mixture toxicity for bixafen+fluopyram+ JAU 6476-S-methyl to illustrate a worst case):							4.8

SV: shortcut value; MAF_{90}: multiple application factor (90^{th} percentile); DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

1 worst-case assumption of 100% formation of the metabolite JAU 6476-desthio from the parent prothioconazole (without correction of molecular weight)

2 Endpoint of the parent divided by 10 used for risk assessment

The TER criterion ≥ 5 is met for all single active substances as well as for TERmix. The risk assessment for use group A covers use group B, thus no further assessment is necessary.

6.2.2.1 Higher tier risk assessment for Ascra XPro

Not required.

6.2.2.2 Drinking water exposure

Justification for waiving the assessment of birds exposed to contaminated drinking water:

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

A comparison of the relevant endpoints with the effective application rates for bixafen, fluopyram and prothioconazole is presented below.

Since Ascra XPro is not intended to be applied on leafy vegetables forming heads or other water collecting structures, the leaf scenario does not have to be considered. Only the puddle scenario is relevant and for the calculation of the application rate to endpoint-ratios the soil effective application rate as well as the respective DT_{50} in soil were considered.

The following values were used for the calculation:

Table 6.2-4: Calculation of MAFmean for drinking water assessment

Active substance	**Application rate / Soil effective application rate (70 % interception)**	**DT_{50} in soil [d]**	**Resulting MAFmean**	**Effective application rate regarding Puddle scenario (70 % interception)**
Bixafen	97.5 / 29.5	200.2	1.95	**57.6**
Fluopyram	97.5 / 29.5	123.05	1.92	**56.8**
Prothioconazole	195 / 136.5	1.77	1.00	**137.1**
JAU 6476-S-methyl	195 / 136.5	15.7	1.54	**210.1**

Note: The applicant's calculation in the core assessment is not correct. The applicant has used the complete application rate instead of the soil relevant application rate, and the tabulated standard MAF_{mean} for application of spray formulations instead of the MAF_{mean} based on DT_{50} in soil.

Table 6.2-5: Application rate to endpoint ratios for birds exposed to bixafen, fluopyram and prothioconazole by the use of Ascra XPro

Intended use	**Exposure Scenario**	**Effective application rate* Full rate / soil effective [g a.s./ha]***	**Koc [L/kg]**	**LD_{50}/NOEL [mg a.s./kg bw]**	**Ratio Application Rate : endpoint**
Bixafen (DT_{50} in soil = 365 d)					
Intended use A	Acute	190.4 / 57.6	3869	> 2000	0.1 /0.03
	Long-term			24.5	7.8 / 2.4
Fluopyram (DT_{50} in soil = 309 d)					
Intended use A	Acute	187.6 / 56.8	279	> 2000	0.1 /0.03
	Long-term			4.5	41.7 / 12.6
Prothioconazole (DT_{50} in soil = 1.8 d)					
	Acute	195.8 / 137.1	1765	> 2000	0.1 / 0.15

Intended use A	Long-term			78	2.5 / 3.8
prothioconazole-S-methyl (DT_{50} in soil = 46 d)					
Intended use A	Acute	300.1 / 210.1	2556.3	> 2000	0.15 / 0.11
	Long-term			7.8	38.5 / 26.9

* effective application rate = application rate multiplied by mean MAF (based on DT_{50} in soil)

Leaf scenario/ Puddle scenario

Assessment not required.

6.2.2.3 Effects of secondary poisoning (MIIIA 10.1.9)

Bixafen (log Pow 3.31), fluopyram (log Pow 3.30), prothioconazole (log Pow 3.82) and its metabolites JAU 6476-desthio (log Pow 3.04) and JAU 6476-S-methyl (log Pow 4.19) will be evaluated for potential effects of secondary poisoning of mammals. The assessment of the risk to mammals exposed to Ascra XPro through secondary poisoning is based on the evaluation of an earthworm eating mammal (10 g bw, food intake rate, FIR = 12.8 g fresh weight/d). The calculation is performed for the worst case intended use group A with the maximal soil relevant amount of the formulation.

The logPow for the other major water metabolite, 1,2,4-triazole is stated by the notifier to be <3 thus it is not further assessed here.

Risk assessment for earthworm-eating birds via secondary poisoning

Dry soil approach

Table 6.2-6: Assessment of the risk for earthworm eating birds from an exposure to the active substances of Ascra XPro through secondary poisoning for the intended use group A

Parameter	Bixafen	Fluopyram	Prothiconazole	comments
PEC_{soil} (twa = 21 d) [mg/kg soil]	0.095[1]	0.09	0.019	2 × 97.5/97.5/195 g/ha, interception 70%, soil layer depth 5 cm, DT50 = 365/309/1.8 d, twa interval = 21 d, with accumulation"
log P_{ow}	3.31	3.3	3.82	-
K_{oc}	3869	279	1765	-
F_{oc}	0.02	0.02	0.02	Default
BCF_{worm}	0.328	4.441	2.27	$BCF_{worm} = (PEC_{worm}/PEC_{soil})$ $= (0.84 + 0.012 \times K_{ow})/ f_{oc} \times K_{oc}$
PEC_{worm}	0.031	0.4	0.042	$PEC_{worm} = PEC_{soil} \times BCF$

Daily dietary dose (mg/kg bw/d)	0.033	0.42	0.044	DDD = PEC_{worm} x 1.05
NOEL (mg/kg bw/d)	30	4.5	78	
TER_{lt}	921	10.7	1756	≥ 5, acceptable risk

[1] Because of the high persistence of the active bixafen in soil the zRMS DE is using the PECsoil accu to address the risk of earthworm eating birds.

Table 6.2-7: Assessment of the risk for earthworm eating birds from an exposure to metabolites of prothioconazole through secondary poisoning for the intended use group A

Parameter	JAU 6476-desthio	JAU 6476-S-methyl	comments
PEC_{soil} (twa = 21 d) [mg/kg soil]	0.115	0.078	2 × 195/195 g/ha, interception 70%, soil layer depth 5 cm, DT50 = 37.6/15.7 d, twa interval = 21 d, with accumulation
log P_{ow}	3.04	4.19	
K_{oc}	575.4	2556.3	
F_{oc}	0.02	0.02	Default
BCF_{worm}	1.216	3.652	BCF_{worm} = (PEC_{worm}/PEC_{soil}) = (0.84 + 0.012 x K_{ow})/ f_{oc} x K_{oc}
PEC_{worm}	0.139	0.286	PEC_{worm} = PEC_{soil} x BCF
Daily dietary dose (mg/kg bw/d)	0.146	0.3	DDD = PEC_{worm} x 1.05
NOEL (mg/kg bw/d)	14.8	7.8[1]	
TER_{lt}	101	26	≥ 5, acceptable risk

[1] Endpoint of the parent divided by 10 used for risk assessment

Risk assessment for fish-eating birds via secondary poisoning

Table 6.2-8: Assessment of the risk for fish eating birds from an exposure to the active substances of Ascra XPro through secondary poisoning for the intended use group A

Parameter	Bixafen	Fluopyram	Prothiconazole	comments
PEC_{sw} (twa = 21 d) [mg/L]	0.01232	0.0488	0.03179	2 × 97.5/97.5/195 g/ha, FOCUS Step 1, DT50 = 1000/1000/1.8 d, twa interval = 21 d,

BCF_{fish}	523	18	18.8	whole fish
PEC_{fish}	6.443	0.879	0.598	$PEC_{fish} = PEC_{water}$ x BCF_{fish}
Daily dietary dose (mg/kg bw/d)	1.025	0.14	0.095	DDD = PEC_{fish} x 0.159
NOEL (mg/kg bw/d)	30	4.5	78	
TER_{lt}	29	32	820	≥ 5, acceptable risk

Table 6.2-9: Assessment of the risk for fish eating birds from an exposure to the prothioconazole metabolites through secondary poisoning for the intended use group A

Parameter	**JAU 6476-desthio**	**JAU 6476-S-methyl**	**comments**
PEC_{sw} (twa = 21 d) [mg/L]	0.03457	0.00405	2 × 195 g/ha, FOCUS Step 1, DT50 = 49.9/40.2 d, twa interval = 21 d,
BCF_{fish}	45	319	whole fish
PEC_{fish}	1.556	1.293	$PEC_{fish} = PEC_{water}$ x BCF_{fish}
Daily dietary dose (mg/kg bw/d)	0.247	0.206	DDD = PEC_{fish} x 0.159
NOEL (mg/kg bw/d)	14.8	7.8	Rat / Endpoint of the parent divided by 10 used for risk assessment
TER_{lt}	60	40	≥ 5, acceptable risk

TER values shown in bold fall below the relevant trigger.

6.2.3 Biomagnification in terrestrial food chains

The active substances bixafen and prothioconazole as well as the prothioconazole-metabolites JAU 6476-desthio and JAU 6476-S-methyl all have a log Kow ≥ 3 which indicates a potential for bioaccumulation. The issues accumulation in the food chain from earthworm to earthworm-eating birds and mammals and from fish to fish-eating birds and mammals already have been assessed above. The third issue in this context, biomagnification in terrestrial food chains, will be assessed here. If the bioaccumulation potential is stated as being low, no further assessment is required.

Table 6.2-10: Assessment of Biomagnification in terrestrial food chains

Active substance	Bixafen	Fluopyram	Prothioconazole	JAU 6476-desthio	JAU 6476-S-methyl
Potential for bioaccumulation (according to EU assessment)	As a result in the toxicology section, bixafen is rapidly and extensively absorbed after oral	Toxicokinetics in general was not different in a study with repeated administration suggesting a	In toxicological studies rapid and extensive distribution was demonstrated, with extensive loss from tissues and organs with time and no significant accumulation. Depuration times in the fish studies were relatively short for		The metabolite prothioconazole-S-methyl has a predicted log Pow of 4.19. No bioconcentration study is available

	administration, but does not bioaccumulate in the body and is rapidly eliminated mainly in bile but also in urine.	low, if any, risk for accumulation.	both compounds (max CT50 0.8 days). M04 is rapidly and almost completely absorbed; it is widely distributed (the highest concentrations found in liver, kidney cortex, erythrocytes and lungs). Excretion occurred predominantly in bile, and the elimination half-life and mean residence time were prolonged due to persistent enterohepatic recirculation. It does not show potential for bioaccumulation.	since the concentration in surface water was predicted to be low from the information available at the time of dossier submission. Bioconcentration of prothioconazole-S-methyl should be considered at Member State level should MS surface water exposure assessment show that this metabolite may contaminate surface water from drainage and/or run-off.

No further assessment is required.

6.2.4 Risk assessment (MIIIA 10.1.3, MIIIA 10.1.4, MIIIA 10.1.5) for baits, pellets, granules, prills or treated seed

Not relevant - Ascra XPro is not formulated as baits, pellets, granules, prills or treated seeds.

6.2.5 Overall conclusions

Dietary risk assessment

Based on the screening and tier 1 assessment step, the calculated TER values for the acute and long-term risk resulting from an exposure of birds to bixafen, fluopyram and prothioconazole (oral exposure from contaminated feed items) according to the GAP of the formulation Ascra XPro achieve the acceptability criteria TER ≥ 10 resp. TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for acute effects. The results of the assessment indicate an acceptable acute and long-term risk for birds due to the intended use of Ascra XPro in cereals according to the label.

Risk assessment for exposure via drinking water

No specific calculations were necessary.

Risk assessment for exposure via secondary poisoning

Based on the calculation of the risk arising from secondary poisoning , the calculated TER values for birds exposed to the active substances bixafen, fluopyram and prothioconazole as well as the metabolites JAU-6476-desthio and JAU-6476-S-methyl of prothioconazole according to the GAP of the formulation Ascra

XPro achieve the acceptability criteria TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for long-term effects.

6.3 Effects on Terrestrial Vertebrates Other Than Birds (MIIIA 10.3, KPC 10.1, KPC 10.1.2)

Table 6.3-1: EU agreed endpoints and new endpoints

Species	Substance	Exposure System	Results	Reference	Internal code
Rattus	Bixafen	oral	$LD_{50} \geq 5000$ mg/kg bw	XXX 01.08.2005 AT02236 ; T 7075636	64681
Rat	Fluopyram (AE C656948)	Acute oral toxicity	LD50 >2000 mg a.s./kg bw/d[1]	XXX 18.10.2005 T5075706	74124
Rat	Fluopyram (AE C656948)	2-generation study	NOAEL=14.5 mg a.s./kg/day	XXX 27.03.2008 201855	34294
Rattus	Prothioconazole (JAU 6476)	oral	$LD_{50} > 6200$ mg/kg bw	XXX 22.05.1998 T7062252 BfR-Bericht 13.12.2009	74190
Mus	Prothioconazole-desthio (JAU 6476-Desthio, SXX 0665)	oral	$LD_{50} = 2235$ mg/kg bw/d	XXX 22.03.1991 20097 ! M-008521-01-1	79512
Rattus	1,2,4-Triazole	oral	$LD_{50} = 1648$ mg/kg bw/d	EFSA-PRAPeR Expert Meeting 14 2006	74104
Rattus	Bixafen + Prothioconazol EC 60+200 G (Ascra XPro)	oral	$LD_{50} = 2000$ mg/kg bw/d	XXX 04.03.2011 10/206-001P	79712
Rattus	Bixafen	2-generation-study	NOAEL = 33.3 mg/kg bw/day (400 mg/kg food)	XXX 31.08.2007 201537	75551
Rattus	Prothioconazole (JAU 6476)	multi-generation-study	NOAEL = 9.7 mg/kg bw/d (parental) NOAEL = 95.6 mg/kg bw/d (reproduction) NOAEL = 95.6 mg/kg bw/d (offspring)	XXX 04.01.2001 98-612-VH	56605

Rattus	Prothioconazole-desthio (JAU 6476-Desthio, SXX 0665)	multi-generation-study	NOAEL = 10 mg/ kg bw/ d reproduction (offspring)	XXX 04.12.2001 109835 ! M-036130-01-1	79513
Rattus	1,2,4-Triazol	multi-generation-study	NOAEL = 15 mg/kg bw/d (offspring)	EFSA-PRAPeR 01.12.2006	74104

6.3.1 Justification for new endpoints

A new acute oral study with the preparation was submitted. No LD_{50} was determined in the study, as only two doses were tested: 300 mg/kg bw (no mortalities) and 2000 mg/kg bw, resulting in 2 mortalities out of 3 test animals (66.7 %). By non-linear interpolation, 1420 mg/kg bw was suggested by the applicant as an estimate LD_{50} and accepted by zRMS.

6.3.2 Risk assessment (MIIIA 10.3.1) for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438). Please see 6.2.2 for detailed information on the estimation of daily intake rates and the assessment of mixture toxicity.

For risk assessment purposes, a risk envelope approach was used. Hence, intended use group A covers the risk for mammals from intended use group B and C (see Table 6.1-2).

6.3.2.1 Assessment of the acute risk

For the estimation of Daily dietary doses (DDD) and the calculation of TER values, please see 6.2.2.1.

The results of the acute and reproductive screening risk assessments are summarized in the following tables.

Table 6.3-2: Acute screening assessment for mammals

Intended use	**Indicator species**	**Endpoint [mg/kg bw/d]**	**SV**	**MAF_{90}**	**DDD [mg/kg bw/d]**	**TER**
Ascra XPro						
Group A (2 x 1.5 L prod./ha, 14 d interval)	Small herbivorous mammal	1420	118.4	1.2	213.120	**6.7** [2]
Group A (1 x 1.2 L prod./ha)				1	142.080	10
Bixafen						
Group A (2 x 97.5 g a.s./ha) [1]	Small herbivorous mammal	> 5000	118.4	1.2	13.853	360
Fluopyram						

Group A (2 x 97.5 g a.s./ha) [1]	Group A (2 x 97.5 g a.s./ha) [1]	> 2000	118.4	1.2	13.853	144
Prothioconazole						
Group A (2 x 195 g a.s./ha) [1]	Small herbivorous mammal	> 6200	118.4	1.2	28.487	218
Prothioconazole metabolite JAU 6476-desthio						
Group A (2 x 195 g a.s./ha) [1]	Small herbivorous mammal	2235	118.4	1.2	27.706	81
Prothioconazole metabolite 1,2,4-triazole						
Group A (2 x 195 g a.s./ha) [1]	Small herbivorous mammal	1648	118.4	1.2	27.706	59

SV: shortcut value; MAF_{90}: multiple application factor (90th percentile); DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

[1] risk assessment for group A covers group B

[2] Tier 1 assessment required

Table 6.3-3: Tier 1 assessment for Ascra XPro, use group A, risk to mammals

Intended use	Indicator species	Endpoint [mg/kg bw/d]	SV	MAF_{90}	DDD [mg/kg bw/d]	TER
Ascra XPro (2 x 1515 g prod./ha[1], BBCH 30 – 61, 14 d interval)						
BBCH ≥ 20	Small insectivorous mammal "shrew"	1420	5.4	1.2	9.82	144
BBCH 30-39	Small omnivorous mammal "mouse"		8.6	1.2	15.64	91
BBCH ≥ 40	omnivorous mammal "mouse"		5.2	1.2	9.45	150
BBCH ≥ 40	Small herbivorous mammal "vole"		40.9	1.2	74.36	19

[1] Based on a product densitiy of 1.01 g/mL

All TER values meet the trigger ≥ 10. The acute risk is acceptable.

6.3.2.1 Assessment of the reproductive risk

In the reproductive risk assessment zRMS proceeded directly to the tier 1 assessment step.

According to EFSA/2009/1438, the calculation of a combined toxicity is not applicable to the risk assessment for reproductive effect. Due to differences in evaluated endpoints and the dependency of the derived NOEL of the test design, any calculated TER_{mix} value can only be used for illustrating purposes.

Hence, in the case of an unacceptable TER_{mix}, it has to be discussed if the results of the toxicity studies present any evidence for a possible concentration additivity of the effects and risks.

The results of the Tier 1 risk assessment is summarized in the following table. Only critical scenarios are presented (i.e. no single diet scenarios). The risk to omnivorous mammals (shrew) is covered by the risk for omnivorous and herbivorous mammals (vole and mouse).

6.3.2.2 Tier-1 risk assessment

For the estimation of Daily dietary doses (DDD) and the calculation of TER values, please see 6.2.2.2. A tier 1 risk assessment is only required for the metabolite Prothioconazole-desthio.

The results of the Tier 1 risk assessment is summarized in the following table. Only critical scenarios are presented (i.e. no single diet scenarios). The risk to omnivorous mammals (shrew) is covered by the risk for omnivorous and herbivorous mammals (vole and mouse).

Table 6.3-4: Reproductive tier 1 risk assessment for terrestrial vertebrates other than birds for Ascra XPro/single active substances and combined risk – use group A (2 x 1.5 L product/ha)

Intended use	Generic focal species	Generic diet composition	Endpoint [mg/kg bw/d]	SV	MAFmean x twa (1.4 x 0.53)	DDDA [mg/kg bw/d]	TER
Bixafen (2 x 97.5 g a.s./ha)							
BBCH ≥ 20	Small insectivorous mammal "shrew"	100% ground dwelling arthropods	33.3	1.9	0.742	0.137	242
BBCH 30 - 39	Small omnivorous mammal "mouse"	25% weeds 50% weed seeds 25% ground arthropods		3.9	0.742	0.282	118
BBCH ≥ 40				2.3		0.166	200
BBCH ≥ 40	Small herbivorous mammal - "vole"	100% grass		21.7	0.742	1.57	21
Fluopyram (2 x 97.5 g a.s./ha)							
BBCH ≥ 20	Small insectivorous mammal "shrew"	100% ground dwelling arthropods	14.5	1.9	0.742	0.137	105
BBCH 30 - 39	Small omnivorous mammal "mouse"	25% weeds 50% weed seeds 25% ground arthropods		3.9	0.742	0.282	51
BBCH ≥ 40				2.3		0.166	87

BBCH ≥ 40	Small herbivorous mammal - "vole"	100% grass		21.7	0.742	1.57	9
Prothioconazole (2 x 195 g a.s./ha)							
BBCH ≥ 20	Small insectivorous mammal "shrew"	100% ground dwelling arthropods	95.6	1.9	0.742	0.275	348
BBCH 30 - 39	Small omnivorous Mammal – "mouse"	25% weeds 50% weed seeds 25% ground arthropods		3.9	0.742	0.564	169
BBCH ≥ 40				2.3		0.333	287
BBCH ≥ 40	Small herbivorous mammal - "vole"	100% grass		21.7	0.742	3.140	30
JAU 6476-desthio (2 x 195 g a.s./ha)[1]							
BBCH ≥ 20	Small insectivorous mammal "shrew"	100% ground dwelling arthropods	10	1.9	0.742	0.275	36
BBCH 30 - 39	Small omnivorous Mammal – "mouse"	25% weeds 50% weed seeds 25% ground arthropods		3.9	0.742	0.564	18
BBCH ≥ 40				2.3		0.333	30
BBCH ≥ 40	Small herbivorous mammal - "vole"	100% grass		21.7	0.742	4.587	**3.2**
TERmix:							
Small herbivorous mammal "vole"							**2.12**

SV: shortcut value; MAF: multiple application factor. DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Conclusion from Tier 1 assessment, use group A

An acceptable risk was concluded for the active substances bixafen and fluopyram. For the metabolite JAU 6476-desthio of prothioconazole the TER values fall below the trigger ≥ 5 for small herbivorous mammals (vole scenario), and thus as a consequence also TERmix was calculated to be below 5.

As the risk is clearly driven by metabolite JAU 6476-desthio, the risk assessment is refined for this substance. Please refer to **Fehler! Verweisquelle konnte nicht gefunden werden.**. Further combitox assessment is not required: The three active substances have different targets in the organism, therefore after refinement for just one active the TERmix does not provide any more information and is not presented in this core assessment.

Conclusion from Tier 1 assessment, use group B

Similarly, for the single application (use group C) only the risk assessment for the metabolite JAU 6476-desthio of prothioconazole is presented in table 6.3-5. The risk from the active substances bixafen and fluopyram was shown to be acceptable even with two-fold application (use group A). Please refer to table 6.3-4.

Table 6.3-5: Tier 1 TER calculations for use group C (1 x 1.5 L/ha) and B* (1 x 1.2 L/ha)

Intended use	Generic focal species	Generic diet composition	Endpoint [mg/kg bw/d]	SV	MAFmean x twa (1 x 0.53)	DDDA [mg/kg bw/d]	TER
JAU 6476-desthio (1 x 195 g a.s./ha, BBCH 30-61)							
BBCH ≥ 20	Small insectivorous mammal "shrew"	100% ground dwelling arthropods	10	1.9	0.53	0.195	51
BBCH 30 - 39	Small omnivorous mammal "mouse"	25% weeds 50% weed seeds 25% ground arthropods		3.9	0.53	0.401	25
BBCH ≥ 40				2.3	0.53	0.236	42
BBCH ≥ 40	Small herbivorous mammal - "vole"	100% grass		21.7	0.53	2.229	**4.5**
JAU 6476-desthio (1 x 156 g a.s./ha, BBCH 30-61)							
BBCH ≥ 40	Small herbivorous mammal - "vole"	100% grass	10	21.7	0.53	1.783	5.6

* Only calculations for the critical scenario Small herbivorous mammal - "vole" are presented

The risk for mammals from use groups C is considered acceptable for all scenarios except from *Small herbivorous mammal - "vole"*. Further refinement will be provided under **Fehler! Verweisquelle konnte nicht gefunden werden.**.

6.3.2.3 Higher tier risk assessment for JAU 6476-desthio (KPC 10.1.2.2)

The reproductive risk from the use of Ascra XPro according to the GAP is clearly driven by the chronic toxicity of metabolite JAU 6476-desthio of prothioconazole. The applicant has submitted a discussion of residue trials (Hall and Duah (2002), Report No.: 111032, and Heinemann (2001), Report No.: RA-2103/99) to address the risk from metabolite JAU 6476-desthio (Neumann, 2009). A summary is presented in Appendix 2.

The trials by Hall and Duah were conducted in the USA. Only a brief summary is available. This summary is provided in this document in Appendix II. The trials have been mentioned in the prothioconazole DAR (2004, Vol. 3 B9), but only regarding the determination of DT_{50} of the parent prothioconazole.

ZRMS will consider it as additional information.

The study by Heinemann was conducted in Germany. It suggests a DT_{50} of 3.4 d for the metabolite.

From these in total 8 dissipation studies, a DT_{50} = 3.2 d was derived for JAU 6476-desthio and agreed for refinement. ZRMS thus considers it applicable for the conditions in the central zone.

The applicant further proposes to introduce a "conversion factor" from parent to metabolite of 29.9 % and RUD values for JAU 6476-desthio, derived from residue trials with various formulations conducted all over Europe.

ZRMS rejects to apply the measured RUD values and will base the assessment on the default RUD. Substance-related residue values should be subject to AIR of the active substance prothioconazole and not be introduced in a product authorization.

However, as all dissipation trials show a faster dissipation than the default 10 d and a shorter DT_{50} had already been agreed during the EU approval process, zRMS will present a higher tier assessment based on DT_{50} = 3.2 d (mean, EU agreed) and 5.04 d (maximum individual value, originating from Hall and Duah).

Table 6.3-6: Refinement of reproductive risk assessment for *vole* exposed to prothioconazole metabolite JAU 6476-desthio according to EFSA Journal (2009) in cereals.

Intended use	Generic focal species	Generic diet composition	Endpoint [mg/kg bw/d]	SV	MAFmean x twa [1]	DDDA [mg/kg bw/d]	TER
JAU 6476-desthio (Group A: 2 x 195 g a.s./ha)							
BBCH ≥ 40	Small herbivorous mammal - "vole"	100% grass	10	21.7	0.54	0.289	**4.4**
					0.39	1.646	6.1

MAF x twa is = 0.54 for DT_{50} = 5.04 d and = 0.39 for DT_{50} = 3.2 d and averaging interval = 21 d. calculated following the moving time window approach

The chronic risk from the metabolite JAU 6476-desthio due to the use of the product Ascra XPro (worst case use group A) is acceptable. Applying the agreed DT_{50} = 3.2 in the calculation, the TER trigger ≥ 5 is met.

The presented refinement option should be applicable throughout the central zone.

6.3.2.4 Drinking water exposure

Not necessary – please refer to 6.2.2.2.

6.3.2.5 Effects of secondary poisoning (MIIIA 10.3.2.3)

Bixafen (log Pow 3.31), fluopyram (log Pow 3.30), prothioconazole (log Pow 3.82) and its metabolites JAU 6476-desthio (log Pow 3.04) and JAU 6476-S-methyl (log Pow 4.19) will be evaluated for potential effects of secondary poisoning of mammals. The assessment of the risk to mammals exposed to Ascra XPro through secondary poisoning is based on the evaluation of an earthworm eating mammal (10 g bw, food intake rate, FIR = 12.8 g fresh weight/d). The calculation is performed for the worst case intended use group A with the maximal soil relevant amount of the formulation.

Risk assessment for earthworm-eating mammals via secondary poisoning

Dry soil approach

Table 6.3-7: Assessment of the risk for earthworm eating mammals from an exposure to the active substances of Ascra XPro through secondary poisoning for the intended use group A

Parameter	Bixafen	Fluopyram	Prothiconazole	comments
PEC_{soil} (twa = 21 d) [mg/kg soil]	0.095	0.09	0.019	2 × 97.5/97.5/195 g/ha, interception 70%, soil layer depth 5 cm, DT50 = 365/309/1.8 d, twa interval = 21 d, with accumulation"
log P_{ow}	3.31	3.3	3.82	-
K_{oc}	3869	279	1765	-
F_{oc}	0.02	0.02	0.02	Default
BCF_{worm}	0.32	4.441	2.27	$BCF_{worm} = (PEC_{worm}/PEC_{soil})$ $= (0.84 + 0.012 \times K_{ow})/ f_{oc} \times K_{oc}$
PEC_{worm}	0.03	0.4	0.042	$PEC_{worm} = PEC_{soil} \times BCF$
Daily dietary dose (mg/kg bw/d)	0.032	0.512	0.054	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	33.3	14.5	95.6	
TER_{lt}	942	28.3	1767	≥ 5, acceptable risk

TER values shown in bold fall below the relevant trigger.

Table 6.3-8: Assessment of the risk for earthworm eating mammals from an exposure to metabolites of prothioconazole through secondary poisoning for the intended use group A

Parameter	JAU 6476-desthio	JAU 6476-S-methyl	comments
PEC_{soil} (twa = 21 d) [mg/kg soil]	0.115	0.078	2 × 195/195 g/ha, interception 70%, soil layer depth 5 cm, DT50 = 37.6/15.7 d, twa interval = 21 d, with accumulation
log P_{ow}	3.04	4.19	
K_{oc}	575.4	2556.3	
F_{oc}	0.02	0.02	Default
BCF_{worm}	1.216	3.652	$BCF_{worm} = (PEC_{worm}/PEC_{soil})$ $= (0.84 + 0.012 \times K_{ow})/ f_{oc} \times K_{oc}$
PEC_{worm}	0.139	0.286	$PEC_{worm} = PEC_{soil}$ x BCF
Daily dietary dose (mg/kg bw/d)	0.178	0.3	DDD = PEC_{worm} x 1.28
NOEL (mg/kg bw/d)	14.8	7.8[1]	
TER_{lt}	83	26	≥ 5, acceptable risk

[1] Endpoint of the parent divided by 10 used for risk assessment

Risk assessment for fish-eating mammal via secondary poisoning

Table 6.3-9: Assessment of the risk for fish eating mammals from an exposure to the active substances of Ascra XPro through secondary poisoning for the intended use group A

Parameter	Bixafen	Fluopyram	Prothiconazole	comments
PEC_{sw} (twa = 21 d) [mg/L]	0.01232	0.0488	0.03179	2 × 97.5/97.5/195 g/ha, FOCUS Step 1, DT50 = 1000/0.0781000/1.8 d, twa interval = 21 d,
BCF_{fish}	523	18	18.8	whole fish
PEC_{fish}	6.443	0.879	0.598	$PEC_{fish} = PEC_{water}$ x BCF_{fish}
Daily dietary dose (mg/kg bw/d)	0.915	0.125	0.085	DDD = PEC_{fish} x 0.142
NOEL (mg/kg bw/d)	33.3	14.5	95.6	
TER_{lt}	36.4	116	1127	≥ 5, acceptable risk

Table 6.3-10: Assessment of the risk for fish eating mammals from an exposure to the prothioconazole metabolites through secondary poisoning for the intended use group A

Parameter	JAU 6476-desthio	JAU 6476-S-methyl	comments
PEC_{sw} (twa = 21 d) [mg/L]	0.03457	0.00405	2 × 97.5/97.5/195 g/ha, FOCUS Step 1, DT50 = 49.9/40.2 d, twa interval = 21 d,
BCF_{fish}	45	319	whole fish
PEC_{fish}	1.556	1.293	$PEC_{fish} = PEC_{water}$ x BCF_{fish}
Daily dietary dose (mg/kg bw/d)	0.221	0.184	DDD = PEC_{fish} x 0.142
NOEL (mg/kg bw/d)	14.8	10	Rat / Endpoint of the parent divided by 10 used for risk assessment
TER_{lt}	67	43	≥ 5, acceptable risk

6.3.3 Biomagnification in terrestrial food chains

Please refer to 6.2.3.

6.3.4 Risk assessment (MIIIA 10.3.1) for baits, pellets, granules, prills or treated seed

Not relevant - Ascra XPro is not formulated as baits, pellets, granules, prills or treated seeds.

6.3.5 Overall conclusions

Dietary risk assessment

Based on the screening and tier 1 assessment steps, the calculated TER values for the acute and long-term risk resulting from an exposure of mammals to the active substances bixafen, fluopyram and prothioconazole as well as the prothioconazole-metabolites JAU 6476-desthio and JAU-6476-S-methyl, (oral exposure and exposure via drinking water and secondary poisoning) according to the GAP of the formulation Ascra XPro achieve the acceptability criteria TER ≥ 10 resp. TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for acute effects. The results of the assessment indicate an acceptable acute and long-term risk for mammals due to the intended use of Ascra XPro in cereals according to the label.

Risk assessment for exposure via drinking water

No specific calculations were necessary.

Risk assessment for exposure via secondary poisoning

Based on the calculation of the risk arising from secondary poisoning , the calculated TER values for mammals exposed to the active substances bixafen, fluopyram and prothioconazole as well as the prothioconazole-metabolites JAU 6476-desthio and JAU-6476-S-methyl according to the GAP of the

formulation Ascra XPro achieve the acceptability criteria TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for long-term effects.

6.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KPC 10.1.3)

Not yet considered.

6.5 Effects on aquatic organisms (MIIIA 10.2, KPC 10.2, KPC 10.2.1)

Table 6.5-1: Endpoints used for risk assessment for aquatic organisms for bixafen and its relevant metabolites

Species	Substance	Exposure System	Results [mg a.s./L]	Reference	Internal code
Toxicity to fish					
Oncorhynchus mykiss	bixafen	4 d static	LC_{50}= 0.095 (nom.)	XXX 11.01.2006 E 280 2990-0	69481
Oncorhynchus mykiss	Metabolite M44	4 d static	LC_{50}> 100 (nom.)	XXX 29.11.2007 B42513	73209
Pimephales promelas	bixafen	33 d flow-trough	NOEC=0.0046 (mm)	XXX 24.01.2006 E 284 2960-1	69484
Toxicity to aquatic invertebrates					
Daphnia magna	bixafen	2 d static	EC_{50}=1.2 (nom.)	Bruns, E. 10.08.2006 E 320 2952-3	69534
Daphnia magna	Metabolite M44	2 d static	EC_{50}> 100 (nom.)	Höger, S. 29.11.2007 B42535	73268
Daphnia magna	bixafen	21 d static	NOEC=0.05 (nom.)	Bruns, E. 21.08.2007 E 321 3124-6	69536
Chironomus riparius	bixafen	28 d static spiked water	NOEC: 0.0156 (ini)	Dorgerloh, M. 23.11.2007 EBDRP088	69485
Chironomus riparius	bixafen	28 d static spiked sediment	NOEC : = 20 mg/kg dry sediment	Bruns, E. 2009 E 416 3597-5	69809
Lumbriculus variegatus	C14-Bixafen	28 d uptake phase	BAF: 2.36 BSAF: 0.31 Steady state,	Gilberg, D. 2012 12P1LB	82879

		10 d depuration phase	total radioactivity 62.2 µg/kg sediment dw CT_{50} < 0.2d Residues: 12% of steady state concentration		
Toxicity to algae and higher aquatic plants					
Pseudokirchneriella subcapitata	bixafen	3 d static	E_yC_{50}=0.0598 mg/L E_bC_{50}= 0.0657 mg/L (nom.) E_rC_{50}=0.0965 mg/L (nom.)	Dorgerloh, M. 04.04.2006 E 323 2932-4	69535
Pseudokirchneriella subcapitata	Metabolite M44	3 d static	E_yC_{50}=22.44 mg/L E_rC_{50}= 26.52 mg/L (nom.)	Zmijowski, G. 19.06.2009 W/17/09	73784
Lemna gibba	*No data.*				

Table 6.5-2: Endpoints used for risk assessment for aquatic organisms for Fluopyram and its relevant metabolites

Species	**Substance**	**Exposure System**	**Results [mg a.s./L]**	**Reference**	**Internal code**
Toxicity to fish					
Oncorhynchus mykiss	Fluopyram tech.	96 h, static	LC_{50} = 1.78 mg/L mm (1.89 mg/L nom.)	XXX 18.09.2006 EBGMP017	68500
Cyprinodon variegatus	Fluopyram tech.	96 h, static	LC50 > 0.98 mg/L mm	XXX 23.10.2006 EBGMP053	68569
Pimephales promelas	Fluopyram	Flowthrough ELS (33 d)	NOEC = 0.135 mg a.s./L (m.m.) length, behavior	XXX 23.10.2006 E 284 3156-9	68517
Toxicity to aquatic invertebrates					
Daphnia magna	Fluopyram	2 d, static	EC_{50} > 17 mg a.s./L (m.m.)	Bruns, E. 25.09.2006 EBGMP046	68522
Crassostrea virginica	Fluopyram	4 d, static	EC_{50} > 0.434 mg/L mm	Palmer et al. 19.12.2006 EBGMP045	68570
Americamysis bahia	Fluopyram	2 d, static	EC_{50} > 0.5 mg/L mm	Palmer, S.J.; Kendall, T.Z.; Krueger, H.O., 19.01.2007, 149A-221	68609

Daphnia magna	Fluopyram	21 d, flow-through	NOEC = 1.25 mg a.s./L nom.	Bruns, E. 12.01.2007 EBGMP047	68523
Chironomus riparius	Fluopyram	28 d, static spiked water	NOEC = 1.39 mg/L ini**.** (emergence rate) EC50 > 3.2 mg/L, ini.	Dorgerloh, M. 26.02.2008 EBGMP121	68533
Toxicity to algae and aquatic plants					
Pseudokirchneriella subcapitata	Fluopyram	3 d, static	E_bC_{50} = 3.97 mg a.s./L m.m. E_rC_{50} = 8.9 mg a.s./L m.m.	Banman &Lam 30.03.2007 EBGMP048	68526
Skeletonema costatum	Fluopyram	4 d, static	E_bC_{50} > 1.13 mg a.s./L nom E_rC_{50}: > 1.13 mg a.s./L nom	Banman, C. S. & Lam, C. V., 23.04.2007 EBGMP050	68610
Pseudokirchneriella subcapitata	Fluopyram-lactame tech. (94 %)	3 d, static	E_bC_{50} > 9.4 mg L nom. E_rC_{50}> 9.4 mg L nom. NOEC=9.4 mg L nom.	Dorgerloh, M. 04.03.2008 E 323 3255-3	68565
Lemna gibba	Fluopyram (AE C656948)	7 d, static	EC50 = 2.32 mg a.s./L nom. Fronds	Dorgerloh, M. 24.10.2007 E 412 3170-8	68564

* Endpoint differing from LoEP / New study submitted

Table 6.5-3: Endpoints used for risk assessment for aquatic organisms for prothioconazole and its relevant metabolites

Species	Substance	Exposure System	Results [mg a.s./L]	Reference	Internal code
Active substance prothioconazole					
Toxicity to fish					
Oncorhynchus mykiss	Prothioconazole (JAU 6476)	4d, static	LC_{50} = 1.83 mg/L nom.	XXX 01.09.1999 DOM 99076	45863
Oncorhynchus mykiss	Prothioconazole (JAU 6476)	ELS, 97d, flow-through	NOEC = 0.308 mg/L nom.	XXX 11.12.2001 DOM 20028	45872
Oncorhynchus mykiss	Prothioconazole (JAU 6476)	ELS, 91d, flow-through	NOEC = 0.49 mg/L nom. *	XXX 06.08.2007, EBJAX313	70485
Toxicity to aquatic invertebrates					

Daphnia magna	Prothioconazole (JAU 6476)	2d, static	EC_{50} = 1.3 mg/L nom.	Heimbach, F. 13.08.1999 HBF/DM 212	45837
Daphnia magna	Prothioconazole (JAU 6476)	21d, static-renewal	NOEC = 0.56 mg/L nom.	Hendel, B.; Sommer, H. 11.04.2001 HDB/RDM 67	45855
Chironomus riparius	Prothioconazole (JAU 6476)	28d	NOEC = 9.14 mg/L nom.	Hendel, B. 14.09.2000 HDB/CH 42	45953
Toxicity to algae and aquatic plants					
Selenastrum capricornutum	Prothioconazole (JAU 6476)	3d	E_bC_{50} = 1.1 mg/L E_rC_{50}= 2.18 mg/L	Dorgerloh, M., 25.10.2000, DOM 99107	45797
Skeletonema costatum	Prothioconazole (JAU 6476)	3d	E_bC_{50} = 0.0171 mg/L $E_rC_{5\,0}$= 0.0456 mg/L	Kern, M.E.; De Haan R.A. 10.03.2004 EBJAX076 (J6883601)	69032
Lemna gibba	Prothioconazole techn. 98.2 %	7 d, static	E_bC_{50} = 0.404 mg/L_{mm} E_rC_{50} > 0.404 mg/L_{mm} NOEC = 0.00334 mg/L_{mm}	Kern, M. E.; Banman, C. S.; Lam, C. V. 03.03.2004 EBJAY002 (J6883701)	69854
Metabolite JAU-6476-Desthio					
Oncorhynchus mykiss	Prothioconazol-JAU-6476-Desthio	4d, static	LC_{50} = 6.63 mg/L nom.	XXX 26.10.1990 FF-298	45882
Oncorhynchus mykiss	Prothioconazol-JAU-6476-Desthio	ELS, 96d, flow-through	NOEC = 0.00334 mg/L nom.	XXX 15.02.2002 1022.013.321	45888
Daphnia magna	Prothioconazol-JAU-6476-Desthio	Acute, 2d, static	EC_{50} > 10 mg/L nom.	Heimbach, F. 16.05.1990 HBF/DM 95	45936
Daphnia magna	Prothioconazol-JAU-6476-Desthio	21d, static-renewal	NOEC = 0.1 mg/L nom.	Dorgerloh, M.; Sommer, H. 10.09.2001 DOM 21036	45686
Americamysis bahia	Prothioconazol-JAU-6476-Desthio	4 d	LC_{50} = > 1.009 mg/L [1]	Blankinship, A.S.; Kendall, T.Z.; Krueger, H.O., 04.09.2003, 149A-130A	65935
Americamysis bahia	Prothioconazol-JAU-6476-Desthio	29 d – flow-through	NOEC = 0.064 mg/L nom. [1]	Blankinship, A.S.; Kendall, T.Z.; Krueger, H.O., 04.09.2003, 149A-130A	65935
Chironomus riparius	Prothioconazol-JAU-6476-Desthio	28d, static	NOEC = 2.0 mg/L nom.	Hendel, B. 19.10.2000 HDB/CH 43	45976

Scenedesmus subspicatus	Prothioconazol-JAU-6476-Desthio)	3d	E_bC_{50} = 0.073 mg/L mm E_rC_{50}=0.55 mg/L mm	Heimbach, F. 20.06.1990 HBF/AL 78; E 323 0401-3	45945
Lemna gibba	Prothioconazol-JAU-6476-Desthio 97.0%	7d, static-renewal	EC_{50} = 0.0394 mg/L mm NOEC = 0.0058 mg/L mm	Kern, M.E.; Banman, C.S.; Lam, C.V. 18.12.2003 200469; EBJAX084 (J6883702)	65917
Metabolite JAU 6476-S-Methyl					
Oncorhynchus mykiss	Prothioconazol-JAU 6476-S-Methyl	4d, static-renewal	LC_{50} =1.79 mg/L mm	XXX 25.09.2001 DOM 21047	45633
Daphnia magna	Prothioconazol-JAU 6476-S-Methyl	2d, static	EC_{50} = 2.8 mg/L nom.	Dorgerloh, M., Sommer, H. 03.09.2001 DOM 21055	45939
Chironomus riparius	Prothioconazol-JAU 6476-S-Methyl	28d, static	NOEC = 0.1 mg/L nom. *	Bruns, E. 14.03.2006 EBJAX303	70238
Selenastrum capricornutum	Prothioconazol-JAU 6476-S-Methyl	3d	E_bC_{50} = 3.77 mg/L mm E_rC_{50} = 47.4 mg/L mm NOEC < 1.03 mg/L mm	Dorgerloh, M.; Sommer, H. 20.07.2001 DOM 21028; E 323 2061-7	45946
Metabolite 1,2,4-Triazole					
Oncorhynchus mykiss	1,2,4-Triazol (CGA 98032)	4d, static	LC_{50} =498 mg/L mm	XXX 30.08.1983 821418	41737
Oncorhynchus mykiss	1,2,4-Triazole	28d, static-renewal	NOEC = 3.2 mg/L nom.	XXX 14.01.2002 DOM 21060	45802
Daphnia magna	1,2,4-Triazole	2d, static	EC_{50} > 100 mg/L nom.	Bell, G. 29.11.1995 ENVIR/95/52	48025
Selenastrum capricornutum	1,2,4-Triazol	3d	E_bC_{50} = 8.2 mg/L E_rC_{50} = 22.5 mg/L NOEC = 4.6 mg/L	Bell, G. 29.11.1995 AGV 50(b)952196	74250
Metabolite JAU 6476- triazolylketone					
Oncorhynchus mykiss	Prothioconazole-triazolylketone (JAU 6476-triazolylketone)	4d, static	LC_{50} > 100 mg/L *	XXX 23.02.2006 E 280 3090-2	70491
Daphnia magna	Prothioconazole-triazolylketone (JAU 6476-triazolylketone)	Acute, 2d, static	EC_{50} > 100 mg/L nom. *	Bruns, E. 23.02.2006 E 320 3104-3	70489
Pseudokirchneriella subcapitata	Prothioconazole-triazolylketone	3d	E_bC_{50} > 100 mg/L nom. *	Dorgerloh, M. 23.02.2006	70487

	(JAU 6476-triazolylketone)		E_rC_{50} > 100 mg/L nom. NOEC > 100 mg/L nom.	E 323 3084-3	

* Studies marked with asterisk were newly submitted and are not described in the DAR. Detailed evaluation is provided in Appendix II.

Table 6.5-4: Endpoints used for risk assessment for aquatic organisms for the formulation Ascra XPro

Species	Substance	Exposure System	Results [mg a.s./L]	Reference	Internal code
Oncorhynchus mykiss	Ascra XPro	96 h, static	LC_{50} = 1.77 mg/L nominal	XXX 13.12.2013 7SRLS13C60	86813
Daphnia magna	Ascra XPro	48 h, static	EC_{50} = 3.39 mg/L nominal	Matlock, D.; Moore, S. 18.12.2013 7SRLS13C62	86812
Pseudokirchneriella subcapitata	Ascra XPro	72 h, static	E_rC_{50} = 2.97 mg/L nominal E_bC_{50} = 1.91 mg/L nominal NOEC = 0.75 mg/L	Matlock, D.; Moore, S. 13.12.2013 7SRLS13C61	86810

6.5.1 Justification for new endpoints

Preparation

New studies with the preparation and metabolites were submitted. They are evaluated in detail in Appendix II.

Prothioconazole-JAU-6476-Desthio

The endpoints from the studies by Blankinship et al. (2003) with *Mysidopsis bahia* are known to zRMS from a study summary document (Neumann, P. (2004): "Summaries of additional ecotoxicological studies with prothioconazole (JAU 6476) and its metabolite prothioconazole-desthio (JAU 6476-desthio) that have been conducted to meet North American registration requirements". No full study reports were provided with the submission, so the results cannot be validated. However, these are the lowest available endpoints for aquatic invertebrates. The acute LC_{50} for mysid shrimp (> 1.009 mg/L) is about ten times lower than the daphnia endpoint (EC_{50} > 10 mg/L) and will be considered in risk assessment. A copy from the provided summary is presented in Appendix II.

The longterm endpoint (NOEC = 0.064 mg/L) does not differ much from the daphnia endpoint (NOEC = 0.1 mg/L), thus the valid daphnia endpoint is preferred and relevant for risk assessment.

6.5.2 Toxicity to exposure ratios for aquatic species (MIIIA 10.2.1)

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "Guidance Document on Aquatic Ecotoxicology", as provided by the Commission Services (SANCO/3268/2001 rev.4 (final), 17 October 2002).

Mixture Toxicity

The applicant provided a calculation of acute mixture toxicity according to the formula of Finney:

Citation from the applicant's core assessment:

$$1 / LC_{50\ expected} = \sum ct_{as} / LC_{50}$$

ct_{as} = w/w fraction of active substance in %

active substances = bixafen, fluopyram, prothioconazole

Table 10.2- 1: Calculation of the acute mixture toxicity of the formulation according to Finney

	Bixafen	Fluopyram	Prothioconazole	BIX + FLU + PTZ EC 260
Content within the product [%]*	6.43	6.43	12.86	
Effects on fish (*O. mykiss*)				
LC_{50} [mg as/L]	0.095	> 1.820	1.830	
LC_{50} – mixed toxicity [mg product/L]	Expected LC_{50} = 1.27			Measured LC_{50} = 1.77
Effects on aquatic invertebrates (*D. magna*)				
EC_{50} [mg as/L]	1.200	> 17	1.300	
EC_{50} – mixed toxicity [mg product/L]	Expected EC_{50} = 6.40			Measured EC_{50} = 3.39
Effects on green algae (*P. subcapitata*)				
E_rC_{50} [mg as/L]	0.097	8.90	2.180	
E_rC_{50} – mixed toxicity [mg product/L]	Expected E_rC_{50} = 1.37			Measured E_rC_{50} = 2.97

* Considering a product density of 1.011 g/cm^3

Based on Finney's formula, the maximum deviation of the expected toxicity of the formulated product from the measured toxicity is 1.27 / 1.77 = 0.72 for fish, 6.40 / 3.39 = 1.89 for daphnids and 1.37 / 2.97 = 0.46 for green algae. These variations are well within the experimental variability of biological systems and far below the factor of 10 used in the Aquatic Guidance Document as indication of a significant difference.

However, in the central zone it is preferred to calculate a mixture toxicity assessment based on the model deviation ratio (MDR).

Calculated mixture toxicity

The default model of Concentration Addition (CA) is applied to calculate the toxicity of the formulated product (ECxmix-CA) based on the toxicity of the active substances using the following equation:

$$ECx_{mix-CA} = \left(\sum_{i=1}^{n} \frac{P_i}{ECx_i} \right)^{-1}$$

where:

n: number of mixture components

i: index from 1…n mixture components

P_i: the i^{th} component as a relative fraction of the mixture composition (note: Σ pi must be 1)

ECx_i: concentration of component i provoking x % effect (pragmatically, NOECi may be inserted, too).

For each endpoint, the calculated toxicity (ECx_{mix-CA}) for the various endpoints is compared to the measured toxicity of the formulation (ECx_{PPP}) as Model Deviation Ratio (MDR) as

$$MDR = \frac{ECx_{mix-CA}}{ECx_{PPP}}$$

Concentrations are both based on the sum of active substances.

The approach of the mixture risk assessment may be simplified if one active substance is driving the toxicity of the formulation. Relative Toxic Units ($\%TU_i$) as calculated for each active substance as

$$\%TU_i = \frac{TU_i}{\sum_{i=1}^{n} TU_i}$$

with TU_i being the concentration of substance i in the product divided by its ECx.

Table 6.5-5: Mixture toxicity and resulting MDR for aquatic organisms for Ascra XPro

Endpoint Active Substance	**ECx_i** **(mg a.s./L)**	**Concentration (C_i) in formulation** **(g a.s./L)**	**P_i**	**relative Toxic Unit** **(%TU)**	**ECx_{mix-CA}** **(mg /L)**	**ECx_{PPP}** **(mg /L)**	**MDR**
Fish, acute toxicity							
Bixafen	0.095	65	0.25	86	0.328	1.77 (0.46 mg a.i.)	0.72
Fluopyram	1.78	65	0.25	5			
Prothioconazole	1.83	130	0.5	9			
***D. magna*, acute toxicity**							
Bixafen	1.2	65	0.25	18	0.855	3.39	0.97

Fluopyram	0.434	65	0.25	49		(0.881 mg a.i.)	
Prothioconazole	1.3	130	0.5	33			
Algal growth inhibition							
Bixafen	0.0598	65	0.25	8	0.02	1.91 (0.497 mg a.i.)	0.039
Fluopyram	0.014	65	0.25	35			
Prothioconazole	0.0171	130	0.5	57			

Density of formulation: 1.010 g/mL, resulting in 0.1287 mg sum a.s./mg product)

The MDR is between 0.2 and 5 for fish and invertebrate endpoints of the formulated product Ascra XPro. Hence, there is no evidence for synergistic effects of the active substances in the product.

The MDR for algae is below 0.2 which indicates less than additive mixture toxicity.

The relative toxic units (%TU_i) indicate if one of the three active substances is dominating the toxicity towards the separate taxonomic groups, i.e., bixafen dominates the acute toxicity towards fish, while fluopyram dominates the toxicity towards aquatic invertebrates and prothioconazole the toxicity towards algae.

The risk assessment for aquatic organisms may therefore be based on single substances only.

The TER calculations have been conducted with the worst-case PEC-values – depending on the characteristics of the respective active substance these were single or multiple application PEC-values.

If risk mitigation options are required on member state level, it should be differentiated between the three proposed application schemes use group A, B and C.

The relevant global maximum FOCUS Step 1, 2 and 3 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting TER values are presented in the following tables.

FOCUS Step 4 – risk mitigation measures

FOCUS Step 4 PEC_{SW} and PEC_{sed} have been provided for the MS in the specific National Addenda.

According to the applicant, for the MS in particular the following scenarios are relevant:

Belgium

Table 9.7- 1: Scenarios to consider for the supported crops

Scenario	D1	D2	**D3**	**D4**	D5	D6	**R1**	R2	R3	R4
Cereals, spring	X	-	**X**	**X**	X	-	**-**	-	-	X
Cereals, winter	X	X	**X**	**X**	X	X	**X**	-	X	X

Austria

Scenario	D1	D2	D3	**D4**	**D5**	D6	**R1**	R2	**R3**	R4
Cereals, spring	X	-	X	**X**	**X**	-	**-**	-	**-**	X
Cereals, winter	X	X	X	**X**	**X**	X	**X**	-	**X**	X

Poland

Scenario	D1	D2	**D3**	**D4**	D5	D6	**R1**	R2	R3	R4
Cereals, spring	X	-	**X**	**X**	X	-	**-**	-	-	X
Cereals, winter	X	X	**X**	**X**	X	X	**X**	-	X	X

Slovenia

Scenario	D1	D2	D3	**D4**	**D5**	**D6**	R1	R2	R3	R4
Cereals, spring	X	-	X	**X**	**X**	**-**	-	-	-	X
Cereals, winter	X	X	X	**X**	**X**	**X**	X	-	X	X

Conclusion: The scenarios D3, D4, D5, D6, R1 and R3 are refined with FOCUS Step 4 calculations if required.

The MS The Netherlands, Germany and United Kingdom base their decisions for risk mitigation measures on specific calculations methods that are not presented here.

6.5.2.1 Toxicity to exposure ratio for the active substances

In the following table the TER values for each FOCUS scenario for each organisms group are given.

Table 6.5-6: PEC_{SW} for bixafen, relevant ecotoxicological endpoints and TER values – use in winter cereals

Scenario	**PEC_{SW} global max**	**Fish acute**	**Fish prolonged**	**Invertebrates acute**	**Invertebrates prolonged**	**Algae**	**Sed. dweller prolonged**	**PEC_{Sed} global max**	**Sed. dweller prolonged**
		O. mykiss	***P.promelas***	***D. magna***	***D. magna***	***P. subcapitata***	**NOEC**	**(multiple appl. PECs)**	**NOEC**
FOCUS		**LC_{50}**	**NOEC**	**EC_{50}**	**NOEC**	**E_bC_{50}**			
		95	4.6	1200	50	65.7	15.6		20000
	[µg/L]	**[µg/L]**	**[µg/L]**	**[µg/L]**	**[µg/L]**	**[µg/L]**	**[µg/L]**	**[µg/kg]**	**[µg/kg]**
Step 1									
	12.410	**8**	**0.4**	**97**	**4**	**5**	**1.3**	410.4	49
Step 2 (multiple appl.)									
N.Europe	1.892	**50**	**2.4**	634	26	35	**8.2**	69.17	289
S.Europe	3.424	**28**	**1.3**	350	15	19	**4.6**	128.4	156
Step 3 (single appl.)									
D1/ditch	0.621	153	**7.4**	1932	81	106	25	5.431	3683
D1/stream	0.476	200	**9.7**	2521	105	138	33	0.643	31104
D2/ditch	0.624	152	**7.4**	1923	80	105	25	-	-
D2/stream	0.513	185	**9.0**	2339	97	128	30	-	-
D3/ditch	0.616	154	**7.5**	1948	81	107	25	0.713	28050
D4/pond	0.021	4524	219.0	57143	2381	3129	743	0.511	39139
D4/stream	0.489	194	**9.4**	2454	102	134	32	0.110	181818
D5/pond	0.021	4524	219.0	57143	2381	3129	743	0.441	45351
D5/stream	0.496	192	**9.3**	1929	101	132	31	0.044	454545
D6/ditch	0.622	153	**7.4**	162	80	106	25	-	-
R1/pond	0.029	3276	158.6	41379	1724	2266	538	-	-
R1/stream	0.406	234	11.3	106	123	162	38	-	-
R3/stream	0.571	166	**8.1**	149	88	115	27	-	-
R4/stream	0.408	233	11.3	106	123	161	38	12.570	1591
TER criterion		100	10	100	10	10	10		10

TER values shown in bold fall below the relevant trigger.

Table 6.5-7: Refined risk assessment for bixafen: risk to aquatic organisms, use in winter cereals

Relevant endpoint: NOEC = 4.6 µg/L, TER trigger: 10

FOCUS Scenario	Mitigation (buffer zone – drift reduction [%]	PECsw [µg/L]	TERLT
Winter cereals, multiple application (2 x 98 g a.s./ha, use group A)			
D3/ditch	5 m – 0 %	0.14	32.9
D4/stream	5 m – 0 %	0.151	30.5
D5/stream	5 m – 0 %	0.165	27.9
D6/ditch	5 m – 0 %	0.150	30.7
R3/stream	5 m – 0 %	0.307	15.0
Winter cereals, single application (1 x 98 g a.s./ha, use group B)			
D3/ditch	5 m – 0 %	0.167	27.5
D4/stream	5 m – 0 %	0.178	25.8
D5/stream	5 m – 0 %	0.181	25.4
D6/ditch	5 m – 0 %	0.168	27.4
R3/stream	5 m – 0 %	0.208	22.1

For the use in winter cereals a 5 m buffer strip is recommended as risk mitigation measure.

Table 6.5-8: PEC_{sw} for bixafen, relevant ecotoxicological endpoints and TER values – use in spring cereals

Scenario	**PEC_{sw} global max**	**Fish acute**	**Fish prolonged**	**Invertebrates acute**	**Invertebrates prolonged**	**Algae**	**Sed. dweller prolonged**	**PEC_{Sed} global max**	**Sed. dweller prolonged**
		O. mykiss	***P.promelas***	***D. magna***	***D. magna***	***P. subcapitata***	***C. riparius***		***C. riparius***
FOCUS		**LC_{50}**	**NOEC**	**EC_{50}**	**NOEC**	**E_bC_{50}**	**NOEC**		**NOEC**
		95	4.6	1200	50	65.7	15.6		20000
	[µg/L]	**[µg/L]**	**[µg/L]**	**[µg/L]**	**[µg/L]**	**[µg/L]**	**[µg/L]**	**[µg/kg]**	**[µg/kg]**
					Step 1				
	12.410	**8**	**0.4**	**97**	**4**	**5**	1.3	410.4	49
					Step 2 (multiple appl.)				
N.Europe	1.892	**50**	**2.4**	634	26	35	4.6	69.17	289
S.Europe	3.424	**28**	**1.3**	350	15	19	**8.2**	128.4	156
					Step 3 (single appl.)				
D1/ditch	0.764 *	124	**6.0**	1571	65	86	20	5.431	3683
D1/stream	0.546	200	**9.7**	2521	105	138	29	0.643	31104
D3/ditch	0.617	154	**7.5**	1948	81	107	25	0.713	28050
D4/pond	0.026 *	3654	177	46154	1923	2527	600	0.511	39139
D4/stream	0.511	194	**9.4**	2454	102	134	31	0.110	181818

D5/pond	0.028 *	3393	164.3	42857	1786	2346	557	0.441	45351
D5/stream	0.529	192	**9.3**	1929	101	132	30	0.044	454545
R4/stream	0.408	233	11.3	106	123	161	38	12.570	1591
TER criterion		100	10	100	10	10	10		10

* PEC value according to multiple application (worst case)

TER-values for fish (long-term) do not meet the TER criterion and indicate a high risk for fish.

Table 6.5-9: Refined risk assessment for bixafen: risk to aquatic organisms, use in spring cereals

Relevant endpoint: NOEC = 4.6 µg/L, TER trigger: 10

FOCUS Scenario	Mitigation (buffer zone – drift reduction [%]	PECsw [µg/L]	TERLT
spring cereals, multiple application (2 x 98 g a.s./ha, use group A)			
D3/ditch	5 m – 0 %	0.140	32.9
D4/stream	5 m – 0 %	0.162	28.4
D5/stream	5 m – 0 %	0.164	28.0
spring cereals, single application (1 x 98 g a.s./ha, use group B)			
D3/ditch	5 m – 0 %	0.167	27.5
D4/stream	5 m – 0 %	0.186	24.7
D5/stream	5 m – 0 %	0.193	23.8

For the use in spring cereals a 5 m buffer strip is recommended as risk mitigation measure.

Table 6.5-10: Aquatic organisms: PECsw for fluopyram, relevant ecotoxicological endpoints and TER values – use in winter cereals

Scenario	**PEC_{SW} global max**	**Fish acute**	**Fish prolonged**	**Invertebrates acute**	**Invertebr. prolonged**	**Algae**	**Sed. dweller prolonged**	**Aquatic plants**
		C.variegatus	***P.promelas***	***C.virginica***	***D. magna***	***S. costatum***	***C. riparius***	***L.gibba***
FOCUS		**LC_{50}**	**NOEC**	**EC_{50}**	**NOEC**	**E_bC_{50}**	**NOEC**	**EC_{50}**
		980	135	> 434	1250	1130	1390	2320
	[µg/L]	**[µg/L]**	**[µg/L]**	**[µg/L]**	**[µg/L]**	**[µg/L]**	**[µg/L] ***	**[µg/L]**
Step 1								
	49.170	20	2.7	9	25	23	28.3	47.2
Step 2 (multiple appl.)								
N.Europe	5.717	171	23.6	76	219	198	243.1	405.8
S.Europe	10.170	96	13.3	43	123	111	136.7	228.1
Step 3 (multiple appl.)								
D1/ditch	4.726	207	28.6	**92**	264	239	294	491
D1/stream	2.953	332	45.7	147	423	383	471	786
D2/ditch	4.257	230	31.7	102	294	265	327	545
D2/stream	2.658	369	50.8	163	470	425	523	873
D3/ditch	0.540	1815	250.0	804	2315	2093	2574	4296
D4/pond	0.673	1456	200.6	645	1857	1679	2065	3447
D4/stream	0.842	1164	160.3	515	1485	1342	1651	2755
D5/pond	0.326	3006	414.1	1331	3834	3466	4264	7116
D5/stream	0.491	1996	274.9	884	2546	2301	2831	4725
D6/ditch	0.588	1667	229.6	738	2126	1922	2364	3946
R1/pond	0.139	7050	971.2	3122	8993	8129	10000	16691
R1/stream	1.457	673	92.7	298	858	776	954	1592
R3/stream	2.487	394	54.3	175	503	454	559	933
R4/stream	2.204	445	61.3	197	567	513	631	1053
TER criterion		100	10	100	10	10	10	10

TER values shown in bold fall below the relevant trigger.

TER-values for invertebrates (acute) do not meet the TER criterion in the D1/ditch scenario and indicate a high risk for aquatic invertebrates. However, as D1 is not relevant in the central zone, no further refinement is presented.

Table 6.5-11: Aquatic organisms: PEC_{sw} for fluopyram, relevant ecotoxicological endpoints and TER values – use in spring cereals

Scenario **FOCUS**	**PEC_{SW} global max** **[µg/L]**	**Fish acute** ***C.variegatus*** **LC_{50}** 980 **[µg/L]**	**Fish prolonged** ***P.promelas*** **NOEC** 135 **[µg/L]**	**Invertebrates acute** ***C.virginica*** **EC_{50}** > 434 **[µg/L]**	**Invertebr. prolonged** ***D. magna*** **NOEC** 1250 **[µg/L]**	**Algae** ***S. costatum*** **E_bC_{50}** 1130 **[µg/L]**	**Sed. dweller prolonged** ***C. riparius*** **NOEC** 1390 **[µg/L]**	**Aquatic plants** ***L.gibba*** **EC_{50}** 2320 **[µg/L]**
Step 1								
	49.170	**20**	**2.7**	**9**	25	23	28.3	47
Step 2 (multiple appl.)								
N.Europe	5.717	171	23.6	**76**	219	198	243.1	406
S.Europe	7.946	123	17	**55**	157	142	175	292
Step 3 (multiple appl.)								
D1/ditch	3.183	308	42	136	393	355	437	729
D1/stream	1.986	493	68	219	629	569	700	1168
D3/ditch	0.541	1811	250	802	2311	2089	2569	4288
D4/pond	0.595	1647	227	729	2101	1899	2336	3899
D4/stream	0.702	1396	192	618	1781	1610	1980	3305
D5/pond	0.254	3858	531	1709	4921	4449	5472	9134
D5/stream	0.480	2042	281	904	2604	2354	2896	4833
R4/stream	1.330	737	102	326	940	850	1045	1744
TER criterion		100	10	100	10	10	10	10

TER values shown in bold fall below the relevant trigger.

All calculated TER values meet the trigger in the Step 3 scenarios.

Table 6.5-12: Aquatic organisms: PEC_{sw} for prothioconazole, relevant ecotoxicological endpoints and TER values – use in winter cereals

Scenario **FOCUS**	**PEC_{SW} global max** **[µg/L]**	**Fish acute** ***O. mykiss*** **LC_{50}** 1830 **[µg/L]**	**Fish prolonged** ***O. mykiss*** **NOEC** 308 **[µg/L]**	**Invertebrates acute** ***D. magna*** **EC_{50}** 1300 **[µg/L]**	**Invertebrates prolonged** ***D. magna*** **NOEC** 560 **[µg/L]**	**Algae** ***S. costatum*** **E_bC_{50}** 17.1 **[µg/L]**	**Sed. dweller prolonged** ***C. riparius*** **NOEC** 9140 **[µg/L]**
Step 1							
	42.350	43	7.3	31	13	**0.4**	216
Step 2 (multiple appl.)							
N.Europe	1.997	916	154	651	280	**8.6**	4577
S.Europe	1.997	916	154	651	280	**8.6**	4577
Step 3 (single appl.)							
D1/ditch	1.237	1479	249	1051	453	889	7389
D1/stream	0.950	1926	324	1368	589	1158	9621
D2/ditch	1.243	1472	248	1046	451	885	7353
D2/stream	1.025	1785	300	1268	546	1073	8917
D3/ditch	1.234	1483	250	1053	454	891	7407
D4/pond	0.043	42558	7163	30233	13023	25581	212558
D4/stream	0.979	1869	315	1328	572	1124	9336
D5/pond	0.043	42558	7163	30233	13023	25581	212558
D5/stream	0.994	1841	310	1308	563	1107	9195
D6/ditch	1.244	1471	248	1045	450	884	7347
R1/pond	0.043	42558	7163	30233	13023	25581	212558
R1/stream	0.813	2251	379	1599	689	1353	11242
R3/stream	1.142	1602	270	1138	490	963	8004
R4/stream	0.813	2251	379	1599	689	1353	11242
TER criterion		100	10	100	10	10	10

TER values shown in bold fall below the relevant trigger.

All calculated TER values meet the trigger in the Step 3 scenarios.

Table 6.5-13: Aquatic organisms: PEC_{sw} for prothioconazole, relevant ecotoxicological endpoints and TER values – use in spring cereals

Scenario	**PEC_{SW} global max**	**Fish acute**	**Fish prolonged**	**Invertebrates acute**	**Invertebrates prolonged**	**Algae**	**Sed. dweller prolonged**
		O. mykiss	***O. mykiss***	***C.virginica***	***D. magna***	***P. subcapitata***	***C. riparius***
FOCUS		**LC_{50}**	**NOEC**	**EC_{50}**	**NOEC**	**E_bC_{50}**	**NOEC**
		1830	308	1300	560	17.1	9140
	[µg/L]	**[µg/L]**	**[µg/L]**	**[µg/L]**	**[µg/L]**	**[µg/L]**	**[µg/L]**
Step 1							
	42.350	**43**	**7.3**	**31**	13	**0.4**	216
Step 2 (multiple appl.)							
N.Europe	1.997	916	154	651	280	**8.6**	4577
S.Europe	1.997	916	154	651	280	**8.6**	4577
Step 3 (single appl.)							
D1/ditch	1.654 *	1106	186	786	339	10	5526
D1/stream	1.093	1674	282	1189	512	16	8362
D3/ditch	1.234	1483	250	1053	454	14	7407
D4/pond	0.049 *	37347	6286	26531	11429	349	186531
D4/stream	1.023	1789	301	1271	547	17	8935
D5/pond	0.057 *	32105	5404	22807	9825	300	160351
D5/stream	1.059	1728	291	1228	529	16	8631
R4/stream	0.817	2240	377	1591	685	21	11187
TER criterion		100	10	100	10	10	10

* PEC value according to multiple application (worst case)

TER values shown in bold fall below the relevant trigger.

All calculated TER values meet the trigger in the Step 3 scenarios.

Table 6.5-14: Aquatic organisms: PEC_{sw} for prothioconazole-metabolite JAU-desthio (M04), relevant ecotoxicological endpoints and TER values – use in winter cereals

Scenario FOCUS	PEC_{SW} global max [µg/L]	Fish acute *O. mykiss* LC_{50} 6630 [µg/L]	Fish prolonged *O. mykiss* NOEC 3.34 [µg/L]	Invertebrates acute *A. bahia* EC_{50} > 1009 [µg/L]	Invertebrates prolonged *A. bahia* NOEC 64 [µg/L]	Algae *S. subcapitatus* E_bC_{50} 73 [µg/L]	Sed. dweller prolonged *C. riparius* NOEC 2000 [µg/L]	Aquatic plants *L.gibba* NOEC 39.4 [µg/L]
Step 1								
	39.860	166	**0.1**	25	**1.6**	**1.8**	50.2	**1.0**
Step 2 (multiple appl.)								
N.Europe	4.028	1646	**0.8**	250	16	18	496.5	**9.8**
S.Europe	7.163	926	**0.5**	141	9	10	279.2	**5.5**
Step 3 (multiple appl.)								
D1/ditch	0.002	3315000	1670	504500	32500	36500	1000000	19700.0
D1/stream	0.001	6630000	3340	1009000	65000	73000	2000000	39400.0
D2/ditch	0.008	828750	417.5	126125	8125	9125	250000	4925.0
D2/stream	0.005	1326000	668	201800	13000	14600	400000	7880.0
D3/ditch	0.001	6630000	3340	1009000	65000	73000	2000000	39400.0
D4/pond	0.029	228621	115	34793	2241	2517	68966	1358.6
D4/stream	0.004	1657500	835	252250	16250	18250	500000	9850.0
D5/pond	0.030	221000	111	33633	2167	2433	66667	1313.3
D5/stream	0.001	6630000	3340	1009000	65000	73000	2000000	39400.0
D6/ditch	0.614 *	11333	**5.7**	1643	106	125	3419	67.4
R1/pond	0.087	76207	38.4	11598	747	839	22989	452.9
R1/stream	0.776	8544	**4.3**	1300	84	94	2577	50.8
R3/stream	0.894	7416	**3.7**	1129	73	82	2237	44.1
R4/stream	1.062	6243	**3.1**	950	61	69	1883	37.1
TER criterion		100	10	100	10	10	10	10

TER values shown in bold fall below the relevant trigger.

* PEC for single use

TER-values for fish (long-term) do not meet the TER criterion and indicate a high risk for fish. The following scenarios fail the TER criterion: D6/ditch, R1/stream, R3/stream, R4/stream

Relevant endpoint: NOEC = 3.34 µg/L. TER criterion: 10

Refined risk assessment with FOCUS step 4 PEC-values are presented:

Table 6.5-15: Refined risk assessment for prothioconazole-metabolite JAU-desthio (M04): risk to aquatic organisms, use in winter cereals

Relevant endpoint: NOEC = 3.34 µg/L, TER trigger: 10

FOCUS Scenario	Mitigation (buffer zone – drift reduction [%]	PECsw [µg/L]	TERLT
Winter cereals, multiple application (2 x 98 g a.s./ha, use group A)			
D6/ditch	5 m – 0 %	0.152	22.0
R1/stream	5 m – 0 %	0.776	**4.3**
	10 m – 0 %	0.353	9.4
	20 m - 0 %	0.185	18.1
R3/stream	5 m – 0 %	0.894	**3.7**
	10 m – 0 %	0.408	**8.2**
	20 m - 0 %	0.214	15.6
R4/stream	5 m – 0 %	1.062	**3.1**
	10 m – 0 %	0.478	**7.0**
	20 m - 0 %	0.249	13.4
Winter cereals, single application (1 x 98 g a.s./ha, use group C)			
D6/ditch	5 m – 0 %	0.166	20.1
R1/stream	5 m – 0 %	0.366	**9.1**
	10 m – 0 %	0.166	20.1
R3/stream	5 m – 0 %	0.461	**7.2**
	10 m – 0 %	0.211	15.8
R4/stream	5 m – 0 %	0.506	**6.6**
	10 m – 0 %	0.229	14.6

Use in winter cereals:

- A 20 m buffer strip is required as risk mitigation measure for multiple applications (use group A).
- A 10 m buffer strip is required as risk mitigation measure for single applications (use group B and C).

Table 6.5-16: Aquatic organisms: PEC_{sw} for prothioconazole-metabolite JAU-6476-Desthio (M04), relevant ecotoxicological endpoints and TER values – use in spring cereals

Scenario FOCUS	PEC_{SW} global max [µg/L]	Fish acute *O. mykiss* LC_{50} 6630 [µg/L]	Fish prolonged *O. mykiss* NOEC 3.34 [µg/L]	Invertebrates acute *A. bahia* EC_{50} > 1009 [µg/L]	Invertebrates prolonged *A. bahia* NOEC 64 [µg/L]	Algae *S. subcapitatus* E_bC_{50} 73 [µg/L]	Sed. dweller prolonged *C. riparius* NOEC 2000 [µg/L]	Aquatic plants *L.gibba* NOEC 39.4 [µg/L]
Step 1								
	39.860	166	**0.1**	250.9	**2.5**	**1.8**	50.2	**1.0**
Step 2								
N.Europe	4.028	1646	**0.8**	2483	25	18	496.5	**9.8**
S.Europe	7.163	926	**0.5**	1396	14	10	279.2	**5.5**
Step 3								
D1/ditch	0.810	8185	**4.1**	1246	79	90	2469	49
D1/stream	0.002	3315000	1670	504500	32000	36500	1000000	19700
D3/ditch	< 0.001	6630000	3340	1009000	64000	73000	2000000	39400
D4/pond	0.025	265200	134	40360	2560	2920	80000	1576
D4/stream	0.004	1657500	835	252250	16000	18250	500000	9850
D5/pond	0.028	236786	119	36036	2286	2607	71429	1407
D5/stream	< 0.001	6630000	3340	1009000	64000	73000	2000000	39400
R4/stream	0.574	11551	**5.8**	1758	111	127	3484	68.6
TER criterion		100	10	100	10	10	10	10

TER values shown in bold fall below the relevant trigger.

TER-values for fish (long-term) do not meet the TER criterion in the D1/ditch scenario and indicate a high risk for aquatic invertebrates. D1 is not relevant in the central zone, thus no further refinement is presented.

Table 6.5-17: Refined risk assessment for prothioconazole-metabolite JAU-desthio (M04): risk to aquatic organisms, use in spring cereals

Relevant endpoint: NOEC = 3.34 µg/L, TER trigger: 10

FOCUS Scenario	Mitigation (buffer zone – drift reduction [%]	PECsw [µg/L]	TERLT
spring cereals, multiple application (2 x 98 g a.s./ha, use group A)			
R4/stream	5 m – 0 %	0.574	**5.8**
	10 m – 0 %	0.261	12.8
spring cereals, single application (1 x 98 g a.s./ha, use group B)			
R4/stream	5 m – 0 %	0.573	**5.8**
	10 m – 0 %	0.261	12.8

Use in spring cereals:

- A 10 m buffer strip is required as risk mitigation measure for single multiple applications (use group A and B).

Table 6.5-18: Aquatic organisms: PEC_{sw} for prothioconazole-metabolite JAU 6476-S-methyl, relevant ecotoxicological endpoints and TER values – use in winter cereals

Scenario **FOCUS**	**PEC_{SW} global max** **[µg/L]**	**Fish acute** ***O. mykiss*** **LC_{50}** 1790 **[µg/L]**	**Invertebrates acute** ***D. magna*** **EC_{50}** 2800 **[µg/L]**	**Algae** ***P. subcapitata*** **E_bC_{50}** 3770 **[µg/L]**	**Sed. dweller prolonged** ***C. riparius*** **NOEC** 100 **[µg/L]**
Step 1					
	4.832	370	579	780	21
Step 2 (multiple appl.)					
N.Europe	0.388	4613	7216	9716	258
S.Europe	0.669	2676	4185	5635	150

Table 6.5-19: Aquatic organisms: PEC_{sw} for prothioconazole-metabolite JAU 6476-S-methyl, relevant ecotoxicological endpoints and TER values – use in spring cereals

Scenario **FOCUS**	**PEC_{SW} global max** **[µg/L]**	**Fish acute** ***O. mykiss*** **LC_{50}** 1790 **[µg/L]**	**Invertebrates acute** ***D. magna*** **EC_{50}** 2800 **[µg/L]**	**Algae** ***P. subcapitata*** **E_bC_{50}** 3770 **[µg/L]**	**Sed. dweller prolonged** ***C. riparius*** **NOEC** 100 **[µg/L]**
Step 1					
	4.832	370	579	780	21
Step 2 (multiple appl.)					
N.Europe	0.388	4613	7216	9716	258
S.Europe	0.529	3384	5293	7127	189

Table 6.5-20: Aquatic organisms: PEC_{sw} for prothioconazole-metabolite 1,2,4-Triazole, relevant ecotoxicological endpoints and TER values – use in winter and spring cereals

Scenario FOCUS	PEC_{SW} global max [µg/L]	Fish acute *O. mykiss* LC_{50} 498300 [µg/L]	Fish prolonged *O. mykiss* NOEC 3200 [µg/L]	Invertebrates acute *D. magna* EC_{50} > 100000 [µg/L]	Algae *P. subcapitata* E_bC_{50} 8200 [µg/L]
Step 1					
	0.301	1625581	10631	332226	27243
Step 2 (multiple appl.)					
N.Europe	0.255	1918824	12549	392157	32157
S.Europe	0.255	1918824	12549	392157	32157

The TER values for all metabolites of prothioconazole meet the trigger with FOCUS Step 2 PEC-calculations.

6.5.2.1 Risk assessment for sediment organisms

Due to the date of the application (2014) a standard risk assessment for sediment organisms is provided in the tables above. The TER trigger values are achieved.
However, because of the persistent characteristics of the active substance bixafen in soil and sediment, attention has to be paid to the sediment risk assessment. Thus a risk assessment approach according to the Scientific Opinion on the effect assessment for pesticides on sediment organisms[1] is considered more appropriate and also presented here.

<u>For risk assessment due to exposure via the water compartment:</u>
A risk assessment based on a spiked-water endpoint and assuming for remobilisation of the a.s. from sediment to water (PECsw,eq,accu) is calculated (approach also conducted in the Peer Review of the a.s. Bixafen, see LoEP).
To allow for a comparison of the accumulated PECsed values with the water-spiked *Chironomus* study, the PECsed,accu values were converted to an equivalent water phase concentration PECsw,eq,accu using the ratio of sediment to water in water-spiked *Chironomus* study, i.e. assuming as a worst case that 100% of residues bound to sediment are released to overlying water. For detailed calculations, please refer to CA section 5, chapter 5.6). The resulting "PECsw,eq,accu" is then compared to the endpoint of the spiked-water test (i.e. 15.6 µg/L, Dorgerloh (2007)).

<u>For risk assessment due to exposure via the sediment compartment:</u>

[1] Scientific Opinion on the effect assessment for pesticides on sediment organisms in edge-of-field surface water. In: EFSA Journal 2015;13(7):4176

i) the zRMS presented the modified equilibrium partitioning (EqP) method like proposed as screening step in the new scientific opinion on the effect assessment for pesticides on sediment organisms in edge-of-field surface water (EFSA Journal 2015; 13(7):4176; Chap 5.3).

The modified equilibrium partitioning (EqP) proposes to extrapolate a sediment toxicity from the most sensitive chronic aquatic endpoint (NOEC = 4.6 µg/L in this case for *P. promelas*). This approach is applicable to substances having a log Kow < 5 (valuable for bixafen). The extrapolated endpoint is then compared to a $PEC_{sed\ accu}$.

The calculation can be done as following:

$$NOEC_{sed;modEqP} = (NOEC_{sw} \times KOC)/400$$

$$NOEC_{sed;modEqP} = (4.6 \times 3869/400) = 44.5\ \mu g\ a.s./kg\ sed$$

ii) as direct consequence from the screening step a risk assessment based on a spiked-sediment endpoint assessed with *Chironomus riparius* and the corresponding PECsed accu is then presented.

For the active substance Bixafen an endpoint is available from a study performed with *Chironomus* in a spiked-sediment design. The study delivers the NOEC of 20000 µg a.s./kg sediment (Dorgerloh, 2007). Compared to the corresponding PECsed accu, an acceptable risk for sediment organisms is expected based on the test performed with *Chironomus*. However, the zRMS DE has some strong concerns about the sensitivity of the species tested (i.e. *Chironomus*) to cover for other targeted benthic species.

Indeed, it is acknowledged that *Chironomus* is a relevant benthic test species for active substances having an insecticide mode of action, however in case of a fungicide mode of action there is no consensus on the relevant benthic test species.
When sediment toxicity testing is triggered, the new scientific opinion proposed a decision scheme to select the appropriate benthic test species (EFSA Journal 2015; 13(7):4176, section 8.2.1., p. 74).

Following this decision scheme, bixafen reaches step 4:

4) Substance for which the criteria in 1 to 3 do not apply and likely with fungicidal/biocidal properties. Two sediment-spiked toxicity tests, one with a soft-bodied organism (e.g. *Lumbriculus variegatus* or *Tubifex tubifex*) **and** a second benthic standard test species other than Oligochaeta are proposed in the Tier 1 effect assessment procedure. The selection of the second test species should be motivated based on available toxicity data for pelagic organisms.
Note that, if the pelagic toxicity data indicate that the most sensitive taxonomic group (e.g. a mollusc) is not represented in the set of standard benthic test species, it may be necessary to conduct a sediment-spiked toxicity test with a non-standard benthic representative of the potential sensitive taxonomic group

(e.g. a benthic mollusc). The lowest chronic EC10/NOEC value is used in the effect assessment and the RAC_{sed} = EC10/10."

With regard to the potentially limited sensitivity of *Chironomus* against fungicides, the zRMS has some concerns about the protectivity of a risk assessment for benthic organisms based on tests performed with *Chironomus* species. This concern is supported by the risk identified at the screening step with the modified equilibrium partitioning (EqP) method.

Therefore for further authorisation dossiers, the zRMS strongly recommends to enlarge the risk assessment of sediment organisms exposed via the sediment compartment to other benthic species (e.g. *Lumbriculus variegates or Tubifex tubifex* **and** a non-standard benthic representative).

Table 6.5-21: Aquatic organisms: Sediment risk assessment for bixafen - relevant ecotoxicological endpoints and TER values for relevant organism groups (use in winter cereals)

Scenario **FOCUS** **[µg/kg]**	**PECsed** **[µg/kg]**	**PECsed,accu**	**PECsw,eq,accu global max** **[µg/L]**	**Sed. dweller prolonged** ***C. riparius*** **NOEC** 15.6 **[µg/L]**	**NOECsed;modEqP 44.5 [µg/kg]**
Step 2					
N.Europe	69.17	309.2	78.8	**0.2**	**0.14**
S.Europe	128.4	574	146.4	**0.11**	**0.08**
Step 3 (single appl.)					
D1/ditch	2.504	11.193	2.854	**5.5**	**4.0**
D1/stream	0.582	2.602	0.663	23.5	17.1
D2/ditch	2.541	11.358	2.896	**5.4**	**3.9**
D2/stream	1.772	7.921	2.020	**7.7**	**5.6**
D3/ditch	0.629	2.812	0.717	21.8	15.8
D4/pond	0.502	2.244	0.572	27.3	19.8
D4/stream	0.068	0.304	0.078	201.3	146.4
D5/pond	0.442	1.976	0.504	31.0	22.5
D5/stream	0.042	0.188	0.048	325.9	237.0
D6/ditch	2.761	12.342	3.147	**5.0**	**3.6**
R1/pond	1.812	8.100	2.065	**7.6**	**5.5**
R1/stream	4.074	18.211	4.644	**3.4**	**2.4**
R3/stream	4.057	18.135	4.624	**3.4**	**2.5**
R4/stream	10.82	48.365	12.333	**1.3**	**0.9**
TER criterion				10	10

TER values shown in bold fall below the relevant trigger

FOCUS Step 4 PECsw,eq,accu-values are calculated starting from a 10 m buffer strip. This minimum requirement results from the aquatic risk assessment for the metabolite prothioconazole JAU-desthio.

Table 6.5-22: Aquatic organisms: FOCUS Step 4 sediment risk assessment for bixafen - relevant ecotoxicological endpoints and TER calculations (use in winter cereals)

Scenario FOCUS [µg/kg]	PECsed [µg/kg]	PECsed,accu	PECsw,eq,accu global max [µg/L]	Sed. dweller prolonged *C. riparius* NOEC 15.6 [µg/L]	Most sensitive endpoint from aquatic tests NOECsed;modEqP 44.5 [µg/kg]
Step 4 (single appl.) 10 m buffer strip					
D6/ditch	0.265	1.185	0.302	51.6	37.6
R1/pond	0.391	1.748	0.446	35.0	25.5
R1/stream	0.376	1.681	0.429	36.4	26.5
R3/stream	0.392	1.752	0.447	34.9	25.4
Step 4 (multiple appl.)					
D6/ditch	0.398	1.779	0.454	34.4	25.0
R1/pond	0.794	3.549	0.905	17.2	12.5
R1/stream	0.754	3.370	0.859	18.2	13.2
R3/stream	0.761	3.402	0.867	18.0	13.1
TER criterion				10	10

Table 6.5-23: Aquatic organisms: FOCUS Step 4 sediment risk assessment for bixafen - relevant ecotoxicological endpoints and TER calculations (use in spring cereals)

Scenario FOCUS [µg/kg]	PECsed [µg/kg]	PECsed,accu	PECsw,eq,accu global max [µg/L]	Sed. dweller prolonged *C. riparius* NOEC 15.6 [µg/L]	Most sensitive endpoint from aquatic tests NOECsed;modEqP 44.5 [µg/kg]
Step 2					
N.Europe	69.17	309.2	78.8	**0.2**	**0.14**
S.Europe	128.4	574	146.4	**0.11**	**0.08**
Step 3 (single appl.)					

D1/ditch	3.100	13.857	3.534	4.4	**3.2**
D1/stream	0.398	1.779	0.454	34.4	25.0
D3/ditch	0.435	1.944	0.496	31.5	22.9
D4/pond	0.299	1.337	0.341	45.8	33.3
D4/stream	0.043	0.192	0.049	318.3	231.5
D5/pond	0.270	1.207	0.308	50.7	36.9
D5/stream	0.028	0.125	0.032	488.8	355.5
R4/stream	5.020	22.439	5.722	2.7	**2.0**
Step 3 (multiple appl.)					
D1/ditch	5.431	24.277	6.191	2.5	**1.8**
D1/stream	0.643	2.874	0.733	21.3	15.5
D3/ditch	0.713	3.187	0.813	19.2	14.0
D4/pond	0.511	2.284	0.582	26.8	19.5
D4/stream	0.110	0.492	0.125	124.4	90.5
D5/pond	0.441	1.971	0.503	31.0	22.6
D5/stream	0.044	0.197	0.050	311.0	226.3
R4/stream	12.57	56.188	14.328	1.1	**0.8**
TER criterion				10	10

TER values shown in bold fall below the relevant trigger

D1 and R4 Scenarios are not relevant for the concerned MS, thus FOCUS Step 4 PEC values were not provided by the applicant.

6.5.2.2 Risk assessment for the product, valid for run-off and not run-off endangered areas (based on drift only)

The risk assessment was based on the active substances only. Please refer to chapter Mixture Toxicity.

6.5.2.3 Consideration of Metabolites

Bixafen forms no major metabolites in surface water and only one minor metabolite in soil (M44, max. 2.9 % at the end of the study). Please refer to **Fehler! Verweisquelle konnte nicht gefunden werden.**. No extra consideration is required.

Prothioconazole forms several relevant metabolites in water and soil:

- JAU 6476-desthio (M04): max. 57 % in soil (field study), max. 32.2 % in water, max. 26.9 % in sediment
- JAU 6476-S-methyl (M01): max. 14.6 % at day 7 in soil, max. 9.6 % at day 7 (2x >5%) in sediment
- 1,2,4-Triazol (M13, CGA 71019): max. 37.2 % at day 121 in water, max. 6.1 % at day 121 in sediment
- JAU 6476-triazolylketone (M42, M6a, WAK4995): max. 8 % at day 56 (2x >5%) in water

Contamination via run-off and drainage cannot be excluded. Ecotoxicological studies are available for these metabolites.

The comparison of the study results for the metabolite JAU 6476-triazolylketone with the results of studies performed with prothioconazole shows that the parent substance is more toxic for aquatic organisms than the metabolite. Thus no further assessment is presented.

For the other metabolites of prothioconazole TER calculations for the exposure through spray drift, run-off and drainage are presented under 6.5.2.1

6.5.2.4 Accumulation in aquatic non-target organisms

For all three active substances bioconcentration study with fish were conducted. The trigger for the bioconcentration factor (BCF) according to Commission Regulation (EU) No 546/2011 (10 June 2011) implementing Regulation (EC) No 1107/2009; Chapter C, is > 100 (not readily biodegradable).

The results are summarised in the following table.

Table 6.5-24: Summary of results concerning bioconcentration of the active substances and relevant metabolites in aquatic organisms (source e.g. LoEP/ EFSA Scientific Report)

Bixafen	Bioconcentration factor (BCF)	695 (whole fish, wet weight) 523 (whole fish, normalized to 6% lipid content)
	95% steady state	5.75 d
	Clearance time (CT50)	1.33 d (0.1 µg/L)
	Level of residues in organisms after the 14 day depuration phase	0.7 µg/kg, 99% depuration by Day 14
Prothioconazole	Bioconcentration factor (BCF)	43.9 - 57.8 X for whole fish (sum of all radiolabelled compounds, JAU 6476 parent, metabolites and mineralization products). 15.1 - 19.1X (edible parts) 18.8 (normalised to 6% lipid content)
	95% steady state	2.3 – 3.5 d (whole fish)
	Clearance time (CT50)	0.47 – 0.80 d (whole fish)
	Level of residues in organisms after the 14 day depuration phase	91 % (nominal concentration of 5 µg/L) and 95 % (nominal concentration of 50 µg/L), respectively, of the mean plateau radioactivity
JAU 6476-desthio	Bioconcentration factor (BCF)	45 (whole fish, normalized to 6% lipid content)
	95% steady state	1.7 – 2 d (whole fish)
	Clearance time (CT50)	0.39 – 0.47 d (whole fish)
	Level of residues in organisms after the 14 day depuration phase	96 % (nominal concentration of 10 µg/L) and 99 % (nominal concentration of 50 µg/L), respectively, of the mean plateau radioactivity

The BCF factor for bixafen of 523 in fish indicates a risk for bioaccumulation. However, the depuration in fish was rapid with a CT50 of 1.3 d and 99% elimination from the whole fish by day 14 of the depuration phase. The risk from bixafen for bioaccumulation in sediment dwellers (Lumbriculus variegatus) is presumably acceptable considering the BAF of 2.36 (in relation to data obtained in ring-testing). A trigger for the bioaccumulation of substances in sediment dwelling organisms is not yet defined.

For prothioconazole and the prothioconazole metabolite JAU 6476-desthio, the trigger < 1000 (readily biodegradable) or < 100 (not readily biodegradable) (set in commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2) was met.

The results of the assessment indicate an acceptable risk of bioaccumulation of the substances in aquatic organisms due to the intended use of Ascra XPro in cereals according to the label.

6.5.3 Overall conclusions

Based on the calculated concentrations of the active substances and relevant metabolites in surface water (PEC_{SW} FOCUS Step 1 and 2), the calculated TER values for the acute and long-term risk resulting from an exposure of aquatic organisms to bixafen and the prothioconazole-metabolite JAU-desthio (M04) according to the GAP of the formulation Ascra XPro do not achieve the acceptability criteria TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate a high risk for aquatic organisms due to the intended use of Ascra XPro in cereals according to the label.

Refined risk assessment with calculation of FOCUS step 4 scenarios lead to acceptable TER values with 20 m spray drift or runoff buffer due to the high risk to fish from metabolite JAU-desthio (M04).

Specific risk mitigation measures have to be implemented on member state level.

6.6 Effects on bees (MIIIA 10.4, KPC 10.3.1)

Effects on bees of Ascra Xpro were not evaluated as part of the EU review of bixafen, fluopyram or prothioconazole. Therefore all relevant data and assessments are provided here and are considered adequate.

Toxicity

Table 6.6-1 presents the results of laboratory bee toxicity studies with the formulation. Further details regarding the tests with the formulation are provided in section 10.4.2. For the sake of completeness the table also presents results of laboratory bee toxicity studies with the active substance.

Table 6.6-1: Results of laboratory bee toxicity studies

Test substance	Exposure route	LD_{50}	Reference
Ascra Xpro	oral 48 h	> 312 µg product/bee	Schmitzer S., (2013) report number: 81781035
	contact 48 h	> 200 µg product/bee	
bixafen tech.	oral 48 h	> 121.4 µg as/bee *	EFSA Journal 2012; 10(11): 2917
	contact 48 h	> 100 µg as/bee *	
fluopyram tech.	oral 48 h	>102.3 µg as/bee *	EFSA Journal 2013;11(4): 3052
	contact 48 h	> 100 µg as/bee *	
prothioconazole tech.	oral 48 h	> 71 µg as/bee *	EFSA Scientific Report (2007) 106, 1-98
	contact 48 h	> 200 µg as/bee *	

* EU agreed endpoint

Exposure

The recommended use pattern for Ascra Xpro includes application in cereals at a maximum application rate of up to 1.5 L product/ha. This maximum single application rate is equivalent to 1515 g product/ha.

Bees may be exposed to Ascra Xpro by direct spraying while bees are foraging on flowers and weeds, through contact with fresh or dried residues or by oral uptake of contaminated pollen, nectar and honey dew.

Hazard quotients

Hazard quotients for oral and contact exposure according to EPPO (2003) Environmental risk assessment scheme for plant protection products (Chapter 10: Honeybees (PP 3/10(2)). Bulletin OEPP/EPPO Bulletin 33: 141-145) were calculated as follows:

Hazard Quotient = max. application rate [g product/ha] / LD_{50} [µg product/bee]

Table 6.6-2: Hazard quotients for honeybees

Test substance	Max. single application rate [g product/ha]	Exposure route	LD_{50} [µg product/bee]	Hazard quotient (HQ)	HQ trigger
Ascra Xpro	1515	oral	> 312 µg	< 4.86	50
		contact	> 200 µg	< 7.58	

Risk assessment

Due to the results of laboratory tests Ascra Xpro is considered to be practically non-toxic to bees. All hazard quotients are clearly below the trigger of 50, indicating that the intended use poses a low risk to bees in the field. Bee brood testing is not required since the test item is not an IGR.

Overall conclusion:
It is concluded that Ascra Xpro will not adversely affect bees or bee colonies when used as recommended.

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6.7 Effects on arthropods other than bees (MIIIA 10.5, KPC 10.3.2)

The applicant provided new studies with the product. It is stated:

"Due to the toxicity profile of the active ingredients for non-target arthropods tier 1 glass plate studies were skipped and extended laboratory studies have been directly conducted on four standard non-target arthropod species." (citation from applicant's dossier)

Table 6.7-1: Toxicity of the active substances to non-target arthropods

Species	Substance	Exposure System	Results	Reference	Internal code
Typhlodromus pyri (protonymphs)	BYF 00587 EC 125 G (12,3 % w/w)	laboratory, residues on glass, 2D	LR_{50} = 115.7 g a.s./ha ER_{50} = 62.3 g a.s./ha	Waltersdorfer, A. 23.11.2006 CW06/070	69627
Aphidius rhopalosiphi	BYF 00587 EC 125 G (12,3 % w/w)	laboratory, on glass, 2D	LR_{50} = 35.5 g a.s./ha ER_{50} = 15.75 g a.s./ha	Waltersdorfer, A. 09.11.2006 CW06/069	69626
Typhlodromus pyri	BYF 00587 EC 125 G (12,3 % w/w	Extended laboratory, 2-D bean leaves	LR_{50} >250 g a.s./ha ER_{50} > 125 g a.s./ha	Jans, D. 13.07.2007 CW07/006	69652
Aphidius rhopalosiphi	BYF 00587 EC 125 G (12,3 % w/w)	Extended laboratory, 3-D	LR_{50} = 244 g a.s./ha ER_{50} > 15.75 g a.s./ha	Waltersdorfer, A. 20.04.2007 CW07/007	69651
Chrysoperla carnea	BYF 00587 EC 125 G (12,3 % w/w)	laboratory, 2-D corn leaves	LR_{50} >246 g a.s./ha ER_{50} > 246 g a.s./ha	Waibel, J. 20.06.2007 CW07/011	69654
Typhlodromus pyri	Fluopyram SC 500	laboratory	LR_{50} >2.0 L/ha	LoEP 2013	
Aphidius rhopalosiphi	Fluopyram SC 400	Laboratory, 2-D	LR_{50} >425 g a.s./ha ER_{50}>425 g a.s./ha	Röhlig, U. 16.04.2013 13 10 48 018 A	86891
Aphidius rhopalosiphi	Fluopyram SC 500	laboratory	LR_{50} >2.0 L/ha	LoEP 2013	
Aleochara bilineata	Fluopyram SC 500	Laboratory, 69d	ER_{50} >2.0 L/ha	LoEP 2013	
Typhlodromus pyri	Prothioconazole EC 250	laboratory, 2-D	LR_{50} = 18.7 g a.s./ha ER_{50} > 11 g a.s./ha	LoEP 2006	
Aphidius rhopalosiphi	Prothioconazole EC 250	laboratory, 2-D	LR_{50} = 139.9 g a.s./ha ER_{50} >112 g a.s./ha g a.s./ha	LoEP 2006	
Typhlodromus pyri	Prothioconazole EC 250	Extended laboratory, bean leaves	LR_{50} = 445.5 g a.s./ha ER_{50} > 380 g a.s./ha	Goßmann, A. 26.11.2001 10193062	82382

Aphidius rhopalosiphi	Prothioconazole EC 250	Extended laboratory, wheat plants	LR_{50} > 600 g a.s./ha ER_{50} > 600 g a.s./ha	LoEP 2006	
Coccinella septempunctata	Prothioconazole EC 250	laboratory, 2-D, 46d	LR_{50} = 229.8 g a.s./ha	LoEP 2006	
Chrysoperla carnea	Prothioconazole EC 250	laboratory, 2-D, 23d	LR_{50} > 600 g a.s./ha	LoEP 2006	
Poecilus cupreus	Prothioconazole EC 250	Quartz sand, 14d	LR_{50} > 600 g a.s./ha	LoEP 2006	
Aleochara bilineata	Prothioconazole EC 250	Quartz sand, 87d	ER_{50} > 400 g a.s./ha	LoEP 2006	

* Endpoint differing from LoEP / New study submitted

Table 6.7-2: Toxicity of the product Ascra XPro to non-target arthropods

Species	Substance	Exposure System	Results	Reference	Internal code
Typhlodromus pyri (protonymphs)	Bixafen + Fluopyram + Prothioconazole EC 260	7d, bean leaf disks, 2-D	LR_{50} = 1191 mL/ha ER_{50}>675 mL/ha	Moll, M. 10.03.2014 83872062	86887
Aphidius rhopalosiphi (adults)	Bixafen + Fluopyram + Prothioconazole EC 260	2d, 3-D, barley seedlings	LR_{50} > 2550 mL/ha ER_{50} > 2550 mL/ha	Moll, M. 10.03.2014 83871002	86886
Chrysoperla carnea	Bixafen + Fluopyram + Prothioconazole EC 260	23d, 2-D, bean leaves	LR_{50} > 2550 mL/ha ER_{50} > 2550 mL/ha	Moll, M. 03.12.2013 83873047	86884
Coccinella septempunctata	Bixafen + Fluopyram + Prothioconazole EC 260	14d, 2-D, bean leaves	LR_{50} > 2550 mL/ha ER_{50} > 2550 mL/ha	Moll, M. 03.12.2013 83874012	86886

* Endpoint differing from LoEP / New study submitted

Table 6.7-3: Toxicity of products other than Ascra XPro containing bixafen and prothioconazole to non-target arthropods

Species	Substance	Exposure System	Results	Reference	Internal code

Typhlodromus pyri	Bixafen + Prothioconazole EC 60+200 g/L (Siltra XPro)	7+7 d extended laboratory study on maize leaves 2-D 1 x 200 – 2000 mL/ha	LR_{50} = 867 mL/ha ER_{50} > 632 mL product/ha (41,5 % reduction of reproduction at 632 mL/ha)	Jans, D. 05.08.2009 CW09/025	79720
		7+7 d (mortality and reproduction assessment) extended laboratory study on maize leaves, semi-field conditions, 3-D Application of the test item on whole plants 2 x 1.0 L/ha, 14 d interval	LR_{50} , ER_{50} > 2 x 1000 mL/ha Limit test 28.2 % reduction of reproduction (not statistically significant)	Jans, D. 05.08.2009 CW09/023	79719
Typhlodromus pyri	BYF 00587 + PTZ EC 75 + 150 G (Aviator XPro)	Ext. Lab., bean leafs, aged residues, 3D Exposed from the day of the last treatment on	LR50 > 3x 1.25 L Präp./ha ER50 > 3x 1.25 L Präp./ha	Rosenkranz, B. 12.09.2008 38631060	69516

6.7.1 Justification for new endpoints

The risk assessment is based on results of studies with the product which were submitted with the application.

For higher tier risk assessment, the applicant referred to studies with similar formulations (Bixafen + Prothioconazole EC 60+200 g/L (“Siltra XPro”), BYF 00587 + PTZ EC 75 + 150 G (“Aviator XPro”)).

ZRMS has checked the composition of the fomulations Ascra XPro, Siltra XPro and Aviator XPro and confirms that they are comparable.

6.7.2 Risk assessment

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

For risk assessment purposes, a risk envelope approach was used. Hence, intended use group A covers the risk for non-target arthropods from intended use group B (see Table 6.1-2).

6.7.2.1 Risk assessment for in-field exposure

Exposure

The in-field exposure, given as predicted environmental rates, PER, for non-target arthropods resulting from the intended uses of Ascra XPro is calculated according to published agreement after ESCORT 2

workshop (Candolfi et al. 2001[2] -hereafter referred to as 'Guidance Document') using the following equation:

$$PER_{in-field} = \text{Application rate (g a.s./ha)} \times \text{MAF}$$

where:

MAF = generic multiple application factor used to take into account the potential build-up of applied substances between applications. This factor integrates number of applications, application interval and degradation kinetics of the active substance

Default MAF values for given numbers of applications are listed in the Guidance Document.

Table 6.7-4: Predicted in-field environmental rates (PER)

Intended use	Exposure	Single appl. rate [mL prod./ha]	MAF	$PER_{in-field}$ [mLprod./ha]
Group A	In-field	1500	1.7	2550
Group B	In-field	1200	1.0	1200

MAF: Multiple application factor; f_{drift}: Drift factor; f_{veg}: Vegetation distribution factor; PER: Predicted environmental rates

Tier 1 risk assessment for in-field exposure

The applicant has not provided laboratory (glass plate) studies with the standard test organisms, thus no tier 1 risk assessment is possible. ZRMS proceeded directly with higher tier risk assessment.

Higher tier risk assessment for in-field exposure

The risk for non-target arthropods exposed in-field to Ascra XPro is being assessed by comparing the environmental rate ($PER_{in-field}$) to the lowest lethal rate (LR_{50}) estimated in toxicity tests with non-target arthropods. With regard to extended laboratory tests and semi-field tests, lethal and sublethal effects of less than 50 % are considered acceptable, provided that the tests covered the appropriate field rate.

The results of the risk assessment are summarised in the following table.

Table 6.7-5: Risk assessment for non-target arthropods (Higher tier) for in-field exposure

Intended use	Species	LR_{50}/ER_{50}	PER [mL/ha]	Risk acceptable

[2] Candolfi, M.P.; Barrett, K.L.; Campbell, P.; Forster, R.; Grandy, N.; Huet, M.C.; Lewis. G.; Oomen, P.A.; Schmuck, R.; Vogt, H. (2001): Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods. ESCORT2 Workshop European Standard Characteristics of Non-Target Arthropod Regulatory Testing. Wageningen, The Netherlands, 46 pp.

		[mL/ha]	Group A	Group B	[yes/no]
Group A, B	*T. pyri*	LR_{50}: 1191, ER_{50}: > 675	2550	1200	No
	A. rhopalosiphi	LR_{50} > 2550, ER_{50} > 2550			Yes
	C. carnea	LR_{50} > 2550, ER_{50} > 2550			Yes
	C. septempunctata	LR_{50} > 2550, ER_{50} > 2550			Yes

PER: Predicted environmental rates

The risk for the predatory mite *T. pyri* is not acceptable. The applicant has provided further aged residue-studies (listed in **Table 6.7-3**).

From the tests with single a.s. formulations (Table 6.7-1) the conclusion can be drawn that the preparation Ascra XPro is more toxic than formulations with only one of the three active substances (ER_{50} Bixafen > >250 g a.s./ha, Fluopyram > 1000 g a.s./ha, Prothioconazole > 380 g a.s./h). Furthermore, that a formulation with fluopyram alone was less toxic than formulations with bixafen or prothioconazole alone.

Thus the assessment has to be based on formulation data.

The applicant provided the following refined risk assessment (citation from the applicant's core assessment):

Since initial effects on non-target arthropods with sensitivity like Typhlodromus pyri in the in-field area cannot be excluded, the potential for recovery needs to be demonstrated.

The potential for recovery can be assessed based on the available endpoint from the extended laboratory study in combination with the expected dissipation on plants of the product. This dissipation can be described by an exponential decay function (residue dissipation following first order kinetics[3]) which will be used to estimate the exposure concentration over time (Figure 1). As a conservative assumption the generic DT_{50} of 10 d (EFSA 2009[4],Escort 3[5]) will be used.

[3] Using the basic equation: $C = C_0 \times e^{-kt}$ with C = actual concentration at time t; C_0 = initial concentration and k= rate constant where $k = \ln 2/DT_{50}$

[4] **EFSA (2009): Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA. The EFSA Journal (2009), 7(12):1438**

[5] **Escort 3: linking non-target arthropod testing and risk assessment with protection goals: the Netherlands: 8-10 March 2010/ Neumann, P. SETAC Europe; SETAC publication 2012**

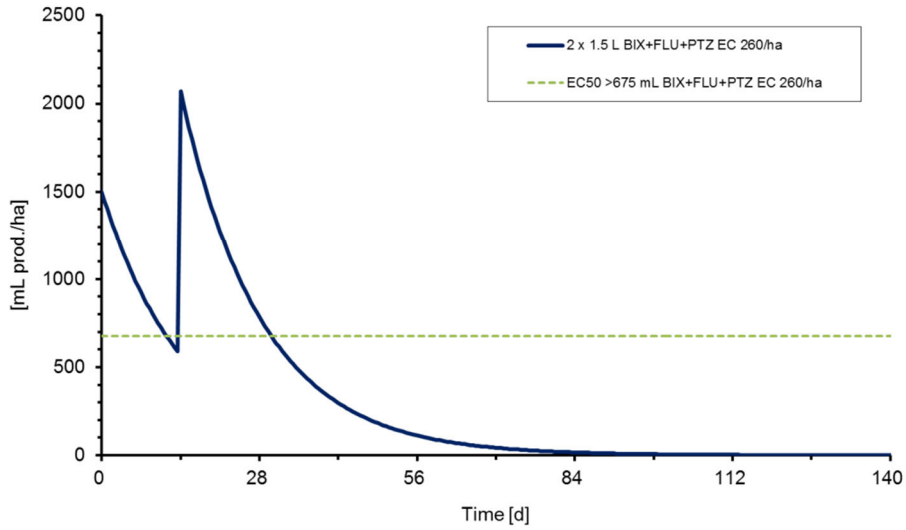

Figure 1: Time course of residues after 2 × 1.5 L product/ha of BIX + FLU + PTZ EC 260 (blue curve) in combination with the ER_{50}-value of the extended laboratory study with T. pyri (green dashed line)

The 50% effect rate (ER_{50}) for Typhlodromus pyri in the extended laboratory study was > 675 mL prod./ha (M-480613-01-1; green dashed line in Figure 1). The residue level of BIX + FLU + PTZ EC 260 will decline within about 2 weeks after the second application below a level equivalent to 675 mL prod./ha. Therefore it can be concluded that the potential for recovery is expected within 2-3 weeks after the last application.

This conclusion is supported by the results of two extended laboratory aged residues studies which were done with formulations containing the active ingredients bixafen and prothioconazole.
Due to the toxicity profile of the three active ingredients bixafen, fluopyram and prothioconazole for non-target arthropods, it is expected that fluopyram does not contribute to the toxicity to Typhlodromus pyri (Table 10.5- 6). Fluopyram showed in the laboratory study no toxicity to Typhlodromus pyri up the highest test rate of 425 g a.s./ha, whereas bixafen and prothioconazole have LR_{50} values of 116 and 18.7 g a.s./ha, respectively.

The results of the two studies are presented in **Table 6.7-3**.

ZRMS has checked the composition of the fomulations Ascra XPro, Siltra XPro and Aviator XPro and confirms that the formulations are comparable. Thus the results from these studies can be used in support of the risk assessment for Ascra XPro.

Table 6.7-6: Higher tier risk assessment for the predatory mite T. pyri - in-field exposure

Intended use	**Species**	**LR_{50}/ER_{50} [mL/ha]**	**PER [mL/ha]**		**Risk acceptable [yes/no]**
			Group A	**Group B**	
Group A, B	*T. pyri*	ER_{50}: 3 x 1.25 L/ha 2875 mL/ha	2 x 1.5 L/ha 2550 mL/ha	1 x 1.2 L/ha 1200 mL/ha	Yes

PER: Predicted environmental rates

An acceptable in-field risk to arthropods can be concluded. Results of a 2-D extended laboratory study with the formulation Ascra XPro indicate the possibility of recolonization of treated areas 2-3 weeks after the second application. Additionally, a supportive aged residue study with a similar formulation containing almost the same co-formulants in comparable portions and two of the three active substances of Ascra XPro indicated acceptable risk at higher application rates.

6.7.2.2 Risk assessment for off-field exposure

Exposure

Exposure of non-target arthropods living in non-target off-field areas to Ascra XPro will mainly be due to spray drift from field applications. Off-field predicted environmental rates (PER-values) were calculated from in-field PERs in conjunction with drift values published by the BBA (2000[6]) as shown in the following equation:

$$Off-field\ PER = \frac{Maximumin-field\ PER\ x \left(drift\ percentile / 100 \right)}{vegetationdistribution\ factor\ (vdf)}$$

where:

vdf = vegetation distribution factor used in combination with test results derived from 2-dimensional exposure set-ups

To account for interception and dilution by three-dimensional vegetation in off-crop areas, a vegetation distribution or dilution factor (vdf, see above) is incorporated into the equation when calculating off-field exposure in conjunction with toxicity endpoints derived from two-dimensional studies (e.g. glass plate or leaf discs). A vdf of 10 is recommended in the ESCORT 2 report when the off-field risk assessment is based on toxicity endpoints obtained in a test design with two-dimensional exposure but has been questioned. Germany considers a vdf of five as a more reliable value to extrapolate from a two dimensional exposure situation to the exposure situation in the field. The exposure estimation was based mainly on the 'Retention Area Index' (RAI) characterizing the total retention area of sprayed plant protection products in a canopy per base area. As a 'realistic worst case scenario, meadow canopies < 20 cm height was chosen (Koch and Weisser, 2004[7]; German Federal Environment Agency UBA, 2006[8]). The derived vdf of 5 agrees well with

[6] BBA (Biologische Bundesanstalt für Land- und Forstwirtschaft) (2000): Abdrifteckwerte für Flächen- und Raumkulturen sowie für den gewerblichen Gemüse-, Zierpflanzen- und Beerenobstanbau. Bundesanzeiger 100, 26. Mai 2000, Köln, pp. 9879.

[7] Koch H and Weisser P, 2004. Die Gesamtoberflaeche in Saumstrukturen als potentielle Retentionsflaeche fuer Driftpartikel, Retention Area Index (RAI). Nachrichtenblatt des Deutschen Pflanzenschutzdienstes, 56, 65-69.

[8] German Federal Environment Agency (UBA), 2006. Exposure calculation for arthropods in field border structures - selection of an appropriate 'vegetation distribution factor'. Parma.

field data by Koch et al. (2003)[9], who compared measured residues of plant protection products on two dimensional surfaces with the measured residues on meadows next to a treated area (factor of 4.4 to 6.5 between median spray residues on leaves when a standard nozzle was used for spray application). For endpoints resulting from 3-dimensional studies, i.e. where spray treatment is applied onto whole plants, the vdf is not used.

The active substances bixafen, fluopyram and prothioconazole have a vapour pressure < 10^{-5} Pa (bixafen: 4.6 x 10^{-8}, fluopyram: 1.2 x 10^{-6} Pa, prothioconazole: extrapolated < $4x10^{-7}$ Pa, respectively) and are therefore classified as non-volatile. Hence, deposition following volatilization has not to be considered.

For the results of study with *T. pyri, C. carnea and C. septempunctata* exposed to Ascra XPro, a vegetation distribution factor has to be considered (studies conducted in 2D environment).

Regarding the results of the study with *A. rhopalosiphi* exposed to Ascra XPro, the vegetation distribution factor does not have to be considered since it was conducted in 3D environment.

Table 6.7-7: Predicted off-field environmental rates (PER) for Ascra XPro

Intended use	Exposure	Single appl. rate [mL prod./ha]	MAF	Drift scenario	f_{drift}	vdf	$PER_{off-field}$ [mL prod./ha]
Group A	Off-field	1500	1.7	Agriculture/ 82.	2.38	10 (EU) (5 - German approach)	6.07 (12.14)
Group B	Off-field	1200	1	Agriculture/ 90.	2.77		3.32 (6.5)

MAF: Multiple application factor; f_{drift}: Drift factor; vdf: Vegetation distribution factor; PER: Predicted environmental rates

Tier 1 risk assessment for off-field exposure

No tier 1 test results are available.

Higher tier risk assessment for off-field exposure

According to ESCORT II , lethal and sublethal effects less than 50 % at the calculated deposition rates including the correction factor are considered acceptable. The correction factor can be lower than 5 if higher

[9] Koch H, Weisser P and Landfried M, 2003. Effect of drift potential on drift exposure in terrestrial habitats. Nachrichtenblatt des Deutschen Pflanzenschutzdienstes, 55, 181-188.

tier tests with the more sensitive of the species affected in tier I and 'two additional species with different biology' were submitted (please refer to European Commission 2002)[10]

Additionally the assessment of the risk to non-target arthropods due to an exposure to Ascra XPro was performed on basis of the calculation of toxicity-exposure ratios (TER values) according the following formula:

$$TER = \frac{L(E)R50\,(L\ product/ha)}{Off-field\ PER\,(L\ product/ha)}$$

The risk is considered acceptable if the values obtained are TER off-field > 10 when the ecotoxicological data resulted from tier 1 tests on glass plates or TER off-field > 5 if higher tier tests with the more sensitive of the species affected in tier I and 'two additional species with different biology' were submitted (please refer to European Commission, 2002)[11].

The results of the risk assessment are summarized in the following table.

Table 6.7-8: Risk assessment for non-target arthropods (Tier 2) for off-field exposure

Intended use	**$PER_{off-field}$ EU (German appr.)*** **[mL prod.//ha]**	**$PER_{off-field}$ x correction factor (5)** **[mL prod./ha]**	**LR_{50}/ER_{50}** **[mL prod./ha]**	**HQ**	**TER**	**Risk acceptable**
Group A	6.07 (12.14)	30.35 (60.7)	ER_{50}: > 675 (*T.pyri*)	0.04 (0.09)	56	Yes
			ER_{50} > 2550 (*A. rhopalosiphi*)	0.01 (0.02)	210	Yes
Group B	3.32 (6.5)	16.62 (33.24)	ER_{50}: > 675 (*T.pyri*)	0.02 (0.05)	102	Yes
			ER_{50} > 2550 (*A. rhopalosiphi*)	0.01 (0.01)	384	Yes

PER: Predicted environmental rates; TER: Toxicity to ecposure ratio. TER values shown in bold fall below the relevant trigger.

* EU: vdf = 10; German approach: vdf = 5

6.7.2.3 Risk mitigation measures

No risk mitigation needed.

[10] European Commission (2002): Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC: Directorate E - Food Safety: plant health, animal health and welfare, international questions; E1 - Plant health.

[11] European Commission. 2002. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC: Directorate E - Food Safety: plant health, animal health and welfare, international questions; E1 - Plant health.

6.7.3 Overall conclusions

In-field

Based on the calculated rates of Ascra XPro in-field, the comparison between experimental effect values and predicted exposure concentrations indicate a risk to sensitive non-target arthropod species. The applicant provided an extrapolation based on conservative estimations that a recolonization of treated areas can be possible two weeks after the second treatment with the formulation Ascra XPro. The applicant furthermore provided higher tier studies with a similar formulation that resulted in effects < 50 % at higher predicted exposure concentrations than expected from the use of Ascra XPro according to the GAP. Therefore, an acceptable in-field risk to non-target arthropods can be concluded.

However, specific environmental conditions in some MS may require risk mitigation measures to ensure the protection goals are met.

Off-field

Based on the calculated rates of Ascra XPro in off-field areas, the calculated HQ and TER values describing the risk resulting from an exposure of non-target arthropods to Ascra XPro according to the GAP of the formulation Ascra XPro achieve the acceptability criteria HQ ≤ 2 (Tier 1)/ of less than 50% effects at calculated drift rates (higher Tier) and of TER ≥ 10 (Tier 1), according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target arthropods due to the intended use of Ascra XPro in cereals according to the label.

6.8 Effects on non-target soil meso- and macrofauna (MIIIA 10.6, KPC 10.4, KPC 10.4.1, KPC 10.4.2)

Table 6.8-1: EU agreed endpoints and new endpoints for earthworms and other soil macro- and mesofauna

Species	Substance	Exposure System	Results	Reference	Internal code
Toxicity of Bixafen and relevant metabolites					
Eisenia fetida	Bixafen	14d, 5% peat	LC_{50} > 1000 mg/kg dw $LC_{50\ corr}$> 500	Lührs, U. 18.10.2006 29612021	69540
Eisenia fetida	Bixafen	56d, 5 % peat	NOEC = 100 mg/kg dw NOEC $_{corr}$ = 50 mg/kg dw	Lührs, U. 23.08.2006 29611022	69541
Toxicity of Fluopyram and relevant metabolites					
Eisenia fetida	Fluopyram	14d, 5% peat	LC_{50} > 1000 mg/kg dw LC_{50} corr> 500	Lechelt-Kunze, C. 17.10.2005 E 310 3018-6	68271
Eisenia fetida	Fluopyram	56d, 5 % peat	NOEC = 27.31 mg product/kg soil, correspondig to 11.42 mg a.i./kg soil NOEC corr = 5.71 mg a.i./kg soil	Heimbach, F., 31.03.2006, E 312 3042-5	68276
Toxicity of Prothioconazole and relevant metabolites					
Eisenia fetida	Prothioconazole (JAU 6476)	14d, 10% peat	LC_{50} > 1000 mg/kg dw $LC_{50\ corr}$> 500	Meisner, P. 10.04.2000 E 310 1769-7	45889
Eisenia fetida	Prothioconazole (JAU 6476 EC 250)	56 d, 10% peat	NOEC: > 1.33 mg/kg dw (highest rate tested) NOEC $_{corr.}$: 0.67 mg/kg dw	Meisner, P., 21.02.2002, E 312 1753-2	45901
Eisenia fetida	Prothioconazole FS 300 G (Skyway XPro)	56 d, 5 % peat	NOEC: 1000 mg product/ha, equivalent to 257 mg a.i./kg soil d.w.	Leicher, T., 25.04.2007, E3123243-8	82409

Eisenia fetida	Prothioconazol-metabolite JAU 6476-S-Methyl	14d, 10% peat	LC_{50} > 1000 mg/kg dw $LC_{50\ corr}$> 500	Heimbach, F. 25.01.2000 E 310 1743-9 ; HBF/Rg 321	45900
Eisenia fetida	Prothioconazol-metabolite JAU-6476-Desthio	14d, 10% peat	LC_{50} > 1000 mg/kg dw $LC_{50\ corr}$> 500	Meisner, P. 29.06.2000 MPE/Rg 338/00 ; E 310 1844-1	45898
Eisenia fetida	Prothioconazol-metabolite JAU 6476-S-Methyl	56d, reproduction, 10% peat	NOEC = 100 mg/kg soil dw $NOEC_{corr}$ = 50 mg/kg soil dw	Heimbach, F. 01.02.2000 E 312 1713-8 ; HBF/Rg 317	45903
Eisenia fetida	Prothioconazol-metabolite JAU-6476-Desthio	56d, reproduction, 10% peat	NOEC = 1.0 mg/kg soil dw $NOEC_{corr}$ = 0.5 mg/kg soil dw	Meisner, P. 31.10.2000 E 312 1799-2 ; MPE/Rg 332/00	45902
5 species (Lumbricus terrestris, L. rubellus, L. castaneus; Aporrectodea caliginosa, A. terrestris longa)	JAU 6476 EC 250	Field study, 12 months	EC_{50} = 200 g a.i./ha	Lechelt-Kunze, C., 28.02.2002 (original study) 02.02.2005 (amendment), E 311 2093-9	76463
Toxicity of the formulation Ascra XPro					
Eisenia fetida	Ascra XPro	56 d 10 % Peat	NOEC = 178 mg produkt/kg dry weight soil $NOEC_{corr}$ = 89 mg/kg soil dw	Friedrich, S. 19.12.2013 13 10 48 183 S	86817

**Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002 (for substances with a log K_{ow} > 2 and 10% peat in the study).

Table 6.8-2: EU agreed endpoints and new endpoints for other soil macro- and mesofauna than earthworms

Species	Substance	Exposure System	Results	Reference	Internal code
Toxicity of Bixafen					
Folsomia candida	Bixafen	28d	NOEC = 7.74 mg/kg dw NOEC $_{corr}$ = 3.87	Lührs, U. 10.08.2007 36952016	69542
Folsomia candida	Bixafen-metabolite of BAS 700 F M 44	28d, 5 % peat	NOEC = 1000 mg a.i./kg soil dw	Royer, S., 25.06.2009 365782	73802
Hypoaspis aculeifer	Bixafen	14d	NOEC = 6.15 mg/kg dw NOEC $_{corr}$ = 3.08	Kratz, M.-A. 04.09.2007 E 428 3292-0	69543
Toxicity of Fluopyram					
Folsomia candida	Fluopyram SC 500	chronic, 28 days, 5% peat	NOEC = 250 mg/kg NOEC 103.8 mg as/kg d.w.soil	Frommholz, U., 14.06.2007, E 314 3248-5	23500
Hypoaspis aculeifer	Fluopyram SC 500	chronic, 14 days, 5% peat	NOEC 1000 mg product/kg d.w.soil NOEC 415 mg as/kg d.w.soil NOEC $_{corr}$ = 207.5	Kratz, M.-A., 16.04.2007, Kra-HR-3/07	68269
Toxicity of Prothioconazole and relevant metabolites					
Folsomia candida	Prothioconazole (JAU 6476)	28 d, chronic	NOEC ≥ 64 mg/kg dw NOEC $_{corr}$ = 32 mg/kg soil dw	Nienstedt, K.M. 31.01.2002 1022.028.641	45918
Folsomia candida	Prothioconazole	28 d, chronic 5 % peat	NOEC = 1000 mg a.i./kg NOEC $_{corr}$ = 500 mg/kg soil dw	Frommholz, U., 12.04.2011, FRM-COLL-118	41072
Folsomia candida	JAU 6476-S-methyl	28d, 10% peat	NOEC = 31.6 mg/kg dw NOEC $_{corr}$ = 15.8 mg/kg soil dw	Moser, T.; Scheffczyk, A. 19.11.2001 P35CR	45922
Folsomia candida	JAU 6476-desthio	28d, 10% peat	NOEC = 62.5 mg/kg dw NOEC $_{corr}$ = 31.3 mg/kg soil dw	Moser, T.; Roembke, J. 12.02.2002 P1CR	45919
Hypoaspis aculeifer	Prothioconazole	34 d, LUFA 2.1 soil	NOEC = 100 mg/kg dw NOEC $_{corr}$ = 50	Hoogendoorn, G.M., 06.09.2000, B060HAE	45923
Toxicity of the formulation Ascra XPro					
Folsomia candida	Ascra XPro	28 d 5 % Peat	NOEC = 100 mg/kg soil dw NOEC $_{corr}$ = 50 mg/kg soil dw	Frommholz, U. 28.03.2014 E 314 4571-5	86890

Hypoaspis aculeifer	Bixafen + Fluopyram + Prothioconazole EC 260	14 d, 5% peat	NOEC = 178 mg/kg soil dw NOEC $_{corr}$ = 89 mg/kg soil dw	Larnaudie Lopez, M. I., 16.12.2013, E 428 4570-0	86882

Table 6.8-3: Organic matter breakdown

Substance	Exposure System	Results	Reference	Internal code
Bixafen	180d	Max 6.6 % deviation in OM degradation, total 0.277 mg bixafen/kg dw soil (10cm soil depth)	LoEP 2012	-/-
Fluopyram SC 500	183d, wheat straw 1. application: 1535 g product/ha (=642 g a.s./ha) 2. application: 717 g product/ha (= 300 g a.s./ha)	76% degradation in control after 133 days (trigger is 60 %) wheat straw degradation in treated plots (rel. to control): after 30 days: 114.4% (n.s.) after 92 days: 106.0% (n.s.) after 173 days: 101.0 % (n.s.) NOEC ≥ 0,514 mg a.s./kg TS	LoEP 2013 (Leicher 2007)	-/-
Prothioconazole FS 100, Prothioconazole EC 250	126d, wheat straw 1. application: 22,9 g a.s./ha (Prothioconazole FS 100) 2. application: 3 x 200 g a.s./ha (Prothioconazole EC 250)	+0.9% difference after 126d	Lechelt-Kunze, C. 24.10.2002 E 427 2121-9	69015

6.8.1 Justification for new endpoints

New studies with the preparation have been submitted. A summary and evaluation by zRMS is provided in Appendix II.

6.8.2 Toxicity exposure ratios for earthworms and other soil macro- and mesofauna, TER_A and TER_{LT} (MIIIA 10.6.1)

The evaluation of the risk for earthworms and other soil macro-organisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

For the calculations of predicted environmental concentrations in soils (PEC soil), reference is made to the environmental fate section (Part B, Section 5) of this submission.

Based on all information about the degradation of bixafen in soil resulting from laboratory studies, field studies, and the soil accumulation study, bixafen is highly persistent. In this respect, the behaviour of

bixafen in soil is source of great concern. Thus, for the active substance bixafen two PECsoil values are presented. The first (0.14948 mg/kg) represents PECsoil calculated with standard assumptions. The second (0.8343 mg/kg) includes an additional uncertainty factor of 10 to the the maximum annual soil concentration PECact in a soil depth of 5 cm in order to address the high persistency and accumulation potential of bixafen.

For convenience the results of the PEC_{soil} calculations from Core Assessment Sec. 5 are presented here:

Table 6.8-4: Results of PEC_{soil} calculation for application of Ascra XPro in cereals (soil bulk density 1.5 g/cm^{-3}, soil depth 5 cm) according to use No A

active substance/ preparation	soil relevant application rate (g/ha)	PEC_{act} (mg/kg)	PEC_{twa} 21 d (mg/kg)	tillage depth (cm)	PEC_{bkgd} (mg/kg)	PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)
Ascra XPro	2 x 455	1.2133	-	-	-	-
Bixafen	2 x 29.25	0.0777	-	20	0.07178	0.14948
Including an additional safety factor to PEC_{bkgd}	2 x 29.25	0.0777	-	20	0.7566	0.8343
Fluopyram	2 x 29.25	0.0747 (d 14)	-	20	0.0235	0.0983
Prothioconazole	2 x 58.5	0.0798 (d 14)	-	-	-	-
JAU6476-S-methyl (M01)	2 x 8.6	0.0194 (d 14)	-	-	-	-
JAU6476-desthio (M04)	2 x 30.3	0.0745 (d 14)	-	-	-	-

For risk assessment purposes, a risk envelope approach was used. Hence, intended use group A covers the risk for earthworms and other soil macro- and mesofauna from use group B (see Table 6.1-2).

The acute risk for earthworms and other non-target soil macro- and mesofauna resulting from an exposure to Ascra XPro and the active substances bixafen and prothioconazole as well as the major soil degradation products of prothioconazole was assessed by comparing the maximum PEC_{SOIL} with the 14-day LC_{50} value to generate acute TER values. The TER_A was calculated as follows:

$$TER_A = \frac{LC_{50}\ (mg/kg)}{PEC_{soil}\ (mg/kg)}$$

The chronic risk for earthworms, other non-target soil macro- and mesofauna and organic matter breakdown resulting from an exposure to Ascra XPro the active substances as well as the major soil degradation products was assessed by comparing the maximum PEC_{SOIL} with the NOEC value to generate chronic TER values. The TER_{LT} was calculated as follows:

$$TER_{LT} = \frac{NOEC\ (mg/kg)}{PEC_{soil}\ (mg/kg)}$$

The results of the risk assessment are summarized in the following table.

Table 6.8-5: TER values for earthworms and other soil macro- and mesofauna (Tier-1), use group A (twofold application), 2 x 1.5 L/ha, 14 d interval

Species	Test item	Time scale	Endpoint [mg/kg soil dw]	Max. PEC_{SOIL} [mg/kg soil dw]	TER
Eisenia fetida	Bixafen	Acute	> 500	0.14948	3345
				0.8343	599
	Bixafen	Chronic	50	0.14948	334
				0.8343	60
	Fluopyram	Acute	> 500	0.0983	5086
	Fluopyram	Chronic	5.71	0.0983	58
	Prothioconazole	Acute	> 500	0.0798	6266
	Prothioconazole	Chronic	> 0.67	0.0798	8
	JAU-6476-S-methyl	Acute	> 500	0.0194	25773
	JAU-6476-S-methyl	Chronic	50	0.0194	2577
	JAU-6476-desthio	Acute	> 500	0.0745	6711
	JAU-6476-desthio	Chronic	0.5	0.0745	7
	Ascra XPro	Chronic	89	1.2133	73
Folsomia candida	Bixafen	Chronic	3.87	0.14948	26
				0.8343	**4.6**
	Prothioconazole	Chronic	32	0.0798	401
	JAU-6476-S-methyl	Chronic	15.8	0.0194	814
	JAU-6476-desthio	Chronic	31.3	0.0745	420
	Ascra XPro	Chronic	50	1.2133	41
Hypoaspis aculeifer	Bixafen	Chronic	3.08	0.14948	21
				0.8343	**3.7**
	Fluopyram SC 500	Chronic	207.5	0.0983	2111
	Prothioconazole	Chronic	50	0.0798	627
	Ascra XPro	Chronic	89	1.2133	73

TER values shown in bold fall below the relevant trigger.

6.8.3 Higher tier risk assessment

a) earthworms

Regarding the TER values for the prothioconazole-metabolite JAU 6476-desthio falling close to the trigger ≥ 5, the applicant pointed out to the peer review of the active substance prothioconazole.:

"During an earthworm field (Lechelt-Kunze, 2002) study where the exposure to JAU 6476-desthio was analytically confirmed, no adverse effects on earthworm populations could be observed at concentrations higher than the calculculated PECsoil. Thus, no unacceptable effects from JAU 6476-desthio on earthworm populations are to be expexted for the intended application rates."

This argumentation is accepted. Overall, the field study indicated that earthworm populations were not adversely affected by repeated applications of JAU 6476 EC 250 (3 x 200 g a.s./ha) seven weeks, 5 months and 11 months after the first application.

b) Other soil macro-organisms than earthworms

If PEC_{soil}-calculations are based on standard assumptions, all TER values meet the trigger ≥ 5.

However, a concern was raised during the peer review with regard to the persistency and accumulation potential of bixafen (see EFSA conclusion EFSA Journal 2012;10(11):2917). It was discussed that standard studies required for the risk assessment may not sufficiently address the concerns regarding bioaccumulation and toxicity to soil and benthic organisms. In order to illustrate the risk arising from the persistent active substance bixafen over the years, the PEC_{soil} calculations for bixafen following the application of Ascra XPro were conducted with an additional safety factor of 10 (please refer to section 5, chapter 5.5). The result are TER ranges from 21 (standard assumption) to **3.7 (including safety factor) for *Hypoaspis aculeifer*** and from 26 (standard assumption) to **4.6 (including safety factor) for *Folsomia candida***. Results from studies with the preparation Ascra XPro cannot disburden the concern appropriately as they do not either consider the accumulation of bixafen.

Considering this, a safe use becomes questionable after several years of continuous use of the product. The concern was discussed at the Pesticides Peer Review experts meeting (PPR 91) and it was concluded that environmental monitoring of potential effects of soil and sediment organisms would be preferable. The experts at the meeting agreed that no monitoring data are stipulated at the EU level, but additional information may be required at national level for soil and sediment-dwelling organisms.

We seek the Member States to consider the persistence of bixafen when addressing the risks of intended uses of the formulation Ascra XPro for the soil compartment.

ZRMS Germany decided to link the national product authorization with a 2 years monitoring study on soil organisms treated with bixafen.

6.8.4 Overall conclusions

Based on standard assumptions for calculating the predicted concentrations of the active substances, their metabolites ans well as the product Ascra XPro in soil, all TER values meet the required trigger of ≥ 10 and 5, respectively, and an acceptable risk can be concluded.

However, it has to be pointed out that due to the uncertainties regarding the fate studies of bixafen in soils, an additional safety factor has been included in the PEC calculations addressing the high persistency of the active substance. If the safety factor is included in the calculation of the predicted concentrations in soil, a high risk to soil macro-organisms from bixafen is indicated. In oder to address these uncertainties monitoring studies are required on national level regarding the fate and ecotoxicologal impacts of the formulation.

6.9 Effects on soil microbial activity (MIIIA 10.7, KPC 10.5)

Table 6.9-1: EU agreed endpoints and new endpoints for soil microorganisms

Substance	Test design	Results	Source	Internal code
Bixafen	N-mineralisation	≤ 3% inhibition at 0.17 mg a.s./kg dw soil and 1.67mg a.s./kg dw soil	Lechelt-Kunze, C., 28.04.2005, E 337 2915-0	69807
	C-mineralisation	≤ 6% inhibition at 0.17mg a.s./kg dw soil and 1.67mg a.s./kg dw soil	Lechelt-Kunze, C., 09.05.2005 E 330 2916-4	69808
Fluopyram	N-mineralisation	<25 % inhibition at 3.33 mg/kg dw soil (2.5 kg/ha), 28d	Leicher, T., 11.12.2006, E 337 3200-8	74129
	C-mineralisation	<25 % inhibition at 3.33 mg/kg dw soil (2.5 kg/ha), 28d	Leicher, T., 14.12.2006, E 330 3198-7	74130
Prothioconazole (JAU 6476)	N-mineralisation	4 % inhibition at 2.71 mg/kg soil dw, 28d	Anderson, J. P. E. 08.12.1999 AJO/203199	69374
	C-mineralisation	5 % inhibition at 2.71 mg/kg soil dw, 28d	Anderson, J. P. E. 08.12.1999 AJO/203099	69379
Prothioconazol-Metabolite 1,2,4-Triazole	N-mineralisation	1.5 % inhibition at 0.353 mg/kg soil dw, 28d	Völkel, W. 16.05.2000 763367	65556
	C-mineralisation	8.3 % stimulation at 0.353 mg/kg soil dw, 28d	Völkel, W. 16.05.2000 763367	65556
Prothioconazol-Metabolite	N-mineralisation	4.5 % stimulation at 2.69 mg/kg soil dw (= 2020 g/ha), 28d	Anderson, J. P. E. 08.12.1999 AJO/203399	69377

JAU 6476-S-Methyl	C-mineralisation	3 % stimulation at 2.69 mg/kg soil dw (= 2020 g/ha), 28d	Anderson, J. P. E. 08.12.1999 AJO/203399	69378
Prothioconazol-Metabolite JAU 6476-Desthio	N-mineralisation	8 % inhibition at 1.37 mg/kg soil dw (= 1030 g/ha), 28d	Anderson, J. P. E. 05.07.2001 AJO/219101	69376
	C-mineralisation	<25 % inhibition at 1.33 mg/kg soil dw (=1000 g/ha), 28d	Leicher, T. 20.07.2007 E 330 3322-6	68729
Ascra XPro	N-mineralisation	9.8 % stimulation at 20.22 mg/kg soil dw (15 L/ha), 28 d	Schulz, L., 11.12.2013, 13 10 48 115 N	86815
	C-mineralisation	*Not required anymore according to Com. Reg. (EU) 284/2013.*		

Justification for new endpoints

A new study with the preparation (N-mineralisation) has been submitted.

6.9.1 Risk assessment

The evaluation of the risk for earthworms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

Please refer to above for the predicted environmental concentrations in soil (PEC_{SOIL}) of the active substances and Ascra XPro.

The results of the risk assessment are summarized in the following table.

Table 6.9-2: Risk assessment for effects on soil micro-organisms

Test substance	**Test concentration (adverse effects < 25%)** **[mg /kg]**	**PEC_{SOIL}** **[mg/kg]**	**Risk acceptable** **[yes/no]**
Bixafen	1.67	0.8343	yes
Fluopyram	3.33	0.0983	yes
Prothioconazole	2.71	0.0798	yes
Prothioconazol-Metabolite JAU 6476-S-Methyl	2.69	0.0194	yes
Prothioconazol-Metabolite JAU 6476-Desthio	1.37	0.0745	yes
Ascra XPro	20.22	1.2133	yes

6.9.2 Overall conclusions

Based on the predicted concentrations of the active substances, relevant soil metabolites and the formulation Ascra XPro in soils, the risk to soil microbial processes following exposure to Ascra XPro according to the GAP of the formulation is considered to be acceptable according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2.

6.10 Effects on non-target plants (MIIIA 10.8, KPC 10.6)

6.10.1 Effects on non-target terrestrial plants (MIIIA 10.8.1)

Table 6.10-1: EU-agreed endpoints and new endpoints for non-target terrestrial plants

Species	Substance	Exposure System	Results	Reference	Internal code
Avena sativa, Fagopyrum esculentum, Brassica napus, Lycopersicon esculentum, Beta vulgaris, Cucumis sativus	BYF 00587 EC 125 g/L (12,9% w/w)	Seedling emergence, 14 d Screening	ER_{25}<2.0 L/ha	Gosch, H.; Nguyen, D. H. 14.08.2007 SE07/09	69538
Avena sativa, Zea mays, Fagopyrum esculentum, Brassica napus, Lycopersicon esculentum, Lolium perenne, Helianthus annus, Beta vulgaris, Cucumis sativus, Glycine max	BYF 00587 EC 125 g/L (12,9% w/w)	Vegetative vigour, 21d	ER_{25}<1.0 L/ha	Gosch, H.; Nguyen, D. H. 14.08.2007 VV07/09	69539
Fagopyrum esculentum	Fluopyram SC 500 (AE C656948)	Seedling emergence, 21 d Screening	ER_{50}>500 g/ha	Bach, F. 12.04.2012 SE12/006	78903
Beta vulgaris	Fluopyram SC 500 (AE C656948)	Vegetative vigour	ER_{50}>250 g/ha	LoEP 2013	
Amaranthus retroflexus, *Beta vulgaris*, *Avena fatua*, *Ipomoea hederacea*, *Galium aparine*, *Setaria viridis*, *Zea mays*, *Abutilon theophrasti*, *Echinochloa crus-galli*, *Alopecurus myosuroides*, *Sinapis alba*	Prothioconazole (JAU 6476)	Seedling emergence, 21 d Screening	ER_{50}=1000 g/ha	Meisner, P.; Kolb, U. 07.07.2000 MPE NTP 13/00	45905
	Prothioconazole (JAU 6476)	Vegetative vigour 17 d, Screening	ER_{50}=1000 g/ha	Meisner, P.; Kolb, U. 07.07.2000 MPE NTP 13/00	45905

Brassica napus, Lycopersicon esculentum, Beta vulgaris, Glycine max, Helianthus annuus, Fagopyrum esculentum, Allium cepa, Lolium multiflorum, Avena sativa, Zea mays	Ascra XPro	Vegetative vigour 21 d	ER_{50} > 1.5 L/ha	Marquardt, J., 19.12.2013, AS318	83043
	Ascra XPro	Seedling emergence 21 d	ER_{50} > 1.5 L/ha	Marquardt, J., 13.02.2014, AS317	83041

6.10.2 Justification for new endpoints

Results from the tests with the preparation are relevant for risk assessment.

6.10.2.1 Risk assessment

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area. Spray drift from the treated areas may lead to residues of a product in off-crop areas. As more than 5 species have been tested, the TER trigger is lowered to 5.

Exposure

Effects on non-target plants are of concern in the off-field environment, where they may be exposed to spray drift. The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates derived by the BBA (2000) from the spray-drift predictions of Ganzelmeier & Rautmann (2000). Any dilution over the 3-dimensional vegetation surface is accounted for in the study design. Therefore, in contrast to the assessment of risks to arthropods from standard laboratory tests, no vegetation distribution factor is considered here.

$PER_{off\text{-}field}$= Maximum $PER_{in\text{-}field}$ (including MAF) x % drift

All active substances are classified as non-volatile (please refer to 0).

For calculation of $PER_{off\text{-}field}$, please refer to 6.7.2.1.

Table 6.10-2: Predicted off-field environmental rates (PER) for Ascra XPro

Intended use	Exposure	Single appl. rate [mL/ha]	Drift scenario	f_{drift}	$PER_{off-field}$ [mL/ha]
Group A (2 x 1.5 L/ha)	Off-field	1500	Agriculture/90.	2.77	41.6
Group B (1 x 1.2 L/ha	Off-field	1200	Agriculture/90.	2.77	33.2

MAF: Multiple application factor; f_{drift}: Drift factor; PER: Predicted environmental rates

Tier 1 assessment

The assessment of the risk to non-target arthropods due to an exposure to Ascra XPro is performed on basis of the calculation of toxicity-exposure ratios (TER values) according the following formula:

$$TER = \frac{ER50\,(L\ product/ha)}{Off-field\ PER\,(L\ product/ha)}$$

The results of the risk assessment are summarized in the following table.

Table 6.10-3: Risk assessment for non-target terrestrial plants exposed to Ascra XPro for its intended uses in cereals

Intended use	ER_{50} [g/ha]	PER [g/ha]	TER
Group A	> 1700	41.6	36
Group B	> 1700	33.2	45

6.10.2.2 Higher tier risk assessment (quantitative risk assessment)

Not relevant.

Risk mitigation measures

No risk mitigation needed.

6.10.2.3 Overall conclusions

Based on the predicted rates of Ascra XPro in off-field areas, the TER values describing the risk for non-target plants following exposure to Ascra XPro according to the GAP of the formulation achieve the acceptability criteria TER ≥ 5 according to commission implementing regulation (EU) No 546/2011,

Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of Ascra XPro in cereals according to the label.

6.11 Effects on other terrestrial organisms (flora and fauna) (KPC 10.7)

6.12 Monitoring data (KPC 10.8)

6.13 Available preliminary data (IIIA 10.9)

6.14 Other/special studies (IIIA 10.10)

Appendix 1 List of data submitted in support of the evaluation

Table A 1: List of data submitted in support of the evaluation

Annex point/ reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not Authority registration No	Data protection claimed [Y/N]	Owner	Relied on Y/N/add
KIIIA 10.1.7 /01	Neumann, P.	2009	JAU 6476-desthio: Residue formation and dissipation rate as determined in plant residue studies for use in ecotoxicological risk assessments Bayer CropScience, Report No.: M-348996-01-1 Date: 2009-06-24 GLP/GEP: n.a., unpublished	Yes	Bayer CropScience	N
KIIIA 10.2 /01	[redacted]	2007	Early life stage toxicity of prothioconazole technical to the rainbow trout (Oncorhynchus mykiss) under flow through conditions Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: EBJAX313, Date: 2007-08-06 GLP/GEP: yes, unpublished	Yes	Bayer CropScience	Y
KIIIA 10.2 /02	Bruns, E.	2006	Chironomus riparius 28-day chronic toxicity test with JAU 6476-S-methyl in a water-sediment system using spiked water Bayer CropScience, Report No.: EBJAX303, Date: 2006-03-14 GLP/GEP: yes, unpublished	Yes	Bayer CropScience	Y
KIIIA 10.2 /03	[redacted].	2006	Acute toxicity of JAU 6476-triazolylketone (tech.) to fish (Oncorhynchus mykiss) under static conditions Bayer CropScience, Report No.: EBJAX306, Date: 2006-02-23 GLP/GEP: yes, unpublished	Yes	Bayer CropScience	Y
KIIIA 10.2 /04	Bruns, E.	2006	Acute toxicity of JAU 6476-triazolylketone (tech.) to the waterflea Daphnia magna in a static laboratory test system Bayer CropScience,	Yes	Bayer CropScience	Y

			Report No.: EBJAX305, Date: 2006-02-23 GLP/GEP: yes, unpublished			
KIIIA 10.2 /05	Dorgerloh, M.	2006	Pseudokirchneriella subcapitata: growth inhibition test with prothioconazole-triazolylketone Bayer CropScience, Report No.: EBJAX304, Date: 2006-02-23 GLP/GEP: yes, unpublished	Yes	Bayer CropScience	Y
KIIIA 10.2.2.1 /01	[redacted]	2013	Acute toxicity of bixafen + fluopyram + prothioconazole EC 260 (65+65+130 g/L) to the rainbow trout (Oncorhynchus mykiss) under static conditions SynTech Research Laboratory Services, LLC, Stilwell, KS, USA Bayer CropScience, Report No.: EBDRR001, Date: 2013-12-13 GLP/GEP: yes, unpublished	Yes	Bayer CropScience	Y
KIIIA 10.2.2.2 /01	Matlock, D.; Moore, S.	2013	Acute toxicity of Bixafen + Fluopyram + Prothioconazole EC 260 (65+65+130 g/L) Daphnia magna under static conditions SynTech Research Laboratory Services, LLC, Stilwell, KS, USA Bayer CropScience, Report No.: EBDRR002 Date: 2013-12-18 GLP/GEP: yes, unpublished	Yes	Bayer CropScience	Y
KIIIA 10.2.2.3 /01	Matlock, D.; Moore, S.	2013	Toxicity of bixafen + fluopyram + prothioconazole EC 260 (65+65+130 g/L) to the green algae Pseudokirchneriella subcapitata during a 72 hour exposure SynTech Research Laboratory Services, LLC, Stilwell, KS, USA Bayer CropScience, Report No.: EBDRR003, Date: 2013-12-13 GLP/GEP: yes, unpublished	Yes	Bayer CropScience	Y
KIIIA 10.2.7 /01	Gilberg, D.	2012	14C-Bixafen: A study on the bioaccumulation in the aquatic oligochaete Lumbriculus variegatus ECT Oekotoxikologie GmbH, Floersheim, Germany Bayer CropScience, Report No.: 12P1LB, Date: 2012-08-30 ...Amended: 2012-09-28 GLP/GEP: yes, unpublished	Yes	Bayer CropScience	add
KIIIA 10.4.2.1 /01	Schmitzer, S	2012	bixafen + fluopyram + prothioconazole EC 260 (65+65+130) G - (acute contact and	Yes	Bayer CropScience	add

			oral) on honey bees (apis mellifera l.) in the laboratory IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 81781035, Date: 2012-10-31 GLP/GEP: yes, unpublished			
KIIIA 10.5.1 /01	Roehlig, U.	2013	Fluopyram SC 400 g/L - Effects of fluopyram SC 400 g/L on the parasitic wasp Aphidius rhopalosiphi (DESTEFANI-PEREZ) in a laboratory test BioChem agrar, Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 018 A, Date: 2013-04-16 GLP/GEP: yes, unpublished	Yes	Bayer CropScience	add
KIIIA 10.5.1 /02	Waltersdorfer, A.	2006	Toxicity to the predatory mite Typhlodromus pyri SCHEUTEN (Acari, Phytoseiidae) in the laboratory BYF 00587 EC 125 G Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: CW06/070, Date: 2006-11-23 GLP/GEP: yes, unpublished	Yes	Bayer CropScience	add
KIIIA 10.5.2 /01	Moll, M.	2014	Effects of bixafen + fluopyram + prothioconazole EC 260 (65 + 65 + 130 g/L) on the parasitoid Aphidius rhopalosiphi, extended laboratory study - Dose response test IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 83871002, Date: 2014-03-10 GLP/GEP: yes, unpublished	Yes	Bayer CropScience	Y
KIIIA 10.5.2 /02	Moll, M.	2014	Effects of bixafen + fluopyram + prothioconazole EC 260 (65 + 65 + 130 g/L) on the predatory mite Typhlodromus pyri, extended laboratory study - Dose response test IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 83872062, Date: 2014-03-10 GLP/GEP: yes, unpublished	Yes	Bayer CropScience	Y
KIIIA 10.5.2 /03	Moll, M.	2013	Effects of bixafen + fluopyram + prothioconazole EC 260 (65 + 65 + 130 g/L) on the ladybird beetle Coccinella septempunctata, extended laboratory study - Dose response test IBACON GmbH, Rossdorf, Germany	Yes	Bayer CropScience	Y

			Bayer CropScience, Report No.: 83874012, Date: 2013-12-03 GLP/GEP: no, unpublished			
KIIIA 10.5.2 /04	Moll, M.	2012	Effects of Bixafen + Fluopyram + Prothioconazole EC 260 (65 + 65 + 130 g/L) on the lacewing Chrysoperla carnea, extended laboratory study - Dose response test IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 83873047, Date: 2012-12-03 GLP/GEP: yes, unpublished	Yes	Bayer CropScience	Y
KIIIA 10.5.2 /05	Jans, D.	2009	Toxicity to the predatory mite Typhlodromus pyri SCHEUTEN (Acari, Phytoseiidae) using an extended laboratory test (under semi-field conditions aged residues on Zea mays) Bixafen + Prothioconazole EC 60 + 200 g/L Bayer CropScience, Report No.: CW09/023, Date: 2009-08-05 GLP/GEP: yes, unpublished	Yes	Bayer CropScience	add
KIIIA 10.5.2 /06	Rosenkranz, B.	2008	Effects of BYF 00587 + PTZ EC 75 + 150 G on the predatory mite Typhlodromus pyri, extended laboratory study - aged residue test - IBACON GmbH, Rossdorf, Germany Report No.: 38631060, Date: 2008-09-12 GLP/GEP: yes, unpublished	Yes		add
KIIIA 10.6.3 /01	Friedrich, S.	2013	Bixafen + fluopyram + prothioconazole EC 260 (65+65+130) G: Sublethal toxicity to the earthworm Eisenia fetida in artificial soil BioChem agrar GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 183 S, Date: 2013-12-19 GLP/GEP: yes, unpublished	Yes	Bayer CropScience	Y
KIIIA 10.6.5 /01	Egeler, Ph.; Gilberg, D.	2009	Fluopyram: A study on the bioaccumulation by the earthworm Eisenia fetida ECT Oekotoxikologie GmbH, Floersheim, Germany Bayer CropScience, Report No.: 08P1RD, Date: 2009-06-19 GLP/GEP: yes, unpublished	Yes	Bayer CropScience	add
KIIIA 10.6.6 /01	Frommholz, U.	2011	Prothioconazole a.s.: Influence on the reproduction of the collembolan	Yes	Bayer CropScience	Y

			species Folsomia candida tested in artificial soil Bayer CropScience, Report No.: FRM-COLL-118/11, Date: 2011-04-12 GLP/GEP: yes, unpublished			
KIIIA 10.6.6 /02	Frommholz, U.	2014	Bixafen + fluopyram + prothioconazole EC 260 (65+65+130) G: Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil Bayer CropScience, Report No.: FRM-Coll-166/14, Date: 2014-03-28 GLP/GEP: yes, unpublished	Yes	Bayer CropScience	Y
KIIIA 10.6.6 /03	Larnaudie Lopez, M. I.	2013	Bixafen + fluopyram + prothioconazole EC 260 (65+65+130) G: Influence on mortality and reproduction of the soil mite species Hypoaspis aculeifer tested in artificial soil Bayer CropScience, Report No.: LAR-HR-96/13, Date: 2013-12-16 GLP/GEP: yes, unpublished	Yes	Bayer CropScience	Y
KIIIA 10.7.1 /01	Leicher, T.	2007	Metabolite JAU 6476-desthio : Determination of effects on carbon transformation in soil Bayer CropScience, Report No.: LRT-C-74/07, Date: 2007-07-20 GLP/GEP: yes, unpublished	Yes	Bayer CropScience	Y
KIIIA 10.7.1 /02	Schulz, L.	2013	Bixafen + fluopyram + prothioconazole EC 260 (65+65+130) G: Effects on the activity of soil microflora - (Nitrogen transformation test BioChem agrar GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 115 N, Date: 2013-12-11 GLP/GEP: yes, unpublished	Yes	Bayer CropScience	Y
KIIIA 10.8.1.2 /01	Marquardt, J.	2013	Bixafen+Fluopyram+Prothioconazole EC 260 (65+65+130 g/L) - On vegetative vigour of terrestrial plants Rheinland-Pfalz (RLP) AgroScience GmbH, Neustadt an der Weinstrase, Germany Bayer CropScience, Report No.: AS318, Date: 2013-12-19 GLP/GEP: yes, unpublished	Yes	Bayer CropScience	Y

KIIIA 10.8.1.3 /01	Marquardt, J.	2014	Effect of bixafen+fluopyram+prothioconazole EC 260 (65+65+130 g/L) - On the seedling emergence and seedling growth of terrestrial plants (Short code of test item: BIX+FLU+PTZ EC 260) Rheinland-Pfalz (RLP) AgroScience GmbH, Neustadt an der Weinstrase, Germany Bayer CropScience, Report No.: AS317, Date: 2014-02-13 GLP/GEP: yes, unpublished	Yes	Bayer CropScience	Y

Table A 2: List of data submitted for other authorization procedures and used in support of the evaluation of the current product

None.

Appendix 2 Detailed evaluation of the new studies (not describes in the respective DAR)

IIA 8.4 Effects from active substances and metabolites

IIA 8.1 Effects on birds

Reference:	KIIIA 10.1.7/01, JAU 6476-desthio: Residue formation and dissipation rate as determined in plant residue studies for use in ecotoxicological risk assessments
Author(s), year:	Neumann P.; 2009
Report/Doc number:	M-348996-01-1
Guidelines:	Not applicable
GLP:	No
Validity:	Unvalidated

Material and methods:

To address the question concerning the amount of formation of JAU 6476-desthio after the application of prothioconazole, two residue studies (Report no. 111032 and RA-2103/99) have been conducted to assess the formation and the dissipation of JAU 6476-desthio after the spray application of 0.2 kg prothioconazole/ha on cereal plants. Within the 2 studies, 6 trials were conducted with the SC480 formulation of prothioconazole and 2 trials were conducted with the EC250 formulation of prothioconazole.

Table 3.1: Measured DT50 for dissipation of JAU 6476-desthio on plants.

Single trial DT50 (d)	Source	Report no.
5.04	Hall & Duah, 2002	111032
3.32		
2.49		
2.50		
3.08		
2.47		
3.40	Heinemann, 2001	RA-2103/99
3.40		
Mean: 3.20		

Table 4.1: Conversion factor of JAU 6476-desthio calculated from total residue levels (prothioconazole + molar equivalents of JAU 6476-desthio) on the day of application (day 0) in 6 trials, and the maximum observed residue level for JAU 6476-desthio in plant material.

Trial	Total residue day 0 [mg/kg]	max. residue JAU 6476-desthio [mg/kg]	conversion factor
J6118-01W	2.09	0.41	19.6%
J6119-01W	6.65	1.69	25.5%
J6120-01W	10.48	1.73	16.5%
J6121-01W	12.14	3.48	28.7%
J6122-01W	5.64	3.68	65.2%
J6123-01W	15.28	3.63	23.8%
			Mean: 29.9%

Comments of zRMS:	No validation possible as all the presented data is aggregated. Consideration was given as far as the discussed studies have been used in the EU authorization process.
Agreed endpoints	None.

IIA 8.2 Effects on aquatic organisms

IIA 8.2.1 Effects on fish

IIA 8.2.3 Effects on aquatic invertebrates

Reference:	KIIA 8.2.3.1, Desthio JAU 6476: A 96-hour flow-through acute toxicity test with the saltwater mysid (Mysidopsis bahia) In: Summaries of additional ecotoxicological studies with prothioconazole (JAU 6476) and its metabolite prothioconazole-desthio (JAU 6476-desthio) that have been conducted to meet North American registration requirements by Neumann, P. ; 2004, Report M0-04-000837
Author(s), year:	Drottar, K. R.; Palmer, S. J.; Kendall, T. Z.; Krueger, H. 0., 2002
Report/Doc number:	11 0979
Guidelines:	EPA
GLP:	Yes
Validity:	Unvalidated (no full study reports available)

Materials and methods: Prothioconazole-desthio (= desthio JAU 6476), purity: 96.5 %, specification: batch No. RUX76-1 05/8a.

Mysid shrimp (Mysidopsis bahia; 24 hold, 2 x 10 per concentration) were exposed in a seawater flow-through test system for 96 h to a control, solvent control (dimethylformamide (DMF)) and the mean measured concentrations of 0.013, 0.026, 0.050, 0.099 and 0.20 mg metabolite/L.

Findings: Toxicity of prothioconazole-desthio to mysid shrimp based on mean measured concentrations

Test substance	**Prothioconazole-desthio**
Test object	***Mysidopsis bahia***
Exposure	96 h, flow-through
LC_{50} (96 h) (95% C.L.) [mg metabolite/L]	0.060 (0.046 - 0.079)
NOEC [mg metabolite/L]	0.026

Observations: Water temperatures were within the 25 ± 2 °C range established for the test. Dissolved oxygen concentrations remained ~ 6.0 mg/L (82% of saturation) throughout the test. Measurements of pH ranged from 8.2 to 8.3. Salinity of the dilution water at test initiation was 21 °/00.

Saltwater mysids in the negative control appeared healthy and normal throughout the test. One mysid in the solvent control appeared lethargic at 72 hours; although at 96 hours, all mysids in the solvent control appeared normal.

Conclusion: The LCs0 (96 h) for prothioconazole-desthio has been determined as 0.060 mg metabolite/L.

It should be pointed out, that this result is in contradiction to the results of the chronic study and that this value could not be confirmed in a repetition of this study that has been conducted together with the chronic study (report no. 200485, appendix 9.1, pp. 78). This repetition resulted in an LC50 (96 h) of> 1.009 mg metabolite/L (based on mean measured concentrations).

Comments of zRMS:	No validation possible as all the presented data is aggregated.
Agreed endpoints	LC50 = > 1.009 mg/L

Reference:	KIIA 8.2.3.2, Desthio JAU-6476: A flow-through lifecycle toxicity test with the saltwater mysid (Mysidopsis bahia) In: Summaries of additional ecotoxicological studies with prothioconazole (JAU 6476) and its metabolite prothioconazole-desthio (JAU 6476-desthio) that have been conducted to meet North American registration requirements by Neumann, P. ; 2004, Report M0-04-000837
Author(s), year:	Blanldnship, A. S.; Kendall, T. Z.; Krueger, H. 0., 2003
Report/Doc number:	200485

Guidelines:	EPA
GLP:	Yes
Validity:	Unvalidated (no full study reports available)

Material and methods: Prothioconazole-destbio (= JAU 6476-destbio), purity: 97.0 %, specification: batch No. RUX76-1 05/8a.

Chronic test: 60 young mysid shrimp(< 24 hold) per test concentration (60 animals per test concentration, 15 animals per retention chamber) were exposed in a seawater flow-through test system for 29 days to a control, a solvent control (dimethylformamide (DMF)) and the mean measured concentrations of 0.0 16, 0.032, 0.064, 0.128 and 0.252 mg metabolite/L. Endpoints recorded were mortality, reproduction (offspring/female/reproductive day) and growth (total dry body weight) of parent animals at the end of the test.

Acute test: Mysid shrimp (Mysidopsis bahia; ~ 24 hold, 2 x 10 per concentration) were exposed in a seawater flow-through test system for 96 h to a control, solvent control (dimethylformamide (DMF)) and the nominal concentrations of0.0625 (mean measured 0.064), 0.125, 0.250 (mean measured 0.247), 0.500 and 1.000 (mean measured 1.009) mg metabolite/L.

Findings:

Chronic test: Chronic toxicity of prothioconazole-desthio on the reproduction of mysid shrimp based on mean measured concentrations

Test substance	**Prothioconazole-desthio**		
Test object	***Mysidopsis bahia***		
Exposure	29 d, flow-through		
Parameters	mortality	offspring / female/ reproductive day	total dry body weight
NOEC [mg metabolite/L]	0.252	0.064	0.252

Observations: Measurements of salinity in the negative control were 20 °/00 throughout the test. Measurements of pH ranged from 8.0 to 8.3 and temperature was maintained within the 25 ±2 °C range established for the test.

Dissolved oxygen concentrations remained~ 5.8 mg/L (79% of saturation) throughout the test.

Acute test: Toxicity of prothioconazole-desthio to mysid shrimp based on mean measured concentrations

Test substance	**Prothioconazole-desthio**
Test object	***Mysidopsis bahia***
Exposure	96 h, flow-through
LC_{50} (96 h) [mg/L]	1.009
NOEC [mg a.i./L]	1.009

Observations: Water temperatures were within the 25 ±2 °C range established for the test. Dissolved oxygen concentrations remained~ 6.2 mg/L (85% of saturation) throughout the test. Measurements of pH ranged from 8.1 to 8.4. Salinity of the dilution water at test initiation and termination was 20 °/00.

Saltwater mysids in the negative control and solvent control appeared healthy and normal throughout the test with mortality in the negative and solvent control after 96 hours of exposure being 5 and 0%, respectively.

Surviving mysids in the Desthio JAU-6476 treatment groups generally appeared normal throughout the study with the exception of one mysid exhibiting erratic swimming in the 0.500 mg metabolite/L treatment group at 24-hours. After 96 hours of exposure, mortality in the 0.064, 0.125, 0.247, 0.500, and 1.009 mg metabolite/L treatment groups was 5, 10, 5, 5, and 0%, respectively. The slight mortality observed in all but the 1.009 mg/L treatment groups was not dose-responsive and was within guideline control criteria for mortality (up to 10% mortality in controls acceptable). Consequently, the NOEC was 1.009 mg metabolite/L and the LC50 value at 96 hours was estimated to be> 1.009 mg metabolite/L.

Conclusion: The chronic NOEC (29 d) for mysid shrimp under flow-through test conditions was determined to be 0.064 mg metabolite/L.

The acute LC50 (96 h) for mysid shrimp under flow-through test conditions was determined to be > 1.009 mg metabolite/L. This LC50 value is considerable higher as the LC50 value that has been determined in a previous acute study (see study report no: 110979). Since the LC50 value of> 1.009 mg metabolite/L is in line with the result of the chronic study and also in line with the result of an additional non-GLP acute study (LCso > 2 mg/L, nominal concentration) that has also been reported within this report (report no. 200485), we consider the LC50 of> 1.009 mg metabolite/L to be relevant for the risk assessment.

Comments of zRMS:	No validation possible as all the presented data is aggregated.
Agreed endpoints	NOEC = 0.064 mg/L nom

IIA 8.2.4 Effects on algae

Reference:	KIIA 8.2.4
Report	Kern, M.E., De Haan, R.A., 2004, Toxicity of JAU 6478 Technical to the Saltwater Diatom *Skeletonema Costatum*, report No: EBJAX076 (J6883601), document No: M-000954-01-1 ICS No. 69032

Guideline(s):	FIFRA Guideline 123-2
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	Yes

Materials and methods

Skeletonema costatum was exposed to JAU 6476 technical (Batch number 6233*0031, purity: 98.2% a.i.) under static conditions (shaken cultures) for approximately 96 hours. The following nominal concentrations were tested (resp. Day 0 measured): Control (<0.5), Solvent Control (<0.5), 3.1 (3.0), 7.7 (7.3), 19.2 (17.5), 48.0 (46.8), and 120 (117) µg a.i./L.

Results and discussion

Toxicity to algae:

Test substance	JAU 6476
Test objectcontrol	*Skeletonema costatum*
Exposure	96 hour, static
96-h – cell density 96-h – yield 96-h – growth rate	25.6 µg a.i./L 20.1 µg a.i./L 49.9 µg a.i./L
72-h – cell density 72-h – yield 72-h – growth rate	18.0 µg a.i./L 17.1 µg a.i./L 45.6 µg a.i./L
96-h Lowest Concentration with an Effect (LOEC)	17.5 µg a.i./L (yield)
96-h Highest Concentration without Toxic Effect (NOEC)	7.3 µg a.i./L (yield)
96-h Toxic Threshold Effect Concentration, TEC(Geometric mean of NOEC and LOEC)	11.3 µg a.i./L (yield)

No physical abnormalities were observed in the controls or treatment groups during the study. The lowest NOEC, LOEC and TEC were determined with the cumulative biomass end point.

Conclusion

Based on regression calculations, yield was the most sensitive parameter in this test. The 96-hour EyC50 and EyC25 values were determined to be 20.1 µg a.i./L and 13.8 µg a.i./L, respectively. The 96-hour toxic threshold effect concentration (TEC – the geometric mean of the NOEC and LOEC) was 11.3 µg a.i./L.

Comments of zRMS:	zRMS considered the 72-h (3d) values relevant
Agreed Endpoints:	EyC50 (72 h) = 0.0171 mg a.i./L ErC50 (72 h) = 0.0456 mg a.i./L

IIA 8.2.5 Effects on higher aquatic plants

Reference:	KIIA 8.2.5, Toxicity of JAU 6476-Desthio to duckweed (Lemna gibba G3) under static-renewal conditions. In: Summaries of additional ecotoxicological studies with prothioconazole (JAU 6476) and its metabolite prothioconazole-desthio (JAU 6476-desthio) that have been conducted to meet North American registration requirements by Neumann, P. ; 2004, Report M0-04-000837
Author(s), year:	Kern, M. E.; Banrnan, C. S.; Lam, C. V.: 2003
Report/Doc number:	200469
Guidelines:	EPA
GLP:	Yes
Validity:	Unvalidated (no full study reports available)

Materials and methods: Prothioconazole-desthio (= JAU 6476-desthio), purity: 97.0%, specification: batch No.: RUX76-105/8a.

The duckweed Lemna gibba G3 was exposed for 7 days under static- renewal conditions (renewed on day 3) to a control, solvent control and the mean measured test concentrations of 0.00242, 0.00578, 0.0143, 0.0356 and 0.0898 mg metabolite/L. Growth was determined by frond counts on days 0, 3, 5, and 7.

Findings: Toxicity of tebuconazole to aquatic plants

Test substance	a.s.
Test object	*Lemna gibba*
Exposure	7 d, static-renewal
7-day EC_{50} - standing crop [mg metabolite/L]	0.0394
7-day EC_{50} - growth rate [mg metabolite/L]	0.0809
7-day EC_{50} cumulative biomass [mg metabolite/L]	0.0568
7-day EC_{50} frond dry weight [mg metabolite/L]	0.0411
NOEC (all endpoints) [mg metabolite/L]	0.0058

Note to the table: It is unclear to zRMS if the word “tebuconazole” in the heading is a typo or if the table is incorrect.

Observations: Observations made on Day 0 and 3 showed no treatment related effects in terms of plant appearance. Reduced frond size was observed at the 0.016 mg metabolite/L on Day 7 and on Days 5 and 7 at 0.040, and 0.100 mg metabolite/L levels.

Conclusion: The EC50 (7 d) based on growth rate has been determined as 0.0809 mg metabolite/L.

Comments of zRMS:	It is unclear to zRMS if the word “tebuconazole” in the heading is a typo or if the table is incorrect. (table was copied from the study summary)
Agreed Endpoints:	EC50 = 0.0394 mg/L mm NOEC = 0.0058 mg/L mm

IIA 8.2.6 Effects on sediment dwelling organisms

IIIA 10.1 Effects on birds

IIIA 10.1.3 Baits: Concentration of active substance in bait in mg/kg

IIIA 10.1.4 Pellets, granules, prills or treated seed

IIIA 10.1.4.1 Amount of active substance in or on each item

IIIA 10.1.4.2 Proportion of active substance LD_{50} per 100 items and per gram of items

IIIA 10.1.5 Size and shape of pellet, granule or prill

IIIA 10.1.6 Acute toxicity of the formulation

IIIA 10.1.7 Supervised cage or field trials

IIIA 10.1.8 Acceptance of bait, granules or treated seeds (palatability testing)

IIIA 10.2 Effects on aquatic organisms

Effects from active substances and metabolites

Effects to aquatic invertebrates

Reference:	KIIIA 10.2, JAU 6476: A 96 hour flowthrough acute toxicity test with the saltwater mysid (Mysidopsis bahia). In: Summaries of additional ecotoxicological studies with prothioconazole (JAU 6476) and its metabolite prothioconazole-desthio (JAU 6476-desthio) that have been conducted to meet North American registration requirements by Neumann, P. ; 2004, Report M0-04-000837
Author(s), year:	Drottar, K. R.; Blankenship, A. S.;Kendall, T. Z.; Krueger, H., 2002
Report/Doc number:	110983
Guidelines:	EPA
GLP:	Yes

Validity:	Unvalidated (no full study reports available)

Materials and methods: Prothioconazole (= JAU 6476), purity: 98.4 %, specification: batch No. 6233/0031.

Mysid shrimp (Mysidopsis bahia; ~ 24 h old, 2 x 10 per concentration) were exposed in a seawater flow-through test system for 96 b to a control, solvent control (d.imethylformamide (DMF)) and the mean measured concentrations of 0.25, 0.51, 0.99, 2.0 and 4.1 mg a.s.IL.

Findings: Toxicity of prothioconazole to mysid shrimp based on mean measured concentrations

Test substance	**Prothioconazole**
Test object	***Mysidopsis bahia***
Exposure	96 h, flow-through
LC_{50} (96 h) (95% C.L.) [mg a.s./L]	2.4 (2.0 - 4.1)
NOEC [mg a.s./L]	0.99

Observations: Water temperatures were within the 25 ± 2 °C range established for the test.

Dissolved oxygen concentrations remained ~ 5.6 mg/L (76% of saturation) throughout the test. Measurements of pH ranged from 8.1 to 8.3. Salinity of the dilution water at test initiation was 21 °/00•

Saltwater mysids in the negative control and in the solvent control appeared healthy and normal throughout the test.

Conclusion: The LCso (96 h) for prothioconazole has been determined as 2.4 mg a.s.IL .

IIIA 10.2.2 Acute toxicity (aquatic) of the preparation

IIIA 10.2.2.1 Fish acute toxicity LC_{50}, freshwater, cold-water species

Reference:	KIIIA 10.2/03, Acute Toxicity of JAU 6476-triazolylketone (tech.) to Fish (Oncorhynchus mykiss) under Static Conditions
Author(s), year:	XXX. ; 2006
Report/Doc number:	EBJAX306
Guidelines:	OECD 203
GLP:	Yes
Deviations:	No

Validity:	Yes

Objective:
A limit test at 100 mg/L was performed in order to show if fish (Rainbow trout) were affected at this test level by the metabolite.

Material and methods:
JAU 6476-triazolylketone (tech.), analysed purity 99.5%, batch no. HSRM 595, Tox-No.: 07490-00, LIMS No.: PBF-2006-0010-TOX-07490.
Test organism: Rainbow trout *(Oncorhynchus mykiss),* mean body length 4.1 cm, mean body weight 0.6 g. Lot F 1/06 A was delivered on January 31, 2006. The biomass loading during testing was 0.45 g fish/L test medium.
Thirty fish were exposed in a limit test for 96 h under static test conditions to a nominal concentration of 100 mg pure metabolite (p.m.)/L against a water control with further 30 fish. Dissolved oxygen concentrations ranged from 91% to 100% oxygen saturation, the pH values ranged from 7.0 to 7.4 and the water temperature ranged from 11.7°C to 12.3°C in all aquaria over the whole testing period.
Recoveries of JAU 6476-triazolylketone were measured in all test levels on day 0, day 2 and day 4 of the exposure period to confirm nominal concentrations.

Findings:
Based on analytical determination of JAU 6476-triazolylketone (in water by HPLC -MS/MS) 95%- 99% (mean 98%) of nominal were found over the whole testing period of 96 hours. All reported results are based on nominal concentrations of the pure metabolite.
There were neither any sub-lethal effects nor any mortality observed in the control group.
Cumulative Mortality was observed as follows (with a total number of 30 fish tested in each test level):

Exposure time	**4 h**		**24 h**		**48h**		**72 h**		**96 h**	
Test level	no.of dead	% dead	no.of dead	% dead	no.of dead	% dead	no.of dead	% dead	no.of dead	% dead
control	0	0	0	0	0	0	0	0	0	0
100mg p.m./L	0	0	0	0	0	0	0	0	0	0

Conclusions:
Test conditions met all validity criteria, given by the mentioned guidelines. In a limit test at 100 mg/L the metabolite of JAU 6476-triazolylketone (tech.) did not cause any mortality to Rainbow trout *(Oncorhynchus mykiss).* So the 96h-LC_{50} is clearly above 100 mg pure metabolite/L.
There were no behavioural effects observed during the whole exposure period. So, the NOEC (no-observed-effect-concentration) after 96 h is considered to be > 100 mg pure metabolite/L.

Study Comments: IIIA 10.2/03	Valid and acceptable.
Agreed endpoint/s: IIIA 10.2/03	LC_{50} > 100 mg metabolite/L

Reference:	KIIIA 10.2.2.1/01, Acute toxicity of bixafen + prothioconazole EC 260 (60+200) G to fish Oncorhynchus mykiss under static conditions
Author(s), year:	XXX.; 2010
Report/Doc number:	EBDRP152
Guidelines:	OECD 203
GLP:	Yes
Deviations:	Yes: The temperature in the test vessels was constantly too low (11.9 – 12.4°C instead of 13 – 17°C)
Validity:	Yes

Material and methods:
Test item: Bixafen + Prothioconazole EC 260 (60+200) G, analyzed content of active substance 1: bixafen 62.28 g / L, analyzed content of active substance 2: prothioconazole 200.1 g / L, specified by Batch ID: 2008-010514, Master recipe ID: 0094630-001, tox no.: 08519-01.
Test organism: Rainbow trout (*Oncorhynchus mykiss*), mean body length 5.4 cm, mean body weight 1.6 g. Lot F 8 / 10 were delivered on June 22, 2010. The biomass loading for this test was 0.40 g fish / L test medium. Ten fish in each test level were exposed for 96 h under static conditions to nominal concentrations of 0.438, 0.875, 1.75, 3.50 and 7.00 mg test item / L against control. Dissolved oxygen concentrations ranged from 87 to 100 % oxygen saturation, the pH values ranged from 6.8 to 7.1 and the water temperature ranged from 11.9°C to 12.4°C in all aquaria over the whole testing period. bixafen was analyzed in all test levels after 0 h, on day 1, on day 2 and on day 4 of the exposure period to confirm nominal concentrations.

Findings:
The analytical determination of bixafen (in water by HPLC - UV) revealed mean measured values of 86 % to 96 % of nominal over the whole testing period of 96 hours. Therefore all results are given as nominal values.In the controls no mortalities or sub-lethal findings were observed. In all test levels ≥ 3.50 mg test item / L all fish died during the entire exposure time. After 96 h of exposure towards the nominal concentration of3.50 mg test item / L 100 % mortality was reached.

Cumulative mortality of *Rainbow trout* was observed as follows (10 fish tested in each test level)

Exposure time	4 h		24 h		48 h		72 h		**96 h**	
Test conc. Test item [mg/L]	no. of dead	% dead	no. of dead	% dead	no. of dead	% dead	no. of dead	% dead	**no. of dead**	**% dead**
control	0	0	0	0	0	0	0	0	**0**	**0**
0.438	0	0	0	0	0	0	0	0	**0**	**0**
0.875	0	0	0	0	0	0	0	0	**0**	**0**
1.750	0	0	1	10	7	70	9	90	**9**	**90**
3.500	0	0	10	100	10	100	10	100	**10**	**100**
7.000	0	0	10	100	10	100	10	100	**10**	**100**

Conclusions:

The test conditions met all validity criteria, given by the mentioned guidelines. Based on nominal concentrations the following results were determined:

LC_{50} (96 h)	**1.34 mg / L test item (C.I. 95%: Not determined due to mathematical reason)**
100% mortality	3.50 mg / L test item
NOLEC (No-observed-lethal-effect-concentration)	0.875 mg / L test item
NOEC (Highest concentration without sub-lethal effects)	0.438 mg / L test item

Study Comments: IIIA 10.2.2.1/01	Valid and acceptable in spite of the low tempereature in the test vessels.
Agreed endpoint/s: IIIA 10.2.2.1/01	LC_{50} = 1.34 mg/L

IIIA 10.2.2.2 Acute toxicity (24 & 48 h) for Daphnia preferably Daphnia magna

Reference:	KIIIA 10.2/04, Acute Toxicity of JAU 6476-Triazolylketone (tech.) to the Waterflea Daphnia magna in a Static Laboratory Test System
Author(s), year:	Bruns, E.; 2006
Report/Doc number:	E 320 3104-3
Guidelines:	OECD 202
GLP:	Yes
Deviations:	No
Validity:	Yes

Objective:
The aim of the study was to determine possible effects of the test item on mobility of *Daphnia magna* during 48 hours in a static laboratory test system, expressed as EC_{50} for immobilisation.

Material and methods:
JAU 6476-triazolylketone (tech.), purity 99.5%, identified as batch HSRM 595; *Daphnia magna* (1st instars < 24 h old, 4 x 5 animals per concentration), exposed in a static test system for 48 hours to nominal concentrations of 0, 0.399, 0.878, 1.93, 4.25, 9.34, 20.6, 45.2 and 100 mg pure metabolite/L without feeding. Recoveries of JAU 6476-triazolylketone were measured at start and end of the 48 hours exposure period.

Findings:

During 48 hours of static exposure, no immobilities occurred at or below the highest tested concentration of 100 mg pure metabolite/L.
Slight sublethal impairments such as being predominantly situated on the bottom of the beaker (due to distinctly decreased frequency of antennae movements) were observed for four (24 h) respectively two (48 h) daphnids exposed to 100 mg pure metabolite/L. Test conditions met all validity criteria, given by the mentioned guidelines.
The measured concentrations of JAU 6476-triazolylketone in the freshly prepared test solutions at test initiation revealed an average recovery of 99% of the aspired nominal concentrations.
At the end of the 48 hours exposure period the average recovery amounts to 100% of the initial measured concentrations, demonstrating stability in the test system.
No residues of JAU 6476-triazolylketone were detected in samples from untreated water control.
All reported results are based on nominal concentrations of the pure metabolite.

Conclusions:
Acute 48 hours static exposure of juvenile *Daphnia magna* to JAU 6476-triazolylketone (tech.) in aqueous solution revealed no immobilisation at or below the highest tested concentration of 100 mg pure metabolite/L.
Based on nominal exposure concentrations, the EC_{50} and the NOEC for immobilisation after 48 hours of static exposure were located above 100 mg pure metabolite/L. NOEC for behavior is set to 45.2 mg/L due to sublethal impairments.

Study Comments: IIIA 10.2/04	Valid and acceptable.
Agreed endpoint/s: IIIA 10.2/04	EC_{50} > 100 mg metabolite/L

Reference:	KIIIA 8.5.2, ^{14}C-Bixafen: A study on the bioaccumulation in the aquatic oligochaete *Lumbriculus variegatus*
Author(s), year:	Gilberg, D., 2012
Report/Doc number:	12P1LB
Guidelines:	OECD 315
GLP:	Yes
Deviations:	No
Validity:	Yes

Material and methods:

Material

Test material: ^{14}C-Bixafen

Description:	[dichlorophenyl-UL-^{14}C] Bixafen
Lot/Batch no.:	KML 9176
Active ingredient content:	>99%
Specific activity:	3.91 MBq/mg; 105.8 µCi/mg
CAS no.:	581809-46-3
Control:	Water, untreated sediment
Solvent:	Acetone, evaporated from sand
Test organisms:	*Lumbriculus variegatus*
Age:	Adults, synchronised to a similar physiological state
Loading:	10 worms/110 mL test medium; sediment-water volume ratio about 1:4.5
Source:	Inhouse culture
Feeding during test:	Feed added to sediment prior to test start
Test units and exposure:	Glass vessels
Replicates:	At least 3 with 10 worms each
Test procedure	
Exposure time:	28 d
Test conditions:	Photo period 16:8
Test medium	Reconstituted water according to OECD 203
Sediment	Artificial sediment according to OECD 315, 79% quartz sand, 2± 0.5% peat, 22% kaolinite clay, 0.4 – 0.5% *Urtica sp.* powder, $CaCO_3$, TOC-content: 1.03%
Water temperature:	19.4 – 22.0 °C
Photoperiod:	16h light: 8h dark, intensity: 502-843 lux
Dissolved oxygen:	36 – 101% of air saturation value
Study design and method:	Static, 28 days uptake phase, 10 days depuration phase
Experimental treatments:	42.6 µg test item/kg sediment ww (62.2 µg/kg sediment dw); 166.7 Bq/g sediment ww, 10000 dpm/g sediment ww

Observations

Analysis of total radioactive residues in worms:	On days -2, 0, 1, 3, 7, 14, 21 and 28 during uptake phase; days 0.19, 1, 2, 4, 7 and 10 during elimination phase; by scintillation counting following extraction, combustion

Results and discussion:

Resiudes in worms and calculated accumulation factors are summarised in the following tables.

Total radioactive residues in worms (uptake and elimination phase)

Test phase	Test duration [days]	Measured total radioactive residues [dpm/g worm wet weight]
Uptake phase	1	13974
	3	11211
	7	14336
	14	18090
	21	22687
	28	23157
	28, Control	<LOQ
Elimination phase	0.19	9244
	1	6500
	2	5294
	4	3296
	7	2997
	10	2860

Steady state was reached after 14 days (no statistically significant differences between residues of sampling dates 14, 21 and 28 as well as less than 20% variation of mean residues at these sampling dates). The residue level at the end of the elimination phase (Day 10) was 12.4% of the mean radioactive residue of Day 28 of the uptake phase.

Accumulation factors based on worm tissue (wet weight) and mean radioactive concentration of test item in sediment (wet weight)

Test duration [days]	Accumulation factor (AF)
1	1.57
3	1.33
7	1.79
14	2.07
21	2.28
28	2.36

The BAF was determined to be 2.36. Uptake kinetics were modelled using nonlinear regression analysis based on total worm tissue weight (ww) and mean radioactive concentration of test item in sediment (ww) at corresponding sampling dates. The BAF_k was determined to be 2.09. The $BSAF_k$ (BAF_k normalised for mean lipid content of worms, i.e. 6.88%, and the TOC-content of the sediment, i.e. 1.03%) was determined to be 0.31.

For calculation of the elimination curve parameters a two-compartment model was used. The CT_{50} was determined to be < 0.2 d.

The test was considered valid as the cumulative mortality of the worms (control and treatments) until the end of the test did not exceed 20% of the initial number (actual: 1.4%). In one control replicate worms not buried in the sediment were observed at day 10. However, this deviation from the guideline was not expected to have influenced the results or the integrity of the study.

Conclusions:

In this bioaccumulation study with *Lumbriculus variegatus* exposed to bixafen treated sediment, the BAF was determined to be 2.36 (day 28) at steady state. Steady state was reached at day 14 of the uptake phase. BAF_k and $BSAF_k$ were determined to be 2.09 and 0.31, respectively. The test item was eliminated quickly from the test organisms. The CT_{50} was determined to be < 0.2 d. The Non-Eliminated Residues (NER) measured after ten days of elimination were 12.4% of the mean radioactivity measured in worm tissue at the end of the uptake phase.

IIA 8.5.2/02

Comments of zRMS:	-
Agreed Endpoints:	NOEC (28 d) = 1.78 mg/L nominal

Reference:	KIIIA 10.2.2.2/01, Acute toxicity of bixafen + prothioconazole EC 260 (60 + 200) G to the waterflea Daphnia magna in a static laboratory test system
Author(s), year:	Bruns, E.; 2006
Report/Doc number:	EBDRP151
Guidelines:	OECD 202
GLP:	Yes
Deviations:	No
Validity:	Yes

Material and methods:
Bixafen + Prothioconazole EC 260 (60 + 200) G ,batch 2008-010514, specification No.: 102000020385-01, content: 6.10 % w/w bixafen, 19.6 % w/w prothioconazole (TOX 08519-01); *Daphnia magna* (1st instars < 24 h old, 6 × 5 animals per concentration), exposed in a static test system for 2×24 hours to nominal concentrations of 0, 1.0, 2.0, 4.0, 8.0 and 16.0 mg / L without feeding. The content of bixafen in exposure media was measured for verification of the test item concentrations.

Findings:

Toxicity to *Daphnia magna* (based on nominal concentrations):

Nominal test concentration (mg / L)	Exposed daphnids (= 100%)	Immobilised daphnids			
		24 h		48 h	
		n	%	n	%
Control	30	0	0.0	0	0.0
1.0	30	0	0.0	0	0.0
2.0	30	0	0.0	0	0.0
4.0	30	3	10.0	6	20.0
8.0	30	18	60.0	29	96.7
16.0	30	29	96.7	30	100

The accompanying chemical analysis of bixafen in the freshly prepared test solutions at test initiation revealed recoveries between 100 % and 104 % (mean: 102 %) of the corresponding nominal concentrations. The corresponding concentrations of the aged test solutions at the end of the 48 hours exposure period ranged between 96 % and 106 % (mean: 102 %) of nominal. None of the measured active ingredients was detected in samples from untreated water control.
No contaminations of bixafen were detected in samples from untreated water control. As the toxicity has to be attributed to the tested formulation as a whole, all results submitted by this report are related to nominal test concentrations of the formulated product.

Conclusions:
No immobilities or other effects on behaviour occurred in untreated control within 48 hours of exposure. Based on nominal concentrations of bixafen + prothioconazole EC 260 (60 + 200) G, the following EC_{50} values for immobilisation after 24 and 48 hours of static exposure were assessed:

Statistical results of probit analysis conducted for determination of EC_{50} values:

Probit analysis for data obtained after	EC_{50} mg formulation/L (nominally)	lower 95% CI mg formulation/L (nominally)	upper 95% CI mg formulation/L (nominally)
24 hours	7.13	6.11	8.33
48 hours	4.98	4.43	5.67

Study Comments: IIIA 10.2.2.2/01	Valid and acceptable.
Agreed endpoint/s: IIIA 10.2.2.2/01	EC_{50} = 4.98 mg/L

IIIA 10.2.2.3 Effects on algal growth and growth rate

Reference:	KIIIA 10.2/05, Pseudokichneriella subcapitata Growth Inhibition Test with Prothioconazole-triazolylketone
Author(s), year:	Dorgerloh, M.; 2006
Report/Doc number:	E 323 3084-3; EBJAX304
Guidelines:	Draft Proposal for Updating OECD Guideline 201: "Freshwater Alga and Cyanobacteria, Growth Inhibition Test" (October 22, 2004)
GLP:	Yes
Deviations:	No
Validity:	Yes

Objective:
The aim of the study was to determine the influence of the test item on exponentially growing *Pseudokirchneriella subcapitata* expressed as NOEC, LOEC and ECX for growth rate of algal biomass (cells per volume).

Material and methods:
JAU 6476-triazolylketone, purity: 99.5%, was tested, specified by batch-no.: HSRM 595, TOX-no.: 07490-00 and LIMS-no.: PBF-2006-0010-TOX-07490. *Pseudokirchneriella subcapitata* (freshwater microalgae, formerly known as *Selenastrum capricornutum)* were exposed in a chronic multigeneration test for 3 days under static exposure conditions to the nominal concentrations of 0.954, 3.05, 9.77, 31.3 and 100 mg pure metabolite (p.m.)/L in comparison to control. The pH values ranged from 7.9 to 8.4 in the controls and the incubation temperature ranged from 22.2°C to 23.5°C (measured in an additional incubated glass vessel) over the whole period of testing at a continuous illumination of 7,929 lux. Quantitative amounts of JAU 6476-triazolylketone were measured in all treatment groups and in the control on day 0 and day 3 of the exposure period.

Findings:
Test conditions met all validity criteria, given by the mentioned guideline.
The analytical findings of JAU 6476-triazolylketone in the treatment levels found on day 0 were 96 to 109% of nominal (average 101%). On day 3 analytical findings of 97% to 109% of nominal (average 102%) were found. All reported results are based on nominal concentrations of the pure metabolite.

The static 72 hour algae growth inhibition test provided the following effects:

Nominal Concentration [mg p.m./L]	Cell Number after 72 h (means) per mL	(0-72h)-Average Specific Growth Rates [days^{-1}]	Inhibition of Average Specific Growth Rate [%]	Doubling Time of Algae Cells [days]
control	236,260	1.054	—	0.658
0.954	252,980	1.077	-2.2	0.644
3.05	266,170	1.090	-3.4	0.636
9.77	245,920	1.067	-1.3	0.650
31.3	233,780	1.049	0.4	0.661
100	223,100	1.033	2.0	0.671

Test initiation with 10,000 cells/mL

Conclusions:
JAU 6476-triazolylketone has no significant toxic effects at concentrations up to nominal 100 mg/L to *Pseudokirchneriella subcapitata.*

Study Comments: IIIA 10.2/05	Valid and acceptable.
Agreed endpoint/s: IIIA 10.2/05	E_bC_{50}, E_rC_{50} > 100 mg metabolite/L NOEC = 100 mg metabolite/L

Reference:	KIIIA 10.2.2.3/01, Pseudokirchneriella subcapitata growth inhibition test with bixafen & prothioconazole EC 260 (60+200) G
Author(s), year:	Bruns, E.; 2010
Report/Doc number:	EBDRP150
Guidelines:	OECD 201
GLP:	Yes
Deviations:	No
Validity:	Yes

Material and methods:
Test item: Bixafen + Prothioconazole EC 260 (60+200) G; analysed a.s. contents: Bixafen: 6.10% and Prothioconazole: 19.6% was tested, specified by batch ID: 2008-010514, sample description: TOX08519-01 and specification no.: 102000020385-01.
Pseudokirchneriella subcapitata (freshwater microalgae, formerly known as *Selenastrum capricornutum*) were exposed in a chronic multigeneration test for 3 days under static exposure conditions to nominal concentrations of 0.0960, 0.307, 0.980, 3.13 and 10.0 mg formulation/L in comparison to a control. The pH values ranged from 7.8 to 8.2 in the controls and the incubation temperature ranged from 21.4°C to 23.5°C (measured in an additional incubated glass vessel) over the whole period of testing at a continuous illumination of 8059 lux.

Quantitative amounts of bixafen were measured in all treatment groups and in the control on day 0 and day 3 of the exposure period.

Findings:
Test conditions met all validity criteria, given by the mentioned guideline(s). The analytical findings of bixafen in the treatment levels found on day 0 were 97 % to 100 % of nominal (average 98 %). On day 3 analytical findings of 95 % to 98 % of nominal (average 97 %) were found. Given that the toxicity cannot be attributed to any of the a.s. compounds but to the formulation as a whole, all results are based on nominal test concentrations of the formulation.

The static 72 hour algae growth inhibition test provided the following effects:

Nominal Concentration [mg form./L]	Cell Number after 72 h (means) per mL*	(0-72 h)-Average Specific Growth Rates [days^{-1}]	Inhibition of Average Specific Growth Rate [%]
control	740000	1.434	--
0.0960	751000	1.439	-0.4
0.307	750000	1.439	-0.3
0.980	745000	1.437	-0.2
3.130	83000	0.695	51.6
10.0	31000	0.355	75.3

* test initiation with 10,000 cells/mL -% inhibition: increase in growth relative to the control

Conclusions:
The (0 – 72 h)-E_rC_{50} for Bixafen + Prothioconazole EC 260 (60+200) G is 3.81 mg formulation/L (95% CI: 1.52-10.50 mg form./L) and the (0 - 72h) – NOE_rC is 0.980 mg form./L.

Study Comments: IIIA 10.2.2.3/01	Valid. ZRMS has recalculated the results.
Agreed endpoint/s: IIIA 10.2.2.3/01	E_bC_{50} = 2.313 mg product/L E_rC_{50} = 3.816 mg product/L E_yC_{50} = 2.127 mg product/L NOEC = 0.98 mg product/L

IIIA 10.2.2.4 Marine or estuarine organisms acute toxicity LC_{50}/EC_{50}

IIIA 10.2.2.5 Marine sediment invertebrates, acute toxicity LC_{50}/EC_{50}

IIIA 10.2.3 Microcosm or mesocosm study

IIIA 10.2.4 Residue data in fish (long-term)

IIIA 10.2.5 Chronic fish toxicity data

IIIA 10.2.5.1 Chronic toxicity (28 day exposure) to juvenile fish.
Analytical data on concentrations in the test media

IIIA 10.2.5.2 Fish early life stage toxicity test.

Reference:	**KIIIA 10.2/01**, Early life stage toxicity of prothioconazole technical to the rainbow trout (*Oncorhynchus mykiss*) under flow through conditions
Author(s), year:	XXX.; 2007
Report/Doc number:	EBJAX313
Guidelines:	FIFRA Guideline 72-4, OPPTS Guideline 850.1400 (draft), OECD Guideline 210
GLP:	Yes
Deviations:	No
Validity:	Acceptable (formally not valid – insufficient hatch in controle replicates)

Objective:
A flow-through early life stage toxicity test was conducted by Bayer CropScience Aquatic Ecotoxicology Laboratory to determine the effects of prothioconazole technical to the Rainbow Trout (*Oncorhynchus mykiss*). This study was designed to establish a no-observed-effect-concentration (NOEC), a lowest-effect-observed-concentration (LOEC) and a Maximum Acceptable Toxicant Concentration (MATC), which equals the geometric mean of the NOEC and LOEC. The NOEC is the highest concentration that causes no statistically verifiable biologically adverse effects in the test population. The LOEC is the lowest concentration that produces at least one statistically significant ($p < 0.05$) biologically adverse effect. The parameters measured in this study were fish hatchability, swim-up, survival, and growth.

Materials and Methods:
Test item: Prothioconazole (techn.); Batch ID: PFV0672333; TOX Number: 07816-00.
Freshly fertilised rainbow trout (Oncorhynchus mykiss) eggs starting at < 24 hours old were observed for time to hatch and hatchability; young fish were assessed for abnormal behaviour, physical changes, swim-up behaviour, mortality and growth (standard length, dry weight); study duration was 91 days under flow through conditions; nominal concentrations (mean measured) were: control (<0.005), solvent control (<0.005), 0.0625 (0.052), 0.125 (0.107), 0.25 (0.22), 0.50 (0.49) and 1.00 (0.94) mg as/L.

Findings:
Fish early life stage toxicity test

Test Substance	Prothioconazole Technical			
Test Object	Rainbow Trout			
Exposure	91 Day, flow-through (ELS)			
Fry Survival (Study Day 91):	NOEC	0.49 mg as/L	LOEC	0.94 mg as/L
Percent Hatch:	NOEC	0.94 mg as/L	LOEC	> 0.94 mg as/L
Time to Hatch:	NOEC	0.94 mg as/L	LOEC	> 0.94 mg as/L
Time to Swim-up (Study Days 46-48):	NOEC	0.49 mg as/L	LOEC	0.94 mg as/L
Growth (Standard Length):	NOEC	0.94 mg as/L	LOEC	> 0.94 mg as/L
Growth (Dry Weight):	NOEC	0.94 mg as/L	LOEC	> 0.94 mg as/L
Morphological & Behavioural Effects:	NOEC	0.49 mg as/L	LOEC	0.94 mg as/L
Maximum Acceptable Toxicant Concentration (MATC)	0.68 mg as/L (based on fry survival, swim-up and morphological/behavioral effects)			

Observations:
With the exception of one fish in the control (exophthalmic) all other symptoms only occurred in the highest test level and were considered to be dose related. The symptoms were either transient in nature (study days 33-45; light-colored) or being associated with fish prior to death. At study termination all surviving fish showed normal behaviour and were without malformations.

Conclusion:
The 91-day exposure to prothioconazole technical resulted in an overall NOEC of 0.49 mg as/L and a LOEC of 0.94 mg as/L based on fry survival, swim-up and morphological/behavioral effects.

Study Comments: IIIA 10.2/01	Hatch in control replicates: 63 % (minimum according to OECD 210 = 66 %), thus formally not valid. In spite of that, zRMS considers hatch in that species (O.mykiss) a common problem and considers the results as acceptable.
Agreed endpoint/s: IIIA 10.2/01	NOEC = 0.49 mg a.i./L LOEC = 0.94 mg/L

IIIA 10.2.5.3 Fish life cycle test.
Analytical data on concentrations in the test media

IIIA 10.2.6 Chronic toxicity to aquatic invertebrates

IIIA 10.2.6.1 Chronic toxicity in Daphnia magna (21-day).
Analytical data on concentrations in the test media

IIIA 10.2.6.2 Chronic toxicity for a representative species of aquatic insects.

Reference:	KIIIA 10.2/02, Chironomus riparius 28-day Chronic Toxicity Test with JAU 6476-S-Methyl in a Water-Sediment System using Spiked Water
Author(s), year:	Bruns, E.; 2006
Report/Doc number:	E 416 3076-7
Guidelines:	Yes (OECD 219)
GLP:	Yes
Deviations:	The concentration of a.s. in the sediment was not determined.
Validity:	Yes

Material and methods:
JAU 6476-S-Methyl, purity: 98.9% was tested, specified by batch-no.: HUPP0658-MP and development-no.: 0245898. First instar of *Chironomus riparius* larvae (4 beakers per test concentration and control with 20 animals each) were exposed in a static test system for 28 days to initial nominal concentrations in the overlying medium (spiked water application) of 0.001, 0.01, 0.10, 1.00 and 10.0 mg pure metabolite/L (mg p.m./L) of a water-sediment system. Dissolved oxygen concentrations ranged in the water phase from 8.0 to 9.3 mg O_2/L, the water pH values ranged from 8.4 to 8.7 and the water temperature ranged from 20.0°C to 20.3°C measured from parallel beakers of each test concentration over the whole period of testing.
Recoveries of JAU 6476-S-Methyl were measured three times during the study: 1 hour, 7 days and 28 days after application in one additional test container of each nominal initial test concentrations of 0.001, 0.10 and 10.0 mg p.m./L and control (only on day 0) of the overlying water and the pore water of the sediment.

Findings:
Analytical Findings: Chemical analysis of overlying water and pore water over time reflect expected aquatic fate data with high recoveries of 92% to 100% for test concentration of 0.001 and 0.10 mg p.m./L at the beginning of the exposure period in the overlying water. For the highest test concentration of 10.0 mg p.m./L only 68% of nominal was found on day 0. The relatively low recovery for the highest test item concentration is related to the water solubility under exposure conditions. The mean % recovery on day 0 was 86.6% of nominal, thus the results are given as initial nominal concentrations for reporting and evaluation of the results.
Biological findings: Start of emergence was on day 14 - 15 for the control and test concentrations from 0.001 to 1.00 mg p.m./L. The start of emergence was delayed for four days at the highest test concentration of 10.0 mg p.m./L. 89.4% of the inserted (n = 160) larvae maturated to adults in the controls (control and solvent control pooled) after 28 days, fulfilling the guideline requirements.
Influence on emergence and development rate after 28 days (based on nominal initial concentrations of the test item in the overlying water):

Emergence

Concentration initial nominal mg p.m./L	Number of introduced midges	Number of emerged midges	Emergence of inserted larvae			Development pooled sex Rate (1/d)
			total [%]	male [%]	female [%]	
Control pooled	160	143	89.4	58.8	30.6	0.060
0.001	80	65	81.3	53.8	27.5	0.058
0.01	80	55	68.8	46.3	22.5	0.059
0.10	80	67	83.7	46.2	37.5	0.060
1.00	80	54	67.5	41.3	26.2	0.056
10.0	80	5	6.3	5.0	1.3	0.050

For further statistical analyses of emergence male and female results were pooled to increase the statistical power. Statistical significance effects ($\alpha = 0.05$) on emergence ratio and development rate of males and of pooled sex were determined at 1.00 mg p.m./L (= LOEC), resulting in a NOEC of 0.10 mg p.m./L. For the development rate of female midges the LOEC was evaluated for 10.0 mg p.m./L, resulting in an NOEC of 1.00 mg p.m./L.

Conclusions:
Test conditions met all validity criteria, given by the mentioned guideline. Results are based on nominal initial concentrations in mg p.m./L of the test item in the overlying water:

Endpoints [mg p.m./L]	NOEC	LOEC	EC_{15}	EC_{50}
Emergence ratio (pooled sex)	0.10	1.00	0.126	1.41
Development rate (pooled sex)	0.10	1.00	8.66	> 10.0

Study Comments: IIIA 10.2/02	Mean concentration of a.s. in the water: 20 % of initial on d 7, 5.8 % of initial on d 28. The concentrations were only determined in overlying water and pore water, not in the sediment (required in OECD 219).
Agreed endpoint/s: IIIA 10.2/02	NOEC = 0.1 mg/L (nom) – development, emergence rate

IIIA 10.2.6.3 Chronic toxicity for a representative species of aquatic gastropod molluscs. Analytical data on concentrations in the test media

IIIA 10.2.7 Accumulation in aquatic non-target organisms. Analytical data on concentrations in the test media

IIIA 10.3.2.1 Acute oral toxicity of the preparation

IIIA 10.3.2.2 Acceptance of bait, granules or treated seeds by terrestrial vertebrates (palatability test)

IIIA 10.3.3 Supervised cage or field trials or other appropriate studies

IIIA 10.4 Effects on bees

IIIA 10.4.2 Acute toxicity of the preparation to bees

The following bee acute toxicity study performed on Ascra Xpro is provided in support of the assessment and has not been previously evaluated. Since no major deviations from the guideline were reported which could have influenced the results of the study only a brief summary and the endpoints are presented below.

Report:	**KIIIA1 10.4.2.1/01** Schmitzer, S., Effects of bixafen + fluopyram + prothioconazole EC 260 (65+65+130) G (acute contact and oral) on honey bees (*Apis mellifera* L.) in the laboratory, IBACON 64380 Rossdorf Germany, project number 81781035
Document No:	M-469774-01-1
Guidelines:	OECD 213 and 214
GLP	Yes

Materials and Methods

In a test under laboratory conditions Ascra Xpro (bixafen + fluopyram + prothioconazole EC 260) was offered to worker honey bees (*Apis mellifera* L.) in oral and contact route. Treatments with the test substance, the control and the reference item (dimethoate) were carried out in three to five replicates containing ten bees each.

Test species:	Worker honey bees *Apis mellifera*
Test substance:	Ascra Xpro (bixafen + fluopyram + prothioconazole EC 260) 1: bixafen 65.61 g/L 2: fluopyram 64.21 g/L 3: prothioconazole 128.5 g/L
Control:	oral: 50 % (w/w) aqueous sugar syrup solution contact: Tap water with 0.5 % Adhäsit
Toxic standard:	Perfekthion EC / BAS 152 11 I (dimethoate) oral: 0.30, 0.15, 0.08 and 0.05 µg as/bee

contact: 0.30, 0.20, 0.15 and 0.10 µg as/bee dissolved in water containing 0.5 % Adhäsit)

Doses: oral (Ascra Xpro sucrose solution): 400.0, 200.0, 100.0, 50.0 and 25.0 µg product/bee
contact (Ascra Xpro dissolved in tap water with 0.5 % Adhäsit): 200 µg product/bee

Bees per dose: 10

Replicates: 3 (oral, dose-response-test)
5 (contact, limit test)

Oral toxicity study:
In a dose response test, three replicates of 10 bees were fed with a sugar/water solution containing Ascra Xpro. The tested concentration was 400.0, 200.0, 100.0, 50.0 and 25.0 µg product/bee. An untreated sugar/water solution was used as water control. Dimethoate was used as toxic standard. The test was conducted at darkness and a temperature of 24 - 25 °C and humidity between 52 and 82 %. Biological observations including mortality and behavioural changes were recorded at 4, 24 and 48 hours after dosing.

Contact toxicity study:
In a limit test, five replicates of 10 bees were exposed to Ascra Xpro dissolved in tap water with 0.5% Adhäsit, administered topically in a small droplet to the thorax of each bee. The tested concentration was 200 µg product/bee. A group of bees treated with an equivalent volume of tap water with 0.5% Adhäsit was used as water control. Dimethoate solved in tap water with 0.5% Adhäsit was used as toxic standard. The test was conducted at darkness and a temperature of 24 - 25 °C and humidity between 52 and 82%. Biological observations, including mortality and behavioural changes were recorded at 4, 24 and 48 hours after application.

Findings

Oral toxicity study:
The maximum nominal dose levels of the test item (400.0 and 200.0 µg product/bee) could not be achieved, because the bees did not ingest the full volume of treated sugar solution even when offered over a period of six hours.
Actual oral doses of 312.0, 165.7, 104.5 and 26.6 µg product/bee resulted in mortality levels of 30.0, 26.7, 3.3 and 3.3% (48 hours after application).
No mortality occurred in the 53.9 µg product/bee treatment group as well as in the control group (50% aqueous sugar syrup solution).

During the first assessment (four hours after application) in the 312.0, 165.7, 104.5 and 53.9 µg product/bee dose level groups moving coordination problems and/or apathy occurred in 40.0, 63.3, 40.0 and 13.3% of the bees, respectively. During the 24 and 48 hours assessment behavioural abnormalities were only observed in the 312.0 µg product/bee treatment group.

Table 10.4.2.1-1: Mortality and behavioural abnormalities of the bees in the oral toxicity test.

Uptaken dosage	After 4 hours		After 24 hours		After 48 hours	
	Mortality	Beh. abn.	Mortality	Beh. abn.	Mortality	Beh. abn.
Test item µg product/bee						

312.0	6.7	40.0	20.0	23.3	30.0	6.7
165.7	0.0	63.3	26.7	0.0	26.7	0.0
104.5	0.0	40.0	3.3	0.0	3.3	0.0
53.9	0.0	13.3	0.0	0.0	0.0	0.0
26.6	0.0	0.0	0.0	0.0	3.3	0.0
water	0.0	0.0	0.0	0.0	0.0	0.0
Reference item µg as/bee						
0.32	6.7	60.0	76.7	13.3	83.3	3.3
0.16	0.0	36.7	46.7	16.7	66.7	0.0
0.08	0.0	13.3	10.0	3.3	26.7	3.3
0.06	0.0	0.0	6.7	0.0	10.0	0.0

Results are averages from three replicates (ten bees each) per dosage/control
Beh. abn. = behavioural abnormalities

Contact toxicity study:
At the end of the contact toxicity test (48 hours after application) 4.0% mortality occurred at 200.0 µg product/bee.
There was no mortality in the control group (water + 0.5% Adhäsit).

During the first assessment (four hours after application) 58% of the bees were behaving abnormal (moving coordination problems and apathy). 24 and 48 hours after the application only one bee were apathetic.

Table 10.4.2.1-2: Mortality and behavioural abnormalities of the bees in the contact toxicity test.

	After 4 hours		After 24 hours		After 48 hours	
Dosage	Mortality	Beh. abn.	Mortality	Beh. abn.	Mortality	Beh. abn.
Test item µg product/bee						
200	0.0	58.0	2.0	2.0	4.0	2.0
water	0.0	0.0	0.0	0.0	0.0	0.0
Reference item µg as/bee						
0.30	4.0	72.0	74.0	12.0	84.0	10.0
0.20	2.0	42.0	52.0	2.0	60.0	0.0

0.15	4.0	0.0	10.0	12.0	40.0	4.0
0.10	2.0	0.0	8.0	0.0	12.0	2.0

Results are averages from five replicates (ten bees each) per dosage/control
Beh. abn.= behavioural abnormalities

Conclusions

The toxicity of Ascra Xpro was tested in both, an acute contact limit test and an acute oral toxicity dose response test on honey bees.
The oral LD_{50} value (24 h, 48 h) was > 312.0 µg product/bee.
The contact LD_{50} value (24 h, 48 h) was > 200.0 µg product/bee, respectively.

IIIA 10.4.2.1 Acute oral toxicity

Refer to IIIA 10.4.2.

IIIA 10.4.2.2 Acute contact toxicity

Refer to IIIA 10.4.2.

IIIA 10.4.3 Effects on bees of residues on crops

Not required.

IIIA 10.4.4 Cage tests

Not required.

IIIA 10.4.5 Field tests

Not required.

IIIA 10.4.6 Investigation of special effects

Not required.

IIIA 10.4.6.1 Larval toxicity

Not required since the test item is not an IGR.

IIIA 10.4.6.2 Long residual effects

Not required.

IIIA 10.4.6.3 Disorienting effects on bees

Not required.

IIIA 10.4.7 Tunnel testing to investigate effects of feeding on contaminated honey dew or flowers

Not required.

MIIIA 10.5 Effects on arthropods other than bees

IIIA 10.5.1 Effects on sensitive species already tested, using artificial substrate

IIIA 10.5.2 Effects on non-target terrestrial arthropods in extended laboratory tests

Reference:	KIIIA 10.5.2/02, Toxicity to the predatory mite Typhlodromus pyri Scheuten (Acari, Phytoseiidae) using an extended laboratory test on Zea mays; Bixafen + Prothioconazole EC 60 + 200 g/L
Author(s), year:	Jans, D.; 2009
Report/Doc number:	CW09/025
Guidelines:	Bluemel et al., 2000; Candolfi et al. 2001
GLP:	Yes
Deviations:	No, but remarkably high application rate of reference item
Validity:	Yes

Materials and methods:
An emulsifiable concentrate formulation of Bixafen + Prothioconazole EC 60 + 200 g/L was tested, specified by sample description: TOX08519-00; specification no.: 102000020385; batch ID: 2008-010514 [analysed content of active ingredient: Bixafen 6.00%w/w, Prothioconazole 19.7% w/w; date of completed analysis: 19 FEB 2009, BCS-D-FT Analysis & Services, D- 40789 Monheim]; density: 1.021 g/mL. The test item was applied at rates of 200, 356, 632, 1125 and 2000 mL product/ha and the effects were compared to a water treated control. A toxic reference (a.i.: dimethoate) applied at 101.4 mL product/ ha (40 g a.i./ha) was included to indicate the relative susceptibility of the test organisms and the test system. Mortality of 100 protonymphs was assessed 1, 4, 7, 10, 12 and 14 days after exposure by counting the number of living and dead mites. The number of escaped mites was calculated as the difference from the total number exposed. The reproduction rate of surviving mites was then evaluated over the period of 7-14 days after treatment by counting the total number of offspring (eggs and larvae) produced. Mortality and reproduction in each of the treatments are summarized below.

Findings:
The mortality / escaping rate in the exposure units up to day 7 after treatment was 19.0%. The mean corrected mortality of the nymphs, and the mean reproduction rate of the surviving females exposed to the test item and the toxic reference is given below:

Test item		Bixafen + Prothioconazole EC 60 + 200 g/L					
Test organism		*Typhlodromus pyri*					
Exposure on		Maize leaves					
		Mortality (7 days after treatment) [%]			Reproduction		
Treatment	mL product/ha	Uncorr.	Corr.	P-Value(*)	Rate	Red. rel. to Control [%]	P-Value(#)
Control	0	19.0			4.7	-	
Test item	200	25.0	7.4	0.394 n. sign.	3.3	30.0	0.147 n.sign.
Test item	356	23.0	4.9	0.394 n. sign.	3.2	32.0	0.01 sign.
Test item	632	40.0	25.9	0.003 Sign.	2.8	41.5	0.0008 sign.
Test item	1125	81.0	76.5	< 0.001 sign.	n.d.	n.d.	-
Test item	2000	92.0	90.1	< 0.001 sign.	n.d.	n.d.	-
Reference item	101.4	100.0	100.0		n.d.	n.d.	-

LR_{50}: 867 mL product/ha; 95% Confidence Interval: (608-1086) (calculated with Probit analysis)
* Fisher's Exact test (one-sided), p-values are adjusted according to Bonferroni-Holm
# Welch test
n.d. not detected
n.sign. not significant
sign. significant

Conclusions:
In this extended laboratory test the effects of Bixafen + Prothioconazole EC 60 + 200 g/L residues on the survival of the predatory mite *Typhlodromus pyri* were determined at the rates of 200, 356, 632, 1125 and 2000 mL product/ha applied to detached maize leaves. At the test rates of 200, 356, 632, 1125 and 2000 mL product/ha a corrected mortality of 7.4%, 4.9%, 25.9%, 76.5% and 90.1% has been observed, respectively. At 200, 356 and 632 mL product/ha the reproduction was reduced by 30.0%, 32.0% and 41.5%, respectively. The figures obtained fulfil the validity criteria of the laboratory method using glass plates. The LR_{50} was calculated to be 867 mL product/ha.

Comments of zRMS:	Acceptable.
Agreed endpoints	LR50 = 867 mL/ha ER50 > 632 mL product/ha (41,5 % reduction of reproduction at 632 mL/ha)

Reference:	KIIIA 10.5.2/05, Toxicity to the predatory mite Typhlodromus pyri Scheuten (Acari, Phytoseiidae) using an extended laboratory test (under semi-field conditions aged residues on Zea mays) Bixafen + Prothioconazole EC 60 + 200 g/L
Author(s), year:	Jans D.; 2009

Report/Doc number:	CW09/023
Guidelines:	Bluemel et al., 2000 modified, Candolfi et al. 2001
GLP:	Yes
Deviations:	No, but remarkably high application rate of reference item
Validity:	Yes

Material and methods:
An emulsifiable concentration of Bixafen + Prothioconazole EC 60 + 200 g/L was tested,specified by sample description: TOX 08519-00; specification no.: 102000020385; batch ID: 2008-010514 [analysed content of active ingredient: Bixafen 6.0 %w/w, Prothioconazole 19.7 %ww; date of completed analysis: 19 FEB 2009, BCS-D-FT Analysis & Services, D- 40789 Monheim]; density: 1.021 g/mL. The test item was applied two times with 1.0 L product/ha in 400 L water/ha on potted maize plants. The time interval between the first and second application was 14 days. The control was treated with deionised water in the same way as the test item. The toxic reference Dimethoate was applied at 0.1016 L product/ha (40 g a.i./ha) in 400 L water/ha on the day of the second application on potted maize plants as well. It was included to indicate the relative susceptibility of the test organisms and the test system. Report No CW09/023 Page 8 (30) Aging of the spray residues of the test item on the potted maize plants took place under natural semi-field conditions with rain protection during the whole study. Mortality of 100 protonymphs was assessed 1, 4, 7, 10, 12 and 14 days after exposure by counting the number of living and dead mites. The number of escaped mites was calculated as the difference from the total number exposed. The reproduction rate of surviving mites was then evaluated over the period of 7-14 days after exposure by counting the total number of offspring (eggs and larvae) produced. From these data the endpoints mortality (after 7 days) and effects on reproduction werecalculated and summarized below.

Findings:

Effects on mortality and reproduction of *Typhlodromus pyri*

Test Item		**Bixafen + Prothioconazole EC 60 + 200 g/L**					
Test organism		***Typhlodromus pyri***					
Exposure on		**Dried spray deposits on maize leaves**					
Start of bioassay		**On the day of the last application**					
		Mortality (%) after 7 days			**Reproduction**		
Treatment	Product/ha	Uncorr.	Corr.	P-Value(*)	Rate	Red. rel. to Control [%]	P-Value(#)
Control	0	13.0			6.9		
Test item	2 × 1 L	28.0	17.2	0.007 sign.	5.0	28.2	0.150 n. sign.
Reference item	0.102 L	99.0	98.9		n.d.	n.d.	

* Fisher's Exact test (one-sided), p-values are adjusted according to Bonferroni-Holm
# one-way ANOVA, Williams test (one-sided)
n.d. = not detected
n. sign. = not significant
sign. = significant

Conclusions:
In this extended laboratory test the effects of Bixafen + Prothioconazole EC 60 + 200 g/L residues (aged under semi-field conditions) on the survival of the predatory mite *Typhlodromus pyri* were determined after application of 2 x 1.0 L product/ha onto *Zea mays* with an application interval of 14 days. In this study

17.2% corrected mortality of the test item was found in the first bioassay started on the day of the last application. There was a reduction in reproductive success relative to the control of 28.2%, which was not statistically significant. Due to these results the initiation of a second bioassay was not necessary. The figures obtained fulfil the validity criteria of the laboratory method using glass plates.

Comments of zRMS:	Acceptable.
Agreed endpoints	LR_{50}, ER_{50} > 2 x 1000 mL/ha

Reference:	KIIIA 10.5.2/05, Effects of BYF 00587 + PTZ EC 75 + 150 G on the Predatory Mite Typhlodromus pyri, Extended Laboratory Study, aged residue test
Author(s), year:	Rosenkranz, B.; 2008
Report/Doc number:	38631060
Guidelines:	Blumel et al., 2000; Oomen 1988
GLP:	Yes
Deviations:	No
Validity:	Yes

BYF 00587+PTZ EC 75+150G (active ingredients: BYF 00587 (Bixafen), purity: 7.7 % w/w, JAU 6476 (Prothioconazole), purity: 14.7 % w/w; batch ID: 2007-002622, sample description: TOX07852-00, master recipe ID: 0037641-001, specification no.: 102000013869.
Test organism: the protonymphs (< 24 hours old) of *Typhlodromus pyri*.

Under extended laboratory conditions protonymphs (< 27 hours old) of *Typhlodromus pyri* (10 mites per replicate) were exposed to freshly dried and aged spray residues of 1.25 L product/ha (diluted in 400 L tap water/ha) on field treated bean plants (10 replicates per treatment group). The test item was applied 3 times under field conditions with a spray interval of 2 weeks. Tap water was used as a control treatment and Dimezyl 40 EC (60.0 mL product/ha diluted in 400 L tap water/ha) as a reference treatment. Three bioassays were performed; the 1st bioassay was started on the day of the last application, all additional bioassays were started weekly, last bioassay was started 14 days after the last application. Assessment of the number of living, escaped and dead mites was conducted until day 7 for each bioassay. Reproduction assessment of surviving mites from the control and from the test item groups was examined in the bioassays where corrected mortality was < 50 %. Mites were sexed and the number of eggs per females was recorded at 3 assessment days within one week.
Dates of work: 2007-10-29 to 2008-06-30

Findings:
The results can be considered as valid, as all validity criteria of the test were met. The control mortality was ≤ 20% at day 7, the corrected mortality in the reference item was ≥ 50% and the number of eggs per female in the control group was ≥ 4 for the second week.

Effects on mortality and reproduction of Typhlodromus pyri

Test Item	**BYF 00587+PTZ EC 75+150G**				
Test object	***Typhlodromus pyri***				
Exposure	**Bean Plants**				
1st bioassay: test start on the day of the last application					
Treatment	Mortality after 7 days[a] [%]		Corrected Mortality [%]	Reproduction[b] [eggs/female]	Effect on reproduction [%]
Control	17.0		--	4.3	--
3 x 1.25 L/ha	50.0	*	39.8	2.9 n.s.	31.8
60 mL Dimezyl 40 EC/ha (Reference Item)	69.0	*	62.7	--	--
2nd bioassay: test start 7 days after the last application					
	Mortality after 7 days[a] [%]		Corrected Mortality [%]	Reproduction[b] [eggs/female]	Effect on reproduction [%]
Control	10.0		--	4.3	--
3 x 1.25 L/ha	39.0	*	32.2	3.1 n.s.	27.7
3rd bioassay: test start 14 days after the last application					
	Mortality after 7 days[a] [%]		Corrected Mortality [%]	Reproduction[b] [eggs/female]	Effect on reproduction [%]
Control	5.6		--	Not performed	--
3 x 1.25 L/ha	25.6	*	21.2		--

[a] n.s. = not significant, * = significant; Fisher Exact Test, $\alpha = 0.05$

[b] n.s. = not significant; Student-t-Test, $\alpha = 0.05$

n.a. = not assessed

Conclusion:

The duration and the extent of effects of fresh dried and aged residues of BYF 00587+PTZ EC 75+150G applied on bean plants (*Phaseolus vulgaris*) on the predatory mite *Typhlodromus pyri* were evaluated under extended laboratory conditions.

On the day of the last application survival was statistically significantly affected at 3 x 1.25 L product/ha (Fisher Exact test, $\alpha = 0.05$). However, the effect on mortality was still lower than the trigger value of 50 % (corrected mortality was 39.8 %) and an assessment on reproductive performance was performed. No unacceptable effects of BYF 00587+PTZ EC 75+150 G on reproduction was observed after exposure to freshly dried residues. Similar to the results on mortality the effect of 31.8 % was below 50 %.

In the 2nd bioassay (7 days after the last application) the effect in the test item treated plot on mortality was 32.2 % (corrected mortality) and still lower than 50 %. Effect on reproduction in this bioassay was 27.7 % and this was not statistically significant compared to the control (Student t-test, $\alpha = 0.05$).

In the 3rd bioassay (14 days after the last application) corrected mortality of the test item treated animals was 21.2 compared to the control. Because there were no effects of BYF 00587+PTZ EC 75+150G on mortality and reproduction of *T. pyri* after exposure to freshly dried and aged residues in the 1st and 2nd bioassay (0 and 7 days after application), it was not necessary to complete the 3rd bioassay and to start further bioassays.

Study Comments: IIIA 10.5.2/06	
Agreed endpoints: IIIA 10.5.2/06	

Materials and methods:
Test item: BYF 00587 + PTZ EC 75 + 150 G; a.s. contents: BYF 00587, purity: 75.3 g/L; JAU 6476 (Prothioconazole), purity: 149 g/L; sample description: TOX07660-00, master recipe ID: 0034288-001, batch no.: 2006-001178, material no.: 06000044, specification no.: 102000013869.
Test organism: the predatory mite *Typhlodromus pyri*, < 24 hours old protonymphs.

Under extended laboratory conditions protonymphs (10 mites per replicate) were exposed to air dried spray deposits of 250, 500, 1000, 2000 and 4000 mL product/ha (diluted in 200 L deionised water/ha) on bean leaves (6 replicates per treatment group). Deionised water was used as a control treatment and Perfekthion (40 mL product/ha diluted in 200 L deionised water/ha) as a reference treatment. Assessment of the number of living, escaped and dead mites was conducted 3 and 7 days after application. For the reproduction assessment surviving mites from the control and from all test item groups where corrected mortality was < 50 % were sexed and the number of eggs per females was recorded at 3 assessment days within one week.

Dates of work: 2006-09-18 to 2006-10-23

Findings:
The results can be considered as valid, as all validity criteria of the test were met. The control mortality on day 7 after exposure was < 20% (5.0% in this study), the corrected mortality in the reference item was > 50% at day 7 after exposure (98.2% in this study) and the average number of eggs/female in the control group exceeded 4 eggs per female for the second week (5.4 in this study).

Effects on mortality and reproduction of *Typhlodromus pyri*

Treatment	mL product/ha	Mortality [a] [%]	Corrected Mortality [%]	Reproduction [b] [eggs/ female]	Effect on reproduction [c] [%]
Control	0	5.0	-	5.4	-
Test item	250	6.7 n.s.	1.8	7.3 n.s.	-35.0
Test item	500	16.7 n.s.	12.3	3.5 n.s.	35.9
Test item	1000	21.7 *	17.5	3.7 n.s.	31.3
Test item	2000	88.3 *	87.7	n.a.	-
Test item	4000	98.3 *	98.2	n.a.	-
Reference item (Perfekthion)	40	98.3 *	98.2	n.a.	-
LR_{50} (CL 95%)	1296 mL product/ha (424 – 2348 mL product/ha)				

[a] n.s. = not significant, * = significant; Fisher Exact Test, $\alpha = 0.05$
[b] n.s. = not significant, * = significant; Dunnett-Test, $\alpha = 0.05$
[c] negative value means increased reproduction compared to the control
n.a. = not applicable
CL = Confidence Limits

Observations:

The reproductive capacity of *Typhlodromus pyri* was tested at 250, 500 and 1000 mL product/ha. There was no statistically significant effect on reproduction at these dose rates compared to the control.

Conclusion:
Under extended laboratory conditions the LR_{50} of BYF 00587 + PTZ EC 75 + 150 G to *Typhlodromus pyri* is 1296 mL product/ha (95% confidence limits: 424 - 2348 mL product/ha).

Study Comments: IIIA 10.5.2/05	Valid and acceptable.
Agreed endpoints: IIIA 10.5.2/05	LR_{50} = 1296 mL product/ha ER_{50} > 1000 mL product/ha

Reference:	KIIIA 10.5.2/01, Toxicity to the parasitoid wasp Aphidius rhopalosiphi (DeStephani-Perez) (Hymenoptera: Braconidae) using an extended laboratory test on barley; Bixafen + Prothioconazole EC 60 + 200 g/L
Author(s), year:	Jans, D.; 2009
Report/Doc number:	CW09/042
Guidelines:	Mead-Briggs et al. 2000, Mead-Briggs et al. 2006, Candolfi et al. 2001
GLP:	Yes
Deviations:	No
Validity:	No

Materials and methods:
An emulsifiable concentrate of Bixafen + Prothioconazole EC 60 + 200 g/L was tested, specified by sample description: TOX 08519-00; specification no.: 102000020385; batch ID: 2008-010514 [analysed content of active ingredient: Bixafen: 6.0% w/w, Prothioconazole: 19.7% w/w; date of completed analysis: 19 FEB 2009, BCS-D-FT Analysis & Services, D- 40789 Monheim]; density: 1.021 g/mL. The test item was applied at rates of 300, 553, 950, 1700 and 3000 mL product/ha and the effects were compared to a water treated control. A toxic reference (a.i.: dimethoate) applied at 12.7 mL product/ha (5 g a.i./ha) was included to indicate the relative susceptibility of the test organisms and the test system. Mortality of 30 females was assessed 2, 24 and 48 hours after exposure. Repellency of the test item was determined during the initial 3 h after the release of the females. Five separate observations were made at 30-minute intervals starting 0-15 minutes after the introduction of all wasps. From the water control and the dose rates 300, 553, 950, 1700 and 3000 mL product/ha, 15 impartially chosen females per treatment were each transferred to a cylinder containing untreated barley seedlings infested with Rhopalosiphum padi for a period of 24 hours. The number of mummies was assessed 11 days later. Mortality, reproduction and repellency in each of the treatments are summarized below.

Findings:

Test item		Bixafen + Prothioconazole EC 60 + 200 g/L						
Test organism		*Aphidius rhopalosiphi*						
Exposure on		Barley seedlings						
		Mortality after 48 h [%]			Reproduction		Repellency	
Treatment	mL product/ha	Uncorr.	Corr.	P-Value(*)	Rate (Mummies per female)	Red. Rel. to Control [%] P-Value (#)	% Wasps on plant	Red. rel. to Control [%] P-Value (#)
Control	0	0			14.1		46.2	
Test item	300	6.7	6.7	0.737 n. sign.	15.0	-6.6 (0.34 n.sign.)	34.6	25 (0.097 n.sign.)
Test item	553	0	0	1.000 n. sign.	11.9	15.6 (0.406 n.sign.)	49.7	- 7.7 (0.116 n.sign.)
Test item	950	13.3	13.3	0.225 n. sign.	9.9	29.9 (0.433 n.sign.)	32.2	30.3 (0.123 n. sign.)
Test item	1700	6.7	6.7	0.737 n. sign.	10.1	28.0 (0.449 n.sign.)	49.9	-8.2 (0.127 n.sign.)
Test item	3000	33.3	33.3	0.002 sign.	9.3	33.6 (0.458 n.sign.)	22.0	52.3 (0.129 n. sign.)
Reference item	12.7	93.3	93.3		n.d.	n.d.	47.3	- 2.4

LR_{50}: > 3000 mL product/ha
* Fisher's Exact test (one-sided), p-values are adjusted according to Bonferroni-Holm
# one-way ANOVA, Williamst test (one-sided)
n.d. = not detected; n.sign = not significant; sign. = significant

Conclusions:
In this extended laboratory test the effects of residues of Bixafen + Prothioconazole EC 60 + 200 g/L on the survival of *Aphidius rhopalosiphi* were determined at 300, 553, 950, 1700 and 3000 mL product/ha, applied to barley seedlings. At the lower rates of 300, 553, 950 and 1700 mL product/ha no or only slight corrected mortality (<13.5%) was detected. In the highest dose rates of 3000 mL product/ha a statistically significant corrected mortality of 33.3% was observed. No reduction in reproductive success relative to the control (-6.6%) was detected at the lowest rate of 300 mL product/ha. At the higher rates of 553, 950, 1700 and 3000 mL product/ha rate a reduction in reproduction of 15.6, 29.9, 28.0 and 33.6, respectively was observed but not statistically significant. No statistically significant dose related repellent effect of the test item was observed. The LR_{50} was estimated to be >3000 mL product/ha.

Study Comments: IIIA 10.5.2/01	Valid and acceptable.
Agreed endpoint/s: IIIA 10.5.2/01	LR_{50} and ER_{50} > 3000 mL product/ha

Reference:	KIIIA 10.5.2/04, Effects of BYF 00587 + PTZ EC 75 + 150 G on the Parasitoid Aphidius rhopalosiphi, Extended Laboratory Study – Dose Response Test
Author(s), year:	Moll, M.; 2007
Report/Doc number:	31204002
Guidelines:	Mead-Briggs etal. 2000, Mead-Briggs etal. 2006
GLP:	Yes
Deviations:	No
Validity:	Yes

Materials and methods:
Test item: BYF 00587 + PTZ EC 75 + 150 G; a.s. contents: BYF 00587, purity: 75.3 g/L; JAU 6476 (Prothioconazole), purity: 149 g/L; sample description: TOX07660-00, master recipe ID: 0034288-001, batch no.: 2006-001178, material no.: 06000044, specification no.: 102000013869.
Test organism: the parasitoid wasp *Aphidius rhopalosiphi*, less than 48 h old adults

Under extended laboratory conditions parasitoid wasps (5 females per replicate) were exposed to dried spray deposits of 46.3, 139, 417, 1250 and 3750 mL product/ha (diluted in 400 L deionised water/ha) on treated potted barley seedlings (6 replicates per treatment group). Deionised water was used as a control treatment and Perfekthion (10.0 mL product/ha diluted in 400 L deionised water/ha) as a reference treatment. The duration of the mortality part was 48 hours. The reproductive performance of the survivors was examined for another 24 hour period using females from the control and from those test item concentrations where corrected mortality was < 53.3%.
Dates of work: 2006-09-18 to 2006-11-14

Findings:
The results can be considered as valid, as all validity criteria of the test were met. Mortality in the water control was 0% (≤ 10% required), corrected mortality of the reference item was 96.7% (> 50% required), mean reproduction per female in water control was 41.6 (≥ 5 required) and not more than 2 wasps produced zero reproduction in the water control (0 wasps in this study).

***Aphidius rhopalosiphi*, extended laboratory testing - dose response test -**

Test item	**BYF 00587 + PTZ EC 75 + 150 G**				
Test object	***Aphidius rhopalosiphi***				
Exposure	**Barley seedlings**				
Treatment	Mortality after 48 h [a] [%]	Corrected mortality after 48 h [%]	Settling rate [b] [% wasps on the plants]	Mummies per female [c]	Reduction of parasitisation efficiency relative to the control [d] [%]
Control	0.0	-	47.3	41.6	-
46.3 mL product/ha	0.0 n.s.	0.0	48.7 n.s.	43.5 n.s.	-4.5
139 mL product/ha	0.0 n.s.	0.0	46.3 n.s.	33.7 n.s.	19.0
417 mL product/ha	6.7 n.s.	6.7	49.3 n.s.	29.3 n.s.	29.7
1250 mL product/ha	0.0 n.s.	0.0	44.7 n.s.	36.1 n.s.	13.4
3750 mL product/ha	53.3 *	53.3	35.3 *	28.3 n.s.	31.9
10.0 mL Perfekthion/ha (Toxic Reference)	96.7 *	96.7	46.0 n.s.	n.a.	-
LR_{50} (CL 95 %)	**3485.16 mL product/ha (2398.42 - 5064.31 mL product/ha)**				

[a] n.s. = not significant, * = significant; Fisher Exact Test, $\alpha = 0.05$
[b] n.s. = not significant, * = significant;
test item: Dunnett-Test, $\alpha = 0.05$; reference item: Student-t-Test, $\alpha = 0.05$
[c] n.s. = not significant; Dunnett-Test, $\alpha = 0.05$
[d] negative value means increased reproductive capacity compared to the control
n.a. =not assessed
CL = Confidence Limits

Observations:
No repellent effect was observed in the test item treatment groups up to and including 1250 mL product/ha and in the reference item group compared to the control. At 3750 mL product/ha the settling rate was statistically significantly lower compared to the control. This might be an indication for a repellent effect of the test item at this rate.
The reproductive capacity of *Aphidius rhopalosiphi* was not affected up to and including 3750 mL product/ha compared to the control.

Conclusion:
Under extended laboratory conditions the LR_{50} of BYF 00587 + PTZ EC 75 + 150 G is 3485.16 mL product/ha (95 % confidence limits: 2398.42 - 5064.31 mL product/ha).
No repellent effect was observed in the test item treatment groups up to and including 1250 mL product/ha and in the reference item group compared to the control. At 3750 mL product/ha the settling rate was statistically significantly lower compared to the control. This might be an indication for a repellent effect of the test item at this rate. The reproductive capacity of *A. rhopalosiphi* was not affected up to and including 3750 mL product/ha compared to the control.

Study Comments: IIIA 10.5.2/04	Valid and acceptable.
Agreed endpoints: IIIA 10.5.2/04	LR_{50}, ER_{50} > 3750 mL product/ha

Reference:	KIIIA 10.5.2/03, Toxicitiy to the ladybird beetle Coccinella septempunctata L. (Coleoptera, Coccinellidae) using an extended laboratory test on Zea mays; Bixafen + Prothioconazole EC 60 + 200 g/L
Author(s), year:	Jans, D., 2009
Report/Doc number:	CW09/043
Guidelines:	Schmuck et al. 2000: his guideline was modified for exposure of Coccinella septempunctata on natural substrate; Candolfi et al. (2001)
GLP:	Yes
Deviations:	No
Validity:	No

Materials and methods:
An emulsifiable concentrate formulation of Bixafen + Prothioconazole EC 60 + 200 g/L was tested, specified by sample description: TOX 08519-00; specification no.: 102000020385; batch ID: 2008-010514 [analysed content of active ingredient: Bixafen: 6.0%w/w, Prothioconazole: 19.7%w/w; date of completed analysis: 19 FEB 2009, BCS-D-FT Analysis & Services, D-40789 Monheim]; density: 1.021 g/mL. The test item was applied to leaves of *Zea mays* at rates of 200, 356, 632, 1125 and 2000 mL product/ha and the effects were compared to a water treated control. A toxic reference (a.i.: dimethoate) applied at 29.1 mL product/ha (11 g a.i./ha) was included to indicate the relative susceptibility of the test organisms and the test system. The preimaginal mortality was monitored over the duration of the study. The fertility and fecundity of the surviving hatched adults were then evaluated over the period of 17 days. Mortality and reproduction in each of the treatments are summarized below.

Findings:

Effects on mortality and reproduction of *Coccinella septempunctata*

Test item		Bixafen + Prothioconazole EC 60 + 200 g/L				
Test organism		*Coccinella septempunctata*				
Exposure on		Maize leaves				
		Mortality [%]			Reproduction	
Treatment	mL product/ha	Uncorr.	Corr.	P-Value(*)	Fertile eggs per female and day	Fertility [hatching rate in %]
Control	0	15.0	-	-	11.9	85.6
Test item	200	20.0	5.9	0.568 n. sign.	12.5	91.5
Test item	356	22.5	8.8	0.568 n. sign.	16.4	94.9
Test item	632	27.5	14.7	0.411 n. sign.	16.0	94.4
Test item	1125	45.0	35.3	0.013 sign.	34.5	96.5
Test item	2000	65.0	58.8	< 0.001 sign.	20.5	95.0
Reference item	29.1	100	100	-	n.d.	n.d.

LR_{50}: 1680 mL product/ha;
95% Confidence Interval: (1068.13 – 3406.91) (calculated with Probit analysis)
* Fisher's exact test (one-sided), p-values are adjusted according to Bonferroni-Holm
n.d. = not detected
n. sign. = not significant
sign. = significant

Conclusions:

In this extended laboratory study the effects of the test item residues of Bixafen + Prothioconazole EC 60 + 200 g/L to larvae of the ladybird beetle *Coccinella septempunctata* were determined. The application was done onto detached leaves of Zea mays. The dose rates of 200, 356 and 632 mL product/ha showed no statistically significant effects on preimaginal mortality. At the lowest rate of 200 mL product/ha 5.9% corrected mortality occurred. With the rates of 356 and 632 mL product/ha 8.8 and 14.7% corrected mortality were found. At the highest test rates of 1125 and 2000 mL product/ha there were statistically significant effects on the preimaginal mortality with 35.3 and 58.8% corrected mortality. Reproduction was assessed for all rates of Bixafen + Prothioconazole EC 60 + 200 g/L. The mean number of fertile eggs per female and day was 11.9 in the control. In the 200, 356 and 632 mL product/ha rates a mean number of 12.5, 16.4 and 16.0 fertile eggs per female and day were found, respectively. 34.5 and 20.5 fertile eggs per female and day were detected with the highest rates of 1125 and 2000 mL product/ha. Because the reproductive performance was within the historical data base for control beetles (≥ 2 fertile eggs per female and day, SCHMUCK ET AL. 2000) this parameter is considered as not impacted by all test item rates. The LR_{50} was calculated to be 1680 mL product/ha.

Study Comments: IIIA 10.5.2/03	Valid and acceptable. However, the females laid remarkably more eggs in the treated groups than in the control groups which might be evidence for stress.
Agreed endpoint/s: IIIA 10.5.2/03	LR_{50} = 1680 mL product/ha

Reference:	KIIIA 10.5.2/06, Effects of BYF 00587 + PTZ EC 75 + 150 G on the Ladybird Beetle Coccinella septempunctata, Extended Laboratory Study - Dose Response Test
Author(s), year:	Moll, M.; 2007
Report/Doc number:	31206012
Guidelines:	Schmuck et al. 2000; this guideline was modified for exposure of Coccinella septempunctata on natural substrate.
GLP:	Yes
Deviations:	No
Validity:	Yes

Materials and methods:
Test item: BYF 00587 + PTZ EC 75 + 150 G; a.s. contents: BYF 00587, purity: 75.3 g/L, JAU 6476 (Prothioconazole), purity: 149 g/L; batch no.: 2006- 001178, sample description: TOX07660-00, master recipe ID.: 0034288-001, material no.: 06000044, specification no.: 102000013869.
Test organism: the Ladybird Beetle *Coccinella septempunctata,* 3-4 day old larvae.

Under extended laboratory conditions approximately 3-4 day old larvae of *Coccinella septempunctata* (1 larva per replicate) were exposed to dried spray deposits of 417, 722, 1250, 2165 and 3750 mL product/ha (diluted in 200 L deionised water/ha) on treated bean leaves (*Phaseolus vulgaris*; 40 replicates per treatment group). Deionised water was used as a control treatment and Perfekthion (50 mL product/ha diluted in 200 L deionised water/ha) as a reference treatment. The duration of the pre-imaginal mortality part was 12-15 days (reference item only 2 days). The reproductive performance of the survivors was examined over 2 weeks (oviposition period) using adults from the control and from those test item concentrations where the corrected mortality was <50.0%. The reference item treatment caused 100% corrected mortality.

Dates of work: 2006-11-10 to 2007-03-22

Findings:
The results can be considered as valid, as all validity criteria of the test were met. The control mortality was ≤ 30% (27.5% in this study), the corrected mortality in the reference item was > 40% (100% in this study) and the average number of viable eggs per female per day in the control group was ≥ 2 (29.4 in this study).

Effects on mortality and reproduction of *Coccinella septempunctata*

Treatment	mL product/ha	Preimaginal mortality [a] [%]	Corrected mortality [b] [%]	Eggs per female per day [c]	Fertile eggs per female per day [c]	Larval hatching rate [c] [%]
Control	0	27.5	-	38.5	29.4	76.9
Test item	417	20.0 n.s.	-10.3	32.1 n.s.	24.7 n.s.	76.9 n.s.
Test item	722	32.5 n.s.	6.9	19.2 *	14.2 *	74.8 n.s.
Test item	1250	27.5 n.s.	0.0	20.2 *	17.0 *	84.1 n.s.
Test item	2165	47.5 n.s.	27.6	29.9 n.s.	23.3 n.s.	79.3 n.s.

Test item	3750	67.5 *	55.2	n.a. [d]	n.a. [d]	n.a. [d]
Reference item (Perfekthion)	50	100.0 *	100.0	n.a. [d]	n.a. [d]	n.a. [d]
LR_{50} (CL 95%)	3391 mL product/ha (2508 – 4585 mL product/ha)					

[a] n.s. = not significant, * = significant; Fisher Exact Test, $\alpha = 0.05$
[b] negative value means lower mortality compared to the control
[c] n.s. = not significant, * = significant; Dunnett-Test, $\alpha = 0.05$, [d] n.a. = not applicable, CL = Confidence Limits

Observations:
Reproduction was > 2 fertile eggs per viable female per day at dose rates of 417, 722, 1250 and 2165 mL product/ha (the highest rate tested), so the reproductive output is within the historical data base for control beetles and therefore this parameter is considered as not impacted by the treatment (Schmuck & al. 2000) up to and including 2165 mL product/ha.

Conclusion:
Under extended laboratory conditions the LR_{50} of BYF 00587 + PTZ EC 75 + 150 G to *Coccinella septempunctata* is 3391 mL product/ha (95% confidence limits = 2508 - 4585 mL product/ha).

Study Comments: IIIA 10.5.2/06	Valid and acceptable
Agreed endpoints: IIIA 10.5.2/06	$LR_{50,}$ = 3391 mL product/ha ER_{50} > 2165 mL product/ha

Reference:	KIIIA 10.5.2/07, Effects of BYF 00587 + PTZ EC 75 + 150 G on the Lacewing Chrysoperla carnea, Extended Laboratory Study
Author(s), year:	Rosenkranz, B.; 2007
Report/Doc number:	31207047
Guidelines:	Vogt et al., 2000: Laboratory method to test effects of plant protection products on larvae of Chrysoperla carnea (Neuroptera: Chrysopidae).
GLP:	Yes
Deviations:	Yes: For the 3rd and 4th check the total number of eggs was calculated on the counted numbers of eggs on the wall of the acrylic cylinder and of eggs on the gauze.
Validity:	Yes

Materials and methods:
Test item: BYF 00587 + PTZ EC 75 + 150 G; a.s. contents: 75.3 g/L BYF 00587, 149 g/L JAU 6476; batch no.: 2006-001178.
Test organism: the Lacewing *Chrysoperla carnea*, 2-3 days old larvae.

Under extended laboratory conditions lacewings (2-3 days old larvae) of *Chrysoperla carnea* (50 larvae per treatment group) were exposed to air dried spray deposits of 46.3 - 3750 mL/ha (diluted in 200 L deionised water/ha) on treated bean leaves (50 replicates each and each containing one larvae). Deionised water was used as a control treatment and Perfekthion (50 mL product/ha diluted in 200 L deionised water/ha) as a reference treatment.
Initial evaluation of the test item took place in a range finding test. Based on these results a main test was designed. Exposure time lasted as long as pupae were transferred to petri dishes for development of adults. Mortality checks were carried out regularly until hatching of adult lacewings. For the reproduction assessment surviving lacewings from the control and from all test item groups displaying less than 50% corrected mortality were sexed and egg deposition and larval hatching rate, was determined (2 assessments/week, 24 hours period each assessment). The toxic standard treatment caused 59.1% corrected mortality.
Dates of work: 2006-09-20 to 2006-12-19

Findings:
The results can be considered as valid, as all validity criteria of the test were met. The control mortality was ≤ 20% (12.0% in this study), the corrected mortality in the reference item was > 50% (64.0% in this study), the average number of eggs per female per day in the control group was ≥ 15 (18.4 in this study) and the mean larval hatching rate in the control group ≥ 70% (95.5% in this study).

Effects on mortality and reproduction of *Chrysoperla carnea*

Treatment	mL product/ha	Mortality [a] [%]	Corrected mortality [%]	Reproduction [b] [eggs/female/day]	Hatching rate [b] [%]
Control	0.0	12.0	-	18.9	95.5
Test item	46.3	22.0 n.s.	11.4	27.1	85.4
Test item	139.0	14.0 n.s.	2.3	17.0	57.5
Test item	417.0	18.0 n.s.	6.8	17.2	81.7
Test item	1250.0	16.0 n.s.	4.5	25.0	72.4
Test item	3750.0	12.0 n.s.	0.0	19.0	76.8
Reference item (Perfekthion)	50.0	64.0 *	59.1	n.a.	n.a.
LR_{50}	> 3750 mL product/ha				

[a] n.s. = not significant, * = significant; Fisher Exact Test, $\alpha = 0.05$
[b] values of the 3rd and 4th fecundity check
n.a. = not applicable

Observations:
The reproduction of *Chrysoperla carnea* was not affected at all dose rates tested (46.3 - 3750 mL product/ha) with the exception of the hatching rate in the 139 mL/ha treated group. This effect on hatching rate is considered to be not test item related, because no effects occurred in the higher rates either on fertility or fecundity of *Chrysoperla carnea*.

Conclusion:
Under extended laboratory conditions the LR_{50} of BYF 00587 + PTZ EC 75 + 150 G to *Chrysoperla carnea* was determined to be > 3750 mL product/ha.

Study Comments: IIIA 10.5.2/07	Valid and acceptable
Agreed endpoints: IIIA 10.5.2/07	LR_{50}, ER_{50}: > 3750 mL product/ha

IIIA 10.5.3 Effects on non-target terrestrial arthropods in semi-field tests

IIIA 10.5.4 Field tests on arthropods species

IIIA 10.6 Effects on earthworms and other soil macro-organisms

IIIA 10.6.2 Acute toxicity to earthworms

Reference:	KIIIA 10.6.2/01, Bixafen + prothioconazole EC 260 (60 + 200) G: acute toxicity to earthworms (Eisenia fetida) tested in artificial soil with 5% peat
Author(s), year:	Leicher, T.; 2010
Report/Doc number:	LRT/RG-A-141/10
Guidelines:	OECD 207
GLP:	Yes
Deviations:	No
Validity:	Yes

Materials and Methods:
Bixafen + Prothioconazole EC 260 (60 + 200) G, contents of a.s. (analysed): 62.28 g/L Bixafen, 200.1 g/L Prothioconazole; Batch-ID: 2008-010514; Sample description: TOX08519-01; Density: 1.021 g/ml. Adult *Eisenia fetida andrei* (4 x 10 animals per concentration, the overall average weight was 0.31 g) were exposed for 14 days in an artificial soil to the nominal concentrations of 100, 178, 316, 562 and 1000 mg test item / kg dry weight soil. The artificial soil comprised 5 % peat. There was no mortality observed in the control vessels. Therefore the validity criteria for the control mortality of < 10 % was fulfilled.

Findings:

Toxicity to earthworms after 14 days

Test concentrations (mg test item/ kg dry weight soil) [a]	Mortality (%) [b] after		Weight alteration of the	
	7 days	14 days	(%)[b]	Williams-Test[c]
Control	0	0	2 ± 3	
100	0	0	1 ± 4	-
178	0	0	-2 ± 3	-
316	0	0	-1 ± 2	-
562	3 ± 5 [d]	3 ± 5 [d]	-5 ± 4	+
1000	35 ± 24	35 ± 24	-8 ± 5	+

Mortality (%) was calculated from the means of 4 replicates each containing ten earthworms.
+ = weights of control and the test concentration do differ statistically significantly
- = weights of control and the test concentration do not differ stastically significantly
[a] test concentrations are nominal concentrations
[b] mean ± standard deviation
[c] Williams-Test (alpha = 0.05, one-sided smaller)
[d] refers to one dead worm in one replicate

Observations:
No morphological and behavioural effects were observed.

Conclusions:

Test item	Bixafen + prothioconazole EC 260 (60 + 200) G
	mg test item/kg dry weight soil
Test object	*Eisenia fetida*
Exposure	14 d
LC_{50} (mg test item/kg dry weight soil)	≥ 1000
95% confidence limits	-
NOEC (no-observed-effect-concentration) (mg test item/kg dry weight soil)	316
LOEC (lowest-observed-effect-concentration) (mg test item/kg dry weight soil)	562

In this study the LC_{50} (14 d) was ≥ 1000 mg test item/kg dry weight soil. The Lowest Observed Effect Concentration (LOEC) of Bixafen + prothioconazole EC 260 (60 + 200) G to earthworms (*Eisenia fetida*) was determined to be 562 mg test item/kg dry weight soil. The No Observed Effect Concentration (NOEC) was determined to be 316 mg test item/kg dry weight soil.

Study Comments: IIIA 10.6.2/01	Valid and acceptable
Agreed endpoint/s: IIIA 10.6.2/01	LC_{50} > 1000 mg product/kg soil dry weight

IIIA 10.6.3 Sublethal effects on earthworms

Reference:	KIIIA 10.6.3/01, Effects of Bixafen + Prothioconazole EC 260 (60+200) G on Reproduction and Growth of Earthworms Eisenia fetida in Artificial Soil with 5% Peat
Author(s), year:	Luehrs U.; 2010
Report/Doc number:	61141022
Guidelines:	OECD 222
GLP:	Yes
Deviations:	No
Validity:	Yes

Materials and Methods:
Bixafen + Prothioconazole EC 260 (060+200) G, specification No.: 102000020385 - 01, material no: 79626940, sample description: TOX08519-01, batch no.: 2008-010514, content: Bixafen (BYF 00587): 60 g/L (nominal), 62.28 g/L (6.10% w/w) (analysed), Prothioconazole (JAU 6476): 200 g/L (nominal), 200.1 g/L (19.6% w/w) (analysed); density: 1.021 g/mL.

Reference item: Luxan Carbendazim 500 FC (active ingredient carbendazim, 500 g/L nominal) is tested at least once a year in a dose response study; control: untreated.
Bixafen + Prothioconazole EC 260 (060+200) G was mixed into the soil at 10, 18, 32, 56 and 100 mg /kg artificial soil (dry weight) to which earthworms *Eisenia fetida* (80 worms per control, 40 worms per test item group) were exposed at temperatures within the range of 18 to 22 °C, light within the range of 400 to 800 lux, 16 h light : 8 h dark, fed weekly with dried cattle manure, initial soil water content 19.5% to 20.9% (50.0% to 53.6% of the maximum water holding capacity), water content at experimental termination 21.9% to 24.2% (56.2% to 62.1% of the maximum water holding capacity); initial pH 5.7 to 5.8, pH 6.3 to 6.5 at experimental termination; Endpoints were mortality, body weight change, feeding activity and reproduction.

Findings:

Validity Criteria	**Recommended**	**Obtained**
Mortality of adults in the control:	≤ 10%	0%
Reproduction per replicate in the control:	≥30	286 to 401
Coefficient of variance of reproduction in control:	≤30%	12.0%

No statistically significant effects on reproduction were observed up to concentration of 100 mg test item/kg soil dry weight (Williams t-test, α = 0.05). No behavioural abnormalities were observed in any of the treatment groups and the feeding activity in all the treated groups was comparable to the control (see following table).

Bixafen + Prothioconazole EC 260 (60 + 200) G [mg test item/kg soil dry weight]	**Control**	**10**	**18**	**32**	**56**	**100**
Mortality (day 28) [%] [1)]	0.0	0.0	0.0	0.0	2.5	0.0
Weight change (day 28) [%] [2)]	35.5	28.4	22.0	28.9	28.2	32.5

No. of juveniles (day 56)	341	301	294	316	319	297
Reproduction in [%] of control (day 56) [3]	-	88.3	86.3	92.7	93.8	87.1
Food consumption [g]	25.0	25.0	25.0	25.0	25.0	25.0
Endpoints [mg/kg soil dry weight]						
NOEC (day 28 mortality and weight)	100					
NOEC (day 56 reproduction)	100					

[1] Fisher's Exact test, α = 0.05, not significally different compared to the control
[2] Williams t-test, α = 0.05, two-sided, not significantly different compared to the control
[3] Williams t-test, α = 0.05, one-sided smaller, not significantly different compared to the control

Conclusion:
In this study the no-observed-effect-concentration (NOEC) of Bixafen + Prothioconazole EC 260 (060+200) G for mortality, growth, reproduction and feeding activity of the earthworm *Eisenia fetida* found was 100 mg test item/kg soil dry weight, *i.e*. the highest concentration tested.

Study Comments: IIIA 10.6.3/01	Valid and acceptable
Agreed endpoint/s: IIIA 10.6.3/01	NOEC = 100 mg product/kg soil dry weight

IIIA 10.6.4 Field tests (effects on earthworms)

IIIA 10.6.5 Residue content of earthworms

IIIA 10.6.6 Effects of other soil non-target macro-organisms

Reference:	KIIIA 10.6.6/01, Prothioconazole a.s.: Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil.
Author(s), year:	Frommholz, U.; 2011
Report/Doc number:	FRM-COLL-118
Guidelines:	OECD 232 adopted (September 07, 2009)
GLP:	Yes
Deviations:	No
Validity:	Yes

Material and methods:
Prothioconazole a.s., analytical findings: 97.1 % w/w, origin batch no.: EDFL004807, customer order no.: TOX 09215-00, specification no.: 102000014040, LIMS no.: 1029715.
10 collembolans (10-12 days old) per replicate (8 replicates for the control group and 4 replicates for each treatment group) were exposed to control (water treated), 62.5, 125, 250, 500 and 1000 mg test item/kg artificial soil dry weight at 20 ± 2°C, 400 – 800 lux, 16h light : 8h dark. During the study, they were fed with granulated dry yeast.
Mortality and reproduction were determined after 28 days.

Findings:

Mortality:

In the control group 5 % of the adult *Folsomia candida* died which is below the allowed maximum of ≤ 20 % mortality. A LC_{50} could not be calculated and is considered to be > 1000 mg test item/kg artificial soil dry weight.

Reproduction:

Concerning the number of juveniles statistical analysis (William's-t test, one-sided smaller, α = 0.05) revealed a statistically significant difference between control and the lowest treatment group with 62.5 mg test item/kg artificial soil dry weight. Because the other test concentrations up to 1000 mg test item/kg artificial soil dry weight revealed no significant difference to the control the NOEC is determined to be ≥ 1000 mg test item/kg artificial soil dry weight.

Test item **Test object** **Exposure**	**Prothioconazole a.s.** ***Folsomia candida*** **Artificial soil**		
mg test item/kg soil dry weight nominal concentration	Adult mortality (%)	Mean number of juveniles ± SD	Reproduction (% of control)
Control	5	1570 ± 188	-
62.5	5	1389 ± 176	89*
125	0	1510 ± 183	96 n.s.
250	5	1593 ± 111	102 n.s.
500	5	1658 ± 123	106 n.s.
1000	5	1608 ± 131	102 n.s.
$NOEC_{reproduction}$ (mg test item/kg soil dry weight) $LOEC_{reproduction}$ (mg test item/kg soil dry weight)			≥1000 >1000

The calculations were performed with un-rounded values

* = statistically significant (William's-t test one-sided-smaller, α = 0.05)

n.s. = statistically not significant (William's-t test one-sided-smaller, α = 0.05)

Conclusions:

$NOEC_{reproduction}$ ≥1000 mg test item/kg artificial soil dry weight.

$LOEC_{reproduction}$ >1000 mg test item/kg artificial soil dry weight.

Validity of the study:

Validity Criteria for the untreated control of the study according to OECD 232 from September 07, 2009

Validity criteria	**Recommended by the guideline**	**Obtained in this study**
Mean adult mortality	≤ 20 %	5 %
Mean number of juveniles per replicate (with 10 collembolans introduced)	≥ 100	1570
Coefficient of variation calculated for the number of juveniles per replicate	≤ 30 %	12 %

Study Comments: IIIA 10.6.6/01	Valid and acceptable.
Agreed endpoint/s: IIIA 10.6.6/01	NOEC = 1000 mg a.i./kg soil dry weight

Reference:	KIIIA 10.6.6/02, Bixafen + prothioconazole EC 260 (60 + 200) G: Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil
Author(s), year:	Frommholz, U.; 2010
Report/Doc number:	FRM-COLL-107/10
Guidelines:	OECD 232 adopted, September 07, 2009: OECD Guidelines for Testing Chemicals – Collembolan Reproduction Test in Soil
GLP:	Yes
Deviations:	No
Validity:	Yes

Materials and methods:

Bixafen + prothioconazole EC 260 (60+200) G (analytical findings: 6.10 % w/w Bixafen (BYF 00587) equivalent to 62.28 g/L, 19.6 % w/w Prothioconazole (JAU 6476) equivalent to 200.1 g/L, density: 1.021 g/mL (20°C), batch ID: 2008-010514, sample description: TOX08519-01, specification no.: 102000020385 - 01, master recipe ID: 0094630-001. 10 collembolans (10-12 days old) per replicate (8 replicates for the control group and 4 replicates for each treatment group) were exposed to control (water treated), 100, 178, 316, 562 and 1000 mg test item/kg artificial soil dry weight at 20 ± 2°C, 400 – 800 lux, 16h light : 8h dark. During the study, they were fed with granulated dry yeast. Mortality and reproduction were determined after 28 days.

Findings:

Test item: **Bixafen + prothioconazole EC 260 (60 + 200) G** **Test object:** ***Folsomia candida*** **Exposure:** **Artificial soil (5% peat)**			
mg test item/ kg soil dry weight Nominal concentration	**Adult mortality (%)**	**Mean number of juveniles±SD**	**Reproduction (% of control)**
Control	5.0	1400 ± 125	-
100	5.0	1396 ± 88	100 n.s.
178	5.0	1433 ± 104	102 n.s.
316	5.0	1427 ± 93	102 n.s.
562	2.5	1002 ± 187	72*
1000	10.0	547 ± 11	39*
			Reproduction
EC_{50} (mg test item/kg soil dry weight): 832[a)] $NOEC_{reproduction}$ (mg test item/kg soil dry weight): 316 $LOEC_{reproduction}$ (mg test item/kg soil dry weight): 562			

The calculations were performed with un-rounded values
[a)] Probit analysis
* = statistically significant (William's t- test one-sided-smaller, α = 0.05)

n.s. = statistically not significant (William's t-test one-sided smaller, α = 0.05)

Validity of the study:

Validity Criteria for the untreated control of the study according OECD 232 from September 07, 2009

Validity criteria	Recommended by the guideline	Obtained in this study
Mean adult mortality	≤ 20%	5%
Mean number of juveniles per replicate (with 10 collembolans introduced)	≥ 100	1400
Coefficient of variation calculated for the number of juveniles per replicate	≤ 30%	8.9%

Observations:

Mortality:

In the control group 5 % of the adult *Folsomia candida* died which is below the allowed maximum of ≤ 20 % mortality. A LC_{50} could not be calculated and is considered to be > 1000 mg test item/kg artificial soil dry weight.

Reproduction:

Concerning the number of juveniles statistical analysis (William's-t test, one-sided smaller, α = 0.05) revealed statistically signifincant difference between control and the treatment groups with 562 and 1000 mg test item/kg artificial soil dry weight. Therefore the No-Observed-Effect-Concentration (NOEC) for reproduction is 316 mg test item/kg artificial soil dry weight. The Lowest-Observed-Effect-Concentration (LOEC) for reproduction is 562 mg test item/kg artificial soil dry weight. The EC50 for reproduction determined by probit analysis is 832 mg test item/kg artificial soil dry
weight.

Conclusion:

$NOEC_{reproduction}$ = 316 mg test item/kg artificial soil dry weight.
$LOEC_{reproduction}$ = 562 mg test item/kg artificial soil dry weight.
EC_{50} (reproduction) = 832 mg test item/kg artificial soil dry weight
(95% confidence limit 732 – 977 mg test item/kg artificial soil dry weight)

Study Comments: IIIA 10.6.6/02	Valid and acceptable.
Agreed endpoint/s: IIIA 10.6.6	NOEC = 316 mg product/kg soil dry weight

IIIA 10.6.7 Effects on organic matter breakdown

IIIA 10.7 Effects on soil microbial activity

IIIA 10.7.1 Laboratory test to investigate impact on soil microbial activity

Reference:	KIIIA 10.7.1/01, Metabolite JAU 6476-desthio : Determination of effects on carbon transformation in soil
Author(s), year:	Leicher, T.; 2007
Report/Doc number:	E 330 3322-6
Guidelines:	OECD 217 (January 21, 2000)
GLP:	Yes
Deviations:	No
Validity:	Yes

Materials and Methods:
Metabolite JAU 6476-desthio, analytical findings: 98.8%; batch No.: RUX76-105-1E, LIMS No.: PBF-2007-0030-TOX-07952, TOX-No.: 07952-00) was used in the test. A loamy sand soil was exposed for 28 d to 0.27 mg and 1.33 mg Metabolite JAU 6476-Desthio/kg dws (application rates were equivalent to 0.2 kg and 1.0 kg Metabolite JAU 6476-Desthio/ha). Glucose was added to the soil samples (2 g/kg dws) to induce maximum respiration rate.

Findings:

Effects on non-target soil micro organisms

Test item	metabolite JAU-desthio	
Test object	Soil micro organisms Carbon-transformation (loamy sand soil)	
Exposure	28 days	
mg test item/kg dws	0.27	1.33
Result (mg CO_2/h/kg dws) after 28 days	95% of control	98% of control

Observations:
During the 28-day tests, 0.2 kg metabolite JAU 6476-desthio/ha and the 5-fold dose of the test item had no relevant influence on carbon transformation after addition of glucose to a loamy sand soil. At the end of the experiment differences in the Carbon Dioxide rates between control soil samples and treated soil samples are <25% and meet the trigger values of the above mentioned guideline for a termination of the study.

Study Comments: IIIA 10.7.1/01	Valid and acceptable.
Agreed endpoint/s: IIIA 10.7.1/01	< 25 % inhibition at 1.33 mg/kg soil dw (=1000 g/ha)

Reference:	KIIIA 10.7.1/02, Bixafen + prothioconazole EC 260 (60+200) G: Determination of effects on nitrogen transformation in soil

Author(s), year:	Frommholz U.; 2010
Report/Doc number:	FRM-N-149-10
Guidelines:	OECD Guideline 216, Adopted January 21, 2000, OECD Guideline for the Testing of Chemicals, Soil Microorganisms: Nitrogen Transformation Test
GLP:	Yes
Deviations:	No
Validity:	Yes

Materials and Methods:
Bixafen + prothioconazole EC 260 (60+200) G (analytical findings: bixafen, 62.28 g/L (6.10 % w/w), prothioconazole, 200.1 g/L (19.6 % w/w); specification No.: 102000020385 - 01, batch ID: 2008-010514, master recipe ID: 0094630-001, sample description: TOX08519-01, density: 1.021 g/mL) was used in the test. A loamy sand soil was exposed for 28 d to 1.33 µL and 13.33 µL test item/kg dry weight soil. Application rates were equivalent to 1 L and 10 L test item/ha. Lucerne-grass-green meal was added to the soil (5 g/kg dry weight soil) to stimulate nitrogen transformation. The coefficients of variation in the control (NO3-N) were between 1 % and 5 %. Therefore the validity criteria for the study, which requires a coefficient of variation ≤ 15 % in the control, was fulfilled.

Findings:

Effects on non-target soil microorganisms

Time Interval (days)	Application rates				
	Bixafen + prothioconazole EC 260 (60 + 200) G				
	control	1.33 µL/kg dry weight soil		13.33 µL/kg dry weight soil	
	Nitrate-N[a)]	Nitrate-N[a)]	% difference to control	Nitrate-N[a)]	% difference to control
0-7	- 1.24 ± 0.01	- 1.30 ± 0.09	5 n.s.	- 1.24 ± 0.16	0 n.s.*
7-14	1.55± 0.09	1.45± 0.13	7 n.s.	2.15± 0.15	39*
14-28	1.04 ± 0.07	1.00 ± 0.03	4 n.s.	0.85 ± 0.10	18*

a) Rate : Nitrate-N in mg/kg dry weight soil/time interval/day, mean of 3 replicates and standard deviation
*= Statistically significant difference to the control (Student t- Test, two-sided, α = 0.05)
n.s.= No statistically significant difference to the control (Student t-Test, two-sided, α = 0.05)
n.s.* = No significant difference to the control, estimated value, because Student t-Test could not be performed.

Observations:
During the 28-day test, 1.33 µL bixafen + prothioconazole EC 260 (60+200) G/kg dry weight soil had no influence on nitrogen transformation in a loamy sand soil amended with lucerne-grass-green meal. The 10-fold dose of the test item caused a temporary stimulation of the daily nitrate rates at the time interval 7-14 days after treatment Even though the 10-fold dose revealed a statistically significant difference to the control at the end of the study, the deviation from the control was still below the threshold value recommended by the guideline. At the end of the test (14-28 day interval), differences in the nitrate-N rates between control soil samples and treated soil samples are < 25 % and meet the trigger values of above mentioned guideline for a termination of the study.

Conclusion:

18 % deviation at 13.33 µL/kg, equivalent to 13.6 mg/kg soil dw (10 L/ha)

Study Comments: IIIA 10.7.1/02	Valid and acceptable
Agreed endpoint/s: IIIA 10.7.1/02	18 % deviation at 13.33 µL/kg, equivalent to 13.6 mg/kg soil dw (10 L/ha)

IIIA 10.7.2 Further laboratory, glasshouse of field testing to investigate impact on soil microbial activity

III 10.8 Effects on non-target plants

III 10.8.1 Effects on non-target terrestrial plants

IIIA 10.8.1.1 Seed germination

IIIA 10.8.1.2 Vegetative vigour

Reference:	KIIIA 10.8.1.2/01, Effect of BIX+PTZ EC 60+200G on vegetative vigour of ten species of terrestrial plants
Author(s), year:	Brockmann, Korfmacher & Teresiak; 2011
Report/Doc number:	AC/10/199
Guidelines:	OECD 208
GLP:	Yes
Deviations:	No
Validity:	Yes

Material and methods:
Test item was BIX+PTZ EC 60+200G, TOX08519-01, specification no. 102000020385-01; batch no. 2008-010514; content of a.i. BIXAFEN: 6.1%, PROTHIOCONAZOLE: 19.6%

Ten species of terrestrial non-target plants (3 monocots and 7 dicots) were treated with the highest nominal product application rate of 1.7 L BIX+PTZ EC 60+200G/ha.
The species tested were sunflower (*Helianthus annuus*), oilseed rape (*Brassica napus*), sugar beet (*Beta vulgaris*); cucumber (*Cucumis sativus*), soybean (*Glycine max*), buckwheat (*Fagopyrum esculentum*), tomato (*Solanum lycopersicon*); oat (*Avena sativa*); ryegrass (*Lolium perenne*); corn (*Zea mays*).
Pots used were plastic containers with 12 cm or 14 cm in diameter (dependent on test species).
Test crops were seeded several days before application to gain plants at BBCH stage 12-14.

Spray treatments were applied once, at test initiation, with a sprayer set at the nominal spray volume of approximately 200 litres/ha (182.33 to 214.20 litres/ha). Control pots were sprayed with deionised water.

Four to ten per pot for each species were tested. Each pot was placed on a separate tray and irrigated only from the bottom.

Plants were assessed for mortality and phytotoxicity on days 7, 14 and 21. At study termination, endpoint determinations were performed for dry weights.

Findings:

A summary of all the assessments for the day 21 vegetative vigour test (Tier 1) for the effects of 1.7 L BIX+PTZ EC 60+200G/ha are shown in the table below:

	sunflower	oilseed rape	sugar beet	cucumber	soybean
Mortality (% compared to control)	0	0	0	0	0
Phytotoxicity (% effects)	< 50%	< 50%	< 50%	< 50%	< 50%
Dry Weight * (% growth inhibition)	16.2#	1.4	4.0#	11.0#	-4.3

statistically significant difference compared to the control (Student t-test, α=0.05)
"-" means an increase of the evaluated endpoint compared to control
* on a per pot basis

	buckwheat	tomato	oat	ryegrass	corn
Mortality (% compared to control)	0	0	0	0	0
Phytotoxicity (% effects)	< 50%	< 50%	< 50%	0	< 50%
Dry Weight * (% growth inhibition)	14.5#	14.2#	-10.2	-6.8	1.5

statistically significant difference compared to the control (Student t-test, α=0.05)
"-" means an increase of the evaluated endpoint compared to control
* on a per pot basis

Statistical analysis has been carried out using the STUDENT-t test within the statistic software ToxRatStd (version 2.09) and any significant differences between control and treatment for any species at the 95% confidence limits are highlighted.

There was no effect of 1.7 L BIX+PTZ EC 60+200G/ha on the mortality following a foliar application of the ten species tested.

In all species, except ryegrass, slight to moderate phytotoxic symptoms were observed.

No significantadverse effect of BIX+PTZ EC 60+200G on dry weight was observed in oilseed rape, soybean, oat, ryegrass and corn.
Significant biomass reduction occurred in sugar beet with 4.0% effect, in cucumber with 11.0%, in tomato with 14.2%, in buckwheat with 14.5% and in sunflower with 16.2%.

Conclusion:

EC_{50} for all tested species > 1.7 L product/ha

Study Comments: IIIA 10.8.1.2/01	Valid and acceptable
Agreed endpoint/s: IIIA 10.8.1.2	EC50 for all tested species > 1.7 L product/ha

IIIA 10.8.1.3 Seedling emergence

Reference:	KIIIA 10.8.1.3/01, Effect of BIX+PTZ EC 60+200G on seedling emergence of ten species of terrestrial plants
Author(s), year:	Brockmann, A.; Korfmacher, R.; Teresiak, H. 2010
Report/Doc number:	AC/10/200
Guidelines:	OECD 227
GLP:	Yes
Deviations:	No
Validity:	Yes

Material and methods:

Test item was BIX+PTZ EC 60+200G, TOX08519-01, specification no. 102000020385-01; batch no. 2008-010514; content of a.i. BIXAFEN: 6.1%, PROTHIOCONAZOLE: 19.6%.

Ten species of terrestrial non-target plants (3 monocots and 7 dicots) were treated with the highest nominal product application rate of 1.7 L BIX+PTZ EC 60+200G/ha.
The species tested were sunflower (*Helianthus annuus*), oilseed rape (*Brassica napus*), sugar beet (*Beta vulgaris*); cucumber (*Cucumis sativus*), soybean (*Glycine max*), buckwheat (*Fagopyrum esculentum*), tomato (*Solanum lycopersicon*); oat (*Avena sativa*); ryegrass (*Lolium perenne*); corn (*Zea mays*).

Tested plant species were sown immediately before application and test duration was 21 days from application.
Pots used were plastic containers from 9 to 12 cm diameter (species dependent).

Spray treatments were applied once, at test initiation, with a sprayer set at the nominal spray volume of 200 litres/ha. Control pots were sprayed with deionised water.
Four to twelve replicates with four to eight seeds per pot for each species were tested. Each pot was placed on a separate tray and irrigated only from the bottom.

Plants were assessed for emergence, survival of emerged seedlings and rated for phytotoxicity on days 7, 14 and 21. At study termination, biomass endpoint determinations were performed for dry weights.

Findings:

A summary of all the assessments for the day 21 seedling emergence and growth test (Tier 1) for the effects of 1.7 L BIX+PTZ EC 60+200G/ha are shown in the table below:

	sunflower	oilseed rape	sugar beet	cucumber	soybean
Emergence (% compared to control)	-2.9	0	2.9	7.7	-3.0
Mortality (% compared to control)	0	0	0	0	0
Phytotoxicity (% effects)	0	0	0	0	0
Dry Weight * (% growth inhibition)	-4.7	5.7	3.1	8.7	-3.6

"-" means an increase of the evaluated endpoint compared to control
* on a per pot basis

	buckwheat	tomato	oat	ryegrass	corn
Emergence (% inhibition)	0	-6.1	0	0	0
Mortality (% compared to control)	0	0	0	0	0
Phytotoxicity (% effects)	0	0	0	0	0
Dry Weight * (% growth inhibition)	3.4	3.7	4.4	7.0	-2.7

"-" means an increase of the evaluated endpoint compared to control
* on a per pot basis

Statistical analysis has been carried out using the STUDENT-t test within the statistic software ToxRatStd (version 2.09). No significant differences between control and treatment for any species at the 95% confidence limits are observed.

None of the tested plant species showed statistically significant effects concerning seedling emergence and plant survival after pre-emergence application of 1.7 L BIX+PTZ EC 60+200G/ha.
None of the tested species showed phytotoxic symptoms.

No statistically significant adverse effects of BIX+PTZ EC 60+200G on dry weights was observed in any tested plant species after application of 1.7 L BIX+PTZ EC 60+200G/ha.

Conclusion:
EC_{50} for all tested species > 1.7 L product/ha

Study Comments: IIIA 10.8.1.3/01	Valid and acceptable.
Agreed endpoint/s: IIIA 10.8.1.3	EC_{50} for all tested species > 1.7 L product/ha

IIIA 10.8.1.4 Terrestrial field testing

MIII 10.8.2 Effects on non-target aquatic plants

IIIA 10.8.2.1 Aquatic plant growth – Lemna

IIIA 10.8.2.2 Aquatic field testing

Comments of zRMS:	<Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information>

Reference:	<OECD Dossier No.>, <Study Titel>
Author(s), year:	<Author>, <Year>
Report/Doc number:	
Guidelines:	<Yes/No (If yes, give guidelines; If no, give justification, e.g., " no guidelines available" or " methods used comparable to guideline(s) <xxx>")>
GLP:	<Yes/No (If no, give justification, e.g., state that GLP was not compulsory at the time the study was performed)>
Deviations:	<Yes/No (If yes, describe deviations from test guidelines)>
Validity:	<Yes/No/Supplementary>

Material and methods:

Materials:

Test material

Description

Lot/Batch no.

Active ingredient content

CAS no.

Control

Solvent

Toxic reference

Test organisms:

Species

Age

Mean body length

Mean body weight

Fish loading

Source

Acclimatisation period

No. of fish

Feeding during test

Test units and exposure:

Type and size

Test procedure

Exposure time

Test conditions:

Test medium

Water hardness

pH value

Environmental conditions:

Water temperature

Photoperiod

Dissolved oxygen

Study design and method:

In life dates

Experimental treatments

Observations

Analysis of test item concentrations

Statistics

Results and discussion:

Analytical data

Mortality and sub-lethal effects

Table A 3:

[a] xxxx

Table A 4: Summary of findings of <product>

Reproduction	<Yes/No (If yes, describe kind of signs>
Mortality	<Yes/No>

Conclusions:

REGISTRATION REPORT
Part B

Section 6: Ecotoxicological studies
Detailed summary of the risk assessment

Product code:	**Ascra XPro / 102000027828**	
Active Substances:	**Bixafen**	**65 g/L**
	Fluopyram	**65 g/L**
	Prothioconazole	**130 g/L**

Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ADDENDUM

Applicant: **Bayer Crop Science**
Date: **25/04/2014**

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Sec 6 ECOTOXICOLOGICAL STUDIES (MIIIA 10)

A full risk assessment according to Uniform Principles for the plant protection product ASCRA XPRO in its intended uses in cereals is documented in detail in the core assessment of the plant protection product ASCRA XPRO dated from May 2017 performed by zRMS Germany.

This document comprises specific risk assessment for some annex points for authorization of the plant protection product ASCRA XPRO in Germany according to the uses listed in Appendix 2.

General information on the formulation ASCRA XPRO can be found in Table 5.1-1 of Section 5 of the National addendum Germany (May 2017).

6.1 Proposed use pattern and considered metabolites

6.1.1 Grouping of intended uses for risk assessment

Full details of the proposed use pattern of the formulation ASCRA XPRO that will be assessed are presented in Appendix 1 and summarized in the table below. The intended uses in Germany are covered by the core assessment.

The following table lists the grouping of the intended uses. For most of the chapters of evaluation a risk envelope approach was performed, as the application regime for group A represents a worst case.

Table 6.1-1: Classification of intended uses in Germany for Ascra XPro

Group*	Crop/ growth stage	Application method / Drift scenario	Number of applications, Minimum application interval, interception, application time	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
A/ 00-001 to 00-007; 00-015 to 00-019	cereals (wheat, rye, triticale) BBCH 30-61	spraying / field crops	2 x, 14 d, 19.04. 1. 70 % 2. 70 %	Bixafen 2 x 97.5 = 195 Fluopyram 2 x 97.5 = 195 Prothioconazole 2 x 195 = 390	Bixafen 1. 29.25 2. 29.25 = 58.5 Fluopyram 1. 29.25 2. 29.25 = 58.5 Prothioconazole 1. 58.5 2. 58.5 = 117
B/ 00-008 to 00-014; 00-020 to 00-021	cereals (barley, oats) BBCH 30-61	spraying / field crops	1 x, 19.04. 70 %	Bixafen 78 Fluopyram 78 Prothioconazole 156	Bixafen 23.4 Fluopyram 23.4 Prothioconazole 46.8
C/ 00-022 to 00-033	cereals (wheat, rye, triticale) BBCH 30-61	spraying / field crops	1 x, 19.04. 70 %	Bixafen 97.5 Fluopyram 97.5 Prothioconazole 195	Bixafen 29.25 Fluopyram 29.25 Prothioconazole 58.5

* For administrative purposes, each intended use of a plant protection product in Germany is assigned with an individual use number from the German Federal Office of Consumer Protection and Food Safety (BVL). A complete list of the individual GAPs in Germany together with their assigned use numbers is given in Appendix 3 of this Addendum.

6.1.2 Consideration of metabolites

Please refer to the core assessment.

6.2 Effects on birds (MIIIA 10.1, KPC 10.1, KPC 10.1.1)

Please refer to the core assessment.

Consequences for authorization:

None.

6.3 Effects on Terrestrial Vertebrates Other Than Birds (MIIIA 10.3, KPC 10.1, KPC 10.1.2)

Please refer to the core assessment.

Consequences for authorization:

None.

6.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KPC 10.1.3)

Please refer to the core assessment.

Consequences for authorization:

None.

6.5 Effects on aquatic organisms (MIIIA 10.2, KPC 10.2, KPC 10.2.1)

6.5.1 Overview

Results of aquatic risk assessment for the intended for uses of ASCRA XPRO in cereals based on FOCUS Surface Water PEC values are presented in the Core assessment, Part B, Section 6, chapter 6.5.

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spray-drift and volatilisation with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route. Hence, aquatic risk assessment differs from those in the core assessment.

The risk assessment for aquatic organism for authorization of ASCRA XPRO is outlined in the following chapters.

6.5.2 Toxicity

Please refer to the core assessment.

6.5.3 Justification for new endpoints

Please refer to the core assessment.

6.5.4 Toxicity to exposure ratios for aquatic species (MIIIA 10.2.1)

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters" (EFSA Journal 2013;11(7):3290).

Mixture Toxicity

Please refer to the core assessment.

The toxicity of the formulation is assumed to be driven by the toxicity of the active substances, especially bixafen and the prothioconazole-metabolite JAU-6476-Desthio (M04).

6.5.4.1 TER values for the entry into surface water via spraydrift and deposition following volatilization

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. The active substances bixafen, fluopyram and prothioconazole have a vapour pressure of < 10^{-5} Pa and are therefore classified as non-volatile. Hence, deposition following volatilization has not been considered. The input parameters are given in Section 5., table 5.6-1 of the core assessment.

Several ecotoxicological endpoints are available to assess the risk of the active substances and the formulation ASCRA XPRO (see chapter 6.5.2). The choice of the relevant scenario is based on the ratio of endpoint to the highest PEC for each active substance and the formulation, related to the relevant trigger TER value.

Table 6.5-1: Decision making of the relevant scenario for risk assessment of aquatic organisms based on the lowest ratio of TER to safety factor

Substance, Max. application rate (g/ha), Drift factor [%], Max. PEC (act) [µg/L]	**Endpoint**	**Species**	**safety factor**	**TER**	**TER/SF**
Bixafen: 2 x 97.5 g a.i./ha, 2.38 % drift, $PEC(act)_{SW}$ = 1.316 µg/L	LC_{50} = 95 µg/L	O. mykiss	100	72.2	0.72
	NOEC = 4.6 µg/L	P. promelas	10	3.5	**0.35**
	EC_{50} = 1200 µg/L	D. magna	100	911.9	9.12
	NOEC = 50 µg/L	D. magna	10	38.0	3.80
	NOEC = 15.6 µg/L	C. riparius	10	11.9	1.19
	E_bC_{50} = 59.8 µg/L	P. subcapitata	10	45.4	4.54
	LC_{50} = 1780 µg/L	O. mykiss	100	1353	14

Fluopyram: 2 x 97.5 g a.i./ha, 2.38 % drift, PEC(act)$_{SW}$ = 1.316 µg/L	NOEC = 135 µg/L	P. promelas	10	103	10
	EC_{50} = > 434 µg/L	C. virginica	100	330	3
	NOEC = 1250 µg/L	D. magna	10	950	95
	NOEC = 1390 µg/L	C. riparius	10	1056	106
	E_bC_{50} = 3970 µg/L	P. subcapitata	10	3017	302
Prothioconazole-metabolite JAU 6476-desthio: 2 x 195 g a.i./ha (worst case assumption), 2.38 % drift, PEC(act)$_{SW}$ = 2.852 µg/L	LC_{50} = 6630 µg/L	O. mykiss	100	2323.9	23.2
	NOEC = 3.34 µg/L	O. mykiss	10	1.2	**0.1**
	EC_{50} = 10000 µg/L	D. magna	100	3505.1	35.1
	NOEC = 100 µg/L	D. magna	10	35.1	3.5
	NOEC = 2000 µg/L	C. riparius	10	701.0	70.1
	E_bC_{50} = 73 µg/L	P. subcapitata	10	25.6	2.6
ASCRA XPRO : 2 x 1500 mL/ha, 2.38 % drift PEC(act)$_{SW}$ = 19.854 µg/L	LC_{50} = 1770 µg/L	O. mykiss	100	89.2	0.89
	EC_{50} = 3390 µg/L	D. magna	100	170.7	1.71
	E_yC_{50} = 1910 µg/L	P. subcapitata	10	96.2	9.62

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio; SF: Safety factor

The value marked in bold is relevant for the risk assessment.

Based on the table above, *P. promelas* provides the lowest TER/SF ratio, derived from a test with the active substance bixafen.

O. mykiss provides the lowest TER/SF ratio, derived from a test with the metabolite JAU 6476-desthio.

Hence, based on all TER/SF, the relevant scenario for risk assessment is “fish, long-term”.

TER-calculations are conducted for JAU 6476-desthio as its concnetrations and effects are driving the risk to aquatic organisms.

Table 6.5-2: Risk assessment for JAU 6476-desthio for aquatic organisms for the entry route via spraydrift and deposition following volatilization under the implementation of different risk mitigation measures (Model EVA 2.1) – use group A

Compound:			JAU 6476-desthio					
Crop/Application rate:			Cereals, 2 x 195 g a.i./ha					
Growth stage and season			BBCH 30 - 61					
Intended use group:			A					
DissT$_{50}$ water (SFO):			57					
PEC-selection:			actual					
Drift-Percentile:			2.38					
Buffer zone	**Entry via spraydrift**		**Entry via deposition following volatilization**		**PECsw; conventional and drift reducing technique**			
					0% conv.	**50% red.**	**75% red.**	**90% red.**
[m]	**[%]**	**[µg/ha]**	**[%]**	**[µg/L]**	**[µg /L]**			
1	2.38	2.852	-/-	-/-	2.852	1.426	0.713	0.285
5	0.47	0.563	-/-	-/-	0.563	0.282	0.141	0.056
10	0.24	0.288	-/-	-/-	0.288	0.144	0.072	0.029
15	0.16	0.192	-/-	-/-	0.192	0.096	0.048	0.019
20	0.12	0.144	-/-	-/-	0.144	0.072	0.036	0.014
Relevant toxicity endpoint: NOEC = 3.34 µg a.i./L (*O. mykiss*) Relevant TER: 10								
Buffer zone [m]					**TER**			
1					**1.2**	**2.3**	**4.7**	11.700
5					**5.9**	11.900	23.700	59.300
10					11.600	23.200	46.500	116.100
15					17.400	34.800	69.700	174.200
20					23.200	46.500	92.900	232.300
Risk mitigation measures			NW 605/606: common 10 m, 50 % 5 m, 75 % 5 m, 90 % * m					

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

Table 6.5-3: Risk assessment for JAU 6476-desthio for aquatic organisms for the entry route via spraydrift and deposition following volatilization under the implementation of different risk mitigation measures (Model EVA 2.1) – use group C

Compound:	JAU 6476-desthio							
Crop/Application rate:	Cereals, 1 x 195 g a.i./ha							
Growth stage and season	BBCH 30 - 61							
Intended use group:	C							
DissT$_{50}$ water (SFO):	57							
PEC-selection:	actual							
Drift-Percentile:	2.77							
Buffer zone	**Entry via spraydrift**		**Entry via deposition following volatilization**		**PECsw; conventional and drift reducing technique**			
					0% conv.	**50% red.**	**75% red.**	**90% red.**
[m]	**[%]**	**[µg/ha]**	**[%]**	**[µg/L]**	**[µg /L]**			
1	2.77	0.900	-/-	-/-	1.801	0.900	0.450	0.180
5	0.57	0.185	-/-	-/-	0.371	0.185	0.093	0.037
10	0.29	0.094	-/-	-/-	0.189	0.094	0.047	0.019
15	0.20	0.065	-/-	-/-	0.130	0.065	0.033	0.013
20	0.15	0.049	-/-	-/-	0.098	0.049	0.024	0.010
Relevant toxicity endpoint: NOEC = 3.34 µg a.i./L (*O. mykiss*) Relevant TER: 10								
Buffer zone [m]					**TER**			
1					**1.900**	**3.700**	**7.400**	18.600
5					**9.000**	18.000	36.100	90.100
10					17.700	35.400	70.900	177.200
15					25.700	51.400	102.800	256.900
20					34.300	68.500	137.000	342.600
Risk mitigation measures	NW 605/606: common 10 m, 50 % 5 m, 75 % 5 m, 90 % * m							

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

Table 6.5-4: Risk assessment for JAU 6476-desthio for aquatic organisms for the entry route via spraydrift and deposition following volatilization under the implementation of different risk mitigation measures (Model EVA 2.1) – use group B

Compound:	JAU 6476-desthio							
Crop/Application rate:	Cereals, 1 x 156 g a.i./ha							
Growth stage and season	BBCH 30 - 61							
Intended use group:	C							
DissT$_{50}$ water (SFO):	57							
PEC-selection:	actual							
Drift-Percentile:	2.77							
Buffer zone	**Entry via spraydrift**		**Entry via deposition following volatilization**		**PECsw; conventional and drift reducing technique**			
					0% conv.	**50% red.**	**75% red.**	**90% red.**
[m]	**[%]**	**[µg/ha]**	**[%]**	**[µg/L]**	**[µg /L]**			
1	2.77	1.440	-/-	-/-	1.440	0.720	0.360	0.144
5	0.57	0.296	-/-	-/-	0.296	0.148	0.074	0.030
10	0.29	0.151	-/-	-/-	0.151	0.075	0.038	0.015
15	0.20	0.104	-/-	-/-	0.104	0.052	0.026	0.010
20	0.15	0.078	-/-	-/-	0.078	0.039	0.020	0.008
Relevant toxicity endpoint: NOEC = 3.34 µg a.i./L (*O. mykiss)* Relevant TER: 10								
Buffer zone [m]					**TER**			
1					**2.3**	**4.6**	**9.3**	23.200
5					11.300	22.500	45.100	112.700
10					22.100	44.300	88.600	221.500
15					32.100	64.200	128.500	321.200
20					42.800	85.600	171.300	428.200
Risk mitigation measures	NW 605/606: common 5 m, 50 % 5 m, 75 % 5 m, 90 % * m							

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

6.5.4.2 TER values for the entry into surface water via run-off and drainage

Regarding the entry into surface water via run-off and drainage, also bixafen poses the highest risk of the active substance of Ascra XPro. The concentration of the active substance bixafen in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.01. The input parameters for bixafen for exposure modelling with EXPOSIT 3.01 are given in the German National Addendum Section 5, chapter 5.6.2.

Table 6.5-5: Risk assessment for JAU 6476-desthio for aquatic organisms for the entry route via run-off and drainage under the implementation of different risk mitigation measures, use group A

Compound:	JAU 6476-desthio	
Application rate:	2 x 30.3 g a.i./ha (soil relevant application rate, thus 0 % interception considered))	
Intended use	Group A: Spray application on cereals, BBCH 30 - 61	
Relevant toxicity endpoint:	NOEC = 3.34 µg a.s./L (*O. mykiss*)	
Relevant TER:	10	
Run-off		
Buffer zone	**PEC**	**TER**
[m]	**[µg/L]**	
0	0.40	**8.45**
5	0.34	**9.75**
10	0.29	11.4
20	0.21	16.3
Drainage		
Time of application	**PEC**	**TER**
	[µg/L]	
Autumn/winter/early spring	0.03	124
Spring/summer	0.01	383
Risk mitigation measures	NW 701	

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

Table 6.5-6: Risk assessment for JAU 6476-desthio for aquatic organisms for the entry route via run-off and drainage under the implementation of different risk mitigation measures, use group C

Compound:	JAU 6476-desthio	
Application rate:	1 x 30.3 g a.i./ha (soil relevant application rate, thus 0 % interception considered))	
Intended use	Group C: Spray application on cereals, BBCH 30 - 61	
Relevant toxicity endpoint:	NOEC = 3.34 µg a.s./L (*O. mykiss*)	
Relevant TER:	10	
Run-off		
Buffer zone	**PEC**	**TER**
[m]	**[µg/L]**	
0	0.21	16
5	0.18	18
Drainage		
Time of application	**PEC**	**TER**
	[µg/L]	
Autumn/winter/early spring	0.01	230
Spring/summer	0.0	705
Risk mitigation measures	-/-	

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

Table 6.5-7: Risk assessment for bixafen for aquatic organisms for the entry route via run-off and drainage under the implementation of different risk mitigation measures

Compound:	bixafen	
Application rate:	2 x 97.5 g a.i./ha, 2 x 70 % interception	
Intended use	Spray application on cereals, BBCH 30 - 61	
Relevant toxicity endpoint:	NOEC = 4.6 µg a.s./L (*P. promelas*)	
Relevant TER:	10	
Run-off		
Buffer zone	**PEC**	**TER**
[m]	**[µg/L]**	
0	0.15	31
5	0.13	36
10	0.11	42
20	0.08	59
Drainage		
Time of application	**PEC**	**TER**
	[µg/L]	
Autumn/winter/early spring	0.02	207
Spring/summer	0.01	638
Risk mitigation measures	-/-	

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

Table 6.5-8: Risk assessment for fluopyram for aquatic organisms for the entry route via run-off and drainage under the implementation of different risk mitigation measures

Compound:	bixafen	
Application rate:	2 x 97.5 g a.i./ha, 2 x 70 % interception	
Intended use	Spray application on cereals, BBCH 30 - 61	
Relevant toxicity endpoint:	EC_{50} > 434 µg a.s./L (*C. virginica*)	
Relevant TER:	100	
Run-off		
Buffer zone	**PEC**	**TER**
[m]	**[µg/L]**	
0	0.5	2517
5	0.43	2905
Drainage		
Time of application	**PEC**	**TER**
	[µg/L]	
Autumn/winter/early spring	0.55	2256
Spring/summer	0.18	6941
Risk mitigation measures	-/-	

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

6.5.4.3 Consideration of Metabolites

Please refer to the core assessment. The risk to aquatic organisms from exposure to the metabolites is covered by the risk assessment for the active substance.

6.5.5 Overall conclusions

Based on the calculated concentrations of bixafen in surface water (EVA 2.1, EXPOSIT 3.0.1), the calculated TER values for the acute and long-term risk resulting from an exposure of aquatic organisms to bixafen according to the GAP of the formulation ASCRA XPRO achieve the acceptability criteria TER ≥ 100 and TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of ASCRA XPRO in cereals according to the label.

Consequences for authorization:

For the authorization of the plant protection product ASCRA XPRO following labeling and conditions of use are mandatory:

Required Labelling

NW 262	bixafen: *P. subcapitata* NOEC < 0.0156 mg/L ASCRA XPRO: *P. subcapitata* NOEC = 0.75 mg/L
NW 264	bixafen: *O. mykiss:* LC_{50} = 0.095 mg/L, *P. promelas*: NOEC = 0.0046 mg/L ASCRA XPRO: *O. mykiss:* LC_{50} = 1.77 mg/L
NW 265	prothioconazole: *L. gibba* NOEC = 0.00334 mg/L

Conditions for use

ASCRA XPRO

All uses	NW 468
Use group A	NW 605/606 (common: 10 m, 50 %: 5 m, 75 %: 5 m, 90 %: * m) NW 701
Use group B	NW 605/606: common 5 m, 50 % 5 m, 75 % 5 m, 90 % * m
Use group C	NW 605/606: common 10 m, 50 % 5 m, 75 % 5 m, 90 % * m

6.6 Effects on bees (MIIIA 10.4, KPC 10.3.1)

Please refer to the core assessment.

Consequences for authorization:

None.

6.7 Effects on arthropods other than bees (MIIIA 10.5, KPC 10.3.2)

Please refer to the core assessment.

6.7.1 Conclusion

Based on the calculated drift rates of ASCRA XPRO in off-field areas, the calculated TER values describing the risk resulting from an exposure of non-target arthropods to ASCRA XPRO according to the GAP of the formulation achieve the acceptability criteria of TER ≥ 10 (Tier 1), according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target arthropods due to the intended use of ASCRA XPRO in cereals according to the label.

Consequences for authorization:

None.

6.8 Effects on non-target soil meso- and macrofauna (MIIIA 10.6, KPC 10.4, KPC 10.4.1, KPC 10.4.2)

Please refer to the core assessment.

6.8.1 Justification for new endpoints

Please refer to the core assessment for studies and endpoints. However, MS Germany does not apply endpoints divided by 2, if these endpoints are derived from studies with 5 % peat in artificial soil substrates. The reasoning is as follows:

<u>German position - division of endpoints for soilorganisms for the use in legislation procedures</u>

The quantity and quality of the organic matter content in soils might exert a strong effect on the sorption and bioavailability of active substances and therefore alter the toxicity of an active substance on soil organisms. Furthermore there exist several uncertainties with respect to the extrapolation of toxicity measured under the conditions of standard lab tests to toxicity under field conditions e.g. the organic matter used in tests with artificial soil has most likely other properties than the humic materials in agricultural soils (1 – 5% organic carbon in natural agricultural soils). In addition toxicity of a compound towards soil organisms has to be seen as a result of complex processes, elicited by combined contact and oral exposure and which is not only modulated by a single factor such as adsorption.

To account the effect of organic carbon content on adsorption and thereby also bioavailability of an active substance under test conditions the current GD recommends to apply the division factor of 2 (which is a pragmatically chosen value based on limited data) on ecotoxicological endpoints derived from studies with lipophilic substances in artificial soil with 10% organic matter content - unless it can be “demonstrated that toxicity is independent of foc“. This refers to the fact that high soil organic carbon contents might reduce

bioavailability of the compound to soil organisms and might therefore result in higher toxicity value endpoints. By the time the current GD was established, tests with soil organisms were conducted with 10% peat.

If it is agreed that the organic carbon content has generally an influence on the bioavailability of lipophilic substances, then a lower carbon content in the test soil than 10% should be reflected in the choice of correction factor for reduced bioavailabilty. Lacking additional knowledge it could be plausible to assume a linear dependency of sorption on organic carbon content. As pointed out by MS & EFSA, other binding sites in the soil matrix might influence bioavailability. However, up to now, no streamlined analysis of existing data or agreed procedure is available on how to decide in situations where sorption is not influenced by the organic carbon content of the soil.

In a pragmatic approach – and in line with the current GD – a linear dependency of sorption on organic carbon content is assumed. Therefore, and by way of simplification, we suggest not to divide the endpoint by 2 if the organic carbon content has been lowered to 5% in the tests with soil organisms exposed to lipophilic substances. The RMS is aware that this proposal does not follow the specific decision taken in PRAPeR meeting 91 on the active substance Penflufen as well as the PPR meeting on general issues in autumn 2015 where MS delegates discussed the pertinence of dividing/not dividing the endpoint of studies on soilorganisms performed with substances with high Pow in a standard soil with a organic matter content of 5% by 2. We strongly feel that these issues should be tackled in the near future, most suitably during the revision of the risk assessment approach for soil organisms exposed to PPP (GD Terrestrial Ecotoxicology).

6.8.2 Toxicity to exposure ratios for earthworms and other soil macro- and mesofauna, TER_A and TER_{LT} (MIIIA 10.6.1)

The evaluation of the risk for earthworms and other soil macro-organisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

For the calculations of predicted environmental concentrations in soils (PEC soil), reference is made to the environmental fate section (Part B, Section 5) of this submission. The resulting maximum PECsoil values for the active substances bixafen and the major soil degradation products are presented in the table below.

For German exposure assessment the applied soil depth is based on experimental data (Fent, Löffler, Kubiak: Ermittlung der Eindringtiefe und Konzentrationsverteilung gesprühter Pflanzenschutzmittelwirkstoffe in den Boden zur Berechnung des PEC-Boden. Abschlussbericht zum Forschungsvorhaben FKZ 360 03 018, UBA, Berlin 1999). Generally for active substances with a $K_{f,oc} < 500$ a soil depth of 2.5 cm is applied whereas for active substances with a $K_{f,oc} > 500$ a soil depth of 1 cm is applied. As soil bulk density 1.5 g cm^{-3} is assumed.

The active substance bixafen has a $K_{f,OC}$ of 3869, thus PEC_{soil} is calculated for a soil depth of 1 cm.

Table 6.8-1: Results of PEC_{soil} calculation for the intended use in cereals used for German risk assessment

plant protection product:		Ascra XPro				
Use group:		A				
Number of applications/intervall:		2 x/ 14 d				
application rate:		Bixafen: 2 x 97.5 = 195 Fluopyram: 2 x 97.5 = 195 Prothioconazole: 2 x 195 = 390 Ascra XPro: 2 x 1515 = 3030*				
crop interception:		2 x 70%				
active substance/ formulation	**soil relevant application rate (g/ha)**	**soil depth$_{act}$ (cm)**	**PEC_{act} (mg/kg)**	**tillage depth (cm)**	**PEC_{bkgd} (mg/kg)**	**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)**
Ascra XPro	2 x 455	1.0	6.0667	-	-	-
Ascra XPro	2 x 455	2.5	2.4267	-	-	-
Bixafen	2 x 29.25	1.0	0.3885	20	0.7566	1.1451
Fluopyram	2 x 29.25	2.5	0.1494	20	0.0235	0.1730
Prothioconazole	2 x 58.5	1.0	0.3968	-	-	-
JAU6476-S-methyl (M01)	2 x 8.6	1.0	0.0950	-	-	-
JAU6476-desthio (M04)	2 x 30.3	1.0	0.3724	-	-	-

* Ascra XPro-density: 1.010 g/ml, 1.5 L/ha applied

The acute risk for earthworms and other non-target soil macro- and mesofauna resulting from an exposure to ASCRA XPRO /bixafen as well as the major soil degradation products of bixafen was assessed by comparing the maximum PEC_{SOIL} with the 14-day LC_{50} value to generate acute TER values. The TER_A was calculated as follows:

$$TER_A = \frac{LC_{50}\ (mg/kg)}{PEC_{soil}\ (mg/kg)}$$

The chronic risk for earthworms, other non-target soil macro- and mesofauna and organic matter breakdown resulting from an exposure to ASCRA XPRO /bixafen as well as the major soil degradation products of bixafen was assessed by comparing the maximum PEC_{SOIL} with the NOEC value to generate chronic TER values. The TER_{LT} was calculated as follows:

$$TER_{LT} = \frac{NOEC\,(mg/kg)}{PEC_{soil}\,(mg/kg)}$$

The results of the risk assessment are summarized in the following table.

Table 6.8-2: TER values for earthworms and other soil macro- and mesofauna (Tier-1) for the use in cereals

Species	**Test item**	**Time scale**	**Endpoint [mg/kg soil dw]**	**Max. PEC_{SOIL} [mg/kg soil dw]**	**TER**
Eisenia fetida	Bixafen	Acute	> 1000	1.1451 (1 cm, PEC_{accu})	837
		Chronic	100		87
	Fluopyram	Acute	> 1000	0.1730 (2.5 cm, PEC_{accu})	5780
		Chronic	11.42		66
	Prothioconazole	Acute	> 1000	0.3968 (1 cm, PEC_{act})	2520
		Chronic	0.67		**2**
	JAU 6476-S-methyl	Acute	> 1000	0.0950 (1 cm, PEC_{act})	10526
		Chronic	50		526
	JAU 6476-desthio	Acute	> 500	0.3724 (1 cm, PEC_{act})	1343
		Chronic	0.5		**1**
	ASCRA XPRO	Chronic	89	6.0667 (1 cm) (1 cm, PEC_{act})	15
Folsomia candida	Bixafen	Chronic	7.74	1.1451 (1 cm, PEC_{accu})	7
	Prothioconazole	Chronic	64	0.3968 (1 cm, PEC_{act})	161
	JAU 6476-S-methyl	Chronic	15.8	0.0950 (1 cm, PEC_{act})	166
	JAU 6476-desthio	Chronic	31.3	0.3724 (1 cm, PEC_{act})	84
	ASCRA XPRO	Chronic	100	6.0667 (1 cm) (1 cm, PEC_{act})	16
Hypoaspis aculeifer	Bixafen	Chronic	6.15	1.1451 (1 cm, PEC_{accu})	5
	ASCRA XPRO	Chronic	178	6.0667 (1 cm) (1 cm, PEC_{act})	29

TER values shown in bold fall below the relevant trigger.

The tier 1 risk assessment for earthworms is below the regarded trigger value of 5 for the active substance prothioconazole as well as ist metabolite JAU 6476-desthio. An earthworm field study has been performed

with the formulation prothioconazole EC 250 (Lechelt-Kunze, 2002) for the EU assessment of prothioconazole. In this study, the influence of repeated applications of JAU 6476 EC 250 on natural earthworm populations of a grassland area has been investigated. JAU 6476 EC 250 has been applied 3 times with an application rate of 200 g a.s./ha with a 14 d interval between the first and the second application and with a 21 d interval between the second and the third application. Soil analyses were performed on both prothioconazole and its metabolite JAU 6476-desthio which indicated an exposure to the metabolite ranging from 56 to 106 µg/kg. In conclusion it is assumed that the effects on earthworms caused by the application of the formulated product JAU 6476 EC 250 during this study are covering the effects of its metabolite JAU 6476-desthio as well. Overall, the study indicated that earthworm populations were not adversely affected by repeated applications of JAU 6476 EC 250 (3 x 200 g a.s./ha) seven weeks, 5 months and 11 months after the first application.

For other soil mesoorganisms (collembolans and mites), the tier 1 risk assessment for the active substance bixafen according to the GAP (use group A) as well as the risk assessment for the product ASCRA XPRO is above the acceptability criteria of TER ≥ 5. However, existing information about a similar product containing the active substances bixafen, prothioconazole and tebuconazole show effects on collembolans in a field study (Schulz, 2015, Report No. 131048009F). Therefore MS Germany seeks to address the concerns from the use of bixafen-containing products of i) persistency of the active substance and ii) effects to soil mesoorganisms with confirming field studies. These studies can be conducted after authorization of the products.

6.8.3 Higher tier risk assessment

Please refer to the core assessment.

6.8.4 Overall conclusions

Based on the predicted concentrations of the active substances and the formulation ASCRA XPRO in soils, the TER values describing the acute and longterm risk for earthworms and other non-target soil organisms following exposure to ASCRA XPRO according to the GAP of the formulation achieve the acceptability criteria TER ≥ 10 resp. TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for soil organisms due to the intended use of ASCRA XPRO in cereals according to the label.

However, in order to observe the high persistency of bixafen due to the exposure under field conditions in agricultural practice as well as the evidence of effects towards soil organisms in the field, this product authorisation has to be combined with

- a 2 years monitoring study on soil organisms as well as a monitoring study regarding the environmental fate of bixafen in soils.

- a 2 years monitoring study on collembolans treated with a bixafen-containing product for all indications.

These studies have already been discussed with the applicant for the authorization of a different product containing bixafen.

Consequences for authorization:

The submission of the following data is mandatory within 4 years after authorization:

- Submission of the results of a 2 years full-fauna-field monitoring study with bixafen.
- Submission of the results of a required field study addressing the environmental fate of bixafen in soils.

6.9 Effects on soil microbial activity (MIIIA 10.7, KPC 10.5)

Please refer to the core assessment.

6.9.1 Justification for new endpoints

Please refer to the core assessment.

6.9.2 Risk assessment

The evaluation of the risk for earthworms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

Please refer to above for the predicted environmental concentrations in soil (PEC_{SOIL}) of bixafen and AS-CRA XPRO .

The results of the risk assessment are summarized in the following table.

Table 6.9-1: Risk assessment for effects on soil micro-organisms

Test substance	**Test concentration (adverse effects < 25%)** **[mg/kg]**	**PEC_{SOIL}** **[mg/kg]**	**Risk acceptable** **[yes/no]**
ASCRA XPRO	13.1 mg/kg soil dw	6.0667	Yes

6.9.3 Overall conclusions

Based on the predicted concentrations of bixafen and ASCRA XPRO in soils, the risk to soil microbial processes following exposure to bixafen and ASCRA XPRO according to the GAP of the formulation AS-CRA XPRO is considered to be acceptable according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.

Consequences for authorization:

None.

6.10 Effects on non-target plants (MIIIA 10.8, KPC 10.6)

6.10.1 Effects on non-target terrestrial plants (MIIIA 10.8.1)

Please refer to the core assessment.

6.10.2 Conclusion

Based on the predicted drift rates of ASCRA XPRO in off-field areas, the TER values describing the risk for non-target plants following exposure to ASCRA XPRO according to the GAP of the formulation achieve the acceptability criteria TER ≥ 10 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of ASCRA XPRO in cereals according to the label.

Consequences for authorization:

None.

Appendix 1 Table of Intended Uses in Germany (according to BVL 21.09.2015)

PPP (product name/code) **ASCRA XPRO** **Formulation type:** **Emulsifiable concentrate (EC)**
active substance 1 **bixafen** **Conc. of as 1:** **100 g/L**
active substance 2 **fluopyram**
active substance 3 **prothioconazole**

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/or situation (crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha; e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	wheat TRZSS	F	stripe rust of grasses *Puccinia striiformis* PUCCST	spraying	BBCH 31 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 0.75 L/ha b) 0.75 L/ha	a) as: 75 g as/ha b) as: 75 g as/ha	100 - 400		
002	DE	wheat TRZSS	F	brown leaf rust of cereals *Puccinia recondita*	spraying	BBCH 31 - 69	a) 1	a) 0.75 L/ha	a) as: 75 g as/ha	100 - 400		

				PUCCRE		from spring at beginning of infestation and/or when first symptoms become visible	b) 1	b) 0.75 L/ha	b) as: 75 g as/ha			
003	DE	wheat TRZSS	F	leaf spot of wheat *Septoria tritici* SEPTTR	spraying	BBCH 31 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 0.75 L/ha b) 0.75 L/ha	a) as: 75 g as/ha b) as: 75 g as/ha	100 - 400		
004	DE	wheat TRZSS	F	*septoria* leaf spot *Septoria nodorum* LEPTNO	spraying	BBCH 31 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 0.75 L/ha b) 0.75 L/ha	a) as: 75 g as/ha b) as: 75 g as/ha	100 - 400		
005	DE	barley HORVX	F	net blotch *Pyrenophora teres* PYRNTE	spraying	BBCH 31 - 59 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 0.75 L/ha b) 0.75 L/ha	a) as: 75 g as/ha b) as: 75 g as/ha	100 - 400		

006	DE	barley HORVX	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	BBCH 31 - 59 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 0.75 L/ha b) 0.75 L/ha	a) as: 75 g as/ha b) as: 75 g as/ha	100 - 400		
007	DE	barley HORVX	F	*Ramularia collo-cygni* Ramularia leaf spot disease RAMULA	spraying	BBCH 31 - 59 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 0.75 L/ha b) 0.75 L/ha	a) as: 75 g as/ha b) as: 75 g as/ha	100 - 400		
008	DE	barley HORVX	F	brown rust of barley *Puccinia hordei* PUCCHD	spraying	BBCH 31 - 59 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 0.75 L/ha b) 0.75 L/ha	a) as: 75 g as/ha b) as: 75 g as/ha	100 - 400		
009	DE	rye SECCE	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 31 - 69 from spring at beginning of infestation and/or when first	a) 1 b) 1	a) 0.75 L/ha b) 0.75 L/ha	a) as: 75 g as/ha b) as: 75 g as/ha	100 - 400		

						symptoms become visible						
010	DE	rye SECCE	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	BBCH 31 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 0.75 L/ha b) 0.75 L/ha	a) as: 75 g as/ha b) as: 75 g as/ha	100 - 400		
011	DE	triticale TTLSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 31 - 69 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 0.75 L/ha b) 0.75 L/ha	a) as: 75 g as/ha b) as: 75 g as/ha	100 - 400		
012	DE	triticale TTLSS	F	stripe rust of grasses *Puccinia striiformis* PUCCST	spraying	BBCH 31 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 0.75 L/ha b) 0.75 L/ha	a) as: 75 g as/ha b) as: 75 g as/ha	100 - 400		
013	DE	triticale TTLSS	F	septoria-species *Septoria spp.* SEPTSP	spraying	BBCH 31 - 61 from spring at beginning of infestation and/or	a) 1 b) 1	a) 0.75 L/ha b) 0.75 L/ha	a) as: 75 g as/ha	100 - 400		

						when first symptoms become visible			b) as: 75 g as/ha			
014	DE	triticale TTLSS	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	BBCH 31 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 0.75 L/ha b) 0.75 L/ha	a) as: 75 g as/ha b) as: 75 g as/ha	100 - 400		

REGISTRATION REPORT

Part B

Section 7: Efficacy Data and Information

Detailed Summary

Product Code: Ascra Xpro

Reg. No.: ZV1 008219-00/00

Active Substance: Bixafen 65 g/L,

Fluopyram 65 g/L, Prothioconazole 130 g/L

central Zone

Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Bayer CropScience

Date: 2016-01-28

Evaluator: Julius Kühn-Institut

Date: ~~2016-08-05~~2017-09-08

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IIIA1 6 Efficacy Data and Information on the plant protection product

General information

For the evaluation of the plant protection product mostly data of the applicant was used and in addition own data and assessments of the zRMS were added. These amendments were not highlighted.
Efficacy assessment will be in the form of 'conclusion box' comments.

Table 6.0-1: Product information

Active substance:	Bixafen Fluopyram Prothioconazole	65 g/L 65 g/L 130 g/L
Effect:	Ascra Xpro is a broad spectrum fungicide against cereal pathogens with systemic properties and contains the active substances bixafen, fluopyram and prothioconazole. This product provides long lasting efficacy (protective), stops latent infections (curative) and prevents further spreading of the disease.	
Crop group:	Cereals	
Pathogens:	Wheat: Powdery mildew (*Erysiphe graminis*) Septoria leaf spot (*Septoria tritici*) Tan spot (*Pyrenophora tritici-repentis*) Brown rust (*Puccinia recondita*) Eye spot (/ *Pseudocercosporella herpotrichoides)* Yellow rust (*Puccinia striiformis*) Glume blotch *(Leptosphaeria nodorum)* Leaf and head blight (*Michrodochium nivale*) Barley: Eye spot (*Pseudocercosporella herpotrichoides)* Powdery mildew (*Erysiphe* graminis) Rhynchosporium leaf spot (*Rhynchosporium secalis*) Net blotch (*Pyrenophora teres*) *Ramularia leaf spot* (*Ramularia collo-cygni*) "Physiological leaf spot" (PLS) Dwarf rust (*Puccinia hordei*) Yellow rust (*Puccinia striiformis*) Rye *Rhynchosporium* leaf spot *(Rhynchosporium secalis)* Brown rust *(Puccinia recondita)* Triticale Powdery mildew *(Erysiphe graminis)* Septoria spp. (*Septoria spp.)* Brown rust *(Puccinia recondita)* Yellow rust (*Puccinia striiformis*) Glume blotch *(Leptosphaeria nodorum)* Tan spot (*Pyrenophora tritici-repentis*) Eye spot (*Pseudocercosporella herpotrichoides)* Oats Powdery mildew *(Erysiphe graminis)* Crown rust *(Puccinia coronata)*	
Crops:	wheat, barley, rye, triticale, oats	
Timing:	For details for the use against different pathogens please check preliminary instructions for use.	

No. of applications:	Max. 2 applications in wheat, rye and triticale Max. 1 application in barley and oats For details please check preliminary instructions for use...
Dose rate:	1.5 L/ha in wheat, rye and triticale 1.2 L/ha in barley and oats
Water amount:	100-400 L/ha
Product use:	Spraying

Bixafen was approved for inclusion into Annex I in accordance with Regulation (EC) No 1107/2009, Council Directive 91/414/EEC (Implementing Regulation (EU) No. 350/2013, dated 17 April 2013) with the entry into force of 1 October 2013.

Fluopyram was included into Annex I of Regulation (EC) No1107/2009, (Implementing Regulation (EU) No.802/2013, dated 22 August 2013) with the entry into force of 1 February 2014.

Prothioconazole was included in Annex I of Directive 91/414, (Directive 2008/44/EC dated 4 April 2008) with the entry into force on 1 August 2008.

Application for registration on cereal crops in the central administrative zone is made in Member states listed in the Table 6.0-2.

Table 6.0-2: central registration zone Member States

Country	Code	Comment
Austria	AT	cMS (concerned Member State)
Belgium	BE	cMS (concerned Member State)
Germany	**DE**	**zRMS (zonal Rapporteur Member state)**
Netherlands	NL	cMS (concerned Member State)
Poland	PL	cMS (concerned Member State)
Slovenia	SI	cMS (concerned Member State)
United Kingdom	UK	cMS (concerned Member State)

Recent registration situation/history of the PPP

To date, the plant protection product Ascra Xpro (bixafen + fluopyram + prothioconazole EC 260) is not registered in any European countries. Table 6.0-3 summarizes the requested uses for the product.

Table 6.0-3: Requested uses for the product Ascra Xpro

Uses		Member State	Requested rates L/ha
Crops	Target(s)		
TRZSS (wheat)	PSDCHE, SEPTTR, LEPTNO, PUCCRE, PUCCST, ERYSGR, PYRNTR, MONGNI	AT, BE, DE, UK, NL, PL, SI	1.5
HORVX (barley)	ERYSGR, RHYNSE, PYRNTE PUCCHD, PSDCHE, RAMUCC, YBFMI,	AT, BE, DE, UK, NL, PL, SI	1.2
SECCE (rye)	ERYSGR, RHYNSE, PUCCRE, PSDCHE	AT, BE, DE, UK, NL, PL, SI	1.5
TTLSS	PSDCHE, SEPTSP, LEPTNO, PUCCRE,	AT, BE, DE, UK,	1.5

(triticale)	PUCCST, ERYSGR, PYRNTR	NL, PL, SI	
AVESS (oats)	ERYSGR, PSDCHE, PUCCCA,	AT, BE, DE, UK, NL, PL, SI	1.2

Information on the active substances (Uptake and mode of action)

The plant protection product Ascra Xpro contains the active substances bixafen, fluopyram and prothioconazole (65+65+130 g/L) as summarized in Table 6.0-4.

The fungicide ingredient bixafen is a novel compound from the group of the succinate dehydrogenase inhibitors (SDHI), described in the chemical class of pyrazole-carboxamide (FRAC classification C2).

Characteristic of bixafen is its specific efficacy against various pathogens of cereal diseases. The ~~drug~~ active substance is primarily used to control *Puccinia recondita*, *Septoria tritici*, *Erysiphe graminis*, *Pyrenophora teres* and used in the cereals.

Due to the mode of action (MoA) is inhibited respiration in the fungus. The active substance~~drug~~ binds bixafen to the complex II of mitochondrial respiratory chain. The biochemical mechanism of action is the inhibition of the formation of succinate dehydrogenase. Thus, the oxidation of succinate to fumarate and ultimately it is prevented the reduction in ubiquinone. Thus, the TCA cycle is interrupted and there is a collapse of the energy supply in the fungal cells.
All previous studies have shown no cross-resistance to QoI fungicides, DMI and SBI fungicides. Due to the mode of action is the risk of resistance by the FRAC as a medium to high-classed and requires a targeted resistance management

The active substance~~drug~~ inhibits very effectively the early stages of fungal development, which is justified by a strong protective effect. The active ingredient has systemic properties, is very rapidly absorbed into the plant and acropetal distributed in the sap. This results in both a protective and curative action. The main effect of bixafen is the inhibition of spore germination, the reduction in the number of appressoria, and mycelial growth are inhibited, including latent infections.

The fungicide is used for foliar application.

Fluopyram is a new broad-spectrum systemic fungicide of the carboxamide group (FRAC ~~Group~~ code 7 - Fungicide Resistance Action Committee), which inhibits the succinate dehydrogenase in the cell respiration of the fungus (mitochondrial respiration, Complex II), thus blocking electron transport. The succinate dehydrogenase is part of tricarboxylic acid cycle (citrate cycle, Krebs cycle). It belongs to a class of flavoproteins, which enter electrons into the mitochondrial respiration chain. Fluopyram has preventive and root systemic activity against Ascomycetes. The main use of fluopyram is the selective control of a variety of fungal diseases like powdery mildew species, *Botrytis cinerea*, *Sclerotinia* spp., *Monilia* spp., and *Alternaria solani*. Preparations containing fluopyram will be applied by foliar spray and are proposed for use in the areas agriculture, horticulture, and viticulture.
Until now no known cross-resistance to other fungicide chemistries such as sterol-inhibitors, anilinopyrimidines, bezimidazoles, quinone outside inhibitors, or phenylamides are known. Fluopyram may exhibit cross-resistance in certain plant-pathogenic fungi to FRAC ~~Group~~ code 7 fungicides. Nevertheless fluopyram should be integrated into an overall disease, pest management, or `Integrated Pest Management' program. The reason is to avoid the probability of a development of resistance of plant pathogens against fungicides having a similar mode of action.

Fluopyram should not be alternating or tank-mixed with any fungicide to which resistance has already developed. Cross resistance to other carboxamide fungicides (FRAC ~~group~~ code 7) could occur.

Prothioconazol is a fungicide belonging to the group of SBI-Class I: Demethylation-Inhibitors (DMI) a subgroup of the Sterol Biosynthesis Inhibitors (SBI)-triazoles. The active ingredient is classified after the target site and code by FRAC to inhibition of biosynthesis in membrane G1: C14- demethylase in sterol biosynthese.
The active ingredient is used in cereals and oilseed rape to control fungal pathogens such as *Erysiphe graminis*, *Puccinia* sp., *Septoria tritici*, *Septoria nodorum*, *Fusarium* sp., *Rhynchosporium secalis*, *Pyrenophora teres*, *Leptosphaeria maculans* and *Sclerotinia sclerotiorum*. Furthermore, the active ingredient to be used as a growth regulator in rapeseed with improved stability and winter hardiness and ornamental plants in the upsetting of the plants. As part of seed dressing to combat seed-borne harmful fungi such as *Fusarium* sp., Microdochium nivale, U*stilago* sp. and *Tilletia* sp.. Prothioconazole is used in cereals.
The biochemical mode of action of the DMI is the inhibition of C14-demethylase in sterol biosynthese.
Based on the current evidence the resistance risk assessment for DMI, SBI-Class I, Triazoles will be medium. It is known a cross resistance between DMI fungicide active against the same fungus. DMI fungicides show no cross resistance to other SBI classes.
The published use pattern for all SBI classes covered by the FRAC SBI Working Group guidelines for management strategy reflects the resistance risk assessment.
The active ingredient has systemic properties, is very rapidly absorbed into the plant and akropetal distributed in the transpiration stream. This results in both a protective and curative action. The result of the effect of prothioconazole is the abnormal formation of fungal infection structures and a strong inhibition of mycelial growth and spore germination. A penetration of the plant or the seed is thus prevented. The active ingredient is selective on a wide range of dicotyledonous and monocotyledonous crop species.

Prothioconazol is used for foliar application and seed treatment.

Table 6.0-4: Details of the active substances as part of the composition of Ascra Xpro

Common name	~~Ascra Xpro~~BIX+FLU+PTZ EC 260
Trade name:	~~bixafen + fluopyram + prothioconazole EC 260~~**Ascra Xpro**
Active substance (s) / content:	1) bixafen (65 g/L), 2) fluopyram (65 g/L) and 3) prothioconazole (130 g/L)
Formulation type:	Emulsion Concentrate (EC)
First active substance:	**Bixafen**
Chemical group:	carboxamides
Mode of action:	~~SDH group of chemicals (~~complex II succinate dehydrogenase inhibitor~~)~~
Biological action:	loco-systemic
Second active substance:	**Fluopyram**
Chemical group:	pyridylethylamide
Mode of action:	~~SDH group of chemicals (~~complex II succinate dehydrogenase inhibitor~~)~~

Formatiert: Schriftart: Nicht Fett
Formatiert: Schriftart: Nicht Fett
Formatiert: Schriftart: Fett

Biological action:	systemic
Third active substance:	**Prothioconazole**
Chemical group:	triazolinthione
Mode of action:	DMI ~~group of chemicals~~ (de-methylation-inhibitor) group of chemicals sterole synthesis inhibition in membranes
Biological action:	systemic

Information on crops and pests

The status of crops and diseases in each country (zRMS and cMS) is shown in Table 6.0-5.

Table 6.0-5: Classification of crop and disease in the rapporteur member state (zRMS) and concern member state (cMS)

Crop / Pathogen	EPPO-Code	Classification of crop/situation		Classification of pest/disease	
		major	minor	major	minor
1	2	3		4	
Wheat / *Septoria tritici*	TRZSS / SEPTTR	AT, BE, DE, NL, PL, UK, SI		AT, BE, DE, NL, PL, SI	
Wheat / *Pyrenophora tritici-repentis*	TRZSS / PYRNTR	AT, BE, DE, NL, PL, UK, SI		BE, DE, NL, PL	AT, SI
Wheat / *Erysiphe graminis*	TRZSS / ERYSGR	AT, BE, DE, NL, PL, UK, SI		AT, BE, DE, NL, PL, SI	
Wheat / *Puccinia recondita*	TRZSS / PUCCRE	AT, BE, DE, NL, PL, UK, SI		AT, BE, DE, NL, PL, SI	
Wheat / *Puccinia striiformis*	TRZSS / PUCCST	AT, BE, DE, NL, PL, UK, SI		AT, BE, DE, NL, SI	PL
Wheat / *Septoria nodorum*	TRZSS / LEPTNO	AT, BE, DE, NL, PL, UK, SI		AT, BE, DE, PL, SI	NL,
Wheat / *Pseudocercosporella herpotrichoides*	TRZSS / PSDCHE	AT, BE, DE, NL, PL, UK, SI		AT, BE, DE, PL	NL, SI
Wheat / *Michrodochium nivale*	TRZSS / MONGNI	AT, BE, DE, NL, PL, UK, SI		AT, BE, NL, PL, SI	DE,
Barley / *Rhynchosporium secalis*	HORVX / RHYNSE	AT, BE, DE, NL, PL, UK, SI		BE, DE, NL, PL, SI	AT
Barley / *Pyrenophora teres*	HORVX / PYRNTE	AT, BE, DE, NL, PL, UK, SI		AT, BE, DE, NL, PL, SI	
Barley / *Erysiphe graminis*	HORVX / ERYSGR	AT, BE, DE, NL, PL, UK,		AT, BE, DE, NL, PL	SI

		SI			
Barley / *Puccinia hordei*	HORVX / PUCCHD	AT, BE, DE, NL, PL, UK, SI		BE, DE, NL, PL	AT, SI
Barley / Physiological leaf spot	HORVX / YBFMI	DE, AT, BE, NL, PL, SI, UK		DE	AT, BE, NL, PL, SI
Barley / *Ramularia collo-cygni*	HORVX / RAMUCC	AT, BE, DE, NL, PL, UK, SI		AT, BE, DE, NL, SI	PL
Barley / *Pseudocerco-sporella herpotrichoides*	HORVX / PSDCHE	AT, BE, DE, NL, PL, UK, SI		AT, DE, PL	BE, NL, SI
Rye / *Puccinia recondita*	SECCE / PUCCRE	AT, DE, PL, SI	BE, NL, UK	AT, BE, DE, PL, SI	NL
Rye / *Rhynchosporium secalis*	SECCE / RHYNSE	AT, DE, PL, SI	BE, NL, UK	BE, DE, NL, PL	AT, SI
Rye / *Blumeria graminis*	SECCE / ERYSGR	AT, DE, PL, SI	BE, NL, UK	AT, BE, NL, PL, SI	DE
Rye / *Pseudocerco-sporella herpotrichoides*	SECCE / PSDCHE	AT, DE, PL, SI	BE, NL, UK	AT, PL	BE, DE, NL, SI
Triticale / *Septoria* spp.	TTLSS / SEPTSP	AT, BE, DE, PL, SI	NL UK,	AT, BE, DE, NL, PL, SI	
Triticale / *Septoria no-dorum*	TTLSS / LEPTNO	AT, BE, DE, PL, SI	NL UK,	AT, BE, DE, NL, PL	SI
Triticale / *Drechslera tritici-repentis*	TTLSS / PYRNTR	AT, BE, DE, PL, SI	NL UK,	BE, DE, PL	AT, NL, SI
Triticale / *Puccinia re-condita*	TTLSS / PUCCRE	AT, BE, DE, PL, SI	NL UK,	AT, BE, DE, PL	NL, SI
Triticale / *Puccinia strii-formis*	TTLSS / PUCCST	AT, BE, DE, PL, SI	NL UK,	AT, BE, DE	NL, PL, SI
Triticale / *Erysiphe gram-inis*	TTLSS / ERYSGR	AT, BE, DE, PL, SI	NL UK,	AT, BE, DE, NL, PL	SI
Triticale / *Pseudocerco-sporella herpotrichoides*	TTLSS / PSDCHE	AT, BE, DE, PL, SI	NL UK,	DE, PL, SI	AT, BE, NL
Oat / *Erysiphe graminis*	AVESS / ERYGR	UK, SI, PL	AT, DE, BE, NL	BE, DE, NL, PL, SI	AT
Oat / *Puccinia coronata*	AVESS / PUCCCA	UK, SI, PL	AT, DE, BE, NL	AT, BE, DE, NL, PL, SI	
Oat / *Pseudocercosporel-la herpotrichoides*	AVESS / PSDCHE	AT, DE, PL, UK, SI	BE, NL	PL	AT, BE, DE, NL, SI

1 common names (see field of use)
2 EPPO-Code
3 classification of crop/situation (major/minor) in zRMS and cMS, if is renamed
4 classification of pest/disease (major/minor) in zRMS and cMS, if is renamed

In the UK the definition major/minor is not an absolute determinant of the number of trials required. Extrapolations based primarily on similarity of diseases are permitted as follows:
- spring wheat: for all diseases from a fully supported claim for winter wheat
- winter barley: yellow rust if data support claims for yellow rust on wheat and brown rust on barley eyespot with 3 confirmatory trials if disease adequately supported on winter wheat
- spring barley: all diseases if fully supported on winter barley with 3 confirmatory trials for powdery mildew
- triticale: all diseases if the claims already supported on a major crop winter wheat or

barley
- rye: same as for triticale
- spelt : extrapolation from winter wheat for same claims
- winter oats: extrapolation from wheat with 3 additional trials for rust and powdery mildew
extrapolation form wheat for eyespot
- spring oats: extrapolation from winter oats

Eyespot caused by *Oculimucula species O. acuformis* – anamorph: *Ramulispora yallundae* and *O. yallundae* – anamorph: *R. herpotrichoides* affects the stem bases of cereal shoots. Infection penetrates through leaf sheaths forming diffuse staining, which change to oval shaped lesions later in the season. In severe attacks, the stems are weakened causing lodging, and white-heads. The risk of severe infection is increased in continual cereal cropping and early drilling.

Septoria leaf blotch caused by *Mycosphaerella graminicola* – anamorph: *Septoria tritici* is a major foliar disease problem for wheat growers. The disease is important in wheat and triticale. The disease spreads to upper leaves by rain splash and direct contact in thicker crops. Disease symptoms appear usually 3-6 weeks after infection. It forms brown spots or stripes with yellow margins covered with characteristic black pycnidia spore cases. The disease affects grain size and specific weight. Many modern wheat cultivars are susceptible to *Septoria tritici*, which is accentuated by high rates of nitrogen fertiliser applied to maximise yields.

Leaf spot & Glume blotch caused by *Leptosphaeria nodorum* - anamorph: *Septoria nodorum* is a disease of wheat, which tends to occur mid to late season as oval yellow and brown lesions on leaves. Later the lesions merge to form large irregular areas of dead tissue. Glumes can also be infected, with purple brown spots which when severe can affect the whole ear. The disease can be very damaging although it is of reduced importance recently compared with *Septoria tritici*.

Powdery mildew caused by *Blumeria graminis* - anamorph: *Erysiphe graminis* has host specific forms in wheat (*f.sp. tritici*), barley (*f.sp. hordei*) and rye (*f.sp. secalis*) which aerial plant parts manifest as fluffy white pustules. All cereals can be affected by powdery mildew. From June onwards, black fruiting bodies (*cleistothecia*) are formed on older lesions. Losses in grain yield from mildew can be due to reduced photosynthesis and increases in respiration and transpiration. Grain number and size can also be adversely affected. Optimum conditions for infection are presence of fungal spores, warm humid weather, and high levels of nitrogen fertiliser leading to rapid plant growth.

Yellow or stripe rust caused by *Puccinia striiformis* in wheat, rye, and secondary triticale, produce small yellow sporulating pustules or stripes on leaves distributed in *foci*. In cool moist conditions the disease can spread rapidly covering leaves, stems and ears. Mild winters and susceptible varieties favour the disease; hence, it is a serious problem in some but not all seasons. Unless effectively controlled it severely reduces grain yield.

Brown rusts caused by *Puccinia recondita* in wheat, rye and triticale, *Puccinia hordei* in barley and *Puccinia coronata* (called Crown rust) in oats produce small brown circular pustules on leaves. Brown rust can be seen at low levels in crops during mild weather in winter or early spring but spread rapidly in warm weather through susceptible varieties. In severe attacks on upper leaves grain yield potential is greatly reduced.

Tan spot caused by *Drechslera tritici-repentis* in wheat is common in France and Germany where warm wet weather occurs during rapid cereal growth. For several years now, it became also an important disease in Belgium in wheat, and secondary in triticale. Firstly it appears on leaf sheaths and can infect stems, leaves and ears. Lesions are small brown spots with a chlorotic halo, which can merge to form large necrotic areas. The disease can reduce grain size by as much as 50%.

Leaf scald caused by *Rhynchosporium commune*/*secalis* in barley and rye, and secondary on triticale, is common in wet, cool maritime climates of Northern Europe. *Rhynchosporium commune*, formerly known as *Rhynchosporium secalis*, is the species affecting barley while *R. secalis* is the species on rye and triticale. Lesions appear as grey-green water soaked patches on leaves or leaf axils and develop dark brown margins, which can spread rapidly to affect the whole leaf area. The disease can result in reduced grain size and yield losses of up to 40%.

Net blotch caused by *Pyrenophora/Drechslera teres* is a disease of barley that manifests on leaves as dark spots with chlorotic margins or more usually with characteristic lesions with crossed narrow dark lines. Wet weather, susceptible varieties and inoculum from previous cropping borne on infected stubble and straw, favour the disease. Symptoms appear 1-2 weeks after infection and can, in severe cases, significantly reduce yields.

Ramularia leaf spot caused by *Ramularia collo-cygni* affects only winter and spring barley. Typical symptoms of *Ramularia* comprise small brown rectangular lesions, often surrounded by a yellow halo. Following high levels of infection, the leaves may senesce rapidly. Lesions are often obvious on dead leaves as black spots. The spores of the fungus are visible on the surface of dead leaves. *Ramularia* is frequently found in association with other leaf spots such as abiotic sun scorch, physiological leaf spot and spotting caused by damage to the leaf wax following the application of some fungicides. *Ramularia* leaf spot can cause extensive damage to the upper leaves in spring and winter barley once crops have finished flowering. This can cause extensive losses in yield and quality.

Ear blight caused by *Fusarium species* covers a group of fungi that can attack cereal crops throughout the growing period of the crop, causing seedling blight, brown foot rot and ear blight. Fungi from the genus '*Fusarium*' were re-classified and the names of the most common cereal pathogen species are; *Monographella nivalis* (*F. nivale*, anamorph: *Michrodochium nivale*), *F. culmorum* (a member of the *F. roseum* group), *F. avenaceum*, *F. graminearum* (*Gibberella zeae*) and *F. poae*. Spores blown or splashed during wet weather infect ears giving rise to 'Ear blight'. Infection may be limited to individual spikelets which can produce characteristic pinkish-red spore masses or the whole ear can be affected which becomes bleached when grain fail to fill. These fungi (predominantly *F. culmorum* and *F. graminearum* but not *M. nivale*), pose a risk to the health of humans and livestock as they release mycotoxins into the developing grain.

Physiological leaf spots (PLS) in winter and spring barley are dependent on genotype-related oxidative stress under field conditions. Typical symptoms are round to irregular shaped lesions, which are often confused with Ramularia symptoms but show no conidia. Especially under high temperatures and strong solar radiation the upper leaves decay quickly. In winter barley, yield losses of up to 40 % and quality reduction are the result. Some fungicides as azoles, strobilurins and carboxamides have been shown to reduce this stress and save yield.

Wheat is the one of the most cultivated arable crops in Europe and for the applicant several diseases are known for their potential to dramatically reduce yields under the climatic conditions of the central regulatory zone.
In wheat, in the maritime climatic EPPO zone, Septoria leaf blotch caused by *Mycosphaerella graminicola / Septoria tritici* is seen as the major threat in most of the European countries growing wheat crops. Due to the already existence of strains with reduced sensitivity especially to strobilurins and azoles it seems to be essential for the applicant to develop new mode of action in order to ensure the protection of the crops. Modern SDHI based products have been recently introduced onto the market and offer a high level of performance and it is of major importance to protect their mode of action on the long term. It is believed that fluopyram, thanks to its intrinsic activity against *Mycosphaerella graminicola* / *Septoria tritici* and its sensitivity pattern which dif-

fers from other SDH inhibitors such as bixafen (refer to point 6.2.8), will reduce the risk of emergence of less sensitive strains to SDHIs.
Moreover for the applicant, tan spot caused by *Drechslera tritici-repentis* is developing in many areas especially in Germany and is more and more frequently observed in many countries. So far no strong products are available in the market and fluopyram, due to its efficacy against the pathogen will offer an effective solution for disease control.
In barley, net blotch caused by *Pyrenophora teres* is also prone to develop resistant strains to chemicals and like for *Septoria* it is essential to develop new solutions to protect existing mode of action and plant protection products.

Therefore the applicant proposed to develop a new co-formulation based on highly effective carboxamides and azoles product (bixafen + prothioconazole) in combination with the pyridinyl-ehtyl-benzamid~~pyridylethylamide~~ fluopyram. The mixture Ascra Xpro combines the spectrum of activity of two broad spectrum ~~carboxamides (~~SDHIs~~)~~ with that of a typical broad spectrum demethylation-inhibitor (DMI) and provides at the same time an efficient tool for resistance prevention by mixing products with different modes of action and resistance pattern.

The product complies with the Uniform Principles.

Conclusion:

The presented data and information about the plant protection product, active substances, crops and pests and the intended uses correspond with the provided EPPO ~~standard~~Standards.

It can be concluded to accept these data and information.

Information on the intended uses in the central zone

Reg.-No.	**008219-00/00**		**GAP rev.1, date: 2016-06-02**
PPP (product name/code):	Ascra Xpro	Formulation type:	EC (a, b)
Active substance 1:	Prothioconazole	Conc. of as 1:	130.00 g/L (c)
Active substance 2:	Fluopyram	Conc. of as 2:	65.00 g/L (c)
Active substance 3:	Bixafen	Conc. of as 3:	65.00 g/L (c)
Applicant:	Bayer CropScience	Professional use:	Yes
Zone(s):	central (d)	Non professional use:	No
Verified by MS:	Yes	Field of use:	Fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. (e)	**Member state(s)**	**Crop and/ or situation (crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)	**Conclusion (efficacy)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
001	DE, AT, BE, NL, PL, SI, UK	wheat (TRZSS)	F	stem break of cereals (*Pseudocercosporella herpotrichoides*) (PSDCHE)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 32	a) 1 b) 2		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha	100 - 400	-		**A C**
002	DE, AT, BE, NL, PL, SI, UK	wheat (TRZSS)	F	powdery mildew (*Erysiphe graminis*) (ERYSGR)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 2 b) 2		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha	100 - 400	-		**A**

003	DE, AT, BE, NL, PL, SI, UK	wheat (TRZSS)	F	leaf spot of wheat (SEPTTR)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 2 b) 2		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha	100 - 400	-		**A C**
004	DE, AT, BE, NL, PL, SI, UK	wheat (TRZSS)	F	tan spot of cereals (*Drechslera tritici-repentis*) (PYRNTR)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 2 b) 2		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha	100 - 400	-		**A**
005	DE, AT, BE, NL, PL, SI, UK	wheat (TRZSS)	F	brown leaf rust of cereals (*Puccinia recondita*) (PUCCRE)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 2 b) 2		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha	100 - 400	-		**A C**
006	DE, AT, BE, NL, PL, SI, UK	wheat (TRZSS)	F	stripe rust of grasses (*Puccinia striiformis*) (PUCCST)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 2 b) 2		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha	100 - 400	-		**A C**
007	DE, AT,	wheat (TRZSS)	F	septoria leaf spot (*Sep-*	spraying	From	a) 2		a) 1.5 L/ha	a) a) a) a.s.	100 - 400	-		**A**

	BE, NL, PL, SI, UK			*toria nodorum*) (LEPTNO)		spring at beginning of infestation and/or when first symptoms become visible 30 to 61	b) 2		b) 3.00 L/ha	1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha				
007a	AT, BE, NL, PL, SI, UK	wheat (TRZSS)	F	Leaf and head blight (*Michrodochium nivale* / MONGNI)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 1 b) 2		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha	100 - 400	-		**A C**
008	DE, AT, BE, NL, PL, SI, UK	barley (HORVX)	F	stem break of cereals (*Pseudocercosporella herpotrichoides*) (PSDCHE)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 34	a) 1 b) 1		a) 1.2 L/ha b) 1.20 L/ha	a) a) a) a.s. 1: 0.156 kg/ha a.s. 2: 0.078 kg/ha a.s. 3: 0.078 kg/ha b) 0.156 kg/ha 0.078 kg/ha 0.078 kg/ha	100 - 400	-		**A C**
009	DE, AT, BE, NL, PL, SI, UK	barley (HORVX)	F	powdery mildew (*Erysiphe graminis*) (ERYSGR)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 1 b) 1		a) 1.2 L/ha b) 1.20 L/ha	a) a) a) a.s. 1: 0.156 kg/ha a.s. 2: 0.078 kg/ha a.s. 3: 0.078 kg/ha b) 0.156 kg/ha 0.078 kg/ha 0.078 kg/ha	100 - 400	-		**A C**
010	DE, AT, BE, NL,	barley (HORVX)	F	leaf blotch of cereals (*Rhynchosporium secal-*	spraying	From spring at	a) 1 b) 1		a) 1.2 L/ha b) 1.20 L/ha	a) a) a) a.s. 1: 0.156	100 - 400	-		**A C**

	PL, SI, UK			*is*) (RHYNSE)		beginning of infestation and/or when first symptoms become visible 30 to 61				kg/ha a.s. 2: 0.078 kg/ha a.s. 3: 0.078 kg/ha b) 0.156 kg/ha 0.078 kg/ha 0.078 kg/ha				
011	DE, AT, BE, NL, PL, SI, UK	barley (HORVX)	F	net blotch (*Pyrenophora teres*) (PYRNTE)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 1 b) 1		a) 1.2 L/ha b) 1.20 L/ha	a) a) a) a.s. 1: 0.156 kg/ha a.s. 2: 0.078 kg/ha a.s. 3: 0.078 kg/ha b) 0.156 kg/ha 0.078 kg/ha 0.078 kg/ha	100 - 400	-		**A**
012	DE, AT, BE, NL, PL, SI, UK	barley (HORVX)	F	brown rust of barley (*Puccinia hordei*) (PUCCHD)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 1 b) 1		a) 1.2 L/ha b) 1.20 L/ha	a) a) a) a.s. 1: 0.156 kg/ha a.s. 2: 0.078 kg/ha a.s. 3: 0.078 kg/ha b) 0.156 kg/ha 0.078 kg/ha 0.078 kg/ha	100 - 400	-		**A C**
013	DE, AT, BE, NL, PL, SI, UK	barley (HORVX)	F	Ramularia leaf spot disease (*Ramularia collo-cygni*) (RAMUCC)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 1 b) 1		a) 1.2 L/ha b) 1.20 L/ha	a) a) a) a.s. 1: 0.156 kg/ha a.s. 2: 0.078 kg/ha a.s. 3: 0.078 kg/ha b) 0.156 kg/ha 0.078 kg/ha 0.078 kg/ha	100 - 400	-		**A C**
014	DE	barley (HORVX)	F	decrease of non-parasitic leaf spots (YBFMI)	spraying	From spring at beginning	a) 1 b) 1		a) 1.2 L/ha b) 1.20 L/ha	a) a) a) a.s. 1: 0.156 kg/ha	100 - 400	-		**A**

						of infestation and/or when first symptoms become visible 30 to 61				a.s. 2: 0.078 kg/ha a.s. 3: 0.078 kg/ha b) 0.156 kg/ha 0.078 kg/ha 0.078 kg/ha				
014a	AT, BE, NL, PL, SI, UK	barley (HORVX)	F	Yellow rust (*Puccinia striiformis*)(PUCCST)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 1 b) 1		a) 1.2 L/ha b) 1.20 L/ha	a) a) a) a.s. 1: 0.156 kg/ha a.s. 2: 0.078 kg/ha a.s. 3: 0.078 kg/ha b) 0.156 kg/ha 0.078 kg/ha 0.078 kg/ha	100 - 400	-		**N**
015	DE, AT, BE, NL, PL, SI, UK	rye (SECCE)	F	leaf blotch of cereals (*Rhynchosporium secalis*) (RHYNSE)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 2 b) 2		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha	100 - 400	-		**A C**
016	DE, AT, BE, NL, PL, SI, UK	rye (SECCE)	F	brown leaf rust of cereals (*Puccinia recondita*) (PUCCRE)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 2 b) 2		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha	100 - 400	-		**N**
016a	AT, BE, NL, PL, SI, UK	rye (SECCE)	F	powdery mildew (*Erysiphe graminis*) (ERYSGR)	spraying	From spring at beginning of infesta-	a) 2 b) 2		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975	100 - 400	-		**N**

						tion and/or when first symptoms become visible 30 to 61				kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha				
016b	AT, BE, NL, PL, SI, UK	rye (SECCE)	F	stem break of cereals (*Pseudocercosporella herpotrichoides*) (PSDCHE)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 1 b) 1		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha	100 - 400	-		**N**
017	DE, AT, BE, NL, PL, SI, UK	triticale (TTLSS)	F	powdery mildew (*Erysiphe graminis*) (ERYSGR)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 2 b) 2		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha	100 - 400	-		**A C**
018	DE, AT, BE, NL, PL, SI, UK	triticale (TTLSS)	F	septoria-species (*Septoria* spp.) (SEPTSP)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 2 b) 2		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha	100 - 400	-		**A C**
019	DE, AT, BE, NL, PL, SI, UK	triticale (TTLSS)	F	brown leaf rust of cereals (*Puccinia recondita*) (PUCCRE)	spraying	From spring at beginning of infestation	a) 2 b) 2		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha	100 - 400	-		**N**

						and/or when first symp-toms become visible 30 to 61				a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha				
019a	AT, BE, NL, PL, SI, UK	triticale (TTLSS)	F	stem break of cereals (*Pseudocercosporella herpotrichoides*) (PSDCHE)	spraying	From spring at beginning of infesta-tion and/or when first symp-toms become visible 30 to 61	a) 1 b) 1		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha	100 - 400	-		**N**
019b	AT, BE, NL, PL, SI, UK	triticale (TTLSS)	F	septoria leaf spot (*Sep-toria nodorum*) (LEPTNO)	spraying	From spring at beginning of infesta-tion and/or when first symp-toms become visible 30 to 61	a) 2 b) 2		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha	100 - 400	-		**N**
019c	AT, BE, NL, PL, SI, UK	triticale (TTLSS)	F	Yellow rust (*Puccinia striiformis*)(PUCCST)	spraying	From spring at beginning of infesta-tion and/or when first symp-toms become visible 30 to 61	a) 2 b) 2		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha	100 - 400	-		**N**
019d	AT, BE, NL, PL, SI, UK	triticale (TTLSS)	F	tan spot of cereals (*Drechslera tritici-repentis*) (PYRNTR)	spraying	From spring at beginning of infesta-tion and/or	a) 2 b) 2		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975	100 - 400	-		**N**

						when first symptoms become visible 30 to 61				kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha				
020	DE, AT, BE, NL, PL, SI, UK	oats (AVESS)	F	powdery mildew (*Erysiphe graminis*) (ERYSGR)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 1 b) 1		a) 1.2 L/ha b) 1.20 L/ha	a) a) a) a.s. 1: 0.156 kg/ha a.s. 2: 0.078 kg/ha a.s. 3: 0.078 kg/ha b) 0.156 kg/ha 0.078 kg/ha 0.078 kg/ha	100 - 400	-		**N**
021	DE, AT, BE, NL, PL, SI, UK	oats (AVESS)	F	crown rust of oats (*Puccinia coronata*) (PUCCCA)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 1 b) 1		a) 1.2 L/ha b) 1.20 L/ha	a) a) a) a.s. 1: 0.156 kg/ha a.s. 2: 0.078 kg/ha a.s. 3: 0.078 kg/ha b) 0.156 kg/ha 0.078 kg/ha 0.078 kg/ha	100 - 400	-		**A C**
021a	AT, BE, NL, PL, SI, UK	oats (AVESS)	F	stem break of cereals (*Pseudocercosporella herpotrichoides*) (PSDCHE)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 1 b) 1		a) 1.2 L/ha b) 1.20 L/ha	a) a) a) a.s. 1: 0.156 kg/ha a.s. 2: 0.078 kg/ha a.s. 3: 0.078 kg/ha b) 0.156 kg/ha 0.078 kg/ha 0.078 kg/ha	100 - 400	-		**N**
022	DE	wheat (TRZSS)	F	stem break of cereals (*Pseudocercosporella herpotrichoides*) (PSDCHE)	spraying	From spring at beginning of infestation and/or when first	a) 1 b) 1		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha	100 - 400	-		**A**

						symp-toms become visible 30 to 32				b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha				
023	DE	wheat (TRZSS)	F	powdery mildew (*Erysiphe graminis*) (ERYSGR)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 1 b) 1		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha	100 - 400	-		**A**
024	DE	wheat (TRZSS)	F	leaf spot of wheat (SEPTTR)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 1 b) 1		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha	100 - 400	-		**A**
025	DE	wheat (TRZSS)	F	tan spot of cereals (*Drechslera tritici-repentis*) (PYRNTR)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 1 b) 1		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha	100 - 400	-		**A**
026	DE	wheat (TRZSS)	F	brown leaf rust of cereals (*Puccinia recondita*) (PUCCRE)	spraying	From spring at beginning of infestation and/or when first symp-	a) 1 b) 1		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha	100 - 400	-		**A**

						toms become visible 30 to 61				0.195 kg/ha 0.195 kg/ha				
027	DE	wheat (TRZSS)	F	stripe rust of grasses (*Puccinia striiformis*) (PUCCST)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 1 b) 1		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha	100 - 400	-		**A**
028	DE	wheat (TRZSS)	F	septoria leaf spot (*Septoria nodorum*) (LEPTNO_1)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 1 b) 1		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha	100 - 400	-		**A**
029	DE	rye (SECCE)	F	leaf blotch of cereals (*Rhynchosporium secalis*) (RHYNSE_1)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 1 b) 1		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha	100 - 400	-		**A**
030	DE	rye (SECCE)	F	brown leaf rust of cereals (*Puccinia recondita*) (PUCCRE)	spraying	From spring at beginning of infestation and/or when first symptoms	a) 1 b) 1		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha	100 - 400	-		**A**

						become visible 30 to 61				0.195 kg/ha				
031	DE	triticale (TTLSS)	F	powdery mildew (*Erysiphe graminis*) (ERYSGR)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 1 b) 1		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha	100 - 400	-		**A**
032	DE	triticale (TTLSS)	F	septoria-species (*Septoria* spp.) (SEPTSP)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 1 b) 1		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha	100 - 400	-		**A**
033	DE	triticale (TTLSS)	F	brown leaf rust of cereals (*Puccinia recondita*) (PUCCRE)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 61	a) 1 b) 1		a) 1.5 L/ha b) 3.00 L/ha	a) a) a) a.s. 1: 0.195 kg/ha a.s. 2: 0.0975 kg/ha a.s. 3: 0.0975 kg/ha b) 0.39 kg/ha 0.195 kg/ha 0.195 kg/ha	100 - 400	-		**N**

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system Crop Life International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references

2 Use official codes/nomenclatures of EU Member States

3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)

4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.

6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 38263-3152-4), including where relevant, information on season at time of application

8 The maximum number of application possible under practical conditions of use must be provided.

9 Minimum interval (in days) between applications of the same product

10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.

11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).

12 If water volume range depends on application equipment (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.

13 PHI - minimum pre-harvest interval

14 Remarks may include: Extent of use/economic importance/restrictions

15 A: Acceptable
R: Acceptable with further restriction
C: To be confirmed by cMS
N: Not acceptable / evaluation not possible
n.r.: Not relevant for section 3

IIIA1 6.1 Efficacy data

The applicant declares that trials in this dossier were carried out by Bayer CropScience, contractor companies and Official Research institutes, all of which follow the EPPO ~~standard~~Standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).
On the basis of the EPPO ~~standard~~Standard PP 1/241 '*Guidance on comparable climates*' the applicant grouped and summarized trials by EPPO climatic zone. EPPO climatic zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region.
The EC central regulatory zone covers countries in EPPO climatic zones maritime, northeast and southeast as described in EPPO ~~standard~~Standard PP~~-~~1/241. This submission includes data from the maritime and northeast and southeast climatic EPPO zones which are representative of the proposed GAP.
For each disease in sections 6.1.2 Minimum effective dose and 6.1.3 Efficacy of the test product, data will be presented in the following pattern:

1- central registration zone all data
2- maritime EPPO zone
3- northeast EPPO zone
4- southeast EPPO zone

This is in order to evaluate performance through the central registration zone as a whole and then evaluate the performance of Ascra Xpro in each of the climatic zones present in the central registration zone for which approval is sought.

Very few successful trials were conducted by the applicant in the southeast climatic EPPO zone and results he considered as first indication of the performance of the plant protection product. Therefore, the results are presented separately in each sections of this summary Presented data were obtained in Slovakia which belongs to the same EPPO climatic zone as Slovenia where the submission is intended for.

Table 6.1-1 presents the number of efficacy tests conducted per country and per year.

Table 6.1-1: Total number of efficacy trials per country and year

Country	EPPO zone	2010	2012	2013	2015	Total
Belgium (BE)	maritime	-	12	8	3	20
Czech Republic (CZ)		-	6	-		6
Denmark (DK)		-	2	6		8
France (FR)		2	30	37		69
Germany (DE)		7	53	34	1	94
Sweden (SE)		-	3	1		4
Switzerland (CH)					1	
United Kingdom (UK)		1	20	27		48
Latvia (LV)	northeast	-	9	7		16
Lithuania (LT)		-	1	5		6
Poland (PL)		-	21	19		40
Slovakia (SK)	southeast	-	5	-		5
Total		10	162	144	5	321

Tables 6.1-2 to 6.1-7 present the number and type of efficacy trials submitted for each use per climatic EPPO zone.

Table 6.1-2: Number and type of efficacy trials per use in wheat

Crop	Target	Country	Year	Type of trial (1)	Number of valid trials / EPPO zone			GEP
					maritime	north-east	south east	
TRZSS	SEPTTR	BE	2012	MED+EFF+PRE (mixture)	3			yes
				MED+EFF	4			yes
			2013	MED+EFF+BRIDGE	4			yes
		DE	2010	PRE (ratio)	3			yes
			2012	PRE (mixture)	2			yes
				MED+EFF	10			yes
			2013	MED+EFF+BRIDGE	7			yes
		FR	2010	PRE (ratio)	2			yes
			2012	PRE (mixture)	3			yes
		UK	2010	PRE (ratio)	1			yes
			2012	MED+EFF+PRE (mixture)	3			yes
				MED+EFF	7			yes
			2103	EFF+MED	1			yes
				MED+EFF+BRIDGE	10			yes
				EFF+BRIDGE	1			yes
		PL	2012	MED+EFF+PRE (mixture)		2		yes
				MED+EFF		3		yes
			2013	MED+EFF+BRIDGE		7		yes
	TOTAL				**61**	**12**		
	PYRNTR	BE	2012	PRE (mixture)	1			yes
				MED+EFF+PRE (mixture)	1			yes
		CZ	2012	MED+EFF	2			yes
		DE	2012	PRE (mixture)	1			yes
				MED+EFF	6			yes
			2013	MED+EFF	2			yes
		FR	2012	MED+EFF+PRE (mixture)	2			yes
			2013	MED+EFF	2			yes
		LV	2012	EFF		6		yes
			2013	EFF		2		yes
		PL	2012	MED+EFF+PRE (mixture)		3		yes
				MED+EFF		2		yes
			2013	MED+EFF		4		yes
		SK	2012	MED+EFF			1	yes
	TOTAL				**17**	**17**	**1**	
	ERYSGR	CZ	2012	MED+EFF	2			yes
		DE	2010	PRE (ratio)	4			yes
			2012	MED+EFF	2			yes
			2013	MED+EFF+BRIDGE	3			yes
		DK	2012	EFF	1			yes

		FR	2012	MED+EFF+PRE (mixture)	1			yes
				MED+EFF	1			yes
		UK	2013	MED+EFF+BRIDGE	1			yes
		LV	2012	EFF		2		yes
		PL	2012	PRE (mixture)		1		yes
			2012	MED+EFF+PRE (mixture)		2		yes
				MED+EFF		4		yes
			2013	MED+EFF+BRIDGE		5		yes
		SE	2012	EFF	1			yes
		SK	2012	MED+EFF			1	y
	TOTAL				**16**	**14**	**1**	
	PUCCRE	BE	2012	MED+EFF+PRE (mixture)	1			yes
				MED+EFF	2			yes
			2013	MED+EFF+BRIDGE	2			yes
		DE	2010	PRE (ratio)	3			yes
			2012	MED+EFF	7			yes
		FR	2012	PRE (mixture)	1			yes
				MED+EFF	2			yes
		UK	2012	MED+EFF	1			yes
		LV	2012	EFF		4		yes
			2013	EFF		1		yes
		PL	2012	PRE (mixture)		2		yes
				MED+EFF+PRE (mixture)		1		yes
				MED+EFF		2		yes
			2013	MED+EFF+BRIDGE		5		yes
	TOTAL				**19**	**15**		
	PUCCST	DE	2012	EFF	2			yes
		DK	2013	EFF	1			yes
		FR	2012	EFF	2			yes
			2013	EFF	3			yes
		UK	2012	EFF	1			yes
			2013	EFF	1			yes
		SE	2012	EFF	1			yes
	TOTAL				**11**			
TRZSS	LEPTNO	CZ	2012	EFF	2			yes
		DE	2010	PRE (ratio)	2			yes
			2012	EFF	2			yes
			2013	EFF	2			yes
		LT	2012	EFF		1		yes
			2013	EFF		1		yes
		LV	2012	EFF		1		yes
			2013	EFF		1		yes
		PL	2012	EFF		1		yes
			2013	EFF		2		yes
		SK	2012	MED+EFF			1	yes
	TOTAL				**8**	**7**	**1**	
	PSDCHE	FR	2013	EFF	3			yes
		UK	2012	EFF	3			yes
			2013	EFF	4			yes

		LT	2013	EFF		1		yes
		LV	2013	EFF		1		yes
		PL	2012	EFF		2		yes
			2013	EFF		6		yes
	TOTAL				**10**	**10**		
	MONGNI	FR	2013	EFF	7			yes
		DE	2013	EFF	1			yes
		LV	2012	EFF		1		yes
		PL	2012	EFF		5		yes
			2013	EFF		3		yes
	TOTAL				**8**	**9**		

(1) PRE = preliminary trial for mixture and ratio justification, MED = minimum effective dose, EFF = efficacy trial, BRIDGE = bridging trial.

Table 6.1-3: Number and type of efficacy trials per use in barley

Crop	Target	Country	Year	Type of trial (1)	Number of valid trials / EPPO zone			GEP
					maritime	north-east	south east	
HORVX	RHYNSE	CZ	2012	MED+EFF	1			yes
		DE	2012	PRE (mixture)	1			yes
				MED+EFF	1			yes
			2013	MED+EFF+BRIDGE	3			yes
		FR	2012	MED+EFF+PRE (mixture)	2			yes
			2013	MED+EFF+BRIDGE	3			yes
		UK	2012	PRE (mixture)	2			yes
				MED+EFF+PRE (mixture)	1			yes
			2013	MED+EFF+BRIDGE	2			yes
		LV	2013	EFF		1		yes
		PL	2012	MED+EFF		1		yes
			2013	MED+EFF		5		yes
	TOTAL				**16**	**7**		
	PYRNTE	BE	2012	MED+EFF	2			yes
			2013	MED+EFF+BRIDGE	1			yes
		CZ	2012	MED+EFF	2			yes
		DE	2012	PRE (mixture)	4			yes
				MED+EFF	1			yes
			2013	MED+EFF+BRIDGE	2			yes
		UK	2012	MED+EFF+PRE (mixture)	1			yes
			2013	MED+EFF+BRIDGE	1			yes
		FR	2012	PRE (mixture)	1			yes
				MED+EFF+PRE (mixture)	2			yes
				MED+EFF	4			yes
			2013	MED+EFF+BRIDGE	6			yes
		PL	2012	MED+EFF		9		yes
			2013	MED+EFF+BRIDGE		5		yes
		SK	2012	MED+EFF			2	yes
	TOTAL				**27**	**14**	**2**	
	COCHSA	SK	2012	MED+EFF			2	yes
	TOTAL						**2**	

	PUCCHD	DE	2012	PRE (mixture)	1			yes
				MED+EFF	1			yes
			2013	MED+EFF+BRIDGE	1			yes
		DK	2013	EFF+BRIDGE	1			yes
		FR	2012	PRE (mixture)	1			yes
				MED+EFF+PRE (mixture)	1			yes
				EFF+PRE (mixture)	1			yes
			2013	MED+EFF+BRIDGE	1			yes
				EFF+BRIDGE	1			yes
		UK	2012	MED+EFF+PRE (mixture)	2			yes
		LV	2012	EFF		2		yes
			2013	EFF		1		yes
		PL	2012	MED+EFF		2		yes
			2013	MED+EFF+BRIDGE		3		yes
	TOTAL				**11**	**8**		
	ERYSGR	CZ	2012	MED+EFF	1			yes
		DE	2012	MED+EFF	1			yes
		FR	2012	MED+EFF+PRE (mixture)	2			yes
			2013	MED+EFF+BRIDGE	4			yes
		UK	2013	MED+EFF+BRIDGE	2			yes
		LV	2012	EFF		2		yes
		PL	2012	MED+EFF		6		yes
			2013	MED+EFF+BRIDGE		4		yes
	TOTAL				**10**	**12**		
	RAMUCC	DE	2012	PRE (mixture)	2			yes
				EFF	1			yes
			2013	EFF	1			yes
		DK	2013	EFF	1			yes
		FR	2012	PRE (mixture)	1			yes
			2013	EFF	3			yes
		UK	2012	PRE (mixture)	1			yes
				EFF+PRE (mixture)	1			yes
		LT	2013	EFF		1		yes
		PL	2012	EFF		3		yes
			2013	EFF		1		yes
	TOTAL	**-**			**11**	**5**		
HORVX	YBFMI	DE	2012	MED+EFF	2			yes
			2013	MED+EFF	1			yes
			2015	EFF	1			yes
		BE	2012	MED+EFF	1			yes
			2015	EFF	3			yes
		FR	2012	MED+EFF	1			yes
		CH	2015	EFF	1			yes
					10			
	PSDCHE	UK	2013	EFF	1			yes
		PL	2012	EFF		1		yes
			2013	EFF		3		yes
	TOTAL	**-**			**1**	**4**		

(1) PRE = preliminary trial for mixture justification, MED = minimum effective dose, EFF = efficacy trial, BRIDGE = bridging trial.

Table 6.1-4: Number and type of efficacy trials per use in rye

Crop	Target	Country	Year	Type of trial (1)	Number of valid trials / EPPO zone			GEP
					maritime	north-east	south east	
SECCE	RHYNSE	DE	2012	EFF	2			yes
			2013	MED+EFF	2			yes
			2013	EFF	1			yes
		DK	2013	EFF	1			yes
		FR	2012	EFF	1			yes
			2013	EFF	1			yes
		LV	2013	EFF		1		yes
		PL	2013	MED+EFF		3		yes
	TOTAL				**8**	**4**		
	PUCCRE	DE	2012	EFF	6			yes
			2013	EFF	3			yes
		DK	2013	EFF	1			yes
		FR	2012	EFF	2			yes
		LV	2013	EFF		1		yes
		PL	2013	EFF		1		yes
	TOTAL				**12**	**2**		

(1) PRE = preliminary trial, MED = minimum effective dose, EFF = efficacy trial, BRIDGE = bridging trial.

Table 6.1-5: Number and type of efficacy trials per use in triticale

Crop	Target	Country	Year	Type of trial (1)	Number of valid trials / EPPO zone			GEP
					maritime	north-east	south east	
TTLSS	SEPTSP	FR	2012	EFF	2			yes
		DE	2012	MED+EFF	1			yes
				EFF	3			yes
		LT	2013	EFF		1		yes
		PL	2012	MED+EFF		2		yes
			2013	MED+EFF		1		yes
	TOTAL				**6**	**4**		
	PUCCRE	DE	2012	EFF	1			yes
		PL	2012	EFF		2		yes
			2013	EFF		2		yes
	TOTAL				**1**	**4**		
TTLSS	ERYSGR	DE	2012	EFF	4			yes
		FR	2012	EFF	3			yes
		LT	2013	EFF		1		yes
		LV	2013	EFF		1		yes
		PL	2012	EFF		1		yes
			2013	EFF		1		yes
	TOTAL				**7**	**4**		

(1) PRE = preliminary trial, MED = minimum effective dose, EFF = efficacy trial, BRIDGE = bridging trial.

Table 6.1-6: Number and type of efficacy trials per use in oats

Crop	Target	Country	Year	Type of trial (1)	Number of valid trials / EPPO zone			GEP
					maritime	north-east	south east	

AVESS	PUCCCA	FR	2012	EFF	2			yes
			2013	EFF	1			yes
	TOTAL				**3**	**-**		
	ERYSGR	DK	2013	EFF	1			yes
	TOTAL				**1**	**-**		

(1) EFF = efficacy trial

The plant protection product Ascra Xpro (BIX+FLU+PTZ EC 260) was tested under the following formulations which are given in table 6.1-7.

Table 6.1-7: Formulations of the plant protection product Ascra Xpro

Product	Formulation type	Active substance	Content g/l or %w/w
BIX+FLU+PTZ SP102000025737	Emulsifiable concentrate (EC)	bixafen fluopyram prothioconazole	65 65 130
BIX+FLU+PTZ SP102000027828	Emulsifiable concentrate (EC)	bixafen fluopyram prothioconazole	65 65 130

Trials in 2012 the applicant conducted with the formulation BIX+FLU+PTZ EC 260 SP102000025737 and in 2013 with the formulation SP102000027828 which was also referred to as Ascra Xpro.
Between the two years a minor change in the formulation was made. The version SP102000025737 used in 2012 contained a mixture of two solvents: Decane acid amide and Rhodiasolv Polarclean. The version SP102000027828 used in 2013 only the solvent Decane acid amide was used and a defoamer (0.1%) was added to the formulation. Changes were not expected to have any significant effect on the biological activity. However efficacy trials containing both formulations were conducted in 2013 to demonstrate comparable performance between the two formulation versions.

Bridging trials

Bridging trials conducted the applicant in 2013 in wheat and barley in the maritime and north-east climatic EPPO zones as shown in table 6.1-8.

Table 6.1-8: Distribution of bridging trials conducted in 2013

Country	EPPO zone	wheat	barley
Belgium (BE)	maritime	6	1
Denmark (DK)		-	1
France (FR)		-	14
Germany (DE)		7	4
United Kingdom (UK)		11	4
Poland (PL)	northeast	7	6
Total		31	30

The main characteristics of the methodology are described in section 6.1.3, as the trials presented below are the same trials used to describe the efficacy of the plant protection product. The trials were conducted according to the requirements of the efficacy EPPO ~~standard~~Standards PP 1/026 (3-4) and PP 1/135 (3). Full details and statistics are available in the compilation of trials report for Ascra Xpro, efficacy tests wheat and efficacy tests barley listed under the point 6.1.3.

A summary of main results is presented below in tables 6.1-9 to 6.1-15.

Table 6.1-9: Efficacy of 102000025737 and 102000027828 against *Septoria tritici* in wheat

Treatment	Dose in L/ha	Mean % control			
		maritime zone – 23 trials		northeast zone – 7 trials	
		mean	min-max	mean	min-max
Untreated	(% severity)	(34.8)	(10-73)	(33.9)	(17-62)
102000025737	1.5	86.3	42-99	88.7	72-99
102000027828	1.5	89.3	76-99	89.9	71-97

Maritime zone: Belgium, Germany, United Kingdom / North-East zone: Poland

Table 6.1-10: Efficacy of 102000025737 and 102000027828 against *Puccinia recondita* in wheat

Treatment	Dose in L/ha	Mean % control			
		maritime zone – 2 trials		northeast zone – 5 trials	
		mean	min-max	mean	min-max
Untreated	(% severity)	(11.3)	(10-13)	(21.0)	(5-36)
102000025737	1.5	82.3	77-87	99.0	97-100
102000027828	1.5	89.9	89-90	98.2	95-100

Maritime zone: Belgium / North-East zone: Poland

Table 6.1-11: Efficacy of 102000025737 and 102000027828 against *Erysiphe graminis* in wheat

Treatment	Dose in L/ha	mean % control			
		maritime zone – 4 trials		northeast zone – 5 trials	
		mean	min-max	mean	min-max
Untreated	(% severity)	(14.0)	(6-23)	(16.6)	(8-27)
102000025737	1.5	87.8	73-97	94.3	89-99
102000027828	1.5	90.7	73-97	97.0	95-100

Maritime zone: Germany, United Kingdom / North-East zone: Poland

Table 6.1-12: Efficacy of 102000025737 and 102000027828 against *Rhynchosporium secalis* in barley

Treatment	Dose in L/ha	mean % control			
		maritime zone – 8 trials		northeast zone – 5 trials	
		mean	min-max	mean	min-max
Untreated	(% severity)	(29.6)	(7-54)	(16.3)	(9-22)
102000025737	1.2	90.6	77-100	84.0	49-100
102000027828	1.2	91.5	79-97	89.1	66-100

Maritime zone: France, Germany, United Kingdom / North-East zone: Poland

Table 6.1-13: Efficacy of 102000025737 and 102000027828 against *Pyrenophora teres* in barley

Treatment	Dose in L/ha	mean % control			
		maritime zone – 10 trials		northeast zone – 5 trials	
		mean	min-max	mean	min-max
Untreated	(% severity)	(46.5)	(9-74)	(26.8)	(8-53)
102000025737	1.2	89.2	74-96	92.8	84-99
102000027828	1.2	90.7	68-98	91.6	85-99

Maritime zone: Belgium, France, Germany, United Kingdom / North-East zone: Poland

Table 6.1-14: Efficacy of 102000025737 and 102000027828 against *Erysiphe graminis* in barley

Treatment	Dose in L/ha	Mean % control			
		maritime zone – 6 trials		northeast zone – 4 trials	
		mean	min-max	mean	min-max
Untreated	(% severity)	(21.8)	(14-33)	(13.2)	(8-22)
102000025737	1.2	96.3	89-100	85.9	74-100
102000027828	1.2	95.7	89-100	88.3	77-100

Maritime zone: France, United Kingdom / Northeast zone: Poland

Table 6.1-15: Efficacy of 102000025737 and 102000027828 against *Puccinia hordei* in barley

Treatment	Dose in L/ha	mean % control			
		maritime zone – 4 trials		northeast zone – 3 trials	
		mean	min-max	mean	min-max
Untreated	(% severity)	(36.2)	(7-94)	(17.1)	(14-19)
102000025737	1.2	95.4	84-100	94.5	87-100
102000027828	1.2	92.8	74-100	96.4	93-100

Maritime zone: Denmark, France, Germany / Northeast zone: Poland

The data demonstrates comparable performance of the two versions against main diseases in both climatic zones with no significant difference in the level of performance between the two climatic zones. Trials conducted in 2012 with the formulation version SP102000025737 can be considered representative of the performance of the formulation version SP102000027828. Therefore the two data sets are evaluated together and throughout the efficacy and minimum effective dose parts of the dossier the formulations are referred to as Ascra Xpro (BIX+FLU+PTZ EC 260 SP102000027828).

Conclusion:

The presented data and information for the comparison between the two formulations of Ascra Xpro, 102000025737 and 102000027828 against main diseases in two climatic zones demonstrate no significant difference.

It can be concluded to accept the comparative data for both versions as one data set.

The plant protection product Ascra Xpro was compared to the following reference products which are listed in table 6.1-16.

Table 6.1-16: Products used for comparison to the plant protection product Ascra Xpro

Product	Formulation type	Active substance	Content g/L or %w/w
Aviator Xpro SP102000013869	Emulsiable concentrate (EC)	bixafen prothioconazole	75 150
Tracker/ Champion/ Bell	Suspension concentrate (SC)	boscalid epoxiconazole	233 67
Skyway Xpro* SP102000014326	Emulsiable concentrate (EC)	bixafen prothioconazole tebuconazole	75 100 100
Input/ Helix**	Emulsiable concentrate (EC)	spiroxamine prothioconazole	300 160
Fandango	Emulsiable concen-	fluoxastrobin	100

	trate (EC)	prothioconazole	100
Proline	Emulsiable concentrate (EC)	prothioconazole	250
Prosaro***	Emulsiable concentrate (EC)	prothioconazole tebuconazole	125 125

* triticale and rye trials in Germany only / ** triticale trials in Germany only / *** rye trials in Germany only

Aviator Xpro and Tracker are the main reference formulations included in all wheat and barley trials and the majority of triticale, rye and oat trials.

Aviator Xpro is a recently approved formulation in Europe containing the new second generation SDHI bixafen and the triazolinthione prothioconazole and represents a high performing comparison product. The formulation is approved for use against diseases of cereal crops in many countries in Europe including most of the countries for which Ascra Xpro is intended for registration.
Tracker/ Champion/ Bell SC 300 is also included in all trials. This formulation contains boscalid and epoxiconazole and is included as it is approved for use against diseases of cereal crops in most European countries.
Skyway Xpro is included in some German trials and represents a high level comparison treatment. Input/ Helix, Fandango and Proline are non-SDHI containing reference products in certain trials and represent strong comparison treatments particularly in barley crops.

IIIA1 6.1.1 Preliminary range-finding tests

Bixafen
The applicant notes that bixafen is a SDHI fungicide with a broad spectrum of activity developed for use mainly on cereals in several EU countries. Bixafen was demonstrated to be active against a wide range of pathogens and exhibited a broad spectrum of activity in the primary screening in monocotyledonous and dicotyledonous plants. Under in vitro conditions, bixafen has a high intrinsic antifungal potential against various test organisms including *Alternaria*, *Botrytis*, *Giberella*, *Pyricularia*, *Rhizoctonia*, *Septoria*, *Ustilago*, *Aspergillus* and *Verticilium*. In greenhouse conditions, bixafen exhibited a very broad spectrum of activity against all important cereal diseases.

To test for preventive activity, the applicant inoculated young plants with the different fungi after the spray coating had dried on. To test for curative activity, he contaminated young plants with the different fungi 48 hours before treatment and placed at 20°C and a relative humidity of 100%. Then, plants were placed in a greenhouse at a temperature of approximately 10°C to 15-22°C depending on the pathogens and a relative atmospheric humidity of approximately 80% to promote the development of diseases. The tests were assessed 6-10 to 21 days after the inoculation depending on the diseases. Main results are shown in table 6.1.1-1.

Table 6.1.1-1: Spectrum of activity of bixafen in monocots (greenhouse test)

Disease/crop	% Control bixafen			% Disease severity (untreated)
	1000 ppm a.s.*	500 ppm a.s.*	250 ppm a.s.*	
Erysiphe graminis (barley, preventive)	100	83	83	60
Septoria nodorum (wheat, preventive)	71	71	71	70
Septoria tritici (wheat, preventive)	100	100	100	90
Drechslera teres (barley, preventive)	100	100	100	90

Rhynchosporium secalis (barley, preventive)	89	89	78	90
Puccinia recondita (wheat, preventive)	100	100	100	90
Pseudocercosporella herpotrichoides, R-type (wheat, preventive)	70	70	60	100
Erysiphe graminis (barley, curative)	78	56	22	90
Septoria tritici (wheat, curative)	100	100	100	100
Pyrenophora teres (barley, curative)	94	89	78	90
Puccinia recondita (wheat, curative)	100	94	89	90
Rhynchosporium secalis (barley, preventive)	70	50	50	100

* ppm= part per million / a.s. = active substance

For the applicant the data show that under greenhouse conditions, bixafen exhibited a very broad spectrum of activity against all important cereal diseases on stems, leaves and ears with a strong preventive and curative activity.

Fluopyram
Fluopyram is a SDHI product with a broad spectrum of activity mainly used on speciality crops and oilseed rape in several EU countries. Furthermore the applicant mentioned that fluopyram was demonstrated to be active against as wide range of fungal diseases in the routine primary and secondary screening procedure under both in vitro and in vivo (greenhouse) conditions.
In the primary and the secondary screening conducted by the applicant in greenhouse on monocotyledonous and dicotyledonous plants fluopyram exhibited a broad spectrum of activity against various diseases including important cereal pathogens such as *Leptosphaeria*, *Septoria*, *Drechslera* and *Erysiphe*.

The applicant conducted tests on young plants with artificial inoculation under controlled conditions. Varieties susceptible to the target diseases were treated at the 1 leaf crop stage and inoculated with the different fungi 24 hours later. Plants were incubated at 18-22°C with a relative humidity of 60-80% during 8-18 days depending on the diseases and then assessed for degree of contamination by estimating the disease development on each plant. Main results of the primary are shown in table 6.1.1-2.

Table 6.1.1-2: Efficacy of Fluopyram in the primary screening (greenhouse test)

Disease / crop	Test code	% Efficacy fluopyram			
		12 ppm a.s.*	37 ppm a.s.*	110 ppm a.s.*	330 ppm a.s.*
Peronospora parasitica / cabbage	2003/03-0011CB	30	20	60	70
	2003/04-0001CB	-	-	20	40
	2003/05-0004CB	17	26	47	47
Alternaria brassicae / radish	2003/03-0011CB	75	88	100	100
	2003/04-0001CB	-	-	100	100
	2003/05-	57	100	100	100

	0004CB				
Botrytis cinerea / cucumber	2003/03-0011CB	25	50	100	100
	2003/04-0001CB	-	-	98	100
	2003/05-0004CB	5	0	25	90
Drechslera teres / barley	2003/03-0011CB	83	100	100	100
	2003/04-0001CB	-	-	100	100
	2003/05-0004CB	96	85	98	100
Puccinia recondita / wheat	2003/03-0011CB	20	40	40	60
	2003/04-0001CB	-	-	25	65
	2003/05-0004CB	10	0	20	10
Erysiphe graminis / wheat	2003/03-0011CB	50	70	70	80
	2003/04-0001CB	-	-	85	93
Septoria nodorum / wheat	2004/03-0001CB	24	69	83	86
Septoria tritici / wheat	2003/05-0004CB	-	25	75	83

* ppm= part per million / a.s. = active substance

For the applicant these data show that fluopyram had a broad spectrum of efficacy against various pathogens including important cereal diseases (*D. teres*, *E. graminis*, *L. nodorum*, *S. tritici*).

Prothioconazole

The applicant notes that prothioconazole is a well known fungicide with a broad spectrum of activity widely used on cereals in several EU countries for many years. Prothioconazole was demonstrated to be active against a wide range of fungal diseases including the important foliar and stem base pathogens of cereals. In greenhouse tests rates between 100-500 ppm (part per million) active substances were effective, exhibiting strong preventive, curative and systemic activity. The range of diseases tested included eyespot (*Oculimacula species*), powdery mildew (*Erysiphe graminis*), brown rust (*Puccinia recondita*), leaf blotch (*Septoria nodorum*) and net blotch (*Pyrenophora teres*)

To test for preventive activity, the applicant inoculated young plants with the different fungi after the spray coating had dried on. To test for curative activity, he contaminated young plants with the different fungi 48 hours before treatment and placed at 20°C and a relative humidity of 100%. Then, plants were placed in a greenhouse at a temperature of approximately 10°C to 15-20°C depending on the pathogens and a relative atmospheric humidity of approximately 80% to promote the development of diseases. The applicant assessed tests 7-10 to 21 days after the inoculation depending on the diseases. Main results are shown in table 6.1.1-3.

Table 6.1.1-3: Spectrum of activity of prothioconazole in monocots (greenhouse tests)

Disease/crop	% Control prothioconazole			% Disease severity (untreated)
	1000 ppm a.s.*	500 ppm a.s.*	100 ppm a.s.*	

Erysiphe graminis (barley, preventive)	100	100	86	88
Erysiphe graminis (barley, curative)	100	100	88	100
Erysiphe graminis (wheat, preventive)	100	88	50	100
Erysiphe graminis (wheat, curative)	94	88	25	100
Septoria nodorum (wheat, preventive)	87	75	50	50
Septoria nodorum (wheat, curative)	62	50	25	50
Pyrenophora teres (barley, preventive)	100	100	67	38
Pyrenophora teres (barley, curative)	87	62	50	50
Puccinia recondita (wheat, preventive)	100	100	0	100
Puccinia recondita (wheat, curative)	100	100	100	88
Pseudocercosporella herpotrichoides, R-type (wheat, preventive)	90	90	50	100

* ppm= part per million / a.s. = active substance

For the applicant the data show that prothioconazole had a very broad spectrum of efficacy against all important cereal diseases (stem, leaf, head) with strong preventive and curative activity.

Bixafen + Fluopyram + Prothioconazole

In order to evaluate the effective dose of Ascra Xpro and to demonstrate the technical benefit of fluopyram in the combination, the applicant conducted 20 field trials in winter wheat and 20 in winter / spring barley in 2012 in cereal growing regions of northwestern and central Europe (Belgium, France, Germany, Poland and United Kingdom) as shown in table 6.1.1-4.

Table 6.1.1-4: Distribution of trials used to justify the mixture

Crop(s) (1)	Country	Years	Number of trials		GEP
			Maritime zone	Northeast zone	
Winter wheat	DE	2012	3		yes
	UK	2012	3		yes
	BE	2012	5		yes
	FR	2012	6		yes
	PL	2012		3	yes
	Total	**-**	**17**	**3**	
Winter barley	DE	2012	5		yes
	FR	2012	6		yes
	UK	2012	3		yes
	Total		**14**	**0**	
Spring barley	FR	2012	3		yes
	UK	2012	3		yes
	Total		**6**	**0**	

The applicant declares that trials were conducted according to approved standards (EPPO), respectively Bayer in-house guidelines which mostly follow the EPPO ~~standard~~Standards but with small deviations regarding the plot size (16 to 27 m² for wheat trials and 11 to 36 m² for barley trials). The spray volumes were in line with farmers' practice, varying from 200-300 L/ha.
The formulated product, Ascra Xpro (bixafen + fluopyram + prothioconazole), was evaluated under the formulation SP102000027828 and compared to the products Aviator Xpro EC 225 (bixafen + prothioconazole) as well as the experimental formulation Fluopyram EC 150 to show the activity of straight fluopyram.
In wheat, Ascra Xpro was tested at 0.9, 1.2 and 1.5 L/ha. All products were sprayed once per season (BBCH 34-49) except in 3 trials where they were applied two times (BBCH 31 and BBCH 39-62) to better cover the period of risk.
In barley, Ascra Xpro was tested at 0.72, 0.96 and 1.2 L/ha. All products were sprayed only once per season (BBCH 31-55).
An overview of the most relevant results on wheat and barley, with the last assessment (disease severity > 5 %) made on the upper leaves per trial, is given in tables 6.1.1-5 and 6.1.1-6.

Table 6.1.1-5: Dose response relationship and efficacy in wheat

Traget diseased yield (n trials)	% disease dt/ha untreated	Mean % control / mean relative yield				
		BIX + FLU + PTZ EC 260			FLU*	STD*
	L/ha	0.9	1.2	1.5	0.65	1.25
	g/ha BIX g/ha FLU g/ha PTZ	59 59 117	78 78 156	98 98 195	- 98 -	94 - 188
E. graminis (n=4)	21.0	71.7	77.9	85.2	75.7	74.4
P. recondita (n=5)	29.7	90.1	92.0	93.5	47.9	93.3
S. tritici (n=13)	60.9	83.4	90.5	93.9	69.7	89.0
P. tritici-repentis (n=8)	38.7	79.3	83.0	89.2	64.9	85.0
Yield (n=18)	67.4	130.1	133.6	136.1	116.6	132.7

* STD= Aviator Xpro EC 225 / FLU = fluopyram EC 150

Table 6.1.1-6: Dose response relationship and efficacy in barley

Target diseases yield (n trials)	% disease dt/ha untreated	Mean % control / mean relative yield				
		BIX + FLU + PTZ EC 260			FLU*	STD*
	L/ha	0.72	0.96	1.2	0.52	1.0
	g/ha BIX g/ha FLU g/ha PTZ	47 47 94	62 62 125	78 78 156	- 78 -	75 - 150
E. graminis (n=2)	45.4	74.8	79.8	81.9	65.3	79.7
P. hordei (n=6)	42.1	84.0	86.6	91.4	25.7	86.5
R. secalis (n=6)	24.5	86.5	90.5	92.4	71.2	92.2
P. teres (n=8)	48.6	79.6	84.6	90.3	61.7	83.9
R. collo-cygni (n=5)	56.3	71.6	75.9	78.8	46.3	73.7
Yield (n=19)	64.9	114.3	115.8	117.4	107.8	116.2

* STD= Aviator Xpro EC 225 / FLU = fluopyram EC 150

The applicant argues that his data of the co-formulated product gave a positive dose response relationship against *Erysiphe graminis*, *Septoria tritici*, *Puccinia recondita* and *Pyrenophora tritici-repentis* on wheat and against *Erysiphe graminis*, *Puccinia hordei*, *Rhynchosporium secalis*, *Pyrenophora teres* and *Ramularia collo-cygni* on barley.
Overall for the applicant, the proposed full label dose of Ascra Xpro at 1.5 L/ha on wheat and 1.2 L/ha on barley showed a regular efficacy, performed consistently better and was generally less variable than the reduced rates. A lower dose rate did not always provide the same level of

efficacy in particular under high disease pressure. The data for economically important diseases demonstrates for the applicant that 1.5 L/ha is required in wheat respectively 1.2 L/ha is required in barley to provide optimum disease control.
For the applicant the mixture bixafen + fluopyram + prothioconazole EC 260 (Ascra Xpro) combines the spectrum of activity of two broad spectrum ~~carboxamides (~~SDHIs~~)~~ with that of a typical broad spectrum de-methylation-inhibitor (DMI), and provides at the same time an efficient tool for resistance prevention by mixing products with different modes of action. Data showed that the addition of fluopyram to bixafen and prothioconazole when applied as an EC 260 co-formulation contributes to an extra activity against *Erysiphe graminis*, *Septoria tritici* and *Pyrenophora tritici-repentis* on wheat and against *Puccinia hordei*, *Pyrenophora teres* and *Ramularia collo-cygni* on barley.

Justification of the ratio – Green house tests
The applicant tested the biological activity of compound combinations in greenhouse trials in order to establish the optimal ratio for a co-formulation containing the three active substances: bixafen, fluopyram and prothioconazole. Following ratios of bixafen/fluopyram/prothioconazole have been tested and compared with preventative and curative spray applications. The combinations were applied in the same total active substance amount of 200 ppm each:

- BIX+FLU+PTZ ratio 1:2:3 33+67+100 ppm
- BIX+FLU+PTZ ratio 1:1:2 50+50+100 ppm
- BIX+FLU+PTZ ratio 1:0.5:1.5 67+33+100 ppm
- BIX+FLU+PTZ ratio 1:1:1 67+67+67 ppm

The plant test systems (variety Monopol for wheat and Villa and Gaulois for barley) were artificially inoculated by the applicant with following pathogens: *Mycosphaerella graminicola , Puccinia triticina, Microdochium nivale, Fusarium graminearum Blumeria graminis f.sp. hordei* and *Pyrenophora teres*.

To test the preventative activity, young plants were sprayed with the different combinations and inoculated with the pathogen as soon as the spray coating had dried. Disease levels were assessed 5, 8 and 20 days after inoculation depending on the pathogen.
To test the curative activity, the applicant inoculated young plants with the pathogen and sprayed with the different combinations 24 to 48 hours later depending on the disease. Assessments were conducted as for the preventative tests.

The applicant shows a summary of main results in tables 6.1.1-7 and 6.1.1-8.

Table 6.1.1-7: Preventive activity in greenhouse tests on wheat and barley

Disease crop	% disease untreated	Mean % efficacy of four BIX+FLU+PTZ ratios			
		1:2:3 ratio	1:1:2 ratio	1:0.5:1.5 ratio	1:1:1 ratio
		33+67+100 ppm	50+50+100 ppm	67+33+100 ppm	67+67+67 ppm
B. graminis barley	80	100	100	100	94
P. teres barley	80	100	100	100	100
P. triticina wheat	90	56	56	78	56
M. graminicola wheat	100	90	100	100	100
M. nivale wheat	70	0	57	43	43
F. gramine-	80	13	38	38	38

arum wheat					

ppm = part per million

Table 6.1.1-8: Curative activity in greenhouse tests on wheat and barley

Disease crop	% disease untreated	Mean % efficacy of four BIX+FLU+PTZ ratios			
		1:2:3 ratio	1:1:2 ratio	1:0.5:1.5 ratio	1:1:1 ratio
		33+67+100 ppm	50+50+100 ppm	67+33+100 ppm	67+67+67 ppm
B. graminis barley	100	100	100	100	100
P. teres barley	80	94	94	88	94
P. triticina wheat	70	100	100	100	86
M. graminicola Wheat	100	100	95	90	100
M. nivale wheat	70	93	100	93	71
F. graminearum wheat	70	86	93	93	93

ppm = part per million

For the applicant data shows that the overall efficacy of the 4 mixtures was good enough to inhibit disease development sufficiently. On barley, the ratio 1:2:3 and 1:1:2 achieved the highest efficacies against *Blumeria graminis* and *Pyrenophora teres* whereas the activity on wheat was almost balanced between the 4 tested ratios against *Puccinia triticina*, *Septoria tritici* and *Fusarium graminearum*. However, the ratio 1:1:2 achieved the best activity against *Microdochium nivale*.

The applicant concluded that the 4 ratios showed potential to reduce disease development in wheat and barley. The 1:1:2 ratio of the mixture bixafen, fluopyram and prothioconazole provided the maximum overall disease control with the broadest spectrum of activity.

Justification of the ratio – Field tests

Ten field experiments were carried out by the development team of Bayer CropScience in France, Germany and United Kingdom in 2010 as shown in table 6.1.1-9 to compare straight compounds, to the mixture bixafen + prothioconazole and to 2 ratios of bixafen + fluopyram + prothioconazole against fungal diseases on wheat.

Table 6.1.1-9: Distribution of field trials used to justify the ratio

Crop	country	year	number of trials maritime zone	GEP
Wheat	DE	2010	7	yes
	FR	2010	2	yes
	UK	2010	1	yes
	Total		**10**	

The trials were conducted according to approved standards (EPPO), respectively Bayer in-house guidelines which mostly follow the EPPO ~~standard~~Standards but with small deviations regarding the plot size (10 to 30 m²). The spray volumes were in line with farmers' practice, varying from 200-400 L/ha.

All products were applied twice with a spray interval of 18-35 days in winter wheat. The first treatment was made at the elongation stage (BBCH 31-32) and the second treatment at about

the flag leaf stage (BBCH39. At each application the combination bixafen + fluopyram + prothioconazole was used at 75+75+150 g (1:1:2 ratio) and at 75+50+150 g (1:0.67:2 ratio), the straight compounds bixafen were applied at 75 g, fluopyram at 75 g and prothioconazole at 150 g a.s./ha and the combination bixafen + prothioconazole at two rates from 75+150 to 94+188 g a.s./ha, respectively. An overview of the most relevant results at the last assessment (disease severity > 5 %) made on the upper leaves of each trial is given in table 6.1.1-10.

Table 6.1.1-10: Justification of the ratio in field conditions

Disease and yield (n trials)	Untreated % disease yield in dt/ha	Mean % control (mean relative for yield)						
		BIX g a.s./ha	FLU g a.s./ha	PTZ g a.s./ha	BIX+PTZ * g a.s./ha		BIX+FLU+PTZ g a.s./ha	
		75 - -	- 75 -	- - 150	75 - 150	94 - 188	75 50 150	75 75 150
E. graminis (n=4)	27.3	31.7	62.7	67.0	74.0	79.4	71.7	79.7
P. recondita (n=3)	16.7	96.1	36.5	85.9	99.1	99.3	98.8	99.3
L. nodorum (n=2)	20.0	39.0	53.0	78.4	91.4	93.8	92.4	95.8
S. tritici (n=7)	41.5	76.3	67.2	79.8	92.0	93.3	93.7	96.6
Yield (n=10)	88.8	112.7	108.7	112.8	115.6	117.2	117.9	118.3

* Aviator Xpro EC 225 (1.0 / 1.25 L/ha)

The applicant concluded that the ratio 1:1:2 gave the best effects. In comparison to 75 g a.s./ha bixafen + 150 g a.s./ha prothioconazole the addition of 75 g a.s./ha fluopyram improved the overall performance and showed clear additional effects against *Septoria* spp. and *Erysiphe graminis*, whereas the additional effect on *Puccinia recondita* is small. For the applicant the combination of these three active substances with different and complementary spectra allows a high level of performance at controlling cereal diseases. The results clearly indicate for him that the fungicide combination containing 75 g a.s./ha bixafen, 75 g a.s./ha fluopyram and 150 g a.s./ha prothioconazole provides superior disease control compared to 75 g a.s./ha bixafen + 150 g a.s./ha prothioconazole and achieves equivalent disease control comparable to the full label rate of the commercial product Aviator Xpro EC 225 which has recently been evaluated and approved in several European countries.

Conclusion:

The presented data correspond with the requirements of the EPPO ~~standard~~Standard PP 1/225. The applicant demonstrated that the combination of three different active substances achieve a better effect than the solo substances or combinations of two substances. Furthermore the ratio 1: 1: 2 of the plant protection product achieved the best efficiency.

It can be concluded to accept the data provided by the applicant for the preliminary range finding test.

Formatiert: Deutsch (Deutschland)

IIIA1 6.1.2 Minimum effective dose tests

An experimental programme was conducted by the applicant in each of the EPPO climatic zones within the central registration zone (maritime, northeast and southeast climatic zone) in 2012 and 2013. Field trials were established in the United Kingdom, Germany and Belgium for the maritime climatic zone, in Poland for the Northeast climatic zone and in Slovakia for the Southeast climatic zone. For some diseases, data was included from appropriate countries from within the same EPPO climatic zone (Czech Republic, Northern France for the maritime zone) in order to provide an adequately robust data set.

In wheat, Ascra Xpro was tested at 0.9 to 1.5 L/ha (60 - 100% dose) for the control of *Septoria tritici, Pyrenophora tritici-repentis, Puccinia triticina and Blumeria graminis*.
In barley, Ascra Xpro was tested at 0.72 to 1.2 L/ha (60 - 100% dose) for the control of *Rhynchosporium commune, Pyrenophora teres, Blumeria graminis and Puccinia hordei*.
The rates represent 60%, 80% and 100% of the full recommended rate of Ascra Xpro in wheat and 60% and 100% of full recommended rate in barley, in accordance with the EPPO ~~standard~~ Standard PP 1/225 '*Minimum effective dose*'. Efficacy was tested over 2 years across a range of geographical locations representing a range of environmental conditions and disease pressure to fully challenge the product.

The applicant declares that all trials are GEP and followed the relevant EPPO ~~standard~~Standards presented in table 6.1.2-1.

Table 6.1.2-1: EPPO ~~standard~~Standards

EPPO ~~standard~~Standard number	Title
PP 1/225	Minimum effective dose
PP 1/026 (3-4)	Foliar and ear diseases on cereals
PP 1/135 (3)	Phytotoxicity assessment
PP 1/152(3)	Design and analysis of efficacy evaluation trials
PP 1/181(4)	Conduct and reporting of efficacy evaluation trials including GEP

The main characteristics of the methodology are described in section 6.1.3, as the trials presented in section 6.1.3 are the same trials used to describe the minimum effective dose.

The applicant conducted trials according to the requirements of the efficacy EPPO ~~standard~~ Standard PP 1/225: *"Minimum effective dose"*. This standard recommends that at least one lower dose than the one recommended should be included in efficacy trials. The number of trials and distribution of trials by disease is presented in tables 6.1.2-2 to 6.1.2-7.

Table 6.1.2-2: Number of minimum effective dose trials in wheat

Country	EPPO zone	2012	2013	Total
Belgium (BE)	maritime	8	6	14
Czech Republic (CZ)		3	-	3
France (FR)		7	2	9
Germany (DE)		18	9	27
United Kingdom (UK)		10	10	20
Total maritime zone		**46**	**27**	**73**
Poland (PL)	northeast	10	8	18
Total northeast zone		**10**	**8**	**18**
Slovakia (SK)	southeast	2	-	2
Total southeast zone		**2**	**-**	**2**

Table 6.1.2-3**:** Distribution of minimum effective dose trials in wheat per use

Country	EPPO zone	Number of trials per year		Total
		2012	2013	
***Septoria tritici* (Septoria Leaf Blotch)**				
Germany	maritime	10	7	**17**
United Kingdom	maritime	10	11	**21**
Belgium	maritime	7	4	**11**
Poland	northeast	5	7	**12**
Total		**32**	**29**	**61**
***Pyrenophora tritici-repentis* (Tan Spot)**				
Germany	maritime	6	2	**8**
Belgium	maritime	1	0	**1**
Czech Republic	maritime	2	0	**2**
France	maritime	2	2	**4**
Poland	northeast	5	4	**9**
Slovakia	southeast	1	0	**1**
Total		**17**	**8**	**25**
***Puccinia triticina* (Brown Rust)**				
Germany	maritime	7	0	**7**
United Kingdom	maritime	1	0	**1**
Belgium	maritime	3	2	**5**
France	maritime	3	0	**3**
Poland	northeast	3	5	**8**
Total		**17**	**7**	**24**
***Blumeria graminis* (Powdery Mildew)**				
Germany	maritime	2	3	**5**
United Kingdom	maritime	0	1	**1**
Czech Republic	maritime	2	0	**2**
France	maritime	2	0	**2**
Poland	northeast	6	5	**11**
Slovakia	southeast	1	0	**1**
Total		**13**	**9**	**22**
***Septoria nodorum* (Leaf spot / Glume blotch)**				
Slovakia	southeast	1	0	**1**
Total		**1**	**0**	**1**

Table 6.1.2-4**: Number** of minimum effective dose trials in barley

Country	EPPO zone	2012	2013	Total
Belgium (BE)	maritime	3	1	4
Czech Republic (CZ)		3	-	3
France (FR)		11	13	24
Germany (DE)		5	5	10

United Kingdom (UK)		5	4	9
Total maritime zone		**27**	**23**	**50**
Poland (PL)	northeast	11	6	17
Total northeast zone		**11**	**6**	**17**
Slovakia (SK)	southeast	1	-	1
Total southeast zone		**1**	**-**	**1**

Table 6.1.2-5**:** Distribution of minimum effective dose trials in barley per use

Country	EPPO zone	Number of trials per year		Total
		2012	2013	
***Rhynchosporium commune* (Leaf Scald)**				
Germany	maritime	1	3	**4**
United Kingdom	maritime	1	2	**3**
Czech Republic	maritime	1	0	**1**
France	maritime	2	3	**5**
Poland	northeast	1	5	**6**
Total		**6**	**13**	**19**
***Pyrenophora teres* (Net Blotch)**				
Germany	maritime	1	2	**3**
United Kingdom	maritime	1	1	**2**
Belgium	maritime	2	1	**3**
Czech Republic	maritime	2	0	**2**
France	maritime	6	6	**12**
Poland	northeast	9	5	**14**
Slovakia	southeast	2	0	**2**
Total		**23**	**15**	**38**
***Puccinia hordei* (Brown/ Dwarf Rust)**				
Germany	maritime	1	1	**2**
United Kingdom	maritime	2	0	**2**
France	maritime	1	1	**2**
Poland	northeast	2	3	**5**
Total		**6**	**5**	**11**
***Blumeria graminis* (Powdery Mildew)**				
Germany	maritime	1	0	**1**
United Kingdom	maritime	0	2	**2**
Czech Republic	maritime	1	0	**1**
France	maritime	2	4	**6**
Poland	northeast	6	4	**10**
Total		**10**	**10**	**20**
Decrease of non-parasitic leaf spots (Physiological leaf spot)				
Germany	maritime	2	1	**3**
Belgium	maritime	1	0	**1**
France	maritime	1	0	**1**

Total	**4**	**1**	**5**

Table 6.1.2-6: Distribution of minimum effective dose trials in rye

Country	EPPO zone	Number of trials per year		Total
		2012	2013	
***Rhynchosporium secalis* (Leaf Scald)**				
Germany	maritime	0	2	**2**
Poland	northeast	0	3	**3**
Total		**0**	**5**	**5**

Table 6.1.2-7: Distribution of minimum effective dose trials in triticale

Country	EPPO zone	Number of trials per year		Total
		2012	2013	
***Mycosphaerella graminicola* (Leaf Blotch)**				
Germany	maritime	0	1	**1**
Poland	northeast	2	1	**3**
Total		**2**	**2**	**4**

The trials are distributed across the maritime and northeast EPPO zones representing the various agro-climatic conditions in the EU central zone and are therefore representative for the various conditions found across the countries within the EU central regulatory zone. The applicant could not conduct successful trials in the southeast EPPO zone.

Ascra Xpro was compared to various reference products as shown in Table 6.1.2-8.

Table 6.1.2-8: List of reference products and used dose rates

Product	Active substance	Content g/L	Dose rate L/ha	a.s. rate g/ha	Tested in country
Wheat trials					
Aviator Xpro	bixafen prothioconazole	75 150	1.0 / 1.25	75 /93.75 150/ 187.5	Belgium, Czech Republic, France, Germany, United Kingdom, Poland
Tracker / Bell / Champion	boscalid epoxiconazole	233 67	1.5	349.5 100.5	Belgium, Czech Republic, France, Germany, United Kingdom, Poland, Slovakia
Barley trials					
Aviator Xpro	bixafen prothioconazole	75 150	1.0	75 150	Belgium, Czech Republic, France, Germany, United Kingdom, Poland
Tracker / Bell / Champion	boscalid epoxiconazole	233 67	1.5	349.5 100.5	Belgium, Czech Republic, France, Germany, United Kingdom, Poland, Slovakia
Triticale and Rye trials					
Aviator Xpro	bixafen prothioconazole	75 150	1.25	93.75 187.5	Belgium, Czech Republic, France, Germany, United

					Kingdom, Poland
Tracker / Bell / Champi-on	boscalid epoxiconazole	233 67	1.5	349.5 100.5	Belgium, Czech Republic, France, Germany, United Kingdom, Poland
Skyway Xpro	bixafen prothioconazole tebuconazole	75 100 100	1.25	93.75 125 125	Germany
Input	prothioconazole spiroxamine	160 300	1.25	200 375	Germany
Prosaro	prothioconazole tebuconazole	125 125	1.0	125 125	Germany

Wheat diseases

For wheat the applicant submitted data for the applied dose rate (1.5 L/ha) and the reduced rates (0.8 N = 1.2 L/ha; 0.6 N= 0.~~72~~9 L/ha). A summary of the minimum effective dose results for wheat for the different EPPO zones is presented in table below.

Table 6.1.2-2 Disease level/efficacy in minimum effective dose trials for wheat

Crop	Pathogen	EPPO Zone	n	Dis-ease level in UTC (%)	Control (%) of test product								
					1 N			0.8 N			0.6 N		
				mean	mean	min	max	mean	min	max	mean	min	max
1		2	3	4	5								
Wheat	*Septoria tritici*	maritime	49 (27)	**39.2**	**88.2**	59	99	**83.8**	53	98	**80.3**	48	99
		northeast	12 (5)	**28.1**	**92.5**	71	100	**93.3**	85	100	**86.4**	65	100
	Pyrenoph-ora tritici-repentis	maritime	15 (11)	**42.8**	**87.5**	73	99	**85.2**	76	97	**75.3**	57	91
		northeast	9 (5)	**11.0**	**93.1**	77	100	**94.9**	90	97	**82.6**	68	97
		southeast	1	**47.3**	**90.7**			**89.6**			**84.2**		
	Puccinia recondita	maritime	16 (14)	**29.4**	**95.7**	78	100	**95.2**	75	100	**89.0**	71	99
		northeast	8 (3)	**21.8**	**98.7**	95	100	**98.5**	97	100	**94.7**	85	100
	Erysiphe graminis	maritime	10 (6)	**14.7**	**89.7**	70	100	**84.9**	51	100	**82.1**	44	94
		northeast	11 (6)	**18.1**	**93.6**	78	100	**86.2**	64	97	**83.6**	51	100
		southeast	1	**4.3**	**99.5**			**97.5**			**94.9**		
	Septoria nodorum	southeast	1	**9.6**	**66.0**			**35.5**			**28.5**		

1 Name
2 EPPO-Zone
3 number of results; () number of 0.8 N
4 disease level at untreated control (UTC) [%]
5 application rate test product (target dose rate (N), reduced dose rates (range of 0.8 N to 0.6 N))

Effect of single and double applications

Single and double spray applications were compared in the EPPO maritime zone. Table 6.1.2-3 presents the application timing of Ascra Xpro and table 6.1.2-4 presents the efficacy of the product against several diseases when applied either once or twice.

Table 6.1.2-3 Application timing of single and double application of Ascra Xpro

Pathogen	Application time for single~~one~~ application	Application time for double~~one~~ application
Septoria tritici	BBCH 31-55	BBCH 31–33 and BBCH 37-61
P. tritici-repentis	BBCH 37-49	BBCH 31–35 and BBCH 43-61
Puccinia recondita	BBCH 37-61	BBCH 31–32 and BBCH 39-61
Erysiphe graminis	BBCH 39-43	BBCH 31–32 and BBCH 39-61

Table 6.1.2-4 Disease level/efficacy in minimum effective dose trials single or double application in the maritime zone

Crop	Pathogen	No. of applications	n	Disease level in UTC (%)	Control (%) of test product								
					1 N			0.8 N			0.6 N		
				mean	mean	min	max	mean	min	max	mean	min	max
1		2	3	4	5								
Wheat	*Septoria tritici*	1	33	**36.3**	**86.7**	59	100	**83.9**	53	98	**79.1**	54	99
		2	16	**45.3**	**91.5**	81	91	**83.5**	68	95	**82.7**	48	98
	P. tritici-repentis	1	8	**38.9**	**89.5**	83	99	**88.1**	81	97	**78.8**	73	83
		2	7	**47.3**	**85.1**	73	99	**83.8**	76	97	**71.4**	57	84
	Puccinia recondita	1	11 (9)	**21.2**	**96.0**	90	100	**96.0**	90	100	**88.0**	74	99
		2	5	**47.7**	**95.2**	78	100	**93.7**	75	99	**91.1**	70	98
	Erysiphe graminis	1	3 (2)	**13.3**	**76.6**	70	87	**67.2**	51	84	**65.7**	44	78
		2	7 (4)	**15.2**	**95.3**	80	99	**93.7**	78	100	**89.1**	71	94

1 Name
2 Number of applications
3 number of results; () number of 0.8 N
4 disease level at untreated control (UTC) [%]
5 application rate test product (target dose rate (N), reduced dose rates (range of 0.8 N to 0.6 N))

Barley diseases

For barley the applicant submitted data for the applied dose rate (1.2 L/ha) and one reduced rate (0.6 N= 0.72 L/ha). A summary of the minimum effective dose results for barley for the different EPPO zones is presented in the table below.

Table 6.1.2-5 Disease level/efficacy in minimum effective dose trials for barley

Crop	Pathogen	EPPO Zone	n	Disease level in UTC (%)	Control (%) of test product					
					1 N			0.6 N		
				mean	mean	min	max	mean	min	max
1		2	3	4	5					
Barley	*Rhynchosporium secalis*	maritime	13	**28.9**	**92.3**	79	100	**88.3**	72	98
		northeast	6	**17.8**	**90.0**	66	100	**77.0**	40	100
	Pyrenophora teres	maritime	22	**32.9**	**90.9**	68	100	**85.6**	57	99
		northeast	14	**19.4**	**92.4**	77	99	**85.3**	75	99

Crop	Pathogen	EPPO Zone	n	Disease level in UTC (%)	Control (%) of test product					
					1 N			0.6 N		
				mean	mean	min	max	mean	min	max
		southeast	2	**6.6**	**86.4**	73	99	**72.0**	48	96
	Puccinia hordei	maritime	6	**28.4**	**89.2**	74	100	**84.1**	61	100
		northeast	5	**27.1**	**96.5**	93	100	**87.5**	69	94
	Erysiphe graminis	maritime	10	**28.1**	**94.1**	80	100	**91.6**	75	100
		northeast	10	**12.5**	**91.4**	77	100	**87.2**	74	96
	Physiological leaf spot	maritime	5	**51.0**	**93.0**			**86.6**		

1 Name
2 EPPO-Zone
3 number of results
4 disease level at untreated control (UTC) [%]
5 application rate test product (target dose rate (N), reduced dose rates (0.6 N))

Triticale and rye diseases

For triticale and rye the applicant submitted data for the applied dose rate (1.5 L/ha) and one reduced rate (0.6 N= 0.9 L/ha). A summary of the minimum effective dose results for triticale and rye for the different EPPO zones is presented in the table below (table 6.1.2-6).

Table 6.1.2-6 Disease level/efficacy in minimum effective dose trials for triticale and rye

Crop	Pathogen	EPPO Zone	n	Disease level in UTC (%)	Control (%) of test product					
					1 N			0.6 N		
				mean	mean	min	max	mean	min	max
1		2	3	4	5					
Triticale	*Septoria* sp.	maritime	1	**44.8**	**91.5**			**85.1**		
		northeast	3	**19.2**	**94.3**	90	99	**84.5**	82	88
Rye	*Rhynchosporium secalis*	maritime	2	**45.0**	**75.9**	68	84	**64.8**	63	67
		northeast	3	**17.4**	**93.4**	81	100	**90.1**	77	99

1 EPPO-Zone
2 number of results
3 disease level at untreated control (UTC) [%]
4 application rate test product (target dose rate (N), reduced dose rates (0.6 N))

Effect of single and double applications
Single and double spray applications were compared in the northeast EPPO zone. Table 6.1.2-7 presents the application timing of Ascra Xpro and table 6.1.2-8 presents the efficacy of the product against two diseases when applied either once or twice.

Table 6.1.2-7 Application timing of single and double application of Ascra Xpro

Pathogen	**Application time for ~~one~~ single application**	**Application time for double~~one~~ application**
Septoria spp.	BBCH 39-41	BBCH 31 and BBCH 47
Rhynchosporium secalis	BBCH 32	BBCH 31–32 and BBCH 59-61

Table 6.1.2-8 Disease level/efficacy in minimum effective dose trials single or double application in the maritime zone

Crop	Pathogen	No. of applications	n	Disease level in UTC (%)	Control (%) of test product					
					1 N			0.6 N		
				mean	mean	min	max	mean	min	max
1		2	3	4	5					
Triticale	*Septoria* spp.	1	2	**11.4**	**96.4**	94	99	**84.9**	82	88
		2	1	**34.8**	**90.1**			**83.3**		
Rye	*Rhynchosporium secalis*	1	1	**20.8**	**99.4**			**98.8**		
		2	2	**15.8**	**90.4**	81	100	**86.7**	77	97

1 Name
2 Number of applications
3 number of results; () number of 0.8 N
4 disease level at untreated control (UTC) [%]
5 application rate test product (target dose rate (N), reduced dose rates (range of 0.8 N to 0.6 N))

Conclusion of the applicant
Based on presented data, the rate of 1.5 L/ha on wheat, triticale and, rye and 1.2 L/ha on barley and oats are proposed for Ascra Xpro as the minimum effective dose for the control of stem base, foliar and ear diseases. These rates provide superior levels of control and less variation in efficacy than reduced rates.
Data have shown that Ascra Xpro at the proposed rates will provide a high level of efficacy under the climatic conditions of the maritime and northeast climatic EPPO zones when applied one to two times per season on wheat, triticale and rye and once per season on barley and oats.
Although a few number of results was available in the southeast EPPO zone, the pattern of results was close to the one observed in the maritime and northeast climatic zones indicating that similar dose rates likely represent the minimum effective dose within this EPPO climatic zone.

Conclusion:

The presented data correspond with the requirements of the EPPO ~~standard~~Standard PP 1/225. The applicant showed a decrease of efficacy as a result of dose reduction by 40%. The dose reduction from 1.5 L/ha to 0.9 L/ha in wheat, triticale and rye and a dose reduction from 1.2 L/ha to 0.72 L/ha in barley caused a decrease of disease control by 2-14%. The justification of the proposed application rate of 1.5 L/ha in wheat, triticale and rye and 1.2 L/ha in barley will be accepted.

It can be concluded to accept the data provided by the applicant to demonstrate the minimum effective dose for wheat, barley, triticale, rye and oat disease control.

IIIA1 6.1.3 Efficacy tests

The testing facilities responsible for the conduct of the trials were the development teams of the country subsidiary organisations of Bayer CropScience, subcontractor companies and official research institutes. All follow the EPPO ~~standard~~Standards and are authorized in accordance to the principles of Good Experimental Practice (GEP).

The cereal field trials presented in this section were conducted in countries belonging to the maritime, northeast and southeast climatic EPPO zones in Europe. Trials belonging to the EU central regulatory zone were conducted in Germany, United Kingdom, Belgium, Czech Republic, Poland and Slovakia. The trials belonging to the EU north regulatory zone were conducted in

Denmark, Sweden, Latvia, Lithuania and Estonia. Trials belonging to the EU south regulatory zone were conducted in the maritime region of France.

An overview of the distribution and number of trials are presented in tables 6.1.3-1 until 6.1.3-7.

Table 6.1.3-1: Efficacy trials used in wheat, barley, rye, triticale and oats

Country	EPPO zone	2012	2013	2015	Total
Wheat					
Belgium (BE)	maritime	8	6		14
Czech Republic (CZ)		3	-		3
Denmark (DK)		1	1		2
France (FR)		9	15		24
Germany (DE)		22	10		32
United Kingdom (UK)		12	14		26
Sweden (SE)		1	-		1
Total maritime zone		**56**	**46**		**102**
Latvia (LV)	northeast	6	3		9
Lithuania (LT)		1	2		3
Poland (PL)		10	8		18
Total northeast zone		**17**	**13**		**30**
Slovakia (SK)	southeast	2	-		2
Total southeast zone		**2**	**-**		**2**
Barley					
Belgium (BE)	maritime	3	1	3	7
Czech Republic (CZ)		3	-		3
Denmark (DK)		-	1		1
France (FR)		12	16		28
Germany (DE)		7	6	1	14
United Kingdom (UK)		5	5		10
Switzerland (CH)				1	1
Total maritime zone		**30**	**29**	**5**	**64**
Latvia (LV)	northeast	3	1		4
Lithuania (LT)		-	1		1
Poland (PL)		8	6		14
Total northeast zone		**11**	**8**		**19**
Slovakia (SK)	southeast	3	-		3
Total southeast zone		**3**	**-**		**3**
Triticale					
France (FR)	maritime	2	1		3
Germany (DE)		4	2		6
Total maritime zone		**6**	**3**		**9**
Latvia (LV)	northeast	-	1		1
Lithuania (LT)		-	1		1
Poland (PL)		2	3		5
Total northeast zone		**2**	**5**		**7**
Rye					
Denmark (DK)	maritime	-	1		1
France (FR)		2	1		3
Germany (DE)		7	5		12
Total maritime zone		**9**	**7**		**16**
Latvia (LV)	northeast	-	1		1

Lithuania (LT)		-	1		1
Poland (PL)		-	3		3
Total northeast zone		**-**	**5**		**5**
Oats					
Denmark (DK)	maritime	-	1		1
France (FR)		2	1		3
Total maritime zone		**2**	**2**		**4**

Table 6.1.3-2: Distribution of trials used against diseases in wheat

Country	EPPO zone	SEPTTR	PYRNTR	ER-YSGR	PUCCRE	PUCCST	LEPTNO	PSDCHE	FUSASP
EU central Regulatory Zone									
DE	maritime	17	8	5	7	2	4	0	1
UK	maritime	22	0	1	1	2	0	7	0
BE	maritime	11	1	0	5	0	0	0	0
CZ	maritime	0	2	2	0	0	2	0	0
PL	northeast	12	9	11	8	0	3	8	8
SK	southeast	0	1	1	0	0	1	0	0
EU Northern Regulatory Zone									
LV	northeast	0	8	2	5	0	2	1	1
LT	northeast	0	0	0	0	0	2	1	0
DK	maritime	0	0	1	0	1	0	0	0
SE	maritime	0	0	1	0	1	0	0	0
EU Southern Regulatory zone									
FR	maritime	0	4	2	3	5	0	3	7
EPPO climatic zone									
maritime		50	15	12	16	11	6	10	8
northeast		12	17	13	13	0	7	10	9
southeast		0	1	1	0	0	1	0	0

Table 6.1.3-3: Distribution of trials used against diseases in barley

Country	EPPO zone	RHYN-SE	PYRNTE	PUC-CHD	ER-YSGR	RAMUCC	PSDCHE	YBFMI
EU central Regulatory Zone								
DE	maritime	4	3	2	1	2	0	4
UK	maritime	3	2	2	2	1	1	
BE	maritime	0	3	0	0	0	0	4
CZ	maritime	1	2	0	1	0	0	
CH	maritime							1
PL	northeast	6	14	5	10	4	4	
SK	south-east	0	2	0	0	0	0	
EU Northern Regulatory Zone								
LV	northeast	1	0	3	2	0	0	
LT	northeast	0	0	0	0	1	0	
DK	maritime	0	0	1	0	1	0	
SE	maritime	0	0	0	0	0	0	
EU Southern Regulatory zone								
FR	maritime	5	12	4	6	1	0	1

EPPO climatic zone							
maritime	13	22	9	10	5	1	10
northeast	7	14	8	12	5	4	
southeast	0	2	0	0	0	0	

Table 6.1.3-4: Distribution of trials conducted against leaf diseases in triticale

Country	EPPO zone	SEPTTR	PUCCRE	ERYSGR
EU central Regulatory Zone				
DE	maritime	4	1	4
PL	northeast	3	4	2
EU Northern Regulatory Zone				
LV	northeast	0	0	1
LT	northeast	1	0	1
EU Southern Regulatory zone				
FR	maritime	2	0	3
EPPO climatic zone				
maritime		6	1	7
northeast		4	4	4

Table 6.1.3-5: Distribution of trials used against leaf diseases in rye

Country	EPPO zone	RHYNSE	PUCCRE
EU central Regulatory Zone			
DE	maritime	5	10
PL	northeast	3	1
EU Northern Regulatory Zone			
LV	northeast	1	1
LT	northeast	1	0
DK	maritime	1	1
EU Southern Regulatory zone			
FR	maritime	2	2
EPPO climatic zone			
maritime		8	13
northeast		5	2

Table 6.1.3-6: Distribution of trials used against leaf diseases in oats

Country	EPPO zone	PUCCCA	ERYSGA
EU Northern Regulatory Zone			
DK	maritime	0	1
EU Southern Regulatory zone			
FR	maritime	3	0
EPPO climatic zone			
maritime		3	1

All trials have been conducted under GEP and in accordance with EPPO ~~standard~~Standards, for specification of EPPO ~~standard~~Standards followed in individual trials, please refer to the compilation of trial reports. They followed the EPPO ~~standard~~Standards listed in table 6.1.3-7.

Table 6.1.3-7: Standards and trial design

GEP	YES
EPPO ~~standard~~Standards	PP 1/26 (3/4), PP 1/28 (2/3), PP 1/135 (2/3), PP 1/152 (3), PP 1/181 (4)
Number of replications	4
Plot design, plot size	Randomised complete block, 20-36 m², except in a number of trials in Germany with 10-20 m²
Crop growth stage (BBCH) at application time	One to two applications on wheat. In approximately half the trials a single application was made, from BBCH 30-32 to BBCH 55-61 depending on targeted diseases. About half the trials received 2 applications at BBCH 31-32 followed with a second application at BBCH 37-49. One application on barley and oats. Approximately 25% were applied at BBCH 31-34 and 75% were made at BBCH 37-61. One to two applications on triticale and rye. Primarily single applications were made with approximately 20% at BBCH 31-34 and 80% at BBCH 55-61. A small number of trials received a two spray programme. Applications are made in line with the proposed GAP.

The applicant compared the test product Ascra Xpro to two main reference products in all crops. The characteristics and dose rates of the reference products tested are shown in table 6.1.3-8.

Table 6.1.3-8: Reference products and dose rates tested

Product	**Active substance**	**content g/L**	**Crop**	**Dose rate L/ha**	**AI rate g/ha**	**Tested in country**
Tracker/ Bell/Champion	boscalid epoxiconazole	233 67	wheat-barley triticale-rye	1.5	349.5 100.5	DK, SE, FIN, LT, LV, PL, UK, DE, SK
Aviator Xpro	bixafen prothioconazole	75 150	wheat-triticale-rye	1.25	93.75 187.5	DK, SE, FIN DE, BE, FR, CH
			barley-oats	1.0	75 150	
Skyway Xpro	bixafen prothioconazole tebuconazole	75 100 100	triticale-rye	1.25	93.75 125 125	DE
Input	prothioconazole spiroxamine	160 300	triticale	1.25	200 375	DE
Prosaro	prothioconazole tebuconazole	125 125	rye	1.0	125 125	DE

The main reference products were Aviator Xpro representing a high level commercial reference and Tracker (Bell/Champion) which has registrations in a range of crops across European countries. In all trials the applicant applied Tracker at a dose rate of 1.5 L/ha which is the recommended dose rate of the product in cereals. Aviator Xpro was applied at 1.25 L/ha in wheat, triticale and rye and 1.0 L/ha in barley and oats.

Formatiert: Deutsch (Deutschland)

In all trials, efficacy was assessed according to EPPO ~~standard~~Standard PP 1/26 "Foliar and ear diseases on cereals". Details are presented in table 6.1.3-9.

Table 6.1.3-9: Assessment methods

Assessment	Efficacy assessments	Pest severity (PESSEV) percentage of attacked leaf area: In all trials, leaf layers with pest severity above 5% were used for the efficacy evaluation. Where disease development was slow and reached levels suitable for assessment later in the season, the number of assessments was reduced to one. For the evaluation, where possible assessments from more than one leaf layer and more than one assessment timing were averaged to give a disease severity and % disease control figure for the trial.
	Phytotoxicity assessments	Crop safety assessments were conducted at each efficacy assessment in most trials (0-100 scale)
	Assessment dates	Efficacy assessments on leaf diseases done where possible two times, 2-4 weeks and 5-7 weeks after application in trials with one application and 3-5 and 5-7 weeks after application in trials with two applications
	Yield	Crop yield was evaluated using small plot combines and yield calculated to 15% moisture. Yield was evaluated where the crop was even and plot size sufficient for accuracy, in most cases this was 20 m², although in some of the trials conducted in Germany a smaller plot size was used, which were nevertheless considered even enough to give an accurate assessment of yield

The applicant declares that all trials presented here fall within the maritime, northeast or southeast climatic EPPO zone as set out by EPPO ~~standard~~Standard PP 1/241(1) "Guidance on comparable climates". The main differences between these climatic zones are higher precipitation rates during the summer period and milder winters in the maritime climatic zone, compared to the northeast and southeast zones. These two factors can have an impact on the disease pressure observed in the field. However, they do not have an impact on the efficacy performance of Ascra Xpro.
For certain diseases where there are marginally to few results in the relevant climatic zone, the applicant included data from the mediterranean climatic zone of France for rust diseases which cycle faster in warmer conditions and therefore result in higher disease severity and a more severe test for the formulation, and also for *Ramularia collo-cygni* which is now a global issue. (refer to the relevant efficacy point).
Data for each disease are presented by the applicant according to the maritime northeast and southeast EPPO zone separately. All trial sites were placed in typical cereal growing areas. Trials covered a wide range of cultivar, soil types and environmental conditions. Results from a wide geographical spread of locations give a broad range of the extremes of disease severity and therefore a more representative and reliable dataset.

Efficacy on wheat

Intended use: 001 (*Pseudocercosporella herpotrichoides* / PSDCHE in wheat; 1 application per use)

Efficacy against *Pseudocercosporella herpotrichoides* in the maritime and northeast climatic EPPO zone

A total of 20 trials, 10 in the maritime zone and 10 in the northeast zone, targeted *Pseudocercosporella herpotrichoides* in 2012 (5 trials) and 2013 (15 trials). The applicant conducted trials in the United Kingdom (7 trials) and Poland (8 trials). Further he included data from the maritime climatic region of France (3 trials) and from Latvia (1 trial) and Lithuania (1 trial) within the northeast climatic zone to support performance of the formulation, representing a good geographical distribution across the zones. One application targeting the pathogen was made from the crop stage BBCH 30 to 32. A summary of main results is shown in tables 6.1.3-10 and 6.1.3-11.

Table 6.1.3-10: Mean efficacy in wheat against *Pseudocercosporella herpotrichoides* in the central registration zone

Treatment	Dose in L/ha	Mean % control on wheat (maritime & northeast EPPO zones together)		
		mean	min-max	count
Untreated (% severity)	-	(37.4)	(2-78)	20
Bell (Tracker, Champion)	1.5	76.7	55-97	20
Aviator Xpro	1.0	73.4	20-93	20
Aviator Xpro	1.25	76.5	26-98	20
Ascra Xpro	**1.5**	**77.2**	**23-99**	**20**

Table 6.1.3-11: Efficacy in wheat against *Pseudocercosporella herpotrichoides* in maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on wheat					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated (% severity)	-	(36.2)	(6-64)	10	(38.7)	(2-78)	10
Bell (Tracker, Champion)	1.5	69.2	55-84	10	84.2	62-97	10
Aviator Xpro	1.0	63.2	20-92	10	83.6	58-93	10
Aviator Xpro	1.25	67.1	26-94	10	85.9	50-98	10
Ascra Xpro	**1.5**	**62.7**	**23-92**	**10**	**91.7**	**75-99**	**10**

Yield benefit in *Pseudocercosporella herpotrichoides* wheat trials

A total of 20 trials (10 from the maritime EPPO zone and 10 from the northeast EPPO zone) are presented in support of disease control in wheat. The applicant conducted trials in France, United Kingdom, Poland, Latvia and Lithuania. The trials included represent a good geographical distribution across the maritime and northeast EPPO zone. A summary of main results is shown in tables 6.1.3-12 and 6.1.3-13.

Table 6.1.3-12: Mean yield benefit in *Pseudocercosporella herpotrichoides* trials in the central registration zone

Treatment	Dose in L/ha	Mean % relative in wheat (maritime & northeast EPPO zones together)		
		mean	min-max	count
Untreated (dt/ha)	-	(67.2)	(36-92)	20
Bell (Tracker, Champion)	1.5	112.9	102-123	20
Aviator Xpro	1.0	112.2	97-132	20
Aviator Xpro	1.25	114.7	100-133	20
Ascra Xpro	**1.5**	**117.3**	**106-133**	**20**

Table 6.1.3-13: Yield benefit in *Pseudocercosporella herpotrichoides* trials in maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in wheat					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated (dt/ha)	-	(71.9)	(51-92)	10	(62.5)	(36-86)	10
Bell (Tracker, Champion)	1.5	109.4	102-118	10	116.3	106-123	10
Aviator Xpro	1.0	109.8	97-123	10	114.5	100-132	10
Aviator Xpro	1.25	111.1	100-130	10	118.4	102-133	10
Ascra Xpro	**1.5**	**113.8**	**106-129**	**10**	**120.7**	**111-133**	**10**

In the central zone as a whole, Ascra Xpro applied at 1.5 L/ha provided good reduction in the severity (77%) of *Pseudocercosporella herpotrichoides*. The formulation provided very similar performance to the reference products Aviator Xpro (76%). The effectiveness in the maritime EPPO zone was 62.7% and in the northeast EPPO zone 91.7%.

Additionally to the efficacy the data showed a grain yield increase of 14% for the maritime EPPO zone and 21% for the northeast EPPO zone. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (TRZSS / PSDCHE):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP_1/214, PP_1/223 and PP_1/226. The applicant showed in 20 trials an excellent efficacy of 77.2% (exceptional achievement) for the control of *Pseudocercosporella herpotrichoides* in wheat based on trials from 2012 and 2013 in the maritime and northeast EPPO zone. Additional a grain yield increase of 17% could also be achieved.

No data were represented for the southeast EPPO zone.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Pseudocercosporella herpotrichoides* in wheat.

DE as zRMS accepts the submitted data. The concerned Member States have to decide themselves whether to accept the lack of data from the southeast EPPO zone or not.

Intended use: 022 (*Pseudocercosporella herpotrichoides* / PSDCHE in wheat, 1 application per use)

See data set intended use no. 001, (same efficacy data)

Conclusion (TRZSS / PSDCHE):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP_1/214, PP_1/223 and PP_1/226. The applicant showed in 20 trials an excellent efficacy of 77.2% (exceptional achievement) for the control of *Pseudocercosporella herpotrichoides* in wheat based on trials from 2012 and 2013 in the maritime and northeast EPPO zone. Additional a grain yield increase of 17% could also be achieved

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Pseudocercosporella herpotrichoides* in wheat.

Intended use: 002 (*Erysiphe graminis* / ERYSGR in wheat; 2 applications per use)

Efficacy data against *Erysiphe graminis* in all climatic EPPO zones
A total of 26 trials, 12 in the maritime, 13 in the northeast and one in the southeast EPPO zone, targeted *Erysiphe graminis* in 2012 (17 trials) and 2013 (9 trials). The trials were conducted in Germany (5 trials), Czech Republic (2 trials), United Kingdom (1 trial), Poland (11 trials) and Slovakia (1 trial) representing a good geographical distribution across the zones. Further data are included from the maritime area of France (2 trials), Denmark (1 trial), Sweden (1 trial) and Latvia (2 trials) within the northeast climatic zone to support performance of the formulation. One to two applications were made from the crop stage BBCH 30 to 61. A summary of main results is shown in tables 6.1.3-14 and 6.1.3-15.

Table 6.1.3-14: Mean efficacy in wheat against *Erysiphe graminis* in the central registration zone

Treatment	Dose in L/ha	Mean % control on wheat		
		mean	min-max	count
Untreated (% severity)	-	(16.3)	(4-38)	26
Bell (Tracker, Champion)	1.5	68.8	22-97	26
Aviator Xpro	1.0	78.2	41-100	19
Aviator Xpro	1.25	83.5	44-100	23
Ascra Xpro	**1.5**	**91.7**	**70-100**	**26**

Table 6.1.3-15: Efficacy in wheat against *Erysiphe graminis* in all climatic EPPO zones

Treatment	Dose in L/ha	Mean % control on wheat								
		maritime EPPO zone			northeast EPPO zone			southeast EPPO zone		
		mean	min-max	count	mean	min-max	count	mean	min-max	count
Untreated (% severity)	-	(16.5)	(6-38)	12	(17.2)	(5-37)	13	(4.3)		1
Bell (Tracker, Champion)	1.5	58.0	22-90	12	77.0	47-97	13	94.9		1
Aviator Xpro	1.0	72.5	41-95	8	82.3	51-100	11			
Aviator Xpro	1.25	78.4	44-95	10	87.5	59-100	13			
Ascra Xpro	**1.5**	**89.6**	**70-100**	**12**	**93.0**	**78-100**	**13**	**99.5**		**1**

Yield benefit in *Erysiphe graminis* wheat trials
A total of 24 trials, 12 from the maritime, 11 from the northeast and one from the southeast EPPO zone, are presented in support of disease control in wheat. The trials were conducted in 2012-2013 in Germany, France, United Kingdom, Denmark, Sweden, Czech Republic, Poland, Latvia and Slovakia. The trials included represent a good geographical distribution across all EPPO zones. A summary of main results is shown in tables 6.1.3-16 and 6.1.3-17.

Table 6.1.3-16: Mean yield benefit in *Erysiphe graminis* trials in the central registration zone

Treatment	Dose in L/ha	Mean % relative in wheat		
		mean	min-max	count
Untreated (dt/ha)	-	(69.5)	(26-97)	24

Bell (Tracker, Champion)	1.5	115.3	102-134	24
Aviator Xpro	1.0	115.6	100-142	17
Aviator Xpro	1.25	119.1	93-150	21
Ascra Xpro	**1.5**	**121.4**	**105-154**	**24**

Table 6.1.3-17: Yield benefit in *Erysiphe graminis* trials in all climatic EPPO zones

Treatment	Dose in L/ha	Mean % control on wheat								
		maritime EPPO zone			northeast EPPO zone			southeast EPPO zone		
		mean	min-max	count	mean	min-max	count	mean	min-max	count
Untreated dt/ha)	-	(80.9)	(60-97)	12	(61.0)	(36-86)	11	(25.8)		1
Bell (Tracker, Champion)	1.5	112.9	102-134	12	117.9	111-123	11	115.8		1
Aviator Xpro	1.0	115.9	102-142	8	115.4	100-132	9			
Aviator Xpro	1.25	118.3	93-150	10	119.9	107-133	11			
Ascra Xpro	**1.5**	**120.1**	**105-154**	**12**	**121.9**	**112-133**	**11**	**133.1**		**1**

In the central registration zone as a whole, Ascra Xpro applied at 1.5 L/ha provided an excellent control of *Erysiphe graminis* (92%). The formulation provided a better performance to the reference product Aviator Xpro (83%) with less variation across trials. The effectiveness in the maritime EPPO zone was 89.6%, in the northeast EPPO zone 93% and in the southeast EPPO zone 99.5%.

Additionally to the efficacy the data showed a grain yield increase of 20% for the maritime, 22% for the northeast and 33% for the southeast EPPO zone. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (TRZSS / ERYSGR):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP 1/214, PP 1/223 and PP 1/226. The applicant showed in 26 trials an excellent efficacy of 91.7% (exceptional achievement) for the control of *Erysiphe graminis* in wheat based on trials from 2012 and 2013 in all EPPO zones. Additional a grain yield increase of 21% could also be achieved.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Erysiphe graminis* in wheat.

Intended use: 023 (*Erysiphe graminis* / ERYSGR in wheat; 1 application per use)

Efficacy data against *Erysiphe graminis* in the maritime climatic EPPO zone
A total of 9 trials were conducted by the applicant in the maritime EPPO zone against ERYSGR in 2012 (6 trials) and 2013 (3 trials). The trials were conducted in Germany (4 trials), France (2 trials), Denmark (1 trial), Sweden (1 trial) and Czech Republic (1 trial) representing a geographical distribution across the maritime EPPO zone. One application was made from the crop stage BBCH 31 to 43. A summary of main results is shown in table 6.1.3-18.

Table 6.1.3-18: Efficacy in wheat against *Erysiphe graminis* in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on wheat		
		mean	min-max	count
Untreated (% severity)	-	(17.2)	(6-47)	9
Bell (Tracker, Champion)	1.5	53.3	22-100	9
Aviator Xpro	1.0	73.1	41-97	6
Aviator Xpro	1.25	75.9	44-98	8
Ascra Xpro	**1.5**	**86.8**	**70-100**	**9**

Yield benefits have been measured in a total of 3 trials in support of disease control in wheat. The applicant conducted trials in Germany and France. A summary of main results is shown in table 6.1.3-19.

Table 6.1.3-19: Yield benefit in *Erysiphe graminis* trials in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in wheat maritime EPPO zone		
		mean	min-max	count
Untreated (dt/ha)	-	(87.3)	(73-95)	3
Bell (Tracker, Champion)	1.5	115.4	102-134	3
Aviator Xpro	1.0	118.8	104-142	3
Aviator Xpro	1.25	121.7	103-150	3
Ascra Xpro	**1.5**	**124.0**	**106-154**	**3**

Data shows that Ascra Xpro achieved a good disease control (87%) at 1.5 L/ha. The mean efficacy level was higher than the one of Aviator Xpro.

Additionally to the efficacy the data showed a grain yield increase of 24%. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (TRZSS / ERYSGR):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP_1/214, PP_1/223 and PP_1/226. The applicant showed in 9 trials a good efficacy of 86.8% (Extensive achievement) for the control of *Erysiphe graminis* in wheat based on trials from 2012 and 2013 in the maritime EPPO zone. Additional a grain yield increase of 24% could also be achieved. No data were represented for the northeast and southeast EPPO zone.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Erysiphe graminis* in wheat in the maritime EPPO zone.

Intended use: 003 (*Septoria tritici* / SEPTTR in wheat; 2 applications per use)

Efficacy data against *Septoria tritici* in the maritime and northeast climatic EPPO zone
A total of 62 trials, 50 in the maritime and 12 in the northeast EPPO zone, targeted SEPTTR in 2012 (32 trials) and 2013 (30 trials). The trials were conducted in Germany (17 trials), United Kingdom (22 trials), Belgium (11 trials) and Poland (12 trials) representing a good geographical distribution across the zones. One to two applications were made from the crop stage BBCH 30 to 61. A summary of main results is shown in tables 6.1.3-20 and 6.1.3-21.

Table 6.1.3-20: Mean efficacy in wheat against *Septoria tritici* in the central registration zone

Treatment	Dose in L/ha	Mean % control on wheat (maritime & northeast EPPO zones together)		
		mean	min-max	count
Untreated (% severity)	-	(36.6)	(7-81)	62
Bell (Tracker, Champion)	1.5	67.3	28-99	62
Aviator Xpro	1.0	81.6	34-100	62
Aviator Xpro	1.25	85.3	46-100	62
Ascra Xpro	**1.5**	**89.2**	**59-100**	**62**

Table 6.1.3-21: Efficacy in wheat against *Septoria tritici* in maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on wheat					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated (% severity)	-	(38.6)	(9-81)	50	(28.1)	(7-62)	12
Bell (Tracker, Champion)	1.5	63.5	28-97	50	83.2	69-99	12
Aviator Xpro	1.0	80.3	34-99	50	87.0	68-100	12
Aviator Xpro	1.25	83.9	46-99	50	91.1	71-100	12
Ascra Xpro	**1.5**	**88.4**	**59-99**	**50**	**92.5**	**71-100**	**12**

Yield benefit in *Septoria tritici* wheat trials

A total of 60 trials (49 from the maritime and 11 from the northeast EPPO zone) are presented in support of disease control in wheat. The trials were conducted in 2012-2013 in Germany, United Kingdom, Belgium, and Poland. The trials represent a good geographical distribution across the maritime and northeast EPPO climatic zones. A summary of main results is shown in Tables 6.1.3-22 and 6.1.3-23.

Table 6.1.3-22: Mean yield benefit in *Septoria tritici* trials in the central registration zone

Treatment	Dose in L/ha	Mean % relative in wheat (maritime & northeast EPPO zones together)		
		mean	min-max	count
Untreated (dt/ha)	-	(74.7)	(31-117)	60
Bell (Tracker, Champion)	1.5	115.4	99-167	60
Aviator Xpro	1.0	118.9	97-207	60
Aviator Xpro	1.25	121.4	100-226	60
Ascra Xpro	**1.5**	**124.2**	**101-243**	**60**

Table 6.1.3-23: Yield benefit in *Septoria tritici* trials in the maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in wheat					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated (dt/ha)	-	(77.9)	(31-117)	49	(60.7)	(36-86)	11
Bell (Tracker, Champion)	1.5	115.7	99-167	49	114.0	104-123	11
Aviator Xpro	1.0	120.5	97-207	49	112.2	100-120	11
Aviator Xpro	1.25	122.5	100-226	49	116.7	102-132	11
Ascra Xpro	**1.5**	**125.3**	**101-243**	**49**	**119.0**	**111-132**	**11**

In the central registration zone as a whole, Ascra Xpro applied at 1.5 L/ha provided a good control of *Septoria tritici* (89%). The formulation provided a better performance to the reference

product Aviator Xpro (85%) with less variation across trials. The effectiveness in the maritime EPPO zone was 88.4% and in the northeast EPPO zone 92.5%.

Additionally to the efficacy the data showed a grain yield increase of 25% for the maritime and 19% for the northeast EPPO zone. Compared to the reference products Aviator Xpro the yield increase was slightly more.

Conclusion (TRZSS / SEPTTR):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP_1/214, PP_1/223 and PP_1/226. The applicant showed in 62 trials a good efficacy of 89.2% (Extensive achievement) for the control of *Septoria tritici* in wheat based on trials from 2012 and 2013 in the maritime and northeast EPPO zone. Additional a grain yield increase of 24% could also be achieved. No data were represented for the southeast EPPO zone.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Septoria tritici* in wheat.

DE as zRMS accepts the submitted data. The concerned Member States have to decide themselves whether to accept the lack of data from the southeast EPPO zone or not.

Intended use: 024 (*Septoria tritici* / SEPTTR in wheat; 1 application per use)

Efficacy against *Septoria tritici* in the maritime climatic EPPO zone
A total of 34 trials were conducted in the maritime EPPO zone against SEPTTR in 2012 (19 trials) and 2013 (15 trials). The trials were conducted in Germany (10 trials), United Kingdom (13 trials) and Belgium (11 trials) representing a good geographical distribution across the EPPO zone. One application was made from the crop stage BBCH 31 to 55. A summary of main results is shown in table 6.1.3-24.

Table 6.1.3-24: Efficacy in wheat against *Septoria tritici* in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on wheat		
		mean	min-max	count
Untreated (% severity)	-	(35.5)	(9-81)	34
Bell (Tracker, Champion)	1.5	62.7	30-97	34
Aviator Xpro	1.0	79.2	34-99	34
Aviator Xpro	1.25	82.4	46-99	34
Ascra Xpro	**1.5**	**86.9**	**59-100**	**34**

Yield benefits have been measured in a total of 34 trials in support of disease control in wheat. The trials were conducted in Germany, United Kingdom and Belgium. A summary of main results is shown in table 6.1.3-25.

Table 6.1.3-25: Yield benefit in *Septoria tritici* trials in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in wheat		
		mean	min-max	count
Untreated (dt/ha)	-	(80.5)	(48-117)	34
Bell (Tracker, Champion)	1.5	113.2	99-153	34
Aviator Xpro	1.0	116.8	97-165	34
Aviator Xpro	1.25	118.1	100-161	34

Ascra Xpro	**1.5**	**120.2**	**101-169**	**34**

Data shows that Ascra Xpro achieved a good disease control (86.9%) at 1.5 L/ha. It was similar to the standard Aviator Xpro with much less variability and more consistent results.

Additionally to the efficacy the data showed a grain yield increase of 20% for the maritime EPPO zone. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (TRZSS / SEPTTR):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP_1/214, PP_1/223 and PP_1/226. The applicant showed in 34 trials a good efficacy of 86.9% (Extensive achievement) for the control of *Septoria tritici* in wheat based on trials from 2012 and 2013 in the maritime EPPO zone. Additional a grain yield increase of 20% could also be achieved. No data were represented for the northeast and southeast EPPO zone.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Septoria tritici* in wheat.

Intended use: 004 (*Pyrenophora tritici-repentis* / PYRNTR in wheat; 2 applications per use)

Efficacy against *Pyrenophora tritici-repentis* in all climatic EPPO zones
A total of 33 trials, 15 in the maritime, 17 in the northeast and one in the southeast EPPO zone, targeted *Pyrenophora tritici-repentis* in 2012 (23 trials) and 2013 (10 trials). The trials were conducted in Belgium (1 trial), Germany (8 trials), Czech Republic (2 trials), Poland (9 trials) and Slovakia (1 trial) representing a good geographical distribution across all zones. Further data are included from the maritime area of France (4 trials) and Latvia (8 trials) within the northeast climatic zone to support performance of the formulation. One to two applications were made from the crop stage BBCH 30 to 61. A summary of main results is shown in tables 6.1.3-26 and 6.1.3-27.

Table 6.1.3-26: Mean efficacy in wheat against *Pyrenophora tritici-repentis* in the central registration zone

Treatment	Dose in L/ha	Mean % control on wheat		
		mean	min-max	count
Untreated (% severity)	-	(29.6)	(7-90)	33
Bell (Tracker, Champion)	1.5	65.5	18-100	33
Aviator Xpro	1.0	78.6	48-99	24
Aviator Xpro	1.25	83.7	56-100	30
Ascra Xpro	**1.5**	**88.9**	**70-100**	**33**

Table 6.1.3-27: Efficacy in wheat against *Pyrenophora tritici-repentis* in all climatic EPPO zones

Treatment	Dose in L/ha	Mean % control on wheat								
		maritime EPPO zone			northeast EPPO zone			southeast EPPO zone		
		mean	min-max	count	mean	min-max	count	mean	min-max	count
Untreated (% severity)	-	(42.8)	(7-90)	15	(16.7)	(9-38)	17	(47.3)		1
Bell (Tracker,	1.5	56.0	18-97	15	73.1	56-	17	78.2		1

Champion)						100				
Aviator Xpro	1.0	76.8	48-99	13	80.7	65-94	11			
Aviator Xpro	1.25	81.9	56-97	13	85.1	66-100	17			
Ascra Xpro	**1.5**	**87.5**	**73-99**	**15**	**89.9**	**70-100**	**17**	**90.7**		**1**

Yield benefit in *Pyrenophora tritici-repentis* wheat trials
A total of 29 trials (13 from the maritime, 15 from the northeast and one in the southeast EPPO zone) are presented in support of disease control in wheat. The trials were conducted in Germany, France, Czech Republic, Poland, Latvia and Slovakia. The trials included represent a good geographical distribution across all EPPO climatic zones. A summary of main results is shown in tables 6.1.3-28 and 6.1.3-29.

Table 6.1.3-28: Mean yield benefit in *Pyrenophora tritici-repentis* trials in the central registration zone

Treatment	Dose in L/ha	Mean % relative in wheat		
		mean	min-max	count
Untreated (dt/ha)	-	(61.7)	(29-91)	28
Bell (Tracker, Champion)	1.5	117.3	103-151	28
Aviator Xpro	1.0	121.0	100-198	20
Aviator Xpro	1.25	123.4	103-151	26
Ascra Xpro	**1.5**	**126.1**	**105-220**	**28**

Table 6.1.3-29: Yield benefit in *Pyrenophora tritici-repentis* trials in all climatic EPPO zones

Treatment	Dose in L/ha	Mean % control on wheat								
		maritime EPPO zone			northeast EPPO zone			southeast EPPO zone		
		mean	min-max	count	mean	min-max	count	mean	min-max	count
Untreated dt/ha)	-	(67.8)	(29-91)	13	(56.5)	(36-70)	15	(60.4)		1
Bell (Tracker, Champion)	1.5	114.9	103-151	13	119.4	106-132	15	110.6		1
Aviator Xpro	1.0	125.2	102-198	11	115.9	100-132	9			
Aviator Xpro	1.25	125.3	93-200	11	121.9	107-135	15			
Ascra Xpro	**1.5**	**128.3**	**105-220**	**13**	**124.2**	**113-143**	**15**	**121.2**		**1**

In the central registration zone as a whole, Ascra Xpro applied at 1.5 L/ha provided a good control of *Pyrenophora tritici-repentis* (89%). The formulation provided a better performance to the reference product Aviator Xpro (84%) with less variation across trials. The effectiveness in the maritime EPPO zone was 87.5% in the northeast EPPO zone 89.9% and in the southeast EPPO zone 90.7%.

Additionally to the efficacy the data showed a grain yield increase of 28% for the maritime, 24% for the northeast and 21% for the southeast EPPO zone. Compared to the reference products Aviator Xpro the yield increase was slightly more.

Conclusion (TRZSS / PYRNTR):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP_1/214, PP_1/223 and PP_1/226. The applicant showed in 33 trials a good efficacy of 88.9 ~~–~~% (Extensive achievement) for the control of *Pyrenophora tritici-repentis* in wheat based on trials from 2012 and 2013 in all EPPO zones. Additional a grain yield increase of 26% could also be achieved.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Pyrenophora tritici-repentis* in wheat.

Intended use: 025 (*Pyrenophora tritici-repentis* / PYRNTR in wheat; 1 application per use)

Efficacy against *Pyrenophora tritici-repentis* in the maritime climatic EPPO zone
A total of 9 trials were conducted in the maritime EPPO zone against PYRNTR in 2012 (6 trials) and 2013 (3 trials). The trials were conducted in Germany (4 trials), France (4 trials) and Belgium (1 trial) representing a good geographical distribution across the EPPO zone. One application was made from the crop stage BBCH 32 to 49. A summary of main results is shown in table 6.1.3-30.

Table 6.1.3-30: Efficacy in wheat against *Pyrenophora tritici-repentis* in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on wheat maritime EPPO zone		
		mean	min-max	count
Untreated (% severity)	-	(37.1)	(17-90)	9
Bell (Tracker, Champion)	1.5	63.8	39-97	9
Aviator Xpro	1.0	80.8	71-99	9
Aviator Xpro	1.25	85.4	80-97	9
Ascra Xpro	**1.5**	**89.3**	**83-99**	**9**

Yield benefits have been measured in a total of 7 trials in support of disease control in wheat. The trials were conducted in Germany and France. A summary of main results is shown in table 6.1.3-31.

Table 6.1.3-31: Yield benefit in *Pyrenophora tritici-repentis* trials in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in wheat		
		mean	min-max	count
Untreated (dt/ha)	-	(73.1)	(58-91)	7
Bell (Tracker, Champion)	1.5	111.9	106-120	7
Aviator Xpro	1.0	116.8	106-131	7
Aviator Xpro	1.25	117.3	107-128	7
Ascra Xpro	**1.5**	**118.3**	**105-132**	**7**

Data shows that Ascra Xpro achieved good to excellent disease control (89.3 %) at 1.5 L/ha. It was overall slightly superior to the standard Aviator Xpro.

Additionally to the efficacy the data showed a grain yield increase of 18%. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (TRZSS / PYRNTR):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP_1/214, PP_1/223 and PP_1/226. The applicant showed in 9 trials a good to excellent efficacy of 89.3% (Extensive achievement) for the control of *Pyrenophora tritici-repentis* in wheat based on trials from 2012 and 2013 in the maritime EPPO zone. Additional a grain yield increase of 18% could also be achieved. No data were represented for the northeast and southeast EPPO zone.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Pyrenophora tritici-repentis* in wheat.

Intended use: 005 (*Puccinia recondita* / PUCCRE in wheat; 2 applications per use)

Efficacy against *Puccinia recondita*, maritime and northeast climatic EPPO zone
A total of 29 trials, 16 in the maritime and 13 in the northeast EPPO zone, targeted *Puccinia recondita* in 2012 (21 trials) and 2013 (8 trials). The trials were conducted in Belgium (5 trials), Germany (7 trials), United Kingdom (1 trial) and Poland (8 trials) representing a good geographical distribution across the zones. The applicant included further data from the maritime area of France (3 trials) and Latvia (5 trials) within the northeast climatic zone to support performance of the formulation. One to two applications were made from the crop stage BBCH 30 to 61. A summary of main results is shown in tables 6.1.3-32 and 6.1.3-33.

Table 6.1.3-32: Mean efficacy in wheat against *Puccinia recondita* in the central registration zone

Treatment	Dose in L/ha	Mean % control on wheat (maritime & northeast EPPO zones together)		
		mean	min-max	count
Untreated (% severity)	-	(27.4)	(5-93)	29
Bell (Tracker, Champion)	1.5	94.2	71-100	29
Aviator Xpro	1.0	93.6	71-100	25
Aviator Xpro	1.25	96.2	75-100	29
Ascra Xpro	**1.5**	**96.6**	**78-100**	**29**

Table 6.1.3-33: Efficacy in wheat against *Puccinia recondita* in the maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on wheat					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated (% severity)	-	(29.4)	(6-93)	16	(25.0)	(5-50)	13
Bell (Tracker, Champion)	1.5	91.1	71-100	16	98.0	95-100	13
Aviator Xpro	1.0	91.4	71-99	16	97.6	92-100	9
Aviator Xpro	1.25	95.0	75-100	16	97.7	88-100	13
Ascra Xpro	**1.5**	**95.7**	**78-100**	**16**	**97.7**	**82-100**	**13**

Yield benefit in *Puccinia recondita* wheat trials
A total of 29 trials (16 from the maritime and 13 from the northeast EPPO zone) are presented in support of disease control in wheat. The trials were conducted in Germany, France, United Kingdom, Belgium, Poland and Latvia. The trials included represent a good geographical distribution across the maritime and northeast EPPO climatic zones. A summary of main results is shown in tables 6.1.3-34 and 6.1.3-35.

Table 6.1.3-34: Mean yield benefit in *Puccinia recondita* trials in the central registration zone

Treatment	Dose in L/ha	Mean % relative in wheat (maritime & northeast EPPO zones together)		
		mean	min-max	count
Untreated (dt/ha)	-	(70.4)	(42-111)	29
Bell (Tracker, Champion)	1.5	118.4	103-147	29
Aviator Xpro	1.0	118.8	102-154	25
Aviator Xpro	1.25	121.5	93-156	29
Ascra Xpro	**1.5**	**123.6**	**105-159**	**29**

Table 6.1.3-35: Yield benefit in *Puccinia recondita* trials in the maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in wheat					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated (dt/ha)	-	(78.4)	(45-111)	16	(60.6)	(42-86)	13
Bell (Tracker, Champion)	1.5	119.1	103-147	16	117.5	106-119	13
Aviator Xpro	1.0	120.2	102-154	16	116.4	110-132	9
Aviator Xpro	1.25	123.1	93-156	16	119.7	107-135	13
Ascra Xpro	**1.5**	**124.6**	**105-159**	**16**	**122.5**	**112-138**	**13**

In the central registration zone as a whole, Ascra Xpro applied at 1.5 L/ha provided excellent overall control of *Puccinia recondita* (97%). The formulation provided similar performance to the reference products Aviator Xpro (94%). The effectiveness in the maritime EPPO zone was 95.7% and in the northeast EPPO zone 97.7%.

Additionally to the efficacy the data showed a grain yield increase of 25% for the maritime and 23% for the northeast EPPO zone. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (TRZSS / PUCCRE):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP_1/214, PP_1/223 and PP_1/226. The applicant showed in 29 trials an excellent efficacy of 96.6% (Exceptional achievement) for the control of *Puccinia recondita* in wheat based on trials from 2012 and 2013 in the maritime and northeast EPPO zone. Additional a grain yield increase of 24% could also be achieved. No data were represented for the southeast EPPO zone.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Puccinia recondita* in wheat.

DE as zRMS accepts the submitted data. The concerned Member States have to decide themselves whether to accept the lack of data from the southeast EPPO zone or not.

Intended use: 026 (*Puccinia recondita* / PUCCRE in wheat; 1 application per use)

Efficacy against *Puccinia recondita* in the maritime climatic EPPO zone
A total of 11 trials were conducted in the maritime EPPO zone against PUCCRE in 2012 (9 trials) and 2013 (2 trials). The trials were conducted in Germany (3 trials), France (3 trials) and

Belgium (5 trials) representing a good geographical distribution across the EPPO zone. One application was made from the crop stage BBCH 37 to 61. A summary of main results is shown in table 6.1.3-36.

Table 6.1.3-36: Efficacy in wheat against *Puccinia recondita* in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on wheat		
		mean	min-max	count
Untreated (% severity)	-	(21.2)	(6-60)	11
Bell (Tracker, Champion)	1.5	91.3	72-100	11
Aviator Xpro	1.0	91.1	75-98	11
Aviator Xpro	1.25	95.3	79-100	11
Ascra Xpro	**1.5**	**96.0**	**90-100**	**11**

Yield benefits have been measured in a total of 11 trials in support of disease control in wheat. The trials were conducted in Germany, France and Belgium and represent a good geographical distribution across the maritime climatic EPPO zone. A summary of main results is shown in table 6.1.3-37.

Table 6.1.3-37: Yield benefit in *Puccinia recondita* trials in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in wheat		
		mean	min-max	count
Untreated (dt/ha)	-	(78.5)	(45-111)	11
Bell (Tracker, Champion)	1.5	121.2	108-147	11
Aviator Xpro	1.0	121.5	107-154	11
Aviator Xpro	1.25	124.9	108-156	11
Ascra Xpro	**1.5**	**125.9**	**109-159**	**11**

Data shows that Ascra Xpro achieved excellent disease control (96.0%) at 1.5 L/ha. It was equal or slightly superior to standards Aviator Xpro.

Additionally to the efficacy the data showed a grain yield increase of 26%. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (TRZSS / PUCCRE):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP 1/214, PP 1/223 and PP 1/226. The applicant showed in 11 trials an excellent efficacy of 96.0% (Exceptional achievement) for the control of *Puccinia recondita* in wheat based on trials from 2012 and 2013 in the maritime EPPO zone. Additional a grain yield increase of 26% could also be achieved. No data were represented for the northeast and southeast EPPO zone.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Puccinia recondita* in wheat.

Intended use: 006 (*Puccinia striiformis* / PUCCST in wheat; 2 applications per use)

Efficacy against *Puccinia striiformis* in the maritime climatic EPPO zone

A total of 11 trials, all in the maritime zone, targeted *Puccinia striiformis* in 2012 (6 trials) and 2013 (5 trials). The trials were conducted in Germany (2 trials), United Kingdom (2 trials). No disease occurred in any of the trials conducted in the northeast zone (Poland, Finland and The Baltics). The applicant included further data from the maritime area of France (5 trials), Denmark (1 trial) and Sweden (1 trial) to support performance of the formulation. One to two applications were made from the crop stage BBCH 31 to 61. A summary of main results is shown in table 6.1.3-38.

Table 6.1.3-38: Efficacy in wheat against *Puccinia striiformis* in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on wheat		
		mean	min-max	count
Untreated (% severity)	-	(23.3)	(11-52)	11
Bell (Tracker, Champion)	1.5	96.3	83-100	10
Aviator Xpro	1.0	93.5	86-100	8
Aviator Xpro	1.25	94.7	86-100	11
Ascra Xpro	**1.5**	**93.6**	**83-100**	**11**

Yield benefit in *Puccinia striiformis* trials
A total of 8 trials, all from the maritime zone, are presented in support of disease control in wheat. The trials were conducted in Germany, France, United Kingdom, Denmark and Sweden. The trials included represent a geographical distribution across the maritime EPPO zone. A summary of main results is shown in table 6.1.3-39.

Table 6.1.3-39: Yield benefit in *Puccinia striiformis* in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in wheat		
		mean	min-max	count
Untreated (dt/ha)	-	(57.9)	(27-81)	8
Bell (Tracker, Champion)	1.5	152.0	110-298	8
Aviator Xpro	1.0	153.9	101-247	8
Aviator Xpro	1.25	152.3	106-243	8
Ascra Xpro	**1.5**	**157.3**	**104-252**	**8**

In the maritime EPPO zone, Ascra Xpro applied at 1.5 L/ha provided excellent overall control of *Puccinia striiformis* (94%) with more than 80% efficacy in all trials. The formulation provided similar performance to the reference products Aviator Xpro (95%).

In the northeast EPPO zone, the disease did not occur in any of the trials conducted in the northeast climatic zone. The applicant suggested that the disease does not have the importance and frequency of occurrence as in the maritime EPPO zone.

Additionally to the efficacy the data showed a grain yield increase of 57%. Compared to the reference products Aviator Xpro the yield increase was slightly higher.

Conclusion (TRZSS / PUCCST):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP 1/214, PP 1/223 and PP 1/226. The applicant showed in 11 trials an excellent efficacy of 93.6% (Exceptional achievement) for the control of *Puccinia striiformis* in wheat based on trials from 2012 and 2013 in the maritime EPPO zone. Additional a grain yield increase of 57% could also be achieved. No data were represented for the northeast and southeast EPPO zone.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Puccinia striiformis* in wheat.

DE as zRMS accepts the submitted data. The concerned Member States have to decide themselves whether to accept the lack of data from the northeast and southeast EPPO zone or not.

Intended use: 027 (*Puccinia striiformis* / PUCCST in wheat; 1 application per use)

Efficacy against *Puccinia striiformis* in the maritime climatic EPPO zone
A total of 7 trials were conducted in the maritime EPPO zone against PUCCST in 2012 (3 trials) and 2013 (4 trials). The trials were conducted in Germany (1 trial), France (5 trials) and Denmark (1 trial) representing a geographical distribution across the EPPO zone. One application was made from the crop stage BBCH 31 to 51. A summary of main results is shown in table 6.1.3-40.

Table 6.1.3-40: Efficacy in wheat against *Puccinia striiformis* in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on wheat		
		mean	min-max	count
Untreated (% severity)	-	(26.4)	(5-52)	7
Bell (Tracker, Champion)	1.5	97.3	92-100	6
Aviator Xpro	1.0	91.9	86-100	5
Aviator Xpro	1.25	93.0	91-100	7
Ascra Xpro	**1.5**	**92.0**	**83-100**	**7**

Yield benefits have been measured in 3 trials in support of disease control in wheat. The trials were conducted in France. A summary of main results is shown in table 6.1.3-41.

Table 6.1.3-41: Yield benefit in *Puccinia striiformis* trials in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in wheat		
		Mean	min-max	Count
Untreated (dt/ha)	-	(43.6)	(27-63)	3
Bell (Tracker, Champion)	1.5	187.4	110-298	3
Aviator Xpro	1.0	166.1	104-247	3
Aviator Xpro	1.25	165.6	106-243	3
Ascra Xpro	**1.5**	**170.1**	**104-252**	**3**

Data shows that Ascra Xpro achieved excellent disease control (92.0%) at 1.5 L/ha. It was overall similar to the standard Aviator Xpro.

Additionally to the efficacy the data of the 3 trials showed a grain yield increase of 70%. Compared to the reference products Aviator Xpro the yield increase was slightly higher.

Conclusion (TRZSS / PUCCST):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP_1/214 and PP_1/223. The number of trials (7) carried out in the maritime EPPO

zone was understated according to the EPPO ~~standard~~Standard PP 1/226. The efficacy for the control of *Puccinia striiformis* in wheat was excellent (92.0%) based on trials from the maritime EPPO zone. The efficacy of *Puccinia striiformis* in the intended use 006 with 2 applications was also excellent (93.6%) and can be extrapolated.

Additional a grain yield increase of 70% could also be achieved. No data were represented for the northeast and southeast EPPO zone.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Puccinia striiformis* in wheat.

Intended use: 007 (*Septoria nodorum* / LEPTNO in wheat; 2 applications per use)

Efficacy against *Septoria nodorum* (LEPTNO) in all EPPO zones
A total of 14 trials, 6 in the maritime, 7 in the northeast and 1 in the southeast EPPO zone, targeted *Septoria nodorum* in 2012 (8 trials) and 2013 (6 trials). The trials were conducted in Czech Republic (2 trials), Germany (4 trials), Poland (3 trials) and Slovakia (1 trial) representing a good geographical distribution across the zones. The applicant included further data from Latvia (2 trials) and Lithuania (2 trials) within the northeast climatic zone to support performance of the formulation. One to two applications were made from the crop stage BBCH 30 to 61. A summary of main results is shown in tables 6.1.3-42 and 6.1.3-43.

Table 6.1.3-42: Mean efficacy in wheat against *Septoria nodorum* in the central registration zone

Treatment	Dose in L/ha	Mean % control on wheat		
		mean	min-max	count
Untreated (% severity)	-	(15.8)	(4-51)	14
Bell (Tracker, Champion)	1.5	73.5	34-98	12
Aviator Xpro	1.0	80.6	60-100	7
Aviator Xpro	1.25	73.3	43-100	10
Ascra Xpro	**1.5**	**84.8**	**59-100**	**14**

Table 6.1.3-43: Efficacy in wheat against *Septoria nodorum* in all climatic EPPO zones

Treatment	Dose in L/ha	Mean % control on wheat								
		maritime EPPO zone			northeast EPPO zone			southeast EPPO zone		
		mean	min-max	count	mean	min-max	count	mean	min-max	count
Untreated (% severity)	-	(16.9)	(12-22)	6	(15.7)	(4-51)	7	(9.6)		1
Bell (Tracker, Champion)	1.5	83.9	70-98	4	73.1	60-83	7	34.8		1
Aviator Xpro	1.0	89.5	81-99	2	77.0	69-100	5			
Aviator Xpro	1.25	75.8	56-99	3	72.3	43-100	7			
Ascra Xpro	**1.5**	**89.8**	**80-99**	**6**	**83.2**	**59-100**	**7**	**66.0**		**1**

Yield benefit in *Septoria nodorum* wheat trials
A total of 13 trials (6 from the maritime, 6 from the northeast and 1 from the southeast EPPO zone) are presented in support of disease control in wheat. The trials were conducted in Germany, Czech Republic, Poland, Latvia, Lithuania and Slovakia. The trials included represent a

good geographical distribution across all climatic EPPO zones. A summary of main results is shown in tables 6.1.3-44 and 6.1.3-45.

Table 6.1.3-44: Mean yield benefit in *Septoria nodorum* trials in the central registration zone

Treatment	Dose in L/ha	Mean % relative in wheat (all zones together)		
		mean	min-max	count
Untreated (dt/ha)	-	(66.4)	(26-106)	13
Bell (Tracker, Champion)	1.5	114.3	105-127	11
Aviator Xpro	1.0	110.5	100-122	6
Aviator Xpro	1.25	118.3	104-132	9
Ascra Xpro	**1.5**	**117.4**	**103-133**	**13**

Table 6.1.3-45: Yield benefit in *Septoria nodorum* trials in the maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on wheat								
		maritime EPPO zone			northeast EPPO zone			southeast EPPO zone		
		mean	min-max	count	mean	min-max	count	mean	min-max	count
Untreated (dt/ha)	-	(85.9)	(63-106)	6	(53.8)	(36-70)	6	(25.8)		1
Bell (Tracker, Champion)	1.5	107.7	105-110	4	118.4	113-127	6	115.8		1
Aviator Xpro	1.0	104.2	101-108	2	113.7	100-122	4			
Aviator Xpro	1.25	111.1	104-116	3	121.9	113-132	6			
Ascra Xpro	**1.5**	**110.1**	**103-115**	**6**	**122.2**	**115-128**	**6**	**133.1**		**1**

In the central registration zone as a whole, Ascra Xpro applied at 1.5 L/ha provided excellent overall control of *Septoria nodorum* (85%). The formulation provided superior performance to the reference product Aviator Xpro (73%) with less variation across trials. The effectiveness in the maritime EPPO zone was 89.8%, in the northeast EPPO zone 83.2% and in the southeast EPPO zone 66.0%.

Additionally to the efficacy the data showed a grain yield increase of 17%. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (TRZSS / LEPTNO):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP 1/214, PP 1/223 and PP 1/226. The applicant showed in 14 trials an excellent efficacy of 84.8 % (Exceptional achievement) for the control of *Septoria nodorum* in wheat based on trials from 2012 and 2013 in all EPPO zones. Additional a grain yield increase of 17% could also be achieved.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Septoria nodorum* in wheat.

Intended use: 028 (*Septoria nodorum* / LEPTNO in wheat; 1 application per use)

Efficacy against *Septoria nodorum*, maritime climatic EPPO zone
A total of 4 trials were successfully conducted in the EPPO maritime zone against LEPTNO in 2012 (2 trials) and 2013 (2 trial). The trials were all conducted in Germany. One application was made from the crop stage BBCH 37 to 39. A summary of main results is shown in table 6.1.3-46.

Table 6.1.3-46: Efficacy in wheat against *Septoria nodorum* in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on wheat		
		mean	min-max	count
Untreated (% severity)	-	(18.7)	(12-22)	4
Bell (Tracker, Champion)	1.5	83.6	70-98	2
Aviator Xpro	1.0	89.5	81-99	2
Aviator Xpro	1.25	75.8	56-99	3
Ascra Xpro	**1.5**	**87.8**	**80-99**	**4**

Yield benefits have been measured in 4 trials in support of disease control in wheat. The trials were conducted in Germany. A summary of main results is shown in table 6.1.3-47.

Table 6.1.3-47: Yield benefit in *Septoria nodorum* trials in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in wheat		
		mean	min-max	count
Untreated (dt/ha)	-	(91.3)	(68-106)	4
Bell (Tracker, Champion)	1.5	107.7	105-110	2
Aviator Xpro	1.0	104.2	101-108	2
Aviator Xpro	1.25	111.1	104-116	3
Ascra Xpro	**1.5**	**109.8**	**103-115**	**4**

Data shows that Ascra Xpro achieved very good disease control (87.8%) at 1.5 L/ha. It was similar to the standard Aviator Xpro.

Additionally to the efficacy the data showed a grain yield increase of 10%. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (TRZSS / LEPTNO):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP_1/214 and PP_1/223. The number of trials (4) carried out in the maritime EPPO zone was understated according to the EPPO ~~standard~~Standard PP_1/226. The efficacy for the control of *Septoria nodorum* in wheat was excellent (87.8%) based on trials from 2012 and 2013 in the maritime EPPO zone. The efficacy of *Septoria nodorum* in the intended use 007 with 2 applications was also excellent (84.8%) and can be extrapolated. Additional a grain yield increase of 10% could also be achieved.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Puccinia striiformis* in wheat.

Intended use: 007a (*Michrodochium nivale* / MONGNI in wheat, 1 application per use)

Efficacy against *Michrodochium nivale* (*Monographella nivalis*, anamorph: *F. nivale*) in maritime and northeast EPPO zone

A total of 17 trials, 8 in the maritime and 9 in the northeast EPPO zone, targeted *Michrodochium nivale* in 2012 (6 trials) and 2013 (11 trials). The trials were conducted in Germany (1 trial) and Poland (8 trials). The applicant included further data from the maritime area of France (7 trials) and Latvia (1 trial) within the northeast climatic EPPO zone to support performance of the formulation, representing a good geographical distribution across the zones. A summary of main results is shown in tables 6.1.3-48 and 6.1.3-49.

Table 6.1.3-48: Mean efficacy in wheat against *Michrodochium nivale* in the central registration zone

Treatment	Dose in L/ha	Mean % control on wheat (maritime & northeast EPPO zones together)		
		mean	min-max	count
Untreated (% severity)	-	(15.5)	(2-40)	17
Bell (Tracker, Champion)	1.5	64.6	46-85	10
Aviator Xpro	1.0	72.3	57-88	8
Aviator Xpro	1.25	79.3	62-98	17
Ascra Xpro	**1.5**	**82.3**	**61-98**	**17**

Table 6.1.3-49: Efficacy in wheat against *Michrodochium nivale* in the maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on wheat					
		maritime zone			northeast zone		
		mean	min-max	count	mean	min-max	count
Untreated (% severity)	-	(17.3)	(5-40)	8	(13.9)	(2-39)	9
Bell (Tracker, Champion)	1.5	56.3	-	1	65.5	46-85	9
Aviator Xpro	1.0	-	-	-	72.3	57-88	8
Aviator Xpro	1.25	76.1	62-95	8	82.1	82-98	9
Ascra Xpro	**1.5**	**77.7**	**61-97**	**8**	**86.4**	**70-98**	**9**

Yield benefit in *Michrodochium nivale* wheat trials

A total of 12 trials (6 from the maritime and 6 from the northeast EPPO zone) are presented in support of disease control in wheat. The trials were conducted in Germany, France, Poland and Latvia. The trials included represent a good geographical distribution across the maritime and northeast climatic EPPO zones. A summary of main results is shown in Tables 6.1.3-50 and 6.1.3-51.

Table 6.1.3-50: Mean yield benefit in *Michrodochium nivale* trials in the central registration zone

Treatment	Dose in L/ha	Mean % relative in wheat (maritime & northeast EPPO zones together)		
		mean	min-max	count
Untreated (dt/ha)	-	(64.7)	(36-119)	12
Bell (Tracker, Champion)	1.5	115.6	104-127	7
Aviator Xpro	1.0	113.6	100-126	5
Aviator Xpro	1.25	120.9	102-135	12
Ascra Xpro	**1.5**	**122.6**	**102-138**	**12**

Table 6.1.3-51: Yield benefit in *Michrodochium nivale* trials in the maritime and northeast climatic EPPO zone

Treatment	Dose in	Mean % relative in wheat	
		maritime zone	northeast zone

	L/ha	mean	min-max	count	mean	min-max	count
Untreated (dt/ha)	-	(80.5)	(44-119)	6	(48.9)	(36-67)	6
Bell (Tracker, Champion)	1.5	110.7	-	1	116.4	104-127	6
Aviator Xpro	1.0	-	-	-	113.6	100-126	5
Aviator Xpro	1.25	116.7	105-129	6	125.1	102-135	6
Ascra Xpro	**1.5**	**117.4**	**102-138**	**6**	**127.9**	**111-138**	**6**

In the central registration zone as a whole, Ascra Xpro applied at 1.5 L/ha provided excellent reduction in disease severity (82%) of *Michrodochium nivale* symptoms. The formulation provided very similar performance to the reference product Aviator Xpro (79%). A similar pattern was also observed by the applicant on disease incidence.

Additionally to the efficacy the data showed a grain yield increase of 23%. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (TRZSS / MONGNI):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP 1/214, PP 1/223 and PP 1/226. The applicant showed in 17 trials an excellent efficacy of 82.3 % (Exceptional achievement) for the control of *Michrodochium nivale* in wheat based on trials from 2012 and 2013 in the maritime and northeast EPPO zones. Additional a grain yield increase of 23% could also be achieved. No data were represented for the northeast and southeast EPPO zone.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Michrodochium nivale* in wheat.

DE as zRMS accepts the submitted data. The concerned Member States have to decide themselves whether to accept the lack of data from the northeast and southeast EPPO zone or not.

Efficacy on barley

Intended use: 008 (*Pseudocercosporella herpotrichoides* / PSDCHE in barley, 1 application per use)

Efficacy against *Pseudocercosporella herpotrichoides* (PSDCHE) in the maritime and northeast climatic EPPO zone
A total of 5 trials, 1 in the maritime zone and 4 in the northeast EPPO zone, targeted *Pseudocercosporella herpotrichoides* in 2012 (1 trial) and 2013 (4 trials). The trials were conducted in United Kingdom (1 trial) and Poland (4 trials). One application was made from the crop stage BBCH 31 to 41. A summary of main results is shown in tables 6.1.3-52 and 6.1.3-53.

Table 6.1.3-52: Mean efficacy against *Pseudocercosporella herpotrichoides* in barley in the central registration zone

Treatment	Dose in L/ha	Mean % control on spring/winter barley (maritime & northeast EPPO zones together)		
		mean	min-max	count
Untreated (% severity)	-	(44.1)	(8-80)	5
Bell (Tracker, Champion)	1.5	76.9	67-83	5

Aviator Xpro	1.0	74.6	35-90	5
Ascra Xpro	**1.2**	**83.9**	**63-92**	**5**

Table 6.1.3-53: Efficacy against *Pseudocercosporella herpotrichoides* in barley in the maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on spring/winter barley					
		maritime EPPO zone			northeast EPPO zone		
		Mean	min-max	Count	Mean	min-max	Count
Untreated (% severity)	-	(17.5)	(-)	1	(50.8)	(8-80)	4
Bell (Tracker, Champion)	1.5	78.8	-	1	76.5	67-83	4
Aviator Xpro	1.0	35.2	-	1	84.5	73-90	4
Ascra Xpro	**1.2**	**62.6**	**-**	**1**	**89.3**	**83-92**	**4**

Yield benefit in *Pseudocercosporella herpotrichoides* barley trials

A total of 5 trials (1 from the maritime and 4 from the northeast EPPO zone) are presented in support of disease control in barley. The trials were conducted in United Kingdom and Poland. A summary of main results is shown in tables 6.1.3-54 and 6.1.3-55.

Table 6.1.3-54: Mean yield benefit in *Pseudocercosporella herpotrichoides* trials in the central registration zone

Treatment	Dose in L/ha	Mean % relative in spring/winter barley (maritime & northeast EPPO zones together)		
		mean	min-max	count
Untreated (dt/ha)	-	(57.6)	(24-88)	5
Bell (Tracker, Champion)	1.5	116.6	97-169	5
Aviator Xpro	1.0	130.3	99-221	5
Ascra Xpro	**1.2**	**140.1**	**104-254**	**5**

Table 6.1.3-55: Yield benefit in *Pseudocercosporella herpotrichoides* trials in the maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in spring/winter barley					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated (dt/ha)	-	(87.4)	(-)	1	(50.2)	(24-63)	4
Bell (Tracker, Champion)	1.5	96.9	-	1	121.5	97-169	4
Aviator Xpro	1.0	98.5	-	1	138.3	105-221	4
Ascra Xpro	**1.2**	**114.2**	**-**	**1**	**146.6**	**104-254**	**4**

In the central registration zone as a whole, Ascra Xpro applied at 1.2 L/ha provided excellent reduction in the severity (84%) of *Pseudocercosporella herpotrichoides*. The formulation provided superior performance to the reference product Aviator Xpro (75%). The effectiveness in the maritime EPPO zone was 62.6% and in the northeast EPPO zone 89.3%. For the applicant the good level of disease control displayed against *Pseudocercosporella herpotrichoides* in barley, along with the good suppression of *Pseudocercosporella herpotrichoides* symptoms in wheat supports the proposed claim for reduction of the severity and incidence of *Pseudocercosporella herpotrichoides* in barley in the EU central registration regulatory zone.

Additionally to the efficacy the data showed a grain yield increase of 14%. Compared to the reference products Aviator Xpro the yield increase was slightly more.

Conclusion (HORVX / PSDCHE):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP_1/214 and PP_1/223. The number of trials (5) carried out in the maritime and northeast EPPO zone was understated according to the EPPO ~~standard~~Standard PP_1/226. The efficacy for the control of *Pseudocercosporella herpotrichoides* in barley was excellent (84.0%) based on trials from 2012 and 2013. The efficacy of *Pseudocercosporella herpotrichoides* in wheat was also excellent (77.2%) and can be extrapolated.
Additional a grain yield increase of 40% could also be achieved.

No data were represented for the southeast EPPO zone.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Pseudocercosporella herpotrichoides* in barley.

DE as zRMS accepts the submitted data. The concerned Member States have to decide themselves whether to accept the lack of data from the southeast EPPO zone or not.

Intended use: 009 (*Erysiphe graminis* / ERYSGR in barley; 1 application per use)

Efficacy against *Erysiphe graminis* in the maritime and northeast EPPO zone
A total of 22 trials, 10 in the maritime and 12 in the northeast EPPO zone, successfully targeted *Erysiphe graminis* in 2012 (12 trials) and 2013 (10 trials). The trials were conducted in Czech Republic (1 trial), Germany (1 trial), United Kingdom (2 trials) and Poland (10 trials) representing a good geographical distribution across the zones. The applicant included further data from the maritime area of France (6 trials) and Latvia (2 trials) from the northeast climatic EPPO zone to support performance of the formulation. One application was made from the crop stage BBCH 31 to 61. A summary of main results is shown in tables 6.1.3-56 and 6.1.3-57.

Table 6.1.3-56: Mean efficacy in barley against *Erysiphe graminis* in the central registration zone

Treatment	Dose in L/ha	Mean % control on spring/winter barley (maritime & northeast EPPO zones together)		
		mean	min-max	count
Untreated (% severity)	-	(19.1)	(6-72)	22
Bell (Tracker, Champion)	1.5	87.1	52-100	22
Aviator Xpro	1.0	91.8	74-100	21
Ascra Xpro	**1.2**	**93.4**	**77-100**	**22**

Table 6.1.3-57: Efficacy in barley against *Erysiphe graminis* in the maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on spring/winter barley					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated (% severity)	-	(28.1)	(14-72)	10	(11.6)	(6-31)	12
Bell (Tracker, Champion)	1.5	87.7	73-100	10	86.6	52-100	12
Aviator Xpro	1.0	93.3	80-100	9	90.6	74-100	12
Ascra Xpro	**1.2**	**94.1**	**80-100**	**10**	**92.8**	**77-100**	**12**

Yield benefit in *Erysiphe graminis* barley trials
A total of 18 trials (9 from the maritime and 9 from the northeast EPPO zone) are presented in support of disease control in barley. The trials were conducted in Germany, United Kingdom,

France, Czech Republic, Poland and Latvia. The trials included represent a good geographical distribution across the maritime and northeast climatic EPPO zones. A summary of main results is shown in tables 6.1.3-58 and 6.1.3-59.

Table 6.1.3-58: Mean yield benefit in *Erysiphe graminis* trials in the central registration zone

Treatment	Dose in L/ha	Mean % relative in spring/winter barley (maritime & northeast EPPO zones together)		
		mean	min-max	count
Untreated (dt/ha)	-	(56.6)	(32-86)	18
Bell (Tracker, Champion)	1.5	118.0	106-150	18
Aviator Xpro	1.0	118.9	94-156	17
Ascra Xpro	**1.2**	**120.0**	**102-155**	**18**

Table 6.1.3-59: Yield benefit in *Erysiphe graminis* trials, maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in spring/winter barley					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated (dt/ha)	-	(59.6)	(43-86)	9	(53.6)	(32-73)	9
Bell (Tracker, Champion)	1.5	114.1	106-131	9	121.8	110-150	9
Aviator Xpro	1.0	112.3	94-131	8	124.8	110-156	9
Ascra Xpro	**1.2**	**114.9**	**102-132**	**9**	**125.0**	**110-155**	**9**

In the central registration zone as a whole, Ascra Xpro applied at 1.2 L/ha provided excellent overall control of *Erysiphe graminis* with a mean control of 93%. The formulation provided comparable performance to the reference product Aviator Xpro (92%). The effectiveness in the maritime EPPO zone was 94.1% and in the northeast EPPO zone 92.8%.

Additionally to the efficacy the data showed a grain yield increase of 20%. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (HORVX / ERYSGR):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP 1/214, PP 1/223 and PP 1/226. The applicant showed in 22 trials an excellent efficacy of 93.0% (Exceptional achievement) for the control of *Erysiphe graminis* in barley based on trials from 2012 and 2013 in the maritime and northeast EPPO zone. Additional a grain yield increase of 20% could also be achieved.

No data were represented for the southeast EPPO zone.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Erysiphe graminis* in barley.

DE as zRMS accepts the submitted data. The concerned Member States have to decide themselves whether to accept the lack of data from the southeast EPPO zone or not.

Intended use: 010 (*Rhynchosporium secalis* / RHYNSE in barley; 1 application per use)

Efficacy against *Rhynchosporium secalis* in the maritime and northeast climatic EPPO zone
A total of 20 trials, 13 in the maritime and 7 in the northeast EPPO zone, targeted *Rhynchosporium secalis* in 2012 (6 trials) and 2013 (14 trials). The trials were conducted in the

Czech Republic (1 trial), Germany (4 trials), United Kingdom (3 trials) and Poland (6 trials) representing a good geographical distribution across the zones. The applicant included further data from the maritime area of France (5 trials) and Latvia (1 trial) within the northeast climatic zone to support performance of the formulation. One trial form Eastern Germany is also used in the summary to complete the data set in Poland.

Justification for the use of 1 trial from the maritime EPPO zone to support efficacy of the product in the northeast EPPO zone:
The applicant conducted one trial in Eastern Germany. Eastern Germany possesses a similar climate to Western Poland and trials from this region are accepted by the Polish authorities as indicative of performance in Western Poland. The untreated disease level was high (32 % severity) and represented a robust test of the performance of Ascra Xpro in conditions representative of the northeast climatic zone.
One application was made from the crop stage BBCH 31 to 49. A summary of main results is shown in tables 6.1.3-60 and 6.1.3-61.

Table 6.1.3-60: Mean efficacy in barley against *Rhynchosporium secalis* in the central registration zone

Treatment	Dose in L/ha	Mean % control on spring/winter barley (maritime & northeast zones together)		
		mean	min-max	count
Untreated (% severity)	-	(24.4)	(6-73)	20
Bell (Tracker, Champion)	1.5	77.0	51-98	20
Aviator Xpro	1.0	86.9	60-100	19
Ascra Xpro	**1.2**	**91.8**	**66-100**	**20**

Table 6.1.3-61: Efficacy in barley against *Rhynchosporium secali*s in the maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on spring/winter barley					
		maritime EPPO zone			northeast EPPO zone (+ maritime)*		
		mean	min-max	count	mean	min-max	count
Untreated (% severity)	-	(28.9)	(6-73)	13	(18.1)	(4-32)	8
Bell (Tracker, Champion)	1.5	74.7	51-92	13	82.5	54-98	8
Aviator Xpro	1.0	90.3	79-100	12	83.1	60-100	8
Ascra Xpro	**1.2**	**92.3**	**79-100**	**13**	**91.9**	**66-100**	**8**

* 7 trials from the northeast EPPO zone + 1 trial from the maritime EPPO zone (DE)

Yield benefit in *Rhynchosporium secalis* barley trials
A total of 17 trials (12 from the maritime and 5 from the northeast EPPO zone) are presented in support of disease control in barley. The trials were conducted in Germany, United Kingdom, France, Czech Republic, Poland and Latvia. The trials included represent a good geographical distribution across the EPPO maritime and northeast climatic EPPO zones. A summary of main results is shown in tables 6.1.3-62 and6.1.3-63.

Table 6.1.3-62: Mean yield benefit in *Rhynchosporium secalis* trials in the central registration zone

Treatment	Dose in L/ha	Mean % relative in spring/winter barley (maritime & northeast EPPO zones together)		
		mean	min-max	count
Untreated (dt/ha)	-	(66.1)	(24-95)	17
Bell (Tracker, Champion)	1.5	111.8	95-169	17
Aviator Xpro	1.0	120.0	100-221	15

Ascra Xpro	**1.2**	**120.8**	**99-254**	**17**

Table 6.1.3-63: Yield benefit in *Rhynchosporium secalis* trials in the maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in spring/winter barley					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated (dt/ha)	-	(71.7)	(46-95)	12	(52.8)	(24-73)	5
Bell (Tracker, Champion)	1.5	109.1	95-118	12	118.3	97-169	5
Aviator Xpro	1.0	113.3	100-126	11	138.3	105-221	4
Ascra Xpro	**1.2**	**112.7**	**99-127**	**12**	**140.3**	**104-254**	**5**

In the central registration zone as a whole, Ascra Xpro applied at 1.2 L/ha provided excellent overall control of *Rhynchosporium secalis* (92%). The formulation provided performance to the reference product Aviator Xpro (87%) with less variation across trials. The effectiveness in the maritime EPPO zone was 92.3% and in the northeast EPPO zone 91.9%.

Additionally to the efficacy the data showed a grain yield increase of 21%. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (HORVX / RHYNSE):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP 1/214, PP 1/223 and PP 1/226. The applicant showed in 20 trials an excellent efficacy of 91.8% (Exceptional achievement) for the control of *Rhynchosporium secalis* in barley based on trials from 2012 and 2013 in the maritime and northeast EPPO zone. Additional a grain yield increase of 21% could also be achieved.

No data were represented for the southeast EPPO zone.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Rhynchosporium secalis* in barley.

DE as zRMS accepts the submitted data. The concerned Member States have to decide themselves whether to accept the lack of data from the southeast EPPO zone or not.

Intended use: 011 (*Pyrenophora teres* / PYRNTE in barley; 1 application per use)

Efficacy against *Pyrenophora teres* in all climatic EPPO zones
A total of 39 trials, 22 in the maritime, 14 in the northeast and 3 in the southeast EPPO zone, targeted *Pyrenophora teres* in 2012 (24 trials) and 2013 (15 trials). The trials were conducted in Belgium (3 trials), Czech Republic (2 trials), Germany (3 trials), United Kingdom (2 trials), Poland (14 trials) and Slovakia (3 trial) representing a good geographical distribution across the zones. The applicant included further data from the maritime area of France (12 trials) to support performance of the formulation. One application was made from the crop stage BBCH 31 to 55. A summary of main results is shown in tables 6.1.3-64 and 6.1.3-65.

Table 6.1.3-64: Mean efficacy in barley against *Pyrenophora teres* in the central registration zone

Treatment	Dose in L/ha	Mean % control on spring/winter barley (all EPPO zones together)		
		mean	min-max	count

Untreated (% severity)	-	25.6	2-74	39
Bell (Tracker, Champion)	1.5	75.8	39-99	39
Aviator Xpro	1.0	87.1	64-100	34
Ascra Xpro	**1.2**	**91.3**	**68-100**	**39**

Table 6.1.3-65: Efficacy in barley against *Pyrenophora teres* in all climatic EPPO zones

Treatment	Dose in L/ha	Mean % control on spring/winter barley								
		maritime EPPO zone			northeast EPPO zone			southeast EPPO zone		
		mean	min-max	count	mean	min-max	count	mean	min-max	count
Untreated (% severity)	-	32.9	5-74	22	19.4	6-53	14	(6.6)	(2-12)	3
Bell (Tracker, Champion)	1.5	71.1	39-93	22	84.4	51-99	14	69.3	60-79	3
Aviator Xpro	1.0	86.6	64-99	20	87.8	76-100	14			
Ascra Xpro	**1.2**	**90.9**	**68-100**	**22**	**92.4**	**77-99**	**14**	**86.4**	**73-99**	**3**

Yield benefit in *Pyrenophora teres* barley trials

A total of 34 trials (21 from the maritime, 11 from the northeast and 2 from the southeast EPPO zone) are presented in support of disease control in barley. The trials were conducted in Germany, United Kingdom, Belgium, France, Czech Republic, Poland and Slovakia. The trials included represent a good geographical distribution across all climatic EPPO zones. A summary of main results is shown in tables 6.1.3-66 and 6.1.3-67.

Table 6.1.3-66: Mean yield benefit in *Pyrenophora teres* trials in the central registration zone

Treatment	Dose in L/ha	Mean % relative in spring/winter barley (all EPPO zones together)		
		mean	min-max	count
Untreated (dt/ha)	-	(63.9)	(10-113)	34
Bell (Tracker, Champion)	1.5	114.0	80-169	34
Aviator Xpro	1.0	121.5	94-221	30
Ascra Xpro	**1.2**	**122.6**	**101-254**	**34**

Table 6.1.3-67: Yield benefit in *Pyrenophora teres* trials in all climatic EPPO zones

Treatment	Dose in L/ha	Mean % control on spring/winter barley								
		maritime EPPO zone			northeast EPPO zone			southeast EPPO zone		
		mean	min-max	count	mean	min-max	count	mean	min-max	count
Untreated (dt/ha)	-	(70.2)	(39-113)	21	(55.6)	(24-73)	11	(42.6)	(11-74)	2
Bell (Tracker, Champion)	1.5	111.4	80-168	21	119.9	97-169	11	109.9	104-116	2
Aviator Xpro	1.0	118.3	94-201	19	127.0	105-221	11			
Ascra Xpro	**1.2**	**119.3**	**101-215**	**21**	**130.4**	**104-254**	**11**	**114.9**	**105-125**	**2**

In the central registration zone as a whole, Ascra Xpro applied at 1.2 L/ha provided excellent overall control of *Pyrenophora teres* (91.3%). The formulation provided slightly better performance to the reference product Aviator Xpro (87.1%) with less variation across trials. The effectiveness in the maritime EPPO zone was 90.9%, in the northeast EPPO zone 92.4% and in the southeast EPPO zone 86.4%.

Additionally to the efficacy the data showed a grain yield increase of 23%. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (HORVX / PYRNTE):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP 1/214, PP 1/223 and PP 1/226. The applicant showed in 39 trials an excellent efficacy of 91.3% (Exceptional achievement) for the control of *Pyrenophora teres* in barley based on trials from 2012 and 2013 in all EPPO zones. Additional a grain yield increase of 23% could also be achieved.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Pyrenophora teres* in barley.

Intended use: 012 (*Puccinia hordei* / PUCCHD in barley; 1 application per use)

Efficacy against *Puccinia hordei* in the maritime, northeast and mediterranean climatic EPPO zone
A total of 17 trials, 7 in the maritime, 8 in the northeast and 2 in the mediterranean EPPO zone targeted *Pyrenophora teres* in 2012 (9 trials) and 2013 (8 trials). The trials were conducted in Germany (2 trials), United Kingdom (2 trials) and Poland (5 trials) representing a good geographical distribution across the zones. The applicant included further data from the maritime area of France (2 trials) and Denmark (1 trial) and Latvia (3 trials) in the northeast climatic EPPO zone to support performance of the formulation.

Justification for the use of 2 trials from the mediterranean EPPO zone to support efficacy of the product in the maritime EPPO zone:
The applicant included two trials with high infestation levels (37-94 % severity) conducted in the mediterranean climatic EPPO zone from southern France. He justified this as the warm dry weather conditions promote very high pressure disease conditions and represent a very robust test of products against this disease.

Justification for the use of 1 trial from the maritime EPPO zone to support efficacy of the product in the northeast EPPO zone:
One trial conducted in Eastern Germany is also used by the applicant. Eastern Germany possesses a similar climate to Western Poland and trials from this region are accepted by the Polish authorities as indicative of performance in Western Poland. The untreated disease level was good (23 % severity) and represented a robust test of the performance of Ascra Xpro in conditions representative of the northeast climatic EPPO zone.

One application was made from the crop stage BBCH 31 to 51. A summary of main results is shown in tables 6.1.3-68 and 6.1.3-69.

Table 6.1.3-68: Mean efficacy in barley against *Puccinia hordei* in the central registration zone

Treatment	Dose in L/ha	Mean % control on spring/winter barley (maritime, northeast & mediterranean EPPO zones together)		
		mean	min-max	count
Untreated (% severity)	-	(29.7)	(7-94)	17
Bell (Tracker, Champion)	1.5	86.2	66-100	17
Aviator Xpro	1.0	92.3	69-100	16

Ascra Xpro	**1.2**	**94.1**	**74-100**	**17**

Table 6.1.3-69: Efficacy in barley against *Puccinia hordei* in the maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on spring/winter barley					
		maritime(+ mediter.)*			northeast (+ maritime)**		
		mean	min-max	count	mean	min-max	count
Untreated (% severity)	-	(34.7)	(7-94)	9	(22.5)	(10-43)	9
Bell (Tracker, Champion)	1.5	82.7	66-100	9	87.7	68-99	9
Aviator Xpro	1.0	92.9	72-100	9	92.2	69-98	8
Ascra Xpro	**1.2**	**92.3**	**74-100**	**9**	**96.0**	**93-100**	**9**

* 7 trials from the EPPO maritime zone + 2 from the EPPO Mediterranean zone (FR)
** 8 trials from the EPPO northeast zone + 1 trial from the EPPO maritime zone (DE)

Yield benefit in *Puccinia hordei* barley trials

A total of 14 trials (7 from the maritime and 7 from the northeast EPPO zone) are presented in support of disease control in barley. The trials were conducted in Germany, United Kingdom, France, Denmark, Poland and Latvia. The trials included represent a good geographical distribution across the maritime and northeast climatic EPPO zones. A summary of main results is shown in tables 6.1.3-70 and 6.1.3-71.

Table 6.1.3-70: Mean yield benefit in *Puccinia hordei* trials in the central registration zone

Treatment	Dose in L/ha	Mean % relative in spring/winter barley (maritime & northeast EPPO zones together)		
		mean	min-max	count
Untreated (dt/ha)	-	(58.8)	(31-88)	14
Bell (Tracker, Champion)	1.5	118.8	104-150	14
Aviator Xpro	1.0	121.2	105-156	13
Ascra Xpro	**1.2**	**122.2**	**108-155**	**14**

Table 6.1.3-71: Yield benefit in *Puccinia hordei* trials in the maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in spring/winter barley					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated (dt/ha)	-	(66.1)	(52-88)	7	(51.6)	(31-73)	7
Bell (Tracker, Champion)	1.5	114.1	104-131	7	123.5	106-150	7
Aviator Xpro	1.0	116.6	110-134	7	126.7	105-156	6
Ascra Xpro	**1.2**	**118.0**	**108-133**	**7**	**126.3**	**110-155**	**7**

In the central registration zone as a whole, Ascra Xpro applied at 1.2 L/ha provided excellent overall control of *Puccinia hordei* (94%). The formulation provided comparable performance to the reference product Aviator Xpro (92%). The effectiveness in the maritime EPPO zone was 92.3% and in the northeast EPPO zone 96.0%.

Additionally to the efficacy the data showed a grain yield increase of 22%. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (HORVX / PUCCHD):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP

1/26, PP_1/214, PP_1/223 and PP_1/226. The applicant showed in 17 trials an excellent efficacy of 94.0% (Exceptional achievement) for the control of *Puccinia hordei* in barley based on trials from 2012 and 2013 in the maritime and northeast EPPO zones. Additional a grain yield increase of 22% could also be achieved.

No data were represented for the southeast EPPO zone.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Puccinia hordei* in barley.

DE as zRMS accepts the submitted data. The concerned Member States have to decide themselves whether to accept the lack of data from the southeast EPPO zone or not.

Intended use: 013 (*Ramularia collo-cygni* / RAMUCC in barley; 1 application per use)

Efficacy against *Ramularia collo-cygni* in the maritime, northeast and mediterranean climatic EPPO zone
A total of 12 trials, 5 in the maritime and 5 in the northeast, plus 2 in the mediterranean EPPO zone targeted *Ramularia collo-cygni* in 2012 (5 trials) and 2013 (7 trials). The trials were conducted in Germany (2 trials), United Kingdom (1 trial) and Poland (4 trials) representing a geographical distribution across the zones. The applicant included further data from the maritime area of France (1 trial) and Denmark (1 trial) and Lithuania (1 trial) in the northeast climatic EPPO zone to support performance of the formulation. In order to increase the number of trials 2 further trials from the mediterranean climatic zone of France were included by the applicant.

Justification for the use of 2 trials from the mediterranean EPPO zone to support efficacy of the product in the maritime EPPO zone:
The applicant based the justification for the inclusion of these trials on the fact that *Ramularia collo-cygni* is now a global issue in Europe. It is largely a seed born disease which grows up within the plant and tends to express symptoms later in the season when the pathogen produced toxin in response to conditions of stress, which can include temperature extremes or significant moisture. Thus the applicant concluded, it is proposed given the nature of the life-cycle and the fact that the disease levels in the mediterranean trials are high and provide a good test, it is justified to include data from the mediterranean zone of France to support data generated within the maritime climatic EPPO zone.
One application was made from the crop stage BBCH 31 to 61. A summary of main results is shown in tables 6.1.3-72 and 6.1.3-73.

Table 6.1.3-72: Mean efficacy in barley against *Ramularia collo-cygni* in the central registration zone

Treatment	Dose in L/ha	Mean % control on spring/winter barley (maritime, northeast & mediterranean together)		
		mean	min-max	count
Untreated (% severity)	-	(38.0)	(5-100)	12
Bell (Tracker, Champion)	1.5	82.1	69-92	12
Aviator Xpro	1.0	90.3	79-99	12
Ascra Xpro	**1.2**	**95.4**	**85-100**	**12**

Table 6.1.3-73: Efficacy in barley against *Ramularia collo-cygni* in the maritime and northeast climatic EPPO zone

Treatment	Dose	Mean % control on spring/winter barley

	in L/ha	maritime EPPO zone (+medit)*			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated (% severity)	-	(58.1)	(24-100)	7	(9.8)	(5-14)	5
Bell (Tracker, Champion)	1.5	84.7	74-92	7	78.5	69-91	5
Aviator Xpro	1.0	94.1	79-99	7	85.1	79-99	5
Ascra Xpro	**1.2**	**96.4**	**93-99**	**7**	**94.0**	**85-100**	**5**

* 5 trials from the EPPO maritime zone + 2 trials from the EPPO mediterranean zone (FR)

Yield benefit in *Ramularia collo-cygni* barley trials

A total of 8 trials (4 from the maritime and 4 from the northeast EPPO zone) are presented in support of disease control in barley. The trials were conducted in Germany, United Kingdom, Denmark, Poland and Lithuania. The trials included represent a good geographical distribution across the maritime and northeast climatic EPPO zones. A summary of main results is shown in tables 6.1.3-74 and 6.1.3-75.

Table 6.1.3-74: Mean yield benefit in *Ramularia collo-cygni* trials in the central registration zone

Treatment	Dose in L/ha	Mean % relative in spring/winter barley (maritime and northeast EPPO zones together)		
		mean	min-max	count
Untreated (dt/ha)	-	(59.5)	(44-85)	8
Bell (Tracker, Champion)	1.5	109.2	97-119	8
Aviator Xpro	1.0	113.7	105-122	8
Ascra Xpro	**1.2**	**113.8**	**103-127**	**8**

Table 6.1.3-75: Yield benefit in *Ramularia collo-cygni* trials in the maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in spring/winter barley					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated (dt/ha)	-	(66.4)	(44-85)	4	(52.7)	(45-63)	4
Bell (Tracker, Champion)	1.5	108.5	104-116	4	109.9	97-119	4
Aviator Xpro	1.0	112.1	106-118	4	115.2	105-122	4
Ascra Xpro	**1.2**	**109.3**	**103-115**	**4**	**118.2**	**104-127**	**4**

In the central registration zone as a whole, Ascra Xpro applied at 1.2 L/ha provided excellent overall control of *Ramularia collo-cygni* (95%). The formulation provided superior performance to the reference product Aviator Xpro (90%) with less variation across the trials. The effectiveness in the maritime EPPO zone was 96.4% and in the northeast EPPO zone 94.0%.

Additionally to the efficacy the data showed a grain yield increase of 14%. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (HORVX / RAMUCC):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP_1/214, PP_1/223 and PP_1/226. The applicant showed in 12 trials an excellent efficacy of 95.4% (Exceptional achievement) for the control of *Ramularia collo-cygni* in barley based on trials from 2012 and 2013 in the maritime and northeast EPPO zones. Additional a grain yield increase of 14% could also be achieved. No data were represented for the southeast EPPO zone.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Ramularia collo-cygni* in barley.

DE as zRMS accepts the submitted data. The concerned Member States have to decide themselves whether to accept the lack of data from the southeast EPPO zone or not.

Intended use: 014 (decrease of non-parasitic leaf spots / YBFMI in barley; 1 application per use)

Efficacy against Physiological leaf spot in the maritime and mediterranean climatic EPPO zone
A total of 10 trials, 9 in the maritime and 1 in the mediterranean EPPO zone targeted Physiological leaf spot in 2012 (4 trials) 2013 (1 trial) and 2015 (5trials). The trials were conducted in Germany (4 trials) and Belgium (4 trial) representing a geographical distribution across the maritime zone. The applicant included further data from the maritime area of France (1 trial) and from Switzerland (1 trial) to support performance of the formulation.
One application was made from the crop stage BBCH 39 to 51. A summary of main results is shown in table 6.1.3-76.

Table 6.1.3-76: Efficacy in barley against Physiological leaf spot in the maritime climatic zone

Treatment	Dose in L/ha	Mean % control on spring/winter barley		
		mean	min-max	count
Untreated (% severity)	-	(38.2)	(6-78)	10
Aviator Xpro	1.0	90.3	80-96	10
Ascra Xpro	**1.2**	**93.1**	**86-98**	10

Yield benefit in Physiological leaf spot barley trials
A total of 10 trials (all from the maritime EPPO zone) are presented in support of disease control in barley. The trials were conducted in Germany, Belgium, Switzerland and France. A summary of main results is shown in table 6.1.3-77.

Table 6.1.3-77: Yield benefit in Physiological leaf spot trials in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in spring/winter barley maritime EPPO zone		
		mean	min-max	count
Untreated (dt/ha)	-	(85.3)	(66-113)	10
Aviator Xpro	1.0	113.1	105-120	10
Ascra Xpro	**1.2**	**115.0**	**107-126**	**10**

In the maritime zone Ascra Xpro applied at 1.2 L/ha provided an outstanding overall control of Physiological leaf spot in Barley (93%, range 86-98%). The formulation provided slightly better performance than the top reference product Aviator Xpro (90%).
Despite the small data set for the applicant, the high level of infestation and disease control, comparable or superior to that provided by the reference product Aviator Xpro, support the proposed claim for control of Physiological leaf spot in Barley in those countries within the maritime climatic EPPO area of the EU central registration regulatory zone.

Additionally to the efficacy the data showed a grain yield increase of 15%. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (HORVX / YBFMI):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP 1/214, PP 1/223 and PP 1/226. The applicant showed in 10 trials an excellent efficacy of 93.1% (Exceptional achievement) for the control of Physiological leaf spot in barley based on trials from 2012, 2013 and 2015 in the maritime EPPO zone. Additional a grain yield increase of 15% could also be achieved.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against Physiological leaf spot in barley.

Intended use: 14a (*Puccinia striiformis* / PUCCST in barley, 1 application per use)

Efficacy against *Puccinia striiformis*
No data were presented by the applicant in barley. For him however, as the disease is similar on wheat, reference is made to the performance of Ascra Xpro against *Puccinia striiformis* in wheat. The disease occurred in 11 trials conducted across the maritime climatic EPPO zone in 2012 and 2013 and Ascra Xpro provided high levels of control (94%). Alongside this the applicant argues, Ascra Xpro also provided excellent control of other rust diseases like *Puccinia hordei* in barley, *Puccinia recondita* in wheat, triticale and rye and *Puccinia coronata* in oats, indicating the high level of activity of this formulation against rust diseases on cereals in general. There were no differences in performance between the maritime and northeast climatic EPPO zones for any of the rust pathogens indicating a consistency of performance regardless of climatic conditions. Therefore the applicant concluded that Ascra Xpro will provide control of *Puccinia striiformis* in barley crops when applied according to guidance.

Conclusion (HORVX / PUCCST):

The presented data don´t correspond with the requirements of the EPPO ~~standard~~Standard PP- 1/226. No data were provided by the applicant for the effectiveness of this intended use against *Puccinia striiformis* in barley. At least a few trials have to be done so that this application can be proposed for the authorization.

It can be concluded that without data the plant protection product Ascra Xpro **cannot be proposed** for authorisation against *Puccinia striiformis* in barley.

Intended use: 015 (*Rhynchosporium secalis* / RHYNSE in rye; 2 applications per use)

Efficacy against *Rhynchosporium secalis* (RHYNSE) in the maritime and northeast climatic EPPO zone
A total of 13 trials, 8 in the maritime and 5 in the northeast EPPO zone, targeted *Rhynchosporium secalis* in 2012 (3 trials) and 2013 (10 trials). The trials were conducted in Germany (5 trials) and Poland (3 trials). The applicant included further data from the maritime area of France (2 trials) and Denmark (1 trial) and Latvia (1 trial) and Lithuania (1 trial) as part of the northeast climatic EPPO zone to support performance of the formulation. In addition 2 trials from eastern Germany (maritime EPPO zone) were used in the summary for the northeast EPPO zone.

Justification for the use of 2 trials from the maritime EPPO zone to support efficacy of the product in the northeast EPPO zone:
The applicant conducted two trials in Eastern Germany. Eastern Germany possesses a similar climate to Western Poland and trials from this region are accepted by the Polish authorities as indicative of performance in Western Poland. The untreated disease levels were high (25-45 %

severity) and represented a robust test of the performance of Ascra Xpro in conditions representative of the northeast climatic EPPO zone.

One to two applications were made from the crop stage BBCH 31 to 61. A summary of main results is shown in tables 6.1.3-78 and 6.1.3-79.

Table 6.1.3-78: Mean efficacy in rye against *Rhynchosporium secalis* in the central registration zone

Treatment	Dose in L/ha	Mean % control on rye (maritime & northeast EPPO zones together)		
		mean	min-max	count
Untreated (% severity)	-	(30.4)	(14-65)	13
Tracker / Prosaro	1.5 / 1.0	70.3	49-90	13
Aviator / Skyway Xpro	1.25	84.6	62-99	12
Ascra Xpro	**1.5**	**87.6**	**68-100**	**13**

Table 6.1.3-79: Efficacy in rye against *Rhynchosporium secalis* in the maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on rye					
		maritime EPPO zone			northeast EPPO zone (+ marit.)*		
		mean	min-max	count	mean	min-max	count
Untreated (% severity)	-	(36.8)	(15-65)	8	(24.4)	(14-45)	7
Tracker / Prosaro	1.5 / 1.0	73.9	50-90	8	65.7	49-71	7
Aviator / Skyway Xpro	1.25	80.7	62-94	7	86.1	74-99	7
Ascra Xpro	**1.5**	**84.5**	**68-94**	**8**	**89.4**	**79-100**	**7**

* 5 trials from the EPPO northeast zone + 2 trials from the EPPO maritime zone (DE)

Yield benefit in *Rhynchosporium secalis* rye trials

A total of 12 trials (8 from the maritime and 4 from the northeast EPPO zone) are presented in support of disease control in rye. The trials were conducted in Germany, France, Denmark, Poland, Latvia and Lithuania. The trials included represent a geographical distribution across the maritime and northeast climatic EPPO zones. A summary of main results is shown in tables 6.1.3-80 and 6.1.3-81.

Table 6.1.3-80: Mean yield benefit in *Rhynchosporium secalis* trials in the central registration zone

Treatment	Dose in L/ha	Mean % relative in rye (maritime & northeast EPPO zones together)		
		mean	min-max	count
Untreated (dt/ha)	-	(60.9)	(40-85)	12
Tracker / Prosaro	1.5 / 1.0	111.0	69-140	12
Aviator / Skyway Xpro	1.25	115.2	94-134	11
Ascra Xpro	**1.5**	**117.1**	**105-142**	**12**

Table 6.1.3-81: Yield benefit in *Rhynchosporium secalis* trials in the maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in rye					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated (dt/ha)	-	(69.4)	(44-85)	8	(44.10)	(40-52)	4
Tracker / Prosaro	1.5 / 1.0	112.4	106-121	8	108.4	69-140	4

Aviator / Skyway Xpro	1.25	115.6	109-121	7	114.5	94-134	4
Ascra Xpro	**1.5**	**115.3**	**105-126**	**8**	**120.8**	**108-142**	**4**

In the central registration zone as a whole, Ascra Xpro applied at 1.5 L/ha provided good mean control of *Rhynchosporium secalis* (88%). The formulation provided comparable performance to the reference product Aviator Xpro (85%). The effectiveness in the maritime EPPO zone was 84.5% and in the northeast EPPO zone 89.4%.

Additionally to the efficacy the data showed a grain yield increase of 17%. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (SECCE / RHYNSE):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP_1/214, PP_1/223 and PP_1/226. The applicant showed in 13 trials a good efficacy of 87.6% (Extensive achievement) for the control of *Rhynchosporium secalis* in rye based on trials from 2012 and 2013 in the maritime and northeast EPPO zones. Additional a grain yield increase of 17% could also be achieved.

No data were represented for the southeast EPPO zone.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Rhynchosporium secalis* in rye.

DE as zRMS accepts the submitted data. The concerned Member States have to decide themselves whether to accept the lack of data from the southeast EPPO zone or not.

Intended use: 029 (*Rhynchosporium secalis* / RHYNSE in rye; 1 application per use)

Efficacy against *Rhynchosporium secalis* (RHYNSE) in the maritime climatic EPPO zone
A total of 8 trials were conducted in the maritime EPPO zone against RHYNSE in 2012 (3 trials) and 2013 (5 trials). The trials were conducted in Germany (5 trials), France (2 trials) and Denmark (1 trial) and reflect the performance of the product in the maritime EPPO zone. One application was made from the crop stage BBCH 43 to 53. A summary of main results is shown in table 6.1.3-82.

Table 6.1.3-82: Efficacy in rye against *Rhynchosporium secalis* in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on rye		
		mean	min-max	count
Untreated (% severity)	-	(36.8)	15-65	8
Bell / Prosaro	1.5 / 1.0	73.9	50-90	8
Aviator / Skyway Xpro	1.25	80.7	62-94	7
Ascra Xpro	**1.5**	**84.5**	**68-94**	**8**

Yield benefits have been measured in all trials in support of disease control in rye. The trials were conducted in Germany, France and Denmark. The trials included represent a geographical distribution across the maritime climatic EPPO zone. A summary of main results is shown in table 6.1.3-83.

Table 6.1.3-83: Yield benefit in *Rhynchosporium secalis* trials in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in rye, maritime EPPO zone		
		mean	min-max	count
Untreated (dt/ha)	-	(69.4)	(44-85)	8
Bell / Prosaro	1.5 / 1.0	112.4	106-121	8
Aviator / Skyway Xpro	1.25	115.6	109-121	7
Ascra Xpro	**1.5**	**115.3**	**105-126**	**8**

Data shows that Ascra Xpro achieved good (84.5%) disease control at 1.5 L/ha. It was at least similar to Aviator / Skyway Xpro.
Alongside this the applicant mentioned, that reference is made to the high and consistent level of control of *Rhynchosporium secalis* in barley across large data sets for 1 application as reported previously.

Additionally to the efficacy the data showed a grain yield increase of 15%. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (SECCE / RHYNSE):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP_1/214 and PP_1/223. The number of trials (8) carried out in the maritime EPPO zone was understated according to the EPPO ~~standard~~Standard PP_1/226. The efficacy for the control of *Rhynchosporium secalis* in rye was good (84.5%) based on trials from 2012 and 2013. The efficacy of *Rhynchosporium secalis* in the intended use 015 with 2 applications was also excellent (91.8%) and can be extrapolated.
Additional a grain yield increase of 15% could also be achieved.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Rhynchosporium secalis* in rye.

Intended use: 016 (*Puccinia recondita* / PUCCRE in rye; 2 applications per use)

Efficacy against *Puccinia recondita* (PUCCRE) in the maritime and northeast climatic EPPO zone
A total of 15 trials, 13 in the maritime and 2 in the northeast EPPO zone, targeted *Puccinia recondita* in 2012 (9 trials) and 2013 (6 trials). The trials were conducted in Germany (10 trials) and Poland (1 trial). The applicant included further data from the maritime area of France (2 trials) and Denmark (1 trial) and Latvia (1 trial) as part of the northeast climatic EPPO zone to support performance of the formulation. In addition trials from eastern Germany (maritime EPPO zone) were used in the summary for the northeast EPPO zone.

Justification for the use of 7 trials from the maritime EPPO zone to support efficacy of the product in the northeast EPPO zone:
Due to the small size of the data set for the northeast climatic EPPO zone area, the applicant made reference to the performance of Ascra Xpro in the trials across the EU central registration regulatory zone as a whole and especially to German trials. The disease control is high in all the climatic regions without significant variation in the levels of control achieved, therefore it is reasoned the data set across the zone can be considered in total. Seven trials conducted in Eastern part of Germany are included. Trials from this region are accepted by the Polish authorities as indicative of performance in Western Poland. The applicant mentioned that the untreated

disease levels were high (26-61 % severity) and represented a robust test of the performance of Ascra Xpro in conditions representative of the northeast climatic EPPO zone.

One application was made from the crop stage BBCH 32 to 59. A summary of main results is shown in tables 6.1.3-84 and 6.1.3-85.

Table 6.1.3-84: Mean efficacy in rye against *Puccinia recondita* in the central registration zone

Treatment	Dose in L/ha	Mean % control on rye (maritime & northeast EPPO zones together)		
		mean	min-max	count
Untreated (% severity)	-	(28.0)	(8-61)	15
Tracker / Prosaro	1.5 / 1.0	80.6	51-100	15
Aviator / Skyway Xpro	1.25	94.2	80-100	13
Ascra Xpro	**1.5**	**94.5**	**81-100**	**15**

Table 6.1.3-85: Efficacy in rye against *Puccinia recondita* in the maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on rye					
		maritime EPPO zone			northeast EPPO zone (+ marit.)*		
		mean	min-max	count	mean	min-max	count
Untreated (% severity)	-	(30.1)	(8-61)	13	(30.6)	(14-61)	9
Tracker / Prosaro	1.5 / 1.0	79.3	51-100	13	78.0	51-99	9
Aviator / Skyway Xpro	1.25	94.7	80-100	11	93.6	80-100	9
Ascra Xpro	**1.5**	**93.9**	**81-100**	**13**	**96.0**	**88-100**	**9**

* 2 trials from the northeast EPPO zone + 7 trials from the maritime EPPO zone (DE)

Yield benefit in *Puccinia recondita* rye trials

A total of 13 trials (12 from the maritime and 1 from the northeast EPPO zone) are presented in support of disease control in rye. The trials were conducted in Germany, France, Denmark and Latvia. The trials included represent a geographical distribution across the maritime and north-east climatic EPPO zones. A summary of main results is shown in tables 6.1.3-86 and 6.1.3-87.

Table 6.1.3-86: Mean yield benefit in *Puccinia recondita* trials in the central registration zone

Treatment	Dose in L/ha	Mean % relative in rye (maritime & northeast EPPO zones together)		
		mean	min-max	count
Untreated (dt/ha)	-	(68.2)	(39-96)	13
Tracker / Prosaro	1.5 / 1.0	115.2	105-140	13
Aviator / Skyway Xpro	1.25	121.7	106-146	11
Ascra Xpro	**1.5**	**124.6**	**105-158**	**13**

Table 6.1.3-87: Yield benefit in *Puccinia recondita* trials in the maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in rye					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated (dt/ha)	-	(70.4)	(39-96)	12	(42.0)	(-)	1
Tracker / Prosaro	1.5 / 1.0	113.1	105-131	12	139.9	-	1
Aviator / Skyway Xpro	1.25	120.5	106-146	10	134.1	-	1
Ascra Xpro	**1.5**	**123.2**	**105-158**	**12**	**141.7**	**-**	**1**

In the central registration zone as a whole, Ascra Xpro applied at 1.5 L/ha provided excellent mean control of *Puccinia recondita* (95%) for one application. The formulation provided comparable performance to the reference product Aviator Xpro (94%). There was no big difference in the level of performance between the maritime and northeast climatic EPPO zones (maritime 93.9% and northeast 96.0%).

Additionally to the efficacy the data showed a grain yield increase of 23% for one application each trial. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (SECCE /PUCCRE):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP 1/214 and PP 1/223. The applied intended use (*Puccinia recondita* in rye) contains two applications, but submitted efficacy field data contain only one application. No trial was provided for two applications in this intended use. The trials do not match the requested indication.

It can be concluded **not** to accept the data provided by the applicant to demonstrate the effectiveness against *Puccinia recondita* in rye with two applications.

Intended use: 030 (*Puccinia recondita* / PUCCRE in rye; 1 application per use)

Efficacy against *Puccinia recondita* (PUCCRE) in the maritime climatic EPPO zone
A total of 13 trials were successfully conducted in the EPPO maritime zone against PUCCRE in 2012 (9 trials) and 2013 (4 trials). The trials were conducted in Germany (10 trials), France (2 trials) and Denmark (1 trial) and reflect the performance of the product in the maritime EPPO zone. One application was made from the crop stage BBCH 32 to 59. A summary of main results is shown in table 6.1.3-88.

Table 6.1.3-88: Efficacy in rye against *Puccinia recondita* in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on rye maritime EPPO zone		
		mean	min-max	count
Untreated (% severity)	-	(30.1)	8-61	13
Bell / Prosaro	1.5 / 1.0	79.3	51-100	13
Aviator / Skyway Xpro	1.25	94.7	80-100	11
Ascra Xpro	**1.5**	**93.9**	**81-100**	**13**

Yield benefits have been measured in 12 trials in support of disease control in rye. The trials were conducted in Germany, France and Denmark. The trials included represent a geographical distribution across the maritime climatic EPPO zone. A summary of main results is shown in table 6.1.3-89.

Table 6.1.3-89: Yield benefit in *Puccinia recondita* trials in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in rye / maritime zone		
		mean	min-max	count
Untreated (dt/ha)	-	(70.4)	(39-96)	12
Tracker / Prosaro	1.5 / 1.0	113.1	105-131	12
Aviator / Skyway Xpro	1.25	120.5	106-146	10
Ascra Xpro	**1.5**	**123.2**	**105-158**	**12**

Data shows that Ascra Xpro achieved excellent disease control (93.9 %) at 1.5 L/ha. It was similar to Aviator / Skyway Xpro.

Additionally to the efficacy the data showed a grain yield increase of 23%. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (SECCE / PUCCRE):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP 1/214, PP 1/223 and PP 1/226. The applicant showed in 13 trials an excellent efficacy of 93.9% (Exceptional achievement) for the control of *Puccinia recondita* in rye based on trials from 2012 and 2013 in the maritime and northeast EPPO zones. Additional a grain yield increase of 23% could also be achieved.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Puccinia recondita* in rye.

Intended use: 016a (*Erysiphe graminis* / ERYSGR in rye, 2 applications per use)

Efficacy against *Erysiphe graminis* in the maritime and northeast climatic EPPO zone
No data were presented by the applicant in rye. However for him, as the disease is very similar on other cereal crops, reference is made to the consistently high levels of control of *Erysiphe graminis* species in both wheat and barley regardless of the climatic EPPO zone. Across 25 trials conducted in wheat in the EU central regulatory zone, Ascra Xpro provided consistently high levels of disease control (91%) and was superior to both commercial reference products. There was no difference in the level of control between the maritime and northeast EPPO climatic zones. Across 22 trials conducted in barley in the EU central regulatory zone, for the applicant it also provided consistently high levels of disease control (93%) with no difference between the maritime and northeast climatic EPPO zones. Given the high level of disease control against *Erysiphe graminis* species in both wheat and barley, the applicant concluded that Ascra Xpro can also be expected to provide similarly high levels of disease control against *Erysiphe graminis* in rye.

Conclusion (SECCE / ERYSGR):

No data were provided by the applicant for the effectiveness of this intended use against *Erysiphe graminis* in rye. At least a few trials have to be done so that this application can be proposed for the authorization.

It can be concluded that without data the plant protection product Ascra Xpro **cannot be proposed** for authorisation against *Erysiphe graminis* in rye.

Intended use: 016b (*Pseudocercosporella herpotrichoides* / PSDCHE in rye, 1 application per use)

Efficacy against *Pseudocercosporella herpotrichoides* in the maritime and northeast climatic EPPO zone
No data were presented by the applicant in rye. However for him, reference is made to the dose of prothioconazole delivered by the formulation (195g.a.s./ha) and the performance of the formulation against Eyespot in both wheat and barley. Prothioconazole is known to provide good

activity against *Pseudocercosporella herpotrichoides*. Ascra Xpro provided good suppression of both incidence and severity of *Pseudocercosporella herpotrichoides* in these crops across all climatic EPPO zones. The same pathogen is responsible for Eyespot in all cereal crops. Therefore the applicant reasoned that Ascra Xpro will provide equivalent control of Eyespot in rye.

Conclusion (SECCE / PSDCHE):

No data were provided by the applicant for the effectiveness of this intended use against *Pseudocercosporella herpotrichoides* in rye. At least a few trials have to be done so that this application can be proposed for the authorization.

It can be concluded that without data the plant protection product Ascra Xpro **cannot be proposed** for authorisation against *Pseudocercosporella herpotrichoides* in rye.

Intended use: 017 (*Erysiphe graminis* / ERYSGR in triticale; 2 applications per use)

Efficacy against *Erysiphe graminis* (ERYSGR) in the maritime and northeast climatic EPPO zone
A total of 11 trials, 7 in the maritime and 4 in the northeast EPPO zone, targeted *Erysiphe graminis* in 2012 (6 trials) and 2013 (5 trials). The trials were conducted in Germany (4 trials) and Poland (2 trials). The applicant included further data from the maritime area of France (3 trials) and Latvia (1 trial) and Lithuania (1 trial) as part of the northeast climatic EPPO zone to support performance of the formulation. In addition 2 trials from eastern Germany (maritime EPPO zone) were used in the summary for the northeast EPPO zone.

Justification for the use of 2 trials from the maritime EPPO zone to support efficacy of the product in the northeast EPPO zone:
The applicant used also two trials conducted in Eastern Germany. Eastern Germany possesses a similar climate to Western Poland and trials from this region are accepted by the Polish authorities as indicative of performance in Western Poland. The untreated disease levels were sufficient (8-9 % severity) to represent a good test of the performance of Ascra Xpro in conditions representative of the northeast climatic EPPO zone.
One to two applications were made from the crop stage BBCH 32 to 53. A summary of main results is shown in tables 6.1.3-90 and 6.1.3-91.

Table 6.1.3-90: Mean efficacy in triticale against *Erysiphe graminis* in the central registration zone

Treatment	Dose in L/ha	Mean % control on triticale (maritime & northeast EPPO zones together)		
		mean	min-max	count
Untreated (% severity)	-	(15.2)	(7-33)	11
Tracker / Input	1.5 / 1.25	81.9	60-100	11
Aviator / Skyway Xpro	1.25	87.3	65-100	9
Ascra Xpro	**1.5**	**89.3**	**69-100**	**11**

Table 6.1.3-91: Efficacy in triticale against *Erysiphe graminis* in the maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on triticale					
		maritime EPPO zone			northeast EPPO zone (+ marit.)*		
		mean	min-max	count	mean	min-max	count
Untreated (% severity)	-	(17.0)	(8-33)	7	(10.9)	(7-15)	6

Tracker / Input	1.5 / 1.25	78.1	60-100	7	89.9	79-100	6
Aviator / Skyway Xpro	1.25	85.0	65-100	5	90.6	82-100	6
Ascra Xpro	**1.5**	**87.4**	**69-100**	**7**	**91.5**	**78-100**	**6**

* 4 trials from the EPPO northeast zone + 2 trials from the EPPO maritime zone (DE)

Yield benefit in *Erysiphe graminis* triticale trials

A total of 11 trials (7 from the maritime and 4 from the northeast EPPO zone) are presented in support of disease control in triticale. The trials were conducted in Germany, France, Poland, Latvia and Lithuania. The trials included represent a geographical distribution across the maritime and northeast climatic EPPO zones. A summary of main results is shown in tables 6.1.3-92 and 6.1.3-93.

Table 6.1.3-92: Mean yield benefit in *Erysiphe graminis* trials in the central registration zone

Treatment	Dose in L/ha	Mean % relative in triticale (maritime & northeast EPPO zones together)		
		mean	min-max	count
Untreated (dt/ha)	-	(64.4)	(42-93)	11
Tracker / Input	1.5 / 1.25	112.7	101-122	11
Aviator / Skyway Xpro	1.25	117.8	105-130	9
Ascra Xpro	**1.5**	**118.8**	**107-135**	**11**

Table 6.1.3-93: Yield benefit in *Erysiphe graminis* trials in the maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in triticale					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated (dt/ha)	-	(68.3)	(42-93)	7	(57.6)	(44-72)	4
Tracker / Input		113.1	109-122	7	112.1	101-122	4
Aviator / Skyway Xpro	1.25	119.1	108-127	5	116.4	105-130	4
Ascra Xpro	**1.5**	**119.3**	**107-133**	**7**	**117.9**	**107-135**	**4**

In the central registration zone as a whole, Ascra Xpro applied at 1.5 L/ha provided good mean control of *Erysiphe graminis* (89%). The formulation provided comparable performance to the reference product Aviator Xpro (87%). There was no difference in the level of performance between the maritime and northeast climatic EPPO zones (maritime 87.4% and northeast 91.5%).

Additionally to the efficacy the data showed a grain yield increase of 19%. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (TTLSS / ERYSGR):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP 1/214, PP 1/223 and PP 1/226. The applicant showed in 11 trials a good to excellent efficacy of 89.3% (Extensive achievement) for the control of *Erysiphe graminis* in triticale based on trials from 2012 and 2013 in the maritime and northeast EPPO zones. Additional a grain yield increase of 19% could also be achieved.

No data were represented for the southeast EPPO zone.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Erysiphe graminis* in triticale.

DE as zRMS accepts the submitted data. The concerned Member States have to decide themselves whether to accept the lack of data from the southeast EPPO zone or not.

Intended use: 031 (*Erysiphe graminis* / ERYSGR in triticale; 1 application per use)

Efficacy against *Erysiphe graminis* (ERYSGR) in the maritime climatic EPPO zone
A total of 7 trials were successfully conducted in the maritime EPPO zone against ERYSGR in 2012 (4 trials) and 2013 (3 trials). The trials were conducted in Germany (4 trials) and France (3 trials) and reflect the performance of the product in the maritime EPPO zone. One application was made from the crop stage BBCH 33 to 51. A summary of main results is shown in table 6.1.3-94.

Table 6.1.3-94: Efficacy in triticale against *Erysiphe graminis* in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on triticale		
		mean	min-max	count
Untreated (% severity)	-	(17.0)	9-33	7
Bell / Input	1.5 / 1.25	78.1	60-100	7
Aviator / Skyway Xpro	1.25	85.0	65-100	5
Ascra Xpro	**1.5**	**87.4**	**69-100**	**7**

Yield benefits have been measured in all trials in support of disease control in triticale. The trials were conducted in Germany and France and represent a geographical distribution across the maritime climatic EPPO zone. A summary of main results is shown in table 6.1.3-95.

Table 6.1.3-95: Yield benefit in *Erysiphe graminis* trials in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in triticale		
		mean	min-max	count
Untreated (dt/ha)	-	(68.3)	(42-93)	7
Tracker / Input	1.5 / 1.25	113.1	109-122	7
Aviator / Skyway Xpro	1.25	119.1	108-127	5
Ascra Xpro	**1.5**	**119.3**	**107-133**	**7**

Data shows that Ascra Xpro achieved good disease control (87.4%) at 1.5 L/ha. It was similar to Aviator / Skyway Xpro (85%).
Alongside this the applicant mentioned, reference is made to the high and consistent level of control of *Erysiphe graminis* in wheat and barley across large data sets for 1 application as reported previously.

Additionally to the efficacy the data showed a grain yield increase of 19%. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (TTLSS / ERYSGR):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP_1/214 and PP_1/223. The number of trials (7) carried out in the maritime EPPO zone was understated according to the EPPO ~~standard~~Standard PP_1/226. The efficacy for the control of *Erysiphe graminis* in triticale was good (87.4%) based on trials from 2012 and 2013. The efficacy of *Erysiphe graminis* in wheat (86.8%) and barley (93%) was good to

excellent and can be extrapolated.
Additional a grain yield increase of ~~15~~19% could also be achieved.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Erysiphe graminis* in triticale.

Intended use: 018 (*Septoria* spp. / SEPTSP in triticale; 2 applications per use)

Efficacy against *Septoria spp.* (SEPTSP) in the maritime and northeast climatic EPPO zone
A total of 10 trials, 6 in the maritime and 4 in the northeast EPPO zone, targeted *Septoria* spp. in 2012 (7 trials) and 2013 (3 trials). The trials were conducted in Germany (4 trials) and Poland (3 trials). The applicant included further data from the maritime area of France (2 trials) and Lithuania (1 trial) as part of the EPPO northeast climatic to support performance of the formulation. In addition 2 trials from eastern Germany were used in the summary for the northeast zone.
Justification for the use of 2 trials from the maritime EPPO zone to support efficacy of the product in the EPPO northeast zone:
The applicant also used two trials conducted in Eastern Germany. Eastern Germany possesses a similar climate to Western Poland and trials from this region are accepted by the Polish authorities as indicative of performance in Western Poland. The untreated disease level was good (10-29 % severity) and represented a robust test of the performance of Ascra Xpro in conditions representative of the northeast climatic EPPO zone.
One to two applications were made from the crop stage BBCH 31 to 51. A summary of main results is shown in tables 6.1.3-96 and 6.1.3-97.

Table 6.1.3-96: Mean efficacy in triticale against *Septoria* spp. in the central registration zone

Treatment	Dose in L/ha	Mean % control on triticale (maritime & northeast EPPO zones together)		
		mean	min-max	count
Untreated (% severity)	-	(23.1)	(5-45)	10
Tracker / Input	1.5 / 1.25	80.5	63-98	10
Aviator / Skyway Xpro	1.25	86.6	73-92	8
Ascra Xpro	**1.5**	**88.0**	**68-98**	**10**

Table 6.1.3-97: Efficacy in triticale against *Septoria* spp. in the maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on triticale					
		maritime EPPO zone			northeast EPPO zone (+ marit.)*		
		mean	min-max	count	mean	min-max	count
Untreated (% severity)	-	(26.1)	(9-45)	6	(18.8)	(5-35)	6
Tracker / Input	1.5 / 1.25	74.0	63-86	6	84.8	63-98	6
Aviator / Skyway Xpro	1.25	83.6	73-91	4	86.6	73-92	6
Ascra Xpro	**1.5**	**84.3**	**68-94**	**6**	**87.7**	**68-99**	**6**

* 4 trials from the EPPO northeast zone + 2 trials from the EPPO maritime zone (DE)

Yield benefit in *Septoria* spp. triticale trials
A total of 10 trials (6 from the maritime and 4 from the northeast EPPO zone) are presented in support of disease control in triticale. The trials were conducted in Germany, France, Poland and Lithuania. The trials included represent a good geographical distribution across the mari-

time and northeast climatic EPPO zones. A summary of main results is shown in tables 6.1.3-98 and 6.1.3-99.

Table 6.1.3-98: Mean yield benefit in *Septoria* spp. trials in the central registration zone

Treatment	Dose in L/ha	Mean % relative in triticale (maritime & northeast EPPO zones together)		
		mean	min-max	count
Untreated (dt/ha)	-	(66.0)	(36-94)	10
Tracker / Input	1.5 / 1.25	115.3	101-139	10
Aviator / Skyway Xpro	1.25	118.5	105-129	8
Ascra Xpro	**1.5**	**119.3**	**107-138**	**10**

Table 6.1.3-99: Yield benefit in *Septoria* spp. trials in the maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in triticale					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated (dt/ha)	-	(75.2)	(55-94)	6	(52.2)	(36-72)	4
Tracker / Input	1.5 / 1.25	112.5	106-122	6	119.5	101-139	4
Aviator / Skyway Xpro	1.25	118.1	110-127	4	118.9	105-129	4
Ascra Xpro	**1.5**	**118.9**	**111-133**	**6**	**119.8**	**107-138**	**4**

In the central registration zone as a whole, Ascra Xpro applied at 1.5 L/ha provided good overall control of *Septoria spp.* (88%). The formulation provided comparable performance to the reference product Aviator Xpro (87%).

Additionally to the efficacy the data showed a grain yield increase of 19%. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (TTLSS / SEPTSP):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP 1/214, PP 1/223 and PP 1/226. The applicant showed in 10 trials a good efficacy of 88% (Extensive achievement) for the control of *Septoria* spp. in triticale based on trials from 2012 and 2013 in the maritime and northeast EPPO zones. Additional a grain yield increase of 19% could also be achieved.

No data were represented for the southeast EPPO zone.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Septoria* spp. in triticale.

DE as zRMS accepts the submitted data. The concerned Member States have to decide themselves whether to accept the lack of data from the southeast EPPO zone or not.

Intended use: 032 (*Septoria* spp. / SEPTSP in triticale; 1 application per use)

Efficacy against *Septoria* spp. (SEPTSP) in the maritime climatic EPPO zone
A total of 6 trials were conducted in the maritime EPPO zone against SEPTSP in 2012 (5 trials) and 2013 (1 trial). The trials were conducted in Germany (4 trials) and France (2 trials) and re-

flect the performance of the product in the maritime EPPO zone. One application was made from the crop stage BBCH 37 to 51. A summary of main results is shown in table 6.1.3-100.

Table 6.1.3-100: Efficacy in triticale against *Septoria* spp. in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on triticale		
		mean	min-max	count
Untreated (% severity)	-	(26.2)	(9-45)	6
Bell / Input	1.5 / 1.25	74.0	63-86	6
Aviator / Skyway Xpro	1.25	83.6	73-90	6
Ascra Xpro	**1.5**	**84.3**	**68-94**	**6**

Yield benefits have been measured in 6 trials in support of disease control in triticale. The trials were conducted in Germany and France and represent a geographical distribution across the maritime climatic EPPO zone. A summary of main results is shown in table 6.1.3-101.

Table 6.1.3-101: Yield benefit in *Septoria* spp. trials in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative on triticale		
		mean	min-max	count
Untreated (dt/ha)	-	(75.2)	(55-94)	6
Tracker / Input	1.5 / 1.25	112.5	106-122	6
Aviator / Skyway Xpro	1.25	118.1	110-127	4
Ascra Xpro	**1.5**	**118.9**	**111-133**	**6**

Data shows that Ascra Xpro achieved satisfactory disease control (84.3%) at 1.5 L/ha. It was similar to Aviator / Skyway Xpro (83.6%).
For the applicant the good disease control against *Septoria* spp. in triticale observed in 6 trials and the also good disease control observed in wheat across 34 trials (87%), as reported previously, supports the proposed claim for control of *Septoria* spp. in triticale for 1 application in countries falling within the maritime EPPO zone.

Additionally to the efficacy the data showed a grain yield increase of 19%. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (TTLSS / SEPTSP):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP_1/214 and PP_1/223. The number of trials (6) carried out in the maritime EPPO zone was understated according to the EPPO ~~standard~~Standard PP_1/226. The efficacy for the control of *Septoria* spp. in triticale was satisfactory (84.3%) based on trials from 2012 and 2013. The efficacy of *Septoria* sp. in the intended use -018 was good (88%) and can be extrapolated.
Additional a grain yield increase of 19% could also be achieved.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Septoria* sp. in triticale.

Intended use: 019 (*Puccinia recondita* / PUCCRE in triticale; 2 applications per use)

Efficacy against *Puccinia recondita* (PUCCRE) in the maritime and northeast climatic EPPO zone

A total of 5 trials, 1 in the maritime and 4 in the northeast EPPO zone, targeted *Puccinia recondita* in 2012 (3 trials) and 2013 (2 trials). The trials were conducted in Germany (1 trial) and Poland (4 trials). One to two applications were made from the crop stage BBCH 31 to 49. A summary of main results is shown in tables 6.1.3-102 and 6.1.3-103.

Table 6.1.3-102: Mean efficacy in triticale against *Puccinia recondita* in the central registration zone

Treatment	Dose in L/ha	Mean % control on triticale (maritime & northeast EPPO zones together)		
		mean	min-max	count
Untreated (% severity)	-	(16.0)	(3-44)	5
Tracker / Input	1.5 / 1.25	94.0	82-100	5
Aviator / Skyway Xpro	1.25	92.5	83-100	5
Ascra Xpro	**1.5**	**96.1**	**89-100**	**5**

Table 6.1.3-103: Efficacy in triticale against *Puccinia recondita* in the maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on triticale					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated (% severity)	-	(7.5)	(-)	1	(18.2)	(3-44)	4
Tracker / Input	1.5 / 1.25	96.7	-	1	93.3	82-100	4
Aviator / Skyway Xpro	1.25	83.3	-	1	94.8	86-100	4
Ascra Xpro	**1.5**	**100**	**-**	**1**	**95.1**	**89-100**	**4**

Yield benefit in *Puccinia recondita* triticale trials

A total of 4 trials (1 from the maritime and 3 from the northeast EPPO zone) are presented in support of disease control in triticale. The trials were conducted in Germany and Poland. A summary of main results is shown in tables 6.1.3-104 and 6.1.3-105.

Table 6.1.3-104: Mean yield benefit in *Puccinia recondita* trials in the central registration zone

Treatment	Dose in L/ha	Mean % relative in triticale (maritime & northeast EPPO zones together)		
		mean	min-max	count
Untreated (dt/ha)	-	(54.4)	(36-72)	4
Tracker / Input	1.5 / 1.25	118.3	97-139	4
Aviator / Skyway Xpro	1.25	120.3	111-129	4
Ascra Xpro	**1.5**	**119.4**	**105-138**	**4**

Table 6.1.3-105: Yield benefit in *Puccinia recondita* trials in the maritime and northeast climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in triticale					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated (dt/ha)	-	(52.7)	(-)	1	(55.0)	(36-72)	3
Tracker / Input	1.5 / 1.25	96.6	-	1	125.5	118-139	3
Aviator / Skyway Xpro	1.25	111.0	-	1	123.4	120-129	3
Ascra Xpro	**1.5**	**105.4**	**-**	**1**	**124.0**	**113-138**	**3**

In the central registration zone as a whole, Ascra Xpro applied at 1.5 L/ha provided excellent mean control of *Puccinia recondita* (96%). The formulation provided comparable performance to

the reference products Aviator Xpro (93%). There was a slight difference in the level of performance between the maritime and northeast climatic EPPO zones.

Additionally to the efficacy the data showed a grain yield increase of 19%. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (TTLSS / PUCCRE):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP 1/214 and PP 1/223. Even though the efficacy for the control of *Puccinia recondita* in triticale was excellent (96.1%) based on trials from 2012 and 2013, the number of trials (5) carried out in the maritime and northeast EPPO zone was understated according to the EPPO ~~standard~~Standard PP 1/226. A grain yield increase of ~~19~~13% could be achieved.

No data were represented for the southeast EPPO zone.

It can be concluded **not to accept** the data provided by the applicant to demonstrate the effectiveness against *Puccinia recondita* in triticale.

Intended use: 033 (*Puccinia recondita* / PUCCRE in triticale; 1 application per use)

Efficacy against *Puccinia triticina* (PUCCRE) in the maritime climatic EPPO zone
One trial was conducted in the maritime EPPO zone against PUCCRE in 2012 in Germany. One application was made from at crop stage BBCH 49. A summary of main results is shown in table 6.1.3-106.

Table 6.1.3-106: Efficacy in wheat against *Puccinia triticina* in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on triticale / 1 application		
		mean	min-max	count
Untreated (% severity)	-	(7.5)	(-)	1
Input	1.25	96.7	-	1
Skyway Xpro	1.25	83.3	-	1
Ascra Xpro	**1.5**	**100**	**-**	**1**

Yield benefits have been measured in 1 trial in support of disease control in triticale. The trial was conducted in Germany. A summary of main results is shown in table 6.1.3-107.

Table 6.1.3-107: Yield benefit in *Puccinia triticina* trials in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative on triticale / 1 application		
		mean	min-max	count
Untreated (dt/ha)	-	(52.7)	(-)	6
Tracker / Input	1.5 / 1.25	96.6	-	1
Aviator / Skyway Xpro	1.25	111.0	-	1
Ascra Xpro	**1.5**	**105.4**	**-**	**1**

Data shows that Ascra Xpro achieved full disease control at 1.5 L/ha. It was similar to the standard Skyway Xpro.
For the applicant the excellent disease control against *Puccinia triticina* in triticale observed in this trial and the excellent disease control observed in wheat across 11 trials (96%), as reported previously, supports the proposed claim for control of *Puccinia recondita* in triticale for 1 application in countries falling within the maritime EPPO zone.

Additionally to the efficacy the data showed a grain yield increase of 5%. Compared to the reference products Aviator Xpro the yield increase was slightly lower.

Conclusion (TTLSS / PUCCRE):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP 1/214 and PP 1/223. Even though the efficacy for the control of *Puccinia recondita* in triticale was excellent (100%) based on the trial from 2012 the number of trials (1) carried out in the maritime EPPO zone was understated according to the EPPO ~~standard~~Standard PP 1/226. A slight grain yield increase of 5% could be achieved.

It can be concluded **not to accept** the data provided by the applicant to demonstrate the effectiveness against *Puccinia recondita* in triticale.

Intended use: 019a (*Pseudocercosporella herpotrichoides* / PSDCHE in triticale, 1 application per use)

Efficacy against *Pseudocercosporella herpotrichoides* in the maritime and northeast climatic EPPO zone
No data were presented by the applicant in triticale. However, for him reference is made to the dose of prothioconazole delivered by the formulation (195 g a.s./ha) and the performance of the formulation against Eyespot in both wheat and barley. Prothioconazole is known to provide good activity against *Pseudocercosporella herpotrichoides*. Ascra Xpro provided good suppression of both incidence and severity of *Pseudocercosporella herpotrichoides* in these crops across all climatic EPPO zones. The same pathogen is responsible for Eyespot in all cereal crops. Therefore it is reasoned that Ascra Xpro will provide equivalent control of Eyespot in triticale.

Conclusion (TTLSS / PSDCHE):

No data were provided by the applicant for the effectiveness of this intended use against *Pseudocercosporella herpotrichoides* in triticale. At least a few trials have to be done so that this application can be proposed for the authorization.

It can be concluded that without data the plant protection product Ascra Xpro **cannot be proposed** for authorisation against *Pseudocercosporella herpotrichoides* in triticale.

Intended use: 019b (*Septoria nodorum* / LEPTNO in triticale, 2 applications per use)

Efficacy against *Septoria nodorum* in the maritime and northeast climatic EPPO zone
No data were presented by the applicant in triticale, since the pathogen did not occur in any of the trials. However, as the disease is similar on wheat, reference is made to the high level of control achieved by Ascra Xpro against *Septoria nodorum* in wheat. Across 13 trials conducted in the EU central regulatory zone, for the applicant Ascra Xpro provided a high level of mean disease control (86%) and was substantially higher than both commercial reference products Aviator Xpro and Tracker (Champion/Bell), indicating good additional activity of the fluopyram element of the formulation. Given the consistently high level of control provided by Ascra Xpro in wheat, the applicant concluded that the formulation will also control *Septoria nodorum* in triticale when applied according to guidance.

Conclusion (TTLSS / LEPTNO):

No data were provided by the applicant for the effectiveness of this intended use against *Septoria nodorum* in triticale. At least a few trials have to be done so that this application can be proposed for the authorization.

It can be concluded that without data the plant protection product Ascra Xpro **cannot be proposed** for authorisation against *Septoria nodorum* in triticale.

Intended use: 019c (*Puccinia striiformis* / PUCCST in triticale, 2 applications per use)

Efficacy against *Puccinia striiformis* in the maritime and northeast climatic EPPO zone
No data were presented by the applicant in triticale since the disease did not occur in any of the trials. However for him, as the disease is similar on wheat, reference is made to the high level of control of yellow rust provided by Ascra Xpro in wheat. Across 11 trials conducted in 2012 and 2013, Ascra Xpro provided high levels of control of *Puccinia striiformis* (94%). In addition to this Ascra Xpro provided high levels of control against the other rust pathogens tested like *Puccinia recondita* in wheat, triticale and rye, *Puccinia hordei* in barley and *Puccinia coronata* in oats. There was no difference in the levels of control between trials conducted in the maritime and northeast climatic EPPO zones for any of the rust pathogens. Therefore the applicant concluded that Ascra Xpro will provide high levels of control of *Puccinia striiformis* in triticale in the central registration zone, regardless of climatic EPPO zone.

Conclusion (TTLSS / PUCCST):

No data were provided by the applicant for the effectiveness of this intended use against *Puccinia striiformis* in triticale. At least a few trials have to be done so that this application can be proposed for the authorization.

It can be concluded that without data the plant protection product Ascra Xpro **cannot be proposed** for authorisation against *Puccinia striiformis* in triticale.

Intended use: 019d (*Pyrenophora tritici-repentis* / PYRNTR in triticale, 2 applications per use)

Efficacy against *Pyrenophora tritici-repentis* in the maritime and northeast climatic EPPO zone
No data were presented by the applicant in triticale. However for him, as the disease is similar on wheat, reference is made to the high level of control given by the Ascra Xpro against this disease in wheat in both, the maritime and northeast climatic EPPO zone. Across 32 trials conducted in 2012 and 2013 Ascra Xpro provided a consistently high level of disease control (89%), superior to that achieved by the reference products Aviator Xpro and Tracker (Champion/Bell). This high level of disease control was maintained in the maritime and northeast climatic EPPO zone indicating a good consistency of performance across a range of environmental conditions. Therefore the applicant concluded that given the high level of control provided by Ascra Xpro against *Pyrenophora tritici-repentis* in wheat, it can be expected that the formulation will give a similar level of disease control of *Pyrenophora tritici-repentis* in triticale when applied according to guidance.

Conclusion (TTLSS / PYRNTR):

No data were provided by the applicant for the effectiveness of this intended use against *Pyrenophora tritici-repentis* in triticale. At least a few trials have to be done so that this application can be proposed for the authorization.

It can be concluded that without data the plant protection product Ascra Xpro **cannot be proposed** for authorisation against *Pyrenophora tritici-repentis* in triticale.

Intended use: 020 (*Erysiphe graminis* / ERYSGR in oats; 1 application per use)

Efficacy against *Erysiphe graminis* (ERYSGR) in the maritime climatic EPPO zone
Oats are cultivated in Europe within limited areas and data were generated only in Denmark (maritime EPPO zone). One trial targeted *Blumeria graminis* in oats in 2013. One application was made at the crop stage BBCH 45. A summary of main results is shown in table 6.1.3-108.

Table 6.1.3-108: Efficacy in oats against *Erysiphe graminis* in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on oats		
		mean	min-max	count
Untreated (% severity)	-	(10.0)	(-)	1
Tracker	1.5	97.8	-	1
Aviator Xpro	1.0	96.5	-	1
Ascra Xpro	**1.2**	**98.5**	**-**	**1**

Yield benefit in *Erysiphe graminis* oats trials
Yield data is presented in support of disease control in oats. The trial was conducted in Denmark and represents a geographical situation in the maritime climatic EPPO zone. A summary of main results is shown in table 6.1.3-109.

Table 6.1.3-109: Yield benefit in *Erysiphe graminis* trials in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in oats		
		mean	min-max	count
Untreated (dt/ha)	-	(67.3)	(-)	1
Bell (Tracker, Champion)	1.5	100.6	-	1
Aviator Xpro	1.0	98.9	-	1
Ascra Xpro	**1.2**	**94.4**	**-**	**1**

In the maritime EPPO zone, Ascra Xpro applied at 1.2 L/ha provided excellent mean control of *Erysiphe graminis* (99%). The formulation provided comparable performance to the reference products Aviator Xpro. Due to the limited data set, the applicant refers to the data against various *Blumeria species* in wheat, barley and triticale regardless of climatic zone, as reference made to the high level of control provided by Ascra Xpro. In barley, with a similar GAP, a high level of disease control (94%) was observed across 10 trials in the maritime EPPO zone. Hence for the applicant, the high level of disease control provided in the trial targeting *Erysiphe graminis* in oats combined with the performance observed in wheat, barley and triticale confirms the activity of Ascra Xpro against this pathogen in the minor crop oats.

Additionally to the efficacy the data showed no grain yield decrease. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (AVESS / ERYSGR):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP

1/26, PP_1/214 and PP_1/223. Even though the efficacy for the control of *Erysiphe graminis* in oats was excellent (98.5%) based on the trial from 2013 the number of trials (1) carried out in the maritime but not central registration EPPO zone was understated according to the EPPO ~~standard~~Standard PP_1/226.

No data were represented for the northeast and southeast EPPO zone.

It can be concluded **not to accept** the data provided by the applicant to demonstrate the effectiveness against *Erysiphe graminis* in oats.

Intended use: 021 (*Puccinia coronata* / PUCCCA in oats; 1 application per use)

Efficacy against *Puccinia coronata* (PUCCCA) in the maritime climatic EPPO zone
Oats are cultivated in Europe within limited areas and data were generated only in France (maritime EPPO zone). Three trials targeted *Puccinia coronata* in oats in 2012 (2 trials) and 2013 (1 trial). One application was made from the crop stage BBCH 43 to 47. A summary of main results is shown in table 6.1.3-110.

Table 6.1.3-110: Efficacy in oats against *Puccinia coronata* in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % control on oats		
		mean	min-max	count
Untreated (% severity)	-	(10.4)	(8-15)	3
Tracker	1.5	84.9	62-97	3
Ascra Xpro	**1.2**	**87.2**	**65-98**	**3**

Yield benefit in *Puccinia coronata* oats trials
The 3 trials are presented in support of disease control in oats. The trials were all conducted in France. A summary of main results is shown in table 6.1.3-111.

Table 6.1.3-111: Yield benefit in *Puccinia coronata* trials in the maritime climatic EPPO zone

Treatment	Dose in L/ha	Mean % relative in oats		
		mean	min-max	count
Untreated (dt/ha)	-	(69.8)	(64-81)	3
Bell (Tracker, Champion)	1.5	101.8	100-109	3
Aviator Xpro	1.0	102.6	-	1
Ascra Xpro	**1.2**	**107.5**	**98-120**	**3**

In the maritime EPPO zone, Ascra Xpro applied at 1.2 L/ha provided good mean control of *Puccinia coronata* (87%) and was equivalent to the reference product Tracker (85%). Due to the limited data set, the applicant made reference to the high level of control provided by Ascra Xpro against various rust species including *Puccinia recondita* in wheat, triticale and rye, *Puccinia striiformis* in wheat and *Puccinia hordei* in barley. For the applicant these data along with the 3 trials in oats confirm the high level of activity the formulation has across this group of pathogens. The results support for the applicant the proposed claim for the control of *Puccinia coronata* in oats in the maritime EPPO zone.

Additionally to the efficacy the data showed a grain yield increase of 8%. Compared to the reference products Aviator Xpro the yield increase was similar.

Conclusion (AVESS / PUCCCA):

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26, PP_1/214 and PP_1/223. The number of trials (3) carried out in the maritime EPPO zone was understated according to the EPPO ~~standard~~Standard PP_1/226. The efficacy for the control of *Puccinia coronata* in oats was good (87.2%) based on trials from 2012 and 2013. Additional a grain yield increase of 7% could also be achieved.

No data were represented for the northeast and southeast EPPO zone.

Because oats are minor use in most of the central countries it can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Puccinia coronata* in oats.

DE as zRMS accepts the submitted data. The concerned Member States have to decide themselves whether to accept the lack of data from the northeast and southeast EPPO zone or not.

Intended use: 021a (*Pseudocercosporella herpotrichoides* / PSDCHE in oats, 1 application per use)

Efficacy against *Pseudocercosporella herpotrichoides* in the maritime and northeast climatic EPPO zone
No data were presented by the applicant for Ascra Xpro for control of Eyespot in oats. However, for him reference is made to the dose of prothioconazole delivered by the formulation (195 g a.s./ha) and the performance of the formulation against Eyespot in both wheat and barley. Prothioconazole is known to provide good activity against *Pseudocercosporella herpotrichoides.* Ascra Xpro provided good suppression of both incidence and severity of *Pseudocercosporella herpotrichoides* in these crops across all climatic EPPO zones. The same pathogen is responsible for Eyespot in all cereal crops. Therefore the applicant reasoned that Ascra Xpro will provide equivalent control of Eyespot in oats.

Conclusion (TTLSS / PSDCHE):

No data were provided by the applicant for the effectiveness of this intended use against *Pseudocercosporella herpotrichoides* in oats. At least a few trials have to be done so that this application can be proposed for the authorization.

It can be concluded that without data the plant protection product Ascra Xpro **cannot be proposed** for authorisation against *Pseudocercosporella herpotrichoides* in oats.

IIIA1 6.1.4 Effects on yield and quality

Data presented in this chapter are from efficacy trials where no or low disease levels occurred so that results reflect the effect of spray applications of Ascra Xpro on cereal crops. Except for the evaluation of the impact on processing procedure, no specific field trials were carried out to evaluate potential effects of the plant protection product on yield and quality. Number of trials, distribution across years, countries and climatic EPPO zones and parameters assessed are presented under each specific point.

IIIA1 6.1.4.1 Impact on the quality of plants and plant products

The impact of Ascra Xpro was evaluated in trials where low levels or no visible disease developed. Those trials are considered valid to assess the crop safety of the product and its impact on quality of the plant produce. Details on the methodology for testing are already described in section 6.1.3. The distribution of trials per crop, country, year and climatic EPPO zone is shown in table 6.1.4.1-1. Following parameters were assessed: hectolitre weight (HLW), thousand grain weight (TGW) and protein content (PRO). Depending on trials, one, two or the three parameters were measured.

Table 6.1.4.1-1: Distribution of trials used to evaluate the effects on the quality of cereal grains

Crop(s)	Country	Years	Number of trials			GEP	Parameter assessed
			maritime	northeast	southeast		
Winter wheat	DE	2012+2013	1+2			yes	HLW, TGW
	UK	2013	4			yes	HLW, TGW, PRO
	LT	2013		1		yes	HLW, TGW, PRO
	SK	2012			1	yes	HLW, TGW, PRO
	Total		**7**	**1**	**1**		
Spring wheat	LT	2013		1		yes	HLW, TGW, PRO
	Total		**0**	**1**	**0**		
Winter barley	BE	2013	1				HLW
	DE	2012+2013	2+1			yes	HLW, TGW, PRO
	UK	2013	1			yes	HLW, TGW
	Total		**5**	**0**	**0**		
Spring barley	SK	2012			1	yes	HLW, TGW, PRO
	Total		**0**	**0**	**1**		
Winter triticale	DE	2012+2013	2+2			yes	HLW, TGW
	Total		**4**				
Winter rye	DE	2012	1			yes	HLW, TGW, PRO
	DK	2013	1			yes	TGW
	Total		**2**	**0**	**0**		
Oats	DK	2013	1			yes	HLW, TGW, PRO
	FR	2012+2013	1+1			yes	HLW, TGW, PRO
	LV	2013		1		yes	HLW, TGW, PRO
	Total		**3**	**1**	**0**		

Wheat (winter and spring)
Data from 9 trials conducted in 2012 and 2013 in the maritime and the northeast climatic EPPO zones (3 in Germany, 4 in United Kingdom and 2 in Lithuania) are presented in tables 6.1.4.1-2 to 6.1.4.1-4.
Ascra Xpro was applied at 1.5 L/ha in either two spray programmes or single spray programmes from BBCH 31to BBCH 65, the majority of applications being made at BBCH 39-55 and representing typical commercial spray timing to protect the upper canopy. Grain samples were collected at harvest and tested for hectolitre weight, thousand grain weight and protein content.

Table 6.1.4.1-2: Effect on quality parameters in wheat in the central registration zone

Treatment	Dose in L/ha	Mean % relative		
		hectolitre weight 9 trials	thousand grain weight 8 trials	protein content 6 trials

		mean	min-max	mean	min-max	mean	min-max
Untreated (g/kg/%)		(72.6)	(50-82)	(43.7)	(37-54)	(12.3)	(11-13)
Tracker	1.5	100.9	98-103	103.0	97-113	99.8	99-101
Aviator Xpro	1.25	101.8	101-105	102.7	94-108	100.1	99-102
Ascra Xpro	**1.5**	**101.6**	**100-106**	**104.6**	**99-113**	**99.6**	**98-101**

Table 6.1.4.1-3: Effect on quality parameters in winter wheat in the maritime EPPO zone

Treatment	Dose in L/ha	Mean % relative					
		Hectolitre weight 7 trials		Thousand grain weight 6 trials		Protein content 4 trials	
		mean	min-max	mean	min-max	mean	min-max
Untreated (g/kg/%)		(73.5)	(50-82)	(45.8)	(42-54)	(12.0)	(11-13)
Tracker	1.5	100.4	98-103	100.8	97-105	100.2	98-101
Aviator Xpro	1.25	101.4	100-105	101.4	94-108	100.1	99-101
Ascra Xpro	**1.5**	**101.0**	**100-103**	**102.3**	**99-108**	**99.8**	**98-101**

Table 6.1.4.1-3: Effect on quality parameters in winter wheat in the northeast EPPO zone

Treatment	Dose in L/ha	Mean % relative					
		Hectolitre weight 1 trial		Thousand grain weight 1 trial		Protein content 1 trial	
		mean	min-max	mean	min-max	mean	min-max
Untreated (g/kg/%)		(77.1)	(-)	(36.8)	(-)	(12.4)	(-)
Tracker	1.5	102.1	-	112.9	-	99.6	-
Aviator Xpro	1.25	101.7	-	108.1	-	101.2	-
Ascra Xpro	**1.5**	**101.6**	**-**	**112.9**	**-**	**100.0**	**-**

In addition, data from 1 trial conducted in the southeast EPPO zone with low disease levels is presented table 6.1.4.1-5.

Table 6.1.4.1-5: Effect on quality parameters in winter wheat in the southeast EPPO zone

Treatment	Dose in L/ha	Mean % relative					
		Hectolitre weight 1 trial		Thousand grain weight 1 trial		Protein content 1 trial	
		mean	min-max	mean	min-max	mean	min-max
Untreated (g/kg/%)		(70.5)	(-)	(42.9)	(-)	(16.3)	(-)
Tracker	1.5	100.6	-	103.9	-	96.8	-
Ascra Xpro	**1.5**	**99.9**	**-**	**105.9**	**-**	**97.5**	**-**

Data from 1 trial conducted in spring wheat is presented in table 6.1.4.1-6.

Table 6.1.4.1-6: Effect on quality parameters in spring wheat in the northeast EPPO zone

Treatment	Dose in L/ha	Mean % relative					
		Hectolitre weight 1 trial		Thousand grain weight 1 trial		Protein content 1 trial	
		mean	min-max	mean	min-max	mean	min-max
Untreated (g/kg/%)		(62.4)	(-)	(37.5)	(-)	(13.4)	(-)
Tracker	1.5	103.2	-	106.4	-	98.5	-
Aviator Xpro	1.25	104.0	-	105.0	-	99.1	-
Ascra Xpro	**1.5**	**105.8**	**-**	**108.4**	**-**	**99.1**	**-**

For the applicant the tests demonstrate that applications of Ascra Xpro on winter and spring wheat had no detrimental effect on the quality of the harvested produce. No significant differences were observed between the plant protection product Ascra Xpro and the untreated check or approved reference products in either winter or spring wheat. Further to this the applicant states that there was no difference observed in crop safety between the maritime, northeast and southeast climatic EPPO zone.

Conclusion for wheat:

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26. Additional a mean thousand grain weight increase of 5% and no conspicuous reduction of the hectolitre weight and protein content in wheat was detected by applying the fungicide.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness in wheat.

Barley (winter and spring)

Data from 5 trials conducted on winter barley in 2012- and 2013 in the maritime climatic EPPO zone (1 in Belgium, 3 in Germany and 1 in United Kingdom) are presented in table 6.1.4.1-7. In addition, the applicant conducted data from 1 trial on spring barley in 2012 in the southeast EPPO zone (Slovakia) with low disease pressure. He presented these data in table 6.1.4.1-8. Eight further experiments, especially for PLS, were carried out and data were analyzed by the applicant as follows in table 6.1.4.1-9.
Ascra Xpro was applied at 1.2 L/ha as single application timing. Most of the treatments were from BBCH 37 to BBCH 47, representing a typical commercial spray timing to protect the upper canopy. Grain samples were collected at harvest and tested for hectolitre weight, thousand grain weight and protein content.

Table 6.1.4.1-7: Effect on quality parameters in winter barley in the maritime EPPO zone

Treatment	Dose in L/ha	Mean % relative					
		Hectolitre weight 5 trials		Thousand grain weight 5 trials		Protein content 1 trial	
		mean	min-max	mean	min-max	mean	min-max
Untreated (g/kg/%)		(64.5)	(62-68)	(48.4)	(41-59)	(14.8)	(-)
Tracker	1.5	100.4	98-105	103.6	99-112	102.0	-
Aviator Xpro	1.0	100.1	96-106	15.6	99-116	102.7	-
Ascra Xpro	**1.2**	**100.7**	**97-106**	**105.4**	**99-119**	**102.0**	**-**

Table 6.1.4.1-8: Effect on quality parameters in spring barley in the southeast EPPO zone

Treatment	Dose in L/ha	Mean % relative					
		Hectolitre weight 1 trial		Thousand grain weight 1 trial		Protein content 1 trial	
		mean	min-max	mean	min-max	mean	min-max
Untreated (g/kg/%)		(64.8)	(-)	(47.8)	(-)	(12.1)	(-)
Tracker	1.5	103.0	-	101.2	-	102.7	-
Ascra Xpro	**1.2**	**101.5**	**-**	**103.4**	**-**	**99.0**	**-**

Table 6.1.4.1-9: Effect on quality parameters in barley with Physiological leaf spot in the maritime EPPO zone

Treatment	Dose in	Mean % relative	
		Hectolitre weight	Thousand grain weight

	L/ha	8 trial		4 trial	
		mean	min-max	mean	min-max
Untreated (g/kg/%)		(63.8)	(58-69)	(51.0)	(48-54)
Aviator Xpro	1.0	103.6	101-106	108.5	106-116
Ascra Xpro	**1.2**	**104.0**	**102-107-**	**110.7**	**104-117**

For the applicant the tests demonstrate that applications of Ascra Xpro on winter and spring barley had no detrimental effect on the quality of the harvested produce. He observed no significant differences between the plant protection product Ascra Xpro and the untreated check or approved reference products in either winter or spring barley.

Conclusion for barley:

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26. Additional a mean thousand grain weight increase of 5% and no conspicuous reduction of the hectolitre weight and protein content in barley was detected by applying the fungicide.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness in barley.

Rye

Data from 2 trials conducted in 2013 in the maritime climatic EPPO zone (1 in Germany and 1 in Denmark) are presented in table 6.1.4.1-10.
Ascra Xpro was applied at 1.5 L/ha as single application timing from BBCH 45 to BBCH 49 representing a typical commercial spray timing to protect the upper canopy. Grain samples were collected at harvest and tested for hectolitre weight, thousand grain weight and protein content.

Table 6.1.4.1-10: Effect on quality parameters in rye in the EPPO maritime zone

Treatment	Dose in L/ha	Mean % relative					
		Hectolitre weight 1 trial		Thousand grain weight 2 trials		Protein content 1 trial	
		mean	min-max	mean	min-max	mean	min-max
Untreated (g/kg/%)		(70.4)	(-)	(33.5)	(33-34)	(8.8)	(-)
Tracker	1.5	101.2	-	97.0	97-97	105.3	-
Aviator Xpro	1.25	100.1	-	102.2	99-105	103.9	-
Ascra Xpro	**1.5**	**99.8**	**-**	**103.0**	**103-103**	**103.0**	**-**

For the applicant the tests demonstrate that applications of Ascra Xpro on rye had no detrimental effect on the quality of the harvested produce. No significant differences were observed between the plant protection product Ascra Xpro and the untreated check or approved reference products.

Triticale

Data from 4 trials conducted in 2013 in the maritime climatic EPPO zone (all in Germany) are presented in the table 6.1.4.1-11.
Ascra Xpro was applied at 1.5 L/ha as single application timing from BBCH 37 to BBCH 49 representing typical commercial spray timing to protect the upper canopy. Grain samples were collected at harvest and tested for hectolitre weight and thousand grain weight.

Table 6.1.4.1-11: Effect on quality parameters in triticale in the maritime EPPO zone

Treatment	Dose in L/ha	Mean % relative			
		Hectolitre weight - 1 trial		Thousand grain weight - 4 trials	
		Mean	min-max	mean	min-max
Untreated (g/kg)		(69.9)	(-)	(41.3)	(35-46)
Tracker	1.5	102.3	-	104.8	101-110
Aviator Xpro	1.25	102.0	-	108	100-119
Ascra Xpro	**1.5**	**100.6**	**-**	**109**	**106-109**

For the applicant the tests demonstrate that applications of Ascra Xpro on triticale had no detrimental effect on the quality of the harvested produce. No significant differences were observed between the plant protection product Ascra Xpro and the untreated check or approved reference products.

Conclusion for rye and triticale:

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26. Additional a mean thousand grain weight increase of 3 - 9%, no reduction of the hectolitre weight and a slight improvement of protein content in rye and triticale was detected by applying the fungicide.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness in rye and triticale.

Oats

None of the trials conducted by the applicant in oats developed low disease levels. However, as supporting evidence, he tested oat trials which developed relatively low disease levels (about 10%) for hectolitre weight, thousand grain weight and protein content. Data from 4 trials conducted in 2012 and 2013 in the maritime and northeast climatic EPPO zones (2 in France, 1 in Denmark and 1 in Latvia) are presented in tables 6.1.4.1-12 to 6.1.4.1-14.
Ascra Xpro was applied at 1.2 L/ha as single application timing from BBCH 43 to BBCH 49 representing typical commercial spray timing to protect the upper canopy. Grain samples were collected at harvest and tested for hectolitre weight, thousand grain weight and protein content.

Table 6.1.4.1-12: Effect on quality parameters in oats in the central registration zone

Treatment	Dose in L/ha	Mean % relative					
		Hectolitre weight 4 trials		Thousand grain weight 3 trials		Protein content 3 trials	
		mean	min-max	mean	min-max	mean	min-max
Untreated (g/kg/%)		(48.9)	(44-53)	(34.1)	(32-36)	(11.1)	(9-13)
Tracker	1.5	99.0	97-100	102.3	97-109	103.4	101.107
Aviator Xpro	1.0	98.6	98-100	100.4	96-104	99.4	97-101
Ascra Xpro	**1.2**	**99.9**	**98-102**	**101.2**	**97-104**	**101.7**	**100-103**

Table 6.1.4.1-13: Effect on quality parameters in oats in the maritime EPPO zone

Treatment	Dose in L/ha	Mean % relative		
		Hectolitre weight 3 trials	Thousand grain weight 2 trials	Protein content 2 trials

		mean	min-max	mean	min-max	mean	min-max
Untreated (g/kg/%)		(50.4)	(47-53)	(34.1)	(32-36)	(10.2)	(9-12)
Tracker	1.5	99.0	97-100	103.1	97-109	104.6	102-107
Aviator Xpro	1.0	99.0	98-100	99.9	96-104	100.6	100-101
Ascra Xpro	**1.2**	**99.4**	**98-100**	**100.3**	**97-104**	**101.4**	**100-103**

Table 6.1.4.1-14: Effect on quality parameters in oats in the northeast EPPO zone

Treatment	Dose in L/ha	Mean % relative					
		Hectolitre weight 1 trial		Thousand grain weight 1 trial		Protein content 1 trial	
		mean	min-max	mean	min-max	mean	min-max
Untreated (g/kg/%)		(44.4)	(-)	(34.0)	(-)	(12.9)	(-)
Tracker	1.5	99.0	-	100.7	-	101.0	-
Aviator Xpro	1.0	97.9	-	101.6	-	96.9	-
Ascra Xpro	**1.2**	**101.6**	**-**	**103.1**	**-**	**102.3**	**-**

For the applicant the tests demonstrate that applications of Ascra Xpro on oats had no detrimental effect on the quality of the harvested produce. No significant differences were observed between the plant protection product Ascra Xpro and the untreated check or approved reference products.

Conclusion for oats:

The presented data correspond with the requirements of the EPPO ~~standard~~Standards PP 1/26. Additional a slight increase in the mean thousand grain weight, the hectolitre weight and protein content in oats was detected by applying the fungicide.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness in oats.

IIIA1 6.1.4.2 Effects on the processing procedure

The effects of Ascra Xpro on the processing procedure have been evaluated in specific trials in order to evaluate the impact of spray applications on malting/brewing and bread making. The testing facilities responsible for the conduct of the field part were the development teams of the country subsidiary organisations of Bayer CropScience. Processing studies were conducted by external co-operators/institutes. Malting and brewing tests were performed at Brewing Research International (BRI), UK and baking tests at GALYS laboratory, FR. All follow the EPPO ~~standard~~Standards and are authorized in accordance to the principles of Good Experimental Practice (GEP).
The field trials were conducted in countries belonging to the maritime climatic EPPO zone in the EU central regulatory zone as shown in table 6.1.4.2-1.

Table 6.1.4.2-1: Distribution of trials used to evaluate the effects on processing procedure

Crop(s)	Country	Years	Number of trials	GEP	Processing procedure
Winter barley	UK	2012	1	yes	Malting / Brewing
Winter	FR	2013	2	yes	Bread making

wheat					
	Total	**-**	**3**		

The applicant conducted field trials in 2012 and 2013 in the most important cereal growing regions. Trials were carried out in farmer's field under natural conditions in situations with low risk of disease development. The applicant established them as a randomised complete block design, with 1 replicate and plot size of 400 m^2 for brewing and with 3 replicates and plot size of 25 m^2 for bread making.
Spray applications were made in line with the proposed GAP. One application was made in winter barley at BBCH 61 and one or two applications were made on wheat at BBCH 37-39 and BBCH 49-62.
The plant protection product Ascra Xpro was applied at 1.2 L/ha in barley and 1.5 L/ha in wheat. The reference products Fandango EC 200 in barley and Opus SC 125 in wheat were applied at 1.25 L/ha and 1.0 L/ha respectively as shown in tables 6.1.4.2-2 and 6.1.4.2-3.

Table 6.1.4.2-2: Product dose rates in wheat (bread making)

Product	active substance	content g/l	dose rate L/ha	a.s. rate g/ha	country
Ascra Xpro	bixafen fluopyram prothioconazole	65 65 130	1.5	97.5 97.5 195	FR
OPUS SC125	epoxiconazole	125	1.0	125	FR

Table 6.1.4.2-3: Product dose rates in barley (brewing)

Product	active substance	content g/l	dose rate l/ha	a.s. rate g/ha	country
Ascra Xpro	bixafen fluopyram prothioconazole	65 65 130	1.2	78 78 156	UK
FANDANGO EC 200	fluoxastrobin Prothioconazole	100 100	1.25	125 125	UK

Crops were harvested at the normal harvest period and grain samples collected and send to BRI, UK for brewing tests and GALYS, FR for baking studies.

As further supporting evidence, the applicant also made reference to studies that were conducted with each of the straight active substances (bixafen, fluopyram and prothioconazole). A summary of main results is presented hereafter.

Brewing studies
Bixafen
Brewing studies were conducted on spring barley grain treated with BYF 00587 EC 125 (bixafen) at Brewing Research International (BRI), UK. BRI is a PSD Officially Recognized Efficacy Testing Facility. Barley cultivar Optic from the 2006 harvest, treated twice (BBCH 37 and BBCH 61) with bixafen at a single (125 g a.s./ha) and a double rate, were provided by Bayer CropScience Ltd, UK and evaluated for malting and brewing performance.
The applicant explains that tests findings showed no significant effects on germination characteristics, protein contents and no influence on malt quality and lager preparation. There were no differences in flavour and aroma between the test beers and controls.
Therefore the applicant concluded that bixafen EC 125 is highly unlikely to have any adverse effects on malting, brewing or fermentation performance, or on malt or beer quality.

Fluopyram
Brewing studies were conducted on winter barley grain treated with fluopyram EC 150 (102000024392) at Brewing Research International (BRI), UK. Barley cultivar Winsome from the

2012 harvest, treated once (BBCH 61) with fluopyram at 78, 125 and 250 g a.s./ha, were provided by Bayer CropScience Ltd, UK and evaluated for malting and brewing performance.
The applicant explains that tests findings showed no significant effects on germination characteristics, protein contents and no influence on malt quality and lager preparation. There were no differences in flavour and aroma between the test beers and controls.
Therefore, the applicant concluded that fluopyram EC 125 is highly unlikely to have any adverse effects on malting, brewing or fermentation performance, or on malt or beer quality.

Prothioconazole
Prothioconazole was evaluated on winter barley in 2000 by Brewing Research International (BRI), UK. Proline EC 250 at a single (200 g a.s./ha) and a double rate was evaluated for malting and brewing performance. Test beers were tasted in comparison to control samples in a triangular taste test.
The applicant explains that test findings showed no significant influence on germination, no effects on malt quality or performance on beer preparation. There were no major differences in aromas or flavours between the control and the test beers.
Therefore, the applicant concluded that Proline EC 250 had no detrimental effects on malting, brewing or malt and beer quality.

Bixafen + Fluopyram + Prothioconazole
Brewing studies were conducted on winter barley grain treated with Ascra Xpro (102000025737) at Brewing Research International (BRI), UK. Barley cultivar Winsome from the 2012 harvest, treated once (BBCH 61) at 1.2 L/ha (N rate), were provided by Bayer CropScience Ltd, UK and evaluated for malting and brewing performance.
The applicant used the approved standard Fandango EC 200 applied at the full rate of 1.25 L/ha (125 g fluoxastrobin + 125 g prothioconazole / ha) as reference.
He explains that tests findings showed no significant effects on germination characteristics, protein contents and no influence on malt quality and lager preparation. There were no differences in flavour and aroma between the test beers and controls.
The applicant concluded that results from the single active substance and the co-formulation provide evidence that a commercial use of bixafen + fluopyram + prothioconazole EC 260 will not have any adverse effects on malting, brewing or fermentation performance, or on malt or beer quality.

Bread making studies

Bixafen
Bread making studies were conducted on winter wheat grain treated with BYF 00587 EC 125 (bixafen) at Centre de Recherches et d'Analyses Agro-alimentaires (CERAAF), FR. CERAAF is COFRC (Comité Français d'accréditation) accredited and recognized by the French authorities for registration purposes. Wheat cultivar Caphorn from the 2006 harvest, treated twice (BBCH 47 and BBCH 69) with BYF 00587 at a single rate (1.0 L/ha), were provided by Bayer CropScience, FR and evaluated for bread making performance.
In the two trials, the applicant found no significant differences between BYF 00587 (125g bixafen/ha) and the standard treatment Horizon EW (250g tebuconazole/ha) neither in term of yields, hectolitre weight nor thousand grain weight. BYF 00587 (bixafen) did not negatively affect the protein content, the Hagberg falling number and the Zeleny index compared to the standard treatment. The applicant detected no significant differences between all treatments and parameters in the Chopin alveogram tests and the bread making quotation tests.
Results from the two tests clearly show for the applicant that BYF 00587 (bixafen) had no significant impact on quality parameters which can influence bread making quality.

Fluopyram

Bread making studies were conducted in France on winter wheat grain treated with fluopyram straight (102000024392 EC 150 g/L) at Centre de Recherches et d'Analyses Agro-alimentaires (CERAAF). The standard Proline EC 250 applied at the full rate of 0.8 L/ha (200 g prothioconazole / ha) was used as reference.
Wheat cultivars Kranich and Ellvis from the 2012 harvest, treated twice (BBCH 39-41 and BBCH 61-63) at a single rate of 125 g a.s./ha, were provided by Bayer CropScience SE and evaluated for bread making performance in France at CERAAF (see above). The two trials were carried out by the applicant in Sweden under the climatic conditions of typical nordic countries.
In the two trials, the applicant found no significant differences between fluopyram straight at 125 g/ha and the standard treatment Proline EC 250 (200g prothioconazole/ha) neither in term of yields, hectolitre weight nor thousand grain weight. Fluopyram alone (102000024392) did not negatively affect the protein content, the Hagberg falling number and the Zeleny index compared to the standard treatment proline EC 250. The applicant found no significant differences between all treatments and parameters in the Chopin alveogram tests and the bread making quotation tests.
Results from the two tests clearly show for the applicant that fluopyram alone at 125 g/ha had no significant impacts on quality parameters which can influence bread making quality.

Prothioconazole
The applicant could not detect residues of prothioconazole in grain samples. Furthermore he suggested that Proline EC 250 has no significant effects on quality parameters, which can influence bread-making quality. Specifically, prothioconazole do not detrimentally affect grain protein, Hagberg Falling number and hectolitre weight compared to the standards.
Studies carried out in France by CERAAF (7 trials between 1997 and 2004) have shown for the applicant that Proline EC 250 at 0.8 L/ha sprayed twice has no significant effects on bread making.
Therefore the applicant argued that Proline EC 250 (200 g/ha prothioconazole) will not have an influence on bread making quality.

Bixafen + Fluopyram + Prothioconazole
Two bread making studies were conducted in France in 2013 on winter wheat grain treated with Ascra Xpro at GALYS laboratory (former CERAAF) which is COFRC (Comité Français d'accréditation) accredited and recognized by the French authorities for registration purposes. The standard Opus SC 125 applied at the full rate of 1.0 L/ha (125 g epoxiconazole / ha) was used as reference.

Wheat cultivars Arezzo and Nara from the 2013 harvest, treated once (BBCH 49-62) and twice (BBCH 37/39-49/62) at a single rate of 1.5 L/ha, were provided by Bayer CropScience France and evaluated for bread making performance in France at GALYS (see above). The two trials were carried out in France under the climatic conditions of the maritime EPPO zone.

In the two trials, the applicant found no significant differences between Ascra Xpro applied once or twice neither in term of yields, hectolitre weight nor thousand grain weight. Compared to the standard treatment Opus SC 125 there was no difference in one location whereas a lower yield was found with Opus in the other location. For the applicant this was likely due to a lower disease control of a low level of disease.

For the applicant data showed that the plant protection product Ascra Xpro did not negatively affect the protein content, the Hagberg falling number and the Zeleny index compared to the standard treatment Opus SC 125. The applicant found no significant differences between all treatments and parameters in the Chopin alveogram tests and the bread making quotation tests.

For the applicant results from the two tests clearly showed that Ascra Xpro applied once at 1.5 L/ha had no significant impacts on quality parameters which can influence bread making quality.

Conclusion:

The presented data correspond with the requirements of the EPPO ~~standard~~Standard PP 1/243. Additional no negative impacts on processing procedures in all trials could be determined by applying the fungicide.

It can be concluded to accept the data provided by the applicant to demonstrate no negative impacts on processing procedures.

IIIA1 6.1.4.3 Effects on the yield of treated plants and plant products

For effects on yields in diseased trials please refer to the point 6.1.3. For each crop and disease, yield data are summarized in comparison to reference products.

The effects of Ascra Xpro on treated plants and plant products were evaluated in trials where low levels or no visible disease developed. Those trials are considered valid to assess the crop safety of the product and its impact on yield of treated plants. Details on the methodology for testing are already described in section 6.1.3. The distribution of trials per crop, country, year and climatic EPPO zone is shown in Table 6.1.4.3-1.

Table 6.1.4.3-1: Distribution of trials used to evaluate the effects on yield of treated cereals

Crop(s)	country	years	Number of trials			GEP
			maritime	northeast	southeast	
winter wheat	DE	2012	2			yes
	UK	2013	7			yes
	LT	2013		1		yes
	SK	2012			1	yes
	Total	**-**	**9**	**1**	**1**	
spring wheat	LT	2012		1		yes
	Total	**-**	**0**	**1**	**0**	
winter barley	BE	2013	1			yes
	DE	2012-2013	2+2			yes
	UK	2013	1			Yes
	Total	**-**	**6**	**0**	**0**	
spring barley	DK	2012	1			yes
	UK	2012-2013	1+3			yes
	SE	2013	1			yes
	SK	2012			1	yes
	Total	**-**	**6**	**0**	**1**	
winter triticale	DE	2012-2013	2+2			yes
	Total	**-**	**4**	**0**	**0**	
winter rye	DE	2013	1			yes
	DK	2013	1			yes
	Total	**-**	**2**	**0**	**0**	

Wheat, winter / spring
Effects on yields in diseased trials are presented for each disease under the point 6.1.3 for 1 and 1-2 applications in comparison to reference products.

Effects on yields in disease-free trials are presented in Tables 6.1.4.3-2 to 6.1.4.3-4. Data from 11 trials conducted in 2012 and 2013 in the maritime and northeast climatic EPPO zones (2 in Germany, 7 in United Kingdom and 2 in Lithuania) are summarized.
Ascra Xpro was applied at 1.5 L/ha in both single and double applications reflecting commercial use patterns and the proposed GAP. Ascra Xpro was compared to the reference product Aviator Xpro and Tracker/Champion/Bell applied at 1.25 L/ha and 1.5 L/ha respectively at the same application timings.

Table 6.1.4.3-2: Effect on yield in winter / spring wheat in the central registration zone

Treatment	Dose in L/ha	Mean % relative in winter / spring wheat		
		mean	min-max	count
Untreated (dt/ha)	-	(81.7)	(57-131)	11
Bell (Tracker, Champion)	1.5	105.7	100-116	11
Aviator Xpro	1.25	105.2	97-117	11
Ascra Xpro	**1.5**	**107.4**	**96-123**	**11**

Table 6.1.4.3-3: Effect on yield in winter wheat in the maritime and northeast EPPO zone

Treatment	Dose in L/ha	Mean % relative in winter wheat					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated (dt/ha)	-	(87.0)	(60-131)	9	(58.8)	(-)	1
Tracker	1.5	103.7	99-115	9	115.9	-	1
Aviator Xpro	1.25	103.8	97-117	9	110.1	-	1
Ascra Xpro	**1.5**	**105.8**	**96-123**	**9**	**114.3**	**-**	**1**

Table 6.1.4.3-4: Effect on yield in spring wheat in the maritime and northeast EPPO zone

Treatment	Dose in L/ha	Mean % relative in spring wheat					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated (dt/ha)	-	(-)	(-)	0	(56.8)	(-)	1
Tracker	1.5	-	-	0	113.6	-	1
Aviator Xpro	1.25	-	-	0	112.5	-	1
Ascra Xpro	**1.5**	**-**	**-**	**0**	**115.4**	**-**	**1**

In addition, data from 1 trial conducted on winter wheat in the southeast EPPO zone in 2012 (Slovakia) is shown below in Table 6.1.4.3-5.

Table 6.1.4.3-5: Effect on yield in winter wheat in the southeast EPPO zone

Treatment	Dose in L/ha	Mean % relative in winter wheat – 1 trial
Untreated (dt/ha)	-	(25.8)
Tracker	1.5	115.8
Ascra Xpro	**1.5**	**133.1**

For the applicant data shows that applications of Ascra Xpro on winter or spring wheat had no detrimental effect on the yield in situations of no to low pest pressure. In all trials, he observed no significant differences between the plant protection product Ascra Xpro and the reference products Aviator X pro and Tracker. In 2 trials in winter wheat and 1 trial in spring wheat, Ascra Xpro and the two reference products achieved significantly higher yields than the untreated check. The applicant observed no differences between the 2 climatic EPPO zones.

The yield in the southeast EPPO zone was rather low likely due to drought conditions. The applicant found no significant difference between the plant protection product Ascra Xpro and the reference product Tracker.

Conclusion:

The presented data (see also point 6.1.3) correspond with the requirements of the EPPO ~~standard~~Standards PP_1/26, PP_1/181, PP_1/214 and PP_1/223. Additional a mean grain yield increase of about 27% in wheat uses could also be achieved by applying the fungicide.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness in wheat.

Barley, winter / spring

The applicant presented effects on yields in diseased trials for each disease under the point 6.1.3 for 1 application in comparison to reference products.

Effects on yields in disease-free trials the applicant presented in tables 6.1.4.3-6 to 6.1.4.3-8. Therefore he showed data from 12 trials (6 on winter and 6 on spring varieties) conducted in 2012 and 2013 in the maritime climatic EPPO zone (1 in Belgium, 4 in Germany, 5 in United Kingdom, 1 in Denmark and 1 in Sweden).
Ascra Xpro was applied at 1.2 L/ha in single applications reflecting commercial use patterns and the proposed GAP. Ascra Xpro was compared to the reference product Aviator Xpro and Tracker/Champion/Bell applied at 1.0 L/ha and 1.5 L/ha respectively at the same application timings.

Table 6.1.4.3-6: Effect on yield in winter / spring barley in the central registration zone

Treatment	Dose in L/ha	Mean % relative in spring/winter barley		
		mean	min-max	count
Untreated (dt/ha)	-	(72.2)	(44-113)	12
Bell (Tracker, Champion)	1.5	105.2	95-120	12
Aviator Xpro	1.0	109.4	97-127	12
Ascra Xpro	**1.2**	**109.0**	**96-117**	**12**

Table 6.1.4.3-7: Effect on yield in winter barley in the maritime EPPO zone

Treatment	Dose in L/ha	Mean % relative in winter barley maritime EPPO zone		
		mean	min-max	count
Untreated (dt/ha)	-	(77.0)	(44-113)	6
Tracker	1.5	100.9	95-106	6
Aviator Xpro	1.0	107.6	97-127	6
Ascra Xpro	**1.2**	**107.0**	**96-117**	**6**

Table 6.1.4.3-8: Effect on yield in spring barley in the maritime and northeast EPPO zone

Treatment	Dose in L/ha	Mean % relative in spring barley maritime EPPO zone		
		mean	min-max	count
Untreated (dt/ha)	-	(67.5)	(56-88)	6
Tracker	1.5	109.5	99-120	6
Aviator Xpro	1.0	111.3	100-119	6
Ascra Xpro	**1.2**	**111.1**	**102-116**	**6**

In addition, data from 1 trial conducted on spring barley in the southeast EPPO zone in 2012 (Slovakia) is shown below in table 6.1.4.3-9.

Table 6.1.4.3-9: Effect on yield in spring barley in the EPPO southeast zone

Treatment	Dose in L/ha	Mean % relative in spring barley – 1 trial
Untreated (dt/ha)	-	(10.9)
Tracker	1.5	115.9
Ascra Xpro	**1.2**	**124.7**

For the applicant data shows that applications of Ascra Xpro on winter or spring barley had no detrimental effect on the yield in situations of low pest pressure. He observed no significant differences between the plant protection product Ascra Xpro and the reference products both on spring and winter barley. In 1 trial in winter barley and 4 trials in spring barley, Ascra Xpro and the two reference products achieved significantly higher yields than the untreated check.
No data were produced in the northeast EPPO zone in absence of disease but given excellent crop safety demonstrated across the trials, coupled with the positive yield response in disease control it is reasoned that application of Ascra Xpro are unlikely to have an adverse impact on yield.

The yield in the southeast EPPO zone was very low likely due to drought conditions. The applicant found no significant difference between the plant protection product Ascra Xpro and the reference product Tracker.

Conclusion:

The presented data (see also point 6.1.3) correspond with the requirements of the EPPO ~~standard~~Standards PP_1/26, PP_1/181, PP_1/214 and PP_1/223. Additional a mean grain yield increase of about 23% in barely uses could also be achieved by applying the fungicide.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness in barley.

Triticale and rye

The applicant presented effects on yields in diseased trials for each disease under the point 6.1.3 for 1 and 1-2 applications in comparison to reference products.

Effects on yields in disease-free trials are presented by the applicant in tables 6.1.4.3-10 and 6.1.4.3-11. Data from 4 trials in triticale all conducted in Germany in 2012 and 2013 and 2 trials in rye conducted in Germany (1 trial) and Denmark (1 trial) in 2012 and 2013 are summarized.
Ascra Xpro was applied at 1.5 L/ha in single application reflecting commercial use patterns and the proposed GAP. Ascra Xpro was compared to the reference product Aviator Xpro (Skyway Xpro in Germany) and Tracker/Champion/Bell applied at 1.5 L/ha.

Table 6.1.4.3-10: Effect on yield in winter triticale in the maritime EPPO zone

Treatment	Dose in L/ha	Mean % relative in winter triticale		
		mean	min-max	count
Untreated (dt/ha)	-	(75.2)	(53-90)	4
Tracker	1.5	108.1	97-117	4
Aviator / Skyway Xpro	1.25	113.1	106-122	4
Ascra Xpro	**1.5**	**112.2**	**105-120**	**4**

Table 6.1.4.3-11: Effect on yield in winter rye in the EPPO maritime zone

Treatment	Dose in L/ha	Mean % relative in winter rye		
		mean	min-max	count
Untreated (dt/ha)	-	(50.8)	(39-62)	2
Tracker	1.5	104.2	-	1
Aviator / Skyway Xpro	1.25	104.7	103-106	2
Ascra Xpro	**1.5**	**110.0**	**104-116**	**2**

For the applicant data shows that applications of Ascra Xpro on winter triticale and winter rye had no detrimental effect on the yield in situations of low pest pressure.
In triticale, he observed no significant differences between the plant protection product Ascra Xpro and the reference products. In 2 trials, Ascra Xpro and the two reference products achieved significantly higher yields than the untreated check.
In rye, the applicant observed no significant differences between the plant protection product Ascra Xpro, the reference products and untreated check.
No data were produced in the northeast EPPO zone in absence of disease but given for the applicant the excellent crop safety demonstrated across the trials, coupled with the positive yield response in disease control it is reasoned that application of Ascra Xpro are unlikely to have an adverse impact on yield.

Conclusion:

The presented data (see also point 6.1.3) correspond with the requirements of the EPPO ~~standard~~Standards PP_1/26, PP_1/181, PP_1/214 and PP_1/223. Additional a mean grain yield increase of about 16% in triticale and 20% in rye uses could also be achieved by applying the fungicide.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness in triticale and rye.

Oats

The applicant presented effects on yields in diseased trials for each disease under the point 6.1.3 for 1 and/or 1-2 applications in comparison to reference products.

The applicant mentioned that all of the trials conducted resulted in levels of disease development and no yield data were available in absence of disease. It is reasoned for the applicant that the crop safety demonstrated across the trials, coupled with the positive yield response in disease control suggest that, given the absence of any adverse effects in other crops where disease was not present, applications of Ascra Xpro are unlikely to have an adverse impact on yield.

Conclusion:

The presented data (see therefore point 6.1.3) correspond with the requirements of the EPPO ~~standard~~Standards PP_1/26, PP_1/181, PP_1/214 and PP_1/223. Additional a mean grain yield increase 2% in oat uses could be achieved by applying the fungicide.

It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness in oats.

IIIA1 6.2 Adverse effects

IIIA1 6.2.1 Phytotoxicity to host crop

The applicant conducted no specific trials to evaluate the crop safety of Ascra Xpro in cereal crops. Crop safety observations have been made in all efficacy trials reported under the point 6.1.3 from approximately 3-5 and/or 5-7 weeks after application coinciding with efficacy assessments.
Spray applications were to reflect the full range of possibilities determined by the GAP:
In wheat, the test material was applied once either at BBCH 31-32 or BBCH 37-55 or twice at BBCH 30-33 and BBCH 37-61.
In barley, the test material was applied as single applications at BBCH 31-34 or BBCH 37-61.
In rye, the test material was applied once either at BBCH 33 or BBCH 37-61or twice at BBCH 32 and BBCH 59.
In triticale, the test material was applied once either at BBCH 33 or BBCH 37-51 or twice at BBCH 31-32 and BBCH 47-53.
In oats, the test material was applied as single applications at BBCH 43-49.

Table 6.2.1-1 presents the list of cultivars/varieties tested in these efficacy trials.

Table 6.2.1-1: Number of trials and varieties tested

Crop	maritime EPPO zone			northeast EPPO zone			southeast EPPO zone		
	N° trials	N° varieties	Countries	N° trials	N° varieties	Countries	N° trials	N° varieties	Countries
Wheat (winter)	102	48	BE, DE, UK, CZ, FR, DK, SE	22	14	PL, LV, LT	2	2	SK
Wheat (spring)	-	-	-	7	6	LT, LV			
Barley (winter)	41	25	DE, UK, FR	15	12	PL, LV	1	1	SK
Barley (spring)	17	9	UK, CZ, FR, DK, SE	6	4	PL, LV, LT	2	2	SK
Rye	19	8	DE, FR, DK	5	4	PL, LV-LT			
Triticale	17	9	DE, FR, DK	7	7	PL, LV, LT			
Oats	5	5	DE, FR, DK	1	1	LV			

Formatiert: Deutsch (Deutschland)

No phytotoxicity was observed in any of the trials conducted in spring wheat, winter and spring barley and oats. Very slight symptoms were observed 2-4 weeks after the last spray application in 1 trial out of 124 in winter wheat, 1 trial out of 26 in winter triticale and 1trial out of 27 in winter rye. The maximum intensity of symptoms is shown in table 6.2.1-2.

Table 6.2.1-2**:** Phytotoxicity observed in winter wheat, triticale and rye

Treatment	Dose in L/ha	% phytotoxicity		
		winter wheat Var. Ritmo	winter triticale Var. Talentro	winter rye Var. Brasetto

Country – year Day after last application		DE - 2013 37	DE - 2012 36	DE – 2012 14
Untreated	-	0	0	0
Input	1.25	-	5.5	-
Prosaro	1.0	-	-	2.0
Tracker	1.5	3.5	-	-
Aviator Xpro	1.25	4.0	-	-
Skyway Xpro	1.25	-	5.3	0.8
Ascra Xpro	**1.5**	**0.8**	**5.5**	**1.5**

In winter wheat, the applicant observed no phytotoxicity in any of the trials except in one trial conducted in Germany in 2013 on the variety Ritmo. The symptoms were transient at an extremely low level (0.8%) and the reference products Aviator Xpro and Champion/Tracker/Bell also displayed similar symptoms with a higher level. In the other trials conducted in the maritime and northeast climatic EPPO zone countries, no symptoms of phytotoxicity occurred.

In spring wheat, the applicant observed no symptoms of phytotoxicity in any of the trials. Therefore it is reasoned for him that given the evidence presented supporting the excellent crop safety that Ascra Xpro will also not result in significant risk of phytotoxicity in countries within the maritime EPPO zone.

In spring and winter barley, the applicant observed no symptoms of phytotoxicity in any of the trials, regardless of country and climatic EPPO zone.

In rye, the applicant observed no phytotoxicity in any of the trials except in one trial conducted in Germany in 2012 on the variety Brasetto. However, the symptoms were transient at a low level (1.5%) and application of the reference products Skyway Xpro and Prosaro resulted in similar symptoms.

In triticale, the applicant observed no phytotoxicity in any of the trials except in one trial conducted in Germany in 2013 on the variety Talentro, where a low level of symptoms (5%) was observed. The reference products Skyway Xpro and Input also resulted in similar symptoms. Given the absence of symptoms in the other trial sites and in the other crops, the applicant concluded that specific environmental/crop conditions in the trial caused in all treatments a low level effect which did not adversely affect final yield.

In oats, the applicant observed no symptoms of phytotoxicity in any of the trials, regardless of country and climatic EPPO zone.

Conclusion:

The presented data correspond with the requirements of the EPPO ~~standard~~Standard PP 1/135. The applicant submitted 133 wheat trials, 82 barley trials, 24 rye trials, 24 triticale and 6 oat trials of the year 2012, 2013 and 2015. A low phytotoxicity on plants was given only in each case one trial in wheat, rye and triticale

Based on this submitted data and on the expert knowledge about bixafen, fluopyram and prothioconazole it can be concluded to accept the data provided by the applicant.

IIIA1 6.2.2 Adverse effects on health of host animals

This is not an EC data requirement.

IIIA1 6.2.3 Adverse effects on site of application

This is not an EC data requirement.

IIIA1 6.2.4 Adverse effects on beneficial organisms (other than bees)

The fungicide Ascra Xpro (130 g/L prothioconazol + 65 g/L fluopyram + 65 g/L bixafen) has been proposed for application in wheat, barley, rye, triticale and oat at a total maximum application rate of 3 L/ha and year (2 applications with an interval of 14 - 21 days in wheat). Taking into account the potential disappearance of the active ingredients between the applications, the worst case exposition can be calculated to be approximately 2.55 L/ha and year (using the maximum default value MAF of 1.7 for 2 applications). This corresponds to 0.33 kg (Prothioconazol) + 0.17 kg (Fluopyram) + 0.17 kg (Bixafen) active substance/ha and year.
Throughout the field trials on effectiveness and selectivity there have been no reports or observations to suggest a detrimental impact of Ascra Xpro on beneficial or non-target organisms. Appropriate studies on the potential adverse effects on beneficial arthropods were available from Registration Report Part B, Section 6, Annex Point IIIA 10.5 (Effects on Arthropods Other Than Bees), Core Assessment.
The toxicity of Ascra Xpro has been investigated by carrying out

- extended laboratory tests on *Typhlodromus pyri, Aphidius rhopalosiphi, Chrysoperla carnea* and *Coccinella septempunctata*.

When laboratory tests and higher tier tests were available for the same species, only the results from the higher tier test are being used for the assessment. These results are presented in Table 6.2.4-1.

Table 6.2.4-1: Effects of Ascra Xpro on beneficial arthropods in extended laboratory tests on natural substrates

Species (Exposed Stage)	Substrate	substance	Rate [g a.s./ha	Corrected Mortality [%]	Sublethal Effect [%]	Reference
T. pyri (PN)	*Phaseolus vulgaris*	Bixafen Fluopyram Prothioconazol	7.8 7.8 15.6	4.5	23.3	83872062 Moll 2014
			13.9 13.9 27.7	9	26.3	
			24.6 24.6 49.3	6.7	37.9	
			43.9 43.9 87.8	11.2	40.4	
			78 78 156	59.6	n.d.	
A. rhopalosi	*Hordeum vulgare*	Bixafen Fluopyram Prothiocona-	16.6 16.6 33.2	0	-6.8	83871002

phi (A)		zol	29.5 29.5 58.9	0	-15.6	Moll 2014
			52.4 52.4 104.8	0	7.2	
			93.2 93.2 186.4	0	-17.0	
			165.8 165.8 331.5	0	-32.8	
C. carnea (L)	*Phaseolus vulgaris*	Bixafen Fluopyram Prothiocona-zol	16.6 16.6 33.2	8.3	-15.0	83873047
			29.5 29.5 58.9	-2.8	26.5	Moll 2013
			52.4 52.4 104.8	5.6	-34.9	
			93.2 93.2 186.4	25.0	-33.8	
			165.8 165.8 331.5	41.7	38.1	
C. septempunctata (L)	*Phaseolus vulgaris*	Bixafen Fluopyram Prothiocona-zol	16.6 16.6 33.2	-2.7	8.2	83874012
			29.5 29.5 58.9	-2,7	41.0	Moll 2013
			52.4 52.4 104.8	-8.1	1.5	
			93.2 93.2 186.4	35.1	3.7	
			165.8 165.8 331.5	13.5	21.6	

PN = protonymphs, A = adults, La = larvae

On the basis of the presented results no effects ≥ 25% are expected for populations of the beneficial organism *Aphidius rhopalosiphi* when Ascra Xpro is applied according to the recommended use pattern. Effects of 25 - 50% are expected for populations of the beneficial organisms *Chrysoperla carnea* and *Coccinella septempunctata* when Ascra Xpro is applied according to the recommended use pattern. Effects of ≥ 50% are expected for populations of the beneficial organism *Typhlodromus pyri* when Ascra Xpro is applied according to the recommended use pattern. However, *Typhlodromus pyri* is not a relevant antagonist for the proposed crops. The results for *Typhlodromus pyri* indicate that the recommended application of Ascra Xpro has ef-

fects ≥ 50% on populations of relevant predatory mites and spiders when applied in the proposed crops.

Classification scheme of the effects:

Laboratory tests on artificial substrates (glass, quartz sand)
< 30% = not harmful
30 – 80% = slightly harmful
> 80% = harmful
Extended laboratory tests on natural substrates, semi-field and field tests
< 25% = not harmful
25 – 50% = slightly harmful
> 50% = harmful

Proposal for classification:

Ascra Xpro is classified as:
- not harmful for the parasitoid wasp *Aphidius rhopalosiphi*.
- slightly harmful for the lacewing *Chrysoperla carnea.*
- slightly harmful for the ladybird *Coccinella septempunctata.*
- harmful for populations of relevant predatory mites and spiders.

Adverse effects on soil quality indicators (e. g. microorganisms, earthworms) are considered in Section 6 Ecotoxicological Studies in the Registration Report.

IIIA1 6.2.5 Adverse effects on parts of plant used for propagating purposes

The propagating material to be considered for these crops is grain seed. Hence the application of Ascra Xpro has been evaluated for its potential negative impact on this propagating material. The applicant conducted germination tests on the harvested grain from several efficacy trials across the EU central regulatory zone and appropriate trials from countries in the maritime and northeast climatic EPPO zones from the EU north and south regulatory zones. The tests were done in both trials with high disease severity and trials with low or no disease severity. The distribution of trials per crop, country, year and climatic EEPO zone is shown in table 6.2.5-1.

Table 6.2.5-1: Distribution of trials used for seed germination tests

Crop(s)	country	years	number of trials		GEP
			maritime EPPO zone	northeast EPPO zone	
winter wheat	CZ	2012	3		yes
	DE	2012-2013	4+3		yes
	DK	2012	1		yes
	FR	2012	2		yes
	UK	2012-2013	4+3		yes
	SE	2012	1		yes
	PL	2012-2013		4+1	yes
	LV	2012		3+1	yes
	Total	-	21	9	
spring wheat	LT	2012		1	yes
	LV	2012		3	yes
		2013		2	yes
	Total	-	0	6	
winter barley	FR	2013	1		yes

	PL	2012-2013		4+3	yes
	Total	-	1	7	
spring barley	CZ	2012	3		yes
	DK	2012	1		yes
	FR	2013	2		yes
	UK	2012-2013	1+1		yes
	SE	2013	1		yes
	LT	2013		1	yes
	LV	2012		3	yes
	PL	2012		1	yes
	Total	-	9	5	
winter triticale	FR	2012-2013	2+2		yes
	LT	2013		1	yes
	LV	2013		1	yes
	PL	2013		2	yes
	Total	-	4	4	
winter rye	DK	2013	1		yes
	FR	2012	1		yes
	LT	2013		1	yes
	LV	2013		1	yes
	PL	2013		1	yes
	Total	-	2	3	
winter/spring oats	DK	2013	1		yes
	FR	2012-2013	2+1		yes
	LV	2013		1	yes
	Total	-	4	1	

The methodology the applicant used for the germination test is in accordance to the international rules established by ISTA (International Seed Testing Association).
He preheated (30-35°C) or prechilled (5°C) seeds collected at harvest for at least 8 days in order to break dormancy. Then, samples were placed at 20° C with 8 hours of light per 24 hours for the duration of the test. The applicant used substrate paper or sand as substrate. The sample size was 4 replicates with 100 seeds. Duration of the trial was 7 to 10 days. Assessment was at least one time at the end of the germination test, the applicant assessed the following: % of normal emerged seedlings, % of abnormal emerged seedlings, % of un-emerged seeds. Assessment of normal and abnormal seedlings and un-emerged seeds was done at least on time. The main results expressed as % of normal emerged seedlings are summarized in tables 6.2.5-2 to 6.2.5-11.

Table 6.2.5-2: Effect on seed germination in wheat in the central registration zone

Treatment	dose in L/ha	% normal emerged seedlings					
		winter wheat			spring wheat		
		mean	min-max	count	mean	min-max	count
Untreated	-	85.8	35-99	30	83.7	59-97	6
Tracker	1.5	85.6	37-100	29	78.7	47-93	6
Aviator Xpro	1.25	85.8	38-100	25	79.4	55-94	6
Ascra Xpro	**1.5**	**88.1**	**47-100**	**30**	**80.3**	**47-96**	**6**

Table 6.2.5-3: Effect on seed germination in winter wheat in the maritime and northeast EPPO zone

Treatment	dose in L/ha	% normal emerged seedlings – winter wheat	
		maritime EPPO zone	northeast EPPO zone

		mean	min-max	count	mean	min-max	count
Untreated	-	89.3	35-99	21	77.7	36-98	9
Tracker	1.5	88.6	37.-100	20	78.9	61-98	9
Aviator Xpro	1.25	87.6	38-100	16	82.6	65-98	9
Ascra Xpro	**1.5**	**89.8**	**47-100**	**21**	**84.2**	**66-98**	**9**

Table 6.2.5-4: Effect on seed germination in spring wheat in the maritime and northeast EPPO zone

Treatment	dose in L/ha	% normal emerged seedlings – spring wheat					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated	-	-	-	-	83.7	59-97	6
Tracker	1.5	-	-	-	78.7	47-93	6
Aviator Xpro	1.25	-	-	-	79.4	55-94	6
Ascra Xpro	**1.5**	**-**	**-**	**-**	**80.3**	**47-96**	**6**

6.2.5-5: Effect on seed germination in barley in the central registration zone

Treatment	dose in L/ha	% normal emerged seedlings					
		winter barley			spring barley		
		mean	min-max	count	mean	min-max	count
Untreated	-	69.8	21-99	8	86.8	37-99	14
Tracker	1.5	75.0	36-99	8	84.7	41-100	14
Aviator Xpro	1.0	73.1	34-99	8	84.9	49-97	14
Ascra Xpro	**1.2**	**73.3**	**29-100**	**8**	**86.4**	**40-100**	**14**

Table 6.2.5-6: Effect on seed germination in winter barley in the maritime and northeast EPPO zone

Treatment	dose in L/ha	% normal emerged seedlings – winter barley					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated	-	96.5	-	1	66.0	21-99	7
Tracker	1.5	93.8	-	1	72.3	3-99	7
Aviator Xpro	1.0	92.8	-	1	70.2	34-99	7
Ascra Xpro	**1.2**	**93.5**	**-**	**1**	**70.4**	**29-100**	**7**

Table 6.2.5-7: Effect on seed germination in spring barley in the maritime and northeast EPPO zone

Treatment	dose in L/ha	% normal emerged seedlings – spring barley					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated	-	95.0	90-99	9	72.0	37-96	5
Tracker	1.5	94.5	85-100	9	67.1	41-96	5
Aviator Xpro	1.0	93.6	90-97	6	74.5	49-96	5
Ascra Xpro	**1.2**	**95.5**	**92-100**	**9**	**70.0**	**40-96**	**5**

Table 6.2.5-8: Effect on germination in rye, triticale and oats in the central registration zone

Treatment	dose in L/ha	% normal emerged seedlings					
		triticale – 8 trials		rye – 5 trials		oats – 5 trials	
		mean	min-max	mean	min-max	mean	min-max
Untreated	-	87.5	71-98	92.0	84-98	85.1	58-97
Bell	1.5	85.9	66-99	83.9	69-95	80.0	45-96
Ascra Xpro	1.2	-	-	-	-	84.9	61-95
Ascra Xpro	**1.5**	**86.8**	**68-98**	**89.4**	**81-95**	**-**	**-**

Table 6.2.5-9: Effect on seed germination in rye in the maritime and northeast EPPO zone

Treatment	dose in L/ha	% normal emerged seedlings – Winter rye					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated	-	92.3	89-96	2	91.8	84-98	3
Tracker	1.5	82.4	78-87	2	84.8	69-95	3
Aviator Xpro	1.25	-	-	-	89.4	83-95	3
Ascra Xpro	**1.5**	**89.4**	**87-92**	**2**	**89.4**	**81-95**	**3**

Table 6.2.5-10: Effect on seed germination in triticale in the maritime and northeast EPPO zone

Treatment	Dose in L/ha	% normal emerged seedlings – triticale					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated	-	89.5	85-93	4	85.5	71-98	4
Tracker	1.5	87.5	82-93	4	84.3	66-99	4
Aviator Xpro	1.25	92.3	91-93	2	87.8	74-98	4
Ascra Xpro	**1.5**	**88.2**	**82-92**	**4**	**85.3**	**68-98**	**4**

Table 6.2.5-11: Effect on seed germination in oats in the maritime and northeast EPPO zone

Treatment	dose in L/ha	% normal emerged seedlings – oats					
		maritime EPPO zone			northeast EPPO zone		
		mean	min-max	count	mean	min-max	count
Untreated	-	92.0	84-97	4	57.7	-	1
Tracker	1.5	88.8	74-96	4	44.8	-	1
Aviator Xpro	1.0	92.5	-	1	54.3	-	1
Ascra Xpro	**1.2**	**90.8**	**80-95**	**4**	**61.3**	**-**	**1**

In wheat, barley, rye, triticale and oats, the data shows that there was no negative effect on germination and early development of grain seeds from plants treated with Ascra Xpro. In all crops a virtually identical pattern of germination to the untreated control and the reference products Aviator Xpro and/or Tracker (Champion/Bell) was found. The applicant detected no difference between the maritime and northeast climatic EPPO zone.
The applicant reported that in barley, grain from some sites in Poland in particular showed low germination rates in the untreated grain, indicating possible disease such as Fusarium/Microdochium present in the sample.

Conclusion:

The presented data correspond with the requirements of the EPPO ~~standard~~Standard PP 1/243. Through the application of the fungicide with the active substances bixafen, fluopyram and prothioconazole no negative effects on the process and on treated plants or plant products used for propagation were detected.

Based on this submitted data and on the expert knowledge about bixafen, fluopyram and prothioconazole it can be concluded to accept the data provided by the applicant.

IIIA1 6.2.6 Impact on succeeding crops

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev2 final, 2002). In the case of a non-herbicide, screening results and/or

Tier 1 studies give first information about the likelihood for terrestrial plant effects. The risk can be considered acceptable if there are no data indicating more than 50% phytotoxic effect at the maximum application rate. The potential effect of Ascra Xpro on succeeding crops has been evaluated on the seedling emergence and seedling growth of eleven terrestrial non-target plant species in a greenhouse study according to OECD-Guideline 208.

As further supporting evidence, reference is also made to studies that the applicant conducted with each of the straight active substances (bixafen, fluopyram and prothioconazole). A summary of main results is presented hereafter.

Bixafen

The applicant observed that over several years of field testing no negative influence on succeeding crops was ever reported following bixafen (BYF 00587 EC 125) applications. The safety of bixafen to succeeding crops was tested in a worst case scenario in a pre-emergence test (greenhouse) against a range of plant species. BYF 00587 EC 125 was tested with 0.5 N, 1 N and 2 N rates (N = maximal single rate of use to be registered). Main results are summarized in table 6.2.6-1.

Table 6.2.6-1: Impact of bixafen in pre-emergence application

Plant species BYF 00587 [g a.s./ha]	% damage (14 days after sowing)			% damage (28 days after sowing)		
	[63]	[125]	[250]	[63]	[125]	[250]
Avena sativa	0	0	0	0	10	6.25
Lolium perenne	0	0	0	10	10	15
Zea mays	0	0	0	0	0	0
Beta vulgaris	0	0	0	0	0	0
Brassica napus	0	0	0	0	0	0
Cucumis sativus	0	0	0	0	0	0
Fagopyrum esc.	0	0	0	0	0	0
Glycine max.	0	0	0	12.5	15	16.25
Helianthus annus	0	0	0	0	0	0
Lycopersicon esc.	0	0	0	0	0	0

For the applicant the data shows that no negative influence on emergence or growth of most of the tested plant species was found up to a dose rate of 2 N (250 g bixafen / ha). He observed some minor damage on *Lolium perenne* and *Glycine max*, but the damage seen was considered to be in the range of natural biological variation as no dose response was evident.

Based on these results, the applicant concluded that BYF 00587 (125 g/l bixafen), when used as proposed, will be safe to any succeeding crops.

Fluopyram

The applicant observed that fluopyram (AE C656948 SC 500) showed no negative influence on succeeding crops over several years of field testings. It was evaluated in a worst case scenario up to 500 g/ha in a pre-emergence test (greenhouse) against a range of plant species. Main results are summarized in table 6.2.6-2.

Table 6.2.6-2: Impact of fluopyram pre-emergence application

Plant species	% damage (14 days after sowing)			% damage (29 days after sowing)		
AE C656948 [g a.s./ha]	[125]	[250]	[500]	[125]	[250]	[500]
Allium cepa	0	0	0	0	0	0

Avena sativa	0	0	0	0	0	0
Lolium perenne	0	0	0	0	0	0
Zea mays	0	0	0	0	0	0
Beta vulgaris	0	0	0	0	0	0
Brassica napus	0	0	0	0	0	0
Cucumis sativus	0	0	0	0	0	0
Fagopyrum esc.	0	0	0	0	0	0
Glycine max.	0	0	0	0	0	0
Helianthus annus	0	0	0	0	0	0

For the applicant the data shows that fluopyram had no effect on a number of plants and caused no crop damage either after 14 days or 29 days. The plant fresh weight data showed no negative effects at all. Based on these results, the applicant concluded that AE C656948 (500 g/l fluopyram), when used as proposed, will be safe to any succeeding crops.

Prothioconazole

Over several years of field testing and commercial uses, no adverse effects on succeeding crops were ever reported following applications of Proline EC 250 (prothioconazole), including double applications at 2N rate.

Glasshouse studies looking at the effects of prothioconazole applied in pre-emergence to a range of species were set up by the applicant to evaluate the effects of the product under severe conditions up to the 3 N application rate. Main results are presented in table 6.2.6-3.

Table 6.2.6-3: Impact of prothioconazole in pre-emergence application

Plant species	% damage after full emergence			
prothioconazole [g a.s./ha]	[200]	[300]	[400]	[600]
Zea mays	0	0	0	0
Beta vulgaris	0	5	10	15
Alopecurus myosuroides	0	0	0	0
Avena fatua	0	0	0	0
Echinochloa crus-galli	0	0	0	0
Setaria viridis	0	0	5	15
Abutilon theophrasti	0	0	0	0
Amaranthus retroflexus	5	15	30	60
Galium aparine	0	0	0	0
Ipomea hederacea	0	0	0	0
Sinapis alba	0	0	0	0

For the applicant the data shows the good safety of prothioconazole to succeeding crops up to 400 g/ha of active substances.
Therefore, he concluded that prothioconazole (Proline EC 250) poses no risk to succeeding crops when used as recommended.

Bixafen + fluopyram + prothioconazole

The applicant used eleven species of terrestrial non-target plants (4 monocotyledonous and 7 dicotyledonous): oilseed rape (*Brassica napus*), cucumber (*Cucumis sativus*), sugar beet (*Beta vulgaris var. altissima*), soybean (*Glycine max*), sunflower (*Helianthus annuus*), tomato (*Solanum lycopersicum*), buckwheat (*Fagopyrum esculentum*), onion (*Allium cepa*), rye grass (*Lolium multiflorum*), oats (*Avena sativa*) and maize (*Zea mays*).The plant protection product Ascra Xpro

was applied at 1.5 L/ha in pre-emergence in a volume of 200 L/ha using a laboratory spray cabin. Seeds were introduced manually into the soil. Six plants per pot and 5 replicates were used. Pots were grown and maintained under glasshouse conditions for all plants with a daily mean temperature at 21°C with a 16 h photoperiod.

Assessments for seedling emergence and phytotoxicity were done by the applicant 7, 14 and 21 days after 50% of the seedlings in the control had emerged (species dependent). At day 21 after 50% emergence of the control seedlings, survival of emerged plants, shoot dry weight and plant development (BBCH) were determined.

The phytotoxicity [%], the emergence rate and shoot dry weight [% inhibition] compared to control at test termination (21 days after 50% emergence of control seedlings) are presented in table 6.2.6-4. All inhibitions were much lower than the 50% trigger for further testing.

Table 6.2.6-4**: Summary of phytotoxicity, emergence rate and shoot dry weight inhibition**

Species	Seedling emergence (% inhibition)	Survival (% inhibition)	Phytotoxicity (%)	Shoot dry weight (% inhibition)
Dicotyledons				
Oilseed rape	10	0	1	1
Cucumber	0	0	0	3
Sugar beet	0	0	0	-1
Soybean	0	0	4	0
Sunflower	7	0	6	14
Tomato	0	0	0	-7
Buckwheat	7	0	0	11
Monocotyledons				
Onion	3	0	0	15
Rye grass	-4	0	0	-10
Oats	3	0	0	-1
Maize	3	0	0	1

Negative figures indicate that there was an increase when compared to the control.

The applicant observed no control mortality > 10% and all control plants remained healthy throughout the entire test period. The rate of seedling emergence was ≥ 70% for all tested plant species. Therefore, the applicant concluded that any adverse influences on the study results can be excluded and the study is considered as valid.

Pre-emergence application of Ascra Xpro did not produce any statistically significant effects on seedling emergence and shoot dry weight. Inhibitions in shoot dry weight were determined by the applicant for all plant species except of sugar beet, soybean, tomato, rye grass and oats. No effects on plant survival were found and only minor phytotoxicity was observed with single species. Also, no effects on plant development (BBCH) were found.

In this study, the applicant treated eleven plant species with Ascra Xpro at a rate of 1.5 L product/ha. For none of the tested species effects on survival, phytotoxicity or shoot dry weight reaching or exceeding the 50% threshold for further testing were found.

As further supportive evidence, the applicant observed no restrictions with respect to succeeding crops following bixafen, fluopyram and prothioconazole treatments in European countries where approval has been granted and as a result it is reasoned that applications of Ascra Xpro are not expected to impose stronger risks to succeeding crops given that lower rates of each active substances will be recommended and that no synergism has been observed when mixing the 3 active substances. Moreover, over several years of field testing, no negative influence on

succeeding crops was ever reported following Ascra Xpro spray applications. Based on the complete absence of any effects in typical cropping situations for the straight products and the co-formulation, the applicant concluded that the plant protection product Ascra Xpro poses no risk to following crops.

Therefore, the applicant concluded that commercial use of Ascra Xpro, will be safe to any succeeding crops when used as recommended.

Conclusion:

The presented data correspond in parts with the requirements of the EPPO ~~standard~~Standard PP 1/207. Results from greenhouse experiments were presented by the applicant. They show no obvious negative effect of bixafen, fluopyram and prothioconazole on germination and plant growth of succeeding crops.

Based on this submitted data and expert knowledge about bixafen, fluopyram and prothioconazole it can be concluded to accept the data provided by the applicant.

IIIA1 6.2.7 Impact on other plants including adjacent crops

The applicant based the risk assessment on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev2 final, 2002). In the case of a non-herbicide, screening results and/or Tier 1 studies give first information about the likelihood for terrestrial plant effects. The risk can be considered acceptable if there are no data indicating more than 50% phytotoxic effect at the maximum application rate. The potential effect of Ascra Xpro on adjacent crops has been evaluated on the vegetative vigour of eleven terrestrial non-target plant species in a greenhouse study according to OECD-Guideline 227.

As further supporting evidence, the applicant also made reference to studies that were conducted with each of the straight active substances (bixafen, fluopyram and prothioconazole). A summary of main results is presented hereafter.

Bixafen
No significant adverse effects on monocotyledonous or dicotyledonous crops were ever reported after bixafen (BYF 00587 EC 125) spray applications in primary and secondary screening tests. The applicant tested safety to adjacent crops of bixafen by direct spray applications in greenhouse post-emergence test onto young plants in the very sensitive seedling stage BBCH 11 to BBCH 21 with 0.5 N, 1 N and 2 N rates. Main results are summarized in table 6.2.7-1.

Table 6.2.7-1: Impact of bixafen in early post-emergence application

Plant species	% damage		
BYF 00587 [g a.s./ha]	[63]	[125]	[250]
Avena sativa	0	0	0
Lolium perenne	0	0	0
Zea mays	5	5	5
Beta vulgaris	5	10	10
Brassica napus	0	5	5
Cucumis sativus	15	20	20
Fagopyrum esculentum	5	5	10
Glycine max.	5	10	10

Helianthus annus	0	5	10
Lycopersicon esculentum	0	0	5

The applicant observed some minor damage on *Beta vulgaris*, *Cucumis sativus*, *Glycine max* and *Fagopyrum esculentum* applying BYF 00587 EC 125 (bixafen) early post-emergence. The damage seen is considered to be in the range of natural biological variation as no dose response is evident.

Based on these results, the applicant concluded that BYF 00587, when used as recommended, will be safe to any adjacent crops.

Fluopyram

The applicant suggested that fluopyram straight (AE C656948 SC 500) did not show significant adverse effects on monocotyledonous or dicotyledonous crops after spray applications in primary and secondary screening tests. It was tested by direct spray applications in greenhouse post-emergence test onto young plants in the very sensitive seedling stage BBCH 11 to BBCH 21 at different rates and up to 500 g/ha. Main results are summarized in table 6.2.7-2.

Table 6.2.7-2: Impact of fluopyram post-emergence application

Plant species	% Damage		
AE C656948 [g a.s./ha]	[125]	[250]	[500]
Allium cepa	0	0	
Avena sativa	0	0	0
Lolium perenne	0	0	0
Zea mays	0	0	0
Beta vulgaris	0	0	5
Brassica napus	0	0	0
Cucumis sativus	0	5	5
Fagopyrum esculentum	0	5	5
Glycine max.	0	0	0
Helianthus annus	0	0	0

The applicant observed some minor damage on *Beta vulgaris*, *Cucumis sativus* and *Fagopyrum esculentum* (maximum 5% damage at 250 or 500 g/ha) applying Fluopyram SC 500 early post-emergence. The damage observed is considered to be in a range of natural biological variation taking into account the very low level of damage.
Based on these results, the applicant concluded that Fluopyram SC 500, when used as recommended, will be safe to any adjacent crops.

Prothioconazole

Over several years of field testing and commercial uses, no adverse effects on adjacent crops were ever reported following applications of Proline EC 250 (prothioconazole), including double applications at 2N rate.

The applicant also tested safety to non-target plants of prothioconazole (Proline EC 250) by direct spray applications to a range of species, as used in the succeeding crop studies. Plants were grown under glasshouse conditions and treated at the susceptible seedling stage (1 to 3 leaves) at rates from N (proposed rate of 200 g a.s.) to 3 N. Main results are presented in table 6.2.7-3.

Table 6.2.7-3: Impact of prothioconazole in early post-emergence application

Plant species		% damage after full emergence			
prothioconazole	[g a.s./ha]	[200]	[300]	[400]	[600]

Zea mays	0	0	0	5
Beta vulgaris	0	0	0	20
Alopecurus myosuroides	0	0	0	20
Avena fatua	0	0	0	0
Echinochloa crus-galli	0	0	0	0
Setaria viridis	0	0	0	10
Abutilon theophrasti	0	0	0	5
Amaranthus retroflexus	0	0	0	20
Galium aparine	0	5	10	15
Ipomea hederacea	0	0	0	0
Sinapis alba	0	10	15	25

For the applicant the results show that at the proposed rate of use no damage occurred on any plant species. Results at higher rates indicated that some species have more potential for damage than others, although levels of effect were generally tolerable at double the proposed rate, therefore indicating a reasonable safety margin across the species tested.

Therefore, the applicant concluded that prothioconazole (Proline EC 250) spray drift poses no risk to adjacent crops.

Bixafen + fluopyram + prothioconazole

The applicant used eleven species of terrestrial non-target plants (4 monocotyledonous and 7 dicotyledonous): oilseed rape (*Brassica napus*), cucumber (*Cucumis sativus*), sugar beet (*Beta vulgaris var. altissima*), soybean (*Glycine max*), sunflower (*Helianthus annuus*), tomato (*Solanum lycopersicum*), buckwheat (*Fagopyrum esculentum*), onion (*Allium cepa*), rye grass (*Lolium multiflorum*), oats (*Avena sativa*) and maize (*Zea mays*).
The plant protection product Ascra Xpro was applied at 1.5 L/ha in post-emergence in a volume of 200 L/ha using a laboratory spray cabin when the test plants reached the 2-4 leaves growth stage (BBCH 12-14). Five plants per pot and 6 replicates were used.
Pots were grown and maintained under glasshouse conditions for all plants with a daily mean temperature at 21°C with a 16 h photoperiod. Following the application, all plants were grown for 20 days.
The applicant carried out assessments for phytotoxicity 7, 14 and 20 days after application (DAA) for all plants. After harvest of all plants at day 20 after application, the shoot dry weight was determined.

The survival [% inhibition], phytotoxicity [%] and the reductions [% inhibition] of shoot dry weight compared to control at test termination are presented in table 6.2.7-4.

Table 6.2.7-4**: Summary of survival, phytotoxicity and reductions of shoot dry weight**

Species	Survival (% inhibition)	Phytotoxicity (%)	Shoot dry weight (% inhibition)
Dicotyledons			
Oilseed rape	0	20	14*
Cucumber	0	30	22*
Sugar beet	0	28	14*
Soybean	0	30	5
Sunflower	0	20	10
Tomato	0	33	20*
Buckwheat	0	33	24*
Monocotyledons			

Onion	0	8	5
Rye grass	0	10	2
Oats	0	0	-7
Maize	0	18	9

Negative figures indicate that there was an increase when compared to the control.
* Statistically significant (Student-t test, one sided smaller; $p \leq 0.05$).

There was no control mortality > 10% observed and all control plants remained healthy throughout the entire test period. Therefore, any adverse influences on the study results can be excluded and the study is considered as valid.
The post-emergence application of Ascra Xpro did not affect the eleven tested plant species concerning survival. With the exception of oats, for each of the tested plant species symptoms of phytotoxicity could be observed. Statistically significant inhibitions of shoot dry weight were observed for oilseed rape, cucumber, sugar beet, tomato and buckwheat; however, all inhibitions were much lower than the 50% trigger for further testing. No clear effects on plant development (BBCH) were found.

In this vegetative vigour study, the applicant treated eleven plant species with Ascra Xpro at a rate of 1.5 L product/ha. For none of the tested species, the applicant found effects on survival, phytotoxicity or shoot dry weight reaching or exceeding the 50% threshold for further testing.

Exposure assessment
Spray drift is considered the key exposure route for terrestrial plants located in the vicinity of the treated area. The drift models produced by the BBA for the exposure assessment of aquatic organisms may be used as a surrogate to cover the exposure assessment of terrestrial plants (Ganzelmeier et al, 1995, updated by Rautmann et al, 2001).
The off-field exposure shown in table 6.2.7-5 for non-target terrestrial plants is based on drift values as given in the Terrestrial Guidance Document including the use of drift reducing spray nozzles. According to SANCO/10329/2002 the drift factor for two applications in field crops without any buffer zone to the adjacent field edge is 2.38%.

Table 6.2.7-5: Off-crop exposure for non-target terrestrial plants

Application rate [mL prod./ha]	distance [m]	drift* (%)	PER no drift reduction [mL prod./ha]
1500	1	2.38	35.7

* Drift value (2 applications, field crops) acc. to Ganzelmeier & Rautmann

Deterministic risk assessment for non-target terrestrial plants
TER values are calculated based on the lowest ER50 values of the plant tests, seedling emergence and vegetative vigour, respectively. A TER of ≥ 5 is considered acceptable if at least six plant species have been tested (deterministic approach).
As no effects > 50% occurred in the seedling emergence and in the vegetative vigour test at the application rate of 1.5 L product/ha, the following risk assessment in table 6.2.7-6 is based on conservative ER50 > 1500 mL product/ha.

Table 6.2.7-6: Deterministic risk assessment for non-target terrestrial plants

Cereals, two applications, 1500 mL prod./ha; ER_{50} > 1500 mL prod./ha			
distance [m]	drift** (%)	PER no drift reduction [mL prod./ha]	TER
1*	2.38	35.7	> 42

* 1 m distance is defined as "no in-crop buffer zone"
** BBA drift values (2 applications, cereals), see Terr. Guidance Doc. SANCO/10329/2002 rev 2 final

Based on this deterministic risk assessment, according to EU requirements the risk for non-target terrestrial plants is considered acceptable. Neither drift reducing spraying equipment nor

a buffer zone is required when the product is applied at application rates recommended according to good agricultural practice.

As further supportive evidence, the applicant observed no restrictions with respect to adjacent crops following bixafen, fluopyram and prothioconazole treatments in European countries where approval has been granted. Studies have shown the absence of any significant crop damage after applications of bixafen at 125/250 g/ha, fluopyram at 500 g/ha and prothioconazole at 200 g/ha. Moreover, over several years of field testing, no negative influence on adjacent crops was ever reported following Ascra Xpro spray applications.

Therefore, the applicant concluded that commercial use of Ascra Xpro will be safe to any adjacent crops when used as recommended.

Conclusion:

The presented data correspond with the requirements of the EPPO ~~standard~~Standard PP 1/256. Results from seedling emergence and vegetative vigour test were submitted by the applicant. Slightly effects of bixafen, fluopyram and prothioconazole on biomass production and visible damage were observed for all test crops, mostly dicotyledons.

Based on this submitted data and expert knowledge about bixafen, fluopyram and prothioconazole it can be concluded to accept the data provided by the applicant.

IIIA1 6.2.8 Possible development of resistance or cross-resistance

Mode of Action
Both bixafen and fluopyram belong to the group of SDHI fungicides. Bixafen is, chemically, a pyrazole-carboxamide analogue, fluopyram a pyridinyl-ethyl-benzamide. Their biochemical mode of action has been shown to rely on the inhibition of the enzyme succinate dehydrogenase (SDH, complex II) within the fungal mitochondrial respiration chain.
The mode of action of the triazoline-thione compound prothioconazole relies on the inhibition of the demethylation at the C14 position in the fungal sterol biosynthesis.

Mechanism of Resistance
SDHI resistance is mostly based on single target site mutations. In contrast to the situation with QoIs, several mutations have been detected up to now which often occur at different positions or subunits of the target enzyme, dependant on the pathogen. The consequences of each of the different mutations for the performance of the entire group of SDHI fungicides are not yet fully understood.
Resistance against DMIs is mostly based on the accumulation of several target site mutations. Thus, the resistance type characteristic for DMIs is often described as “continuous selection” or “shifting”.

Cross Resistance
Both, bixafen and fluopyram exhibit in general a positive cross-resistance pattern to other SDHI fungicides, although certain differences in the cross-resistance pattern can be observed between different members of the group of SDHI fungicides, dependant on the chemical group and on the kind and position of target site mutations in the succinate dehydrogenase enzyme.
Principally, all DMI fungicides show a positive cross-resistance although the degree of cross-resistance is never 100%. DMIs do not show positive cross-resistance towards other SBI fungicide classes (amines, keto-reductase inhibitors) or towards other important fungicide groups such as QoI or SDHI fungicides. It is, therefore, wise to accept this finding as the basis of an anti-resistance strategy.

Evidence of Resistance, Sensitivity Data and Resistance Risk

According to EPPO ~~standard~~Standard PP 1/213 'Resistance risk analysis' information about the following topics should be reported for the zone:
1-Mode of action / Mechanism of resistance
2-Evidence of resistance and cross-resistance

Table 6.2.8-1: Resistance risk assessment of the product

Fungicide classes	Active substance(s)	Fungicide risk	Combined risk		
- QoI fungicides - MBC fungicides - phenylamides		high = 3	3	6	9
- SDHI fungicides* - SBI fungicides - amines - anilino-pyrimidines - phenylpyrroles	Bixafen (SDHI) Fluopyram (SDHI) Prothioconazole (SBI)	medium = 2	2	4	6
- multi-site fungicides (e.g. copper, sulfur, dithiocarbamates) - MBI-R inhibitors - phosphonates - host plant defence inducers		low = 1	1	2	3
		Pathogen risk	low = 1	med. = 2	high = 3
		Pathogens submitted	PUCCRE PUCCHD PSDCHE	SEPTTR PYRNTR PYRNTE RHYNSE	ERYSGR ERYSGH RAMUCC

* according to FRC, SDHI fungicides are regarded to bear a `medium-to-high´ resistance risk (www.frac.info)

Sensitivity data / Monitoring data / Changes in field performance (according to the authors´ knowledge)

Table 6.2.8-2: Sensitivity evaluation for wheat pathogens and active substance(s)

Pathogen	Zone	Bixafen	Fluopyram	Prothioconazole
Zymoseptoria tritici (Mycospohaerella graminicola)	maritime	2a	2a	3a
	northeast	1	1	2a
	southeast	1	1	1
Blumeria graminis f.sp. *tritici*	maritime	1	1	2a
	northeast	1	1	2a
	southeast	1	1	1
Pyrenophora tritici-repentis	maritime	1	1	1
	northeast	1	1	1
	southeast	1	1	1
Puccinia triticina	maritime	1	1	2a
	northeast	1	1	1
	southeast	1	1	1

Oculimacula spp.	maritime	1	1	2a
	northeast	1	1	1
	southeast	1	1	1

►1) no cases of field resistant strains reported for active substance (full sensitivity)
►2a) first field strains with reduced *in-vitro* sensitivity (dose-response still given or/and shifting-type)
►2b) first field strains with full *in-vitro* resistance (no dose-response given / disruptive type)
►3a) moderate frequency of strains with reduced *in-vitro* sensitivity (dose-response still given / shifting-type)
►3b) moderate frequency of strains with full *in-vitro* resistance (no dose-response given / disruptive type)
►4) field performance possibly reduced / high frequency of strains with reduced *in-vitro* sensitivity
►5) field performance strongly affected / high frequency of strains with full *in-vitro* resistance

Table 6.2.8-3: Sensitivity evaluation for barley pathogens and active substance(s)

Pathogen	Zone	Bixafen	Fluopyram	Prothiocona-zole
B. graminis f.sp. *hordei*	maritime	1	1	2a
	northeast	1	1	2a
	southeast	1	1	1
Pyrenophora teres	maritime	3a	3a	1
	northeast	1	1	1
	southeast	1	1	1
Rhynchosporium secalis	maritime	1	1	1
	northeast	1	1	1
	southeast	1	1	1
Puccinia hordei	maritime	1	1	1
	northeast	1	1	1
	southeast	1	1	1
Ramularia collo-cygni	maritime	1	1	1
	northeast	1	1	1
	southeast	1	1	1

►1) no cases of field resistant strains reported for active substance (full sensitivity)
►2a) first field strains with reduced *in-vitro* sensitivity (dose-response still given or/and shifting-type)
►2b) first field strains with full *in-vitro* resistance (no dose-response given / disruptive type)
►3a) moderate frequency of strains with reduced *in-vitro* sensitivity (dose-response still given / shifting-type)
►3b) moderate frequency of strains with full *in-vitro* resistance (no dose-response given / disruptive type)
►4) field performance possibly reduced / high frequency of strains with reduced *in-vitro* sensitivity
►5) field performance strongly affected / high frequency of strains with full *in-vitro* resistance

At Bayer CropScience, the sensitivity of European populations of cereal pathogens towards SDHI fungicides has been investigated since more than 10 years. During this period of time, no resistance cases of practical relevance have been reported so far for bixafen or fluopyram. The presented bixafen and fluopyram data show mostly a very stable sensitivity status for the studied pathogens and are, therefore, fully in line with latest reports of the FRC SDHI Working Group. Particularly for Septoria leaf blotch, wheat brown rust and barley dwarf rust the actual sensitivity of populations stayed still in the range of the `baseline sensitivity´ as seen over the past years. In addition, no change in the sensitivity of both eyespot types and a stable sensitivity status for scald could be observed. With *Ramularia collo-cygni*, monitoring studies showed as well a high and homogeneous intrinsic activity of bixafen towards populations originating from different European countries. Overall, in regard to the pathogens mentioned above sensitivity differences could not be observed between fungal populations originating from different countries out of the same European zone or between European zones. However, in 2012, within four isolates single target site mutations have been detected for the first time (C-T79N and C-W80S in Septoria leaf blotch, B-H277Y in net blotch), but resistance factors were reported to be low. Since then, with *Zymoseptoria tritici*, occurrence of further single strains with reduced sensitivity was reported by the FRC SDHI Working Group in France, Germany, Ireland and UK, as well as presence of additional mutations (SDH subunit C: N86S, SDH subunit B: N225T). As resistance factors were again reported to be low, and due to the strong intrinsic activity of bixafen, such isolates were not found in the long-term monitoring studies at Bayer CropScience. In contrast,

with *Pyrenophora teres*, an increased percentage of strains with reduced in vitro sensitivity have been observed particularly in Germany, Belgium, and France, and a multitude of different mutations in addition to the above mentioned B-H277Y mutation was identified (C-N75S, C-G79R, C-H134R, C-S135R, D-D124N, D-D124E, D-H134R, D-D145G). With these new mutants, in the used laboratory test systems a clear dose-response was always given with pyrazole-carboxamides such as bixafen. As first in planta studies showed partially decreased performance of solo applied bixafen dependent of the mutation type, further in vivo greenhouse- and fitness studies are currently ongoing at Bayer CropScience in order to characterize the new strains in more detail and to gain more knowledge on their relevance and competitiveness under practical conditions.
Since December 2009, the resistance risk of SDHIs is classified as 'medium-to-high'.
Generally, resistance to DMI fungicides has been observed for several pathogens and crops. In cereals, in spite of the long-term and intensive use of DMI fungicides against pathogens a multitude of papers have been published until now describing resistance findings of individual compounds and fungi, partly already more than 20 years ago. Nevertheless, although showing often no longer the initial level of activity in all these cases DMIs are still widely used on the practical level. The sensitivity of European populations of cereal pathogens towards SBI fungicides has been investigated at Bayer CropScience since more than 15 years. Overall, the presented prothioconazole data show mostly a stable sensitivity status for the studied pathogens and are, therefore, fully in line with latest reports of the FRC SBI Working Group. Particularly for wheat powdery mildew, barley powdery mildew, net blotch and wheat brown rust, the actual sensitivity of populations stayed still in the range of variability as seen over the past 10 years. In addition, only a slight change in the sensitivity of both eyespot types during the last two years and a stable sensitivity status for scald could be observed. For Ramularia leaf spot monitoring studies available since 2010 show as well a very stable sensitivity status. However, in 2009, with prothioconazole an increase of mean EC50 values has been detected with *Z. tritici* in most of the studied countries. According to FRC, this trend slowed down in 2010 to 2012 and was stable in 2013. For 2014, the sensitivity was reported to be in the same range as in 2011. In this context, as the DMI sensitivity of Septoria leaf blotch has been thoroughly investigated by different research groups with focus on mutations of the target enzyme cyp51, it is worthwhile to note that different publications demonstrated a clearly lower impact of such mutations on the prothioconazole sensitivity compared to other DMI fungicides. However, outliers with higher EC50 values in lab tests were detected since 2009, and an increasing number of combinations of cyp51 mutations have been identified particular in UK and Ireland from which some of them can influence the sensitivity.
In regard to the different European zones, sensitivity differences could be observed between fungal populations originating from different countries out of the same European zone, e.g. with *Blumeria graminis f.sp. tritici*, as strains from the Czech Republic are somewhat more sensitive than British strains. Also brown rust was found to be more sensitive in Poland than in, e.g., Northern France or England. Available monitoring data from countries located in the Western part of the Northern European zone, e.g. for Swedish or Danish powdery mildew populations, showed often a similar sensitivity status as in Western-central Europe. Further data are required in order to clarify, if similar sensitivity gradients exist between Western- and Eastern parts of the Northern European zone as observed between Western- and Eastern parts of the central European zone. Southern Europe: based on the monitoring experience with cereal pathogens, the DMI sensitivity is mostly higher in Southern European countries than in central- or Northern Europe as become obvious, e.g., with *Z. tritici* in Spain or with *P. triticina* in Italy.
The resistance risk of DMI fungicides is still classified as "medium" or "moderate".

Acceptability of Resistance Risk
The use of mixtures or alternation systems (or both) of fungicide groups showing no cross-resistance is clearly an important resistance risk modifier out of the spectrum of modifiers that are meanwhile well accepted on the advisory and on the farmer level. Therefore, the co-formulation of the SDHI fungicides bixafen and fluopyram with the SBI fungicide prothioconazole can be automatically regarded as a resistance risk modifier for each mode of action, reducing

the development or occurrence of fungal strains less sensitive towards the individual non-cross resistant partner compound being effective on the same pathogen. In addition, the incomplete cross-resistance pattern as described above for different chemical classes of SDHI fungicides and specific SDHI target site mutants and the fungicidal spectrum of Ascra® in cereals covering several non-high risk pathogens reduces the overall resistance risk.
An acceptable resistance risk for bixafen, fluopyram and prothioconazole is therefore most probably given when the approved resistance risk modifiers that are in use for SDHI- and SBI fungicides are equally implemented for bixafen, fluopyram and prothioconazole. It seems to be quite probable that the adaptation of these approved rules to Ascra® is still effective and sufficient. Under this precondition, if the general recommendations of the FRC SDHI Working Group and of the FRC SBI Working Group are respected, the overall risk for Ascra® use in cereals is acceptable without further specific measures.

Resistance Management Strategy and Use Pattern
The low number of resistance reports with cereal pathogens and SDHI fungicides and the relatively slow development of DMI resistance give good opportunities for an effective resistance management. Particularly based on 25 years' experience with DMI use in different crops, some resistance modifiers have evolved that have been proved to be effective tools in resistance management for this fungicide group and that are meanwhile well accepted on the advisory and on the farmer level. The resistance management for Ascra® is orientated at the approved modifiers for other DMI- and SDHI fungicides. Especially the guidelines of the FRC SBI Working Group for the use of prothioconazole and the guidelines of the FRC SDHI Working Group for foliar application of bixafen and fluopyram in cereals are fully implemented.
In summary, a maximum of 2 Ascra® sprays per cereal crop at manufacturers recommended rates cover all FRC guidelines given for foliar applications of SDHI- and DMI fungicides.

Communication and Implementation of the Management Strategy
The resistance management for prothioconazole in cereals is coordinated as for all SBI fungicides by the FRC SBI Working Group and for bixafen and fluopyram by the FRC SDHI Working Group. Bayer CropScience is an active member in both Working Groups. All resistance management recommendations of the groups are automatically applied for Ascra® as well. This statement includes future changes that may eventually be necessary if the available information basis should change. The anti-resistance strategy for Ascra® is communicated to the advisory and the farmer's level essentially on the label. In addition, leaflets and brochures that describe the product properties in a detailed manner contain the essential anti-resistance strategy points.

Conclusion:

The presented data correspond with the requirements of the EPPO ~~standard~~Standard PP 1/213. The applicant addresses all points of the EPPO ~~standard~~Standard to evaluate the possible actual resistance risk of bixafen, fluopyram and prothioconazole. Based on FRAC assessment the applicant stated the risk of resistance due to the mode of action:

for SDHI fungicides it will be assessed as medium to high depends on the pathogen (combined resistance risk = 4-6)

and for DMI fungicides (SBI-class I; Triazole) it will be assessed as depends on the pathogen (combined resistance risk = 2-4)

Based on this submitted data, further information in BAD and expert knowledge about bixafen, fluopyram and prothioconazole it can be concluded to accept the data provided by the applicant.

IIIA1 6.3 Economics

This is not an EC data requirement.

IIIA1 6.4 Benefits

IIIA1 6.4.1 Survey of alternative pest control measures

This is not an EC data requirement.

IIIA1 6.4.2 Compatibility with current management practices including IPM

This is not an EC data requirement.

IIIA1 6.4.3 Contribution to risk reduction

This is not an EC data requirement.

IIIA1 6.5 Other/special studies

Spray tank washing
The product can be easily removed from spray tanks with water detergent. Any remaining diluted product or spray tank residues should they fail to be removed prior to treating another crop, would be unlikely to result in any damage even if used at full rate based on the absence of damage in the adjacent crops test reported in section IIIA 6.2.7.

The applicant concluded that Ascra Xpro sprayed as recommended poses no risk to other crops should tank residues fail to be fully removed.

IIIA1 6.6 Summary and assessment of data according to points 6.1 to 6.5

Table 6.6-1: Proposed uses for Ascra Xpro

Crop	Target	application rate max. L/ha	spray volume L/ha	max. number of applications / interval in days	timing of application
TRZAX (wheat)	PSDCHE, ERYSGR, SEPTTR, PYRNTR, PUCCRE, PUCCST, LEPTNO, MONGNI	1.5	100-400	2 / 14	BBCH 30-61
HORVX (barley)	PSDCHE,ERYSGR, RHYNSE, PYRNTE PUCCHD, RAMUCC, YBFMI,	1.2	100-400	1	BBCH 30-61
SECCE (rye)	RHYNSE, PUCCRE, ERYSGR, PSDCHE	1.5	100-400	2 / 14	BBCH 30-61
TTLSS (triticale)	ERYSGR, SEPTSP, PUCCRE, PSDCHE, LEPTNO, PUCCST, PYRNTR	1.5	100-400	2 / 14	BBCH 30-61
AVESS (oats)	ERYSGR, PUCCCA, PSDCHE	1.2	100-400	1	BBCH 30-61

The plant protection product Ascra Xpro has been developed by Bayer CropScience as a new fungicide product for the control of foliar diseases in cereals. It belongs to the SDH and DMI group of fungicides and has shown a broad spectrum of efficacy against the most economically important diseases of cereals caused by fungi from the classes of Basidiomycetes, Ascomycetes and Deuteromycetes.

It is an EC formulation containing 65 g/L bixafen, 65 g/L fluopyram and 130 g/L prothioconazole.

The mixture bixafen + fluopyram + prothioconazole EC 260 combines the spectrum of activity of two broad spectrum ~~carboxamides (~~SDHIs~~)~~ with that of a typical broad spectrum demethylation-inhibitor (DMI), and provides at the same time an efficient tool for resistance prevention by mixing products with different modes of action. Data showed that the addition of fluopyram to bixafen and prothioconazole when applied as an EC 260 co-formulation contributes to an extra activity against *Erysiphe graminis*, *Septoria tritici* and *Pyrenophora tritici-repentis* on wheat and against *Puccinia hordei*, *Pyrenophora teres* and *Ramularia collo-cygni* on barley.

Data showed that the 1/1/2 ratio of the mixture bixafen, fluopyram and prothioconazole provided the maximum overall disease control with the broadest spectrum of activity in wheat and barley. The combination of these three active substances with different and complementary spectra allows a high level of performance at controlling cereal diseases.

Data from the minimum effective dose study have shown that the rate of 1.2 L/ha in barley and oats and 1.5 L/ha in wheat, rye and triticale is needed to achieve an effective and reliable control of the main diseases. These rates provide good levels of control and less variation in efficacy than reduced rates and to the reference products in the conditions of the maritime and northeast EPPO zones. Although few number of results was available in the southeast EPPO zone, the pattern of results was close to the one observed in the maritime and northeast climatic EPPO zones indicating that similar dose rates likely represent the minimum effective dose within this climatic EPPO zone.

Field trials conducted in central Europe have confirmed the following spectrum of efficacy

Wheat (winter and spring)

Septoria tritici (Septoria leaf spot)	: application BBCH 30-61
Pyrenophora tritici-repentis (Tan spot)	: application BBCH 30-61
Erysiphe graminis (Powdery mildew)	: application BBCH 30-61
Puccinia recondita (Brown rust)	: application BBCH 30-61
Puccinia striiformis (Yellow rust)	: application BBCH 30-61
Septoria nodorum (Leaf spot and Glume blotch)	: application BBCH 30-61
Pseudocercosporella herpotrichoides (Eyespot)	: application BBCH 30-34*
Michrodochium nivale (Leaf and head blight)	: application BBCH 30-61

* *Pseudocercosporella herpotrichoides* (Eyespot) suppression via application during the early stem extension period.

Applied once or two times per season the formulation provided superior and more consistent disease control than the reference products Aviator Xpro and Tracker (Champion/Bell) on the key foliar diseases *Septoria tritici*, *Pyrenophora tritici-repentis*, *Erysiphe graminis* and *Septoria nodorum* where fluopyram adds additional activity and similarly very high levels of control of the other pathogens, and reflecting the excellent disease control and crop safety, delivered superior yield responses to the standards.

Barley and oats (winter and spring)

Rhynchosporium secalis (Rhynchosporium leaf spot)	: application BBCH 30-61
Pyrenophora teres (Net blotch)	: application BBCH 30-61
Erysiphe graminis (Powdery mildew)	: application BBCH 30-61
Puccinia hordei (Brown/ Dwarf rust)	: application BBCH 30-61
Puccinia striiformis (Yellow rust)	: application BBCH 30-61
Ramularia collo-cygni (Leaf spot)	: application BBCH 30-61
Pseudocercosporella herpotrichoides (Eyespot)	: application BBCH 30-34*
PLS (Physiological leaf spot)	: application BBCH 39-51
Puccinia coronata (Crown rust)	: application BBCH 30-61

* *Pseudocercosporella herpotrichoides.* (Eyespot) suppression via application during the early stem extension period.

Applied once per season the formulation provided superior and more consistent disease control than the reference products Aviator Xpro and Tracker (Champion/Bell) on key foliar diseases *Rhynchosporium secalis*, *Pyrenophora teres* and *Ramularia collo-cygni* where fluopyram delivers additional activity and similarly high levels of control on the other pathogens consistent with the reference products, reflecting the excellent disease control and crop safety, delivered superior yield responses to the standards.

Triticale and rye (winter and spring)

Septoria sp. (*Septoria* spp.)	: application BBCH 30-61
Septoria nodorum (Leaf and Glume blotch)	: application BBCH 30-61
Pyrenophora tritici-repentis (Tan Spot)	: application BBCH 30-61
Puccinia recondita (Brown Rust)	: application BBCH 30-61
Puccinia striiformis (Yellow Rust)	: application BBCH 30-61
Erysiphe graminis (Powdery Mildew)	: application BBCH 30-61
Rhynchosporium secalis (Leaf scald)	: application BBCH 30-61
Pseudocercosporella herpotrichoides (Eyespot)	: application BBCH 30-34*

* *Pseudocercosporella herpotrichoides.* (Eyespot) suppression via application during the early stem extension period.

Applied once or two times per season the formulation provided good levels of control, consistent with that achieved by the reference products Aviator Xpro and Tracker (Champion/Bell) on key foliar diseases of triticale, rye and oats and, reflecting the good to excellent disease control and crop safety, delivered substantial yield benefits over the untreated.

For the applicant the high level of control and yield benefit, generated from a large data set was very consistent across the different climatic EPPO zones discussed with no differences in the level of disease control delivered by Ascra Xpro on any of the pathogens targeted. Overall the data support the GAP and use pattern proposed.

Only few data were available in the southeast EPPO zone but the pattern of results was very close to the one observed in the maritime and northeast climatic EPPO zones. Given the good and consistent levels of disease control observed in these two climatic zones, for the applicant it is reasoned that presented data also support the label claims in the southeast EPPO zone.

On wheat, triticale and rye a maximum application rate of 1.5 litres of product per hectare is recommended with a maximum number of 2 applications per year in 100-400 litres water.
On barley and oats a maximum application rate of 1.2 litres of product per hectare is recommended with a maximum number of one application per year in 100-400 litres water.

On all cereal crops, applied from the beginning of stem elongation (BBCH 30) up to early flowering (BBCH 61) it provides a broad spectrum of diseases control and increases yield production and quality.

For the applicant field data have shown that Ascra Xpro, when used as recommended, is safe to cereal crops. The product has demonstrated a good to excellent crop tolerance to all varieties tested.

Studies have shown that undesirable effects are not expected on succeeding crops, adjacent crops, part of plants used for propagating purposes and beneficial organisms.

Studies have demonstrated that adverse effects on processing procedures are unlikely.

The resistance management intended for Ascra Xpro has been proposed and is believed to be very effective at protecting the efficacy of the product on the long term.

Ascra Xpro is classified as not harmful for *Aphidius rhopalosiphi,* as slightly harmful for *Chrysoperla carnea* and *Coccinella septempunctata,* and as harmful for populations of relevant predatory mites and spiders.

IIIA1 6.7 List of test facilities including the corresponding certificates

Organisation	Address	GEP
Bayer CropScience Deutschland GmbH	Elisabeth-Selbert-Strasse 4a, 40764 Langenfeld, Germany	yes
Bayer CropScience Limited	Cambridge Science Park, Milton Road, Cambridge, CB4 0WB, United Kingdom	yes
Bayer CropScience NV	T.a.v. de heer Peeters, J.E. Mommaertslaan 14, 1831 Diegem (Machelen), Belgium	yes
Bayer Sp. z o.o. (Bayer CropScience Poland)	Bayer CropScience / Development Al. Jerozolimskie 158, 02-326 Warszawa, Poland	yes
Bayer CropScience France	16 Rue Jean-Marie Leclair, CP 106, 69266 Lyon Cedex 09, France	yes
Bayer A/S	Arne Jacobsens Allé 13, 6; 2300 København S, Denmark	yes
Bayer AB	Kronoslättsföretagspark, Västanväg 245 42 Staffannstorp, Sweden	yes
Landwirtschaftskammer NRW	Nevinghoft, Munster, 48147	yes
Landwirtschaftskammer S-H	Gruner Kamp 15-17, Rendsburg 24768	yes
LfULG, Ref. Pfl.-schutz	Waldheimer Str. Nossen, 01683	yes
CropWorks Ltd.	Bankfoot, Perth, PH1 4AQ, United Kingdom	yes
Oxford Agricultural Trials Ltd	West Farm Barn, Launton Rd, Stratton Audley, Bicester OX27 9AS	yes
Aarhus University (Pesticide Efficacy Testing Flakkebjerg)	University of Aarhus, Faculty of Agricultural Sciences, Forsøgsvej 1, 4200 Slagelse, Denmark	yes
Agrolab AB	Agrolab AB, Desideriavägen 10, 23791 Bjärred, Sweden	yes

LRCAF, Lithuanian Research Centre for Agriculture and Forestry	Instituto 1, Akademija, LT 58344, Lithuania	yes
LPPRC, Latvian Plant Protection Research Centre Riga	Lielvardes 36/38, LV-1008 Latvia	yes
DITANA spol. s.r.o.	CSA 780, 783 53 Velka Bystrice, Czech Republic	yes
Zemedelska zkusebni stanice Kujavy, s.r.o.	Kujavy 48, 74245, Czech Republic	yes
ATC Agrocentre GmBH	Organizacni Slozka, Blatnicka 179, Uhersky Ostroh 68724	yes
Institute of Plant Protection – National Research Institute in Poznan, Sosnicowice Branch	Gliwicka 29, Sosnicowice, 44-153	yes
Plant Protection Insititut - National Research Centre	60-318 Poznan, Wladyslawa Wegorka 20, Poland	yes
University of Technology and Life Sciences	Ksiedza Augustyna Kordeckiego 20, 85-225 Bydgoszcz, Poland	yes
Uniwersytet Przyrodniczy	University of Life Sciences in Lublin, 20-950 Lublin, 13 Akademicka Street, Poland	yes
Staphyt	Ziebicka 2, Poznan, 60-164	yes
Bayer CropScience SA	Centre de Recherche de La Dargoire - 14, impasse Pierre Baizet, CS 99163, 69263 Lyon CEDEX 09, France	no
Bayer CropScience AG	Biological Research Alfred Nobel strasse 50 D-40789 Monheim, Germany.	no
Bayer CropScience AG	Global Biology Herbicides, Industrial Park Höchst, H 872 D-65926 Frankfurt, Germany.	no

Appendix 1: List of data submitted in support of the evaluation

List of data submitted by the applicant and relied on

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 3.9	Meyer, G., Kretschmer, S.	2014	Proposed label for the plant protection product Ascra Xpro (BAY 21070 F) - BIX+FLU+PTZ EC 260 Ascra Xpro (BAY 21070 F) BIX+FLU+PTZ EC260 (Bixafen 65 g/L+ Fluopyram 65 + Prothioconazole 130 g/L) M-485228-01-1 BCS N/N N 2629841/381606	N	J		Bayer CropScience
KIIIA1 3.9	Meyer, G., Kretschmer, S.	2014	Proposed label for the plant protection product Ascra Xpro (BAY 21070 F) - BIX+FLU+PTZ EC 260 Ascra Xpro (BAY 21070 F) BIX+FLU+PTZ EC260 (Bixafen 65 g/L+ Fluopyram 65 + Prothioconazole 130 g/L) M-485228-01-1 BCS N/N N 2629842/381607	N	J		Bayer CropScience

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KIIIA1 6.1.1	Kuck, K. H.; Mauler-Machnik, A.; Wachendorff-Neumann, U.	2001	Results of JAU 6476 in the primary and secondary screening against different fungal diseases in monocots and dicots M-032406-01-1 BAY N/N N 2629868/381609	N	J		Bayer CropScience
KIIIA1 6.1.1	Dahmen, P.; Voerste, A.; Wachendorff-Neumann, U.	2007	Results of bixafen in the primary and secondary screening against different fungal diseases in monocots and dicots M-295435-01-1 BCS N/N N 2629869/381610	N	J		Bayer CropScience
KIIIA1 6.1.1	Derolez, F.	2008	Results of fluopyram in the primary and secondary screening against different fungal diseases in monocots and dicots M-309069-01-1 BCS N/N N 2629870/381611	N	J		Bayer CropScience

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KIIIA1 6.1.1	Krieg, U.	2014	Preliminary range finding tests bixafen + fluopyram + prothioconazole 260 EC (065+065+130 g/l) - Preliminary dose response / mixture justification M-480323-01-1 BCS N/J N 2629871/381612	N	J		Bayer CropScience
KIIIA1 6.1.1	Dahmen, P.; Krieg, U.	2014	Justification of the mixture (ratio justification) bixafen & fluopyram & prothioconazole EC 260 (065+065+130 g/l) M-477822-01-1 BCS N/N N 2629872/381613	N	J		Bayer CropScience
KIIIA1 6.1.1	Krieg, U.	2014	Justification of the mixture bixafen + fluopyram + prothioconazole 260 EC (065+065+130 g/l) - Justification of the a.s. ratio M-480324-01-1 BCS N/J N 2629873/381614	N	J		Bayer CropScience

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KIIIA1 6.1.2	Flind, A. C.	2014	Compilation of trial reports for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Efficacy tests - Wheat (winter and spring) M-484127-01-1 BCS N/J N 2629874/381615	N	J		Bayer CropScience
KIIIA1 6.1.2	Flind, A. C.	2014	Compilation of trial reports for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Efficacy tests - Barley (winter and spring) M-484128-01-1 BCS N/J N 2629875/381616	N	J		Bayer CropScience
KIIIA1 6.1.2	Flind, A. C.	2014	Compilation of trial reports for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Efficacy tests - Triticale, rye, spelt and oats M-484129-01-1 BCS N/J N 2629876/381617	N	J		Bayer CropScience

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KIIIA1 6.1.3	Flind, A. C.	2014	Compilation of trial reports for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Efficacy tests - Wheat (winter and spring) M-484127-01-1 BCS N/J N 2629877/381618	N	J		Bayer CropScience
KIIIA1 6.1.3	Flind, A. C.	2014	Compilation of trial reports for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Efficacy tests - Barley (winter and spring) M-484128-01-1 BCS N/J N 2629878/381619	N	J		Bayer CropScience
KIIIA1 6.1.3	Flind, A. C.	2014	Compilation of trial reports for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Efficacy tests - Triticale, rye, spelt and oats M-484129-01-1 BCS N/J N 2629879/381620	N	J		Bayer CropScience

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KIIIA1 6.1.4.1	Flind, A. C.	2014	Compilation of trial reports for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Effects on yield quality and germination M-484142-01-1 BCS N/J N 2629880/381621	N	J		Bayer CropScience
KIIIA1 6.1.4.2	Baxter, D.	2002	Report to BBPA of pesticide evaluation malting and brewing trials with barleys treated with UK756 and UK831 M-043866-01-1 BAY N/N N 2629881/381622	N	J		Bayer CropScience
KIIIA1 6.1.4.2	Baxter, D.	2007	Malting and brewing trials with barley treated with BYF00587 M-290407-01-1 BCS N/N N 2629882/381623	N	J		Bayer CropScience

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KIIIA1 6.1.4.2	Fabrèges, C.	2014	Compilation of trial report for BIX+FLU+PTZ 260 EC, FLU+PTZ SE 250, FLU EC 150 - (bixafen 65 g/L + fluopyram 65 g/L + prothioconazole 135 g/L) - (fluopyram 125 g/L + prothioconazole 125 g/L) - (fluopyram 150 g/L) - Effects on the processing procedure: Ma M-481773-01-1 BCS N/J N 2629883/381624	N	J		Bayer CropScience
KIIIA1 6.1.4.2	Slaiding, I.	2014	Final report on malting and brewing trials of the cereal fungicide fluopyram M-484758-01-1 BCS N/J N 2629884/381625	N	J		Bayer CropScience
KIIIA1 6.1.4.2	Besancenot, P.	2005	Proline - Dossier Biologique (Tome I/III) M-277653-01-1 BCS N/N N 2629885/381626	N	J		Bayer CropScience

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KIIIA1 6.1.4.2	Bezet, B.	2006	Resulats d'analyses de qualite sur ble tendre - Recolte 2006 M-293390-01-1 BCS N/N N 2629886/381627	N	J		Bayer CropScience
KIIIA1 6.1.4.2	Fabrèges, C.	2013	Compilation of trial report for Fluopyram + prothioconazole SE 250 - Bread making studies - Wheat - Sweden 2012 M-460504-01-1 BCS N/N N 2629887/381628	N	J		Bayer CropScience
KIIIA1 6.1.4.2	Fabrèges, C.	2014	Compilation of trial report for bixafen + fluopyram + prothioconazole EC 260 - Bread making studies - Wheat - France 2013 M-479925-01-1 BCS N/J N 2629888/381629	N	J		Bayer CropScience

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KIIIA1 6.1.4.3	Flind, A. C.	2014	Compilation of trial reports for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Effects on yield quality and germination M-484142-01-1 BCS N/J N 2629889/381630	N	J		Bayer CropScience
KIIIA1 6.1	Flind, A.; Fabrèges, C.	2014	Summary of the efficacy data and information on the plant protection product for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Central zone M-484787-01-1 BCS N/N N 2629890/381631	N	J		Bayer CropScience
KIIIA1 6.2.1	Flind, A. C.	2014	Compilation of trial reports for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Efficacy tests - Wheat (winter and spring) M-484127-01-1 BCS N/J N 2629891/381632	N	J		Bayer CropScience

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KIIIA1 6.2.1	Flind, A. C.	2014	Compilation of trial reports for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Efficacy tests - Barley (winter and spring) M-484128-01-1 BCS N/J N 2629892/381633	N	J		Bayer CropScience
KIIIA1 6.2.1	Flind, A. C.	2014	Compilation of trial reports for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Efficacy tests - Triticale, rye, spelt and oats M-484129-01-1 BCS N/J N 2629893/381634	N	J		Bayer CropScience
KIIIA1 6.2.5	Flind, A. C.	2014	Compilation of trial reports for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Effects on yield quality and germination M-484142-01-1 BCS N/J N 2629894/381635	N	J		Bayer CropScience

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KIIIA1 6.2.6	Drewes, M.	2001	Influence of JAU 6476 EC on non-target plants M-043853-01-1 BAY N/N N 2629895/381636	N	J		Bayer CropScience
KIIIA1 6.2.6	Hills, M.	2007	Evaluation of the pre-emergence (PPI) biological activity of BYF 00587 EC 125 G M-295621-01-1 BCS N/N N 2629896/381637	N	J		Bayer CropScience
KIIIA1 6.2.6	Hills, M.	2007	Evaluation of the pre-emergence (PPI) biological activity of AE C656948 SC 500 M-297136-01-1 BCS N/N N 2629897/381638	N	J		Bayer CropScience
KIIIA1 6.2.7	Drewes, M.	2001	Influence of JAU 6476 EC on non-target plants M-043853-01-1 BAY N/N N 2629898/381639	N	J		Bayer CropScience

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KIIIA1 6.2.7	Hills, M.	2007	Evaluation of the post-emergence biological activity of BYF 00587 EC 125 G M-295623-01-1 BCS N/N N 2629899/381640	N	J		Bayer CropScience
KIIIA1 6.2.7	Hills, M.	2007	Evaluation of the post emergence biological activity of AE C656948 SC 500 M-297155-01-1 BCS N/N N 2629900/381641	N	J		Bayer CropScience
KIIIA1 6.2.8	Mehl, A.; Manger-Jacob, F.	2014	Statement - Information on the occurrence or possible occurrence of the development of resistance of the plant protection product Ascra for use in cereals (for submission in Europe) - Bixafen 65 g/L + fluopyram 65 g/L + prothioconazole 130 g/L - EC 260 M-483732-01-1 BCS N/N N 2629901/381642	N	J		Bayer CropScience

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KIIIA1 6	Flind, A.; Fabrèges, C.	2014	Summary of the efficacy data and information on the plant protection product for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Central zone M-484787-01-1 BCS N/N N 2629902/381643	N	J		Bayer CropScience
KIIIA1 10.5.2	Moll, M.	2014	Effects of bixafen + fluopyram + prothioconazole EC 260 (65 + 65 + 130 g/L) on the parasitoid Aphidius rhopalosiphi, extended laboratory study - Dose response test M-480611-01-1 BCS J/J N 2629969/381653	N	J		Bayer CropScience
KIIIA1 10.5.2	Moll, M.	2014	Effects of bixafen + fluopyram + prothioconazole EC 260 (65 + 65 + 130 g/L) on the predatory mite Typhlodromus pyri, extended laboratory study - Dose response test M-480613-01-1 BCS J/J N 2629970/381654	N	J		Bayer CropScience

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KIIIA1 10.5.2	Moll, M.	2013	Effects of bixafen + fluopyram + prothioconazole EC 260 (65 + 65 + 130 g/L) on the ladybird beetle Coccinella septempunctata, extended laboratory study - Dose response test M-476172-01-1 BCS N/N N 2629971/381655	N	J		Bayer CropScience
KIIIA1 10.5.2	Moll, M.	2013	Effects of Bixafen + Fluopyram + Prothioconazole EC 260 (65 + 65 + 130 g/L) on the lacewing Chrysoperla carnea, extended laboratory study - Dose response test M-476030-01-1 BCS J/J N 2629972/381656	N	J		Bayer CropScience
KIIIA1 10.8.1.2	Marquardt, J.	2013	Bixafen+Fluopyram+Prothioconazole EC 260 (65+65+130 g/L) - On vegetative vigour of terrestrial plants M-476483-01-1 BCS J/J N 2629982/381659	N	J		Bayer CropScience

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KIIIA1 10.8.1.3	Marquardt, J.	2014	Effect of bixafen+fluopyram+prothioconazole EC 260 (65+65+130 g/L) - On the seedling emergence and seedling growth of terrestrial plants (Short code of test item: BIX+FLU+PTZ EC 260) M-478325-01-1 BCS J/J N 2629983/381660	N	J		Bayer CropScience
MIIIA1 Sec 1	Bayer CropScience	2014	dRR - B1 - core assess. - DE - 008219-00/00 - Ascra Xpro M-482427-01-1 BCS O/O N 2629987/381664	N	O		Bayer CropScience
MIIIA1 Sec 1	Bayer CropScience	2014	dRR - B1 - core assess. - DE - 008219-00/00 - Ascra Xpro M-482427-01-1 BCS O/O N 2629988/381665	N	O		Bayer CropScience
MIIIA1 Sec 6	Bayer CropScience	2014	dRR - B6 - core assess. - DE - 008219-00/00 - Ascra Xpro M-484053-01-1 BCS O/O N 2629997/381668	N	O		Bayer CropScience

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MIIIA1 Sec 6	Bayer CropScience	2014	dRR - B6 - core assess. - DE - 008219-00/00 - Ascra Xpro M-484053-01-1 BCS O/O N 2629998/381669	N	O		Bayer CropScience
MIIIA1 Sec 7	Bayer CropScience	2014	dRR - B7 - core assess. - DE - 008219-00/00 - Ascra Xpro M-484814-01-1 BCS O/O N 2629999/381670	N	O		Bayer CropScience
MIIIA1 Sec 7	Bayer CropScience	2014	dRR - B7 - core assess. - DE - 008219-00/00 - Ascra Xpro M-484814-01-1 BCS O/O N 2630000/381671	N	O		Bayer CropScience
KIIIA1 6.1.2	Meyer, G.	2014	Dose response and efficacy of bixafen + fluopyram + prothioconazole EC 65+65+130 g/L against physiological leaf spots in barley M-485226-01-1 BCS N/J N 2630001/381672	N	J		Bayer CropScience

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KIIIA1 6.1.3	Meyer, G.	2014	Dose response and efficacy of bixafen + fluopyram + prothioconazole EC 65+65+130 g/L against physiological leaf spots in barley M-485226-01-1 BCS N/J N 2630002/381673	N	J		Bayer CropScience
KIIIA1 6	Meyer, G.	2014	Summary of the efficacy data and information on the plant protection product for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - National addendum M-485415-01-1 BCS N/N N 2630003/381674	N	J		Bayer CropScience
KIIIA1 6	Meyer, G.	2014	Summary of the efficacy data and information on the plant protection product for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - National addendum M-485415-01-1 BCS N/N N 2630004/381675	N	J		Bayer CropScience

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MIIIA1 Sec 6	Bayer CropScience	2014	dRR - B6 - nat. add. - DE - 008219-00/00 - Ascra Xpro M-484485-01-1 BCS O/O N 2630015/381680	N	O		Bayer CropScience
MIIIA1 Sec 6	Bayer CropScience	2014	dRR - B6 - nat. add. - DE - 008219-00/00 - Ascra Xpro M-484485-01-1 BCS O/O N 2630016/381681	N	O		Bayer CropScience
MIIIA1 Sec 7	Bayer CropScience	2014	dRR - B7 - nat. add. - DE - 008219-00/00 - Ascra Xpro M-485540-01-1 BCS O/O N 2630017/381682	N	O		Bayer CropScience
MIIIA1 Sec 7	Bayer CropScience	2014	dRR - B7 - nat. add. - DE - 008219-00/00 - Ascra Xpro M-485540-01-1 BCS O/O N 2630018/381683	N	O		Bayer CropScience

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Document N	Bayer CropScience	2014	dRR - A - DE - 008219-00/00 - Ascra Xpro M-485223-01-1 BCS O/O N 2630019/381684	N	O		Bayer CropScience
Document N	Bayer CropScience	2014	dRR - A - DE - 008219-00/00 - Ascra Xpro M-485223-01-1 BCS O/O N 2630020/381685	N	O		Bayer CropScience
MIIIA1 Sec 7	van Noorloos, B.	2014	Ascra XPRO - Table of uses M-487595-01-1 ! BN20140019 BCS N/N N 2681615/381740	N	J		Bayer CropScience
MIIIA1 Sec 7	van Noorloos, B.	2014	Attachment: BN20140019 Ascra Xpro Table of uses.doc M-487595-01-1 ! BN20140019 BCS N/N N 2681616/381741	N	J		Bayer CropScience

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MIIIA1 Sec 7	Meyer, G.	2016	REGISTRATION REPORT - Part B - Section 7: Efficacy Data and Information - Detailed summary of the risk assessment - Bixafen + fluopyram + prothioconazole EC 260 (65+65+130 g/L) Cental zone M-485540-02-1 O/O N 3018092/434392	N	O		Bayer CropScience
MIIIA1 Sec 7	Fabregèges, C.	2016	REGISTRATION REPORT- Part B - Section 7: Efficacy Data and Information - Concise summary of the risk assessment M-484814-04-1 O/O N 3018094/434393	N	O		Bayer CropScience
KIIIA1 6.2.7	Marquardt, J.	2013	Bixafen+Fluopyram+Prothioconazole EC 260 (65+65+130 g/L) - On vegetative vigour of terrestrial plants M-476483-01-1 O/J N 3018095/434394	N	J		Bayer CropScience

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KIIIA1 6.2.6	Marquardt, J.	2014	Effect of bixafen+fluopyram+prothioconazole EC 260 (65+65+130 g/L) - On the seedling emergence and seedling growth of terrestrial plants (Short code of test item: BIX+FLU+PTZ EC 260) M-478325-01-1 O/J N 3018096/434395	N	J		Bayer CropScience
KIIIA1 6.2.8	Mehl, A., Manger-Jacob, F.	2016	Statement - Information on the occurrence or possible occurrence of the development of resistance of the plant protection product Ascra for use in cereals (for submission in Europe) M-483732-02-1 O/O N 3018097/434396	N	J		Bayer CropScience
KIIIA1 6	Flind, A., Fabrèges, C.	2016	Summary of the efficacy data and Information on the plant protection product for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L- Cental zone M-484787-04-1 O/O N 3018098/434397	N	J		Bayer CropScience

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MIIIA1 Sec 7	Fabrèges, C.	2016	Registration report - Part B - Section 7: Efficacy data and information - Concise summary of the risk assessment - Bixafen + fluopyram + prothioconazole EC 260 (65+65+130 g/l) - Central zone M-484814-04-1 O/O N 3018099/434398	N	O		Bayer CropScience
KIIIA1 6.1.2	Meyer, G.	2014	Dose response and efficacy of bixafen + fluopyram + prothioconazole EC 65+65+130 g/L against physiological leaf spots in barley M-485226-02-1 O/J N 3018100/434399	N	J		Bayer CropScience
MIIIA1 Sec 7	Meyer, G.	2016	REGISTRATION REPORT - Part B - Section 7: Efficacy Data and Information - Detailed summary of the risk assessment - Bixafen + fluopyram + prothioconazole EC 260 (65+65+130 g/L) Cental zone M-485540-02-1 O/O N 3018101/434400	N	O		Bayer CropScience

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KIIIA1 6.1.2	Fabrèges, C.	2015	Compilation of trial report for BIX+FLU+PTZ EC 260 - Bixafen 65 g/L + fluopyram 65 g/L + prothioconazole 130 g/L - Efficacy tests in wheat and barley in EPPO south-east zone M-526442-01-1 O/J N 3018102/434401	N	J		Bayer CropScience
MIIIA1 Sec 7	Anonymous	2015	Registration report - Part B - Section 7: Efficacy data and information - Concise summary of the risk assessment - Bixafen + fluopyram + prothioconazole EC 260 (65+65+130 g/l) - Central Zone - GAP-tables M-545620-01-1 O/O N 3018103/434403	N	O		Bayer CropScience
KIIIA1 6.1.3	Meyer, G.	2014	Dose response and efficacy of bixafen + fluopyram + prothioconazole EC 65+65+130 g/L against physiological leaf spots in barley M-485226-02-1 O/J N 3064255/434405	N	J		Bayer CropScience

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KIIIA1 6.1.3	Fabrèges, C.	2015	Compilation of trial report for BIX+FLU+PTZ EC 260 - Bixafen 65 g/L + fluopyram 65 g/L + prothioconazole 130 g/L - Efficacy tests in wheat and barley in EPPO south-east zone M-526442-01-1 O/J N 3064257/434406	N	J		Bayer CropScience
KIIIA1 6.1.3	Fabrèges, C.	2015	Compilation of trial report for BIX+FLU+PTZ EC 260 - Bixafen 65 g/L + fluopyram 65 g/L + prothioconazole 130 g/L - Efficacy tests in wheat and barley in EPPO south-east zone M-526442-01-1 O/J N 3064262/434407	N	J		Bayer CropScience
KIIIA1 6.1.4.3	Fabrèges, C.	2015	Compilation of trial report for BIX+FLU+PTZ EC 260 - Bixafen 65 g/L + fluopyram 65 g/L + prothioconazole 130 g/L - Efficacy tests in wheat and barley in EPPO south-east zone M-526442-01-1 O/J N 3064263/434408	N	J		Bayer CropScience

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KIIIA1 6.2.1	Fabrèges, C.	2015	Compilation of trial report for BIX+FLU+PTZ EC 260 - Bixafen 65 g/L + fluopyram 65 g/L + prothioconazole 130 g/L - Efficacy tests in wheat and barley in EPPO south-east zone M-526442-01-1 O/J N 3064264/434409	N	J		Bayer CropScience

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List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

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List of data submitted by the applicant and not relied on

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List of data relied on and not submitted by the applicant but necessary for evaluation

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
~~Data Point~~	~~Author(s)~~	~~Year~~	~~Title~~ ~~Report-No.~~ ~~Source~~ ~~GLP/GEP~~ ~~Published~~ ~~Authority registration No./JKI-No.~~	~~Vertebrate study (J=Yes O=Open N=No)~~	~~Data protection claimed Y/N~~	~~Justification if data protection is claimed~~	~~Owner~~
~~KIIIA1 3.9~~	~~Meyer, G., Kretschmer, S.~~	~~2014~~	~~Proposed label for the plant protection product Ascra Xpro (BAY 21070 F) - BIX+FLU+PTZ EC 260 Ascra Xpro (BAY 21070 F) BIX+FLU+PTZ_EC260 (Bixafen 65 g/L+ Fluopyram 65 + Prothioconazole 130 g/L)~~ ~~M-485228-01-1~~ ~~BCS~~ ~~N/N~~ ~~N~~ ~~2629841/381606~~	~~N~~	~~J~~		~~Bayer CropScience~~

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KIIIA1 3.9	Meyer, G., Kretschmer, S.	2014	Proposed label for the plant protection product Ascra Xpro (BAY 21070 F) - BIX+FLU+PTZ EC 260 Ascra Xpro (BAY 21070 F) BIX+FLU+PTZ_EC260 (Bixafen 65 g/L+ Fluopyram 65 + Prothioconazole 130 g/L) M-485228-01-1 BCS N/N N 2629842/381607	N	J		Bayer CropScience
KIIIA1 6.1.1	Kuck, K. H.; Mauler-Machnik, A.; Wachendorff-Neumann, U.	2001	Results of JAU 6476 in the primary and secondary screening against different fungal diseases in monocots and dicots M-032406-01-1 BAY N/N N 2629868/381609	N	J		Bayer CropScience

Feldfunktion geändert

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KIIIA1 6.1.1	Dahmen, P.; Voerste, A.; Wachendorff-Neumann, U.	2007	Results of bixafen in the primary and secondary screening against different fungal diseases in monocots and dicots M-295435-01-1 BCS N/N N 2629869/381610	N	J		Bayer CropScience
KIIIA1 6.1.1	Derolez, F.	2008	Results of fluopyram in the primary and secondary screening against different fungal diseases in monocots and dicots M-309069-01-1 BCS N/N N 2629870/381611	N	J		Bayer CropScience
KIIIA1 6.1.1	Krieg, U.	2014	Preliminary range finding tests bixafen + fluopyram + prothioconazole 260 EC (065+065+130 g/l) - Preliminary dose response / mixture justification M-480323-01-1 BCS N/J N 2629871/381612	N	J		Bayer CropScience

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KIIIA1 6.1.1	Dahmen, P.; Krieg, U.	2014	Justification of the mixture (ratio justification) bixafen & fluopyram & prothioconazole EC 260 (065+065+130 g/l) M-477822-01-1 BCS N/N N 2629872/381613	N	J		Bayer CropScience
KIIIA1 6.1.1	Krieg, U.	2014	Justification of the mixture bixafen + fluopyram + prothioconazole 260 EC (065+065+130 g/l) - Justification of the a.s. ratio M-480324-01-1 BCS N/J N 2629873/381614	N	J		Bayer CropScience
KIIIA1 6.1.2	Flind, A. C.	2014	Compilation of trial reports for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Efficacy tests - Wheat (winter and spring) M-484127-01-1 BCS N/J N 2629874/381615	N	J		Bayer CropScience

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KIIIA1 6.1.2	Flind, A. C.	2014	Compilation of trial reports for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Efficacy tests - Barley (winter and spring) M-484128-01-1 BCS N/J N 2629875/381616	N	J		Bayer CropScience
KIIIA1 6.1.2	Flind, A. C.	2014	Compilation of trial reports for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Efficacy tests - Triticale, rye, spelt and oats M-484129-01-1 BCS N/J N 2629876/381617	N	J		Bayer CropScience
KIIIA1 6.1.3	Flind, A. C.	2014	Compilation of trial reports for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Efficacy tests - Wheat (winter and spring) M-484127-01-1 BCS N/J N 2629877/381618	N	J		Bayer CropScience

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KIIIA1 6.1.3	Flind, A. C.	2014	Compilation of trial reports for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Efficacy tests - Barley (winter and spring) M-484128-01-1 BCS N/J N 2629878/381619	N	J		Bayer CropScience
KIIIA1 6.1.3	Flind, A. C.	2014	Compilation of trial reports for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Efficacy tests - Triticale, rye, spelt and oats M-484129-01-1 BCS N/J N 2629879/381620	N	J		Bayer CropScience
KIIIA1 6.1.4.1	Flind, A. C.	2014	Compilation of trial reports for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Effects on yield quality and germination M-484142-01-1 BCS N/J N 2629880/381621	N	J		Bayer CropScience

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KIIIA1 6.1.4.2	Baxter, D.	2002	Report to BBPA of pesticide evaluation malting and brewing trials with barleys treated with UK756 and UK831 M-043866-01-1 BAY N/N N 2629881/381622	N	J		Bayer CropScience
KIIIA1 6.1.4.2	Baxter, D.	2007	Malting and brewing trials with barley treated with BYF00587 M-290407-01-1 BCS N/N N 2629882/381623	N	J		Bayer CropScience
KIIIA1 6.1.4.2	Fabrèges, C.	2014	Compilation of trial report for BIX+FLU+PTZ 260 EC, FLU+PTZ SE 250, FLU EC 150 - (bixafen 65 g/L + fluopyram 65 g/L + prothioconazole 135 g/L) - (fluopyram 125 g/L + prothioconazole 125 g/L) - (fluopyram 150 g/L) - Effects on the processing procedure: Ma M-481773-01-1 BCS N/J N 2629883/381624	N	J		Bayer CropScience

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KIIIA1 6.1.4.2	Slaiding, I.	2014	Final report on malting and brewing trials of the cereal fungicide fluopyram M-484758-01-1 BCS N/J N 2629884/381625	N	J		Bayer CropScience
KIIIA1 6.1.4.2	Besancenot, P.	2005	Proline - Dossier Biologique (Tome I/III) M-277653-01-1 BCS N/N N 2629885/381626	N	J		Bayer CropScience
KIIIA1 6.1.4.2	Bezot, B.	2006	Resulats d'analyses de qualite sur ble tendre - Recolte 2006 M-293390-01-1 BCS N/N N 2629886/381627	N	J		Bayer CropScience

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KIIIA1 6.1.4.2	Fabrèges, C.	2013	Compilation of trial report for Fluopyram + prothioconazole SE 250 - Bread making studies - Wheat - Sweden 2012 M-460504-01-1 BCS N/N N 2629887/381628	N	J		Bayer CropScience
KIIIA1 6.1.4.2	Fabrèges, C.	2014	Compilation of trial report for bixafen + fluopyram + prothioconazole EC 260 - Bread making studies - Wheat - France 2013 M-479925-01-1 BCS N/J N 2629888/381629	N	J		Bayer CropScience
KIIIA1 6.1.4.3	Flind, A. C.	2014	Compilation of trial reports for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Effects on yield quality and germination M-484142-01-1 BCS N/J N 2629889/381630	N	J		Bayer CropScience

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KIIIA1 6.1	Flind, A.; Fabrèges, C.	2014	Summary of the efficacy data and information on the plant protection product for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - central zone M-484787-01-1 BCS N/N N 2629890/381631	N	J		Bayer CropScience
KIIIA1 6.2.1	Flind, A. C.	2014	Compilation of trial reports for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Efficacy tests - Wheat (winter and spring) M-484127-01-1 BCS N/J N 2629891/381632	N	J		Bayer CropScience
KIIIA1 6.2.1	Flind, A. C.	2014	Compilation of trial reports for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Efficacy tests - Barley (winter and spring) M-484128-01-1 BCS N/J N 2629892/381633	N	J		Bayer CropScience

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KIIIA1 6.2.1	Flind, A. C.	2014	Compilation of trial reports for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Efficacy tests - Triticale, rye, spelt and oats M-484129-01-1 BCS N/J N 2629893/381634	N	J		Bayer CropScience
KIIIA1 6.2.5	Flind, A. C.	2014	Compilation of trial reports for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - Effects on yield quality and germination M-484142-01-1 BCS N/J N 2629894/381635	N	J		Bayer CropScience
KIIIA1 6.2.6	Drewes, M.	2001	Influence of JAU 6476 EC on non-target plants M-043853-01-1 BAY N/N N 2629895/381636	N	J		Bayer CropScience

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KIIIA1 6.2.6	Hills, M.	2007	Evaluation of the pre-emergence (PPI) biological activity of BYF 00587 EC 125 G M-295621-01-1 BCS N/N N 2629896/381637	N	J		Bayer CropScience
KIIIA1 6.2.6	Hills, M.	2007	Evaluation of the pre-emergence (PPI) biological activity of AE C656948 SC 500 M-297136-01-1 BCS N/N N 2629897/381638	N	J		Bayer CropScience
KIIIA1 6.2.7	Drewes, M.	2001	Influence of JAU 6476 EC on non-target plants M-043853-01-1 BAY N/N N 2629898/381639	N	J		Bayer CropScience

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KIIIA1 6.2.7	Hills, M.	2007	Evaluation of the post-emergence biological activity of BYF 00587 EC 125 G M-295623-01-1 BCS N/N N 2629899/381640	N	J		Bayer CropScience
KIIIA1 6.2.7	Hills, M.	2007	Evaluation of the post emergence biological activity of AE C656948 SC 500 M-297155-01-1 BCS N/N N 2629900/381641	N	J		Bayer CropScience
KIIIA1 6.2.8	Mehl, A.; Manger-Jacob, F.	2014	Statement - Information on the occurrence or possible occurrence of the development of resistance of the plant protection product Ascra for use in cereals (for submission in Europe) - Bixafen 65 g/L + fluopyram 65 g/L + prothioconazole 130 g/L - EC 260 M-483732-01-1 BCS N/N N 2629901/381642	N	J		Bayer CropScience

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KIIIA1 6	Flind, A.; Fabrèges, C.	2014	Summary of the efficacy data and information on the plant protection product for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L – central zone M-484787-01-1 BCS N/N N 2629902/381643	N	J		Bayer CropScience
KIIIA1 10.5.2	Moll, M.	2014	Effects of bixafen + fluopyram + prothioconazole EC 260 (65 + 65 + 130 g/L) on the parasitoid Aphidius rhopalosiphi, extended laboratory study - Dose response test M-480611-01-1 BCS J/J N 2629969/381653	N	J		Bayer CropScience

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KIIIA1 10.5.2	Moll, M.	2014	Effects of bixafen + fluopyram + prothioconazole EC 260 (65 + 65 + 130 g/L) on the predatory mite Typhlodromus pyri, extended laboratory study - Dose response test M-480613-01-1 BCS J/J N 2629970/381654	N	J		Bayer CropScience
KIIIA1 10.5.2	Moll, M.	2013	Effects of bixafen + fluopyram + prothioconazole EC 260 (65 + 65 + 130 g/L) on the ladybird beetle Coccinella septempunctata, extended laboratory study - Dose response test M-476172-01-1 BCS N/N N 2629971/381655	N	J		Bayer CropScience

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KIIIA1 10.5.2	Moll, M.	2013	Effects of Bixafen + Fluopyram + Prothioconazole EC 260 (65 + 65 + 130 g/L) on the lacewing Chrysoperla carnea, extended laboratory study - Dose response test M-476030-01-1 BCS J/J N 2629972/381656	N	J		Bayer CropScience
KIIIA1 10.8.1.2	Marquardt, J.	2013	Bixafen+Fluopyram+Prothioconazole EC 260 (65+65+130 g/L) - On vegetative vigour of terrestrial plants M-476483-01-1 BCS J/J N 2629982/381659	N	J		Bayer CropScience
KIIIA1 10.8.1.3	Marquardt, J.	2014	Effect of bixafen+fluopyram+prothioconazole EC 260 (65+65+130 g/L) - On the seedling emergence and seedling growth of terrestrial plants (Short code of test item: BIX+FLU+PTZ EC 260) M-478325-01-1 BCS J/J N 2629983/381660	N	J		Bayer CropScience

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MIIIA1 Sec 1	Bayer CropScience	2014	dRR - B1 - core assess. - DE - 008219-00/00 - Ascra Xpro M-482427-01-1 BCS O/O N 2629987/381664	N	O		Bayer CropScience
MIIIA1 Sec 1	Bayer CropScience	2014	dRR - B1 - core assess. - DE - 008219-00/00 - Ascra Xpro M-482427-01-1 BCS O/O N 2629988/381665	N	O		Bayer CropScience
MIIIA1 Sec 6	Bayer CropScience	2014	dRR - B6 - core assess. - DE - 008219-00/00 - Ascra Xpro M-484053-01-1 BCS O/O N 2629997/381668	N	O		Bayer CropScience

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MIIIA1 Sec 6	Bayer CropScience	2014	dRR - B6 - core assess. - DE - 008219-00/00 - Ascra Xpro M-484053-01-1 BCS O/O N 2629998/381669	N	O		Bayer CropScience
MIIIA1 Sec 7	Bayer CropScience	2014	dRR - B7 - core assess. - DE - 008219-00/00 - Ascra Xpro M-484814-01-1 BCS O/O N 2629999/381670	N	O		Bayer CropScience
MIIIA1 Sec 7	Bayer CropScience	2014	dRR - B7 - core assess. - DE - 008219-00/00 - Ascra Xpro M-484814-01-1 BCS O/O N 2630000/381671	N	O		Bayer CropScience

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KIIIA1 6.1.2	Meyer, G.	2014	Dose response and efficacy of bixafen + fluopyram + prothioconazole EC 65+65+130 g/L against physiological leaf spots in barley M-485226-01-1 BCS N/J N 2630001/381672	N	J		Bayer CropScience
KIIIA1 6.1.3	Meyer, G.	2014	Dose response and efficacy of bixafen + fluopyram + prothioconazole EC 65+65+130 g/L against physiological leaf spots in barley M-485226-01-1 BCS N/J N 2630002/381673	N	J		Bayer CropScience
KIIIA1 6	Meyer, G.	2014	Summary of the efficacy data and information on the plant protection product for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - National addendum M-485415-01-1 BCS N/N N 2630003/381674	N	J		Bayer CropScience

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KIIIA1 6	Meyer, G.	2014	Summary of the efficacy data and information on the plant protection product for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L - National addendum M-485415-01-1 BCS N/N N 2630004/381675	N	J		Bayer CropScience
MIIIA1 Sec 6	Bayer CropScience	2014	dRR - B6 - nat. add. - DE - 008219-00/00 - Ascra Xpro M-484485-01-1 BCS O/O N 2630015/381680	N	O		Bayer CropScience
MIIIA1 Sec 6	Bayer CropScience	2014	dRR - B6 - nat. add. - DE - 008219-00/00 - Ascra Xpro M-484485-01-1 BCS O/O N 2630016/381681	N	O		Bayer CropScience

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MIIIA1 Sec 7	Bayer CropScience	2014	dRR - B7 - nat. add. - DE - 008219-00/00 - Ascra Xpro M-485540-01-1 BCS O/O N 2630017/381682	N	O		Bayer CropScience
MIIIA1 Sec 7	Bayer CropScience	2014	dRR - B7 - nat. add. - DE - 008219-00/00 - Ascra Xpro M-485540-01-1 BCS O/O N 2630018/381683	N	O		Bayer CropScience
Document N	Bayer CropScience	2014	dRR - A - DE - 008219-00/00 - Ascra Xpro M-485223-01-1 BCS O/O N 2630019/381684	N	O		Bayer CropScience

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Document N	Bayer CropScience	2014	dRR - A - DE - 008219-00/00 - Ascra Xpro M-485223-01-1 BCS O/O N 2630020/381685	N	O		Bayer CropScience
MIIIA1 Sec 7	van Noorloos, B.	2014	Ascra XPRO - Table of uses M-487595-01-1 ! BN20140019 BCS N/N N 2681615/381740	N	J		Bayer CropScience
MIIIA1 Sec 7	van Noorloos, B.	2014	Attachment: BN20140019 Ascra Xpro Table of uses.doc M-487595-01-1 ! BN20140019 BCS N/N N 2681616/381741	N	J		Bayer CropScience

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MIIIA1 Sec 7	Meyer, G.	2016	REGISTRATION REPORT - Part B - Section 7: Efficacy Data and Information - Detailed summary of the risk assessment - Bixafen + fluopyram + prothioconazole EC 260 (65+65+130 g/L) Cental zone M-485540-02-1 O/O N 3018092/434392	N	O		Bayer CropScience
MIIIA1 Sec 7	Fabregèges, C.	2016	REGISTRATION REPORT- Part B - Section 7: Efficacy Data and Information - Concise summary of the risk assessment M-484814-04-1 O/O N 3018094/434393	N	O		Bayer CropScience
KIIIA1 6.2.7	Marquardt, J.	2013	Bixafen+Fluopyram+Prothioconazole EC 260 (65+65+130 g/L) - On vegetative vigour of terrestrial plants M-476483-01-1 O/J N 3018095/434394	N	J		Bayer CropScience

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KIIIA1 6.2.6	Marquardt, J.	2014	Effect of bixafen+fluopyram+prothioconazole EC 260 (65+65+130 g/L) - On the seedling emergence and seedling growth of terrestrial plants (Short code of test item: BIX+FLU+PTZ EC 260) M-478325-01-1 O/J N 3018096/434395	N	J		Bayer CropScience
KIIIA1 6.2.8	Mehl, A., Manger-Jacob, F.	2016	Statement - Information on the occurrence or possible occurrence of the development of resistance of the plant protection product Ascra for use in cereals (for submission in Europe) M-483732-02-1 O/O N 3018097/434396	N	J		Bayer CropScience

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KIIIA1 6	Flind, A., Fabrèges, C.	2016	Summary of the efficacy data and Information on the plant protection product for bixafen + fluopyram + prothioconazole EC 65+65+130 g/L – Central zone M-484787-04-1 O/O N 3018098/434397	N	J		Bayer CropScience
MIIIA1 Sec 7	Fabrèges, C.	2016	Registration report – Part B – Section 7: Efficacy data and information - Concise summary of the risk assessment – Bixafen + fluopyram + prothioconazole EC 260 (65+65+130 g/l) – central zone M-484814-04-1 O/O N 3018099/434398	N	O		Bayer CropScience

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KIIIA1 6.1.2	Meyer, G.	2014	Dose response and efficacy of bixafen + fluopyram + prothioconazole EC 65+65+130 g/L against physiological leaf spots in barley M-485226-02-1 O/J N 3018100/434399	N	J		Bayer CropScience
MIIIA1 Sec 7	Meyer, G.	2016	REGISTRATION REPORT - Part B - Section 7: Efficacy Data and Information - Detailed summary of the risk assessment - Bixafen + fluopyram + prothioconazole EC 260 (65+65+130 g/L) Central zone M-485540-02-1 O/O N 3018101/434400	N	O		Bayer CropScience

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KIIIA1 6.1.2	Fabrèges, C.	2015	Compilation of trial report for BIX+FLU+PTZ EC 260 - Bixafen 65 g/L + fluopyram 65 g/L + prothioconazole 130 g/L - Efficacy tests in wheat and barley in EPPO south-east zone M-526442-01-1 O/J N 3018102/434401	N	J		Bayer CropScience
MIIIA1 Sec 7	Anonymous	2015	Registration report - Part B - Section 7: Efficacy data and information - Concise summary of the risk assessment - Bixafen + fluopyram + prothioconazole EC 260 (65+65+130 g/l) - central Zone - GAP tables M-545620-01-1 O/O N 3018103/434403	N	O		Bayer CropScience

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KIIIA1 6.1.3	Meyer, G.	2014	Dose response and efficacy of bixafen + fluopyram + prothioconazole EC 65+65+130 g/L against physiological leaf spots in barley M-485226-02-1 O/J N 3064255/434405	N	J		Bayer CropScience
KIIIA1 6.1.3	Fabrèges, C.	2015	Compilation of trial report for BIX+FLU+PTZ EC 260 - Bixafen 65 g/L + fluopyram 65 g/L + prothioconazole 130 g/L - Efficacy tests in wheat and barley in EPPO south-east zone M-526442-01-1 O/J N 3064257/434406	N	J		Bayer CropScience
KIIIA1 6.1.3	Fabrèges, C.	2015	Compilation of trial report for BIX+FLU+PTZ EC 260 - Bixafen 65 g/L + fluopyram 65 g/L + prothioconazole 130 g/L - Efficacy tests in wheat and barley in EPPO south-east zone M-526442-01-1 O/J N 3064262/434407	N	J		Bayer CropScience

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KIIIA1 6.1.4.3	Fabrèges, C.	2015	Compilation of trial report for BIX+FLU+PTZ EC 260 - Bixafen 65 g/L + fluopyram 65 g/L + prothioconazole 130 g/L - Efficacy tests in wheat and barley in EPPO south-east zone M-526442-01-1 O/J N 3064263/434408	N	J		Bayer CropScience
KIIIA1 6.2.1	Fabrèges, C.	2015	Compilation of trial report for BIX+FLU+PTZ EC 260 - Bixafen 65 g/L + fluopyram 65 g/L + prothioconazole 130 g/L - Efficacy tests in wheat and barley in EPPO south-east zone M-526442-01-1 O/J N 3064264/434409	N	J		Bayer CropScience

Appendix 2: GAP table

GAP-Table of intended uses for Germany

GAP rev. (2), date: 2015-02-13

PPP (product name/code)	**Ascra Xpro**	**Formulation type:**	**EC**
active substance 1	Prothioconazole	**Conc. of as 1:**	**130 g/L**
active substance 2	Fluopyram	**Conc. of as 2:**	**65 g/L**
active substance 3	Bixafen	**Conc. of as 3:**	**65 g/L**
Applicant:	**Bayer CropScience**	**professional use**	☒
Zone(s):	**central EU**	**non professional use**	☐

Verified by MS: **yes**

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: develop-mental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	wheat TRZSS	F	stem break of cereals *Pseudocercosporella herpotrichoides* PSDCHE	spraying	BBCH 30 - 32 from spring at beginning of infestation and/or when first symp-toms become visible	a) 1 b) 2	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g	100 - 400	F	

									as/ha			
002	DE	wheat TRZSS	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F	
003	DE	wheat TRZSS	F	leaf spot of wheat *Septoria tritici* SEPTTR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F	
004	DE	wheat TRZSS	F	tan spot of cereals *Drechslera tritici-repentis* PYRNTR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F	
005	DE	wheat TRZSS	F	brown leaf rust of cereals	spraying	BBCH 30 - 61 from spring at beginning of	a) 2 b) 2	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g	100 - 400	F	

				Puccinia recondita PUCCRE		infestation and/or when first symptoms become visible	(14 - 21 d)		as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha			
006	DE	wheat TRZSS	F	stripe rust of grasses *Puccinia striiformis* PUCCST	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F	
007	DE	wheat TRZSS	F	septoria leaf spot *Septoria nodorum* LEPTNO	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F	
008	DE	barley HORVX	F	stem break of cereals *Pseudocercosporella herpotrichoides* PSDCHE	spraying	BBCH 30 - 34 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b)) as1: 156	100 - 400	F	

									g as/ha as2: 78 g as/ha as3: 78 g as/ha			
009	DE	barley HORVX	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b)) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha	100 - 400	F	
010	DE	barley HORVX	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b)) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha	100 - 400	F	
011	DE	barley HORVX	F	net blotch *Pyrenophora teres* PYRNTE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b)) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g	100 - 400	F	

									as/ha			
012	DE	barley HORVX	F	brown rust of barley *Puccinia hordei* PUCCHD	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b)) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha	100 - 400	F	
013	DE	barley HORVX	F	Ramularia leaf spot disease *Ramularia collo-cygni* RAMUCC	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b)) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha	100 - 400	F	
014	DE	barley HORVX	F	decrease of non-parasitic leaf spots YBFMI	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b)) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha	100 - 400	F	
015	DE	rye SECCE	F	leaf blotch of cereals *Rhynchosporium secalis*	spraying	BBCH 30 - 61 from spring at beginning of	a) 2 b) 2	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g	100 - 400	F	

				RHYNSE		infestation and/or when first symptoms become visible	(14 - 21 d)		as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha			
016	DE	rye SECCE	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F	
017	DE	triticale TTLSS	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F	
018	DE	triticale TTLSS	F	septoria-species *Septoria spp.* SEPTSP	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g	100 - 400	F	

									as/ha as2: 195 g as/ha as3: 195 g as/ha			
019	DE	triticale TTLSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (14 - 21 d)	a) 1.5 L/ha b) 3 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 390 g as/ha as2: 195 g as/ha as3: 195 g as/ha	100 - 400	F	
020	DE	oat AVESS	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b)) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha	100 - 400	F	
021	DE	oat AVESS	F	crown rust of oats *Puccinia coronata* PUCCCA	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.2 L/ha b) 1.2 L/ha	a) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g as/ha b)) as1: 156 g as/ha as2: 78 g as/ha as3: 78 g	100 - 400	F	

									as/ha			
022	DE	wheat TRZSS	F	stem break of cereals *Pseudocercosporella herpotrichoides* PSDCHE	spraying	BBCH 30 - 32 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F	
023	DE	wheat TRZSS	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F	
024	DE	wheat TRZSS	F	leaf spot of wheat *Septoria tritici* SEPTTR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F	
025	DE	wheat TRZSS	F	tan spot of cereals *Drechslera tritici-*	spraying	BBCH 30 - 61 from spring at beginning of	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g	100 - 400	F	

				repentis PYRNTR		infestation and/or when first symptoms become visible			as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha			
026	DE	wheat TRZSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F	
027	DE	wheat TRZSS	F	stripe rust of grasses *Puccinia striiformis* PUCCST	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F	
028	DE	wheat TRZSS	F	septoria leaf spot *Septoria nodorum* LEPTNO	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g	100 - 400	F	

									as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha			
029	DE	rye SECCE	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F	
030	DE	rye SECCE	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F	
031	DE	triticale TTLSS	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g	100 - 400	F	

									as/ha			
032	DE	triticale TTLSS	F	septoria-species *Septoria spp.* SEPTSP	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F	
033	DE	triticale TTLSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1.5 L/ha b) 1.5 L/ha	a) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha b) as1: 195 g as/ha as2: 97.5 g as/ha as3: 97.5 g as/ha	100 - 400	F	

Remarks:

(1) Numeration of uses in accordance with the application/as verified by MS
(2) Member State(s) or zone for which use is applied for
(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(4) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(5) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds, developmental stages
(6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(7) Growth stage of treatment(s) (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(8) The maximum number of applications possible under practical conditions of use for each single application and per year (permanent crops) or crop (annual crops) must be provided
(9) Min. interval between applications (days) were relevant
(10) The application rate of the product a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. kg or L product / ha)
(11) The application rate of the active substance a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. g or kg / ha)
(12) The range (min/max) of water volume under practical conditions of use must be given (L/ha)
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions/minor use etc.

REGISTRATION REPORT
Part B

Section 8 Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product name: Ascra Xpro

Active Substances: Bixafen 65 g/L

Fluopyram 65 g/L

Prothioconazole 130 g/L

Central Zone

Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Bayer CropScience

Date: 06/11/2017

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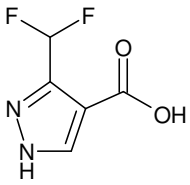
8 RELEVANCE OF METABOLITES IN GROUNDWATER

8.1 General information

The metabolite BYF 00587-desmethyl-pyrazole-4-carboxylic acid (M44) is predicted by the applicant to occur in groundwater at concentrations above 0.1µg/L. Assessment of the relevance of this metabolite according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore required.
General information on the metabolite is provided in Table 8.1-1.

Table 8.1-1: General information on the metabolite(s)

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessmnent	
Bixafen	bixafen metabolite BYF 00587-desmethyl-pyrazole-4-carboxylic acid metabolite (M44)		Max PEC_{gw} Based on:	2.158 µg/L Spring cereals PELMO (Scenario Joikoinen)

8.2 Relevance assessment of BYF 00587-desmethyl-pyrazole-4-carboxylic acid metabolite (M44)

Summary:

The risk assessment of the active substance bixafen at EU level identified a data gap concerning the groundwater exposure assessment of metabolite BYF 00587-desmethyl-pyrazole-4-carboxylic acid metabolite (M44) (see EFSA Journal 2012;10(11):2917).
However, EFSA points out that M44 is a common metabolite of other active substances (fluxapyroxad, isopyrazam). EFSA refers to available toxicological data for the metabolite M700F002 of fluxapyroxad, which is the same as the metabolite M44 of bixafen and was deemed as not relevant in the fluxapyroxad dossier (DAR). The main points are reported here in a brief summary.

BYF 00587-desmethyl-pyrazole-4-carboxylic acid metabolite (M44) is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.
An overview of the relevance assessment for BYF 00587-desmethyl-pyrazole-4-carboxylic acid metabolite (M44) is given in Table 8.2-1.

Table 8.2-1: Summary of the relevance assessment for BYF 00587-desmethyl-pyrazole-4-carboxylic acid metabolite (M44)

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC_{gw}	2.158 µg/L
			Based on	Spring cereals PELMO (Scenario Joikoinen)
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	Non genotoxic
		Stage 3	Toxic properties of metabolite;	
			Classification of parent	none
			Classification of metabolite	none
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	Not acceptable
	STEP 5		Refined risk assessment	acceptable
			Predicted exposure (% of ADI)	4,316 µg/d / 60 kg bw; 0.072 µg/kg bw/d; ADI = 0.3 mg/kg bw/d => Exposure ~0.024 % ADI
			ADI based on	ADI for M44; EFSA Journal 2012;10(11):2917

* N/A: not applicablexa

8.2.1 STEP 1: Exclusion of degradation products of no concern

BYF 00587-desmethyl-pyrazole-4-carboxylic acid metabolite (M44) does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

8.2.2 STEP 2: Quantification of potential groundwater contamination

The PEC of Bixafen and its metabolite M44 in ground water have been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PELMO.

Table 8.22-1: Input parameters related to Bixafen for PEC_{GW} modelling

Parameter	Endpoint used for PEC_{GW} calculation	Values in accordance to EU endpoint in LoEP	Remarks/Reference
Molecular weight (g/mol)	414.2	yes	

DT_{50} in soil (d)	200.2	yes	
K_{Foc}	3869 (arithm mean)	yes	
1/n	0.88	yes	
Plant uptake factor	0		

Table 8.22-2: Input parameters related to metabolites of Bixafen for PEC_{GW} modelling

Parameter	Endpoint used for PEC_{GW} calculation	Values in accordance to EU endpoint in LoEP	Remarks/Reference
Metabolite 1	**M44**		
Molecular weight (g/mol)	162.1	yes	
Formation fraction	1		The formation fraction was set to 1
DT_{50} in soil (d)	25.9	yes	
K_{Foc}	7.7	yes	
1/n	0.964	yes	
Plant uptake factor	0		

Table 8.22-3: PEC_{GW} at 1 m soil depth for Bixafen and its metabolites for the application of Ascra Xpro in cereals (based on geom. mean for DT_{50} value and arithm. mean for K_{Foc})

Crop/Group/use No.	Scenario	80th percentile PEC_{GW} at 1 m soil depth (µg L^{-1}) groundwater model: FOCUS PELMO 5.5.3		
		Bixafen	**metabolite M44**	
A/Wintercereals	**Châteaudun**	<0.001	0.486	
	Hamburg	<0.001	1.652	
	Jokioinen	<0.001	2.158	
	Kremsmünster	<0.001	1.036	
	Okehampton	<0.001	1.115	
	Piacenza	<0.001	0.863	
	Porto	<0.001	0.808	
	Sevilla	<0.001	0.272	
	Thiva	<0.001	0.386	

For the metabolites M44 a groundwater concentration of ≥ 0.1 µg/L cannot be excluded in all FOCUS groundwater scenarios.

8.2.3 STEP 3: Hazard assessment – identification of relevant metabolites

8.2.3.1 STEP 3, Stage 1: screening for biological activity

The Guidance Document states that metabolites with a biological activity comparable or higher than the parent are considered as relevant.
Bixafen is a new fungicide with SDHI mode of action for protective and curative use. A fungicide screening test was conducted to compare the biological activity of BYF 00587-desmethyl-pyrazole-4-carboxylic acid metabolite (M44) with the biological activity of bixafen (Dahmen, P. 2013, M-444623-01-1).
BYF 00587-desmethyl-pyrazole-4-carboxylic acid metabolite (M44) showed no biological activity against the major cereal diseases *Pyrenophora teres*, *Puccinia triticina* and *Septoria tritici*.
Overall, considering the comparative biological data for bixafen and BYF 00587-desmethyl-pyrazole-4-carboxylic acid metabolite (M44), it can be concluded that this metabolite does not have comparable or higher biological activity than the parent bixafen. As stage 1 of Step 3 is passed, BYF 00587-desmethyl-pyrazole-4-carboxylic acid metabolite (M44) must further be screened in Stage 2.

8.2.3.2 STEP 3, Stage 2: screening for genotoxicity

BYF 00587-desmethyl-pyrazole-4-carboxylic acid metabolite (M44 / M700F002) was screened for genotoxic activity by a data package of *in vitro* genotoxicity studies (see DAR fluxapyroxad). M44 / M700F002 was non-genotoxic as shown by a negative Ames test (Schulz & Landsiedel, 2007; ASB2010-7913), by a negative chromosome aberration test (Schulz & Landsiedel, 2008a; ASB2010-7914) and a negative gene mutation test with mammalian cells (Schulz & Landsiedel, 2008b; ASB2010-7928).
Also a negative mouse micronucleus test (Schulz & Landsiedel, 2009; ASB2010-7929) for M44 / M700F002 is available.

M44 is considered not relevant and is further evaluated in Stage 3.

8.2.3.3 STEP 3, Stage 3: screening for toxicity

The parent bixafen to BYF 00587-desmethyl-pyrazole-4-carboxylic acid metabolite (M44) is neither classified as acutely or chronically toxic or very toxic nor for reproductive toxicity nor for any carcinogenic properties. There are no reasons to expect that BYF 00587-desmethyl-pyrazole-4-carboxylic acid metabolite (M44) may be toxic or highly toxic.
Against this background, M44 is not considered relevant and is further evaluated in Step 4.

However, this conclusion is amended by additional data from the fluxapyroxad dossier: BYF 00587-desmethyl-pyrazole-4-carboxylic acid metabolite (M44 / M700F002) has been subject to targeted testing for reproductive toxicity ([redacted], 2009 ASB2010-7916), and short term toxicity ([redacted], 2009 ASB2010-7912). Toxicological endpoints were derived: ADI of 0.3 mg/kg bw/d and ARfD as being not necessary.

8.2.4 STEP 4: Exposure assessment – threshold of concern approach

BYF 00587-desmethyl-pyrazole-4-carboxylic acid metabolite (M44) was not considered relevant in the hazard assessment of Step 3.

The potential exposure to BYF 00587-desmethyl-pyrazole-4-carboxylic acid metabolite (M44) is > 0.75 µg/L but <10 µg/L. A further assessment in Step 5 is required.

8.2.5 STEP 5: Refined risk assessment

BYF 00587-desmethyl-pyrazole-4-carboxylic acid metabolite (M44) has a PECgw between 0.75 µg/L and 10 µg/L. A refined assessment of the potential toxicological significance including the selected ADI is presented here.

Justification for the selected ADI:

It is referred to EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance fluxapyroxad (BAS 700 F) (EFSA Journal 2012; 10(1):2522) where the metabolite M700F002, which is the same as the metabolite M44 of bixafen, has been assessed. Thus, an ADI 0.3 mg/kg bw/d is used for the following consideration.

Calculation of risk (% ADI) for 60-kg adult (consuming 2.0 l/day):

Predicted maximum levels of M44 in groundwater are up to 2.158 µg/L. Exposure to BYF 00587-desmethyl-pyrazole-4-carboxylic acid metabolite (M44) for a 60 kg person consuming 2 L of drinking water per day containing 2.158 µg M44/L would be:

2.158 µg/L x 2 L / 60 kg = 4.316 µg/person/day = 0.000072 mg/kg bw/day = 0.024% of the ADI.

An exposure of BYF 00587-desmethyl-pyrazole-4-carboxylic acid metabolite (M44) as high as 0.009 % of its ADI is considered to be acceptable.

It can be concluded that metabolite M44 meets all the criteria of Step 5. Thus, a concentration of 0.809 µg/L of M44 in the groundwater can be accepted.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
	EFSA	2012	Peer review of the pesticide risk assessment of the active substance bixafen EFSA Journal 2012;10(11):2917			
	EFSA	2012	Conclusion on the peer review of the pesticide risk assessment of the active substance fluxapyroxad (BAS 700 F). EFSA Journal 2012; 10(1):2522			
	United Kingdom	2001	Draft Assessment Report (DAR) on the active substance BAS 700 F (fluxapyroxad) prepared by the rapporteur Member State the United Kingdom in the framework of Directive 91/414/EEC, January 201			
KIIA 5.8	[redacted]	2009	Reg.No. 5435595 (metabolite of BAS 700 F): Repeated dose 90-day oral toxicity study in Wistar rats; Administration in the diet R958945_11265 ! 2009/1012026 ! 50S0441/07091 ! 47923616 GLP: Open (5) Yes (5) Published: No (5) Open (5) BVL-1947740, BVL-1983293, BVL-2072295, BVL-2153913, BVL-2153913, BVL-2153913, BVL-2153913, BVL-2430507, BVL-2430507, BVL-2430507, ASB2010-7912	Yes	BAS SYL	Add
KIIA 5.8	[redacted]	2009	Reg.No. 5435595 (metabolite of BAS 700 F): Prenatal developmental toxicity study in New Zealand white rabbits - Oral administration (gavage) 2009/1072509 ! 40R0441/07117 ! R958945_11262 GLP: Open (8) Yes (9) Published: No (9) Open (8) BVL-1947752, BVL-1983299, BVL-2072307, BVL-2153919, BVL-2153919, BVL-2153919, BVL-2153919, BVL-2178163, BVL-2183565, BVL-2184020, BVL-2275963, BVL-2275963, BVL-2275963, BVL-2275963, BVL-2430508, BVL-2430508, BVL-2430508, ASB2010-7916	Yes	BAS SYD SYL Syngenta Agro	Add
KIIA 5.8	Schulz, M.; Landsiedel, R.	2007	Reg.No. 5435595 (metabolite of BAS 700 F): Salmonella typhimurium / Escherichia coli reverse mutation assay (standard plate test and preincubation test) 2007/1051931 ! 40M0441/074079 GLP: Open (3) Yes (4) Published: No (4) Open (3) BVL-1947742, BVL-1983294, BVL-2072297, BVL-2153914, BVL-2153914, BVL-2153914, BVL-2153914, ASB2010-7913	Yes	BAS	Add
KIIA 5.8	Schulz, M.; Landsiedel, R.	2008a	Reg.No. 5435595 (metabolite of BAS 700 F): In vitro chromosome aberration assay in V79 cells 2008/1002741 ! 32M0441/074074 GLP: Open (3) Yes (4) Published: No (4) Open (3) BVL-1947744, BVL-1983295, BVL-2072299, BVL-2153915, BVL-2153915, BVL-2153915, BVL-2153915, ASB2010-7914	Yes	BAS	Add

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protec-tion claimed	Owner	How considered in dRR *
KIIA 5.8	Schulz, M.; Landsiedel, R.	2008b	Reg.No. 5435595 (metabolite of BAS 700 F): In vitro gene mutation test in CHO cells (HPRT locus assay) 2008/1014199 ! 50M0441/074075 GLP: Open (3) Yes (4) Published: No (4) Open (3) BVL-1947746, BVL-1983296, BVL-2072301, BVL-2153916, BVL-2153916, BVL-2153916, BVL-2153916, ASB2010-7928	Yes	BAS	Add
KIIA 5.8	Schulz, M.; Landsiedel, R.	2009	Reg.No. 5435595 (metabolite of BAS 700 F): Micronucleus test in bone marrow cells of the mouse 2009/1072508 ! 26M0441/074180 GLP: Open Published: Open) BVL-2153917, ASB2010-7929	Yes	BAS	Add

*Y: Yes, relied on
N: No, not relied on
Add: Relied on, study not submitted by applicant