DRAFT REGISTRATION REPORT
Part A

Risk Management

Product code: **Aviator Xpro**

Active Substance: **Bixafen 75 g/L**
Prothioconazole 150 g/L

COUNTRY: Germany

Central Zone

Zonal Rapporteur Member State: DE

NATIONAL ASSESSMENT

Applicant: **Bayer Crop Science**

Date: **24 June 2014**

Table of Contents

PART A – Risk Management

This document describes the acceptable use conditions required for the re-registration of BIX+PTZ EC 225 specification number 102000013869 version 03, containing the active substances bixafen (75 g/L) + prothioconazole (150g/L) on cereals 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.

The information, data and assessments provided in the 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+PTZ EC 225 where that data has not been considered in the EU review. Otherwise assessments for the safe use of BIX+PTZ EC 225 have been made using endpoints agreed in the EU review of bixafen and for prothioconazole.

This document describes the specific conditions of use and labelling required in Germany for the re-registration of BIX+PTZ EC 225 on cereals.

Appendix 1: due to technical reasons, the authorisation of the final product in Germany will be found under Appendix 4.

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

Appendix 4 of this document includes the final product authorisation in Germany (later).

1 Details of the application

1.1 Application background

This application was submitted by Bayer CropScience AG on 30 March 2012 , evaluation starts on 19 April 2012.

The application was for re-registration of BIX+PTZ EC 225, an emulsifiable concentrate containing bixafen (75 g/L) + prothioconazole (150g/L) for use as a fungicide on cereals (wheat, rye, triticale, barley).

1.2 Annex I inclusion

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

Bixafen was approved in accordance with Regulation (EC) 1107/2009 (350/2013) and Annex to Commission Implementing Regulation (EU) No 540/2011 was amended.

The approval for Bixafen (2013/350/EC) provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on the Bixafen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 March 2013, shall be taken into account.

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.

Prothioconazole was included on Annex I of Directive 91/414/EEC on 1 August 2008 under Inclusion Directive ***2008/44/EC.***.

The Annex I Inclusion Directive for prothioconazole (2008**/44/EC)** provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on the 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 this overall assessment:

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.
- information to allow the assessment of consumer exposure to triazole metabolite derivatives in primary crops, rotational crops, and products of animal origin,

- the protection of aquatic organisms. Risk mitigation measures 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 were all addressed in the submission.

Besides the zonal Rapporteur Member State Germany, authorisations are not applied for in other member states .

1.3 Regulatory approach

To obtain approval the product BIX+PTZ EC 225 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 re-registration of this product/use in Germany on cereals (wheat, rye, triticale and barley).

1.4 Data protection claims

The reference list included in the dossier defines the list of studies and reports, submitted with the application, for which a claim for data protection was made. This claim for protection was made as the studies and reports were submitted and used as the basis for approval for the first time in Germany. Based on Article 13.4b of Directive 91/414/EC Bayer S.A.S. (Bayer CropScience) claim 10 years protection for these studies and reports. The authority confirms that these studies and reports are protected for 10 years from the data of authorisation of the product and thus can not be used for the benefit of another applicant.

1.5 Letters of Access

Data access has been proven.
Bayer CropScience is the owner of all data. This point is not relevant.

2 Details of the authorisation

2.1 Product identity

Product Name	Aviator Xpro
Authorization Number	026764-00/00
Function	fungicide
Applicant	Bayer Crop Science AG
Composition	Bixafen 75 g/L, Prothioconazole 150 g/L
Formulation type	emulsifiable concentrate EC
Packaging	canister, fluorinated HDPE, 1 – 15 L; canister, Coex, 1 – 15 L for professional users

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:	
Eye Irrit. 2	
Hazard pictograms:	
GHS07	exclamation mark
GHS08	health hazard
GHS09	environment
Signal word:	
Warning	
Hazard statements:	
H319	Causes serious eye irritation.
H361d	Suspected of damaging the unborn child.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Precautionary statemtents:	
Not proposed for all sections by zRMS Germany, to be decided by applicant	
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-deschloro. May produce an allergic reaction.	
15 percent of the mixture consist of ingredients of unknown inhalation toxicity.	

2.2.3 R and S phrases under Directive 2003/82/EC (Annex IV and V)

None:

2.2.4 Other phrases

2.2.4.1 Restrictions linked to the PPP under Regulation (EC) No 547/2011

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.
SB110	The directive concerning requirements for personal protective gear in plant protection, "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety must be observed.
SE110	Wear tight fitting eye protection when handling the undiluted product.
SF245-01	Treated areas/crops may not be entered until the spray coating has dried.
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	
WMFG1	Mode of action (FRAC-group): G1 (for prothioconazole)
WMFC2	Mode of action (FRAC group): C2 (for bixafen)
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)
NN2001	The product is classified as slightly harmful for populations of relevant beneficial insects.
NN2002	The product is classified as slightly harmful for populations of relevant beneficial predatory mites and spiders.
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	
-	

2.2.4.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions (mandatory labelling):
See 2.3 (Product uses)

Integrated pest management (IPM)/sustainable use	
Ecosystem protection	
NW 605-1 Uses-No.: 001-019	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
NW 606 Uses-No.: 001-019	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
NW706 Uses-No.: 001-019	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 20 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.

2.3 Product uses

date: 2014-04-16

PPP (product name/code) **Aviator Xpro** **Formulation: Type:** **EC**
active substance 1 **Bixafen** **Conc. of as 1: 75 g/L**
active substance 2 **Prothioconazol** **Conc. of as 2: 150 g/L**

Applicant: **Bayer CropScience** **professional use** ☒ **non professional use** ☐

Zone(s): **central EU**

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		
1	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 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	as 1 a) 93.8 g/ha b) 187.6 g/ha as 2 a) 187.5 g/ha b) 375 g/ha	150 – 400	F*	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. NW605-1/606 (*,5,5/10), NW706
2	DE	wheat TRZSS	F	Septoria leaf blotch of wheat *Septoria tritici* SEPTTR	spraying	BBCH 30 – 61 From spring at beginning of infestation and/or when first symptoms become	a) 2 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	as 1 a) 93.8 g/ha b) 187.6 g/ha as 2 a) 187.5 g/ha b) 375 g/ha	150 – 400	F*	NW605-1/606 (*,5,5/10), NW706

						visible						
3	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 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	as 1 a) 93.8 g/ha b) 187.6 g/ha as 2 a) 187.5 g/ha b) 375 g/ha	150 – 400	F*	NW605-1/606 (*,5,5/10), NW706
4	DE	wheat TRZSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 – 69 From spring at beginning of infestation and/or when first symptoms become visible	a) 2 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	as 1 a) 93.8 g/ha b) 187.6 g/ha as 2 a) 187.5 g/ha b) 375 g/ha	150 – 400	F*	NW605-1/606 (*,5,5/10), NW706
5	DE	wheat TRZSS	F	eyespot of cereals *Pseudocercosporella herpotrichoides* PSDCHE	spraying	BBCH 30-37 From spring at beginning of infestation and/or when first symptoms become visible	a) 2 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	as 1 a) 93.8 g/ha b) 187.6 g/ha as 2 a) 187.5 g/ha b) 375 g/ha	150 – 400	F*	NW605-1/606 (*,5,5/10), NW706
6	DE	wheat TRZSS	F	stripe rust of cereals *Puccinia striiformis* PUCCST	spraying	BBCH 30 – 61 From spring at beginning of infestation and/or when first symptoms become visible	a) 2 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	as 1 a) 93.8 g/ha b) 187.6 g/ha as 2 a) 187.5 g/ha b) 375 g/ha	150 – 400	F*	NW605-1/606 (*,5,5/10), NW706
7	DE	wheat TRZSS	F	leaf and glume blotch *Septoria nodorum (Stagonospora nodorum)* LEPTNO	spraying	BBCH 30 – 61 From spring at beginning of infestation and/or when first symptoms become visible	a) 2 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	as 1 a) 93.8 g/ha b) 187.6 g/ha as 2 a) 187.5 g/ha b) 375 g/ha	150 – 400	F*	NW605-1/606 (*,5,5/10), NW706
8	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) 2 (14 -21 days) b) 2	a) 1.0 L/ha b) 2.0 L/ha	as 1 a) 75 g/ha b) 150 g/ha as 2 a) 150 g/ha b) 300 g/ha	150 – 400	F*	NW605-1/606 (*,5,5/10), NW706

9	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) 2 (14 -21 days) b) 2	a) 1.0 L/ha b) 2.0 L/ha	<u>as 1</u> a) 75 g/ha b) 150 g/ha <u>as 2</u> a) 150 g/ha b) 300 g/ha	150 – 400	F*	NW605-1/606 (*,5,5/10), NW706
10	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) 2 (14 -21 days) b) 2	a) 1.0 L/ha b) 2.0 L/ha	<u>as 1</u> a) 75 g/ha b) 150 g/ha <u>as 2</u> a) 150 g/ha b) 300 g/ha	150 – 400	F*	NW605-1/606 (*,5,5/10), NW706
11	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) 2 (14 -21 days) b) 2	a) 1.0 L/ha b) 2.0 L/ha	<u>as 1</u> a) 75 g/ha b) 150 g/ha <u>as 2</u> a) 150 g/ha b) 300 g/ha	150 – 400	F*	NW605-1/606 (*,5,5/10), NW706
12	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) 2 (14 -21 days) b) 2	a) 1.0 L/ha b) 2.0 L/ha	<u>as 1</u> a) 75 g/ha b) 150 g/ha <u>as 2</u> a) 150 g/ha b) 300 g/ha	150 – 400	F*	NW605-1/606 (*,5,5/10), NW706
13	DE	barley HORVX	F	Physiologic leaf spots (PLS) MEHITE	spraying	BBCH 30 – 61 From spring at beginning of infestation and/or when first symptoms become visible	a) 2 (14 -21 days) b) 2	a) 1.0 L/ha b) 2.0 L/ha	<u>as 1</u> a) 75 g/ha b) 150 g/ha <u>as 2</u> a) 150 g/ha b) 300 g/ha	150 – 400	F*	NW605-1/606 (*,5,5/10), NW706
14	DE	rye SECCE	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 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	<u>as 1</u> a) 93.8 g/ha b) 187.6 g/ha <u>as 2</u> a) 187.5 g/ha b) 375 g/ha	150 – 400	F*	NW605-1/606 (*,5,5/10), NW706
15	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 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	<u>as 1</u> a) 93.8 g/ha b) 187.6 g/ha <u>as 2</u> a) 187.5 g/ha b) 375 g/ha	150 – 400	F*	NW605-1/606 (*,5,5/10), NW706

16	DE	rye SECCE	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 – 69 From spring at beginning of infestation and/or when first symptoms become visible	a) 2 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	<u>as 1</u> a) 93.8 g/ha b) 187.6 g/ha <u>as 2</u> a) 187.5 g/ha b) 375 g/ha	150 – 400	F*	NW605-1/606 (*,5,5/10), NW706
17	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 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	<u>as 1</u> a) 93.8 g/ha b) 187.6 g/ha <u>as 2</u> a) 187.5 g/ha b) 375 g/ha	150 – 400	F*	NW605-1/606 (*,5,5/10), NW706
18	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 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	<u>as 1</u> a) 93.8 g/ha b) 187.6 g/ha <u>as 2</u> a) 187.5 g/ha b) 375 g/ha	150 – 400	F*	NW605-1/606 (*,5,5/10), NW706
19	DE	triticale TTLSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 – 69 From spring at beginning of infestation and/or when first symptoms become visible	a) 2 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	<u>as 1</u> a) 93.8 g/ha b) 187.6 g/ha <u>as 2</u> a) 187.5 g/ha b) 375 g/ha	150 – 400	F*	NW605-1/606 (*,5,5/10), NW706

<u>General remarks/explanations:</u>
The GAP-Sheet should indicate if the displayed information was provided by the applicant OR was revised by the zRMS (due to the product label and Annex III data).

The zRMS has to verify the presented information and to ask (the applicant) for clarification of missing details (e.g. BBCH stages, EC-codes of crops).

All abbreviations in the GAP-Sheet used must be explained. Use separate worksheet for each product.

Make use of existing standards like EPPO and BBCH.

Product: Please indicate the specific variant of the active substance if relevant.

If additional components have to be added to the applied product (tankmixtures), all relevant information must be provided in the column remarks.

As the product usually will be determined either for professional or non professional use, this information should be given here. Otherwise to be indicated in column 4 of the GAP-sheet (conditions / location of use).

Formulation:
<u>Type:</u>
e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

Refer to:

- GCPF Codes - GIFAP Technical Monograph No 2, (1989), 6th Edition – Revised May 2008 – Catalogue of pesticide formulation types and international coding system.
- Technical Monograph n°2, 6th Edition - Revised May 2008 - Catalogue of pesticide formulation types and international coding system (CropLife International) [1)].

Conc. of as:
g/kg or g/L

In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.

Safener/Synergist: Since safeners and synergists are in scope of REG 1107/2009, information about safeners/synergists should be included in the GAP table as well.

Zone(s): All relevant zone(s) should be indicated. For interzonal uses (e.g. greenhouse, seed treatment, etc.) "EU" should be chosen.

Explanations to the particular columns:
No.: Numeration would be important when references are necessary e. g. to the dossier or to the authorisation certificate.

Member state(s): For a better general view of the valid uses for the particular zones/MS it would be helpful to mention both (the zone as well as the MS) in the column. However, to keep the table clearly arranged it seems dispensable to cite the zone; each MS is distinctly allocated to one zone; moreover the zone(s) are cited in the head of the table.

Desirably MS are put in order accordant to the zone they belong.

Crop and/or situation: The common name(s) of the crop and the EC (EPPO)-Codes or at least the scientific name(s) [EU and Codex classifications (both)] should be used; where relevant, the situation should be described (e.g. fumigation of a structure). In case of crop groups all single crops belonging to that group should be mentioned, (either in the respective table element or – in case of a very extensive crop group - at least in a footnote).

If it is not possible to mention all single crops belonging to a crop group (e.g. for horticulture), it should be referred to appropriate crop lists (e.g. EPPO, residue (codex). It would be desirable to have a "joint list" of crop groups for the zones.

Exceptions of specific crops/products/objects or groups of these and restrictions to certain uses (e.g. only for seed production, fodder) must be indicated.

This column should also include when indicated information concerning "crop destination or purpose of crop" and which part of plants will be used / processed (e. g. for medicinal crops roots or leaves or seeds).

Conditions / location of use: Outdoor or field use (F), glasshouse application (G) or indoor application (I)

"Glasshouse" indicates that the respective trials are acceptable for all zones.

As results achieved in compartments without controlled conditions (temperature, light exposure), e.g. simple plastic tunnels [for those GAPs field trials have to be conducted in the respective zone the use is applied for], are not considered to be applicable for use in other zones the kind of glasshouse should be clearly indicated.

[Remark: Greenhouse definitions are at the moment under evaluation].

Conditions include also information concerning the substrate (natural soil, artificial substrate).

[1)] http://www.croplife.org/files/documentspublished/1/en-us/PUB-TM/4147_PUB-TM_2008_05_01_Technical_Monograph_2_-_Revised_May_2008.pdf

Pests or Group of pests controlled: Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and suckling 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.

If necessary – in case of pest groups - exceptions (e.g. sucking insects excluding scale insects) should be indicated.

In some cases, the set of pests concerned for a given crop may vary in different parts of the EU region (where appropriate the pests should be specified individually).

If the product is used as growth regulator the target organism is the specific crop, whose development should be influenced; the aim could also be e.g. an empty room for treatment.

Application details:
Method / Kind:
Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench, drilling, high precision drilling (with or without pneumatic systems).

Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used (e.g. ultra low volume equipment (ULVA) or low volume equipment (LVA)) should be indicated if relevant.

Timing of Application / Growth stage of crop & season:
Time(s), period, first and last treatment, e.g. autumn or spring pre- or post-emergence, at sufficient pest density or begin of infection, including restrictions (e.g. not during flowering).

Growth stage of crop (BBCH-code, …) – period, first and last treatment.

Since the BBCH-codes are accomplished in the individual member states at different time periods the month(s) of application should be indicated in addition.

BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

It seems sensible to constrain specifications in this column only to the crop, - information concerning the pest should be dealt in column “pest or group of Pests controlled”.

In certain circumstances it might be helpful to give information about the expected rate of interception related to the BBCH codes. In many minor crops no BBCH/interception rate scenarios have been specified so far. This could also simplify grouping for the envelope approach.

Number of applications and interval between applications
a) Maximum number of applications per growing season used for the named crop/pest combination possible under practical conditions of use.

b) The proposed maximum number in the crop including applications on all pests/targets on the same crop in a growing season should be given.

It should be clearly indicated whether the displayed number of applications is per season, per crop cycle or per pest generation.

Minimum interval (in days) between applications of the same product. The figure for the interval between the applications is to be set in brackets.

Application rate:
Application rate of the product per ha:
a)-(Maximum) product rate per treatment (usually kg or L product / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).

b) Maximum product rate per growing season (especially if limited) or per crop cycle should be cited.

Especially in three dimensional crops other dose expressions (kg/l per 10.000 m² leaf wall area or kg/l per ha per meter crown (canopy) height) should be given additionally.

For seed treatment also the load of product (l/g, kg) per kg, 100 kg or unit treated seed should be stated beside the application rate per hectare. The number of seeds per (seed) unit is to be given. The maximum seed drilling rate (=number of seed sown/maximum seed volume) per row and ha should be indicated.

Information concerning the sowing method (precision drilling, …) would be advantageous.

See also EPPO-Guideline PP 1/239 Dose expression for plant protection products (please note, additional EPPO-guidelines may be developed).

Application rate of the active substance per ha:
a)-(Maximum) as rate per treatment (usually kg active substance / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).

b) Maximum as rate per growing season (especially if limited) or per crop cycle should be cited.

The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg active substance / ha).

In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.

Water L/ha:
It should be clearly indicated if a stated water volume range depends upon the developmental stage of the crop (low volume – early crops stage, high volume – late crop stage) which causes a consistent concentration of the spray solution, or if a water volume range indicates different spray solution concentrations.

In the last mentioned case extremely low water volumes (indicating high concentrated spray solutions) need to be covered within selectivity trials.

If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.

PHI (days) – minimum pre harvest interval: PHI - minimum pre-harvest interval

For some crop situations a specific PHI may not be relevant. If so an explanation (e. g. the PHI is covered by the time remaining between application and harvest.) should be given in the remarks column (e.g. crop harvest at maturity or specific growth stages).

Remarks: Remarks may include: amount of safener/synergist per ha or extent of use/economic importance/restrictions, e.g. limiting the number of uses per crop and season, if several target pests/diseases are controlled with the same product.

If additional components (other ppp or adjuvant) should be used with the applied product (tankmixtures), all relevant information must be provided in the column remarks. In addition, it should be mentioned as well those mixtures are recommended or mandatory.

Additional recommendations:
For the description of uses of a PPP the following EPPO Standards should be considered:

- EPPO Standard PP 1/240 “Harmonized basic information for databases on plant protection products”
- EPPO Standard PP1/ 248 “Harmonized classification and coding of the uses of plant protection products“

Whereas EPPO Standard PP1/ 248 gives more general information on possible description of uses, EPPO Standard PP 1/240 especially gives an overview of all points necessary to fully understand a use.

Ad EPPO-Guidelines, see: http://archives.eppo.org/EPPOStandards/efficacy.htm

Use EPPO extrapolation tables, see http://www.eppo.org/PPPRODUCTS/extrapolation/tables.htm

EPPO Plant Protection Thesaurus: http://eppt.eppo.org/

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:

Bixafen + Prothioconazole EC 225 (75+150 g/L) is not explosive, not flammable and not oxidizing. Its pH is within the range that naturally occurs e.g. in soil. Its stability allows storage under practical and commercial conditions. The technical properties indicate that no particular problems have to be expected when it is used as recommended.

Implications for labelling: none

Compliance with FAO specifications:
There are no FAO specifications for bixafen or prothioconazole.

Compliance with FAO guidelines:
The product Aviator Xpro complies with the general requirements for an EC formulation according to the FAO/WHO manual (2010).

Compatibility of mixtures:
No tank mixtures are recommended for Aviator Xpro.

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 Aviator 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 submitted HPLC method is applicable for the simultaneous quantitative determination of the content of bixafen and prothioconazole in formulations (e.g. Bixafen + Prothioconazole EC 225 (75+150 g/L)). The method has been completely validated by checking the parameters linearity, precision, accuracy, specificity and interference from excipients.
Up to now there is no CIPAC method available for the determination of bixafen or prothioconazole in formulations.
The HPLC-MS/MS-method 2001-0051701-1 is applicable for the quantitative determination of the content of the relevant impurity **prothioconazole-desthio** in formulations e.g. Bixafen + Prothioconazole EC 225.
The GC method AM012408MF2 is applicable for the quantitative determination of the relevant impurity **toluene** in formulations e.g.‘ Bixafen + Prothioconazole EC 225.

Both methods have been completely validated on 'Bixafen + Prothioconazole EC 225 (75+150 g/L)' by checking the parameters linearity, precision, accuracy, specificity and interference from excipients.

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 in food of plant and animal origin, soil, water and air. Methods for body fluids or tissues are not required since bixafen and prothioconazole are not classified as toxic or very toxic nor classified according to GHS as follows: Acute toxicity (cat. 1 - 3), CMR (cat. 1) or STOT (cat. 1).
Analytical methods used to meet the requirements of the Annex to Regulation (EU) No 544/2011, Part A, point 4.2 can be applied. The applicant is owner of the data packages used for the approval of the active substances.
Additional LC-MS/MS methods for the determination of prothioconazole residues in food of plant and animal origin, soil and water were provided and were found acceptably validated.

3.1.3 Mammalian Toxicology (Part B, Section 3)

3.1.3.1 Acute Toxicity (Part B, Section 3)

Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for Bixafen + Prothioconazole EC 225

Type of test, model system (Guideline)	**Result**	**Acceptability**	**Classification (acc. to the criteria in Dir. 67/548/EEC)**	**Classification (acc. to the criteria in Reg. 1272/2008)**	
LD_{50} oral, rat (OECD 425)	> 2000 mg/kg bw	Yes	None	None	
LD_{50} dermal, rat (OECD 402)	> 2000 mg/kg bw	Yes	None	None	
LC_{50} inhalation, rat	Not submitted, not necessary. Justification presented in Annex 2. Bixafen: LC50 (rat) > 5.38 mg/L air Prothioconazole: LC50 (rat) > 4.99 mg/L air Prothioconazole-desthio (prothioconazole metabolite): LC50 (rat) > 5.08 mg/L air				
Skin irritation, rabbit (OECD 404)	Non-irritant	Yes	None	None	
Eye irritation, rabbit (OECD 405)	Irritant	Yes	Xi; R36	Warning; H319	
Skin sensitisation, mouse (OECD 429, LLNA)	Non-sensitising	Yes	None	None	
Supplementary studies for combinations of plant protection products	No data – not required				

Additional toxicological information relevant for classification/labelling of Bixafen + Prothioconazole EC 225

	Substance (Concentration in product, % w/w)	**Classification of the substance (acc. to the criteria in Dir. 67/548/EEC and/or in Reg. 1272/2008)**	**Reference**	**Classification of product (acc. to the criteria in Dir. 67/548/EEC, in Dir. 1999/45/EC and/or in Reg. 1272/2008)**
Toxicological properties of active substance(s) (relevant for classification of product)	Prothioconazole (14.85 % (w/w))	R63 (≥ 5 % (w/w)) H361d (≥ 3 % (w/w))	BfR proposal in accordance with EFSA conclusion on prothioconazole	(R63) [1)] (H361d) [1)]
Toxicological properties of non-active substance(s) (relevant for classification of product)	Impurity prothioconazole-deschloro (2-[2-(1-chlorocyclopropyl)-2-hydroxy-3-phenylpropyl]-2,4-dihydro-3H-1,2,4-triazole-3-thione) (0.23 % (w/w))	R43 (≥ 0.1 % (w/w)) H317; EUH208 (≥ 0.1 % (w/w))	BfR proposal in accordance with EFSA conclusion on prothioconazole	'Contains prothioconazole-deschloro. May produce an allergic reaction.' [2)] EUH208 [2)]
Further toxicological information	No data – not required			

[1)] up to now no legal classification

[2)] up to now no legal classification but unequivocal results in animal study, therefore used for classification of the product

3.1.3.2 Operator Exposure (Part B, Section 3)

Operator exposure was assessed against the AOEL-systemic agreed in the EU review (bixafen 0.13 mg/kg bw/d and prothioconazol: 0.2 mg/kg bw/d). Dermal absorption data of studies conducted with different but more or less comparable formulations with the single active substances have been used. The detailed evaluation is provided in Part B.3. According to the model calculations, it can be concluded that the risk for the operator using Aviator Xpro in cereals is acceptable with the use of personal protective equipment described in 2.2.3.1.

3.1.3.3 Bystander Exposure (Part B, Section 3)

Since the bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for bixafen, prothioconazole and its metabolite prothioconazole-desthio 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. The product is a mixture of two active substances (see confidential part).The combined toxicological effect of these active substances has not been investigated, since no harmonized evaluation concept is available on EU-level.

3.1.3.4 Worker Exposure (Part B, Section 3)

The worker exposure was estimated using the "German model". Even without any PPE the estimated consumption of AOEL was acceptable for all active substances.

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

See 2.2.

3.1.4 Residues and Consumer Exposure (Part B, Section 4)

3.1.4.1 Residues (Part B, Section 4)

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". From German point of view 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, 0.05 mg/kg for rye and wheat; prothioconazole: 0.3 mg/kg for barley, 0.1 mg/kg for rye and wheat) as laid down in Reg. (EU) 396/2005 is not expected.

3.1.4.2 Consumer exposure (Part B, Section 4)

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

Bixafen	
ADI	0.02 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	11 % (based on NL children, mean body weight 17.1 kg)
NTMDI (% ADI) according to NVS II model	9 % (based on German children aged 2-4 years, individual consumption/body weight ratio)
ARfD	0.2 mg/kg bw
IESTI (EFSA PRIMo) (% ARfD)	barley: < 1 % (based on NL adults) rye: < 1 % (based on UK infants with 8.7 kg bw) wheat: < 1 % (based on UK children aged 4-6 years)
NESTI (NVS II model) (% ARfD)	barley: < 1 % (based on DE general population, 14-80 yrs) rye: < 1 % (based on DE children aged 2-4 years) wheat: < 1 % (based on DE children aged 2-4 years)

Prothioconazole	
ADI	0.01 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	87 % (based on UK toddler)
NTMDI (% ADI) according to NVS II model	23 % (based on DE women in childbearing age 14-50 years)
Factors included in TMDI	Conversion factors (monitoring to risk assessment): 10 for milk and muscle, 4 for fat, 2 for liver and kidney, cereal grain, oilseeds, potatoes, root vegetables, brassica vegetables and leek
ARfD	0.01 mg/kg bw
IESTI (EFSA PRIMo) (% ARfD)	barley : 1 % (based on NL adults with 63 kg bw) rye: 1 % (based on UK infant with 8.7 kg bw) wheat: 3 % (based on UK children aged 4-6 years)
NESTI (NVS II model) (% ARfD)	barley: 1 % (based on DE general population) 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	Conversion factor of 2

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

A full exposure assessment for the plant protection product Aviator Xpro in its intended uses in cereals is documented in detail in the core assessment of the plant protection product Aviator Xpro dated from 2013 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 Aviator Xpro in Germany according to its intended use in cereals.

Table: Overview on uses

Use No	**Crop growth stage**	**Application method / Drift scenario**	**Number of applications, Minimum application interval, interception, application time (season)**	**Application rate, cumulative (g as/ha)**	**Soil effective application rate (g as/ha)**
001-007, 014-019 (Use group A)	Wheat, Rye, Triticale BBCH 30-69	Field, Spray	2 x, 14 d, spring 1. 70 % 2. 70 % Winter cereals: 1. Appl.: 19.4.=>169d and 183d after emergence Spring cereals: 1. Appl: 28.4.= >27 d and 41d after emergence	Bixafen: 2 x 93.75 = 187.5 Prothioconazol: 2 x 187.5= 375	Bixafen: 1. 28.125 2. 28.125 Prothioconazol: 1. 56.25 2. 56.25

008-013 (Use group B)	Barley BBCH 30-61	Field, Spray	2 x, 14d, spring 1. 70%, 14d 2. 70%, 10d	Bixafen: 2 x 75=150 Prothioconazol: 2 x 150 = 300	Bixafen: 1. 22.5 2. 22.5 Prothioconazol: 1. 45 2. 45

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.
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.

Consequences for authorization:

The authorization of the product "Skyway Xpro" in Germany for the use groups A1, A2 and B has to be linked with a monitoring study over several years to investigate the realistic worst case soil concentration which will be build up due to accumulation processes with the granted product.

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.

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

3.1.5.1 Predicted Environmental Concentration in Soil (PEC_{soil}) (Part B, Section 5, Points 9.4 and 9.5)

For the intended use of the plant protection product Aviator Xpro in cereals PECsoil was calculated for the active substances Bixafen and Prothioconazole considering a soil depth of 1 cm (KOC>500). Due to the slow degradation of the active substance Bixafen in soil the accumulation potential of Bixafen 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.

Table: Overview PECsoil relevant for risk assessment

active substance/ formulation	**soil relevant application rate (g/ha)****	**soil depth (cm)**	**PEC_{accu} (mg/kg)**
Bixafen	2 x 28.125 g/ha	1	1.21*
Prothioconazole	2 x 56,25 g/ha M:344.3	1	0.3816
Metabolite M04	Ff=0.8, M: 312.2	1	0.4509
Product Aviator Xpro	Density 1.01, 1x 2525 g/ha	1	16.8335

* No degradation, incl. background conc. additional assessment factor of 10
** worst case use considered

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

3.1.5.2 Predicted Environmental Concentration in Ground Water (PEC_{GW}) (Part B, Section 5, Point 9.6)

1. Direct leaching into groundwater
Results of modelling with FOCUSPELMO 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 and spring cereals.
For the metabolite M44 of Bixafen concentrations of ≥ 0.1 µg/L in groundwater can not be excluded in the intended uses.
An assessment of metabolite M44 regarding its relevance for groundwater is necessary (see Section 8).
According to the results of the groundwater simulation with FOCUS-PELMO 5.5.3, a groundwater contamination of the active substance Prothioconazole and the metabolites M01/ JAU-6476-S-methyl and M04/ JAU 6476-Desthio in concentrations of ≥ 0.1 µg/L is not expected for the intended uses in winter and spring cereals.

Table: Overview PECgw Bixafen and M44

Use No.	**Szenario**	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUSPELMO 5.5.3	
		Bixafen	**M44**
1 to 19	Hamburg	<0.001	1.596

2. Ground water contamination by bank filtration due to surface water exposure via run-off and drainage
According to modelling with EXPOSIT 3, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance Bixafen due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.
According to modelling with EXPOSIT 3, 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.

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 Aviator Xpro in cereals PECsw was calculated for the active substances Bixafen 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 substances Bixafen and Prothioconazole is $< 10^{-5}$ Pa / Hence the active substance Bixafen and Prothioconazole are regarded as non-volatile. Therefore, exposure of surface water by the active substance Bixafen and Prothioconazole due to deposition following volatilization were not considered.
The concentrations of the active substances Bixafen and Prothioconazole in adjacent ditch due to surface run-off and drainage were calculated using the model EXPOSIT.

Table: Overview of PECsw values relevant for risk assessment.

active substance/ formulation	**relevant application rate (g/ha) – scenario agriculture**	**PECsw Spray drift (µg/L) 1 m – ditch**	**PECsed-accu (µg/kg) 1 m – ditch 82.Perc**	**PECrun-off (µg/L) Ditch - 0 m**	**PECdrainage (µg/L) Autumn/winter/early spring**	**PECdrainage (µg/L) Spring/summer**
Bixafen	93.75 (worst case)	1.266 - 82.Perc	108.76	0.31	0.05	0.01
Prothioconazole	187.5 (worst case)	2.465 – 82 perc	-	0.12	0.01	< 0.01
Metabolit Prothioconazole -Desthio	187.5 (worst case)	2.465 – 82 perc	-	0.6	0.82	0.27
Product Aviator Xpro	1.25 L Product/ha	11.5 – 90 Perc.	-	-	-	-

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 (PEC_{Air}) (Part B, Section 5, Point 9.9)

The vapour pressure at 20 °C of the active substance Bixafen is $< 10^{-5}$ Pa. Hence Bixafen is regarded as non-volatile. Thus, exposure of surface water and terrestrial non-target areas by the active substance Bixafen due to deposition following volatilization does not need to be considered.

The vapour pressure at 20 °C of the active substance Prothioconazole is $< 10^{-5}$ Pa ($<< 4 \times 10^{-7}$ Pa; see Table 5.3-2 of part B5). Hence the active substance Prothioconazole is regarded as non-volatile. Therefore, it is not necessary to consider the exposure to surface water and terrestrial non-target areas by the active substance Prothioconazole due to deposition following volatilization.

Implications for labelling resulting from environmental fate assessment:

For the authorization of the plant protection product Aviator 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 Aviator Xpro is considered to be not readily degradable in the sense of the CLP regulation (R53).

R and S phrases under Directive 2003/82/EC (Annex IV and V)

none

Other labels /conditions for use

Labelling

none

Conditions of use:

none.

Further data requirements:

none

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

A full risk assessment according to Uniform Principles for the plant protection product Aviator Xpro in its intended uses in cereals is documented in detail in the core assessment of the plant protection product Aviator Xpro dated from October 2013 performed by Germany.
The following chapters summarise specific risk assessment for non-target organisms and hence risk mitigation measures for the authorization of Aviator Xpro in Germany according to its intended uses in cereals.
For reasons of better readability the intended uses in of the plant protection product Aviator Xpro in Germany are summarised as follows:

Use No	**Crop/growth stage**	**Application method / Drift scenario**	**Number of applications, Minimum application interval, interception, application time (season)**	**Application rate, cumulative (g as/ha)**	**Soil effective application rate (g as/ha)**
001-007, 014-019 (Use group A)	Wheat, Rye, Triticale / BBCH 30-69	Field, Spray	2 x, 14 d,spring 1. 70 % 2. 70 % Winter cereals: 1. Appl.: 19.4.=>169d and 183d after emergence Spring cereals: 1. Appl: 28.4.= >27 d and 41d after emergence	Bixafen: 2 x 93.75 = 187,5 Prothioconazol: 2 x 187.5= 375	Bixafen: 1. 28.125 2. 28.125 Prothioconazol: 1. 56.25 2. 56.25
008-013 (Use group B)	Barley / BBCH 30-61	Field, Spray	2 x, 14d, spring 1. 70%, 14d 2. 70%, 10 d	Bixafen: 2 x 75=150 Prothioconazol: 2 x 150 = 300	Bixafen: 1. 22.5 2. 22.5 Prothioconazol: 1. 45 2. 45

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: Overview endpoints birds and mammals

Species	**Substance**	**Exposition Duration System**	**Results Toxicity**
Colinus virginianus	bixafen	1 d acute	LD_{50} > 2000 mg/kg bw
Colinus virginianus	prothioconazole (JAU 6476)	1 d acute	LD_{50} > 2000 mg/kg bw
Colinus virginianus	bixafen	6 wk reproduction	**NOAEL: 30 mg/kg bw/d**
Anas platyrhynchos	prothioconazole (JAU 6476)	147 d, Reproduction	NOEC: 78 mg/kg bw/d (according to LoEP)
Colinus virginianus	JAU 6476-desthio	22 wk reproduction	**NOEL: 14.8 mg/kg bw/d**

rat	bixafen	acute oral	LD50 >5000 mg a.i./kg bw/d1)
rat	prothioconazole (JAU 6476)	acute oral	LD50 >6200 mg a.i./kg bw/d2)
rat	prothioconazole-desthio (JAU 6476-desthio)	acute oral	LD50 = 2235 mg a.i./kg bw/d
rat	Aviator Xpro	acute oral	LD_{50} >2000 mg/kg bw/d
rat	bixafen	chronic 2-generation study	NOAEL = 34.6 mg/kg bw/day
rat	prothioconazole (JAU 6476)	chronic 2-generation study	NOAELrepro = 95.6 mg/kg bw/day NOAELparental = 9.7 mg/kg bw/day
rat	Prothioconazole-desthio (JAU 6476-desthio)	chronic 2-generation study	NOAEL= 10 mg/kg bw/day offspring: dystocia, decreased neonatal viability NOAEL : 2.5 mg/kg bw/d parental: histopathological alterations in the liver

Based on the higher tier assessment step, the calculated TER values for the acute and long-term risk resulting from an exposure of mammals to bixafen, prothioconazole and JAU 6476-desthio (oral exposure and exposure via drinking water and secondary poisoning) according to the GAP of the formulation Aviator 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 Aviator Xpro in crops according to the label.
Based on the calculation of the risk arising from the uptake of bixafen, prothioconazole and JAU 6476-desthio via drinking water, the calculated TER values for mammals exposed to the active substances bixafen, prothioconazole and JAU 6476-desthio according to the GAP of the formulation Aviator 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 , further refinement is not necessary.
Based on the calculation of the risk arising from secondary poisoning, the calculated TER values for mammals exposed to the active substances bixafen, prothioconazole and JAU 6476-desthio according to the GAP of the formulation Aviator 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, further refinement is not necessary.

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 Aviator Xpro in cereals based on FOCUS Surface Water PEC values is presented in the core assessment, Part B, Section 6, chapter 6.4.
Relevant for the aquatic risk assessment concerning spray drift and run off is a NOEC of 0.00334 mg Prothioconazol-Metab.(JAU-6476-Desthio)/L observed in a Fish FLC-study and a NOEC of 0.0046 mg Bixafen/L observed in prolonged fish test. This leads under consideration of a safety factor of 10 to a regulatory acceptable concentration of 0.000334 mg Prothioconazol-Metab.(JAU-6476-Desthio)/L. All chronic fish studies with the active substances demonstrated a high toxicity.

Species	Substance	Exposition Duration	Results Toxicity	Regulatory acceptable

		System		concentration
Pimephales promelas	BYF 00587 tech (Bixafen, 95.8 % ai)	28 d Flow-through ELS	NOEC : 0.0046 mg/L [1)] Growth measured	0.00046 mg/L (SF: 10)
Oncorhynchus mykiss	Prothioconazole	97 d Flow-through	NOEC : 0.308 mg/L Reproduction nominal	0.0308 mg/L (SF10)
Oncorhynchus mykiss	Prothioconazol-Metab. (JAU-6476-Desthio)	96 d Flow-through	NOEC : 0.00334 mg/L [2)] Deformation NOEC : 0.053 mg/L Reproduction nominal	0.000334 mg/L (SF 10)

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
The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. The vapour pressures at 20 °C of the active substances bixafen and prothioconazole are $< 10^{-5}$ Pa. Therefore, exposure of surface water by the active substances bixafen and prothioconazole due to deposition following volatilization was not considered.

The aquatic risk assessment of spray drift entries in surface water by the use of Aviator Xpro in cereals according to use group A and B is based on the following endpoints:

For the active ingredient **bixafen** the most sensitive acute endpoint divided by the corresponding safety factor is **NOEC = 0.0046 mg a.s./L (*Pimephales promelas*).** For bixafen also a risk assessment concentrating on accumulation in sediment was done, not indicating a higher risk, taking into account a NOEC of 20 mg as/kg sediment from a ***Chironomus riparius*** study.
For the active ingredient **prothioconazole** the most sensitive endpoint, given by the lowest ratio of endpoint divided by the corresponding safety factor, is **EbC50 = 0.018 mg a.s./L *(Skeletonema costatum).***
However an assessment based on the prothioconazol algae endpoint does not cover the potential risk of endocrine effects caused by the **metabolite JAU 6476-desthio,** which is structurally very similar to the active substance. An ELS study was provided for the metabolite JAU 6476-desthio and the **NOEC = 0.00334 mg/L *(Oncorhynchus mykiss)*** presents the worst case for the ratio of endpoint divided by the corresponding safety factor (on the national level also a FFLC test is known for the metabolite, thus possible endocrine effects are sufficiently addressed and no further assessment factor is needed here).

Based on the relevant toxicity of the active substances bixafen and prothioconazole, the calculated TER values for the risk to aquatic organism resulting from an exposure of surface water by spraydrift to Aviator Xpro according to the use groups A and B only achieve the acceptability criteria of TER $\geq$ 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 (see below) are applied.

2. Exposure by surface run-off and drainage
The concentration of the active substances bixafen and prothioconazole (Metabolit desthio-prothioconazole) in adjacent ditch due to surface runoff and drainage was calculated using the model EXPOSIT 3.01.
The calculated TER values for the risk to aquatic organisms resulting from an exposure of surface water

by the active substances bixafen and prothioconazole (Metabolit desthio-prothioconazole) due to run-off and drainage according to the use groups A and B 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 (20 m buffer stripe and no application on drained areas between November and March) are applied
Consequences for authorization:
For the authorization of the plant protection product Aviator Xpro the following labelling and conditions of use are mandatory:

Required Labelling

NW 262	The product is toxic for algae. Bixafen: *Pseudokirchnerilla subcapitata* EbC50 : 0.0657 mg/L Prothioconazole: *Skeletonema costatum* EbC50: 0.018 mg/L
NW 264	The product is toxic for fish and aquatic invertebrates. Bixafen: *Daphnia magna* NOEC: 0.05 mg/L Prothioconazole *Daphnia magna* NOEC: 0.56 mg/L
NW 265	The product is toxic for higher aquatic plants. Prothioconazole-Desthio: *Lemna gibba*, EC50 = 0.0394 mg/L Prothioconazole: *Lemna gibba*, Ec50= 0.074 mg/L

Conditions for use

NW 605-1	Drift reduction 90 % 0 m; 75 % 5 m; 50 % 5 m
NW 606	10 m vegetated buffer strip
NW 706	20 m vegetated buffer strip

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

Bees

The recommended use pattern for Aviator Xpro includes application in cereal species at a maximum application rate of up to 1.25 L/ha. Bees may be exposed to 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.
Due to the results of laboratory tests Aviator Xpro is considered to be practically non-toxic to bees. The oral and contact toxicity end points are below 100 µg/bee. 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.

Other non-target arthropods

Based on the calculated rates of Aviator Xpro in off-field areas, the calculated TER values for the risk resulting from an exposure of non-target arthropods to Aviator Xpro according to the GAP of the formulation Aviator Xpro achieve the acceptability criteria of 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 arthropods due to the intended use of

Aviator Xpro in cereals according to the label.

Table: Relevant endpoint for risk assessment of non-target-arthropods

Species	Test type	Correction factor	L/ER50
			(mL product/ha)
T.pyri	3D	-	1.25 l/ha

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

Based on the predicted concentrations of bixafen, prothioconazole and formulation Aviator Xpro in soils, the TER values describing the acute and longterm risk for earthworms and other non-target soil organisms following exposure to active substances and the formulation Aviator Xpro according to the GAP of the formulation Aviator 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. The results of the assessment indicate an acceptable risk for soil organisms due to the intended use of Aviator Xpro in cereals according to the label.

Table: Overview Endpoints earthworms and other soil organisms studies with Aviator Xpro

Species	Substance	Exposition Duration System	Results Toxicity
Eisenia fetida	Aviator Xpro	56 d chronic 5% peat	NOEC = 75 L pr/ha NOEC= 9.375 L pr/ha reproduction[1]
Folsomia candida	Aviator Xpro	28 d chronic	NOEC= 104 mg/kg dw Reproduction NOEC= 208 mg kg/dw

[1] Lower endpoint is used for risk assessment by UBA. Recalculation of test showed that reproduction rates were different compared to the control in treatment group 18.75 L/ha (statistic evaluation was done with Williams-test, with Tox-Rat). Thus NOEC for reproduction effects is 9.375 L/ha.

The results of the assessment indicate an acceptable risk for soil organisms due to the intended use of Aviator Xpro in cereals according to the label. However, the submitted field study (Schulz, 2015) shows effects on the observed population of soil macroorganisms (collembolans) already at the lowest tested concentration of 2 x 1.25 L/ha, which corresponds to the GAP of the use group A. Therefore, a 2 years monitoring study is also required for the use group A.

Consequences for authorization:

A 2 years monitoring study of soil macroorganisms (collembolans) is required for the use group A.

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

According to SANCO/10329/2002 rev2 final a test for assessing effects on organic matter breakdown (litterbag) is required where:

- DT_{90f} > 365 days or
- DT_{90f} is between 100 and 365 days and
- Effects on soil microflora > 25 % or TER_{LT} earthworm < 5
- or Collembola TER_{LT} < 5

For the active ingredient bixafen no DT_{90f} value is known. For prothioconazole the DT_{90f} is clearly below 100 days. As no risk was identified for earthworms, soil micro-organisms and non-target arthropods from the use of Aviator Xpro, an evaluation of effects on organic matter breakdown is not necessary. However, for the active substanceand prothioconazole a litter bag study was evaluated within the EU review process and no relevant effects were shown.

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 prothioconazole in soils, the risk to soil microbial processes following exposure to bixafen and prothioconazole according to the GAP of the formulation Aviator 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)

Non-Target Plants

Relevant toxicity endpoint is an ER50 > 1.25 L/ha observed in a vegetative vigour and seedling emergence study with Aviator Xpro.
Based on the predicted rates of formulation Aviator Xpro in off-field areas, the TER values describing the risk for non-target plants following exposure to formulation Aviator Xpro according to the GAP of the formulation Aviator 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. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of Aviator Xpro in cereals according to the label.

Implications for labelling resulting from ecotoxicological assessment:

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

Relevant toxicity	Active substance: bixafen (content 7.5 %) EbC50= 0.0657 mg/L (*Pseudokirchnerie-lla subcapitata*) M-factor = 10 Active substance: prothiconazole (content 15 %) EbC50 = 0.018 mg/L (*Skeletonema costatum*) M-factor = 10 EC50 = 3.0 mg/L (*Daphnia magna*)
Classification and labelling according to Regulation 1272/2008	
Hazard sysmbol	GHS09
Signal word	No signal word used
Hazard statement	H410

R and S phrases under Directive 2003/82/EC (Annex IV and V)
None
Other labels /conditions for use
Labelling

NW 262	The product is toxic for algae. Bixafen: *Pseudokirchnerilla subcapitata* EbC50 : 0.0657 mg/L Prothioconazole: *Skeletonema costatum* EbC50: 0.018 mg/L
NW 264	The product is toxic for fish and aquatic invertebrates. Bixafen: *Daphnia magna* NOEC: 0.05 mg/L Prothioconazole *Daphnia magna* NOEC: 0.56 mg/L
NW 265	The product is toxic for higher aquatic plants. Prothioconazole-Desthio: *Lemna gibba*, EC50 = 0.0394 mg/L Prothioconazole: *Lemna gibba*, Ec50= 0.074 mg/L

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.
NW 605-1	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
NW 606	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: 10 m
NW 706	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 **20 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.

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

The plant protection product Aviator Xpro has been developed as a foliar fungicide product for the control of diseases in cereals. It belongs to the carboxamides chemical class (complex II inhibitor) and the DMIs group of fungicides and has shown a broad spectrum of efficacy against the most economically important diseases of cereal crops caused by fungi from the classes of Basidiomycetes, Ascomycetes and Deuteromycetes.

Aviator Xpro has demonstrated crop tolerance to all cereal varieties tested. It has been shown to achieve effective and reliable control of the main cereals diseases at the dose rate of 1.25 L/ha in wheat, rye and triticale resp. 1.0 L/ha in barley. For the use of Aviator Xpro in cereals a maximum number of two applications per year and per crop in 150-400 litre water are recommended. Applied from BBCH 30 up to the early flowering stage (BBCH 61) on barley and up to the end of flowering (BBCH 69) on wheat, rye and triticale it provides a broad spectrum of disease control and increased grain yields.

Undesirable effects are not expected on succeeding crops, adjacent crops, part of plants used for propagating purposes and beneficial organisms. Studies demonstrated that adverse effects on processing procedures are unlikely. The mixture of prothioconazole and bixafen provides a proper resistance management.

The product is classified as slightly harmful for populations of relevant spider, spider mites, and relevant beneficial insects. Soil quality will not be affected by the use of the product as recommended.

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, residues) an authorisation can be granted.

Aviator Xpro has demonstrated excellent crop tolerance to all cereal varieties tested. It has been shown to achieve effective and reliable control of the main cereals diseases at the dose rate of 1.25 L/ha in wheat, rye and triticale resp. 1.0 L/ha in barley. From the efficacy point of view the product can be granted with all uses.

The product is classified as non-hazardous to bees, even when the maximum application rate as slightly harmful for populations of relevant spider, spider mites, and relevant beneficial insects. Soil quality will not be affected by the use of the product as recommended.

With respect to toxicology, residues and consumer protection an authorisation can be granted.

With respect to fate and ecotoxicology assessment, an authorisation can be granted under the conditions that further information are collected with the approval of the plant protection product. 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.

An authorisation can be granted.

3.3 Substances of concern for national monitoring

none

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

The authorisation is connected with the requirement to collect the following monitoring data until the 31. December 2020.

Annex III point	Data
9.5 (OECD)	The authorization of the product "Skyway Xpro" in Germany has to be linked with a monitoring study over several years to investigate the realistic worst case soil concentration which will be built up due to accumulation processes.
10.6.6 (OECD)	The authorization of the product "Skyway Xpro" in Germany has to be linked with a 2 years monitoring study on collembolans treated with the granted product for all indications.

Appendix 1 – Copy of the product authorisation see Appendix 4

Appendix 2 – Copy of the product label

- Evaluator to present a copy of the approved product label for <*MS country*>

Appendix 3 – Letter of Access

- Applicant could provide copies of the letters of access to the protected data / third party data that was needed for evaluation of the formulation

Appendix 4 – Copy of the product authorisation

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

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

Dr. Birgit Schreiber
Referentin

TELEFON +49 (0)531 299-3457
TELEFAX +49 (0)531 299-3002
E-MAIL birgit.schreiber@bvl.bund.de

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

IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.026764-00/00.66301
(bitte bei Antwort angeben)

DATUM 18. April 2016

ZV1 026764-00/00

Aviator Xpro

Zulassungsverfahren für Pflanzenschutzmittel

Bescheid

Das oben genannte Pflanzenschutzmittel

mit den Wirkstoffen:	150 g/l	Prothioconazol
	75 g/l	Bixafen
Zulassungsnummer:	026764-00	
Versuchsbezeichnungen:	BAY-18530-F-0-EC	
Antrag vom:	30. März 2012	

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
026764-00/00-007	Blatt- und Spelzen-bräune (Septoria nodorum)	Weizen	
026764-00/00-015	Blattfleckenkrankheit (Rhynchosporium secalis)	Roggen	
026764-00/00-016	Braunrost (Puccinia recondita)	Roggen	
026764-00/00-019	Braunrost (Puccinia recondita)	Triticale	
026764-00/00-004	Braunrost (Puccinia recondita)	Weizen	
026764-00/00-003	DTR-Blattdürre (Drechslera tritici-re-pentis)	Weizen	
026764-00/00-008	Echter Mehltau (Ery-siphe graminis)	Gerste	
026764-00/00-014	Echter Mehltau (Ery-siphe graminis)	Roggen	
026764-00/00-017	Echter Mehltau (Ery-siphe graminis)	Triticale	
026764-00/00-001	Echter Mehltau (Ery-siphe graminis)	Weizen	
026764-00/00-006	Gelbrost (Puccinia striiformis)	Weizen	
026764-00/00-005	Halmbruchkrankheit (Pseudocercospo-rella herpotrichoides)	Weizen	
026764-00/00-013	Minderung nichtpa-rasitärer Blattflecken	Gerste	
026764-00/00-010	Netzfleckenkrankheit (Pyrenophora teres)	Gerste	
026764-00/00-009	Rhynchosporium secalis	Gerste	
026764-00/00-018	Septoria-Arten (Sep-toria spp.)	Triticale	

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
026764-00/00-002	Septoria-Blattdürre (Septoria tritici)	Weizen	
026764-00/00-012	Sprenkelkrankheit (Ramularia collo-cy-gni)	Gerste	
026764-00/00-011	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 375 der Verordnung vom 31. August 2015 (BGBl. I S. 1474), 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 Prothioconazol und Bixafen 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	COEX	1		1,00	15,00	l
Kanister	HDPE, fluoriert	1		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.

(NN2002)
Das Mittel wird als schwach 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.

(SB110)
Die Richtlinie für die Anforderungen an die persönliche Schutzausrüstung im Pflanzenschutz "Persönliche Schutzausrüstung beim Umgang mit Pflanzenschutzmitteln" des Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit ist zu beachten.

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

(SF245-01)
Behandelte Flächen/Kulturen erst nach dem Abtrocknen des Spritzbelages wieder betreten.

(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:

(VH632)
Der Gehalt an Toluol im technischen Wirkstoff Bixafen darf 2 g/kg nicht überschreiten.

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
Begründung:
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. In der Monitoringstudie sind Bodenproben von ausgewählten Flächen, auf denen Bixafen häufig angewendet wurde und auch weiterhin angewendet werden soll, über mehrere Jahre hinweg hinsichtlich der Bixafen-Konzentration zu untersuchen. Zusätzlich sind auch die Konzentrationen von den anderen Wirkstoffen aus den Bixafen-enthaltenden Präparaten als Referenz für die mikrobielle Aktivität der Böden zu messen.
Bei der Standortwahl ist auf eine "realistic worst-case"-Situation hinsichtlich Bodenkonzentrationen zu achten. Dies beinhaltet Faktoren, welche die Initialkonzentration (Bodendichte) als auch die Abbaurate (Temperatur, Bodenfeuchte) und mögliches Leaching (organischer Kohlenstoffgehalt, Bodenart) beeinflussen. Mindestens ein Standort sollte hinsichtlich Bodentyp und Bodenart dem Standort, in welchem sich Bixafen in der Bodenakkumulationsstudie (Heinemann, 2011, Studiennummer: MEF-11/204) als persistent erwiesen hat, entsprechen.
Das Umweltbundesamt bittet zur Absprache der Studiendetails um Vorlage eines Entwurfs des Studienplans.

Antragspunkt:
KIIIA1 10.6.6 (Bixafen-haltige Produkte)
Termin:
31. Dezember 2020
Begründung:
Zulassungsbegleitende Durchführung einer zwei-jährigen Bodenmonitoringstudie mit Produkten, die den Wirkstoff Bixafen enthalten nach Absprache des Studiendesigns mit dem Umweltbundesamt.
Begründung:

Die Vorlage der o.g. Studie ist notwendig, da auf Basis der verfügbaren Unterlagen das Risiko für Bodenmakroorganismen nicht vollständig ausgeräumt ist. Nach Auswertung wurden bereits in der niedrigsten Testkonzentration signifikante Effekte auf die Population der Collembolen festgestellt. Darüber hinaus weist die vorliegende Studie Mängel im i) Design als auch in der ii) statistischen Auswertung auf. Eine ausführliche Auswertung der Studie ist dem Core Assessment des Draft Registration Reports, Sektion 6, Kapitel 6.7 zu entnehmen. Das Umweltbundesamt bittet zur Absprache der Studiendetails um Vorlage eines Entwurfs des Studienprotokolls. Die Vorlage der Prüfunterlagen ist zum Ausschluss der Gefährdungen durch das Mittel AVIATOR XPRO, die aufgrund der derzeitigen Datenlage nicht abschätzbar sind, und somit zur Sicherstellung des in § 1 Nr. 3 PflSchG genannten Schutzzweckes erforderlich.

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.

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:

(S1) Achtung

Gefahrenpiktogramme:

(GHS07) Ausrufezeichen

(GHS08) Gesundheitsgefahr

(GHS09) Umwelt

Gefahrenhinweise (H-Sätze):

(EUH 208-0164)

Enthält Prothioconazol-des-chloro. Kann allergische Reaktionen hervorrufen.

(EUH 401)

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

(H319)
Verursacht schwere Augenreizung.

(H361d)
Kann vermutlich das Kind im Mutterleib schädigen.

(H410)
Sehr giftig für Wasserorganismen mit langfristiger Wirkung.

Sicherheitshinweise (P-Sätze):
(P501)
Inhalt/Behälter ... zuführen.

Abgelehnte Anwendungsgebiete bzw. Anwendungen

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

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
Momentan gibt es aus dem Bereich der toxikologischen Bewertung seitens des BVL keinen Vorschlag für P-Sätze gemäß Verordnung (EG) Nr. 1272/2008 (CLP-Verordnung).

Gemäß Verordnung (EG) Nr. 1272/2008 ist das Gemisch mit folgendem Hinweis zu kennzeichnen:
"15 Prozent des Gemisches bestehen aus einem oder mehreren Bestandteilen von unbekannter (akuter oraler, dermaler oder inhalativer) Toxizität."

Zu KIIIA1 6.2.8:
Hinweis und Begründung für die Kennzeichnungsauflage zum Wirkungsmechanismus

(WMFG1: Prothioconazol und WMFC2: Bixafen):
Die FRAC-Klassifizierung ist als neutrale Information direkt jedem einzelnen Wirkstoff (hier: Prothioconazol und Bixafen) zuzuordnen. Die Kennzeichnung erleichtert der Praxis die Bestimmung des Wirkungsmechanismus von Fungiziden und ermöglicht so ein gezieltes Wirkstoffmanagement.

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: 026764-00/00-001

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:	
-	1,25 l/ha in 150 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 AVIATOR XPRO bzw. die darin enthaltenen Wirkstoffe Bixafen und Prothioconazol weisen ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Algen, Fische, aquatische Invertebraten und aquatische Pflanzen auf. Für die aktive Substanz Bixafen ist der sensitivste Endpunkt die NOEC = 0.0046 mg a.s./L (Pimephales promelas). Für die aktive Substanz Prothioconazol ist der sensitivste Endpunkt ein EbC50 = 0.018 mg a.s./L (Skeletonema costatum). Ein Risikoassessment auf Grundlage des Prothioconazol Endpunktes für Algen deckt nicht die potentiellen Risiken durch endokrine Effekte durch den Metaboliten JAU 6476-desthio ab, der strukturell große Ähnlichkeit mit der aktiven Substanz aufweist. Für den Metaboliten JAU 6476-desthio wurde deshalb ein ELS-Test vorgelegt, der eine NOEC von 0.00334 mg/L (Oncorhynchus mykiss) aufweist. Auf nationaler Ebene ist ein FFLC-Test für den Metaboliten bekannt, so dass potentielle endokrine Effekte ausreichend adressiert sind.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen der Wirkstoffe Bixafen und Prothioconazol des Mittels AVIATOR XPRO in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1a/Sektion 6, Kapitel 6.4).

(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 Anwendungsbestimmung NW605-1.

(NW706)
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 20 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 AVIATOR XPRO enthaltene Wirkstoff Prothioconazol mit seinem Metaboliten Prothioconazol-Desthio (JAU 3476-desthio) weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für O. mykiss von 3,34 µg a.i./L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 300 mg/L; DT50 Boden = 23,1 d; Koc = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01 und einen Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW706 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten Prothiconazol-Desthio (JAU 6476-desthio) in Oberflächengewässer zu gewährleisten. Weiter Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1b/ Sektion 6, Kapitel 7.5).

Anlage 1 zugelassene Anwendung: 026764-00/00-002

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:	
-	1,25 l/ha in 150 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 AVIATOR XPRO bzw. die darin enthaltenen Wirkstoffe Bixafen und Prothioconazol weisen ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Algen, Fische, aquatische Invertebraten und aquatische Pflanzen auf. Für die aktive Substanz Bixafen ist der sensitivste Endpunkt die NOEC = 0.0046 mg a.s./L (Pimephales promelas). Für die aktive Substanz Prothioconazol ist der sensitivste Endpunkt ein EbC50 = 0.018 mg a.s./L (Skeletonema costatum). Ein Risikoassessment auf Grundlage des Prothioconazol Endpunktes für Algen deckt nicht die potentiellen Risiken durch endokrine Effekte durch den Metaboliten JAU 6476-desthio ab, der strukturell große Ähnlichkeit mit der aktiven Substanz aufweist. Für den Metaboliten JAU 6476-desthio wurde deshalb ein ELS-Test vorgelegt, der eine NOEC von 0.00334 mg/L (Oncorhynchus mykiss) aufweist. Auf nationaler Ebene ist ein FFLC-Test für den Metaboliten bekannt, so dass potentielle endokrine Effekte ausreichend adressiert sind.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen der Wirkstoffe Bixafen und Prothioconazol des Mittels AVIATOR XPRO in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1a/Sektion 6, Kapitel 6.4).

(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 Anwendungsbestimmung NW605-1.

(NW706)
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 20 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 AVIATOR XPRO enthaltene Wirkstoff Prothioconazol mit seinem Metaboliten Prothioconazol-Desthio (JAU 3476-desthio) weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für O. mykiss von 3,34 µg a.i./L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 300 mg/L; DT50 Boden = 23,1 d; Koc = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01 und einen Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW706 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten Prothiconazol-Desthio (JAU 6476-desthio) in Oberflächengewässer zu gewährleisten. Weiter Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1b/ Sektion 6, Kapitel 7.5).

Anlage 1 zugelassene Anwendung: 026764-00/00-003

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:	
-	1,25 l/ha in 150 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 AVIATOR XPRO bzw. die darin enthaltenen Wirkstoffe Bixafen und Prothioconazol weisen ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Algen, Fische, aquatische Invertebraten und aquatische Pflanzen auf. Für die aktive Substanz Bixafen ist der sensitivste Endpunkt die NOEC = 0.0046 mg a.s./L (Pimephales promelas). Für die aktive Substanz Prothioconazol ist der sensitivste Endpunkt ein EbC50 = 0.018 mg a.s./L (Skeletonema costatum). Ein Risikoassessment auf Grundlage des Prothioconazol Endpunktes für Algen deckt nicht die potentiellen Risiken durch endokrine Effekte durch den Metaboliten JAU 6476-desthio ab, der strukturell große Ähnlichkeit mit der aktiven Substanz aufweist. Für den Metaboliten JAU 6476-desthio wurde deshalb ein ELS-Test vorgelegt, der eine NOEC von 0.00334 mg/L (Oncorhynchus mykiss) aufweist. Auf nationaler Ebene ist ein FFLC-Test für den Metaboliten bekannt, so dass potentielle endokrine Effekte ausreichend adressiert sind.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen der Wirkstoffe Bixafen und Prothioconazol des Mittels AVIATOR XPRO in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1a/Sektion 6, Kapitel 6.4).

(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 Anwendungsbestimmung NW605-1.

(NW706)
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 20 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 AVIATOR XPRO enthaltene Wirkstoff Prothioconazol mit seinem Metaboliten Prothioconazol-Desthio (JAU 3476-desthio) weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für O. mykiss von 3,34 µg a.i./L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 300 mg/L; DT50 Boden = 23,1 d; Koc = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01 und einen Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW706 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten Prothiconazol-Desthio (JAU 6476-desthio) in Oberflächengewässer zu gewährleisten. Weiter Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1b/ Sektion 6, Kapitel 7.5).

Anlage 1 zugelassene Anwendung: 026764-00/00-004

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 69
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:	
-	1,25 l/ha in 150 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 AVIATOR XPRO bzw. die darin enthaltenen Wirkstoffe Bixafen und Prothioconazol weisen ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Algen, Fische, aquatische Invertebraten und aquatische Pflanzen auf. Für die aktive Substanz Bixafen ist der sensitivste Endpunkt die NOEC = 0.0046 mg a.s./L (Pimephales promelas). Für die aktive Substanz Prothioconazol ist der sensitivste Endpunkt ein EbC50 = 0.018 mg a.s./L (Skeletonema costatum). Ein Risikoassessment auf Grundlage des Prothioconazol Endpunktes für Algen deckt nicht die potentiellen Risiken durch endokrine Effekte durch den Metaboliten JAU 6476-desthio ab, der strukturell große Ähnlichkeit mit der aktiven Substanz aufweist. Für den Metaboliten JAU 6476-desthio wurde deshalb ein ELS-Test vorgelegt, der eine NOEC von 0.00334 mg/L (Oncorhynchus mykiss) aufweist. Auf nationaler Ebene ist ein FFLC-Test für den Metaboliten bekannt, so dass potentielle endokrine Effekte ausreichend adressiert sind.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen der Wirkstoffe Bixafen und Prothioconazol des Mittels AVIATOR XPRO in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1a/Sektion 6, Kapitel 6.4).

(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 Anwendungsbestimmung NW605-1.

(NW706)
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 20 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 AVIATOR XPRO enthaltene Wirkstoff Prothioconazol mit seinem Metaboliten Prothioconazol-Desthio (JAU 3476-desthio) weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für O. mykiss von 3,34 µg a.i./L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 300 mg/L; DT50 Boden = 23,1 d; Koc = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01 und einen Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW706 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten Prothiconazol-Desthio (JAU 6476-desthio) in Oberflächengewässer zu gewährleisten. Weiter Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1b/ Sektion 6, Kapitel 7.5).

Anlage 1 zugelassene Anwendung: 026764-00/00-005

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 37
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:	
-	1,25 l/ha in 150 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 AVIATOR XPRO bzw. die darin enthaltenen Wirkstoffe Bixafen und Prothioconazol weisen ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Algen, Fische, aquatische Invertebraten und aquatische Pflanzen auf. Für die aktive Substanz Bixafen ist der sensitivste Endpunkt die NOEC = 0.0046 mg a.s./L (Pimephales promelas). Für die aktive Substanz Prothioconazol ist der sensitivste Endpunkt ein EbC50 = 0.018 mg a.s./L (Skeletonema costatum). Ein Risikoassessment auf Grundlage des Prothioconazol Endpunktes für Algen deckt nicht die potentiellen Risiken durch endokrine Effekte durch den Metaboliten JAU 6476-desthio ab, der strukturell große Ähnlichkeit mit der aktiven Substanz aufweist. Für den Metaboliten JAU 6476-desthio wurde deshalb ein ELS-Test vorgelegt, der eine NOEC von 0.00334 mg/L (Oncorhynchus mykiss) aufweist. Auf nationaler Ebene ist ein FFLC-Test für den Metaboliten bekannt, so dass potentielle endokrine Effekte ausreichend adressiert sind.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen der Wirkstoffe Bixafen und Prothioconazol des Mittels AVIATOR XPRO in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1a/Sektion 6, Kapitel 6.4).

(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 Anwendungsbestimmung NW605-1.

(NW706)
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 20 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 AVIATOR XPRO enthaltene Wirkstoff Prothioconazol mit seinem Metaboliten Prothioconazol-Desthio (JAU 3476-desthio) weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für O. mykiss von 3,34 µg a.i./L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 300 mg/L; DT50 Boden = 23,1 d; Koc = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01 und einen Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW706 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten Prothiconazol-Desthio (JAU 6476-desthio) in Oberflächengewässer zu gewährleisten. Weiter Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1b/ Sektion 6, Kapitel 7.5).

Anlage 1 zugelassene Anwendung: 026764-00/00-006

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:	
-	1,25 l/ha in 150 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 AVIATOR XPRO bzw. die darin enthaltenen Wirkstoffe Bixafen und Prothioconazol weisen ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Algen, Fische, aquatische Invertebraten und aquatische Pflanzen auf. Für die aktive Substanz Bixafen ist der sensitivste Endpunkt die NOEC = 0.0046 mg a.s./L (Pimephales promelas). Für die aktive Substanz Prothioconazol ist der sensitivste Endpunkt ein EbC50 = 0.018 mg a.s./L (Skeletonema costatum). Ein Risikoassessment auf Grundlage des Prothioconazol Endpunktes für Algen deckt nicht die potentiellen Risiken durch endokrine Effekte durch den Metaboliten JAU 6476-desthio ab, der strukturell große Ähnlichkeit mit der aktiven Substanz aufweist. Für den Metaboliten JAU 6476-desthio wurde deshalb ein ELS-Test vorgelegt, der eine NOEC von 0.00334 mg/L (Oncorhynchus mykiss) aufweist. Auf nationaler Ebene ist ein FFLC-Test für den Metaboliten bekannt, so dass potentielle endokrine Effekte ausreichend adressiert sind.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen der Wirkstoffe Bixafen und Prothioconazol des Mittels AVIATOR XPRO in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1a/Sektion 6, Kapitel 6.4).

(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 Anwendungsbestimmung NW605-1.

(NW706)
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 20 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 AVIATOR XPRO enthaltene Wirkstoff Prothioconazol mit seinem Metaboliten Prothioconazol-Desthio (JAU 3476-desthio) weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für O. mykiss von 3,34 µg a.i./L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 300 mg/L; DT50 Boden = 23,1 d; Koc = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01 und einen Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW706 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten Prothiconazol-Desthio (JAU 6476-desthio) in Oberflächengewässer zu gewährleisten. Weiter Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1b/ Sektion 6, Kapitel 7.5).

Anlage 1 zugelassene Anwendung: 026764-00/00-007

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:	
-	1,25 l/ha in 150 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 AVIATOR XPRO bzw. die darin enthaltenen Wirkstoffe Bixafen und Prothioconazol weisen ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Algen, Fische, aquatische Invertebraten und aquatische Pflanzen auf. Für die aktive Substanz Bixafen ist der sensitivste Endpunkt die NOEC = 0.0046 mg a.s./L (Pimephales promelas). Für die aktive Substanz Prothioconazol ist der sensitivste Endpunkt ein EbC50 = 0.018 mg a.s./L (Skeletonema costatum). Ein Risikoassessment auf Grundlage des Prothioconazol Endpunktes für Algen deckt nicht die potentiellen Risiken durch endokrine Effekte durch den Metaboliten JAU 6476-desthio ab, der strukturell große Ähnlichkeit mit der aktiven Substanz aufweist. Für den Metaboliten JAU 6476-desthio wurde deshalb ein ELS-Test vorgelegt, der eine NOEC von 0.00334 mg/L (Oncorhynchus mykiss) aufweist. Auf nationaler Ebene ist ein FFLC-Test für den Metaboliten bekannt, so dass potentielle endokrine Effekte ausreichend adressiert sind.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen der Wirkstoffe Bixafen und Prothioconazol des Mittels AVIATOR XPRO in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1a/Sektion 6, Kapitel 6.4).

(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 Anwendungsbestimmung NW605-1.

(NW706)
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 20 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 AVIATOR XPRO enthaltene Wirkstoff Prothioconazol mit seinem Metaboliten Prothioconazol-Desthio (JAU 3476-desthio) weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für O. mykiss von 3,34 µg a.i./L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 300 mg/L; DT50 Boden = 23,1 d; Koc = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01 und einen Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW706 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten Prothiconazol-Desthio (JAU 6476-desthio) in Oberflächengewässer zu gewährleisten. Weiter Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1b/ Sektion 6, Kapitel 7.5).

Anlage 1 zugelassene Anwendung: 026764-00/00-008

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:	2
- für die Kultur bzw. je Jahr:	2
- Abstand:	14 bis 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	1 l/ha in 150 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 AVIATOR XPRO bzw. die darin enthaltenen Wirkstoffe Bixafen und Prothioconazol weisen ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Algen, Fische, aquatische Invertebraten und aquatische Pflanzen auf. Für die aktive Substanz Bixafen ist der sensitivste Endpunkt die NOEC = 0.0046 mg a.s./L (Pimephales promelas). Für die aktive Substanz Prothioconazol ist der sensitivste Endpunkt ein EbC50 = 0.018 mg a.s./L (Skeletonema costatum). Ein Risikoassessment auf Grundlage des Prothioconazol Endpunktes für Algen deckt nicht die potentiellen Risiken durch endokrine Effekte durch den Metaboliten JAU 6476-desthio ab, der strukturell große Ähnlichkeit mit der aktiven Substanz aufweist. Für den Metaboliten JAU 6476-desthio wurde deshalb ein ELS-Test vorgelegt, der eine NOEC von 0.00334 mg/L (Oncorhynchus mykiss) aufweist. Auf nationaler Ebene ist ein FFLC-Test für den Metaboliten bekannt, so dass potentielle endokrine Effekte ausreichend adressiert sind.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen der Wirkstoffe Bixafen und Prothioconazol des Mittels AVIATOR XPRO in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1a/Sektion 6, Kapitel 6.4).

(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 Anwendungsbestimmung NW605-1.

(NW706)
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 20 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 AVIATOR XPRO enthaltene Wirkstoff Prothioconazol mit seinem Metaboliten Prothioconazol-Desthio (JAU 3476-desthio) weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für O. mykiss von 3,34 µg a.i./L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 300 mg/L; DT50 Boden = 23,1 d; Koc = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01 und einen Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW706 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten Prothiconazol-Desthio (JAU 6476-desthio) in Oberflächengewässer zu gewährleisten. Weiter Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1b/ Sektion 6, Kapitel 7.5).

Anlage 1 zugelassene Anwendung: 026764-00/00-009

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: 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:	2
- für die Kultur bzw. je Jahr:	2
- Abstand:	14 bis 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	1 l/ha in 150 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 AVIATOR XPRO bzw. die darin enthaltenen Wirkstoffe Bixafen und Prothioconazol weisen ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Algen, Fische, aquatische Invertebraten und aquatische Pflanzen auf. Für die aktive Substanz Bixafen ist der sensitivste Endpunkt die NOEC = 0.0046 mg a.s./L (Pimephales promelas). Für die aktive Substanz Prothioconazol ist der sensitivste Endpunkt ein EbC50 = 0.018 mg a.s./L (Skeletonema costatum). Ein Risikoassessment auf Grundlage des Prothioconazol Endpunktes für Algen deckt nicht die potentiellen Risiken durch endokrine Effekte durch den Metaboliten JAU 6476-desthio ab, der strukturell große Ähnlichkeit mit der aktiven Substanz aufweist. Für den Metaboliten JAU 6476-desthio wurde deshalb ein ELS-Test vorgelegt, der eine NOEC von 0.00334 mg/L (Oncorhynchus mykiss) aufweist. Auf nationaler Ebene ist ein FFLC-Test für den Metaboliten bekannt, so dass potentielle endokrine Effekte ausreichend adressiert sind.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen der Wirkstoffe Bixafen und Prothioconazol des Mittels AVIATOR XPRO in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1a/Sektion 6, Kapitel 6.4).

(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 Anwendungsbestimmung NW605-1.

(NW706)
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 20 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 AVIATOR XPRO enthaltene Wirkstoff Prothioconazol mit seinem Metaboliten Prothioconazol-Desthio (JAU 3476-desthio) weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für O. mykiss von 3,34 µg a.i./L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 300 mg/L; DT50 Boden = 23,1 d; Koc = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01 und einen Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW706 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten Prothiconazol-Desthio (JAU 6476-desthio) in Oberflächengewässer zu gewährleisten. Weiter Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1b/ Sektion 6, Kapitel 7.5).

Anlage 1 zugelassene Anwendung: 026764-00/00-010

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:	2
- für die Kultur bzw. je Jahr:	2
- Abstand:	14 bis 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	1 l/ha in 150 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 "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 AVIATOR XPRO bzw. die darin enthaltenen Wirkstoffe Bixafen und Prothioconazol weisen ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Algen, Fische, aquatische Invertebraten und aquatische Pflanzen auf. Für die aktive Substanz Bixafen ist der sensitivste Endpunkt die NOEC = 0.0046 mg a.s./L (Pimephales promelas). Für die aktive Substanz Prothioconazol ist der sensitivste Endpunkt ein EbC50 = 0.018 mg a.s./L (Skeletonema costatum). Ein Risikoassessment auf Grundlage des Prothioconazol Endpunktes für Algen deckt nicht die potentiellen Risiken durch endokrine Effekte durch den Metaboliten JAU 6476-desthio ab, der strukturell große Ähnlichkeit mit der aktiven Substanz aufweist. Für den Metaboliten JAU 6476-desthio wurde deshalb ein ELS-Test vorgelegt, der eine NOEC von 0.00334 mg/L (Oncorhynchus mykiss) aufweist. Auf nationaler Ebene ist ein FFLC-Test für den Metaboliten bekannt, so dass potentielle endokrine Effekte ausreichend adressiert sind.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen der Wirkstoffe Bixafen und Prothioconazol des Mittels AVIATOR XPRO in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1a/Sektion 6, Kapitel 6.4).

(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 Anwendungsbestimmung NW605-1.

(NW706)
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 20 m haben. Dieser Randstrei-

fen 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 AVIATOR XPRO enthaltene Wirkstoff Prothioconazol mit seinem Metaboliten Prothioconazol-Desthio (JAU 3476-desthio) weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für O. mykiss von 3,34 µg a.i./L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 300 mg/L; DT50 Boden = 23,1 d; Koc = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01 und einen Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW706 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten Prothiconazol-Desthio (JAU 6476-desthio) in Oberflächengewässer zu gewährleisten. Weiter Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1b/ Sektion 6, Kapitel 7.5).

Anlage 1 zugelassene Anwendung: 026764-00/00-011

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:	2
- für die Kultur bzw. je Jahr:	2
- Abstand:	14 bis 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	1 l/ha in 150 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 AVIATOR XPRO bzw. die darin enthaltenen Wirkstoffe Bixafen und Prothioconazol weisen ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Algen, Fische, aquatische Invertebraten und aquatische Pflanzen auf. Für die aktive Substanz Bixafen ist der sensitivste Endpunkt die NOEC = 0.0046 mg a.s./L (Pimephales promelas). Für die aktive Substanz Prothioconazol ist der sensitivste Endpunkt ein EbC50 = 0.018 mg a.s./L (Skeletonema costatum). Ein Risikoassessment auf Grundlage des Prothioconazol Endpunktes für Algen deckt nicht die potentiellen Risiken durch endokrine Effekte durch den Metaboliten JAU 6476-desthio ab, der strukturell große Ähnlichkeit mit der aktiven Substanz aufweist. Für den Metaboliten JAU 6476-desthio wurde deshalb ein ELS-Test vorgelegt, der eine NOEC von 0.00334 mg/L (Oncorhynchus mykiss) aufweist. Auf nationaler Ebene ist ein FFLC-Test für den Metaboliten bekannt, so dass potentielle endokrine Effekte ausreichend adressiert sind.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen der Wirkstoffe Bixafen und Prothioconazol des Mittels AVIATOR XPRO in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1a/Sektion 6, Kapitel 6.4).

(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 Anwendungsbestimmung NW605-1.

(NW706)
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 20 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 AVIATOR XPRO enthaltene Wirkstoff Prothioconazol mit seinem Metaboliten Prothioconazol-Desthio (JAU 3476-desthio) weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für O. mykiss von 3,34 µg a.i./L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 300 mg/L; DT50 Boden = 23,1 d; Koc = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01 und einen Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW706 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten Prothiconazol-Desthio (JAU 6476-desthio) in Oberflächengewässer zu gewährleisten. Weiter Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1b/ Sektion 6, Kapitel 7.5).

Anlage 1 zugelassene Anwendung: 026764-00/00-012

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:	2
- für die Kultur bzw. je Jahr:	2
- Abstand:	14 bis 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	1 l/ha in 150 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 AVIATOR XPRO bzw. die darin enthaltenen Wirkstoffe Bixafen und Prothioconazol weisen ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Algen, Fische, aquatische Invertebraten und aquatische Pflanzen auf. Für die aktive Substanz Bixafen ist der sensitivste Endpunkt die NOEC = 0.0046 mg a.s./L (Pimephales promelas). Für die aktive Substanz Prothioconazol ist der sensitivste Endpunkt ein EbC50 = 0.018 mg a.s./L (Skeletonema costatum). Ein Risikoassessment auf Grundlage des Prothioconazol Endpunktes für Algen deckt nicht die potentiellen Risiken durch endokrine Effekte durch den Metaboliten JAU 6476-desthio ab, der strukturell große Ähnlichkeit mit der aktiven Substanz aufweist. Für den Metaboliten JAU 6476-desthio wurde deshalb ein ELS-Test vorgelegt, der eine NOEC von 0.00334 mg/L (Oncorhynchus mykiss) aufweist. Auf nationaler Ebene ist ein FFLC-Test für den Metaboliten bekannt, so dass potentielle endokrine Effekte ausreichend adressiert sind.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen der Wirkstoffe Bixafen und Prothioconazol des Mittels AVIATOR XPRO in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1a/Sektion 6, Kapitel 6.4).

(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 Anwendungsbestimmung NW605-1.

(NW706)
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 20 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 AVIATOR XPRO enthaltene Wirkstoff Prothioconazol mit seinem Metaboliten Prothioconazol-Desthio (JAU 3476-desthio) weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für O. mykiss von 3,34 µg a.i./L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 300 mg/L; DT50 Boden = 23,1 d; Koc = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01 und einen Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW706 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten Prothiconazol-Desthio (JAU 6476-desthio) in Oberflächengewässer zu gewährleisten. Weiter Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1b/ Sektion 6, Kapitel 7.5).

Anlage 1 zugelassene Anwendung: 026764-00/00-013

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:	2
- für die Kultur bzw. je Jahr:	2
- Abstand:	14 bis 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	1 l/ha in 150 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 AVIATOR XPRO bzw. die darin enthaltenen Wirkstoffe Bixafen und Prothioconazol weisen ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Algen, Fische, aquatische Invertebraten und aquatische Pflanzen auf. Für die aktive Substanz Bixafen ist der sensitivste Endpunkt die NOEC = 0.0046 mg a.s./L (Pimephales promelas). Für die aktive Substanz Prothioconazol ist der sensitivste Endpunkt ein EbC50 = 0.018 mg a.s./L (Skeletonema costatum). Ein Risikoassessment auf Grundlage des Prothioconazol Endpunktes für Algen deckt nicht die potentiellen Risiken durch endokrine Effekte durch den Metaboliten JAU 6476-desthio ab, der strukturell große Ähnlichkeit mit der aktiven Substanz aufweist. Für den Metaboliten JAU 6476-desthio wurde deshalb ein ELS-Test vorgelegt, der eine NOEC von 0.00334 mg/L (Oncorhynchus mykiss) aufweist. Auf nationaler Ebene ist ein FFLC-Test für den Metaboliten bekannt, so dass potentielle endokrine Effekte ausreichend adressiert sind.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen der Wirkstoffe Bixafen und Prothioconazol des Mittels AVIATOR XPRO in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1a/Sektion 6, Kapitel 6.4).

(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 Anwendungsbestimmung NW605-1.

(NW706)
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 20 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 AVIATOR XPRO enthaltene Wirkstoff Prothioconazol mit seinem Metaboliten Prothioconazol-Desthio (JAU 3476-desthio) weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für O. mykiss von 3,34 µg a.i./L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 300 mg/L; DT50 Boden = 23,1 d; Koc = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01 und einen Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW706 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten Prothiconazol-Desthio (JAU 6476-desthio) in Oberflächengewässer zu gewährleisten. Weiter Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1b/ Sektion 6, Kapitel 7.5).

Anlage 1 zugelassene Anwendung: 026764-00/00-014

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Echter Mehltau (Erysiphe graminis)

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:	
-	1,25 l/ha in 150 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 AVIATOR XPRO bzw. die darin enthaltenen Wirkstoffe Bixafen und Prothioconazol weisen ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Algen, Fische, aquatische Invertebraten und aquatische Pflanzen auf. Für die aktive Substanz Bixafen ist der sensitivste Endpunkt die NOEC = 0.0046 mg a.s./L (Pimephales promelas). Für die aktive Substanz Prothioconazol ist der sensitivste Endpunkt ein EbC50 = 0.018 mg a.s./L (Skeletonema costatum). Ein Risikoassessment auf Grundlage des Prothioconazol Endpunktes für Algen deckt nicht die potentiellen Risiken durch endokrine Effekte durch den Metaboliten JAU 6476-desthio ab, der strukturell große Ähnlichkeit mit der aktiven Substanz aufweist. Für den Metaboliten JAU 6476-desthio wurde deshalb ein ELS-Test vorgelegt, der eine NOEC von 0.00334 mg/L (Oncorhynchus mykiss) aufweist. Auf nationaler Ebene ist ein FFLC-Test für den Metaboliten bekannt, so dass potentielle endokrine Effekte ausreichend adressiert sind.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen der Wirkstoffe Bixafen und Prothioconazol des Mittels AVIATOR XPRO in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1a/Sektion 6, Kapitel 6.4).

(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 Anwendungsbestimmung NW605-1.

(NW706)
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 20 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 AVIATOR XPRO enthaltene Wirkstoff Prothioconazol mit seinem Metaboliten Prothioconazol-Desthio (JAU 3476-desthio) weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für O. mykiss von 3,34 µg a.i./L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 300 mg/L; DT50 Boden = 23,1 d; Koc = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01 und einen Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW706 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten Prothiconazol-Desthio (JAU 6476-desthio) in Oberflächengewässer zu gewährleisten. Weiter Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1b/ Sektion 6, Kapitel 7.5).

Anlage 1 zugelassene Anwendung: 026764-00/00-015

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:	
-	1,25 l/ha in 150 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 AVIATOR XPRO bzw. die darin enthaltenen Wirkstoffe Bixafen und Prothioconazol weisen ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Algen, Fische, aquatische Invertebraten und aquatische Pflanzen auf. Für die aktive Substanz Bixafen ist der sensitivste Endpunkt die NOEC = 0.0046 mg a.s./L (Pimephales promelas). Für die aktive Substanz Prothioconazol ist der sensitivste Endpunkt ein EbC50 = 0.018 mg a.s./L (Skeletonema costatum). Ein Risikoassessment auf Grundlage des Prothioconazol Endpunktes für Algen deckt nicht die potentiellen Risiken durch endokrine Effekte durch den Metaboliten JAU 6476-desthio ab, der strukturell große Ähnlichkeit mit der aktiven Substanz aufweist. Für den Metaboliten JAU 6476-desthio wurde deshalb ein ELS-Test vorgelegt, der eine NOEC von 0.00334 mg/L (Oncorhynchus mykiss) aufweist. Auf nationaler Ebene ist ein FFLC-Test für den Metaboliten bekannt, so dass potentielle endokrine Effekte ausreichend adressiert sind.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen der Wirkstoffe Bixafen und Prothioconazol des Mittels AVIATOR XPRO in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1a/Sektion 6, Kapitel 6.4).

(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 Anwendungsbestimmung NW605-1.

(NW706)
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 20 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 AVIATOR XPRO enthaltene Wirkstoff Prothioconazol mit seinem Metaboliten Prothioconazol-Desthio (JAU 3476-desthio) weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für O. mykiss von 3,34 µg a.i./L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 300 mg/L; DT50 Boden = 23,1 d; Koc = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01 und einen Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW706 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten Prothiconazol-Desthio (JAU 6476-desthio) in Oberflächengewässer zu gewährleisten. Weiter Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1b/ Sektion 6, Kapitel 7.5).

Anlage 1 zugelassene Anwendung: 026764-00/00-016

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 69
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:	
-	1,25 l/ha in 150 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 AVIATOR XPRO bzw. die darin enthaltenen Wirkstoffe Bixafen und Prothioconazol weisen ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Algen, Fische, aquatische Invertebraten und aquatische Pflanzen auf. Für die aktive Substanz Bixafen ist der sensitivste Endpunkt die NOEC = 0.0046 mg a.s./L (Pimephales promelas). Für die aktive Substanz Prothioconazol ist der sensitivste Endpunkt ein EbC50 = 0.018 mg a.s./L (Skeletonema costatum). Ein Risikoassessment auf Grundlage des Prothioconazol Endpunktes für Algen deckt nicht die potentiellen Risiken durch endokrine Effekte durch den Metaboliten JAU 6476-desthio ab, der strukturell große Ähnlichkeit mit der aktiven Substanz aufweist. Für den Metaboliten JAU 6476-desthio wurde deshalb ein ELS-Test vorgelegt, der eine NOEC von 0.00334 mg/L (Oncorhynchus mykiss) aufweist. Auf nationaler Ebene ist ein FFLC-Test für den Metaboliten bekannt, so dass potentielle endokrine Effekte ausreichend adressiert sind.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen der Wirkstoffe Bixafen und Prothioconazol des Mittels AVIATOR XPRO in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1a/Sektion 6, Kapitel 6.4).

(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 Anwendungsbestimmung NW605-1.

(NW706)
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 20 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 AVIATOR XPRO enthaltene Wirkstoff Prothioconazol mit seinem Metaboliten Prothioconazol-Desthio (JAU 3476-desthio) weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für O. mykiss von 3,34 µg a.i./L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 300 mg/L; DT50 Boden = 23,1 d; Koc = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01 und einen Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW706 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten Prothiconazol-Desthio (JAU 6476-desthio) in Oberflächengewässer zu gewährleisten. Weiter Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1b/ Sektion 6, Kapitel 7.5).

Anlage 1 zugelassene Anwendung: 026764-00/00-017

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:	
-	1,25 l/ha in 150 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 AVIATOR XPRO bzw. die darin enthaltenen Wirkstoffe Bixafen und Prothioconazol weisen ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Algen, Fische, aquatische Invertebraten und aquatische Pflanzen auf. Für die aktive Substanz Bixafen ist der sensitivste Endpunkt die NOEC = 0.0046 mg a.s./L (Pimephales promelas). Für die aktive Substanz Prothioconazol ist der sensitivste Endpunkt ein EbC50 = 0.018 mg a.s./L (Skeletonema costatum). Ein Risikoassessment auf Grundlage des Prothioconazol Endpunktes für Algen deckt nicht die potentiellen Risiken durch endokrine Effekte durch den Metaboliten JAU 6476-desthio ab, der strukturell große Ähnlichkeit mit der aktiven Substanz aufweist. Für den Metaboliten JAU 6476-desthio wurde deshalb ein ELS-Test vorgelegt, der eine NOEC von 0.00334 mg/L (Oncorhynchus mykiss) aufweist. Auf nationaler Ebene ist ein FFLC-Test für den Metaboliten bekannt, so dass potentielle endokrine Effekte ausreichend adressiert sind.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen der Wirkstoffe Bixafen und Prothioconazol des Mittels AVIATOR XPRO in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1a/Sektion 6, Kapitel 6.4).

(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 Anwendungsbestimmung NW605-1.

(NW706)
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 20 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 AVIATOR XPRO enthaltene Wirkstoff Prothioconazol mit seinem Metaboliten Prothioconazol-Desthio (JAU 3476-desthio) weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für O. mykiss von 3,34 µg a.i./L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 300 mg/L; DT50 Boden = 23,1 d; Koc = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01 und einen Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW706 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten Prothiconazol-Desthio (JAU 6476-desthio) in Oberflächengewässer zu gewährleisten. Weiter Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1b/ Sektion 6, Kapitel 7.5).

Anlage 1 zugelassene Anwendung: 026764-00/00-018

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:	
-	1,25 l/ha in 150 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 AVIATOR XPRO bzw. die darin enthaltenen Wirkstoffe Bixafen und Prothioconazol weisen ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Algen, Fische, aquatische Invertebraten und aquatische Pflanzen auf. Für die aktive Substanz Bixafen ist der sensitivste Endpunkt die NOEC = 0.0046 mg a.s./L (Pimephales promelas). Für die aktive Substanz Prothioconazol ist der sensitivste Endpunkt ein EbC50 = 0.018 mg a.s./L (Skeletonema costatum). Ein Risikoassessment auf Grundlage des Prothioconazol Endpunktes für Algen deckt nicht die potentiellen Risiken durch endokrine Effekte durch den Metaboliten JAU 6476-desthio ab, der strukturell große Ähnlichkeit mit der aktiven Substanz aufweist. Für den Metaboliten JAU 6476-desthio wurde deshalb ein ELS-Test vorgelegt, der eine NOEC von 0.00334 mg/L (Oncorhynchus mykiss) aufweist. Auf nationaler Ebene ist ein FFLC-Test für den Metaboliten bekannt, so dass potentielle endokrine Effekte ausreichend adressiert sind.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen der Wirkstoffe Bixafen und Prothioconazol des Mittels AVIATOR XPRO in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1a/Sektion 6, Kapitel 6.4).

(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 Anwendungsbestimmung NW605-1.

(NW706)
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 20 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 AVIATOR XPRO enthaltene Wirkstoff Prothioconazol mit seinem Metaboliten Prothioconazol-Desthio (JAU 3476-desthio) weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für O. mykiss von 3,34 µg a.i./L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 300 mg/L; DT50 Boden = 23,1 d; Koc = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01 und einen Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW706 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten Prothiconazol-Desthio (JAU 6476-desthio) in Oberflächengewässer zu gewährleisten. Weiter Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1b/ Sektion 6, Kapitel 7.5).

Anlage 1 zugelassene Anwendung: 026764-00/00-019

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Braunrost (Puccinia recondita)

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 69
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:	
-	1,25 l/ha in 150 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 AVIATOR XPRO bzw. die darin enthaltenen Wirkstoffe Bixafen und Prothioconazol weisen ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Algen, Fische, aquatische Invertebraten und aquatische Pflanzen auf. Für die aktive Substanz Bixafen ist der sensitivste Endpunkt die NOEC = 0.0046 mg a.s./L (Pimephales promelas). Für die aktive Substanz Prothioconazol ist der sensitivste Endpunkt ein EbC50 = 0.018 mg a.s./L (Skeletonema costatum). Ein Risikoassessment auf Grundlage des Prothioconazol Endpunktes für Algen deckt nicht die potentiellen Risiken durch endokrine Effekte durch den Metaboliten JAU 6476-desthio ab, der strukturell große Ähnlichkeit mit der aktiven Substanz aufweist. Für den Metaboliten JAU 6476-desthio wurde deshalb ein ELS-Test vorgelegt, der eine NOEC von 0.00334 mg/L (Oncorhynchus mykiss) aufweist. Auf nationaler Ebene ist ein FFLC-Test für den Metaboliten bekannt, so dass potentielle endokrine Effekte ausreichend adressiert sind.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen der Wirkstoffe Bixafen und Prothioconazol des Mittels AVIATOR XPRO in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1a/Sektion 6, Kapitel 6.4).

(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 Anwendungsbestimmung NW605-1.

(NW706)
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 20 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 AVIATOR XPRO enthaltene Wirkstoff Prothioconazol mit seinem Metaboliten Prothioconazol-Desthio (JAU 3476-desthio) weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für O. mykiss von 3,34 µg a.i./L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 300 mg/L; DT50 Boden = 23,1 d; Koc = 575), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01 und einen Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW706 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Metaboliten Prothiconazol-Desthio (JAU 6476-desthio) in Oberflächengewässer zu gewährleisten. Weiter Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Kapitel IV, 4.1b/ Sektion 6, Kapitel 7.5).

REGISTRATION REPORT
Part B

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

Detailed summary of the risk assessment

Product code:	**BIX+PTZ EC 225** **Aviator Xpro EC 225**	
Active Substances:	**Bixafen**	**75 g/L**
	Prothioconazole	**150 g/L**

Central Zone
Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: **Bayer CropScience**

Date: **19-04-2016**

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 plant protection product BIX + PTZ EC 225 specification number 102000013869 version 03, which contains the active substances bixafen (75 g/L) and prothioconazole (150g/L).

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

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)	**Prothioconazole** (Reg. (EU) No 540/2011)
Purity of active substance	min 950 g/kg	min 970 g/kg
Relevant impurities	–	Toluene: < 5 g/kg Prothioconazole-desthio (2-(1-chlorocyclopropyl)1-(2-chlorophenyl)-3-(1,2,4-triazol-1-yl)-propan-2-ol): < 0.5 g/kg

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 + PTZ EC 225 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

Name:	Bayer CropScience Deutschland GmbH
Address:	Elisabeth-Selbert-Straße 4a 40764 Langenfeld Germany
Contact:	Stefanie Kretschmer
Telephone number:	+ 49 2173 2076 245
Fax:	+ 49 2173 2976 459
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

Name	Bayer CropScience AG
Address:	Alfred-Nobel-Strasse 50 D-40789 Monheim am Rhein Germany

Location of the manufacturing site

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	Minimum purity:	950 g/kg
Prothioconazole	Minimum purity:	970 g/kg

Detailed information on impurities

There has been no change in the composition of the active substance(s) since their approval. Therefore please refer to the respective Annex II dossiers.

.

CONFIDENTIAL information - data provided separately (Part C).

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

Trade name:	Aviator Xpro
Company code number:	BYF 00587 + Prothioconazole EC 075+150

Bixafen + Prothioconazole 225 EC (75+150 g/L)
Bixafen + Prothioconazole EC 225 (75+150 g/L)
BIX+PTZ EC 225
BIX+PTZ EC 75+150 G (internal name)
102000013869 (specification no.)
06000044 (material no.)
0090489-001 (internal code)

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	75 g/L
content of pure prothioconazole	150 g/L
limits bixafen:	67.5 – 82.5 g/L
limits prothioconazole	141 – 159 g/L

Technical active substance:

content of technical bixafen: at minimum purity (97.5 %):	78.9 g/L	(7.8 % w/w)
content of technical epoxiconazole at minimum purity (92.0 %):	154.6 g/L	(15.3 % 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	Prothioconazole
1.4.3.2	CAS No.	581809-46-3	178928-70-6
1.4.3.2	EINECS No.	–	–
1.4.3.2	CIPAC No.	819	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 does not contain any impurities of toxicological or ecotoxicological concern.

Prothioconazol contains < 5 g/kg toluene and < 0.5 g/kg prothioconazole-desthio. The origin of this impurity has been discussed in the document JM II for Annex I inclusion .

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

The formulation was not the representative formulation for the inclusion of prothioconazole into Annex I of Directive 91/414/EEC nor the representative formulation in the ongoing Annex 1 review of bixafen. The specification and purity are given under point 1.4.

The following batches have been used in the physico-chemical studies:

1. Spec. 102000013869, batch 2006-001178; 75.3 g/L bixafen; 149 g/L prothioconazole.
2. Spec. 102000013869, batch 2007-002622; 76.5 g/L Bixafen, 147 g/L Prothioconazole.

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 2006-001178	clear brown liquid with an amine like odour.	N	Gueldner, W., Hoppe, M., 2007 M-280652-01-1.	acceptable
Explosive properties (IIIA 2.2.1)	EEC A 14	Batch 2006-001178	The exothermic decomposition energy is 292 J/g, which is lower than 500 J/g (UN recommendation); Formulation is not explosive	Y	Rexer, K.; Bittner, B., 2006 FOR0883(PC)01 (M-277997-01-1)	acceptable
Oxidizing properties (IIIA 2.2.2)	EEC A 21	Batch 2006-001178	The mean time for the pressure rise from 690 kPa to 2070 kPa measured for sample: min 20 s reference mixture: max 6.8 s. The substance is not considered an	Y	Rexer, K.; Bittner, B., 2006 FOR0883(PC)01 (M-277997-01-1)	acceptable

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			oxidizing substance.			
Flash point (IIIA 2.3.1)	EEC A 9	Batch 2006-001178	No flash point up to 100 °C.	Y	Rexer, K.; Bittner, B., 2006 FOR0883(PC)01 (M-277997-01-1)	acceptable
Flammability (IIIA 2.3.2)	-	-	not required for liquid formulations	-	-	acceptable
Auto-flammability (IIIA 2.3.3)	EEC A 15, DIN 51794	Batch 2006-001178	375 °C	Y	Rexer, K.; Bittner, B., 2006 FOR0883(PC)01 (M-277997-01-1)	acceptable.
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 75.3	Batch 2006-001178	4.8 (1 % in de-ionized water at room temperature)	Y	Gueldner, W., Hoppe, M., 2006 1410505427. (M-280652-01-1)	acceptable.
Kinematic viscosity (IIIA 2.5.1)	CIPAC MT 192 = OECD 114	Batch 2006-001178	γ = 77 mm²/s (calculated for 20 °C) γ = 31 mm²/s (calculated for 40 °C)	Y	Gueldner, W., Hoppe, M., 2006 1410505427. (M-280652-01-1)	acceptable. Viscosity does not trigger R 65.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Dynamic viscosity (IIIA 2.5.2)	OECD 114 CIPAC MT 192	Batch 2006-001178	η = 80.8 mPa s at 20 °C and a shear rate of 20 s^{-1} η = 78.2 mPa s at 20 °C and a shear rate of 100 s^{-1} η = 33.4 mPa s at 40 °C and a shear rate of 20 s^{-1} η = 30.7 mPa s at 40 °C and a shear rate of 100 s^{-1}	Y	Gueldner, W., Hoppe, M., 2006 1410505427. (M-280652-01-1)	acceptable.
Surface tension (IIIA 2.5.3)	EEC A 5 OECD 115	Batch 2006-001178	σ = 32.0 mN/m (undiluted at 25 °C)	Y	Gueldner, W., Hoppe, M., 2006 1410505427. (M-280652-01-1)	acceptable.
Relative density (IIIA 2.6.1)	EEC A 3 OECD 109	Batch 2006-001178	d_4^{20} = 1.006 d_4^{40} = 0.990	Y	Gueldner, W., Hoppe, M., 2006 1410505427. (M-280652-01-1)	acceptable.
Bulk or tap density (IIIA 2.6.2)	-	-	nor required for liquid formulations	-	-	acceptable
Storage Stability after 14 days at 54° C (IIIA 2.7.1)	CIPAC MT 46.3	Batch 2006-001178 Batch 2007-002622	Stable in (COEX) PA, (COEX) E-VAL and HDPE. Paneling was observed on HDPE package. Additional study with JAU 6476-desthio investigation shows stability for 2 weeks at 54 °C in (COEX) PA. For individual results please see tables 2.16-1 to 2.16-3 below.	Y	Gueldner, W., Hoppe, M., 2008 1510505582 (M-311041-01-1) Gueldner, W., Hoppe, M., 2008 1510505583 (M-311052-01-1) Gueldner, W., Hoppe,	acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
					M., 2008 1510505584 (M-311494-01-1) Gueldner, W., 2008 1410505498 (M-297856-01-1)	
Stability after storage for other periods and/or temperatures (IIIA 2.7.2)	-	-	not required since formulation is stable at 54 °C for 14 days, see 2.7.1	-	-	acceptable.
Minimum content after heat stability testing (IIIA 2.7.3)	-	-	The active substance content did not decline to less than 95 % of the content prior to the test. JAU 6476-desthio an impurity of prothioconazole was found only below 0.01 % before and after storage.	-	-	acceptable.
Effect of low temperatures on stability (IIIA 2.7.4)	CIPAC MT 39.3	Batch 2006-001178	Stable throughout the test period of 7 days at 0 °C Packaging material: COEX/E-VAL., COEX/PA, HDPE	Y	Gueldner, W., Hoppe, M., 2008 1510505582 (M-311041-01-1) Gueldner, W., Hoppe, M., 2008 1510505583 (M-311052-01-1) Gueldner, W., Hoppe, M., 2008 1510505584	acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
					(M-311494-01-1)	
Ambient temperature shelf life (IIIA 2.7.5)	CropLife International, Technical monograph no 17	Batch 2006-001178	The preparation is stable for two years at ambient temperatures in (COEX) PA, (COEX) E-VAL and HDPE. Paneling was observed in (COEX) PA and HDPE package.	Y	Gueldner, W., Hoppe, M., 2008 1510505582 (M-311041-01-1) Gueldner, W., Hoppe, M., 2008 1510505583 (M-311052-01-1) Gueldner, W., Hoppe, M., 2008 1510505584 (M-311494-01-1)	acceptable.
Shelf life in months (if less than 2 years) (IIIA 2.7.6)	-	-	Please refer to 2.7.5	-	-	acceptable.
Wettability (IIIA 2.8.1)	-	-	not required for liquid formulations	-	-	acceptable
Persistence of foaming (IIIA 2.8.2)	CIPAC MT 47.2	Batch 2006-001178 Batch 2007-002622	CIPAC water D, 0.8 %: 10 s: 61.5 mL 1 min: 58 mL 3 min: 34.5 mL 12 min: 28 mL 10 s: 27 mL 1 min: 4 mL 3 min: 1 mL 12 min: 0 mL	Y	Gueldner, W., Hoppe, M., 2006 1410505427. (M-280652-01-1) Gueldner, W., 2008 1410505498 (M-297856-01	acceptable; the difference between the two experimental results is remarkable!

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Suspensibility (IIIA 2.8.3.1)	-	-	not required for EC formulations	-	-	acceptable
Spontaneity of dispersion (IIIA 2.8.3.2)	-	-	not required for EC formulations	-	-	acceptable
Dilution stability (IIIA 2.8.4)	-	-	not required for EC formulations	-	-	acceptable
Dry sieve test (IIIA 2.8.5.1)	-	-	not required for EC formulations	-	-	acceptable
Wet sieve test (IIIA 2.8.5.2)	-	-	not required for EC formulations	-	-	acceptable
Particle size distribution (IIIA 2.8.6.1)	-	-	not required for EC formulations	-	-	acceptable
Nominal size range of granules (IIIA 2.8.6.2)	-	-	not required for EC formulations	-	-	acceptable
Dust content (IIIA 2.8.6.3)	-	-	not required for EC formulations	-	-	acceptable
Particle size of dust (IIIA 2.8.6.4)	-	-	not required for EC formulations	-	-	acceptable

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Friability and attrition (IIIA 2.8.6.5)	-	-	not required for EC formulations	-	-	acceptable
Emulsifiability (IIIA 2.8.7.1)	CIPAC MT 36.3	Batch 2006-001178	0.4 % + 0.8 % in CIPAC water A Initial emulsification: spontaneously 0.4 % + 0.8 % in CIPAC water D Initial emulsification: spontaneously 0.4 % + 0.8 % in CIPAC water A Separation after 30 min: 0.0 ml Separation after 2 h: 0.0 ml Separation after 24 h: trace of sediment 0.4 % + 0.8 % in CIPAC water D Separation after 30 min: 0.0 ml Separation after 2 h: 0.0 ml Separation after 24 h: 0.0 ml 0.4 % in CIPAC water A Re-emulsification. after 24 h: completely separation after 24.5 h: 0.0 ml 0.8 % in CIPAC water A Re-emulsification. after 24 h: completely separation after 24.5 h: trace of sediment 0.4 % +0.8 % in CIPAC water D Emulsific. after 24 h: completely	N	Gueldner, W., Hoppe, M., 2006 1410505427. (M-280652-01-1)	acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
	CIPAC MT 173	Batch 2007-002622	separation after 24.5 h: 0.0 ml 0.8 % in CIPAC water A stability after 30 sec bixafen 99 % prothioconazole 99 % 30 min bixafen 99 % prothioconazole 99 % 4 hrs bixafen 99 % prothioconazole 99 % 0.8 % in CIPAC water D stability after 30 sec bixafen 99 % prothioconazole 99 % 30 min bixafen 100 % prothioconazole 100 % 4 hrs bixafen 99 % prothioconazole 99 % all at 30 °C 0.8 % in CIPAC water A+D Re-emulsification. after 4 h: completely 0.8 % in CIPAC water A stability after 4.5 hrs bixafen 100 % prothioconazole 100 % 0.8 % in CIPAC water D stability after 4.5 hrs		Gueldner, W., 2008 1410505498 (M-297856-01-1)	

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			bixafen 101 % prothioconazole 101 % all at 30 °C			
Flowability (IIIA 2.8.8.1)	-	-	not required for liquid formulations	-	-	acceptable
Pourability (including rinsed residue) (IIIA 2.8.8.2)	-	-	not required for EC formulations	-	-	acceptable
Dustability following accelerated storage (IIIA 2.8.8.3)	-	-	not required for liquid formulations	-	-	acceptable
Physical compatibility of tank mixes (IIIA 2.9.1)	-	-	tank mixtures are not recommended	-	-	acceptable
Chemical compatibility of tank mixes (IIIA 2.9.2)	-	-	tank mixtures are not recommended	-	-	acceptable
Distribution to seed (IIIA 2.10.1)	-	-	formulation is not intended for seed treatment	-	-	acceptable
Adhesion to seeds	-	-	formulation is not intended for seed	-	-	acceptable

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
(IIIA 2.10.2)			treatment			
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

Bixafen + Prothioconazole EC 225 (75+150 g/L) is not explosive, not flammable and not oxidizing. Its pH is within the range that naturally occurs e.g. in soil. Its stability allows storage under practical and commercial conditions. The technical properties indicate that no particular problems have to be expected, when it is used as recommended.

Table 2.16- 1: Results referring to the point IIIA 2.7.1 and 2.7.5: Storage stability after 14 days at 54 °C and 2 years at ambient temperature - HDPE

Packaging Material: HDPE Fluorinated

	Initial	2 weeks 54 °C	2 years at ambient temp.
A.S. Content			
bixafen	7.49 % = 75.3 g/L	7.53 % = 75.8 g/L	7.60 %** = 76.5 g/L
prothioconazole	14.8 % = 149 g/L	14.5 % = 146 g/L	13.8 %** = 139 g/L
Impurity JAU 6476-desthio	not reported	not reported	< 0.01 %**
Packaging stability HDPE fluorinated	no negative effects observed	no negative effects observed	no negative effects observed
weight change	-	< 0.1 % no significant change	< 0.1 % no significant change
deformation of packaging	no paneling no ballooning	8-9 mm paneling	14-15 mm paneling
leakage	no leakage	no leakage	no leakage
effect on closure	leak proof	leak proof	leak proof
packaging/preparation interaction	no seepage, no crystallisation, no sedimentation	no seepage, no crystallisation, no sedimentation	no seepage, no crystallisation, no sedimentation
Appearance colour, physical state	clear brown liquid	clear brown liquid	clear brown liquid
odour (olfactory)	amine-like	amine-like	amine-like
Acidity/Alkalinity *, method: CIPAC MT 191	not determined	not determined	not determined
pH-Value, method: CIPAC MT 75.3 (1 % in deionized water)	4.8	4.8	4.6
Relative density, method: OECD 109 D420	1.006	1.006	1.006
Persistent foaming, method: CIPAC MT 47.2, 0.8 % of the preparation in CIPAC D water			
after 10 sec	61.5 mL	66 mL	74 mL
after 1 min	58 mL	56.5 mL	55 mL
after 3 min	34.5 mL	38 mL	37 mL
after 12 min	28 mL	20 mL	22 mL
Emulsifiability, method: CIPAC MT 36.3 **0.4 % in CIPAC A water**			
initial emulsification	spontaneously	spontaneously	spontaneously

after 30 min	0 mL	0 mL	0 mL
after 2 h	0 mL	0 mL	0 mL
after 24 h	trace of sediment	0 mL	0 mL
re-emulsification after 24 h	completely	completely	completely
after 24.5h	0 mL	0 mL	0 mL

* only if pH <4 or pH >10 ** GLP Data

	Initial	2 weeks 54 °C	2 years at ambient temp.
Emulsifiability, method: CIPAC MT 36.3 , **0.8 % in CIPAC A water**			
initial emulsification	spontaneously	spontaneously	spontaneously
after 30 min	0 mL	0 mL	0 mL
after 2 h	0 mL	0 mL	0 mL
after 24 h	trace of sediment	trace of sediment	0 mL
re-emulsification after 24 h	completely	completely	completely
after 24.5h	trace of sediment	trace of sediment	0 mL
Emulsifiability, method: CIPAC MT 36.3 , **0.4 % in CIPAC D water**			
initial emulsification	spontaneously	spontaneously	spontaneously
after 30 min	0 mL	0 mL	0 mL
after 2 h	0 mL	0 mL	0 mL
after 24 h	0 mL	0 mL	0 mL
re-emulsification after 24 h	completely	completely	completely
after 24.5 h	0 mL	0 mL	0 mL
Emulsifiability, method: CIPAC MT 36.3**, 0.8 % in CIPAC D water**			
initial emulsification	spontaneously	spontaneously	spontaneously
after 30 min	0 ml	0 ml	0 mL
after 2 h	0 ml	0 ml	0 mL
after 24 h	0 ml	0 ml	0 mL
re-emulsification after 24 h	completely	completely	completely
after 24.5 h	0 ml	0 ml	0 mL

Low temperature stability, CIPAC MT 39.3, after 7 days at 0 °C

Result: < 0.05 ml grey sediment.

Table 2.16- 2: Results referring to the point IIIA 2.7.1 and 2.7.5: Storage stability after

14 days at 54 °C and 2 years at ambient temperature – COEX/PA

Packaging Material: COEX/PA

	Initial	2 weeks 54 °C	2 years at ambient temp.
A.S. Content			
bixafen	7.49 % = 75.3 g/L	7.48 % = 75.2 g/L	7.61 %** = 76.5 g/L
prothioconazole	14.8 % = 149 g/L	14.4 % = 145 g/L	14.3 %** = 144 g/L
Impurity JAU 6476-desthio	not reported	not reported	< 0.01 %**
Packaging stability COEX/PA	no negative effects observed	no negative effects observed	no negative effects observed
weight change	not necessary	< 0.1 % no significant change	< 0.1 % no significant change
deformation of packaging	no paneling no ballooning	no paneling no ballooning	7-8 mm paneling
leakage	no leakage	no leakage	no leakage
effect on closure	leak proof	leak proof	leak proof
packaging/preparation interaction	no seepage, no crystallisation, no sedimentation	no seepage, no crystallisation, no sedimentation	no seepage, no crystallisation, no sedimentation
Appearance colour, physical state	clear brown liquid	clear brown liquid	clear brown liquid
odour (olfactory)	amine-like	amine-like	amine-like
Acidity/Alkalinity *, method: CIPAC MT 191	not determined	not determined	not determined
pH-Value, method: CIPAC MT 75.3 (1% in de-ionized water)	4.8	4.8	4.8
Relative density, method: OECD 109 D420	1.006	1.006	1.005
Persistent foaming, method: CIPAC MT 47.2, **0.8 % of the preparation in CIPAC D water**			
after 10 sec	61.5 mL	63 mL	63 mL
after 1 min	58 mL	58 mL	55 mL
after 3 min	34.5 mL	36 mL	33 mL
after 12 min	28 mL	23 mL	21 mL
Emulsifiability, method: CIPAC MT 36.3 , **0.4 % in CIPAC A water**			
initial emulsification	spontaneously	spontaneously	spontaneously
after 30 min	0 mL	0 mL	0 mL
after 2 h	0 mL	0 mL	0 mL
after 24 h	trace of sediment	0 mL	0 mL
re-emulsification after 24 h	completely	completely	completely
after 24.5h	0 mL	0 mL	0 mL

* only if pH <4 or pH >10 ** GLP Data

	Initial	2 weeks 54 °C	2 years at ambient temp.

Emulsifiability, method: CIPAC MT 36.3, **0.8 % in CIPAC A water**			
initial emulsification	spontaneously	spontaneously	spontaneously
after 30 min	0 mL	0 mL	0 mL
after 2 h	0 mL	0 mL	0 mL
after 24 h	trace of sediment	0 mL	0 mL
re-emulsification after 24 h	completely	completely	completely
after 24.5h	trace of sediment	0 mL	0 mL

Emulsifiability, method: CIPAC MT 36.3**, 0.4 % in CIPAC D water**			
initial emulsification	spontaneously	spontaneously	spontaneously
after 30 min	0 mL	0 mL	0 mL
after 2 h	0 mL	0 mL	0 mL
after 24 h	0 mL	0 mL	0 mL
re-emulsification after 24 h	completely	completely	completely
after 24.5 h	0 mL	0 mL	0 mL

Emulsifiability, method: CIPAC MT 36.3 , **0.8 % in CIPAC D water**			
initial emulsification	spontaneously	spontaneously	spontaneously
after 30 min	0 mL	0 mL	0 mL
after 2 h	0 mL	0 mL	0 mL
after 24 h	0 mL	0 mL	0 mL
re-emulsification after 24 h	completely	completely	completely
after 24.5 h	0 mL	0 mL	0 mL

Low temperature stability, CIPAC MT 39.3, after 7 days at 0 °C

Result: < 0.05 ml grey sediment.

Table 2.16- 3: Results referring to the point IIIA 2.7.1 and 2.7.5: Storage stability after

14 days at 54 °C and 2 years at ambient temperature – COEX/E-VAL

Packaging Material: COEX/E-VAL

	Initial	2 weeks 54 °C	2 years at ambient temp.
A.S. Content			
bixafen	7.49 % = 75.3 g/L	7.49 % = 75.3 g/L	7.61 %** = 76.5 g/L
prothioconazole	14.8 % = 149 g/L	14.5 % = 146 g/L	14.6 %** = 147 g/L
Impurity JAU 6476-desthio	not reported	not reported	< 0.01 %**
Packaging stability COEX/E-VAL	no negative effects observed	no negative effects observed	no negative effects observed
weight change	not necessary	< 0.1 % no significant change	< 0.1 % no significant change
deformation of packaging	no paneling no ballooning	no paneling no ballooning	no paneling no ballooning
leakage	no leakage	no leakage	no leakage
effect on closure	leak proof	leak proof	leak proof
packaging/preparation interaction	no seepage, no crystallisation, no sedimentation	no seepage, no crystallisation, no sedimentation	no seepage, no crystallisation, no sedimentation
Appearance colour, physical state	clear brown liquid	clear brown liquid	clear brown liquid
odour (olfactory)	amine-like	amine-like	amine-like
Acidity/Alkalinity *, method: CIPAC MT 191	not determined	not determined	not determined
pH-Value, method: CIPAC MT 75.3 (deionized water)	4.8	4.9	4.9
Relative density, method: OECD 109 D420	1.006	1.006	1.005
Persistent foaming, method: CIPAC MT 47.2, **0.8 % of the preparation in CIPAC D water**			
after 10 sec	61.5 mL	62 mL	71 mL
after 1 min	58 mL	52 mL	55 mL
after 3 min	34.5 mL	33 mL	37 mL
after 12 min	28 mL	17 mL	22 mL
Emulsifiability, method: CIPAC MT 36.3 , **0.4 % in CIPAC A water**			
initial emulsification	spontaneously	spontaneously	spontaneously
after 30 min	0 mL	0 mL	0 mL
after 2 h	0 mL	0 mL	0 mL
after 24 h	trace of sediment	0 mL	0 mL
re-emulsification after 24 h	completely	completely	completely
after 24.5h	0 mL	0 mL	0 mL

* only if pH <4 or pH >10 ** GLP Data

	Initial	2 weeks 54 °C	2 years at ambient temp.
Emulsifiability, method: CIPAC MT 36.3, **0.8 % in CIPAC A water**			
initial emulsification	spontaneously	spontaneously	spontaneously

after 30 min	0 mL	0 mL	0 mL
after 2 h	0 mL	0 mL	0 mL
after 24 h	trace of sediment	0 mL	0 mL
re-emulsification after 24 h	completely	completely	completely
after 24.5h	trace of sediment	0 mL	0 mL
Emulsifiability, method: CIPAC MT 36.3, **0.4 % in CIPAC D water**			
initial emulsification	spontaneously	spontaneously	spontaneously
after 30 min	0 mL	0 mL	0 mL
after 2 h	0 mL	0 mL	0 mL
after 24 h	0 mL	0 mL	0 mL
re-emulsification after 24 h	completely	completely	completely
after 24.5 h	0 mL	0 mL	0 mL
Emulsifiability, method: CIPAC MT 36.3, **0.8 % in CIPAC D water**			
initial emulsification	spontaneously	spontaneously	spontaneously
after 30 min	0 mL	0 mL	trace of sediment
after 2 h	0 mL	0 mL	trace of sediment
after 24 h	0 mL	trace of sediment	0.1 mL sediment
re-emulsification after 24 h	completely	completely	completely
after 24.5 h	0 mL	trace of sediment	0 mL

Low temperature stability, CIPAC MT 39.3, after 7 days at 0 °C

Result: < 0.05 ml grey sediment.

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

No experimental testing has been performed by BVL.

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

See GAP table

IIIA 3.2 Nature of the Effects on Harmful Organisms

Fungicidal effect

IIIA 3.3 Details of Intended Use

See GAP table

IIIA 3.3.1 Details of existing and intended uses

See GAP table

IIIA 3.3.2 Details of harmful organisms against which protection is afforded

See GAP table

IIIA 3.3.3 Effects achieved

See part B, Section 7

IIIA 3.4 Proposed Application Rates (Active Substance and Preparation)

See GAP table

IIIA 3.5 Concentration of the Active Substance in the Material Used

Insert summary information.

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

See GAP table

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

See GAP table

IIIA 3.7.2 Growth stages of crops or plants to be protected

See GAP table

IIIA 3.7.3 Development stages of the harmful organism concerned

See GAP table

IIIA 3.7.4 Duration of protection afforded by each application

See GAP table

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

See GAP table

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

Not necessary

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

1 L bottle	- Type:	Co-extruded blow-moulded container
	-Material:	High density polyethylene (HDPE) container with an internal barrier layer made of polyamide (PA) or High density polyethylene (HDPE) container with an internal barrier layer made of ethylene vinyl alcohol copolymer (E-VAL) or Fluorinated High density polyethylene (HDPE) container
	- Shape/Size:	bottle 1 L
	- Opening:	KS 50 (DIN 6063, 50 mm)
	- Type of closure:	Injection moulded, polyethylene or polypropylene copolymer, HF seal

Outer packaging

Type: Corrugated case (12*1 L)

5 L bottle	- Type:	Co-extruded blow-moulded container
	- Material:	High density polyethylene (HDPE) container with an internal barrier layer made of polyamide (PA) or High density polyethylene (HDPE) container with an internal barrier layer made of ethylene vinyl alcohol copolymer (E-VAL) or Fluorinated High density polyethylene (HDPE) container
	- Shape/Size:	Container 5 L
	- Opening:	ECPA 63 (ECPA 63 mm Standard)
	- Type of closure:	Injection moulded, polyethylene or polypropylene copolymer, HF seal

Outer packaging

Type: Corrugated case (4*5 L)

15 L bottle	- Type:	Co-extruded blow-moulded container
	- Material:	High density polyethylene (HDPE) container with an internal barrier layer made of polyamide (PA) or High density polyethylene (HDPE) container with an internal barrier layer made of ethylene vinyl alcohol copolymer (E-VAL) or Fluorinated High density polyethylene (HDPE) container
	- Shape/Size:	Container 15 L
	- Opening:	ECPA 63 (ECPA 63 mm Standard)
	- Type of closure:	Injection moulded, polyethylene or polypropylene copolymer, HF seal

Outer packaging

Type: Corrugated case (1*15 L)

Complying with CropLife International recommendation for one way agrochemical packaging design criteria for liquids and solids [Guidelines for the safe formulation and packaging of crop protection products (Guideline 6)].

IIIA 4.1.2 Suitability of the packaging and closures

Statement of compliance:

As described in IIIA1 4.1.1, packages have been tested and comply with Annex A.5 of ADR respectively Annex V of RID respectively of IMDG – Code.

IIIA 4.1.3 Resistance of the packaging material to its contents

Report:	**KIIIA1 4.1.3/01, Güldner, W. & Hoppe, M., 2008**
Title:	Storage stability and shelf life of bixafen + prothioconazole EC 225 (75+150 g/L) - [Packaging material: HDPE fluorinated] - Final report
Document No:	14 1050 5582, M-311041-01-1
Guidelines:	EU Directive 91/414/EEC modified by Directive 94/37/EC
GLP	Yes

The resistance of packaging material to its content has been tested in accordance with CIPAC Handbook MT46.
The packaging material fluorinated HDPE was found to be stable and suitable for use with the formulation for at least 2 years at ambient conditions. No negative interactions with the formulation could be observed. It is expected that fluorinated HDPE will safely withstand normal handling and practical use. Therefore fluorinated HDPE could be recommended as packaging material.

Report:	**KIIIA1 4.1.3/02, Güldner, W. & Hoppe, M., 2008**
Title:	Storage stability and shelf life of bixafen + prothioconazole EC 225 (75+150 g/L) - [Packaging material: COEX/E-VAL] - Final report
Report No & Document No	14 1050 5584, M-311494-01-1
Guidelines:	EU Directive 91/414/EEC modified by Directive 94/37/EC
GLP	Yes

The resistance of packaging material to its content has been tested in accordance with CIPAC Handbook MT46.

The packaging material COEX/E-VAL was found to be stable and suitable for use with the formulation for at least 2 years at ambient conditions. No negative interactions with the formulation could be observed. It is expected that COEX/E-VAL will safely withstand normal handling and practical use. Therefore COEX/E-VAL could be recommended as packaging material.

Report:	**KIIIA1 4.1.3/03, Güldner, W. & Hoppe, M., 2008**
Title:	Storage stability and shelf life of bixafen + prothioconazole EC 225 (75+150 g/L) - [Packaging material: COEX/PA] - Final report
Report No & Document No	14 1050 5583, M-311052-01-1
Guidelines:	EU Directive 91/414/EEC modified by Directive 94/37/EC
GLP	Yes

The resistance of packaging material to its content has been tested in accordance with CIPAC Handbook MT46.
The packaging material COEX/PA was found to be stable and suitable for use with the formulation for at least 2 years at ambient conditions. No negative interactions with the formulation could be observed. It is expected that COEX/PA will safely withstand normal handling and practical use. Therefore COEX/PA could be recommended as packaging material.

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 spayed. 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

This study is requested for herbicides (in case of problems of residues when spraying occurs to avoid phytotoxicity in fields) and insecticides (decontamination of tanks if residues occur).

Report:	**KIIIA 4.2.2/01, 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 of the general formula $y = a\, e^{-bx}$. 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

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

IIIA 4.4.1 Warehouse storage

The product should be stored under secure conditions which prevent the product entering any body of water and, prevents any misuse by non authorized persons.

- Keep away from food, drink and animal feedings stuffs.
- Smoking, eating and drinking should be prohibited in the application area.

- Use only in area provided with appropriate exhaust ventilation.
- Keep container tightly closed in a dry and well-ventilated place.
- Keep away from heat and sources of ignition.

For more information see:
- Guidelines for the safe handling of pesticides during their formulation, packing, storage and transport (GCPF)
- Guidelines for the safe warehousing of crop protection products (GCPF).

IIIA 4.4.2 User level storage

The product should be stored under secure conditions which prevents the product entering any body of water and, prevents any misuse by non authorized persons. Compliance with recommendations for safe storage of crop protection products at the farm as given in GIFAP Guidelines for the avoidance, limitations and disposal of pesticide waste on the farm.

- Keep away from food, drink and animal feeding stuffs.
- Smoking, eating and drinking should be prohibited in the application area.
- Store in original container.
- Keep containers tightly closed in a dry, cool and well-ventilated place.

IIIA 4.4.3 Transport

Land transport: ADR/RID/ADNR

UN N°:	3082
Labels:	9
Packaging group:	III
Hazard n°:	90
Description of the goods	Environmentally hazardous substance, liquid, N.O.S. (BIXAFEN SOLUTION)
Tunnel code	E

Sea transport: IMDG

UN N°:	3082
Labels:	9
Packaging group:	III
EmS	F-A, S-F
Marine pollutant:	Yes
Description of the goods	Environmentally hazardous substance, liquid, N.O.S. (BIXAFEN SOLUTION)

Air transport: IATA

UN N°:	3082
Labels:	9
Packaging group:	III
Description of the goods	Environmentally hazardous substance, liquid, N.O.S. (BIXAFEN SOLUTION)

IIIA 4.4.4 Fire

Extinguish fires with water spray, carbon dioxide (CO_2), foam or sand.
Wear a self-contained breathing apparatus.

IIIA 4.4.5 Nature of protective clothing proposed

If product is handled such that there is a risk

- Wear respirator conforming to EN140 or equivalent for respiratory protection.
- Wear standard coverall and type 6 suit to protect skin and body.
- Wear goggles conforming to EN166 (Field of use 5 or equivalent) to protect eyes
- Wear CE marked (or equivalent) nitrile rubber gloves to protect hands.

IIIA 4.4.6 Characteristics of protective clothing proposed

See previous point IIIA 4.4.5

IIIA 4.4.7 Suitability and effectiveness of protective clothing and equipment

Safety goggles or a face shield are recommended to protect eyes from contact with the product. Protective clothing is recommended as routine hygienic measure. Chemical resistant gloves (nitrile rubber) are well known to sufficiently protect hands from contact with the product handled.

IIIA 4.4.8 Procedures to minimise the generation of waste

Product
To minimize product waste, users are required not to prepare more than they will use for treatment.

Package
To minimize packaging waste, empty and rinsed containers should be delivered to a local container collection program, where available. Otherwise, they should be rendered unusable e.g. by puncturing, and disposed of in accordance with local regulations.
To minimize generation of leftovers, users are recommended not to store more than they will use within the shelf life period of the product.

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

In the event of fire the following can be released: hydrogen cyanide (hydrocyanic acid), carbon monoxide (CO), nitrogen oxides (NO_x).

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

Prevent entry into drains, waters or soil.
Use approved industrial vacuum cleaner for removal.
Keep in suitable, closed containers for disposal

IIIA 4.5.2 Decontamination of areas, vehicles and buildings

Clean floors and contaminated objects with plenty of water.
Keep in suitable, closed containers for disposal.

IIIA 4.5.3 Disposal of damaged packaging, adsorbents and other materials

All contaminated cleaning materials should be placed in closable receptacles and must be incinerated in a suitable incineration plant holding a permit delivered by the competent authorities.
Waste key for the unused product: 020108 agrochemical waste containing dangerous substances

IIIA 4.5.4 Protection of emergency workers and bystanders

For emergency workers it is a standard safety precaution to wear goggles, rubber gloves, mouth-and-nose-mask, respiratory equipment and protective clothing (as described in point IIIA 4.4.5) during clean-up operations. Bystanders should be requested to leave the emergency site.

IIIA 4.5.5 First aid measures

General advice:	Move out of dangerous area. Remove contaminated clothing immediately and dispose of safely. Place and transport a victim in a stable position (lying sideways).
After inhalation:	Call a physician or poison control center immediately. Move the patient into fresh air. Keep patient warm and at rest.
After skin contact:	Wash off thoroughly with plenty of water and soap. If available with polyethyleneglycol 400, subsequently rinse with water.
After eye contact:	In case of eye contact, rinse the eye immediately with plenty of water, also under eyelids for at least 15 minutes. If contact lenses are present, remove them after the first 5 minutes of rinsing then continue to rinse the eye for a further 10 minutes.
After ingestion:	Do NOT induce vomiting. Call a physician or poison control center immediately.

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 BIX+PTZ EC 225 is below the 60 % threshold, a study of the pyrolytic behaviour of the active substance under controlled conditions at 800 °C and the content of polyhalogenated dibenzo-p-dioxins and dibenzo-furans in the product of pyrolysis is not required.

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:	**KIIIA1 4.8.1/01, Schneider, K, 2008**
Title:	Bixafen: Incineration as a safe means of disposal and pyrolytic behaviour under controlled conditions.
Report No & Document No	M- 298415-01-1
Guidelines:	EU Directive 91/414/EEC modified by Directive 94/37/EC (Statement).
GLP	Not relevant

Since **bixafen (BYF 00587)** 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:	**KIIIA1 4.8.1/02, Schneider, K, 2008**
Title:	Prothioconazole: Incineration as a safe means of disposal and pyrolytic behaviour under controlled conditions.
Report No & 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

No methods other than controlled incineration are recommended for disposal.

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 BAS 512 16 F 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 (-)	Autor, Jahr, Dokumentennr.
Oxidizing properties	Not oxidizing (-)	
Flammability	Auto-ignition temperature is 375 °C	
Content of hydrocarbon	< 10 % (w/w)	

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*
KIIIA1 2.1 /01 2.4.2/01 2.5.1/01 2.5.2/01 2.5.3/01 2.6.1/01 2.8.2/01 2.8.7.1/01 2.8.7.2/01 2.8.7.3/01	Gueldner, W.; Hoppe, M.	2006	Physical, chemical and technical properties of BYF 00587 + Prothioconazole EC 075+150 Bayer CropScience, Report No.: 14 1050 5427, Edition Number: M-280652-01-1 Date: 2006-11-02 GLP, unpublished	Yes	Bayer Crop Science	1
KIIIA1 2.2.1 /01 2.2.2/01 2.3.1/01 2.3.3/01	Rexer, K.; Bittner, P.	2006	Safety relevant technical properties of BYF 00587 + Prothioconazole emulsifiable concentrate 75 + 150 g/litre - Recipe identification: Specification number 102000013869 - Batch identification: 2006-001178 Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: FOR0883(PC)01, Edition Number: M-277997-01-1 Date: 2006-09-26 GLP, unpublished	Yes	Bayer Crop Science	1
KIIIA1 2.7.1 /01 2.7.3/01 2.7.4/01 2.7.5/01 4.1.3/01	Gueldner, W.; Hoppe, M.	2008	Storage stability and shelf life of bixafen + prothioconazole EC 225 (75+150 g/L) - [Packaging material: HDPE fluorinated] - Final report Bayer CropScience, Report No.: 14 1050 5582, Edition Number: M-311041-01-1 Date: 2008-11-14 GLP, unpublished	Yes	Bayer Crop Science	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 2.7.1 /02 2.7.3/02 2.7.4/02 2.7.5/02 4.1.3/02	Gueldner, W.; Hoppe, M.	2008	Storage stability and shelf life of bixafen + prothioconazole EC 225 (75+150 g/L) - [Packaging material: COEX/PA] - Final report Bayer CropScience, Report No.: 14 1050 5583, Edition Number: M-311052-01-1 Date: 2008-11-14 GLP, unpublished	Yes	Bayer Crop Science	1
KIIIA1 2.7.1 /03 2.7.3/03 2.7.4/03 2.7.5/03 4.1.3/03	Gueldner, W.; Hoppe, M.	2008	Storage stability and shelf life of bixafen + prothioconazole EC 225 (75+150 g/L) - [Packaging material: COEX/E-VAL] - Final report Bayer CropScience, Report No.: 14 1050 5584, Edition Number: M-311494-01-1 Date: 2008-11-19 GLP, unpublished	Yes	Bayer Crop Science	1
KIIIA1 2.7.1 /04 2.7.3/04 2.8.2/02 2.8.7.1/02 2.8.7.2/02 2.8.7.3/02 5.2.4/01	Gueldner, W.	2008	Determination of emulsion stability and persistent foam of bixafen + prothioconazole EC 225 (75+150 g/L) - [Packaging material: COEX(PA)] - Final report (2 weeks) Bayer CropScience, Report No.: 14 1050 5498, Edition Number: M-297856-01-1 Date: 2008-02-13 GLP, unpublished	Yes	Bayer Crop Science	1
KIIIA1 4.1.1 /01	Santos, S.	2008	Bixafen + prothioconazole 225 EC (75 + 150g/L) - Description for 0.5, 1, 3, 5 and 10 litre packaging Bayer CropScience, Report No.: M-298569-01-1, Edition Number: M-298569-01-1 Date: 2008-02-21 Non GLP, unpublished	Yes	Bayer Crop Science	

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 4.8.1 /01	Schneider, K.	2008	Bixafen Incineration as a safe means of disposal and pyrolytic behaviour under controlled conditions Code: BYF 00587 Bayer CropScience, Report No.: M-298415-01-1, Edition Number: M-298415-01-1 Date: 2008-03-05 Non GLP, unpublished	Yes	Bayer Crop Science	
KIIIA1 4.8.1 /02	Schneider, K.	2008	Prothioconazole - Incineration as a safe means of disposal and pyrolytic behaviour under controlled conditions Bayer CropScience, Report No.: M-302076-01-1, Edition Number: M-302076-01-1 Date: 2008-06-03 Non GLP, unpublished	Yes	Bayer Crop Science	
KIIIA1 11.3 /01	Anon.	2008	BIX+PTZ EC 75+150 G Bayer CropScience AG, Report No.: M-296944-06-1, Edition Number: M-296944-06-1 Date: 08-11-2011 Non GLP, unpublished	Yes	Bayer Crop Science	

* 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

date: 2014-04-16

PPP (product name/code) **Aviator Xpro**

active substance 1 **Bixafen**

active substance 2 **Prothioconazol**

Formulation: **Type:** **EC**
Conc. of as 1: **75 g/L**
Conc. of as 2: **150 g/L**

Applicant: **Bayer CropScience** **professional use** ☒ **non professional use** ☐

Zone(s): **central EU**

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 /**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between	kg, L product / ha a) max. rate	g, kg as/ha a) max. rate	Water L/ha		

		purpose of crop)		of the pest or pest group)			applications) a) per use b) per crop/ season	per appl. b) max. total rate per crop/season	per appl. b) max. total rate per crop/season	min / max		tank mixtures
1	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 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	<u>as 1</u> a) 93.8 g/ha b) 187.6 g/ha <u>as 2</u> a) 187.5 g/ha b) 375 g/ha	150 – 400	F*	* 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.
2	DE	wheat TRZSS	F	Septoria leaf blotch of wheat *Septoria tritici* SEPTTR	spraying	BBCH 30 – 61 From spring at beginning of infestation and/or when first symptoms become visible	a) 2 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	<u>as 1</u> a) 93.8 g/ha b) 187.6 g/ha <u>as 2</u> a) 187.5 g/ha b) 375 g/ha	150 – 400	F*	
3	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 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	<u>as 1</u> a) 93.8 g/ha b) 187.6 g/ha <u>as 2</u> a) 187.5 g/ha	150 – 400	F*	

									b) 375 g/ha			
4	DE	wheat TRZSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 – 69 From spring at beginning of infestation and/or when first symptoms become visible	a) 2 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	<u>as 1</u> a) 93.8 g/ha b) 187.6 g/ha <u>as 2</u> a) 187.5 g/ha b) 375 g/ha	150 – 400	F*	
5	DE	wheat TRZSS	F	eyespot of cereals *Pseudocercosporella herpotrichoides* PSDCHE	spraying	BBCH 29 – 32 From spring at beginning of infestation and/or when first symptoms become visible	a) 2 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	<u>as 1</u> a) 93.8 g/ha b) 187.6 g/ha <u>as 2</u> a) 187.5 g/ha b) 375 g/ha	150 – 400	F*	
6	DE	wheat TRZSS	F	stripe rust of cereals *Puccinia striiformis* PUCCST	spraying	BBCH 30 – 61 From spring at beginning of infestation and/or when first symptoms become visible	a) 2 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	<u>as 1</u> a) 93.8 g/ha b) 187.6 g/ha <u>as 2</u> a) 187.5 g/ha b) 375 g/ha	150 – 400	F*	

7	DE	wheat TRZSS	F	leaf and glume blotch *Septoria nodorum (Stagonospora nodorum)* LEPTNO	spraying	BBCH 30 – 61 From spring at beginning of infestation and/or when first symptoms become visible	a) 2 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	<u>as 1</u> a) 93.8 g/ha b) 187.6 g/ha <u>as 2</u> a) 187.5 g/ha b) 375 g/ha	150 – 400	F*	
8	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) 2 (14 -21 days) b) 2	a) 1.0 L/ha b) 2.0 L/ha	<u>as 1</u> a) 75 g/ha b) 150 g/ha <u>as 2</u> a) 150 g/ha b) 300 g/ha	150 – 400	F*	
9	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) 2 (14 -21 days) b) 2	a) 1.0 L/ha b) 2.0 L/ha	<u>as 1</u> a) 75 g/ha b) 150 g/ha <u>as 2</u> a) 150 g/ha b) 300 g/ha	150 – 400	F*	
10	DE	barley	F	net blotch	spraying	BBCH 30 – 61 From spring at beginning of	a) 2 (14 -21		<u>as 1</u>	150 – 400	F*	

		HORVX		*Pyrenophora teres* PYRNTE		infestation and/or when first symptoms become visible	days) b) 2	a) 1.0 L/ha b) 2.0 L/ha	a) 75 g/ha b) 150 g/ha <u>as 2</u> a) 150 g/ha b) 300 g/ha			
11	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) 2 (14 -21 days) b) 2	a) 1.0 L/ha b) 2.0 L/ha	<u>as 1</u> a) 75 g/ha b) 150 g/ha <u>as 2</u> a) 150 g/ha b) 300 g/ha	150 – 400	F*	
12	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) 2 (14 -21 days) b) 2	a) 1.0 L/ha b) 2.0 L/ha	<u>as 1</u> a) 75 g/ha b) 150 g/ha <u>as 2</u> a) 150 g/ha b) 300 g/ha	150 – 400	F*	
13	DE	barley HORVX	F	Physiologic leaf spots (PLS) MEHITE	spraying	BBCH 30 – 61 From spring at beginning of infestation and/or when first	a) 2 (14 -21 days)	a) 1.0 L/ha	<u>as 1</u> a) 75 g/ha	150 – 400	F*	

						symptoms become visible	b) 2	b) 2.0 L/ha	b) 150 g/ha <u>as 2</u> a) 150 g/ha b) 300 g/ha			
14	DE	rye SECCE	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 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	<u>as 1</u> a) 93.8 g/ha b) 187.6 g/ha <u>as 2</u> a) 187.5 g/ha b) 375 g/ha	150 – 400	F*	
15	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 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	<u>as 1</u> a) 93.8 g/ha b) 187.6 g/ha <u>as 2</u> a) 187.5 g/ha b) 375 g/ha	150 – 400	F*	
16	DE	rye SECCE	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 – 69 From spring at beginning of infestation and/or when first symptoms	a) 2 (14 -21 days) b) 2	a) 1.25 L/ha	<u>as 1</u> a) 93.8 g/ha b) 187.6 g/ha	150 – 400	F*	

						become visible		b) 2.5 L/ha	as 2 a) 187.5 g/ha b) 375 g/ha			
17	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 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	as 1 a) 93.8 g/ha b) 187.6 g/ha as 2 a) 187.5 g/ha b) 375 g/ha	150 – 400	F*	
18	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 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	as 1 a) 93.8 g/ha b) 187.6 g/ha as 2 a) 187.5 g/ha b) 375 g/ha	150 – 400	F*	
19	DE	triticale TTLSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 – 69 From spring at beginning of infestation and/or when first symptoms become visible	a) 2 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	as 1 a) 93.8 g/ha b) 187.6 g/ha as 2	150 – 400	F*	

									a) 187.5 g/ha b) 375 g/ha			

General remarks/explanations:

The GAP-Sheet should indicate if the displayed information was provided by the applicant OR was revised by the zRMS (due to the product label and Annex III data).

The zRMS has to verify the presented information and to ask (the applicant) for clarification of missing details (e.g. BBCH stages, EC-codes of crops).

All abbreviations in the GAP-Sheet used must be explained. Use separate worksheet for each product.

Make use of existing standards like EPPO and BBCH.

Product: Please indicate the specific variant of the active substance if relevant.

If additional components have to be added to the applied product (tankmixtures), all relevant information must be provided in the column remarks.

As the product usually will be determined either for professional or non professional use, this information should be given here. Otherwise to be indicated in column 4 of the GAP-sheet (conditions / location of use).

Formulation:

Type:

e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

Refer to:

- GCPF Codes - GIFAP Technical Monograph No 2, (1989), 6th Edition – Revised May 2008 – Catalogue of pesticide formulation types and international coding system.
- Technical Monograph n°2, 6th Edition - Revised May 2008 - Catalogue of pesticide formulation types and international coding system (CropLife International) [1)].

Conc. of as:

g/kg or g/L

[1)] http://www.croplife.org/files/documentspublished/1/en-us/PUB-TM/4147_PUB-TM_2008_05_01_Technical_Monograph_2_-_Revised_May_2008.pdf

In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.

Safener/Synergist: Since safeners and synergists are in scope of REG 1107/2009, information about safeners/synergists should be included in the GAP table as well.

Zone(s): All relevant zone(s) should be indicated. For interzonal uses (e.g. greenhouse, seed treatment, etc.) "EU" should be chosen.

Explanations to the particular columns:

No.: Numeration would be important when references are necessary e. g. to the dossier or to the authorisation certificate.

Member state(s): For a better general view of the valid uses for the particular zones/MS it would be helpful to mention both (the zone as well as the MS) in the column. However, to keep the table clearly arranged it seems dispensable to cite the zone; each MS is distinctly allocated to one zone; moreover the zone(s) are cited in the head of the table.

Desirably MS are put in order accordant to the zone they belong.

Crop and/or situation: The common name(s) of the crop and the EC (EPPO)-Codes or at least the scientific name(s) [EU and Codex classifications (both)] should be used; where relevant, the situation should be described (e.g. fumigation of a structure). In case of crop groups all single crops belonging to that group should be mentioned, (either in the respective table element or – in case of a very extensive crop group - at least in a footnote).

If it is not possible to mention all single crops belonging to a crop group (e.g. for horticulture), it should be referred to appropriate crop lists (e.g. EPPO, residue (codex). It would be desirable to have a "joint list" of crop groups for the zones.

Exceptions of specific crops/products/objects or groups of these and restrictions to certain uses (e.g. only for seed production, fodder) must be indicated.

This column should also include when indicated information concerning "crop destination or purpose of crop" and which part of plants will be used / processed (e. g. for medicinal crops roots or leaves or seeds).

Conditions / location of use: Outdoor or field use (F), glasshouse application (G) or indoor application (I)

"Glasshouse" indicates that the respective trials are acceptable for all zones.

As results achieved in compartments without controlled conditions (temperature, light exposure), e.g. simple plastic tunnels [for those GAPs field trials have to be conducted in the respective zone the use is applied for], are not considered to be applicable for use in other zones the kind of glasshouse should be clearly indicated.

[Remark: Greenhouse definitions are at the moment under evaluation].

Conditions include also information concerning the substrate (natural soil, artificial substrate).

Pests or Group of pests controlled: Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and suckling 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.

If necessary – in case of pest groups - exceptions (e.g. sucking insects excluding scale insects) should be indicated.

In some cases, the set of pests concerned for a given crop may vary in different parts of the EU region (where appropriate the pests should be specified individually).

If the product is used as growth regulator the target organism is the specific crop, whose development should be influenced; the aim could also be e.g. an empty room for treatment.

Application details:

Method / Kind:

Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench, drilling, high precision drilling (with or without pneumatic systems).

Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used (e.g. ultra low volume equipment (ULVA) or low volume equipment (LVA)) should be indicated if relevant.

Timing of Application / Growth stage of crop & season:

Time(s), period, first and last treatment, e.g. autumn or spring pre- or post-emergence, at sufficient pest density or begin of infection, including restrictions (e.g. not during flowering).

Growth stage of crop (BBCH-code, …) – period, first and last treatment.

Since the BBCH-codes are accomplished in the individual member states at different time periods the month(s) of application should be indicated in addition.

BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

It seems sensible to constrain specifications in this column only to the crop, - information concerning the pest should be dealt in column “pest or group of Pests controlled”.

In certain circumstances it might be helpful to give information about the expected rate of interception related to the BBCH codes. In many minor crops no BBCH/interception rate scenarios have been specified so far. This could also simplify grouping for the envelope approach.

Number of applications and interval between applications

a) Maximum number of applications per growing season used for the named crop/pest combination possible under practical conditions of use.

b) The proposed maximum number in the crop including applications on all pests/targets on the same crop in a growing season should be given.

It should be clearly indicated whether the displayed number of applications is per season, per crop cycle or per pest generation.

Minimum interval (in days) between applications of the same product. The figure for the interval between the applications is to be set in brackets.

Application rate:

Application rate of the product per ha:

a)-(Maximum) product rate per treatment (usually kg or L product / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).

b) Maximum product rate per growing season (especially if limited) or per crop cycle should be cited.

Especially in three dimensional crops other dose expressions (kg/l per 10.000 m² leaf wall area or kg/l per ha per meter crown (canopy) height) should be given additionally.

For seed treatment also the load of product (l/g, kg) per kg, 100 kg or unit treated seed should be stated beside the application rate per hectare. The number of seeds per (seed) unit is to be given. The maximum seed drilling rate (=number of seed sown/maximum seed volume) per row and ha should be indicated.

Information concerning the sowing method (precision drilling, …) would be advantageous.

See also EPPO-Guideline PP 1/239 Dose expression for plant protection products (please note, additional EPPO-guidelines may be developed).

Application rate of the active substance per ha:

a)-(Maximum) as rate per treatment (usually kg active substance / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).

b) Maximum as rate per growing season (especially if limited) or per crop cycle should be cited.

The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg active substance / ha).

In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.

Water L/ha:

It should be clearly indicated if a stated water volume range depends upon the developmental stage of the crop (low volume – early crops stage, high volume – late crop stage) which causes a consistent concentration of the spray solution, or if a water volume range indicates different spray solution concentrations.

In the last mentioned case extremely low water volumes (indicating high concentrated spray solutions) need to be covered within selectivity trials.

If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.

PHI (days) – minimum pre harvest interval: PHI - minimum pre-harvest interval

For some crop situations a specific PHI may not be relevant. If so an explanation (e. g. the PHI is covered by the time remaining between application and harvest.) should be given in the remarks column (e.g. crop harvest at maturity or specific growth stages).

Remarks: Remarks may include: amount of safener/synergist per ha or extent of use/economic importance/restrictions, e.g. limiting the number of uses per crop and season, if several target pests/diseases are controlled with the same product.

If additional components (other ppp or adjuvant) should be used with the applied product (tankmixtures), all relevant information must be provided in the column remarks. In addition, it should be mentioned as well those mixtures are recommended or mandatory.

Additional recommendations:

For the description of uses of a PPP the following EPPO Standards should be considered:

- EPPO Standard PP 1/240 “Harmonized basic information for databases on plant protection products”
- EPPO Standard PP1/ 248 “Harmonized classification and coding of the uses of plant protection products“

Whereas EPPO Standard PP1/ 248 gives more general information on possible description of uses, EPPO Standard PP 1/240 especially gives an overview of all points necessary to fully understand a use.

Ad EPPO-Guidelines, see: http://archives.eppo.org/EPPOStandards/efficacy.htm

Use EPPO extrapolation tables, see http://www.eppo.org/PPPRODUCTS/extrapolation/tables.htm

EPPO Plant Protection Thesaurus: http://eppt.eppo.org/

REGISTRATION REPORT
Part B

Section 2: Analytical Methods

Detailed summary of the risk assessment

Product code:	**BIX+PTZ EC 225** **Aviator Xpro EC 225**	
Active Substances:	**Bixafen**	**75 g/L**
	Prothioconazole	**150 g/L**

Central Zone
Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant:	**Bayer CropScience**
Date:	**19 April 2016**

Table of Contents

IIIA 5 METHODS OF ANALYSIS

This document summarises the information related to the analytical methods relevant for the plant protection product BIX+PTZ EC 225 specification number 102000013869 version 03, which contains the active substances bixafen (75 g/L) + prothioconazole (150g/L).

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 the 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 or prothioconazole-desthio was performed.

IIIA 5.1.2 Analytical standards for the pure active substance

No analytical standard was provided by the applicant.
Analytical standards for pure active substances are available and can be provided on 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

Analytical methods for the determination of bixafen and prothioconazol and their impurities and relevance of CIPAC methods were evaluated as part in the EU review. The respective data are considered adequate and are not included in this submission. Additional studies to support the registration of BIX+PTZ EC 225 not previously assessed are given below. All relevant data are provided and are considered adequate.

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 the formulation contains two active substances.

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+PTZ EC 225 has not previously been reviewed.

Report:	KIIIA1 5.2.2/01, Zitzmann, W., 2006
Title:	Determination of BYF 00587 and Prothioconazole in Formulations - Assay - HPLC, External Standard
Document No:	AM006906MF1 M-268757-01-2
Guidelines:	
GLP	non GLP

Report:	KIIIA1 5.2.2/02, Odendahl, A., 2006
Title:	Validation of HPLC-method AM006906MF1 -determination of BYF 00587 and Prothioconazole in formulations-
Document No:	VB1-AM006906MF1 M-268788-01-1
Guidelines:	
GLP	non GLP

Method description

The components are separated by reversed phase chromatography using isocratic elution (water + 1 mL acetic acid per litre / acetonitrile (50/50 v/v)). The active ingredient is stabilized by L-cysteine-hydrochloride-monohydrate. After UV detection at 254 nm, the quantitative evaluation is carried out by comparing the peak areas with those of reference substances, using an external standard.

Method validation

Table containing the methods and validation of the methods (formulation BIX+PTZ EC 225)

Analyte	**Linearity n = 6**	**Accuracy n = 6 Mean [%]**	**Repeatability n = 6 [%RSD]**	**Specificity/Interferences**
bixafen	50 – 150 % r = 1.000	101.26 %	0.36 % RSDr (max): 1.98 %	The UV-spectra of active substance and reference substance show no spectral difference; the retention times of active ingredient and reference substance are identical. No interferences were noted. Chromatograms of formulation with and without active substances present were submitted.
prothioconazole	50 – 150 % r = 1.000	101.08 %	0.17 % RSDr (max): 1.79 %	

Summary
The HPLC method AM006906MF1 is applicable for the simultaneous quantitative determination of the content of bixafen and prothioconazole in formulations (e.g. Bixafen + Prothioconazole EC 225 (75+150 g/L)). The method has been completely validated by checking the parameters linearity, precision, accuracy, specificity and interference from excipients.

IIIA 5.2.3 Applicability of existing CIPAC methods

Up to now there is no CIPAC method available for the determination of bixafen or prothioconazole in formulations.

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

prothioconazole-desthio

Report:	KIIIA1 5.2.4/01, Gueldner, W., 2008
Title:	Determination of emulsion stability and persistent foam of bixafen + prothioconazole EC 225 (75+150 g/L) - [Packaging material: COEX(PA)] - Final report (2 weeks)
Document No:	14 1050 5498 M-297856-01-1
Guidelines:	
GLP	Yes

Prothioconazole-desthio (JAU 6476-desthio), an impurity of prothioconazole, was found only below 0.01 % in the preparation 'Bixafen + Prothioconazole EC 225 (75+150 g/L)' before and after storage. There is no degradation of prothioconazole to prothioconazole-desthio measurable.
Analytical method was LC-MS/MS, as described under **5.2.4/02.**

Report:	KIIIA1 5.2.4/02, Schulz, F., 2008
Title:	Determination of prothioconazole-desthio (SXX 0665) in formulations ; assay HPLC-MS/MS, external standard
Document No:	2001-0051701-01 M-078059-01-2
Guidelines:	
GLP	non GLP

Report:	KIIIA1 5.2.4/03, Odendahl, A. & Schulz, F., 2008
Title:	Validation of HPLC-MS/MS -method 2001-0051701-1 - Determination of prothioconazole-desthio in formulations - bixafen + prothioconazole EC 225 (75+150 g/L)
Document No:	VB3-2001-0051701 M-296913-03-1
Guidelines:	
GLP	non GLP

Method description

Prothioconazole-desthio is separated from the formulation components on a reversed phase column using isocratic elution. Eluent: (water + 0.1 mL/L formic acid) and (acetonitrile + 0.1 mL/L formic acid), (50/50 %). After MS/MS detection, the quantitative evaluation is carried out by comparing the peak areas with those of reference substance, using an external standard.

Method validation

Table containing the methods and validation of the methods (formulation BIX+PTZ EC 225)

Analyte	**Linearity n = 6**	**Accuracy n = 6 Mean [%]**	**Repeatability n = 6 [%RSD]**	**Specificity/Interferences**
	50 – 150 % r = 0.9998	91.3 %	1.10 % RSDr (max): 4.11 %	The retention times of reference item, analyte in the sample and in the spiked sample are identical; confirmation by mass spectrometry analysis: a) mol ion (m/z = 312), b) fragment ion (m/z = 70); No interferences were found

The LOQ was determined based on the signal to noise ratio: < 0.01 % (= 100 ppm).

toluene

Report:	KIIIA 5.2.4/04, Schulz, F., 2009
Title:	Determination of the impurity toluene in formulations ; assay – GLC, internal standard
Document No:	AM012408MF2 M-319820-02-1
Guidelines:	
GLP	non GLP

Report:	KIIIA 5.2.4/05, Odendahl, A. and Schulz, F.,2010
Title:	Validation of GLC-method AM012408MF2 – Determination of the impurity toluene in formulations – bixafen + prothioconazole EC 225 (75+150 g/L)
Document No:	VB2-AM012408MF2 M-346632-01-1
Guidelines:	
GLP	non GLP

Method description
After addition of a reference substance (o-xylol or p-xylol) as internal standard and dilution with a suitable solvent (acetone) the content is determined by gas chromatography using an FID detector.

Method validation
Table containing the methods and validation of the methods (formulation BIX+PTZ EC 225)

Analyte	**Linearity n = 6**	**Accuracy n = 6 Mean [%]**	**Repeatability n = 6 [%RSD]**	**Specificity/Interferences**
	50 – 150 % r = 0.9998	98.2 %	0.97 % RSDr (max): 4.36 %	GC: retention times of analyte in the sample and reference item are identical. GC-MS: The MS-spectra of analyte from reference item and sample show no spectral difference, the retention times are identical. Chromatograms of standards, sample and spiked sample were checked; no interferences were found.

The LOQ was determined based on the signal to noise ratio: 0.002 % (= 20 ppm).

Summary
The HPLC-MS/MS -method 2001-0051701-1 is applicable for the quantitative determination of the content of **prothioconazole-desthio** in formulations e.g. Bixafen + Prothioconazole EC 225..
The GC method AM012408MF2 is applicable for the quantitative determination of **toluene** in formulations e.g.‘ Bixafen + Prothioconazole EC 225.
Both methods have been completely validated on a ‘Bixafen + Prothioconazole EC 225 (75+150 g/L)’ by checking the parameters linearity, precision, accuracy, specificity and interference from excipients.

IIIA 5.2.5 Description of analytical methods for the determination of formulants

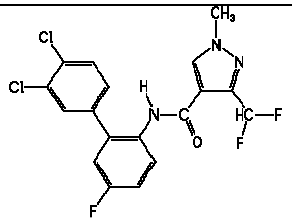
No formulants with toxicological or ecotoxicological relevant compounds are present in the formulation. Therefore, no analytical methods for the determination of formulants are necessary.

IIIA 5.3 Description of Analytical Methods for the Determination of Residues

IIIA 5.3.1 Evaluation of bixafen

The conclusion regarding the peer review of the analytical methods for residues of bixafen is 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 definiton substance code IUPAC name formula	**Structural formula**
Bixafen, BYF00587 *N*-(3′,4′-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide $C_{18}H_{12}Cl_2F_3N_3O$	

IIIA 5.3.1.1 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 5.3-2: Relevant residue definitions

Matrix	Relevant residue	Reference Remarks
Plant material	Bixafen	Regulation (EU) No 834/2013; annex IIIA; DAR, vol.1, list of endpoints, 07/2011, ASB2011-11716
Foodstuff of animal origin	Sum of bixafen and bixafen-desmethyl, expressed as bixafen	Regulation (EU) No 834/2013; annex IIIA; DAR, vol.1, list of endpoints, 07/2011, ASB2011-11716
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
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

An overview of the acceptable methods and possible data gaps for analysis of bixafen in plant matrices is given in the following tables. A new study was provided but not required for assessment. For further explanation see section 2.3.1.8.

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*	Open	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)

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
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	DAR, section B.5.2, ASB2011-11716
Ballesteros & Portet, 2008 ASB2009-5827	Acidic, dry fatty	0.01 mg/kg	LC-MS/MS, Zorbax Eclipse C18, ESI+, m/z 414→394	ILV of Bardel & Schöning, 2006	DAR, section B.5.2, ASB2011-11716

IIIA 5.3.1.3 Description of Analytical Methods for the Determination of Residues of Bixafen in Animal Matrices

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

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

The study on extraction efficiency was evaluated in the DAR, chapter 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**
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	DAR, section B.5.2, 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	DAR, section B.5.2, ASB2011-11716

IIIA 5.3.1.4 Description of Methods for the Analysis of Bixafen in Soil

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

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, 2006a*	Brumhard & Freitag, 2006a*

*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
Brumhard & Freitag, 2006a ASB2009-5833	0.005 mg/kg	LC-MS/MS, Purospher Star RP 18, ESI+, m/z 414→394, 414→266	Confirmation included	DAR, section B.5.3.1 ASB2011-11716

IIIA 5.3.1.5 Description of Methods for the Analysis of Bixafen in Water

An overview of the acceptable methods and possible data gaps for analysis of bixafen in surface and drinking water is given in the following table. New studies were not provided. The acceptable analytical methods are validated for surface water only. Because the LOQ is clearly below the drinking water limit, the methods are also accepted for drinking water.

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 drinking water and surface water

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

IIIA 5.3.1.6 Description of Methods for the Analysis of Bixafen in Air

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
Class, 2007 ASB2009-5838	10 µg/m^3	LC-MS/MS; Waters XTerra MS C18, ESI+, m/z 414→394; 414→266	Confirmation included	DAR, section B.5.3.3 ASB2011-11716

IIIA 5.3.1.7 Description of Methods for the Analysis of Bixafen in Body Fluids and Tissues

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

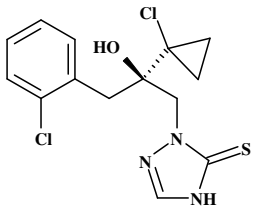
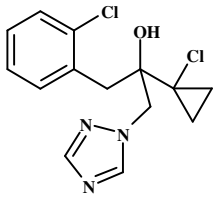
Other studies which had been evaluated in the DAR were not needed, because all requirements for registration are already fulfilled. The following additional studies were provided which are not included in the DAR. They were not considered in the assessment of bixafen for the reasons outlined below:

- Brumhard & Koch, 2007 (ASB2009-5835): not required, analytical method for the desmethyl metabolite which is not included in the residue definition for soil;
- Justus & Kuhnke, 2008 (ASB2009-5825): not relevant, extraction efficiency for total toxic residue does not correspond to the residue definition for monitoring.

IIIA 5.3.2 Evaluation of Prothioconazole

The conclusion 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 5.3-16: Information on the active substance prothioconazole

Name of component of residue definiton 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 $C_{14}H_{15}Cl_2N_3O$	

Glucuronide conjugate of Prothioconazole-desthio	

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	Prothioconazole-desthio	Regulation (EU) No 834/2013, annex III part A EFSA Scientific Report (2007) 106, 1-98, ASB2012-3641
Foodstuff of animal origin	Sum of prothioconazole-desthio and its glucuronide conjugate, expressed as prothioconazole-desthio	Regulation (EU) No 834/2013, annex III part A 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+, EFSA Scientific Report (2007) 106, 1-98, ASB2012-3641

Table 5.3-18: Levels for which compliance is required

Matrix	MRL	Reference for MRL/level Remarks
Plant, high water content	0.02 mg/kg	Regulation (EU) No 834/2013, annex III part A
Plant, acidic commodities	0.02 mg/kg	Regulation (EU) No 834/2013, annex III part A
Plant, dry commodities	0.02 mg/kg	Regulation (EU) No 834/2013, annex III part A
Plant, high oil content	0.02 mg/kg	Regulation (EU) No 834/2013, annex III part A
Plant, difficult matrices (hops, spices, tea)	0.02 mg/kg	Regulation (EU) No 834/2013, annex III part A
Meat	0.05 mg/kg	Regulation (EU) No 834/2013, annex III part A
Milk	0.01 mg/kg	Regulation (EU) No 834/2013, annex

		III part A
Eggs	0.05 mg/kg	Regulation (EU) No 834/2013, annex III part A
Fat	0.05 mg/kg	Regulation (EU) No 834/2013, annex III part A
Liver, kidney	0.05 mg/kg	Regulation (EU) No 834/2013, annex III part A
Soil	0.05 mg/kg	Common limit
Drinking water	0.1 µg/L	General limit for drinking water
Surface water	308 µg/L prothioconazole 3.3 µg/L prothioconazole-desthio	NOEC *Oncorhynchus mykiss* NOEC *Oncorhynchus mykiss*, EFSA Scientific Report (2007) 106, 1-98, ASB2012-3641
Air	60 µg/m^3 prothioconazole 3 µg/m³ prothioconazole-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+
Body fluids	Not required	Not classified as T / T+

IIIA 5.3.2.2 Description of Analytical Methods for the Determination of Residues of Prothioconazole in Plant Matrices

An overview of the acceptable methods and possible data gaps for analysis 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 5.3-19: 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	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 5.3-20: Statement on extraction efficiency

	Method for products of plant origin
Required, available from:	Haas, 2001, RIP2002-1041

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

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
Weeren & Pelz, 2000 MET2002-402	High water content, acidic, dry, fatty	0.02 mg/kg	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	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

IIIA 5.3.2.3 Description of Analytical Methods for the Determination of Residues of Prothioconazole in Animal Matrices

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

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	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 5.3-23: Statement on extraction efficiency

	Method for products of animal origin
Required, available from:	Weber, Weber & Spiegel, 2002, RIP2002-1046

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

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
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 selec B, ESI+, m/z	Confirmation included, selectivity of	Appendix 2

Author(s), year	Matrix	Method LOQ	Principle of method	Comment	Evaluated in
			312→70, 312→125 (prothioconazole-desthio)	both transitions for liver and kidney not proven	
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 (prothioconazole-desthio)	Confirmation included, ILV of Freitag, 2007	Appendix 2

IIIA 5.3.2.4 Description of Methods for the Analysis of Prothioconazole in Soil

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

Table 5.3-25: 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 5.3-26: Methods for soil

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Schramel, 2000 MET2002-405	0.006 mg/kg prothioconazole 0.006 mg/kg prothioconazole-desthio	LC-MS/MS, Superspher 60 RP select B, ESI+, m/z 344→326 (prothioconazole), m/z 312→70 (prothioconazole-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 confirmation, 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 BB, ESI+, m/z 344→326, 344→189 (prothioconazole), m/z 312→70, 312→125 (prothioconazole-desthio)	Confirmation included	Appendix 2

IIIA 5.3.2.5 Description of Methods for the Analysis of Prothioconazole in Water

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

Table 5.3-27: 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 5.3-28: Methods for drinking water and surface water

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Sommer, 2001 MET2002-411	0.1 µg/L prothioconazole 0.05 µg/L prothioconazole-desthio	LC-MS/MS, RP18, ESI+, m/z 344→326 (prothioconazole) m/z 312→70 (prothioconazole-desthio)	No confirmation, 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 prothioconazole 0.05 µg/L prothioconazole-desthio	LC-MS/MS, RP18, ESI+, m/z 344→326, 344→189 (prothioconazole) m/z 312→70, 312→125 (prothioconazole-desthio)	Confirmation incuded	Appendix 2

IIIA 5.3.2.6 Description of Methods for the Analysis of Prothioconazole in Air

An overview of the acceptable methods and possible data gaps for analysis of prothioconazole residues in air is given in the following table. For the detailed evaluation of new studies it is referred to Appendix 2.

Table 5.3-29: 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 5.3-30: Methods for air

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Maasfeld, 2000a MET2002-408	15 µg/m^3	LC-MS/MS, Superspher 60 RP Select B, ESI-, m/z	Only for prothioconazole; no confirmation	DAR, vol. 3, B.5.2 ASB2010-10593

		342→100		
Maasfeld, 2000b MET2005-361	0.6 µg/m^3	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 5.3.2.7 Description of Methods for the Analysis of Prothioconazole in Body Fluids and Tissues

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 5.3.2.8 Other Studies/ Information

Other studies which had been evaluated in the DAR were not needed, because all requirements for registration are already fulfilled. Further studies were not considered in the assessment for the reasons outlined below:

- Opitz, Huser Schwarz, 2005 (MET2005-324): Statement not required, because methods for eggs are available now;
- Anft & Bardel, 2005 (MET2005-360): The study includes validation data for a 2nd MS/MS transition for confirmation. It is not considered in the assessment because a confirmatory method for air is not required.

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

Bixafen:
Formally, an independent laboratory validation of the method of Bardel & Schöning, 2006 for plant commodities of high water content is missing. However, the method has been validated for 3 further commodities in an independent laboratory. Therefore, in agreement with the EU review process an ILV for high water content commodities is not required.

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

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	Zitzmann, W.	2006	Determination of BYF 00587 and Prothioconazole in Formulations - Assay - HPLC, External Standard Bayer CropScience, Report No.: AM006906MF1, Edition Number: M-268757-01-2 Date: 2006-03-29 Non GLP, unpublished	Yes	Bayer Crop Science	**5**
KIIIA 5.2.2 /02	Odendahl, A.	2006	Validation of HPLC-method AM006906MF1 -determination of BYF 00587 and Prothioconazole in formulations- Bayer CropScience, Report No.: VB1-AM006906MF1 Edition Number: M-268788-01-1 Date: 2006-03-24 Non GLP, unpublished	Yes	Bayer Crop Science	**1**
KIIIA 5.2.4 /01	Gueldner, W.	2008	Determination of emulsion stability and persistent foam of bixafen + prothioconazole EC 225 (75+150 g/L) - [Packaging material: COEX(PA)] - Final report (2 weeks) Bayer CropScience, Report No.: 14 1050 5498, Edition Number: M-297856-01-1 Date: 2008-02-13 GLP, unpublished	Yes	Bayer Crop Science	**1**
KIIIA 5.2.4 /02	Schulz, F.	2008	Determination of prothioconazole-desthio (SXX 0665) in formulations ; assay HPLC-MS/MS, external standard Bayer CropScience, Report No.: 2001-0051701-01, Edition Number: M-078059-01-2 Date: 2001-10-22 GLP/GEP: no, unpublished **CONFIDENTIAL**	No	Bayer Crop Science	**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	Odendahl, A.; Schulz, F.	2008	Validation of HPLC-MS/MS - method 2001-0051701-01 - Determination of prothioconazole-desthio in formulations - bixafen + prothioconazole EC 225 (75+150 g/L) Bayer CropScience, Report No.: VB3-2001-0051701, Edition Number: M-296913-03-1 Date: 2008-01-30 GLP/GEP: no, unpublished **CONFIDENTIAL**	No	Bayer Crop Science	**1**
KIIIA 5.2.4 /04	Schulz, F.	2008	Determination of the impurity toluene in formulations ; assay - GLC, internal standard Bayer CropScience, Report No.: AM012408MF2, Edition Number: M-319820-02-1 Date: 2008-12-04 **...Amended: 2009-04-14** GLP/GEP: no, unpublished **CONFIDENTIAL**	No	Bayer Crop Science	**1**
KIIIA 5.2.4 /05	Odendahl, A.; Schulz, F.	2009	Validation of GLC-method AM012408MF2 - Determination of the impurity toluene in formulations - bixafen + prothioconazole EC 225 (75+150 g/L) BCS, Report No.: VB2-AM012408MF2, Edition Number: M-346632-01-1 Date: 2009-04-28 GLP/GEP: no, unpublished **CONFIDENTIAL**	No	Bayer Crop Science	**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 *
	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 ! EFSA-Q-2011-01192 ASB2012-14631			
	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: Yes Published: No BVL-2456930, ASB2013-9506	Yes	BAY	Add
	United Kingdom	2004	Prothioconazole: (Draft Assessment Report) Vol. 1-4 GLP: Open Published: Yes ASB2010-10593	Open		Add
	United Kingdom	2011	Bixafen: Draft Assessment Report (DAR) ASB2011-11716			Add
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: Yes Published: No BVL-2295388, ASB2009-5831	Yes	BAY	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: Yes Published: No BVL-2295384, ASB2009-5827	Yes	BAY	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: Yes Published: No BVL-2295383, ASB2009-5826	Yes	BAY	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.; 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: Yes Published: No BVL-2295387, ASB2009-5830	Yes	BAY	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: Yes Published: No BVL-2291527, MET2002-403	Yes	BAY	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: Yes Published: No BVL-2295385, ASB2009-5828	Yes	BAY	N
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: Yes Published: No BVL-2291539, MET2002-404	Yes	BAY	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: Yes Published: No BVL-2291524, MET2002-397	Yes	BAY	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: Yes Published: No BVL-2291536, MET2002-398	Yes	BAY	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: Yes Published: No BVL-2291537, MET2002-399	Yes	BAY	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	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: Yes Published: No BVL-2291534, MET2002-400	Yes	BAY	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: Yes Published: No BVL-2291525, MET2002-401	Yes	BAY	Y
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: Yes Published: No BVL-2295382, ASB2009-5825	Yes	BAY	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: No Published: No BVL-2291540, MET2005-324	Yes	BAY	N
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: Yes Published: No BVL-2295380, ASB2009-5823	Yes	BAY	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: Yes Published: No BVL-2295386, ASB2009-5829	Yes	BAY	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: Yes Published: No BVL-2295381, ASB2009-5824	Yes	BAY	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	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: Yes Published: No BVL-2291535, MET2002-402	Yes	BAY	Y
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: Yes Published: No BVL-2283225, BVL-2295523, ASB2011-13494	Yes	BAY	Y
KIIA 4.3, KIIIA1 5.3.1	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: Yes Published: No BVL-2283223, BVL-2295522, ASB2010-11620	Yes	BAY	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: Yes Published: No BVL-2283231, BVL-2295526, ASB2008-6472	Yes	BAY	Y
KIIA 4.3, KIIIA1 5.3.1	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: Yes Published: No BVL-2283227, BVL-2295524, ASB2008-275	Yes	BAY	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: Yes Published: No BVL-2283229, BVL-2295525, ASB2008-276	Yes	BAY	Y
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: Yes Published: No BVL-2295390, ASB2009-5834	Yes	BAY	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: Yes Published: No BVL-2295391, ASB2009-5835	Yes	BAY	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: Yes Published: No BVL-2291544, MET2002-405	Yes	BAY	Y
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: Yes Published: No BVL-2291545, MET2002-406	Yes	BAY	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: Yes Published: No BVL-2291543, MET2002-407	Yes	BAY	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: Yes Published: No BVL-2295389, BVL-2295393, ASB2009-5833	Yes	BAY	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, 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: Yes Published: No BVL-2283232, BVL-2291546, MET2005-358	Yes	BAY	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: Yes Published: No BVL-2295392, ASB2009-5837	Yes	BAY	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: Yes Published: No BVL-2291528, MET2002-411	Yes	BAY	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: Yes Published: No BVL-2283234, BVL-2291531, MET2005-359	Yes	BAY	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: Yes Published: No BVL-2295394, ASB2009-5838	Yes	BAY	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: Yes Published: No BVL-2291530, MET2002-408	Yes	BAY	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: Yes Published: No BVL-2291541, MET2005-361	Yes	BAY	Y
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: Yes Published: No BVL-2283237, BVL-2291532, MET2005-360	Yes	BAY	N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
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: No Published: No BVL-2291529, MET2002-409	Yes	BAY	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: No Published: No BVL-2291533, MET2002-410	Yes	BAY	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: Yes Published: No BVL-2289278, RIP2002-1041	Yes	BAY	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: Yes Published: No BVL-2289328, ASB2009-5940	Yes	BAY	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: Yes Published: No BVL-2289288, RIP2002-1046	Yes	BAY	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 1.1 Analytical methods for bixafen

A 1.1.1 Extraction efficiency of enforcement methods for foodstuff

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 the proposed monitoring method for plant matrices of Bardel & Schöning, 2006.

Results and discussions

The extraction efficiency is expressed as the amount of total toxic residues (TRR) extracted by the residue analytical method compared to 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 method 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

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 standard is used for calibration.

Results and discussions

Table A 1: Recovery results from method validation of prothioconazole-desthio using the 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
Acidic- citrus fruit	0.01 0.1	5 5	104 96	3.3 7.0	m/z 312→70
Acidic- citrus fruit	0.01 0.1	5 5	109 98	7.8 5.7	m/z 312→125
High water content-peas fruit	0.01 0.1	5 5	107 99	7.0 2.2	m/z 312→70
High water content-peas fruit	0.01 0.1	5 5	100 109	5.4 3.0	m/z 312→125
Fatty- rape seed	0.01	5	97	7.1	m/z 312→70

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery (%)	RSD (%)	Comments
	0.1	5	95	5.6	
Fatty- rape seed	0.01 0.1	5 5	96 95	4.7 6.4	m/z 312→125
Dry- wheat grain	0.01 0.1	5 5	99 96	2.6 3.6	m/z 312→70
Dry- wheat grain	0.01 0.1	5 5	97 92	5.0 2.6	m/z 312→125
High water content – corn green material	0.01 0.1		115 100	4.2 2.1	m/z 312→70
High water content – corn green material	0.01 0.1		107 96	5.2 2.0	m/z 312→125

Table A 2: 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 (duplicated points) or 5 levels (single points)? (yes/ no)	Yes	
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 1.2.2.1 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 3: Recovery results from method validation of prothioconazole-desthio using the 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	92 97	6.3 9.2	m/z 312→70
Milk	0.01 0.1	5 5	91 95	5.1 8.0	m/z 312→125
Meat	0.01 0.1	5 5	92 91	7.4 7.0	m/z 312→70
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 91	4.3 5.6	m/z 312→70
Kidney	0.01 0.1	5 5	92 87	6.4 4.5	m/z 312→125
Liver	0.01 0.1	5 5	95 99	2.1 0.9	m/z 312→70
Liver	0.01 0.1	5 5	93 97	3.0 1.7	m/z 312→125
Fat	0.01 0.1	5 5	90 86	4.1 2.2	m/z 312→70

Fat	0.01 0.1	5 5	91 87	6.0 2.1	m/z 312→125
Egg	0.01 0.1	5 5	92 88	1.9 2.3	m/z 312→70
Egg	0.01 0.1	5 5	88 88	3.9 2.1	m/z 312→125

Table A 4: 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
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 5: 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	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 6: 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	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 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	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 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	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 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 (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 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) but not described because 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 given for milk. But 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. Because the validation of hydrolysis steps is not clearly defined in the SANCO/825/00 guideline, this point is of minor importance. Chromatograms for meat, eggs, fat and liver or kidney are presented in Amendment no. 1.

Comments of zRMS:	For deficiencies see above.

A 1.2.2.2 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 10: Recovery results from the independent laboratory validation of prothio-conazole-desthio in milk, meat, eggs using the 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
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→70
Milk	0.01 0.1	5 5	101 101	2 3	m/z 312→125
Eggs	0.01 0.1	5 5	90 87	1 4	m/z 312→70
Eggs	0.01 0.1	5 5	89 86	3 3	m/z 312→125

Table A 11: 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	Yes	Yes

absent (yes/no)		

Table A 12: 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 13: 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) but not described because not included in the residue definition. The study shows some deficiencies. Calibration graphs are only given for milk. But 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. Because the validation of hydrolysis steps is not clearly defined in the SANCO/825/00 guideline, this point is of minor importance.

Comments of zRMS:	Acceptable.

A 1.2.2.3 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 14: Recovery results from method validation of prothioconazole-desthio in meat, fat, liver, kidney and milk using the 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
Meat	0.01 0.1	5 5	92 91	3.1 1.6	m/z 312→125
Liver	0.01 0.1	5 5	87 88	3.5 2.4	m/z 312→70
Liver	0.01 0.1	5 5	86 88	3.0 3.3	m/z 312→125
Kidney	0.01	5	81	12.1	m/z 312→70

	0.1	5	90	5.2	
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	0.5 7.8	m/z 312→70
Fat	0.01 0.1	5 5	89 88	1.7 7.0	m/z 312→125
Milk	0.004 0.04	5 5	88 90	7.7 1.1	m/z 312→70
Milk	0.004 0.04	5 5	82 91	7.6 1.8	m/z 312→125

Table A 15: 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	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 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	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 17: 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	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 18: 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	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 19: 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 (e.g. in µg/ml or ng/µl)	0.04 – 8 ng/mL	0.04 – 8 ng/mL
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	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) but not described because not included in the residue definition.
The study shows some deficiencies. Calibration graphs are missing for fat, liver and kidney. But 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. Because the validation of hydrolysis steps is not clearly defined in the SANCO/825/00 guideline, this point is of minor importance. Chromatograms for liver and kidney are missing to prove the selectivity of method for these matrices.
No additional confirmatory method is necessary because two MS/MS transitions were validated.

Comments of zRMS:	For deficiencies see above.

A 1.2.2.4 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 20: Recovery results from the independent laboratory validation of prothioconazole-desthio in milk, meat, liver and fat using the 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

Milk	0.004 0.04	5 5	82 90	3 3	m/z 312→125
Meat	0.01 0.1	5 5	83 89	1 4	m/z 312→70
Meat	0.01 0.1	5 5	82 89	2 4	m/z 312→125
Liver	0.01 0.1	5 5	89 88	2 3	m/z 312→70
Liver	0.01 0.1	5 5	89 89	2 3	m/z 312→125
Fat	0.01 0.1	5 5	73 71	5 2	m/z 312→70
Fat	0.01 0.1	5 5	73 71	4 2	m/z 312→125

Table A 21: 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 (duplicated points) or 5 levels (single points)?	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 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	Yes
Assessment of matrix effects is presented (yes/no)	No	No

	Prothioconazole-desthio, m/z 312→70	**Prothioconazole-desthio, m/z 312→125**
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Table A 23: 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	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 24: 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	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) but not described because not included in the residue definition.
Nevertheless, the study shows some deficiencies. Calibration graphs are missing for fat, liver and meat. But this point is of minor importance because the slopes, the intercepts and the regression coefficients for all matrices are given. 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 this point is of minor importance.
No additional confirmatory method is necessary because two MS/MS transitions were validated.

Comments of zRMS:	Acceptable.

A 1.2.3 Description of Methods for the Analysis of Soil

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 JAU6476-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 25: 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 26: 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 27: 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	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 quantitation of prothioconazole-desthio residues in soil

	Prothioconazole-desthio, m/z 312→125	**Prothioconazole, 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	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

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 JAU6476-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 29: Recovery results from method validation of prothioconazole 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	0.05 0.5	5 5	10250 / 96.7 93968 / 96.9	3.4 2.6	m/z 344→326
Surface water	0.05 0.5	5 5	2188 / 98.3 20548 / 97.5	4.2 2.5	m/z 344→189

Table A 30: Recovery results from method validation of prothioconazole-desthio in soil 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	0.05 0.5	5 5	11176 / 95.6 119000 / 99.0	3.6 1.6	m/z 312→125
Surface water	0.05 0.5	5 5	17948 / 100 186113 / 99.4	0.6 2.0	m/z 312→70

Table A 31: 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=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	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 32: Characteristics for the analytical method used for the quantitation of prothioconazole-desthio residues in soil

	Prothioconazole-desthio, m/z 312→125	**Prothioconazole, 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	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 1.2.5.1 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 Heinemann, 2000 (MET2002-399) 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 amount of total toxic residues (TRR) 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 1.2.5.2 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 (MET2001-400) using acetonitrile/water as extraction solvent.

Results and discussions

The extraction efficiency is expressed as the amount of total toxic residues (TRR) extracted by the residue analytical method compared to the metabolism study. The three major compounds JAU6476-3-hydroxy-desthio, JAU6476-4-hydroxy-desthio and JAU6476-desthio were detected after hydrolysis. The recovery of the TTR was 79.6% for milk, between 88.0 % for muscle, 90.4 % for liver, 93.6 % for kidney and 112.2 % for fat.

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: Aviator Xpro

Active Substances: 75 g/L Bixafen

150 g/L Prothioconazole

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Bayer Crop Science AG

Date: 19 April 2016

Table of Contents

3 Mammalian Toxicology

3.1 Summary

Table 3.1-1: Information on Bixafen + Prothioconazole EC 225 *

Product name and code	Bixafen + Prothioconazole EC 225 (BIX + PTZ EC 225) / Aviator Xpro (BAY-18530-F-0-EC)
Formulation type	Emulsifiable concentrate (EC)
Active substance(s) (incl. content)	Bixafen; 75 g/L Prothioconazole; 150 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 Bixafen + Prothioconazole EC 225 can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

In accordance with Directives 67/548/EEC and 1999/45/EC and according to 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 Directives 67/548/EEC and 1999/45/EC	
Hazard symbol(s):	Xi
Indication(s) of danger:	Irritant
Risk phrases:	36
Safety phrases:	2-24-26-36-37-39-46
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use.
	'Contains prothioconazole-deschloro. May produce an allergic reaction.'

C&L according to Regulation (EC) No 1272/2008	
Hazard class(es), categories:	Eye Irrit. 2
Signal word:	Warning
Hazard statement(s):	H319
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	'Contains prothioconazole-deschloro. May produce an allergic reaction.' [EUH208]
	'15 percent of the mixture consist of ingredients of unknown inhalation toxicity.'

Table 3.1-3: Summary of risk assessment for operators, workers, bystanders and residents for Bixafen + Prothioconazole EC 225

	Result	**PPE / Risk mitigation measures**
Operators	Acceptable	- Avoid any unnecessary contact with the product. Misuse can lead to health damage. - The directive concerning requirements for personal protective gear in plant protection, "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety must be observed. - Wear tight fitting eye protection when handling the undiluted product. - Wear standard protective gloves (plant protection) when handling the undiluted product. - Wear standard protective gloves (plant protection) when handling/applying the product ready for application. - Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product. - Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when applying/handling the product ready for application. - Wear a rubber apron when handling the undiluted product.
Workers	Acceptable	- Treated areas/crops may not be entered until the spray coating has dried.
Bystanders	Acceptable	None
Residents	Acceptable	None

The risk assessment according to the German model has shown that the estimated operator exposure towards bixafen, prothioconazole and its metabolite prothioconazole-desthio in Bixafen + Prothioconazole EC 225 will not exceed the particular systemic AOEL, if PPE is worn. The risk assessment according to the UK-POEM has shown that the estimated operator exposure towards bixafen, prothioconazole and its metabolite prothioconazole in Bixafen + Prothioconazole EC 225 will exceed the particular systemic AOEL for prothioconazole-desthio even if gloves are worn during mixing/loading and application. However, according to exposure data submitted by the applicant the exposure to prothioconazole and prothioconazole-desthio will be below the particular systemic AOEL provided that gloves and workwear plus sturdy footwear are worn during mixing/loading and application and vehicles with closed cabins are used during application of the product.

No unacceptable risk was identified for workers, bystanders and residents.

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))	**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**	**critical gap for operator, worker, bystander or resident exposure**	**Operator**	**Worker**	**Bystander**	**Residents**
Cereals	F	Spraying, LCTM	2	a) Bixafen: 0.09375 kg/ha; Prothioconazole: 0.1875 kg/ha b) Bixafen: 0.1875 kg/ha; Prothioconazole: 0.3125 kg/ha	150-400					

	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
[3] LC: low crops, TM: tractor-mounted

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 the following tables.

Table 3.2-1: Information on bixafen

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 Dir. 67/548/EEC)	Regulation (EC) No 1272/2008 (Table 3.2): substance not listed up to and including 1st ATP Proposal Germany: none additional
with regard to toxicological data (according to the criteria in Reg. 1272/2008)	Regulation (EC) No 1272/2008 (Table 3.1): substance not listed up to and including 1st ATP Proposal Germany: none additional

Table 3.2-2: Information on prothioconazole

Reference doses		
	Value	Source
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 Dir. No 67/548/EEC, as amended)	**Prothioconazole:** Regulation (EC) No 1272/2008 (as amended): substance not listed Proposal EU Peer Review (EFSA Scientific Report (2007) 106, 1-98): Irritant, R43 Harmful, Repr. 3, R63 Proposal Germany: Harmful, Repr. 3, R63 **Impurity: deschloro prothioconazole:** Regulation (EC) No 1272/2008 (as amended): substance not listed Proposal Germany: Irritant, R43 **Prothioconazole metabolite JAU 6476-desthio:** Regulation (EC) No 1272/2008 (as amended): substance not listed Proposal EU Peer Review (EFSA Scientific Report (2007) 106, 1-98): Toxic, Repr. 2, R61 Proposal Germany: none additional
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 Germany: Warning, Repr.2, H361d **Impurity: deschloro prothioconazole:** Regulation (EC) No 1272/2008 (as amended): substance not listed Proposal Germany: Warning, Skin Sens. 1, H317 **Prothioconazole metabolite JAU 6476-desthio:** Regulation (EC) No 1272/2008 (as amended): substance not listed Proposal Germany: Danger, Repr. 1B, H360D

3.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for Bixafen + Prothioconazole EC 225 is given in Table 3.3-1. Full summaries of studies on the product are presented in Appendix 2. MSDS on Bixafen + Prothioconazole EC 225 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 Bixafen + Prothioconazole EC 225

Type of test, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Dir. 67/548/EEC)	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD_{50} oral, rat (OECD 425)	> 2000 mg/kg bw	Yes	None	None	[redacted], 2007

LD_{50} dermal, rat (OECD 402)	> 2000 mg/kg bw	Yes	None	None	[redacted], 2007
LC_{50} inhalation, rat	Not submitted, not necessary. Justification presented in Annex 2. Bixafen: LC50 (rat) > 5.38 mg/L air Prothioconazole: LC50 (rat) > 4.99 mg/L air Prothioconazole-desthio (prothioconazole metabolite): LC50 (rat) > 5.08 mg/L air				
Skin irritation, rabbit (OECD 404)	Non-irritant	Yes	None	None	[redacted], 2007
Eye irritation, rabbit (OECD 405)	Irritant	Yes	Xi; R36	Warning; H319	[redacted], 2007
Skin sensitisation, mouse (OECD 429, LLNA)	Non-sensitising	Yes	None	None	[redacted], 2007
Supplementary studies for combinations of plant protection products	No data – not required				

Table 3.3-2: Additional toxicological information relevant for classification/labelling of Bixafen + Prothioconazole EC 225

	Substance (Concentration in product, % w/w)	**Classification of the substance (acc. to the criteria in Dir. 67/548/EEC and/or in Reg. 1272/2008)**	**Reference**	**Classification of product (acc. to the criteria in Dir. 67/548/EEC, in Dir. 1999/45/EC and/or in Reg. 1272/2008)**
Toxicological properties of active substance(s) (relevant for classification of product)	Prothioconazole (14.85 % (w/w))	R63 (≥ 5 % (w/w)) H361d (≥ 3 % (w/w))	BfR proposal in accordance with EFSA conclusion on prothioconazole	(R63) [1)] (H361d) [1)]
Toxicological properties of non-active substance(s) (relevant for classification of product)	Impurity prothioconazole-deschloro (2-[2-(1-chlorocyclopropyl)-2-hydroxy-3-phenylpropyl]-2,4-dihydro-3H-1,2,4-triazole-3-thione) (0.23 % (w/w))	R43 (≥ 0.1 % (w/w)) H317; EUH208 (≥ 0.1 % (w/w))	BfR proposal in accordance with EFSA conclusion on prothioconazole	'Contains prothioconazole-deschloro. May produce an allergic reaction.' [2)] EUH208 [2)]
Further toxicological information	No data – not required			

[1)] up to now no legal classification – not considered for classification of product

[2)] up to now no legal classification but unequivocal results in animal study, therefore used for classification of the product

3.4 Dermal Absorption

A summary of the dermal absorption endpoints for the active substances in Bixafen + Prothioconazole EC 225 are presented in Table 3.4-1.

Table 3.4-1: Dermal absorption endpoints for active substances in Bixafen + Prothioconazole EC 225

	Bixafen		Prothioconazole		Prothioconazole-desthio	
	Value	**Reference**	**Value**	**Reference**	**Value**	**Reference**
Concentrate	1 %	EFSA Conclusion (EFSA Journal 2012;10(11):2917)	25 %	Default (EFSA Journal 2012)	75 %	Default * (EFSA Journal 2012)
Dilution	4 %	EFSA Conclusion (EFSA Journal 2012;10(11):2917)	75 %	Default (EFSA Journal 2012)	75 %	Default (EFSA Journal 2012)

* worst case, because concentration of prothioconazole-desthio after conversion of prothioconazole unknown

3.4.1 Justification for proposed values - Bixafen

The proposed endpoint for bixafen is based on a dermal absorption study on a formulation similar to Bixafen + Prothioconazole EC 225 (same co-formulants but without prothioconazole). The study is summarized in Table 3.4-2. No detailed summary is provided as the study has already been assessed and accepted at EU level.

Table 3.4-2: Summary of dermal absorption studies for bixafen

Formulation in study	**Concentrate Spray dilution**	**Test, Reference**	**Acceptability of study**	**Justification provided on representativity of study formulation for current product**	**Acceptability of justification**
EC 125 formulation	1 % for the concentrate (applied dose appr. 1.25 mg/cm^2) and 4 % for the dilution (applied dose appr. 0.0063 mg/cm^2)	*in vitro* human skin (Rascle, 2008)* ASB2009-5918	Yes	Not required	Endpoint can be used for current product

* study was reviewed at EU level

3.4.2 Justification for proposed values - Prothioconazole

No data on the dermal absorption for prothioconazole and prothioconazole-desthio in an EC formulation like Bixafen + Prothioconazole EC 225 are available. Justification for default values according to Guidance on Dermal Absorption (EFSA Journal 2012; 10(4):2665) are presented in Table 3.4-3 and Table 3.4-4.

Table 3.4-3: Default dermal absorption endpoints for prothioconazole

	Value	**Justification for value**	**Acceptability of justification**
Concentrate	25 %	product containing 150 g/kg active substance (> 50 g/kg)	no dermal absorption study on prothioconazole in EC formulation available and data on other formulation

Dilution	75 %	in use dilution containing 0.3125 g/L active substance (≤ 50 g/L)	types not applicable; default value used

Table 3.4-4: Default dermal absorption endpoints for prothioconazole-desthio

	Value	Justification for value	Acceptability of justification
Concentrate	75 %	worst case, because concentration of prothioconazole-desthio after conversion of prothioconazole unknown (≤ 50 g/kg)	no dermal absorption study on prothioconazole-desthio in EC formulation available and data on other formulation types not applicable; default value used
Dilution	75 %	in use dilution containing less than 50 g/L substance	

Dermal absorption data for prothioconazole and prothioconazole-desthio are available for an SC formulation containing 480 g/L prothioconaziole. The data cannot be used for the current product as the composition of both formulations differs substantially. Moreover, the concentration of prothioconazole-desthio in the spray solution will be below the tested concentration in the study (1.44 g/L). The studies are summarized in 3.4-5. No detailed summaries are provided as the studies have already been assessed and accepted at EU level.

Table 3.4-5: Summary of dermal absorption studies for prothioconazole / - desthio

Formulation in study	Concentrate Spray dilution	Test, Reference	Acceptability of study	Justification provided on representativity of study formulation for current product	Acceptability of justification
SC 480 formulation	3 % (applied dose appr. 5.32 µg/cm²) based on urinary and faecal excretion (prothioconazole)	rhesus monkey *in vivo* ([redacted], 2005)* ASB2007-5082	Yes	SC formulation, not EC formulation like product under evaluation	Endpoint cannot be used for current product
SC 480 formulation	20 % (applied dose appr. 6.13 µg/cm²) based on urinary and faecal excretion (desthio)	rhesus monkey *in vivo* ([redacted], 2003)* TOX2005-300	Yes	SC formulation, not EC formulation like product under evaluation	Endpoint cannot be used for current product

* study was reviewed at EU level

3.5 Exposure Assessment of Plant Protection Product

Table 3.5-1: Product information and toxicological reference values used for exposure assessment

Product name and code	Bixafen + Prothioconazole EC 225 (BIX + PTZ EC 225) / Aviator Xpro (BAY-18530-F-0-EC)		
Formulation type	Emulsifiable concentrate (EC)		
Category	Fungicide		
Container size(s), short description	1 L bottle (50 mm opening); 5L or 15 L bottle (63 mm opening)		
Active substance(s)	**Bixafen**	**Prothioconazole**	**Prothioconazole-desthio**

(incl. content)	75 g/L	150 g/L	(prothioconazole metabolite)
AOEL systemic	0.13 mg/kg bw/d	0.2 mg/kg bw/d	0.01 mg/kg bw/d
Inhalative absorption	100 %	100 %	100 %
Oral absorption	100 %	100 %	100 %
Dermal absorption	Concentrate: 1 % Dilution: 4 % (Dilution rate: 1:200) Bixafen EC 125	Concentrate: 25 % Dilution: 75 % Default *	Concentrate: 75 % ('worst-case') Dilution: 75 % Default *

* no dermal absorption data for this formulation or similar formulation available

3.5.1 Selection of critical use and justification

The critical GAP used for the exposure assessment of the plant protection product is shown in Table 3.1-4.

3.5.2 Operator exposure

3.5.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of Bixafen + Prothioconazole EC 225 according to the critical use is presented in Table 3.5-2. Outcome of the estimation is presented in Table 3.5-3. Detailed calculations are given in Appendix 3.

Table 3.5-2: Exposure models for intended uses

Critical use(s)	Cereals (max. 1.25 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]
Critical use(s)	Cereals (max. 1.25 L product/ha)
Model(s)	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 3.5-3: Estimated operator exposure

		Bixafen		Prothioconazole		Prothioconazole-desthio	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/ day)**	**% of systemic AOEL**	**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: 0.09375 kg bixafen/ha + 0.1875 kg prothioconazole/ha + 0.09375 kg prothioconazole-desthio/ha [1)]							
German Model (Geometric mean) Body weight: 70 kg	no PPE [2)]	0.0029	2.2	0.1142	57.1	0.0892	892.4
	gloves m/l+ appl. and coverall appl.	0.0002	0.2	0.0062	3.1	0.0034	34.1
UK POEM (Application volume: 150 L/ha Container: 5 L [4)] Body weight: 60 kg	no PPE [3)]	0.0196	15.0	0.7317	365.9	0.4471	4471.1
	gloves m/l+ appl.	0.0035	2.7	0.1102	55.1	0.0632	632.0

1) risk assessment based on an assumed conversion of prothioconazole to prothioconazole-desthio of 50% ('worst case', see summary of field studies, Appendix 4)

2) no PPE: Operator wearing T-shirt and shorts

3) no PPE: Operator wearing long sleeved shirt, long trousers ("permeable") but no gloves

4) Based on the work rate of 50 ha/day and the proposed maximum application rate of 1.25 L product /ha, the amount of product required to treat 50 hectares would be 62.5 litres. It is unrealistic to consider that a 1 litre container would be used throughout a full working day of boom spraying as this would require 63 separate pouring operations/day. Therefore, the 5 litre container gives the realistic worst case dermal exposure during mixing/loading

3.5.2.2 Measurement of operator exposure

Three operator exposure studies were conducted to determine the exposure to prothioconazole and its metabolite prothioconazole-desthio 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). 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 prothioconazole-desthio 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 = 9.375 kg prothioconazole/day (50 ha)
BW:	body weight = 70 kg

The results for prothioconazole and prothioconazole-desthio are given in the tables below. The exposure to prothioconazole and its metabolite prothioconazole-desthio 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 0.6 % of the syst. AOEL, the actual exposure for prothioconazole-desthio amounts to 13.5 % of the syst. AOEL.

Table 3.5-4: 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	1.0875	0.81563	
$D_{potential\ hands}$	1.06	9.9375	7.45313	
$D_{potential}$	1.176	11.025	8.26875	**59.06**
$D_{actual\ body}$	0.010	0.09375	0.07028	
$D_{actual\ hands}$	0.002	0.01875	0.01406	
D_{actual} *	0.012	0.1125	0.08438	**0.60**
I_m	0.00022	0.00206	0.00206	
I_a	0.00031	0.00291	0.00291	
I	0.00053	0.00497	0.00497	**0.04**
Total (potential)				**59.1**
Total (actual)				**0.6**

* protective gloves and one layer of workwear and sturdy footwear during mixing/loading and application, closed cabin during application

Table 3.5-5: Estimated operator exposure to prothioconazole-desthio (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	2.35313	1.76484	**252.12**
D_{actual} *	0.013	0.12188	0.09140	**13.06**
$I_{m/a}$	0.00034	0.00319	0.00319	**0.46**
Total (potential)				**252.6**
Total (actual)				**13.5**

* protective gloves and one layer of workwear and sturdy footwear during mixing/loading and application; closed cabin during application

3.5.3 Worker exposure

3.5.3.1 Estimation of worker exposure

Table 3.5-6 shows the exposure model used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with Bixafen + Prothioconazole EC 225 according to the critical use. Outcome of the estimation is presented in Table 3.5-7. Detailed calculations are in Appendix 3.

Table 3.5-6: Exposure models for intended uses

Critical use(s)	Cereals (max. 2 x 1.25 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 3.5-7: Estimated worker exposure

		Bixafen		Prothioconazole		Prothioconazole-desthio	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**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 0.09375 kg bixafen/ha + 2 x 0.1875 kg prothioconazole/ha + 2 x 0.09375 kg prothioconazole-desthio/ha [1)]							
2 hours/day [2)], TC: 1500 cm^2/person/h [3)] Body weight: 60 kg	no PPE [4)]	0.0004	0.3	0.0141	7.0	0.0070	70.3

1) risk assessment based on an assumed conversion of prothioconazole to prothioconazole-desthio of 50% (see summary of field studies, Appendix 4)
2) 2 h/day for professional applications for maintenance, inspection or irrigation activities etc.
3) US-EPA policy paper [EPA, Science Advisory Council for Exposure; 2000; Agricultural Default Transfer Coefficients, Policy # 003.1, May 7 1998 revised 7 August 2000].
4) no PPE: Worker wearing long sleeved shirt, long trousers ("permeable") but no gloves

3.5.3.2 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, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

3.5.4 Bystander and resident exposure

3.5.4.1 Estimation of bystander and resident exposure

Table 3.5-8 shows the exposure model used for estimation of bystander and resident exposure to bixafen, prothioconauole and prothioconazole-desthio. Outcome of the estimation is presented in Table 3.5-9. Detailed calculations are given in Appendix 3.

Table 3.5-8: Exposure models for intended uses

Critical use(s)	Cereals (max. 2 x 1.25 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 3.5-9: Estimated bystander and resident exposure

	Bixafen		Prothioconazole		Prothioconazole-desthio	
Model data	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**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: 2 x 0.09375 kg bixafen/ha + 2 x 0.1875 kg prothioconazole/ha + 2 x 0.09375 kg prothioconazole-desthio/ha [1)]						
Bystanders (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.00017	0.1	0.00649	3.2	0.00325	32.5
Bystanders (children) Drift rate: 2.77 % (1 m) Body weight: 16.15 kg	0.00014	0.1	0.00507	2.5	0.00253	25.3
Residents (adult) Drift rate: 2.38 % (1 m) Body weight: 60 kg	0.00002	0.02	0.00081	0.4	0.00041	4.1
Residents (children) Drift rate: 2.38 % (1 m) Body weight: 16.15 kg	0.00010	0.1	0.00122	0.6	0.00061	6.1

1) risk assessment based on an assumed conversion of prothioconazole to prothioconazole-desthio of 50% (see summary of field studies, Appendix 4)

3.5.4.2 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, prothioconazole and its metabolite prothioconazole-desthio 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.

3.5.5 Statement on combined exposure

The product is a mixture of two active substances (see confidential part).

The combined toxicological effect of these active substances has not been investigated, since no harmonized evaluation concept is available on EU-level.

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 *
KIIIA1 7.1.1	[redacted]	2007	Bixafen & Prothioconazole EC 75 + 150: Acute toxicity in the rat after oral administration AT04095 ! T0077844 ! M-292722-01-1 GLP: Yes Published: No BVL-2283338, ASB2009-5913	Yes	BAY	Y
KIIIA1 7.1.2	[redacted]	2007	Bixafen & Prothioconazole EC 75 + 150: Acute toxicity in the rat after dermal application AT04096 ! T2077846 ! M-292717-01-1 GLP: Yes Published: No BVL-2283340, ASB2009-5914	Yes	BAY	Y
KIIIA1 7.1.4	[redacted]	2007	Bixafen & Prothioconazole EC 75 + 150: Acute skin irritation/corrosion on rabbits AT04080 ! T7077580 ! M-292508-01-1 GLP: Yes Published: No BVL-2283342, ASB2009-5915	Yes	BAY	Y
KIIIA1 7.1.5	[redacted]	2007	Bixafen & Prothioconazole EC 75 + 150: Acute eye irritation on rabbits AT04081 ! T8077581 ! M-292511-01-1 GLP: Yes Published: No BVL-2283344, ASB2009-5916	Yes	BAY	Y
KIIIA1 7.1.6	[redacted]	2007	Bixafen + Prothioconazole EC 75 + 150: Evaluation of potential dermal sensitization in the local lymph node assay in the mouse SA07171 ! M-293215-01-1 GLP: Yes Published: No BVL-2283346, ASB2009-5917	Yes	BAY	Y
KIIIA1 7.3.3	Maasfeld, W.; Sutor, P.; Hamacher, G.	2009	Operator exposure and safety to Prothioconazole containing products in spray applications M-327173-01-1 GLP: No Published: No BVL-2283348, ASB2010-11547	No	BAY	Y
KIIIA1 7.6.2	Rascle, J.B.	2008	BYF 00587: Comparative in vitro dermal absorption study using human and rat skin BVL-2283352, ASB2009-5918		BAY	Y
KIIIA1 7.6	[redacted]	2005	A study to determine the dermal absorption of JAU 6476 SC 480 when administered dermally to male Rhesus monkeys BVL-2283350, ASB2007-5082		BAY	N
KIIA 5.8	[redacted]	2003	A study to determine the dermal absorption of [14C]SXX 0665 in SC 480 formulation when administered dermally to male Rhesus monkeys BVL-2289518, TOX2005-300		BAY	N

*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

The studies on acute oral and dermal toxicity and on irritation and sensitisation were performed with Bixafen + Prothioconazole EC 225 (BIX + PTZ EC 225). Thus, no bridging is necessary.

A 2.2 Acute oral toxicity

Comments of zRMS:	Acceptable (no deviations from below mentioned test guideline), used for evaluation

Reference: 7.1.1
Report: Bixafen & Prothioconazole EC 75+150: Acute toxicity in the rat after oral administration, [redacted], 2007, AT04095, ASB2009-5913
Guideline(s): OECD 425 (2006)
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	Bixafen & Prothioconazole EC 75+150 (2007-002622)
Species	Rat, Wistar (HsdCpb:Wu strain)
No. of animals (group size)	5 females (nulliparous, non-pregnant)
Dose(s)	2000 mg/kg bw
Exposure	Once by gavage
Vehicle/Dilution	Tap 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 & Prothioconazole EC 75+150

Dose [mg/kg bw]	**Toxicological results [1)]**	**Duration of signs**	**Time of death**	**LD_{50} [mg/kg bw] (14 days)**
Female rats				
2000	1/4/5	day 1 – day 2	day 2	> 2000

[1)] 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 & Prothioconazole EC 75+150

Mortality:	Mortality occurred.
Clinical signs:	The observed clinical signs were decreased motility, piloerection, temporary creeping gait and temporary tremor.

Body weight:	Body weight gain was considered to be normal.
Macroscopic examination:	In the animals that died during the observation period, the following changes were detected: light coloured, watery change-in-contents intestine and gas-filled stomach. The necropsy performed at the end of the post treatment observation period in the animals dosed with 2000 mg/kg bw revealed no particular findings.

Conclusion

Under the experimental conditions, the oral LD_{50} of Bixafen + Prothioconazole EC 225 is higher than 2000 mg/kg bw in rats. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

A 2.3 Acute percutaneous (dermal) toxicity

Comments of zRMS:	Acceptable (no deviations from below mentioned test guideline), used for evaluation

Reference: 7.1.2
Report: Bixafen & Prothioconazole EC 75+150: Acute toxicity in the rat after dermal administration, [redacted], 2007, AT04096, ASB2009-5914
Guideline(s): OECD 402 (1987), 67/548/EEC - method B.3.
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	Bixafen & Prothioconazole EC 75+150 (2007-002622)
Species	Rat, Wistar (HsdCpb:Wu strain)
No. of animals (group size)	5 males and 5 females (nulliparous, non-pregnant)
Dose(s)	2000 mg/kg bw
Exposure	24 hours (dermal, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 3: Results of acute dermal toxicity study in rats of Bixafen & Prothioconazole EC 75+150

Dose [mg/kg bw]	**Toxicological results [1)]**	**Duration of signs**	**Time of death**	**LD_{50} [mg/kg bw] (14 days)**
Male rats				
2000	0/0/5	--	--	> 2000
Female rats				

2000	0/2/5	day 3 – day 12	--	> 2000

[1)] 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 & Prothioconazole EC 75+150

Mortality:	No mortality occurred.
Clinical signs:	Local clinical signs were observed in two females: partial encrustation and partial formation of scale of the test area.
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 + Prothioconazole EC 225 is higher than 2000 mg/kg bw in rats. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

A 2.4 Acute inhalation toxicity

Testing is not triggered according to 94/79/EEC because this formulation

- is not a gas or liquefied gas,
- is not a smoke generating formulation or fumigant,
- is not to be used with fogging equipment,
- is not a vapour releasing preparation,
- is not an aerosol,
- is not a powder, is dust-free, and hence does not contain a significant proportion of particles of diameter < 50 µm (> 1 % on a weight basis),
- is not to be applied from aircraft,
- does not contain active substances with a vapour pressure > 1 x 10^{-2} Pa (vapour pressure bixafen: 4.6 x 10^{-8} Pa at 20°C; vapour pressure prothioconazole: < 4 x 10^{-7} Pa at 20°C)
- is not to be used in enclosed spaces such as warehouses or glasshouses

Therefore, there is no risk by the inhalation route which negates the need for an acute inhalation study in compliance with animal welfare regulations.

Comments of zRMS:	Justification for waiving of the study acceptable.

A 2.5 Skin irritation

Comments of zRMS:	Acceptable (no deviations from below mentioned test guideline), used for evaluation

Reference: 7.1.4
Report: Bixafen & Prothioconazole EC 75+150: Acute skin irritation/corrosion on rabbits, [redacted], 2007, AT04080, ASB2009-5915
Guideline(s): OECD 404 (2002), 67/548/EEC - method B.4., EPA OPPTS 870.2500
Deviations: No

GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	Bixafen & Prothioconazole EC 75+150 (2007-002622)
Species	Rabbit, New Zealand White
No. of animals (group size)	3 females (nulliparous, non-pregnant)
Initial test using one animal	Yes
Exposure	0.5 mL (4 hours, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 5: Skin irritation of Bixafen & Prothioconazole EC 75+150

Animal No.		**Scores after treatment [1)]**				**Mean scores (24-72 h)**	**Reversible [day]**
		1 h	**24 h**	**48 h**	**72 h**		
1	Erythema Oedema	2 1	3 2	3 2	1 1	2.3 1.7	7 7
2	Erythema Oedema	1 0	1 0	1 0	1 0	1.0 0.0	7 -
3	Erythema Oedema	0 0	1 0	1 0	1 0	1.0 0.0	7 -

[1)] scores in the range of 0 to 4

Clinical signs:	None

Conclusion

Under the experimental conditions, Bixafen + Prothioconazole EC 225 is not a skin irritant. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

A 2.6 Eye irritation

Comments of zRMS:	Acceptable (no deviations from below mentioned test guideline), used for evaluation

Reference: 7.1.5
Report: Bixafen & Prothioconazole EC 75+150: Acute Eye Irritation on Rabbits, [redacted], 2007, AT04081, ASB2009-5916
Guideline(s): OECD 405 (2002), 67/548/EEC - method B.5., EPA OPPTS 870.2400
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	Bixafen & prothioconazole EC 75+150 (2007-002622)
Species	Rabbit, New Zealand White
No. of animals (group size)	3 females
Initial test using one animal	Yes
Exposure	0.1 mL (single instillation in conjunctival sac)
Irrigation (time point)	No
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 6: Eye irritation of Bixafen & Prothioconazole EC 75+150

Animal No.		Scores after treatment [1)]				Mean scores (24-72 h)	Reversible [day]
		1 h	24 h	48 h	72 h		
1	Corneal opacity	1	2	2	2	2.0	14
	Iritis	0	1	1	0	0.7	3
	Redness conjunctivae	2	3	3	2	2.7	14
	Chemosis conjunctivae	2	2	1	0	1.0	3
2	Corneal opacity	1	2	2	2	2.0	7
	Iritis	0	0	0	0	0.0	--
	Redness conjunctivae	2	3	3	2	2.7	7
	Chemosis conjunctivae	2	2	2	1	1.7	7
3	Corneal opacity	1	2	2	2	2.0	14
	Iritis	1	1	0	0	0.3	2
	Redness conjunctivae	2	2	2	2	2.0	14
	Chemosis conjunctivae	1	2	1	0	1.0	3

[1)] 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:	None

Conclusion

Under the experimental conditions, Bixafen + Prothioconazole EC 225 is an eye irritant. Thus, classification is required according to the classification criteria of Council Directive 67/548/EEC (Xi; R36) and subsequent regulations as well as according to Regulation (EC) No. 1272/2008 ('Warning', H319).

A 2.7 Skin sensitization

Comments of zRMS:	Acceptable (no deviations from below mentioned test guideline), used for evaluation

Reference: 7.1.6
Report: Bixafen + Prothioconazole EC 75+150: Evaluation of potential dermal sensitization in the local lymph node assay in the mouse, [redacted], 2007, SA 07171, ASB2009-5917
Guideline(s): OECD 429 (2002)
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	Bixafen + Prothioconazole EC 75+150 (2007-002622)
Species	Mouse (CBA/J strain)
No. of animals (group size)	Test substance group: 3 x 5 female mice Vehicle control goup: 5 female mice
Range finding:	Yes
Exposure (concentration(s), no. of applications)	2.5 %, 5 % and 10 %
Vehicle	1 % Pluronic Acid in water
Reliability check	Classical positive control substances routinely tested.
Remarks	No individual study results for positive control given.

Results and discussions

Table A 7: Results of skin sensitization study of Bixafen + Prothioconazole EC 75+150

	No. of animals	**Concentration [%]**	**DPM / group**	**Stimulation index (SI)**
Bixafen & prothioconazole EC 75+150	5	2.5	7086	1.8
	5	5	6731	1.7
	5	10	5257	1.3
Test Vehicle Control Group	5	0	3956	--

Clinical signs:	None

Conclusion

Under the experimental conditions, Bixafen + Prothioconazole EC 225 is not a skin sensitizer. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

A 2.8 Supplementary studies for combinations of plant protection products

None; not required.

A 2.9 Data on co-formulants

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

No new studies were submitted.

A 2.11 Other/Special Studies

None; not required.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations

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):	0.09375	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):	1	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	0.38	mg/person/kg a.s.
	4	% (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**		
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 0.09375 x 20 x 1%) / 70			(2.4 x 0.09375 x 20 x 0.01 x 1%) / 70		
External dermal exposure	4.5	mg/person	External dermal exposure	0.045	mg/person
External dermal exposure	0.064286	mg/kg bw/d	External dermal exposure	0.000643	mg/kg bw/d
Systemic dermal exposure	**0.000643**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000006**	**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 0.09375 x 20 x 4%) / 70			(0.38 x 0.09375 x 20 x 0.01 x 4%) / 70		
External dermal exposure	0.7125	mg/person	External dermal exposure	0.007125	mg/person
External dermal exposure	0.010179	mg/kg bw/d	External dermal exposure	0.000102	mg/kg bw/d
Systemic dermal exposure	**0.000407**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000004**	**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 0.09375 x 20 x 4%) / 70			(1.6 x 0.09375 x 20 x 0.05 x 4%) / 70		
External dermal exposure	3	mg/person	External dermal exposure	0.15	mg/person
External dermal exposure	0.042857	mg/kg bw/d	External dermal exposure	0.002143	mg/kg bw/d
Systemic dermal exposure	**0.001714**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000086**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$			$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$		
(0.06 x 0.09375 x 20 x 4%) / 70			(0.06 x 0.09375 x 20 x 4%) / 70		
External dermal exposure	0.1125	mg/person	External dermal exposure	0.1125	mg/person
External dermal exposure	0.001607	mg/kg bw/d	External dermal exposure	0.001607	mg/kg bw/d
Systemic dermal exposure	**0.000064**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000064**	**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	8.325	mg/person	Total external dermal exposure	0.314625	mg/person
Total external dermal exposure	0.118929	mg/kg bw/d	Total external dermal exposure	0.004495	mg/kg bw/d
Total systemic dermal exposure	**0.002829**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.000161**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in cereals					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M \times AR \times A \times IA) / BW$			$SIE_{OM} = (I_M \times AR \times A \times IA) / BW$		
(0.0006 x 0.09375 x 20 x 100%) / 70			(0.0006 x 0.09375 x 20 x 100%) / 70		
External inhalation exposure	0.001125	mg/person	External inhalation exposure	0.001125	mg/person
External inhalation exposure	0.000016	mg/kg bw/d	External inhalation exposure	0.000016	mg/kg bw/d
Systemic inhalation exposure	**0.000016**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000016**	**mg/kg bw/d**

Inhalation exposure during application					
$SIE_{OA} = (I_A \times AR \times A \times IA) / BW$			$SIE_{OA} = (I_A \times AR \times A \times IA) / BW$		
(0.001 x 0.09375 x 20 x 100%) / 70			(0.001 x 0.09375 x 20 x 100%) / 70		
External inhalation exposure	0.001875	mg/person	External inhalation exposure	0.001875	mg/person
External inhalation exposure	0.000027	mg/kg bw/d	External inhalation exposure	0.000027	mg/kg bw/d
Systemic inhalation exposure	**0.000027**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000027**	**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	0.003	mg/person	Total external inhalation exposure	0.003	mg/person
Total external inhalation exposure	0.000043	mg/kg bw/d	Total external inhalation exposure	0.000043	mg/kg bw/d
Total systemic inhalation exposure	**0.000043**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.000043**	**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	0.201	mg/person	Total systemic exposure	0.014235	mg/person
Total systemic exposure	**0.002871**	**mg/kg bw/d**	**Total systemic exposure**	**0.000203**	**mg/kg bw/d**
% of AOEL	**2.2**	**%**	**% of AOEL**	**0.2**	**%**

1) reduction factor for gloves is 0.01 (professional appl.)

2) reduction factor for protective garment is 0.05 (professional appl.)

Table A 10: Estimation of operator exposure towards bixafen using the UK-POEM (no PPE)

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)					
Active substance	**Bixafen**				
Product	Aviator Xpro				
Formulation type	organic solvent-based				
Concentration of a.s.	75	mg/mL			
Dose	1.25	L preparation/ha	(0.094 kg a.s./ha)		
Application volume	150	L/ha			
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Container	5 litres 45 or 63 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	1	%			
Dermal absorption from spray	4	%			
EXPOSURE DURING MIXING AND LOADING					
Container size	5	Litres			
Hand contamination/operation	0,01	mL			
Application dose	1.25	Litres product/ha			
Work rate	50	ha/day			
Number of operations	13	/day			
Hand contamination	0.13	mL/day			
Protective clothing	None				
Transmission to skin	100	%			
Dermal exposure to formulation	0.13	mL/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Application volume	150	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	0.13	mL/day	41.55	mL/day
Concen. of a.s. product or spray	75	mg/mL	0.625	mg/mL
Dermal exposure to a.s.	9.75	mg/day	25.969	mg/day
Percent absorbed	1	%	4	%
Absorbed dose	0.098	mg/day	1.039	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.01	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	0.625	mg/mL		
Inhalation exposure to a.s.	0.038	mg/day		
Percent absorbed	100	%		
Absorbed dose	0.038	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	1.174	mg/day		
Operator body weight	60	kg		
Operator exposure	0.02	mg/kg bw/day		
Amount of AOEL	**15.0**	**%**		

Table A 11: Estimation of operator exposure towards bixafen using the UK-POEM (gloves m/l +appl.)

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)					
Active substance	**Bixafen**				
Product	Aviator Xpro				
Formulation type	organic solvent-based				
Concentration of a.s.	75	mg/mL			
Dose	1.25	L preparation/ha	(0.094 kg a.s./ha)		
Application volume	150	L/ha			
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Container	5 litres 45 or 63 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	1	%			
Dermal absorption from spray	4	%			
EXPOSURE DURING MIXING AND LOADING					
Container size	5	Litres			
Hand contamination/operation	0,01	mL			
Application dose	1.25	Litres product/ha			
Work rate	50	ha/day			
Number of operations	13	/day			
Hand contamination	0.13	mL/day			
Protective clothing	Gloves				
Transmission to skin	10	%			
Dermal exposure to formulation	0.013	mL/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Application volume	150	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	0.013	mL/day	6.45	mL/day
Concen. of a.s. product or spray	75	mg/mL	0.625	mg/mL
Dermal exposure to a.s.	0.975	mg/day	4.031	mg/day
Percent absorbed	1	%	4	%
Absorbed dose	0.01	mg/day	0.161	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.01	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	0.625	mg/mL		
Inhalation exposure to a.s.	0.038	mg/day		
Percent absorbed	100	%		
Absorbed dose	0.038	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	0.209	mg/day		
Operator body weight	60	kg		
Operator exposure	0.003	mg/kg bw/day		
Amount of AOEL	**2.7**	**%**		

A 3.1.2 Calculations for prothioconazole

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):	0.1875	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 13: Estimation of operator exposure towards prothioconazole using the German model

Without PPE			**With PPE**		
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 0.1875 x 20 x 25%) / 70			(2.4 x 0.1875 x 20 x 0.01 x 25%) / 70		
External dermal exposure	9	mg/person	External dermal exposure	0.09	mg/person
External dermal exposure	0.128571	mg/kg bw/d	External dermal exposure	0.001286	mg/kg bw/d
Systemic dermal exposure	**0.032143**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000321**	**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 0.1875 x 20 x 75%) / 70			(0.38 x 0.1875 x 20 x 0.01 x 75%) / 70		
External dermal exposure	1.425	mg/person	External dermal exposure	0.01425	mg/person
External dermal exposure	0.020357	mg/kg bw/d	External dermal exposure	0.000204	mg/kg bw/d
Systemic dermal exposure	**0.015268**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000153**	**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 0.1875 x 20 x 75%) / 70			(1.6 x 0.1875 x 20 x 0.05 x 75%) / 70		

External dermal exposure	6	mg/person	External dermal exposure	0.3	mg/person
External dermal exposure	0.085714	mg/kg bw/d	External dermal exposure	0.004286	mg/kg bw/d
Systemic dermal exposure	**0.064286**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.003214**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)}$ x AR x A x DA) / BW			$SDE_{OA(C)} = (D_{A(C)}$ x AR x A x DA) / BW		
(0.06 x 0.1875 x 20 x 75%) / 70			(0.06 x 0.1875 x 20 x 75%) / 70		
External dermal exposure	0.225	mg/person	External dermal exposure	0.225	mg/person
External dermal exposure	0.003214	mg/kg bw/d	External dermal exposure	0.003214	mg/kg bw/d
Systemic dermal exposure	**0.002411**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.002411**	**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	16.65	mg/person	Total external dermal exposure	0.62925	mg/person
Total external dermal exposure	0.237857	mg/kg bw/d	Total external dermal exposure	0.008989	mg/kg bw/d
Total systemic dermal exposure	**0.114107**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.006099**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in cereals					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M$ x AR x A x IA) / BW			$SIE_{OM} = (I_M$ x AR x A x IA) / BW		
(0.0006 x 0.1875 x 20 x 100%) / 70			(0.0006 x 0.1875 x 20 x 100%) / 70		
External inhalation exposure	0.00225	mg/person	External inhalation exposure	0.00225	mg/person
External inhalation exposure	0.000032	mg/kg bw/d	External inhalation exposure	0.000032	mg/kg bw/d
Systemic inhalation exposure	**0.000032**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000032**	**mg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A$ x AR x A x IA) / BW			$SIE_{OA} = (I_A$ x AR x A x IA) / BW		
(0.001 x 0.1875 x 20 x 100%) / 70			(0.001 x 0.1875 x 20 x 100%) / 70		
External inhalation exposure	0.00375	mg/person	External inhalation exposure	0.00375	mg/person
External inhalation exposure	0.000054	mg/kg bw/d	External inhalation exposure	0.000054	mg/kg bw/d
Systemic inhalation exposure	**0.000054**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000054**	**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	0.006	mg/person	Total external inhalation exposure	0.006	mg/person
Total external inhalation exposure	0.000086	mg/kg bw/d	Total external inhalation exposure	0.000086	mg/kg bw/d
Total systemic inhalation exposure	**0.000086**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.000086**	**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	7.9935	mg/person	Total systemic exposure	0.432938	mg/person
Total systemic exposure	**0.114193**	**mg/kg bw/d**	**Total systemic exposure**	**0.006185**	**mg/kg bw/d**
% of AOEL	**57.1**	**%**	**% of AOEL**	**3.1**	**%**

1) reduction factor for gloves is 0.01 (professional appl.)

2) reduction factor for protective garment is 0.05 (professional appl.)

Table A 14: Estimation of operator exposure towards prothioconazole using the UK-POEM (no PPE)

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)			
Active substance	**Prothioconazole**		
Product	Aviator Xpro		
Formulation type	organic solvent-based		
Concentration of a.s.	150	mg/mL	
Dose	1.25	L preparation/ha	(0.188 kg a.s./ha)
Application volume	150	L/ha	
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Container	5 litres 45 or 63 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	5	Litres			
Hand contamination/operation	0,01	mL			
Application dose	1.25	Litres product/ha			
Work rate	50	ha/day			
Number of operations	13	/day			
Hand contamination	0.13	mL/day			
Protective clothing	None				
Transmission to skin	100	%			
Dermal exposure to formulation	0.13	mL/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Application volume	150	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	0.13	mL/day		41.55	mL/day
Concen. of a.s. product or spray	150	mg/mL		1.25	mg/mL
Dermal exposure to a.s.	19.5	mg/day		51.938	mg/day
Percent absorbed	25	%		75	%
Absorbed dose	4.875	mg/day		38.953	mg/day
INHALATION EXPOSURE DURING SPRAYING					
Inhalation exposure	0.01	mL/h			
Duration of exposure	6	h			
Concentration of a.s. in spray	1.25	mg/mL			
Inhalation exposure to a.s.	0.075	mg/day			
Percent absorbed	100	%			
Absorbed dose	0.075	mg/day			
PREDICTED EXPOSURE					
Total absorbed dose	43.903	mg/day			
Operator body weight	60	kg			
Operator exposure	0.732	mg/kg bw/day			
Amount of AOEL	**365.9**	**%**			

Table A 15: Estimation of operator exposure towards prothioconazole using the UK-POEM (gloves m/l + appl.)

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)			
Active substance	**Prothioconazole**		
Product	Aviator Xpro		
Formulation type	organic solvent-based		
Concentration of a.s.	150	mg/mL	
Dose	1.25	L preparation/ha	(0.188 kg a.s./ha)
Application volume	150	L/ha	
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Container	5 litres 45 or 63 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	5	Litres			
Hand contamination/operation	0,01	mL			
Application dose	1.25	Litres product/ha			
Work rate	50	ha/day			
Number of operations	13	/day			
Hand contamination	0.13	mL/day			
Protective clothing	Gloves				
Transmission to skin	10	%			
Dermal exposure to formulation	0.013	mL/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Application volume	150	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	0.013	mL/day		6.45	mL/day
Concen. of a.s. product or spray	150	mg/mL		1.25	mg/mL
Dermal exposure to a.s.	1.95	mg/day		8.063	mg/day
Percent absorbed	25	%		75	%
Absorbed dose	0.488	mg/day		6.047	mg/day
INHALATION EXPOSURE DURING SPRAYING					
Inhalation exposure	0.01	mL/h			
Duration of exposure	6	h			
Concentration of a.s. in spray	1.25	mg/mL			
Inhalation exposure to a.s.	0.075	mg/day			
Percent absorbed	100	%			
Absorbed dose	0.075	mg/day			
PREDICTED EXPOSURE					
Total absorbed dose	6.609	mg/day			
Operator body weight	60	kg			
Operator exposure	0.11	mg/kg bw/day			
Amount of AOEL	**55.1**	**%**			

A 3.1.3 Calculations for prothioconazole-desthio

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):	0.09375	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):	75	% (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.

* 50 % conversion of prothioconazole to prothioconazole-desthio assumed

Table A 17: Estimation of operator exposure towards prothioconazole-desthio using the German model

Without PPE			**With PPE**		
Operators: Systemic dermal exposure after application in cereals					
Dermal exposure during mixing/loading					
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)}$ x AR x A x DA) / BW			$SDE_{OM(H)} = (D_{M(H)}$ x AR x A x PPE [1)] x DA) / BW		
(2.4 x 0.09375 x 20 x 75%) / 70			(2.4 x 0.09375 x 20 x 0.01 x 75%) / 70		
External dermal exposure	4.5	mg/person	External dermal exposure	0.045	mg/person
External dermal exposure	0.064286	mg/kg bw/d	External dermal exposure	0.000643	mg/kg bw/d
Systemic dermal exposure	**0.048214**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000482**	**mg/kg bw/d**
Dermal exposure during application					
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)}$ x AR x A x DA) / BW			$SDE_{OA(H)} = (D_{A(H)}$ x AR x A x PPE [1)] x DA) / BW		
(0.38 x 0.09375 x 20 x 75%) / 70			(0.38 x 0.09375 x 20 x 0.01 x 75%) / 70		
External dermal exposure	0.7125	mg/person	External dermal exposure	0.007125	mg/person
External dermal exposure	0.010179	mg/kg bw/d	External dermal exposure	0.000102	mg/kg bw/d
Systemic dermal exposure	**0.007634**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000076**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)}$ x AR x A x DA) / BW			$SDE_{OA(B)} = (D_{A(B)}$ x AR x A x PPE [2)] x DA) / BW		
(1.6 x 0.09375 x 20 x 75%) / 70			(1.6 x 0.09375 x 20 x 0.05 x 75%) / 70		
External dermal exposure	3	mg/person	External dermal exposure	0.15	mg/person
External dermal exposure	0.042857	mg/kg bw/d	External dermal exposure	0.002143	mg/kg bw/d
Systemic dermal exposure	**0.032143**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001607**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)}$ x AR x A x DA) / BW			$SDE_{OA(C)} = (D_{A(C)}$ x AR x A x DA) / BW		
(0.06 x 0.09375 x 20 x 75%) / 70			(0.06 x 0.09375 x 20 x 75%) / 70		
External dermal exposure	0.1125	mg/person	External dermal exposure	0.1125	mg/person
External dermal exposure	0.001607	mg/kg bw/d	External dermal exposure	0.001607	mg/kg bw/d
Systemic dermal exposure	**0.001205**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001205**	**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	8.325	mg/person	Total external dermal exposure	0.314625	mg/person
Total external dermal exposure	0.118929	mg/kg bw/d	Total external dermal exposure	0.004495	mg/kg bw/d
Total systemic dermal exposure	**0.089196**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.003371**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in cereals					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M$ x AR x A x IA) / BW			$SIE_{OM} = (I_M$ x AR x A x IA) / BW		
(0.0006 x 0.09375 x 20 x 100%) / 70			(0.0006 x 0.09375 x 20 x 100%) / 70		
External inhalation exposure	0.001125	mg/person	External inhalation exposure	0.001125	mg/person
External inhalation exposure	0.000016	mg/kg bw/d	External inhalation exposure	0.000016	mg/kg bw/d
Systemic inhalation exposure	**0.000016**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000016**	**mg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A$ x AR x A x IA) / BW			$SIE_{OA} = (I_A$ x AR x A x IA) / BW		
(0.001 x 0.09375 x 20 x 100%) / 70			(0.001 x 0.09375 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.001875	mg/person	External inhalation exposure	0.001875	mg/person
External inhalation exposure	0.000027	mg/kg bw/d	External inhalation exposure	0.000027	mg/kg bw/d
Systemic inhalation exposure	**0.000027**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000027**	**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	0.003	mg/person	Total external inhalation exposure	0.003	mg/person
Total external inhalation exposure	0.000043	mg/kg bw/d	Total external inhalation exposure	0.000043	mg/kg bw/d
Total systemic inhalation exposure	**0.000043**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.000043**	**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	6.24675	mg/person	Total systemic exposure	0.238969	mg/person
Total systemic exposure	**0.089239**	**mg/kg bw/d**	**Total systemic exposure**	**0.003414**	**mg/kg bw/d**

% of AOEL	**892.4**	**%**	**% of AOEL**	**34.1**	**%**

1) reduction factor for gloves is 0.01 (professional appl.)
2) reduction factor for protective garment is 0.05 (professional appl.)

Table A 18: Estimation of operator exposure towards prothioconazole-desthio using the UK-POEM (no PPE)

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)					
Active substance	**Prothioconazole-desthio**				
Product	Aviator Xpro				
Formulation type	organic solvent-based				
Concentration of a.s.	75	mg/mL *			
Dose	1.25	L preparation/ha	(0.094 kg a.s./ha)		
Application volume	150	L/ha			
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Container	5 litres 45 or 63 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	75	%			
Dermal absorption from spray	75	%			
EXPOSURE DURING MIXING AND LOADING					
Container size	5	Litres			
Hand contamination/operation	0,01	mL			
Application dose	1.25	Litres product/ha			
Work rate	50	ha/day			
Number of operations	13	/day			
Hand contamination	0.13	mL/day			
Protective clothing	None				
Transmission to skin	100	%			
Dermal exposure to formulation	0.13	mL/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Application volume	150	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	0.13	mL/day		41.55	mL/day
Concen. of a.s. product or spray	75	mg/mL		0.625	mg/mL
Dermal exposure to a.s.	9.75	mg/day		25.969	mg/day
Percent absorbed	75	%		75	%
Absorbed dose	7.313	mg/day		19.477	mg/day
INHALATION EXPOSURE DURING SPRAYING					
Inhalation exposure	0.01	mL/h			
Duration of exposure	6	h			
Concentration of a.s. in spray	0.625	mg/mL			
Inhalation exposure to a.s.	0.038	mg/day			
Percent absorbed	100	%			
Absorbed dose	0.038	mg/day			

PREDICTED EXPOSURE		
Total absorbed dose	26.827	mg/day
Operator body weight	60	kg
Operator exposure	0.447	mg/kg bw/day
Amount of AOEL	**4471.1**	**%**

* 50 % conversion of prothioconazole to prothioconazole-desthio assumed

Table A 19: Estimation of operator exposure towards prothioconazole-desthio using the UK-POEM (gloves m/l + appl.)

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)					
Active substance	**Prothioconazole-desthio**				
Product	Aviator Xpro				
Formulation type	organic solvent-based				
Concentration of a.s.	75	mg/mL *			
Dose	1.25	L preparation/ha	(0.094 kg a.s./ha)		
Application volume	150	L/ha			
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Container	5 litres 45 or 63 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	75	%			
Dermal absorption from spray	75	%			
EXPOSURE DURING MIXING AND LOADING					
Container size	5	Litres			
Hand contamination/operation	0,01	mL			
Application dose	1.25	Litres product/ha			
Work rate	50	ha/day			
Number of operations	13	/day			
Hand contamination	0.13	mL/day			
Protective clothing	Gloves				
Transmission to skin	10	%			
Dermal exposure to formulation	0.013	mL/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Application volume	150	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	0.013	mL/day		6.45	mL/day
Concen. of a.s. product or spray	75	mg/mL		0.625	mg/mL
Dermal exposure to a.s.	0.975	mg/day		4.031	mg/day
Percent absorbed	75	%		75	%
Absorbed dose	0.731	mg/day		3.023	mg/day
INHALATION EXPOSURE DURING SPRAYING					
Inhalation exposure	0.01	mL/h			
Duration of exposure	6	h			
Concentration of a.s. in spray	0.625	mg/mL			

Inhalation exposure to a.s.	0.038	mg/day
Percent absorbed	100	%
Absorbed dose	0.038	mg/day
PREDICTED EXPOSURE		
Total absorbed dose	3.792	mg/day
Operator body weight	60	kg
Operator exposure	0.063	mg/kg bw/day
Amount of AOEL	**632.0**	**%**

* 50 % conversion of prothioconazole to prothioconazole-desthio assumed

A 3.2 Worker exposure calculations

A 3.2.1 Calculations for bixafen

Table A 20: 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):	0.09375	kg a.s./ha	**Transfer coefficient (TC):**	1500	cm²/person/h
Number of applications (NA):	2		**Work rate per day (WR):**	2	h/d
Body weight (BW):	60	kg/person	**PPE**	5	%
Dermal absorption (DA):	4	% ('worst case')			
AOEL	0.13	mg/kg bw/d			

Table A 21: Estimation of worker exposure towards bixafen using the German re-entry model

Without PPE [1)]			**With PPE**		
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 PPE x DA) / BW		
(1 x 1500 x 2 x 0.09375 x 2 x 4%) / 60			(1 x 1500 x 2 x 0.09375 x 2 x 5% x 4%) / 60		
External dermal exposure	0.5625	mg/person	External dermal exposure	0.028125	mg/person
External dermal exposure	0.009375	mg/kg bw/d	External dermal exposure	0.000469	mg/kg bw/d
Total systemic exposure	0.0225	mg/person	Total systemic exposure	0.001125	mg/person
Total systemic exposure	**0.000375**	**mg/kg bw/d**	**Total systemic exposure**	**0.000019**	**mg/kg bw/d**
% of AOEL	**0.3**	**%**	**% of AOEL**	**0.01**	**%**

[1)] acceptable without PPE: Worker wearing long sleeved shirt, long trousers (“permeable”) but no gloves (allocation of BVL code SF245-01 for spray applications)

A 3.2.2 Calculations for prothioconazole

Table A 22: 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):	0.1875	kg a.s./ha	**Transfer coefficient (TC):**	1500	cm²/person/h
Number of applications (NA):	2		**Work rate per day (WR):**	2	h/d
Body weight (BW):	60	kg/person	**PPE**	5	%
Dermal absorption (DA):	75	% ('worst case')			
AOEL	0.2	mg/kg bw/d			

Table A 23: Estimation of worker exposure towards prothioconazole using the German re-entry model

Without PPE [1)]	**With PPE**
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 PPE x DA) / BW
(1 x 1500 x 2 x 0.1875 x 2 x 75%) / 60	(1 x 1500 x 2 x 0.1875 x 2 x 5% x 75%) / 60

External dermal exposure	1.125	mg/person	External dermal exposure	0.05625	mg/person
External dermal exposure	0.01875	mg/kg bw/d	External dermal exposure	0.000938	mg/kg bw/d
Total systemic exposure	0.84375	mg/person	Total systemic exposure	0.042188	mg/person
Total systemic exposure	**0.014063**	**mg/kg bw/d**	**Total systemic exposure**	**0.000703**	**mg/kg bw/d**
% of AOEL	**7**	**%**	**% of AOEL**	**0.4**	**%**

1) acceptable without PPE: Worker wearing long sleeved shirt, long trousers ("permeable") but no gloves (allocation of BVL code SF245-01 for spray applications)

A 3.2.3 Calculations for prothioconazole-desthio

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):	0.09375	kg a.s./ha *	**Transfer coefficient (TC):**	1500	cm²/person/h
Number of applications (NA):	2		**Work rate per day (WR):**	2	h/d
Body weight (BW):	60	kg/person	**PPE**	5	%
Dermal absorption (DA):	75	% ('worst case')			
AOEL	0.01	mg/kg bw/d			

* 50 % conversion of prothioconazole to prothioconazole-desthio assumed

Table A 25: Estimation of worker exposure towards prothioconazole-desthio using the German re-entry model

Without PPE 1)			**With PPE**		
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 PPE x DA) / BW		
(1 x 1500 x 2 x 0.09375 x 2 x 75%) / 60			(1 x 1500 x 2 x 0.09375 x 2 x 5% x 75%) / 60		
External dermal exposure	0.5625	mg/person	External dermal exposure	0.028125	mg/person
External dermal exposure	0.009375	mg/kg bw/d	External dermal exposure	0.000469	mg/kg bw/d
Total systemic exposure	0.421875	mg/person	Total systemic exposure	0.021094	mg/person
Total systemic exposure	**0.007031**	**mg/kg bw/d**	**Total systemic exposure**	**0.000352**	**mg/kg bw/d**
% of AOEL	**70.3**	**%**	**% of AOEL**	**3.5**	**%**

1) acceptable without PPE: Worker wearing long sleeved shirt, long trousers ("permeable") but no gloves (allocation of BVL code SF245-01 for spray applications)

A 3.3 Bystander and resident exposure calculations

A 3.3.1 Calculations for bixafen

Table A 26: Input parameters considered for the estimation of bystander exposure

Intended use(s):	Cereals		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR):	0.09375	kg a.s./ha	**Exposed body surface area (BSA):**	1	m² (adults)
	9.375	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):	4	% ('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 27: Estimation of bystander exposure towards bixafen

Adults			**Children**		
Bystander: Systemic dermal exposure during/after application in cereals (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(9.375 x 2.77% x 1 x 4%) / 60			(9.375 x 2.77% x 0.21 x 4%) / 16.15		
External dermal exposure	0.259688	mg/person	External dermal exposure	0.054534	mg/person

External dermal exposure	0.004328	mg/kg bw/d	External dermal exposure	0.003377	mg/kg bw/d
Systemic dermal exposure	**0.000173**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000135**	**mg/kg bw/d**
Bystander: Systemic inhalation exposure during/after application in cereals (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 0.09375 x 20 x 5 x 100%) / 60			(0.000575 / 360 x 0.09375 x 20 x 5 x 100%) / 16.15		
External inhalation exposure	0.000026	mg/person	External inhalation exposure	0.000015	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	0.010414	mg/person	Total systemic exposure	0.002196	mg/person
Total systemic exposure	**0.000174**	**mg/kg bw/d**	**Total systemic exposure**	**0.000136**	**mg/kg bw/d**
% of AOEL	**0.13**	**%**	**% of AOEL**	**0.10**	**%**

Table A 28: Input parameters considered for the estimation of resident exposure

Intended use(s):	Cereals		**Drift (D):**	2.38	% (FC, 1 m)
Application rate (AR):	0.09375	kg a.s./ha	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
	0.0009375	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):	4	% ('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 29: Estimation of resident exposure towards bixafen

Adults			**Children**		
Residents: Systemic dermal exposure after application in cereals (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		
(0.0009375 x 2 x 2.38% x 5% x 7300 x 2 x 4%) / 60			(0.0009375 x 2 x 2.38% x 5% x 2600 x 2 x 4%) / 16.15		
External dermal exposure	0.032576	mg/person	External dermal exposure	0.011603	mg/person
External dermal exposure	0.000543	mg/kg bw/d	External dermal exposure	0.000718	mg/kg bw/d
Systemic dermal exposure	**0.000022**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000029**	**mg/kg bw/d**
Residents: Systemic inhalation exposure after application in cereals (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		
			(0.0009375 x 2 x % x 5% x 50% x 20 x 20 x 2 x 100%) / 16.15		
			External oral exposure	0.000893	mg/person
			External oral exposure	0.000055	mg/kg bw/d
			Systemic oral exposure	**0.000055**	**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		
			(0.0009375 x 2 x % x 20% x 25 x 100%) / 16.15		
			External oral exposure	0.000223	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	0.001303	mg/person	Total systemic exposure	0.00158	mg/person
Total systemic exposure	**0.000022**	**mg/kg bw/d**	**Total systemic exposure**	**0.000098**	**mg/kg bw/d**
% of AOEL	**0.02**	**%**	**% of AOEL**	**0.08**	**%**

A 3.3.2 Calculations for prothioconazole

Table A 30: Input parameters considered for the estimation of bystander exposure

Intended use(s):	Cereals		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR):	0.1875	kg a.s./ha	**Exposed body surface area (BSA):**	1	m² (adults)
	18.75	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:	0.2	mg/kg bw/d	**Exposure duration (T):**	5	min

Table A 31: Estimation of bystander exposure towards prothioconazole

Adults			**Children**		
Bystander: Systemic dermal exposure during/after application in cereals (via spray drift)					
$SDE_B = (AR \times D \times BSA \times DA) / BW$			$SDE_B = (AR \times D \times BSA \times DA) / BW$		
(18.75 x 2.77% x 1 x 75%) / 60			(18.75 x 2.77% x 0.21 x 75%) / 16.15		
External dermal exposure	0.519375	mg/person	External dermal exposure	0.109069	mg/person
External dermal exposure	0.008656	mg/kg bw/d	External dermal exposure	0.006753	mg/kg bw/d
Systemic dermal exposure	**0.006492**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.005065**	**mg/kg bw/d**
Bystander: Systemic inhalation exposure during/after application in cereals (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 0.1875 x 20 x 5 x 100%) / 60			(0.000575 / 360 x 0.1875 x 20 x 5 x 100%) / 16.15		
External inhalation exposure	0.000052	mg/person	External inhalation exposure	0.00003	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	0.389583	mg/person	Total systemic exposure	0.081831	mg/person
Total systemic exposure	**0.006493**	**mg/kg bw/d**	**Total systemic exposure**	**0.005067**	**mg/kg bw/d**
% of AOEL	**3.25**	**%**	**% of AOEL**	**2.53**	**%**

Table A 32: Input parameters considered for the estimation of resident exposure

Intended use(s):	Cereals		**Drift (D):**	2.38	% (FC, 1 m)
Application rate (AR):	0.1875	kg a.s./ha	**Transfer coefficient (TC):**	7300	cm²/h (adults)
	0.001875	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:	0.2	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	cm²/d

Table A 33: Estimation of resident exposure towards prothioconazole

Adults			Children		
Residents: Systemic dermal exposure after application in cereals (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		
(0.001875 x 2 x 2.38% x 5% x 7300 x 2 x 75%) / 60			(0.001875 x 2 x 2.38% x 5% x 2600 x 2 x 75%) / 16.15		
External dermal exposure	0.065153	mg/person	External dermal exposure	0.023205	mg/person
External dermal exposure	0.001086	mg/kg bw/d	External dermal exposure	0.001437	mg/kg bw/d
Systemic dermal exposure	**0.000814**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001078**	**mg/kg bw/d**
Residents: Systemic inhalation exposure after application in cereals (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		
			(0.001875 x 2 x % x 5% x 50% x 20 x 20 x 2 x 100%) / 16.15		
			External oral exposure	0.001785	mg/person
			External oral exposure	0.000111	mg/kg bw/d
			Systemic oral exposure	**0.000111**	**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		
			(0.001875 x 2 x % x 20% x 25 x 100%) / 16.15		
			External oral exposure	0.000446	mg/person
			External oral exposure	0.000028	mg/kg bw/d
			Systemic oral exposure	**0.000028**	**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	0.048864	mg/person	Total systemic exposure	0.019635	mg/person
Total systemic exposure	**0.000814**	**mg/kg bw/d**	**Total systemic exposure**	**0.001216**	**mg/kg bw/d**
% of AOEL	**0.41**	**%**	**% of AOEL**	**0.61**	**%**

A 3.3.3 Calculations for prothioconazole-desthio

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):	0.09375	kg a.s./ha *	**Exposed body surface area (BSA):**	1	m² (adults)
	9.375	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

* 50 % conversion of prothioconazole to prothioconazole-desthio assumed

Table A 35: Estimation of bystander exposure towards prothioconazole-desthio

Adults			Children		
Bystander: Systemic dermal exposure during/after application in cereals (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(9.375 x 2.77% x 1 x 75%) / 60			(9.375 x 2.77% x 0.21 x 75%) / 16.15		
External dermal exposure	0.259688	mg/person	External dermal exposure	0.054534	mg/person
External dermal exposure	0.004328	mg/kg bw/d	External dermal exposure	0.003377	mg/kg bw/d
Systemic dermal exposure	**0.003246**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.002533**	**mg/kg bw/d**
Bystander: Systemic inhalation exposure during/after application in cereals (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 0.09375 x 20 x 5 x 100%) / 60			(0.000575 / 360 x 0.09375 x 20 x 5 x 100%) / 16.15		

External inhalation exposure	0.000026	mg/person	External inhalation exposure	0.000015	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	0.194792	mg/person	Total systemic exposure	0.040916	mg/person
Total systemic exposure	**0.003247**	**mg/kg bw/d**	**Total systemic exposure**	**0.002533**	**mg/kg bw/d**
% of AOEL	**32.47**	**%**	**% of AOEL**	**25.33**	**%**

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):	0.09375	kg a.s./ha *	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
	0.0009375	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:	0.01	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

* 50 % conversion of prothioconazole to prothioconazole-desthio assumed

Table A 37: Estimation of resident exposure towards prothioconazole-desthio

Adults			**Children**		
Residents: Systemic dermal exposure after application in cereals (via deposits caused by spray drift)					
$SDE_R = (AR \times NA \times D \times TTR \times TC \times H \times DA) / BW$			$SDE_R = (AR \times NA \times D \times TTR \times TC \times H \times DA) / BW$		
(0.0009375 x 2 x 2.38% x 5% x 7300 x 2 x 75%) / 60			(0.0009375 x 2 x 2.38% x 5% x 2600 x 2 x 75%) / 16.15		
External dermal exposure	0.032576	mg/person	External dermal exposure	0.011603	mg/person
External dermal exposure	0.000543	mg/kg bw/d	External dermal exposure	0.000718	mg/kg bw/d
Systemic dermal exposure	**0.000407**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000539**	**mg/kg bw/d**
Residents: Systemic inhalation exposure after application in cereals (via vapour)					
$SIE_R = (AC_V \times IR \times IA) / BW$			$SIE_R = (AC_V \times IR \times IA) / BW$		
(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)		
			$SOE_{R(H)} = (AR \times NA \times D \times TTR \times SE \times SA \times Freq \times H \times OA) / BW$		
			(0.0009375 x 2 x % x 5% x 50% x 20 x 20 x 2 x 100%) / 16.15		
			External oral exposure	0.000893	mg/person
			External oral exposure	0.000055	mg/kg bw/d
			Systemic oral exposure	**0.000055**	**mg/kg bw/d**
			Residents: Systemic oral exposure (object-to-mouth transfer)		
			$SOE_{R(O)} = (AR \times NA \times D \times DFR \times IgR \times OA) / BW$		
			(0.0009375 x 2 x % x 20% x 25 x 100%) / 16.15		
			External oral exposure	0.000223	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	0.024432	mg/person	Total systemic exposure	0.009818	mg/person
Total systemic exposure	**0.000407**	**mg/kg bw/d**	**Total systemic exposure**	**0.000608**	**mg/kg bw/d**
% of AOEL	**4.07**	**%**	**% of AOEL**	**6.08**	**%**

Appendix 4 Detailed evaluation of exposure study relied upon

Comments of zRMS:	Acceptable; used in evaluation

Reference:	OECD Series on testing and assessment no. 9 (1997): Guidance Document for the conduct of studies of occupational exposure to pesticides during agricultural application
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
GLP:	Yes (certified laboratory)
Acceptability:	The reports are considered to be acceptable.

Operator exposure to prothioconazole and its metabolite prothioconazole-desthio 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 had 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 analyzing 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 prothioconazole-desthio, respectively.

Table A 38: 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 39: Normalized dermal exposure to prothioconazole-desthio (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**

Although 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 prothioconazole-desthio 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 prothiocoonazole-desthio concurrently on his undergarments.

Exposure to the head was determined for 15 replicates. In all cases – for prothioconazole as well as for prothioconazole-desthio – 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 prothioconazole-desthio is presented in Table A 40. 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). Prothioconazole-desthio was not found in any sample.

Table A 40: Normalized inhalation exposure to prothioconazole and prothioconazole-desthio (in µg/kg prothioconazole)

Study	Operator ID	Prothioconazole		Pro.-desthio	
		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 41.

Table A 41: 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 prothioconazole-desthio 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 active substance 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 42: Specific exposure figures for prothioconazole-desthio during downward directed boom application

Type of exposure	Prothioconazole-desthio [mg/kg a.s.]
Potential dermal exposure	0.251
Actual dermal exposure	0.013
Inhalation exposure	0.00034

The conversion of prothioconazole to prothioconazole-desthio 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. The highest percentages of conversion were found for low absolute amounts of prothioconazole.

REGISTRATION REPORT
Part B

Section 4: Metabolism and Residues

Detailed summary of the risk assessment

Product name: Aviator Xpro

Active Substances: 75 g/L Bixafen
150 g/L Prothioconazole

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Bayer Crop Science AG

Date: 19 April 2016

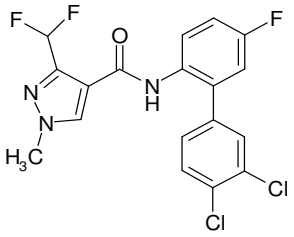
Table of Contents

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), 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 of 12 months (ASB2009-5839). 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 days. Both analytes remained stable during at least 12 months of storage.

4.1.1.2 Metabolism in plants and plant residue definition

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), 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, pulses/oilseeds – 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

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), 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	Sum of bixafen and bixafen-desmethyl, expressed as bixafen (Reg. (EC) No. 396/2005)

Animal residue definition for risk assessment	Sum of bixafen and bixafen-desmethyl (M21), free and conjugated expressed as bixafen equivalent (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 which also cover the uses on cereals applied for in Germany is provided in the following tables. 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).

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	–	12.0 [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)							**0.094**	**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).

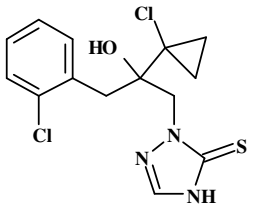
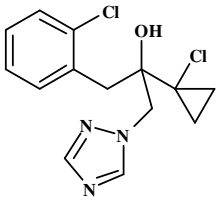
Table 4.1-9: Results of livestock feeding studies (Annex IIA, point 6.4)

	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)

	Ruminant:	**Poultry:**	**Pig:**
	Expected residue levels (sum of bixafen and desmethyl-bixafen) in animal matrices (mg/kg):		
Muscle	Max = 0.14 Mean = 0.03	<0.02* (MRL)	<0.02* (MRL)
Liver	Max = 1.0 Mean = 0.41	<0.02* (MRL)	<0.02* (MRL)
Kidney	Max = 0.22 Mean = 0.1	<0.02* (MRL)	<0.02* (MRL)
Fat	Max = 0.30 Mean = 0.14	<0.02* (MRL)	<0.02* (MRL)
Milk	Max = 0.04 Mean = 0.02	–	–
Eggs	–	<0.02* (MRL)	–

4.1.2 Prothioconazole

Table 4.1-10: 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

4.1.2.1 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 (ASB2012-3641) and EFSA's Reasoned Opinion on the modification of the existing MRLs for prothioconazole in various root vegetables (ASB2012-3393).

Table 4.1-11: Stability of residues (Annex IIA, point 6.1)

Stability of prothioconazole and prothioconazole-desthio	The stability of prothioconazole and prothio-conazole-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).

4.1.2.2 Metabolism in plants and plant residue definition

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 (ASB2012-3641) and EFSA´s Reasoned Opinion on the modification of the existing MRLs for prothioconazole in various root vegetables (ASB2012-3393).

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	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 similar? (yes/no)	Yes
Plant residue definition for monitoring	Prothioconazole-desthio (Reg. (EC) No 396/2005)

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 (EFSA, 2007, ASB2012-3641) 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, oilseeds, potatoes, root vegetablesbrassica vegetables, leek: 2 cereal straw, rape straw: 3 (EFSA, 2007, ASB2012-3641)

4.1.2.3 Metabolism in livestock and animal residue definition

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 (ASB2012-3641) and EFSA´s Reasoned Opinion on the modification of the existing MRLs for prothioconazole in various root vegetables (ASB2012-3393).

Table 4.1-13: 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, metabolite identzification: ASB2009-4302): [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. 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): 6 days
Animal residue definition for monitoring	Sum of prothioconazole-desthio and its glucuronide conjugate, expressed as prothioconazole-desthio (Reg. (EC) No 396/2005)
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 (EFSA, 2007, ASB2012-3641) 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 and muscle: 10 fat: 4 liver and kidney: 2
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	Not concluded. log Pow for prothioconazole-desthio 3.04 at 22 °C, but no indication as fat soluble (“F”) in EU residue legislation

4.1.2.4 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 4.1-14: 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.

4.1.2.5 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, 2010, ASB2012-3393) and which also cover the uses applied for is provided in Table 4.1-15.

Table 4.1-15: Calculation of the dietary burden of prothioconazole-desthio (based on all relevant uses authorized in the EU which are currently known (EFSA, 2010, ASB2012-3393))

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
Grains (Cereals)	86	70	40	–	40	0.020 [a]	0.016	0.009	–	0.009
Straw (Cereals)	86	–	20	50	–	2.250 [b]	–	0.523	1.308	–
Root and Tubers (e.g. Potatoes)	15	20	30	50	60	0.010 [c]	0.013	0.020	0.033	0.040
Oil seed	86	10	10	–	–	0.010 [d]	0.001	0.001	–	–
Intake (mg/kg dry weight feed)							**0.031**	**0.554**	**1.341**	**0.049**
Intake (mg/kg bw/d)							**0.002**	**0.020**	**0.057**	**0.002**
Intake (mg/animal/d)							**0.004**	**11.074**	**20.122**	**0.148**

[a] STMR, based on the following cGAP: 2x 0.19 kg as/ha, PHI: BBCH 30-69/ PHI F
[b] HR, based on the following cGAP: 2x 0.15 kg as/ha, PHI: BBCH 25-69/ PHI=F
[c] HR, based on the following cGAP: 1x 0.032 kg as/ha, PHI: F
[d] STMR, based on the following cGAP: 2x 0.13 kg as/ha, PHI: F

Table 4.1-16: Conditions of requirement of livestock feeding studies on prothioconazole-desthio

	Ruminant:	**Poultry:**	**Pig:**
Expected intakes by livestock ≥0.1 mg/kg diet (dry weight basis) (yes/no – If yes, specify the level)	Yes: 0.55 (dairy) 1.34 (beef)	No	No
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

previously been 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 (ASB2012-3641).

Table 4.1-17: 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	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	<0.01	<0.01
Liver	<0.01 (0.03 at feeding level)	<0.01	<0.01
Kidney	<0.01 (0.02 at feeding level)	<0.01	<0.01
Fat	<0.01	<0.01	<0.01
Milk	<0.01	–	–
Eggs	–	<0.01	–

4.2 Evaluation of the intended uses

4.2.1 Selection of critical use and justification

The GAPs for cereal uses (wheat, barley, rye, triticale) reported for the central zone are presented in Table 4.2-1. They have been used for consumer intake and risk assessment.

Table 4.2-1: GAPs 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**	**kg as/ha** **a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha** **min / max**		
001-003, 006-007	DE	wheat	F	powdery mildew (*Erysiphe graminis*), leaf spot of wheat, tan spot of cereals (*Drechslera tritici-repentis*), stripe rust of grasses (*Puccinia striiformis*), septoria leaf spot (*Septoria nodorum*)	spraying	BBCH 30 - 61; from spring	a) 2 (14 to 21 days) b) 2	a) 1.25 b) 2.5	a) bixafen: 0.0938 prothioconazole: 0.1875 b) bixafen: 0.1876 prothioconazole: 0.375	150/400	F	
004	DE	wheat	F	brown leaf rust of cereals (*Puccinia recondita*)	spraying	BBCH 30 - 69; from spring	a) 2 (14 to 21 days) b) 2	a) 1.25 b) 2.5	a) bixafen: 0.0938 prothioconazole: 0.1875 b) bixafen: 0.1876 prothioconazole: 0.375	150/400	F	
005	DE	wheat	F	stem break of cereals (*Pseudocercosporella herpotrichoides*)	spraying	BBCH 30 - 37; from spring	a) 1 b) 2	a) 1.25 b) 2.5	a) bixafen: 0.0938 prothioconazole: 0.1875 b) bixafen: 0.1876 prothioconazole: 0.375	150/400	F	
008- 013	DE	barley	F	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 - 61; from spring	a) 2 (14 to 21 days) b) 2	a) 1 b) 2	a) bixafen: 0.075 prothioconazole: 0.15 b) bixafen: 0.15 prothioconazole: 0.3	150/400	F	

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**	**kg as/ha** **a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha** **min / max**		
0014-015	DE	rye	F	powdery mildew (*Erysiphe graminis*) leaf blotch of cereals (*Rhynchosporium secalis*)	spraying	BBCH 30 - 61; from spring	a) 2 (14 to 21 days) b) 2	a) 1.25 b) 2.5	a) bixafen: 0.0938 prothioconazole: 0.1875 b) bixafen: 0.1876 prothioconazole: 0.375	150/400	F	
016	DE	rye	F	brown leaf rust of cereals (*Puccinia hordei*)	spraying	BBCH 30 - 69; from spring	a) 2 (14 to 21 days) b) 2	a) 1.25 b) 2.5	a) bixafen: 0.0938 prothioconazole: 0.1875 b) bixafen: 0.1876 prothioconazole: 0.375	150/400	F	
017-018	DE	triticale	F	powdery mildew (*Erysiphe graminis*) Septoria-species (*Septoria spp.*)	spraying	BBCH 30 - 61; from spring	a) 2 (14 to 21 days) b) 2	a) 1.25 b) 2.5	a) bixafen: 0.0938 prothioconazole: 0.1875 b) bixafen: 0.1876 prothioconazole: 0.375	150/400	F	
019	DE	triticale	F	brown leaf rust of cereals (*Puccinia hordei*)	spraying	BBCH 30 - 69; from spring	a) 2 (14 to 21 days) b) 2	a) 1.25 b) 2.5	a) bixafen: 0.0938 prothioconazole: 0.1875 b) bixafen: 0.1876 prothioconazole: 0.375	150/400	F	

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 Cereals (wheat, barley, rye, triticale)

4.2.2.1 Residues in primary crops

The following tables give a brief overview of the supervised residue trials selected for the assessment of bixafen and prothioconazole in cereals. 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 cereals

Commodity	Region [a]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [b]	HR (mg/kg) [c]	Median CF [d]
			Enforcement (bixafen)	Risk assessment (sum of bixafen and bixafen-desmethyl, expressed as bixafen)*			
Wheat grain	NEU	Outdoor	Trials with 2x0.075-0.094 kg/ha: <0.01 (5), 0.01, 0.02, 0.04 Trials with 2x0.13 kg/ha: <0.01 (6), 0.01 (2), 0.03 (2)	Trials with 2x0.075-0.094 kg/ha: <0.02 (5), 0.02, 0.04, 0.07 Trials with 2x0.13 kg/ha: <0.02 (6), 0.02 (2), 0.04 (2)	0.02 0.02	0.07 0.04	1
Barley grain	NEU	Outdoor	Trials with 2x0.075 kg/ha: <0.01 (2), 0.03, 0.04 (2), 0.05 (3), 0.07 (2) Trials with 2x0.13 kg/ha: 0.02, 0.04 (3), 0.05, 0.07, 0.08, 0.09 (2), 0.10	Trials with 2x0.075 kg/ha: <0.02 (2), 0.04, 0.05, 0.06 (3), 0.07, 0.08, 0.09 Trials with 2x0.13 kg/ha: 0.03, 0.05 (3), 0.06, 0.08, 0.10 (3), 0.11	0.06 0.07	0.09 0.11	1
Wheat straw	NEU	Outdoor	Trials with 2x0.075-0.094 kg/ha: 0.21, 0.25, 0.27, 0.30, 0.45, 0.65, 0.68, 1.1 Trials with 2x0.13 kg/ha: 0.52, 0.93, 0.95, 1.3, 1.8, 1.9, 3.6, 4.1, 8.4, 10	Trials with 2x0.075-0.094 kg/ha: 0.43, 0.46, 0.47, 0.50, 0.69, 0.81, 0.96, 1.5 Trials with 2x0.13 kg/ha: 0.78, 1.2, 1.3, 1.5, 2.1, 2.5, 3.8, 4.4, 9.7, 11	0.595 2.3	1.5 11	1
Barley straw	NEU	Outdoor	Trials with 2x0.075 kg/ha: 0.22, 0.26, 0.39, 0.47, 0.56, 1.1, 1.2, 1.3, 3.3, 5.1 Trials with 2x0.13 kg/ha: 0.64, 0.68, 0.70, 0.77, 1.1 (2), 3.7, 4.8, 5.4, 10.0	Trials with 2x0.075 kg/ha: 0.25, 0.38, 0.49, 0.56, 0.68, 1.2, 1.3 (2), 3.5, 5.7 Trials with 2x0.13 kg/ha: 0.73, 0.74, 0.84, 0.85, 1.2 (2), 3.9, 5.2, 5.6, 12	0.94 1.2	5.7 12	1

* 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.

For bixafen ten trials on barley and eight trials on wheat were conducted in accordance with the intended application rate of 2x 0.075 kg/ha. Further overdosed residue trials were available covering an application rate of 2x 0.13 kg/ha. Overall, the available trials are considered sufficient.

Table 4.2-3 Overview of the selected supervised residue trials for prothioconazole in cereals

Commodity	Region [a]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [b]	HR (mg/kg) [c]	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)*			
Wheat grain	NEU	Outdoor	<0.01 (12)	<0.02 (12)	0.02	0.02	2
Barley grain	NEU	Outdoor	<0.01 (18), 0.01	<0.02 (18), 0.02	0.02	0.02	2
Wheat straw	NEU	Outdoor	0.02, 0.03 (4), 0.04 (2), 0.06 (2), 0.07, 0.08, 0.10, 0.28	0.06, 0.09 (4), 0.12 (2), 0.18 (2), 0.21, 0.24, 0.30, 0.84	0.12	0.84	3
Barley straw	NEU	Outdoor	0.02 (3), 0.03, 0.04, 0.05 (2), 0.06, 0.08, 0.10 (2), 0.11, 0.12, 0.14, 0.21, 0.28, 0.30, 0.36, 0.56	0.06 (3), 0.09, 0.12, 0.15 (2), 0.18, 0.24, 0.30 (2), 0.33, 0.36, 0.42, 0.63, 0.84, 0.90, 1.08, 1.68	0.30	1.68	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.

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

See GAP table. Due to application at up to BBCH 69 only, the PHIs are covered by the growing period remaining between the envisaged application and harvest ("F"). It is not necessary to set a specific pre-harvest interval in days.

4.3 Consumer intake and risk assessment

4.3.1 Bixafen

The consumer intake and risk assessment is based on the appropriate input values given in Table 4.3-1 and the toxicological reference values stated in Table 4.3-2. For the detailed calculation results it is referred to Appendix 3.

Table 4.3-1: Residue input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
wheat, rye, triticale	0.05	MRL	0.02	STMR
barley	0.5	MRL	0.07	STMR
others	variable	MRL	--	--

Table 4.3-2: Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.02 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	11 % (based on NL children, mean body weight 17.1 kg)
NTMDI (% ADI) according to NVS II model	9 % (based on German children aged 2-4 years, individual consumption/body weight ratio)
IEDI (EFSA PRIMo) (% ADI)	Not required
NEDI (NVS II model) (% ADI)	Not required
Factors included in IEDI and NEDI	None
ARfD	0.2 mg/kg bw
IESTI (EFSA PRIMo) (% ARfD)	barley: < 1 % (based on NL adults) rye: < 1 % (based on UK infants with 8.7 kg bw) wheat: < 1 % (based on UK children aged 4-6 years)
NESTI (NVS II model) (% ARfD)	barley: < 1 % (based on DE general population, 14-80 yrs) rye: < 1 % (based on DE children aged 2-4 years) wheat: < 1 % (based on DE children aged 2-4 years)
Factors included in IESTI and NESTI	None

4.3.2 Prothioconazole

The consumer intake and risk assessment is based on the appropriate input values given in Table 4.3-3 and the toxicological reference values stated in Table 4.3-4. For the detailed calculation results it is referred to Appendix 3.

Table 4.3-3: Residue input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
wheat, rye, triticale	0.1	MRL	0.02	STMR
barley	0.3	MRL	0.02	STMR
others	variable	MRL	--	--

Table 4.3-4: Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.01 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	87 % (based on UK toddler)
NTMDI (% ADI) according to NVS II model	23 % (based on DE women in childbearing age 14-50 years)
IEDI (EFSA PRIMo) (% ADI)	Not required
NEDI (NVS II model) (% ADI)	Not required
Factors included in TMDI	Conversion factors (monitoring to risk assessment): 10 for milk and muscle, 4 for fat, 2 for liver and kidney, cereal grain, oilseeds, potatoes, root vegetables, brassica vegetables and leek
ARfD	0.01 mg/kg bw
IESTI (EFSA PRIMo) (% ARfD)	barley : 1 % (based on NL adults with 63 kg bw) rye: 1 % (based on UK infant with 8.7 kg bw) wheat: 3 % (based on UK children aged 4-6 years)
NESTI (NVS II model) (% ARfD)	barley: 1 % (based on DE general population) 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	Conversion factor of 2

4.4 Proposed maximum residue levels (MRLs)

No new MRLs are required.

4.5 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, 0.05 mg/kg for rye and wheat; prothioconazole: 0.3 mg/kg for barley, 0.1 mg/kg for rye and wheat) as laid down in Reg. (EU) 396/2005 is not expected.

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

As far as consumer health protection is concerned, zRMS (BfR/ DE) agrees with the authorization of the intended uses.

Appendix 1 Reference list

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 *
	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			Add, publicly available
	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			Add, publicly available
	EFSA	2010	Reasoned Opinion - Modification of the existing MRLs for Prothioconazole in various root vegetables EFSA Journal 2010; 8(7):1675, 1-28 ASB2012-3393			Add, publicly available
	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			Add, publicly available
	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			Add, publicly available
	United Kingdom	2004	Prothioconazole: (Draft Assessment Report) Vol. 1-4 GLP: Open Published: Yes ASB2010-10593			Add
	United Kingdom	2011	Bixafen: Draft Assessment Report ASB2011-11716			Add
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: Yes Published: No BVL-2289321, ASB2009-5839	Yes	BAY	Y
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: Yes Published: No BVL-2289289, RIP2002-1036	Yes	BAY	Y
KIIA1 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: Yes Published: No BVL-2283354, ASB2010-11627	Yes	BAY	Y
KIIA 6.2	Borchers, H.; Klein, O.; Reiner, H.	2007	Prothioconazole: List of metabolites MEF-07/032 ! M-282478-02-1 GLP: No Published: No BVL-2289268, ASB2009-4270	Yes	BAY	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	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: Yes Published: No BVL-2289270, ASB2009-4274	Yes	BAY	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: Yes Published: No BVL-2289286, ASB2009-4272	Yes	BAY	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: Yes Published: No BVL-2289281, ASB2009-4276	Yes	BAY	Y
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: Yes Published: No BVL-2289278, RIP2002-1041	Yes	BAY	Y
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: Yes Published: No BVL-2289269, RIP2002-1042	Yes	BAY	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: Yes Published: No BVL-2289273, RIP2002-1038	Yes	BAY	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: Yes Published: No BVL-2289285, ASB2009-4296	Yes	BAY	Y
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: Yes Published: No BVL-2289274, RIP2002-1037	Yes	BAY	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: Yes Published: No BVL-2289312, BVL-2289322, ASB2009-5872	Yes	BAY	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: Yes Published: No BVL-2289323, ASB2009-5873	Yes	BAY	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	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: Yes Published: No BVL-2289325, ASB2009-5875	Yes	BAY	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: Yes Published: No BVL-2289324, ASB2009-5874	Yes	BAY	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: Yes Published: No BVL-2289266, RIP2002-1039	Yes	BAY	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: Yes Published: No BVL-2289327, ASB2009-5877	Yes	BAY	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: Yes Published: No BVL-2289326, ASB2009-5876	Yes	BAY	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: Yes Published: No BVL-2289264, ASB2009-4297	Yes	BAY	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: Yes Published: No BVL-2289271, RIP2002-1054	Yes	BAY	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: Yes Published: No BVL-2289328, ASB2009-5940	Yes	BAY	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: Yes Published: No BVL-2289329, ASB2009-5941	Yes	BAY	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: No Published: No BVL-2289277, ASB2009-4302	Yes	BAY	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]	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: Yes Published: No BVL-2289276, ASB2009-4301	Yes	BAY	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: Yes Published: No BVL-2289265, RIP2002-1044	Yes	BAY	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: Yes Published: No BVL-2289287, RIP2002-1045	Yes	BAY	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: Yes Published: No BVL-2289288, RIP2002-1046	Yes	BAY	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: Yes Published: No BVL-2289389, RIP2002-1057	Yes	BAY	Y
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: Yes Published: No BVL-2289390, RIP2002-1053	Yes	BAY	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: Yes Published: No BVL-2289391, RIP2002-1070	Yes	BAY	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	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: Yes Published: No BVL-2289397, RIP2002-1055	Yes	BAY	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: Yes Published: No BVL-2289290, RIP2002-1069	Yes	BAY	Y
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: Yes Published: No BVL-2289279, RIP2002-1058	Yes	BAY	Y
KIIA 6.3	Heinemann, O.; Elke, K.	2001	Determination of residues of JAU6476-desthio & KWG4168 on spring wheat following spray application of JAU6476 & KWG4168 460 EC in Great Britain, France, Germany and Italy RA-2092/00 ! M-087669-01-1 ! MO-01-021572 GLP: Yes Published: No BVL-1648799, BVL-1648800, BVL-1830919, BVL-2307527, RIP2004-733	Yes	BAY	Add
KIIA 6.3	Heinemann, O.; Elke, K.	2001	Determination of residues of JAU6476-desthio & KWG4168 on spring barley following spray application of JAU6476 & KWG4168 460 EC in Germany, France and Great Britain RA-2096/00 ! M-088981-01-1 ! MO-01-022206 GLP: Yes Published: No BVL-1648797, BVL-1648798, BVL-1830921, BVL-2307534, RIP2004-735	Yes	BAY	Add
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: Yes Published: No BVL-2289399, RIP2002-1068	Yes	BAY	Y
KIIA 6.3 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: Yes Published: No BVL-2289342, ASB2009-5954	Yes	BAY	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 6.3	Schöning, R.; Erler, S.	2008	Determination of the residues of BYF 00587, JAU 6476 and KWG 4168 in/on winter wheat and spring wheat after spraying of BYF 00587 & JAU 6476 & KWG 4168 (400 EC) in the field in Northern France, the Netherlands, the United Kingdom and Germany (incl. amendment No. 1 dated 2008-03-18) RA-2040/07 ! M-298182-01-1 ! M-298182-02-1 GLP: Yes Published: No BVL-1818284, BVL-1830912, BVL-2117202, BVL-2297929, BVL-2307529, ASB2008-6485	Yes	BAY	Add
KIIA 6.3	Schöning, R.; Erler, S.	2008	Determination of the residues of BYF 00587, JAU 6476 and KWG 4168 in/on spring barley and winter barley after spraying of BYF 00587 & JAU 6476 & KWG 4168 (400 EC) in the field in Northern France, Germany, the United Kingdom and the Netherlands RA-2042/07 ! M-298147-01-1 GLP: Yes Published: No BVL-1818286, BVL-1830882, BVL-2117203, BVL-2297931, BVL-2307537, ASB2008-6491	Yes	BAY	Add
KIIA 6.3	Schöning, R.; Erler, S.	2008	Determination of the residues of BYF 00587 and JAU 6476 in/on spring wheat and winter wheat after spraying of BYF 00587 & JAU 6476 (225 EC) in the field in the Netherlands, Northern France, the United Kingdom and Germany RA-2037/07 ! M-298112-01-1 GLP: Yes Published: No BVL-2283356, ASB2009-5970	Yes	BAY	Y
KIIA 6.3	Schöning, R.; Erler, S.	2008	Determination of the residues of BYF 00587 and JAU 6476 in/on spring barley after spraying of BYF 00587 & JAU 6476 (225 EC) in the field in Northern France and Germany (incl. amendment No. 1 dated 2008-04-23 + amendment No. 0002 dated 2008-08-19) RA-2039/07! M-298114-01-1 ! M-298114-02-1 ! M-298114-03-1 GLP: Yes Published: No BVL-2283360, ASB2009-5991	Yes	BAY	Y
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: Yes Published: No BVL-2289334, ASB2009-5946	Yes	BAY	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: Yes Published: No BVL-2289330, ASB2009-5942	Yes	BAY	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
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: Yes Published: No BVL-2289335, ASB2009-5947	Yes	BAY	Y
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: Yes Published: No BVL-2289331, ASB2009-5943	Yes	BAY	Y
KIIA 6.3	Schoening, R.; Schmeer, K.	2007	Determination of the residues of BYF 00587 and JAU 6476 in/on spring barley and winter barley after spraying of BYF 00587 & JAU 6476 (225 EC) in the field in Northern France, Sweden, the United Kingdom and Germany RA-2328/06 ! M-294779-01-1 GLP: Yes Published: No BVL-2283358, ASB2009-5976	Yes	BAY	Y
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: Yes Published: No BVL-2289336, ASB2009-5948	Yes	BAY	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: Yes Published: No BVL-2289339, ASB2009-5951	Yes	BAY	Y
KIIA 6.4.2	[redacted]	2001	JAU6476-desthio - Dairy cattle feeding study MR-535/00 ! P 673003007 ! MO-01-019272 GLP: Yes Published: No BVL-2289275, RIP2002-1080	Yes	BAY	Y
KIIA 6.4.2	[redacted]	2008	Bixafen: Feeding study with dairy cows MR-07/340 ! P673074704 ! M-296420-01-1 GLP: Yes Published: No BVL-2289340, ASB2009-5952	Yes	BAY	Y
KIIA 6.5.1	Gilges, M.	2001	Hydrolysis of JAU6476 under conditions of processing MR-166/00 ! M1771021-9 ! MO-01-001955 GLP: Yes Published: No BVL-2289267, RIP2002-1081	Yes	BAY	Y
KIIA 6.5.1	Gilges, M.	2001	Hydrolysis of JAU 6476-desthio under conditions of processing MR-106/00 ! MO-01-001956 GLP: Yes Published: No BVL-2283362, ASB2012-5968	Yes	BAY	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: Yes Published: No BVL-2289341, ASB2009-5953	Yes	BAY	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 6.6.2	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: Yes Published: No BVL-2289282, ASB2009-4303	Yes	BAY	Y
KIIA 6.6.2	Haas, M.	2001	Confined rotational crop study with JAU6476 MR-159/00 ! M1300891-2 ! MO-01-011374 GLP: Yes Published: No BVL-2289283, RIP2002-1082	Yes	BAY	Y
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: Yes Published: No BVL-2289344, ASB2009-5956	Yes	BAY	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: Yes Published: No BVL-2289343, ASB2009-5955	Yes	BAY	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: Yes Published: No BVL-2289345, ASB2009-5957	Yes	BAY	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 Northern France (incl. amendment No. 1 dated 2008-02-25) RA-2143/06 ! M-296525-01-1 ! M-296525-02-1 GLP: Yes Published: No BVL-2289346, ASB2009-5958	Yes	BAY	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: Yes Published: No BVL-2289347, ASB2009-5959	Yes	BAY	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: Yes Published: No BVL-2289348, ASB2009-5960	Yes	BAY	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
MIIIA1 Sec 4	Applicant	2012	Bixafen + Prothioconazol / Aviator Xpro (102000013869): Residues in or on treated products, food and feed - Tier 2, IIIA-8 - Draft Registration Report - Part B - National assessment M-425532-01-1 ! MIII / Sec. 4 GLP: Yes Published: No BVL-2283452, BVL-2283453, ASB2012-10546	Yes	BAY	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 wheat

Reference:	OECD KIIA1 6.3
Report	ASB2009-5942, ASB2009-5943, ASB2008-6485, ASB2009-5970
Guideline(s):	Yes, EC guidance working document 7029/VI/95 rev. 5 (1997-07-22)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 2: Residues of bixafen in spring soft 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)	:	125 g/l	Indoors / outdoors	: Outdoors (European North)
Formulation	(e.g. WP)	:	EC	Other a.i. in formulation	
Commercial product	(name)	:	BYF 000587 EC 125 G, treated with formulation BYF000587 EC 125 G (125 g/l Bixafen, BYF 00587)	(content and common name)	:
Applicant		:	Bayer CropScience AG	Residues calculated as	: 8.1 Bixafen (BYF 00587) 8.2 Bixafen-desmethyl 8.3 Sum of Bixafen and bixafen-desmethyl, calculated as bixafen

Active ingredient	: Bixafen (BYF 00587)
Crop / crop group	: Spring Soft Wheat
Submission date	: 2008-12-16

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)
RA-2006/07, R 2007 0093/8, 0093-07 United Kingdom IP21 4BQ Diss (Norfolk) 2008-01-11	Belvoir	1) 2007-03-18 (sowing) 2) 2007-06-13 - 2007-06-20 3) 2007-08-31 - 2007-09-01	0.13 0.13	318 300	0.042 0.042	2007-06-01 2007-06-19[4]	BBCH 69	green forage rest of plant ears of grain grain straw	0.57 2.7 0.36 0.06 <0.01 0.52	0.16 0.17 0.25 0.05 <0.01 0.26	0.73 2.9 0.61 0.11 <0.02 0.78	0[5] 0 35 35 73 73	4) spraying 5) before last treatment analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg max sample storage: 5 months ASB2009-5943
RA-2006/07, R 2007 0095/4, 0095-07 Sweden 245 93 Staffanstorp 2008-01-11	Vinjett	1) 2007-04-04 (sowing) 2) 2007-06-11 - 2007-06-18 3) 2007-08-20 - 2007-08-21	0.13 0.13	300 300	0.042 0.042	2007-06-07 2007-06-13[4]	BBCH 65	green forage rest of plant ears of grain grain straw	2.8 3.2 1.4 0.18 <0.01 0.93	0.14 0.15 0.70 0.17 <0.01 0.31	3.0 3.3 2.1 0.35 <0.02 1.2	0[5] 0 35 35 69 69	4) spraying 5) before last treatment analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg max sample storage: 5 months ASB2009-5943
RA-2006/07, R 2007 0155/1, 0155-07 Germany 51399 Burscheid 2008-01-11	Thasos	1) 2007-04-04 (sowing) 2) 2007-06-06 - 2007-06-15 3) 2007-08-14	0.13 0.13	300 300	0.042 0.042	2007-06-06 2007-06-19[4]	BBCH 69	green forage grain straw	1.5 4.5 2.0 1.4 1.0 0.03 <0.01 4.1 0.55	0.24 0.26 0.29 0.30 0.31 0.01 <0.01 0.30 0.21	1.7 4.8 2.3 1.7 1.3 0.04 <0.02 4.4 0.76	0[5] 0 7 14 28 35 56 35 56	4) spraying 5) before last treatment analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg max sample storage: 5 months ASB2009-5943

Table A 3: Residues of bixafen in spring soft wheat

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Bixafen (BYF 00587)
Crop / crop group : Spring Soft Wheat

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2008-12-16

Content of a.i. (g/kg or g/l) : 119.4 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : BYF 000587 EC, treated with formulation BYF000587 EC 125 (actual 119.4 g/l Bixafen, BYF 00587)
Applicant : Bayer CropScience AG

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) :
Residues calculated as : 8.1 Bixafen (BYF 00587)
8.2 Bixafen-desmethyl
8.3 Sum of Bixafen and bixafen-desmethyl, calculated as bixafen

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)
RA-2320/06, R 2006 0421/1, 0421-06 France 37210 Cham-bourg sur Indre 2007-10-01	Tecnico	1) 2006-03-13 (sowing) 2) 2006-06-15 - 2006-06-22 3) 2006-07-26	0.13 0.13	300 300	0.042 0.042	2006-06-08 2006-06-22[4)]	BBCH 69	green forage grain straw	1.9 7.1 0.01 10.0	0.19 0.21 <0.01 0.78	2.1 7.3 0.02 11.0	0[5)] 0 34 34	4) spraying 5) before last treatment analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg max sample storage: 4 months ASB2009-5942

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)
RA-2320/06, R 2006 0424/6, 0424-06 Sweden 245 93 Staffanstorp 2007-10-01	Vinjett	1) 2006-04-29 (sowing) 2) 2006-06-27 - 2006-07-02 3) 2006-08-17 - 2006-08-18	0.13 0.13	300 300	0.042 0.042	2006-06-21 2006-07-02[4)]	BBCH 69	green forage grain straw	1.8 4.6 4.1 3.2 3.2 <0.01 <0.01 8.4 7.8	0.12 0.13 0.36 0.39 0.50 <0.01 <0.01 1.2 1.3	2.0 4.8 4.5 3.6 3.7 <0.02 <0.02 9.7 9.1	0[5)] 0 7 14 28 35 47 35 47	4) spraying 5) before last treatment analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg max sample storage: 4 months ASB2009-5942
RA-2320/06, R 2006 0425/4, 0425-06 United Kingdom IP24 3TQ Thetford (Norfolk) 2007-10-01	Paragon	1) 2005-12-06 (sowing) 2) 2006-06-10 - 2006-06-17 3) 2006-07-25 - 2006-08-10	0.13 0.13	300 300	0.042 0.042	2006-06-05 2006-06-16[4)]	BBCH 69	green forage grain straw	0.83 2.7 2.1 1.8 1.8 0.03 0.01 3.6 3.1	0.07 0.08 0.13 0.13 0.13 <0.01 <0.01 0.26 0.18	0.91 2.8 2.2 1.9 2.0 0.04 0.02 3.8 3.3	0[5)] 0 7 14 28 34 38 34 38	4) spraying 5) before last treatment analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg max sample storage: 4 months ASB2009-5942

Table A 4: Residues of bixafen in spring soft 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) : 50 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : FAR 01285-00, EC, treated with formulation FAR 01285-00, EC (100 g/l Prothioconazole, JAU 6476; 250 g/l Spiroxamin, KWG 4168 + 50 g/l Bixafen, BYF 00587)
Applicant : Bayer CropScience Deutschland GmbH

Active ingredient : Bixafen (BYF 00587)
Crop / crop group : Spring Soft Wheat

Submission date : 2008-10-15

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) : 100 g/l Prothioconazole, 250 g/l Spiroxamine

Residues calculated as : 8.1 Bixafen (BYF 00587)
8.2 Bixafen-desmethyl calculated as Bixafen
8.3 Sum of Bixafen and bixafen-desmethyl, calculated as bixafen

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)
RA-2040/07, R 2007 0444/5 Netherlands 1681 ND Zwaagdijk-Oost 2008-02-27	Baldus	1) 2007-04-06 (sowing) 2) 2007-06-15 - 2007-06-27 3) 2007-08-24 - 2007-09-03	0.075 0.075	300 300	0.025 0.025	2007-06-11 2007-06-27[4]	BBCH 69	green forage green forage grain straw	0.28 1.7 <u>0.01</u> 0.01 0.23 <u>0.25</u>	0.09 0.10 0.01 <0.01 0.23 0.10	0.37 1.8 <u>0.02</u> 0.02 <u>0.46</u> 0.36	0[5] 0 35 61 35 61	4) spraying 5) before last treatment analytical method: 01013/M001 (electrospray ionization, ESI+ and ESI- (HPLC-MS/MS)), LOQ: 0.01 mg/kg, max. sample storage: 7 months <u>ASB2008-6485</u>

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)
RA-2040/07, R 2007 0523/9 United Kingdom IP21 4BQ Thrandeston/ Diss (Norfolk) 2008-02-27	Belvoir	1) 2007-03-18 (sowing) 2) 2007-06-13 - 2007-06-20 3) 2007-08-31 - 2007-09-01	0.075 0.075	300 300	0.025 0.025	2007-06-01 2007-06-19[4]	BBCH 69	green forage green forage rest of plant ears of grain grain straw	0.35 1.7 0.21 0.02 <0.01 0.30	0.10 0.11 0.17 0.03 <0.01 0.19	0.45 1.8 0.37 0.05 <0.02 0.50	0[5] 0 35 35 73 73	4) spraying 5) before last treatment analytical method: 01013/M001 (electrospray ionization, ESI+ and ESI- (HPLC-MS/MS)), LOQ: 0.01 mg/kg, max. sample storage: 5 months ASB2008-6485
RA-2040/07, R 2007 0524/7 Germany 51399 Burscheid 2008-02-27	Thasos	1) 2007-04-04 (sowing) 2) 2007-06-06 - 2007-06-15 3) 2007-08-14	0.075 0.075	300 300	0.025 0.025	2007-06-06 2007-06-19[4]	BBCH 69	green forage grain straw	0.85 2.9 0.02 <0.01 0.43 0.45	0.15 0.14 0.01 <0.01 0.23 0.24	1.0 3.1 0.04 <0.02 0.66 0.69	0[5] 0 35 56 35 56	4) spraying 5) before last treatment analytical method: 01013/M001 (electrospray ionization, ESI+ and ESI- (HPLC-MS/MS)), LOQ: 0.01 mg/kg, max. sample storage: 6 months ASB2008-6485

Table A 5: Residues of bixafen in spring soft 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) : 75 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : BAY 18530 F, treated with formulation FAR 01282-00, 225 EC (150 g/l Prothioconazole, JAU 6476 + 75 g/l Bixafen, BYF 00587)
Applicant : Bayer CropScience Deutschland GmbH

Active ingredient : Bixafen
Crop / crop group : Spring Soft Wheat

Submission date : 2009-03-02

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) : 150 g/l Prothioconazole (JAU 6476)

Residues calculated as : 8.1 Bixafen (BYF 00587)
8.2 BYF00587-desmethyl
8.3 Sum of Bixafen and bixafen-desmethyl, calculated as bixafen

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)
RA-2037/07, R 2007 0418/6, 0418-07 Netherlands 1681 ND Zwaagdijk-Oost 2008-02-25	Baldus	1) 2007-04-06 (sowing) 2) 2007-06-15 - 2007-06-27 3) 2007-08-24 - 2007-09-03	0.094 0.094	300 300	0.031 0.031	2007-06-11 2007-06-27[4]	BBCH 69	green forage grain straw	0.35 1.8 0.46 0.38 0.09 <u>0.04</u> <0.01 <u>0.21</u> 0.20	0.12 0.09 0.12 0.13 0.08 0.03 <0.01 0.23 0.14	0.46 1.9 0.58 0.52 0.16 <u>0.07</u> <0.02 <u>0.43</u> 0.34	0[5] 0 7 14 28 35 61 35 61	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI-), LOQ: 0.01/0.02 mg/kg, max. sample storage: 5 months ASB2009-5970

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)
RA-2037/07, R 2007 0420/8, 0420-07 United Kingdom IP21 4BQ Diss (Norfolk) 2008-02-25	Belvoir	1) 2007-03-18 (sowing) 2) 2007-06-13 - 2007-06-20 3) 2007-08-31 - 2007-09-01	0.094 0.094	300 300	0.031 0.031	2007-06-01 2007-06-19[4]	BBCH 69	green forage	0.62	0.14	0.76	0[5]	4) spraying 5) before last treatment
									1.8	0.11	1.9	0	analytical method: 01013 (electrospray ionization, ESI+ and ESI-), LOQ: 0.01/0.02 mg/kg, max. sample storage: 5 months
								rest of plant	0.25	0.20	0.45	35	
								ears of grain	0.06	0.07	0.12	35	
								grain	<0.01	<0.01	<0.02	73	
								straw	0.27	0.20	0.47	73	ASB2009-5970
RA-2037/07, R 2007 0421/6, 0421-07 Germany 49377 Vechta-Langförden 2008-02-25	Thasos	1) 2007-04-05 (sowing) 2) 2007-06-21 - 2007-07-05 3) 2007-08-27 - 2007-08-28	0.094 0.094	300 300	0.031 0.031	2007-06-14 2007-07-05[4]	BBCH 69	green forage	0.23	0.05	0.28	0[5]	4) spraying 5) before last treatment
									2.3	0.05	2.4	0	analytical method: 01013 (electrospray ionization, ESI+ and ESI-), LOQ: 0.01/0.02 mg/kg, max. sample storage: 5 months
								rest of plant	0.56	0.12	0.67	35	
								ears of grain	0.09	0.05	0.14	35	
								grain	<0.01	<0.01	<0.02	53	
								straw	0.65	0.16	0.81	53	ASB2009-5970

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Acceptable.

Reference:	OECD KIIA 6.3
Report	ASB2009-5942, ASB2009-5943, ASB2008-6485, ASB2009-5970
Guideline(s):	Yes, EC guidance working document 7029A/I/95 rev. 5 (1997-07-22)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 6: Residues of bixafen in winter soft 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)	:	125 g/l
Formulation	(e.g. WP)	:	EC
Commercial product	(name)	:	BYF 000587 EC 125 G, treated with formulation BYF000587 EC 125 G (125 g/l Bixafen, BYF 00587)
Applicant		:	Bayer CropScience AG

Active ingredient	:	Bixafen (BYF 00587)
Crop / crop group	:	Winter Soft Wheat
Submission date	:	2008-12-16
Indoors / outdoors	:	Outdoors (European North)
Other a.i. in formulation (content and common name)	:	
Residues calculated as	:	8.1 Bixafen (BYF 00587) 8.2 Bixafen-desmethyl 8.3 Sum of Bixafen and bixafen-desmethyl, calculated as bixafen

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)
RA-2006/07, R 2007 0091/1, 0091-07 France 37120 Braslou 2008-01-11	Mendel	1) 2006-10-16 (sowing) 2) 2007-05-15 - 2007-05-25 3) 2007-07-04 - 2007-07-14	0.13 0.13	300 300	0.042 0.042	2007-04-30 2007-05-22[4)]	BBCH 69	green forage rest of plant ears of grain grain straw	2.6 1.4 0.88 0.65 0.45 0.97 0.17 <0.01 0.95	0.09 0.14 0.18 0.26 0.09 0.33 0.12 <0.01 0.35	2.7 1.6 1.1 0.92 0.54 1.3 0.29 <0.02 1.3	0[5)] 0 7 14 28 35 35 44 44	4) spraying 5) before last treatment analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg, max. sample storage: 5 months ASB2009-5943
RA-2006/07, R 2007 0094/6, 0094-07 France 37310 Chambourg sur Indre 2008-01-11	Apache	1) 2006-10-19 (sowing) 2) 2007-05-09 - 2007-05-18 3) 2007-07-07	0.13 0.13	300 300	0.042 0.042	2007-04-25 2007-05-18[4)]	BBCH 69	green forage rest of plant ears of grain grain straw	0.70 3.6 1.8 1.2 1.1 1.5 0.14 <0.01 1.9	0.16 0.19 0.25 0.28 0.45 0.63 0.10 <0.01 0.60	0.86 3.8 2.0 1.5 1.5 2.1 0.24 <0.02 2.5	0[5)] 0 7 14 28 35 35 56 56	4) spraying 5) before last treatment analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg, max. sample storage: 5 months ASB2009-5943

Table A 7: Residues of bixafen in winter soft 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) : 119.4 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : BYF 000587 EC 125, treated with formulation BYF000587 EC 125 (actual 119.4 g/l Bixafen, BYF 00587)
Applicant : Bayer CropScience AG

Active ingredient : Bixafen (BYF 00587)
Crop / crop group : Winter Soft Wheat

Submission date : 2008-12-16

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) :

Residues calculated as :
8.1 Bixafen (BYF 00587)
8.2 Bixafen-desmethyl
8.3 Sum of Bixafen and bixafen-desmethyl, calculated as bixafen

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)
RA-2320/06, R 2006 0423/8, 0423-06 France 95710 Chaussy 2007-10-01	Isengrain	1) 2005-10-09 (sowing) 2) 2006-06-10 - 2006-06-20 3) 2006-07-20 - 2006-08-15	0.13 0.13	300 300	0.042 0.042	2006-05-23 2006-06-13[4]	BBCH 69	green forage grain straw	1.1 3.0 <0.01 1.8	0.09 0.09 <0.01 0.27	1.2 3.0 <0.02 2.1	0[5] 0 37 37	4) spraying 5) before last treatment analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg, max. sample storage: 4 months ASB2009-5942
RA-2320/06, R 2006 0426/2, 0426-06 Germany 51377 Leverkusen 2007-10-01	Batis	1) 2005-10-18 (sowing) 2) 2006-06-09 - 2006-06-15 3) 2006-07-24	0.13 0.13	300 300	0.042 0.042	2006-05-22 2006-06-19[4]	BBCH 69	green forage grain straw	0.31 2.2 1.3 0.92 0.59 0.01 1.3	0.05 0.05 0.06 0.10 0.11 <0.01 0.20	0.36 2.3 1.4 1.0 0.70 0.02 1.5	0[5] 0 7 14 28 35 35	4) spraying 5) before last treatment analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg, max. sample storage: 4 months ASB2009-5942

Table A 8: Residues of bixafen in winter soft 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) : 50 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : FAR 01285-00, treated with formulation FAR 01285-00, EC (100 g/l Prothioconazole, JAU 6476; 250 g/l Spiroxamin, KWG 4168 + 50 g/l Bixafen, BYF 00587),
Applicant : Bayer CropScience Deutschland GmbH

Active ingredient : Bixafen (BYF 00587)
Crop / crop group : Winter Soft Wheat

Submission date : 2008-10-15

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) : 100 g/l Prothioconazole, 250 g/l Spiroxamine

Residues calculated as :
8.1 Bixafen (BYF 00587)
8.2 Bixafen-desmethyl
8.3 Sum of Bixafen and bixafen-desmethyl, calculated as bixafen

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)
RA-2040/07, R 2007 0443/7 France 37120 Braslou 2008-02-27	Mendel	1) 2006-10-16 (sowing) 2) 2007-05-15 - 2007-05-25 3) 2007-07-04 - 2007-07-14	0.075 0.075	300 300	0.025 0.025	2007-04-30 2007-05-22[4]	BBCH 69	green forage	0.29	0.07	0.36	0[5]	4) spraying 5) before last treatment
									1.7	0.05	1.8	0	analytical method: 01013/M001 (electrospray ionization, ESI+ and ESI- (HPLC-MS/MS)), LOQ: 0.01 mg/kg, max. sample storage: 7 months
								rest of plant	0.65	0.24	0.9	35	
								ears of grain	0.19	0.13	0.32	35	
								grain	<0.01	<0.01	<0.02	44	
								straw	0.68	0.28	0.96	44	ASB2008-6485

Table A 9: Residues of bixafen in winter soft 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) : 75 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : BAY 18530 F, treated with formulation FAR 01282-00, 225 EC (150 g/l Prothioconazole, JAU 6476 + 75 g/l Bixafen, BYF 00587)
Applicant : Bayer CropScience Deutschland GmbH

Active ingredient : Bixafen
Crop / crop group : Winter Soft Wheat

Submission date : 2009-03-02

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) : 150 g/l Prothioconazole (JAU 6476)

Residues calculated as : 8.1 Bixafen (BYF 00587)
8.2 BYF00587-desmethyl calculated as Bixafen
8.3 Sum of Bixafen and bixafen-desmethyl, calculated as bixafen

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)
RA-2037/07, R 2007 0419/4, 0419-07 France 37210 Chambourg sur Indre 2008-02-25	Mercato	1) 2006-10-09 (sowing) 2) 2007-05-09 - 2007-05-18 3) 2007-07-13	0.094 0.094	300 300	0.031 0.031	2007-04-25 2007-05-18[4)]	BBCH 69	green forage rest of plant ears of grain grain straw	0.44 2.8 1.2 0.68 0.52 0.63 0.11 <0.01 1.1	0.13 0.13 0.20 0.18 0.23 0.30 0.08 <0.01 0.46	0.57 3.0 1.4 0.86 0.75 0.93 0.19 <0.02 1.5	0[5)] 0 7 14 28 35 35 55 55	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI-), LOQ: 0.01/0.02 mg/kg, max. sample storage: 5 months ASB2009-5970

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Acceptable.

Reference:	OECD KIIA 6.3
Report	RIP2002-1057, RIP2002-1058, RIP2004-733, ASB2008-6485, ASB2009-5970
Guideline(s):	Yes, EC Guidance 7029/VI/95 rev.5
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 10: Residues of prothioconazole in spring soft 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)	:	200 g/l and 250 g/l	Indoors / outdoors	: Outdoors (European North)
Formulation	(e.g. WP)	:	FS and EC	Other a. i. in formulation	
Commercial product	(name)	:	JAU 6476 FS 200 and JAU 6476 EC 250	(common name and content)	:
Applicant		:	Bayer CropScience	Residues calculated as	: Prothioconazole-desthio

Active ingredient	: Prothioconazole (JAU 6476)
Crop / crop group	: Spring wheat
Submission date	: September 2003

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2003/99 R 1999 0266 2 0266-99	Thasos	1) 1999-03-26 2) 1999-06-18- 1999-06-21 3) 1999-08-12	15 g/100kg seed *			1999-03-26[4] (FS)	end of flowering	seed(s) forage ears of grain	140* <0.05 <0.01	-90 -26 -0	4) seed treatment 5) spraying
DE-51399 Burscheid, Versuchsgut Höfchen 2002-05-08			0.20 0.20 0.20	300 300 300	0.067 0.067 0.067	1999-05-27 1999-06-01 1999-06-22[5] (EC)		rest of plant	0.96 0.57 0.19 0.07 0.04 0.21 1.6 1.1 0.36 0.23 0.16	0 7 14 21 28 -0 0 7 14 21 28	analytical methods: JAU6476-desthio 00647 (HPLC-MS/MS), LOQ's: forage/plant/straw 0.05 mg/kg, grain/ear 0.01 mg/kg, max. sample storage: 21 months *Prothioconazole (JAU6476), analytical method: 00598/M001 RIP2002-1057
								grain straw	<0.01 <0.01 0.14 0.20	35 51 35 51	

Table A 11: Residues of prothioconazole in spring soft wheat

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Prothioconazole (JAU 6476)
Crop / crop group : Spring wheat

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : September 2003

Content of a.i. (g/kg or g/l) : 250 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : JAU 6476 EC 250 = BAY 14120 F Proline
Applicant : Bayer CropScience

Indoors / outdoors : Outdoors (European North)
Other a. i. in formulation (common name and content) :
Residues calculated as : Prothioconazole-desthio

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2104/00, R 2000 0454/0, 0454-00 SE-24030 Flyinge 2002-05-08	Vinjett	1) 2000-05-06 2) 2000-07-11- 2000-07-18 3) 2000-09-19	0.20 0.20 0.20	300 300 300	0.067 0.067 0.067	2000-06-16 2000-06-24 2000-07-17	BBCH 69	ears of grain rest of plant grain straw	0.06 1.6 0.52 0.18 0.05 0.18 0.89 0.32 0.23 0.25 <0.01 0.14	-0 0 7 14 35 -0 0 7 14 35 64 64	 analytical method: 00647 (RP-HPLC-ESI-MS/MS) LOQ: 0.01 mg/kg (grain, ear), 0.05 mg/kg (rest of plant, straw) max. sample storage: 13 months RIP2002-1058

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2104/00, R 2000 0457/5, 0457-00 DE-51399 Burscheid, Versuchsgut Höfchen 2002-05-08	Lavett	1) 2000-03-23 2) 2000-06-15- 2000-06-18 3) 2000-08-16	0.20 0.20 0.20	300 300 300	0.067 0.067 0.067	2000-05-26 2000-06-05 2000-06-19	BBCH 69	ears of grain rest of plant straw grain	<0.01 1.4 0.40 0.18 0.03 0.19 1.6 0.57 0.20 0.08 0.09 <0.01	-0 0 7 14 35 -0 0 7 14 35 58 58	 analytical method: 00647 (RP-HPLC-ESI-MS/MS) LOQ: 0.01 mg/kg (grain, ear), 0.05 mg/kg (rest of plant, straw) max. sample storage: 13 months RIP2002-1058
RA-2104/00, R 2000 0474/5, 0474-00 FR-27700 Fresne L'Archeveque Northern France 2002-05-08	Furio	1) 2000-03-10 2) 2000-06-23- 2000-07-06 3) 2000-08-17	0.20 0.20 0.20	300 300 300	0.067 0.067 0.067	2000-05-16 2000-06-06 2000-07-06	BBCH 69	ears of grain rest of plant straw grain 	<0.01 0.79 0.09 0.06 <0.05 1.5 0.11 0.12 0.07 0.08 <0.01 <0.01	-0 0 7 14 -0 0 7 14 35 42 35 42	 analytical method: 00647 (RP-HPLC-ESI-MS/MS) LOQ: 0.01 mg/kg (grain, ear), 0.05 mg/kg (rest of plant, straw) max. sample storage: 13 months RIP2002-1058

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2104/00, R 2000 0475/3, 0475-00 GB-IP31 3SH Thurston, Bury St. Edmunds 2002-05-08	Chablis	1) 2000-03-23 2) 2000-06-18- 2000-06-28 3) 2000-08-23	0.20 0.20 0.20	300 300 300	0.067 0.067 0.067	2000-05-22 2000-06-05 2000-06-28	BBCH 69	ears of grain rest of plant straw grain	<0.01 0.80 0.26 0.07 0.02 0.74 2.4 1.0 0.50 0.32 0.27 <0.01	-0 0 7 14 35 -0 0 7 14 35 56 56	 analytical method: 00647 (RP-HPLC-ESI-MS/MS) LOQ: 0.01 mg/kg (grain, ear), 0.05 mg/kg (rest of plant, straw) max. sample storage: 13 months RIP2002-1058
RA-2104/00, R 2000 0476/1, 0476-00 DE-40789 Monheim, Versuchsgut Laacherhof 2002-05-08	Lavett	1) 2000-03-23 2) 2000-06-10- 2000-06-15 3) 2000-07-31	0.20 0.20 0.20	300 300 300	0.067 0.067 0.067	2000-05-16 2000-05-26 2000-06-15	BBCH 69	ears of grain rest of plant straw grain	<0.01 0.86 0.99 0.32 0.05 0.17 1.6 1.8 0.72 0.11 0.15 <0.01	-0 0 6 14 35 -0 0 6 14 35 49 49	 analytical method: 00647 (RP-HPLC-ESI-MS/MS) LOQ: 0.01 mg/kg (grain, ear), 0.05 mg/kg (rest of plant, straw) max. sample storage: 13 months RIP2002-1058

Table A 12: Residues of prothioconazole in spring soft wheat

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Prothioconazole (JAU 6476)
Crop / crop group : Spring Wheat

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2004-06-24

Content of a.i. (g/kg or g/l) : 160 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : Input
Applicant : Bayer CropScience Deutschland GmbH

Indoors / outdoors : Outdoors (European North)
Other a. i. in formulation (common name and content) : 300 g/l Spiroxamine
Residues calculated as : Protioconazole-desthio

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2092/00, 0081-00 United Kingdom IP31 3SH Thorston 2001-11-28	Chablis	1) 2000-03-23 (sowing) 2) 2000-06-18 - 2000-06-28 3) 2000-08-23	0.20 0.20	300 300	0.067 0.067	2000-05-22 2000-06-28[4)]	BBCH 69	rest of plant ears of grain grain straw	2.2 0.08 0.06 1.1 0.03 0.02 <0.01 <0.01 0.06 0.06	0 28 35 0 28 35 42 56 42 56	4) spraying analytical method: 00647 (RP-HPLC-ESI-MS/MS), LOQ's: ears/grain 0.01 mg/kg, plant/straw 0.05 mg/kg, max. sample storage: 13 months RIP2004-733
RA-2092/00, 0430-00 D-51399 Burscheid 2001-11-28	Lavett	1) 2000-03-23 (sowing) 2) 2000-06-15 - 2000-06-18 3) 2000-08-16	0.20 0.20	300 300	0.067 0.067	2000-05-26 2000-06-19[4)]	BBCH 69	rest of plant ears of grain grain straw	2.4 0.05 0.06 <0.05 1.7 0.06 0.04 0.04 <0.01 0.07	0 28 35 42 0 28 35 42 58 58	4) spraying analytical method: 00647 (RP-HPLC-ESI-MS/MS), LOQ's: ears/grain 0.01 mg/kg, plant/straw 0.05 mg/kg, max. sample storage: 14 months RIP2004-733

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2092/00, 0431-00 D-40789 Monheim 2001-11-28	Lavett	1) 2000-03-23 (sowing) 2) 2000-06-10 - 2000-06-15 3) 2000-07-31	0.20 0.20	300 300	0.067 0.067	2000-05-16 2000-06-15[4)]	BBCH 69	rest of plant ears of grain grain straw	2.9 0.39 0.36 1.5 0.10 0.07 <0.01 <0.01 0.28 0.14	0 28 35 0 28 35 41 49 41 49	4) spraying analytical method: 00647 (RP-HPLC-ESI-MS/MS), LOQ's: ears/grain 0.01 mg/kg, plant/straw 0.05 mg/kg, max. sample storage: 13 months RIP2004-733
RA-2092/00, 0433-00 France 27700 Fresne lÀrcheveque 2001-11-28	Furio	1) 2000-03-10 (sowing) 2) 2000-06-23 - 2000-07-06 3) 2000-08-17	0.20 0.20	300 300	0.067 0.067	2000-05-16 2000-07-06[4)]	BBCH 69	rest of plant ears of grain grain straw	1.9 0.06 0.92 0.04 <0.01 <0.01 0.06 0.06	0 28 0 28 35 42 35 42	4) spraying analytical method: 00647 (RP-HPLC-ESI-MS/MS), LOQ's: ears/grain 0.01 mg/kg, plant/straw 0.05 mg/kg, max. sample storage: 13 months RIP2004-733

Table A 13: Residues of prothioconazole in spring soft wheat

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Prothioconazole
Crop / crop group : Spring Soft Wheat

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2008-10-15

Content of a.i. (g/kg or g/l) : 100 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : FAR 01285-00, EC treated with formulation FAR 01285-00, EC (100 g/l Prothioconazole, JAU 6476; 250 g/l Spiroxamin, KWG 4168 + 50 g/l Bixafen, BYF 00587),
Applicant : Bayer CropScience Deutschland GmbH

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) : 50 g/l Bixafen (BYF 00587), 250 g/l Spiroxamine
Residues calculated as : Prothioconazole-desthio

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2040/07, R 2007 0444/5 Netherlands 1681 ND Zwaagdijk-Oost 2008-02-27	Baldus	1) 2007-04-06 (sowing) 2) 2007-06-15 - 2007-06-27 3) 2007-08-24 - 2007-09-03	0.15 0.15	300 300	0.050 0.050	2007-06-11 2007-06-27[4)]	BBCH 69	green forage green forage grain straw	0.03 0.92 <u>≤0.01</u> <0.01 <u>0.02</u> 0.02	0[5)] 0 35 61 35 61	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI- (HPLC-MS/MS)) LOQ: 0.01 mg/kg, max. sample storage: 6 months ASB2008-6485

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2040/07, R 2007 0523/9 United Kingdom IP21 4BQ Thrandeston/ Diss (Norfolk) 2008-02-27	Belvoir	1) 2007-03-18 (sowing) 2) 2007-06-13 - 2007-06-20 3) 2007-08-31 - 2007-09-01	0.15 0.15	300 300	0.050 0.050	2007-06-01 2007-06-19[4)]	BBCH 69	green forage green forage rest of plant ears of grain grain straw	0.04 0.92 0.01 <0.01 <0.01 0.03	0[5)] 0 35 35 73 73	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI- (HPLC-MS/MS)) LOQ: 0.01 mg/kg, max. sample storage: 6 months ASB2008-6485
RA-2040/07, R 2007 0524/7 Germany 51399 Burscheid 2008-02-27	Thasos	1) 2007-04-04 (sowing) 2) 2007-06-06 - 2007-06-15 3) 2007-08-14	0.15 0.15	300 300	0.050 0.050	2007-06-06 2007-06-19[4)]	BBCH 69	green forage grain straw	0.16 1.5 <0.01 <0.01 0.04 0.04	0[5)] 0 35 56 35 56	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI- (HPLC-MS/MS)) LOQ: 0.01 mg/kg, max. sample storage: 6 months ASB2008-6485

Table A 14: Residues of prothioconazole in spring soft wheat

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Prothioconazole
Crop / crop group : Spring Soft Wheat

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2009-03-02

Content of a.i. (g/kg or g/l) : 150 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : treated with formulation FAR 01282-00, 225 EC (150 g/l Prothioconazole, JAU 6476 + 75 g/l Bixafen, BYF 00587)
Applicant : Bayer CropScience Deutschland GmbH

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) : 75 g/l Bixafen (BYF 00587)
Residues calculated as : Protioconazole-desthio

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2037/07, R 2007 0418/6, 0418-07 Netherlands 1681 ND Zwaagdijk-Oost 2008-02-25	Baldus	1) 2007-04-06 (sowing) 2) 2007-06-15 - 2007-06-27 3) 2007-08-24 - 2007-09-03	0.19 0.19	300 300	0.063 0.063	2007-06-11 2007-06-27[4)]	BBCH 69	green forage grain straw	0.07 0.86 0.09 0.04 <0.01 <u><0.01</u> <0.01 0.02 <u>0.03</u>	0[5)] 0 7 14 28 35 61 35 61	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI-), LOQ: 0.01 mg/kg, max. sample storage: 5 months ASB2009-5970

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2037/07, R 2007 0420/8, 0420-07 United Kingdom IP21 4BQ Diss (Norfolk) 2008-02-25	Belvoir	1) 2007-03-18 (sowing) 2) 2007-06-13 - 2007-06-20 3) 2007-08-31 - 2007-09-01	0.19 0.19	300 300	0.063 0.063	2007-06-01 2007-06-19[4)]	BBCH 69	green forage rest of plant ears of grain grain straw	0.14 1.1 0.02 <0.01 <u><0.01</u> <u>0.03</u>	0[5)] 0 35 35 73 73	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI-), LOQ: 0.01 mg/kg, max. sample storage: 5 months ASB2009-5970
RA-2037/07, R 2007 0421/6, 0421-07 Germany 49377 Vechta-Langförden 2008-02-25	Thasos	1) 2007-04-05 (sowing) 2) 2007-06-21 - 2007-07-05 3) 2007-08-27 - 2007-08-28	0.19 0.19	300 300	0.063 0.063	2007-06-14 2007-07-05[4)]	BBCH 69	green forage rest of plant ears of grain grain straw	0.02 1.2 0.03 0.01 <u><0.01</u> <u>0.04</u>	0[5)] 0 35 35 53 53	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI-), LOQ: 0.01 mg/kg, max. sample storage: 5 months ASB2009-5970

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Acceptable.

Reference:	OECD KIIA 6.3
Report	RIP2002-1057, ASB2008-6485, ASB2009-5970
Guideline(s):	Yes, EC Guidance 7029/VI/95 rev.5
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 15: Residues of prothioconazole in winter soft 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)	:	200 g/l and 250 g/l
Formulation	(e.g. WP)	:	FS and EC
Commercial product	(name)	:	JAU 6476 FS 200 and JAU 6476 EC 250
Applicant		:	Bayer CropScience

Active ingredient	:	Prothioconazole (JAU 6476)
Crop/crop group	:	Winter Soft Wheat
Submission date	:	June 2002
Indoors/outdoors	:	Outdoors (European North)
Other a. i. in formulation (common name and content)	:	
Residues calculated as	:	Prothioconazole -desthio

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2003/99, R 1999 0023 6, 0023-99 DE-51399 Burscheid, Versuchsgut Höfchen 2002-05-08	Bandit	1) 1998-11-12 2) 1999-06-12- 1999-06-15 3) 1999-08-04	15 g/100kg seed * 0.20 0.20 0.20	 300 300 300	 0.067 0.067 0.067	1998-11-12[4)] (FS) 1999-05-07 1999-05-25 1999-06-15[5)] (EC)	BBCH 69	seed(s) forage ears of grain rest of plant straw grain 	141* <0.05 0.78 0.05 0.03 1.2 0.16 0.13 0.25 0.31 <0.01 <0.01	-236 -39 0 21 28 0 21 28 35 50 35 50	4) seed treatment 5) spraying analytical methods: JAU6476-desthio 00647 (HPLC-MS/MS), LOQ's: forage/plant/straw 0.05 mg/kg, grain/ear 0.01 mg/kg, max. sample storage: 21 months *Prothioconazole (JAU6476), analytical method: 00598/M001 RIP2002-1057
RA-2003/99, R 1999 0025 2, 0025-99 DE-40789 Monheim, Versuchsgut Laacher Hof 2002-05-08	Bandit	1) 1998-11-12 2) 1999-06-05- 1999-06-10 3) 1999-07-26	15 g/100kg seed * 0.20 0.20 0.20	 300 300 300	 0.067 0.067 0.067	1998-11-12[4)] (FS) 1999-05-05 1999-05-19 1999-06-10[5)] (EC)	BBCH 69	seed(s) forage ears of grain rest of plant straw grain 	139* <0.05 0.79 0.07 0.04 1.2 0.46 0.40 0.67 0.72 <0.01 <0.01	-231 -36 0 21 28 0 21 28 35 46 35 46	4) seed treatment 5) spraying analytical methods: JAU6476-desthio 00647 (HPLC-MS/MS), LOQ's: forage/plant/straw 0.05 mg/kg, grain/ear 0.01 mg/kg, max. sample storage: 21 months *Prothioconazole (JAU6476), analytical method: 00598/M001 RIP2002-1057

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2003/99, R 1999 0026 0, 0026-99 FR-27220 Mousseaux-Neuville 2002-05-08	Sideral	1) 1998-10-22 2) 1999-05-21-1999-06-03 3) 1999-07-16	15 g/100kg seed * 0.20 0.20 0.20	 300 300 300	 0.067 0.067 0.067	1998-10-22[4)] (FS) 1999-04-26 1999-05-12 1999-06-03[5)] (EC)	BBCH 69	seed(s) forage ears of grain rest of plant straw grain	114* <0.05 0.59 0.02 0.02 0.60 0.09 0.13 0.11 0.11 <0.01 <0.01	-224 -38 0 21 28 0 21 28 35 43 35 43	4) seed treatment 5) spraying analytical methods: JAU6476-desthio 00647 (HPLC-MS/MS), LOQ's: forage/plant/straw 0.05 mg/kg, grain/ear 0.01 mg/kg, max. sample storage: 21 months *Prothioconazole (JAU6476), analytical method: 00598/M001 RIP2002-1057

Table A 16: Residues of prothioconazole in winter soft wheat

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Prothioconazole (JAU 6476)
Crop/crop group : Winter Soft Wheat

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : September 2003
Indoors/outdoors : Outdoors (European North)
Other a. i. in formulation (common name and content) :
Residues calculated as : Prothioconazole -desthio

Content of a.i. (g/kg or g/l) : 250 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : JAU 6476 EC 250 = BAY 14120 F
Applicant : Bayer CropScience

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2003/99, R 1999 0027 9, 0027-99 GB-IP31 3SH Thurston, Bury St. Edmunds 2002-05-08	Abbot	1) 1998-10-09 2) 1998-06-01-1999-06-10 3) 1999-08-02	0.20 0.20 0.20	300 300 300	0.067 0.067 0.067	1999-04-30 1999-05-15 1999-06-09	BBCH 69	ears of grain rest of plant straw grain	<0.01 1.2 0.07 0.02 0.02 0.19 1.8 0.21 0.14 0.14 0.19 <0.01	-0 0 21 28 35 -0 0 21 28 35 54 54	 analytical method: JAU6476-desthio 00647 (HPLC-MS/MS), LOQ's: forage/plant/straw 0.05 mg/kg, grain/ear 0.01 mg/kg, max. sample storage: 21 months RIP2002-1057

Table A 17: Residues of prothioconazole in winter soft wheat

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Prothioconazole
Crop / crop group : Winter Soft Wheat

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2008-10-15

Content of a.i. (g/kg or g/l) : 100 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : FAR 01285-00, EC, treated with formulation FAR 01285-00, EC (100 g/l Prothioconazole, JAU 6476; 250 g/l Spiroxamine, KWG 4168 + 50 g/l Bixafen, BYF 00587),
Applicant : Bayer CropScience Deutschland GmbH

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) : 50 g/l Bixafen (BYF 00587), 250 g/l Spiroxamine
Residues calculated as : Prothioconazole-desthio

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2040/07, R 2007 0443/7 France 37120 Braslou 2008-02-27	Mendel	1) 2006-10-16 (sowing) 2) 2007-05-15 - 2007-05-25 3) 2007-07-04 - 2007-07-14	0.15 0.15	300 300	0.050 0.050	2007-04-30 2007-05-22[4)]	BBCH 69	green forage rest of plant ears of grain grain straw	0.04 0.84 0.08 0.02 <0.01 0.08	0[5)] 0 35 35 44 44	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI- (HPLC-MS/MS)) LOQ: 0.01 mg/kg, max sample storage: 7 months ASB2008-6485

Table A 18: Residues of prothioconazole in winter soft wheat

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Prothioconazole
Crop / crop group : Winter Soft Wheat

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2009-08-12

Content of a.i. (g/kg or g/l) : 150 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : treated with formulation FAR 01282-00, 225 EC (150 g/l Prothioconazole, JAU 6476 + 75 g/l Bixafen, BYF 00587)
Applicant : Bayer CropScience Deutschland GmbH

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) : 75 g/l Bixafen (BYF 00587)
Residues calculated as : Prothioconazole-desthio

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2037/07, R 2007 0419/4, 0419-07 France 37210 Chambourg sur Indre 2008-02-25	Mercato	1) 2006-10-09 (sowing) 2) 2007-05-09 - 2007-05-18 3) 2007-07-13	0.19 0.19	300 300	0.063 0.063	2007-04-25 2007-05-18[4)]	BBCH 69	green forage green forage rest of plant ears of grain grain straw	0.08 1.7 0.32 0.12 0.06 0.07 0.01 <0.01 0.10	0[5)] 0 7 14 28 35 35 55 55	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI-), LOQ: 0.01 mg/kg, max. sample storage: 5 months ASB2009-5970

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Acceptable.

A 2.2.3 Magnitude of residues in barley

Reference:	OECD KIIA 6.3
Report	ASB2009-5946, ASB2009-5947, ASB2009-5948, ASB2009-5954, ASB2009-5976, ASB2009-5991
Guideline(s):	Yes, EC Guidance 7029/VI/95 rev.5, 7035/VI/95 rev. 5 (1997-07-22), IVA-Richtlinie: Rückstandsversuche, Teil I-III (1992)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 19: Residues of bixafen in spring 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)	:	EC
Commercial product	(name)	:	BYF 000587 EC 125 G, treated with formulation BYF000587 EC 125 G (125 g/l Bixafen, BYF 00587)
Applicant		:	Bayer CropScience AG

Active ingredient	:	Bixafen (BYF 00587)
Crop / crop group	:	Spring Barley
Submission date	:	2008-12-16
Indoors / outdoors	:	Outdoors (European North)
Other a.i. in formulation (content and common name)	:	
Residues calculated as	:	8.1 Bixafen (BYF 00587) 8.2 Bixafen-desmethyl 8.3 Sum of Bixafen and bixafen-desmethyl, calculated as bixafen

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)
RA-2003/07, R 2007 0081/4, 0081-07 France 95510 St. Cyr en Arthies 2008-01-11	Heinley	1) 2007-03-12 (sowing) 2) 2007-05-28 - 2007-06-07 3) 2007-07-25 - 2007-08-04	0.13 0.13	300 300	0.042 0.042	2007-05-10 2007-05-29[4]	BBCH 61	green forage rest of plant ears of grain grain straw	0.47 3.4 2.1 1.5 0.41 0.54 0.16 0.04 0.64	0.07 0.07 0.13 0.14 0.08 0.11 0.04 0.01 0.08	0.54 3.5 2.2 1.7 0.49 0.64 0.20 0.05 0.73	0[5] 0 7 14 28 34 34 58 58	4) spraying 5) before last treatment analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg, max. sample storage: 5 months ASB2009-5947
RA-2003/07, R 2007 0082/2, 0082-07 France 80700 Carrépuis 2008-01-11	Prestige	1) 2007-03-23 (sowing) 2) 2007-05-28 - 2007-06-05 3) 2007-07-25 - 2007-08-05	0.13 0.13	300 300	0.042 0.042	2007-05-23 2007-05-31[4]	BBCH 61	green forage rest of plant ears of grain grain straw	1.5 4.3 0.66 0.09 0.02 0.77	0.09 0.10 0.09 0.02 <0.01 0.08	1.6 4.4 0.75 0.11 0.03 0.84	0[5] 0 35 35 60 60	4) spraying 5) before last treatment analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg, max. sample storage: 5 months ASB2009-5947
RA-2003/07, R 2007 0160/8, 0160-07 Germany 49377 Vechta-Langförden 2008-01-11	Tocada	1) 2007-04-05 (sowing) 2) 2007-06-28 - 2007-07-02 3) 2007-08-02 - 2007-08-03	0.13 0.13	300 300	0.042 0.042	2007-06-04 2007-06-28[4]	BBCH 61	green forage grain straw	0.37 2.5 1.5 0.90 1.1 0.10 0.70	0.08 0.07 0.11 0.09 0.07 0.01 0.04	0.45 2.6 1.6 0.99 1.2 0.11 0.74	0[5] 0 7 14 28 35 35	4) spraying 5) before last treatment analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg, max. sample storage: 5 months ASB2009-5947

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)
RA-2003/07, R 2007 0161/6, 0161-07 United Kingdom PE356 EN Sandringham 2008-01-11	Tippel	1) 2007-02-01 (sowing) 2) 2007-05-23 - 2007-06-04 3) 2007-08-05 - 2007- 08-15	0.13 0.13	300 300	0.042 0.042	2007-05-14 2007-06-04[4)]	BBCH 69	green forage grain straw	0.36 2.4 1.3 0.84 0.39 0.04 0.05 0.45 1.1	0.07 0.07 0.08 0.11 0.09 0.01 0.01 0.13 0.14	0.43 2.4 1.4 0.94 0.48 0.05 0.06 0.58 1.2	0[5)] 0 8 14 28 35 66 35 66	4) spraying 5) before last treatment analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg, max. sample storage: 5 months ASB2009-5947
RA-2003/07, R 2007 0162/4, 0162-07 Belgium 6210 Villers-Perwin 2008-01-11	Beatrix	1) 2007-03-15 (sowing) 2) 2007-06-05 - 2007-06-10 3) 2007-07-25 - 2007-07-31	0.13 0.13	300 300	0.042 0.042	2007-05-18 2007-06-05[4)]	BBCH 61	green forage grain straw	0.18 2.8 0.07 0.09 0.68	0.07 0.09 0.02 0.01 0.17	0.24 2.9 0.09 0.10 0.85	0[5)] 0 34 65 34	4) spraying 5) before last treatment analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg, max. sample storage: 5 months ASB2009-5947

Table A 20: Residues of bixafen in spring 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) : 119.4 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : BYF 000587 EC 125, treated with formulation BYF000587 EC 125 (actual 119.4 g/l Bixafen, BYF 00587)
Applicant : Bayer CropScience AG

Active ingredient : Bixafen (BYF 00587)
Crop / crop group : Spring Barley

Submission date : 2008-12-16

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) :

Residues calculated as :
8.1 Bixafen (BYF 00587)
8.2 Bixafen-desmethyl
8.3 Sum of Bixafen and bixafen-desmethyl, calculated as bixafen

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)
RA-2322/06, R 2006 0432/7, 0432-06 France 95510 St. Cyr en Arthies 2007-09-13	Carafe	1) 2006-03-18 (sowing) 2) 2006-06-18 - 2006-06-24 3) 2006-07-20 - 2006-08-10	0.13 0.13	300 300	0.042 0.042	2006-05-24 2006-06-20[4)]	BBCH 61	green forage grain straw	1.4 4.4 0.04 5.4	0.08 0.08 <0.01 0.18	1.4 4.4 0.05 5.6	0[5)] 0 34 34	4) spraying 5) before last treatment analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg, max. sample storage: 6 months ASB2009-5946

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)
RA-2322/06, R 2006 0434/3, 0434-06 Sweden 245 61 Staffanstorp 2007-09-13	Pasadena	1) 2006-05-02 (sowing) 2) 2006-07-04 - 2006 3) 2006-08-17 - 2006-08-18	0.13 0.13	300 300	0.042 0.042	2006-06-22 2006-07-04[4)]	BBCH 61	green forage grain straw	1.7 7.0 4.1 3.7 4.6 0.09 0.06 10.0 4.3	0.23 0.25 0.51 0.60 0.49 0.02 0.01 1.4 0.66	1.9 7.3 4.6 4.4 5.1 0.10 0.07 12.0 5.0	0[5)] 0 7 14 28 36 45 36 45	4) spraying 5) before last treatment analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg, max. sample storage: 6 months ASB2009-5946
RA-2322/06, R 2006 0437/8, 0437-06 Germany 53913 Swisttal-Heimerzheim 2007-09-13	Class	1) 2006-03-22 (sowing) 2) 2006-06-22 - 2006-06-30 3) 2006-07-25 - 2006-07-27	0.13 0.13	300 300	0.042 0.042	2006-05-31 2006-06-22[4)]	BBCH 61	green forage grain straw	0.88 3.9 2.0 2.7 2.8 0.07 4.8	0.11 0.10 0.12 0.21 0.20 0.01 0.37	0.99 4.0 2.1 2.9 3.0 0.08 5.2	0[5)] 0 7 13 28 35 35	4) spraying 5) before last treatment analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg, max. sample storage: 6 months ASB2009-5946
RA-2324/06, R 2006 0444/0, 0444-06 Sweden 245 93 Staffanstorp 2007-10-04	Prestige	1) 2006-04-28 (sowing) 2) 2006-06-29 - 2006-07-05 3) 2006-08-08 - 2006-08-09	0.25 0.25	300 300	0.083 0.083	2006-06-15 2006-06-29[4)]	BBCH 61	green forage grain	9.1 0.23	0.18 0.03	9.3 0.26	0 40	4) spraying see also study RA-3324/06, ASB2009-5954 analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg, max. sample storage: 4 months ASB2009-5948

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)
RA-2324/06, R 2006 0445/9, 0445-06 Germany 53913 Swisttal-Heimerzheim 2007-10-04	Class	1) 2006-03-22 (sowing) 2) 2006-06-22 - 2006-06-30 3) 2006-07-25 - 2006-07-27	0.25 0.25	300 300	0.083 0.083	2006-05-31 2006-06-22[4)]	BBCH 61	green forage grain	6.1 0.13	0.18 0.02	6.3 0.15	0 35	4) spraying see also study RA-3324/06, ASB2009-5954 analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg, max. sample storage: 4 months ASB2009-5948
RA-2324/06, R 2006 0446/7, 0446-06 France 80700 Fresnoy les Roye 2007-10-04	Scarlett	1) 2006-03-21 (sowing) 2) 2006-06-20 - 2006-07-05 3) 2006-07-22 - 2006-07-27	0.25 0.25	300 300	0.083 0.083	2006-05-31 2006-06-22[4)]	BBCH 61	green forage grain	7.8 0.20	0.17 0.02	8.0 0.22	0 46	4) spraying see also study RA-3324/06, ASB2009-5954 analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg, max. sample storage: 4 months ASB2009-5948
RA-2324/06, R 2006 0447/5, 0447-06 Germany 51399 Burscheid 2007-10-04	Barke	1) 2006-03-23 (sowing) 2) 2006-06-13 - 2006-06-16 3) 2006-07-26	0.25 0.25	300 300	0.083 0.083	2006-05-15 2006-06-13[4)]	BBCH 61	green forage grain	6.3 0.03	0.07 <0.01	6.4 0.04	0 43	4) spraying see also study RA-3324/06, ASB2009-5954 analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg, max. sample storage: 4 months ASB2009-5948

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)
RA-3324/06, R 2006 0444/0, 0444-06, processing Sweden 245 93 Staffanstorp 2007-10-04	Prestige	1) 2006-04-28 (sowing) 2) 2006-06-29 - 2006-07-05 3) 2006-08-08 - 2006-08-09	0.25 0.25	300 300	0.083 0.083	2006-06-15 2006-06-29[4)]	BBCH 61	grain, RAC	0.23	0.03	0.26	40	4) spraying see also study RA-2324/06, ASB2009-5948 analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg, max. sample storage: 8 months ASB2009-5954
								pearl barley	0.04	0.01	0.05	40	
								pearl barley rub off	0.74	0.09	0.84	40	
								brewer's malt	0.22	0.06	0.27	40	
								yeast	0.04	0.01	0.05	40	
								malt culms	0.17	0.06	0.23	40	
								hops draff	0.17	0.03	0.20	40	
								brewer's grain	0.23	0.04	0.27	40	
								beer	<0.01	<0.01	<0.02	40	
RA-3324/06, R 2006 0445/9, 0445-06, processing Germany 53913 Swisttal-Heimerzheim 2007-10-04	Class	1) 2006-03-22 (sowing) 2) 2006-06-22 - 2006-06-30 3) 2006-07-25 - 2006-07-27	0.25 0.25	300 300	0.083 0.083	2006-05-31 2006-06-22[4)]	BBCH 61	grain, RAC	0.13	0.02	0.15	35	4) spraying see also study RA-2324/06, ASB2009-5948 analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg, max. sample storage: 8 months ASB2009-5954
								pearl barley	0.03	0.01	0.04	35	
								pearl barley rub off	0.67	0.07	0.74	35	
								brewer's malt	0.12	0.03	0.15	35	
								yeast	0.01	<0.01	0.02	35	
								malt culms	0.14	0.04	0.18	35	
								hops draff	0.09	0.02	0.10	35	
								brewer's grain	0.14	0.03	0.16	35	
								beer	<0.01	<0.01	<0.02	35	

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)
RA-3324/06, R 2006 0446/7, 0446-06, processing France 80700 Fresnoy les Roye 2007-10-04	Scarlett	1) 2006-03-21 (sowing) 2) 2006-06-20 - 2006-07-05 3) 2006-07-22 - 2006-07-27	0.25 0.25	300 300	0.083 0.083	2006-05-31 2006-06-22[4)]	BBCH 61	grain, RAC	0.20	0.02	0.22	46	4) spraying see also study RA-2324/06, ASB2009-5948 analytical method: 01012 (HPLC-MS/MS), LOQ 0.01 mg/kg, max. sample storage: 8 months ASB2009-5954
								pearl barley	0.04	0.01	0.05	46	
								pearl barley rub off	0.91	0.06	0.97	46	
								brewer's malt	0.16	0.04	0.20	46	
								yeast	0.04	<0.01	0.05	46	
								malt culms	0.14	0.03	0.17	46	
								hops draff	0.13	0.02	0.15	46	
								brewer's grain	0.17	0.03	0.19	46	
								beer	<0.01	<0.01	<0.02	46	
RA-3324/06, R 2006 0447/5, 0447-06, processing Germany 51399 Burscheid 2007-10-04	Barke	1) 2006-03-23 (sowing) 2) 2006-06-13 - 2006-06-16 3) 2006-07-26	0.25 0.25	300 300	0.083 0.083	2006-05-15 2006-06-13[4)]	BBCH 61	grain, RAC	0.03	<0.01	0.04	43	4) spraying see also study RA-2324/06, ASB2009-5948 analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg, max. sample storage: 8 months ASB2009-5954
								pearl barley	<0.01	<0.01	<0.02	43	
								pearl barley rub off	0.11	0.01	0.12	43	
								brewer's malt	0.01	<0.01	0.02	43	
								yeast	<0.01	<0.01	<0.02	43	
								malt culms	0.01	<0.01	0.02	43	
								hops draff	0.01	<0.01	0.02	43	
								brewer's grain	0.01	<0.01	0.02	43	
								beer	<0.01	<0.01	<0.02	43	

Table A 21: Residues of bixafen in spring 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) : 75 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : BAY 18530 F, treated with formulation FAR 01282-00, 225 EC (150 g/l Prothioconazole, JAU 6476 + 75 g/l Bixafen, BYF 00587)
Applicant : Bayer CropScience Deutschland GmbH

Active ingredient : Bixafen
Crop / crop group : Spring Barley

Submission date : 2009-03-02

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) : 150 g/l Prothioconazole (JAU 6476)

Residues calculated as : 8.1 Bixafen (BYF 00587)
8.2 BYF00587-desmethyl
8.3 Sum of Bixafen and bixafen-desmethyl, calculated as bixafen

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)
RA-2039/07, R 2007 0426/7, 0426-07 France 95510 St. Cyr en Arthies 2008-02-25	Heinley	1) 2007-03-12 (sowing) 2) 2007-05-28 - 2007-06-07 3) 2007-07-25 - 2007-08-04	0.075 0.075	300 300	0.025 0.025	2007-05-10 2007-05-29[4]	BBCH 61	green forage	0.38	0.06	0.44	0[5]	4) spraying 5) before last treatment
									2.1	0.06	2.2	0	analytical method: 01013 (electrospray ionization, ESI+ and ESI-) LOQ 0.01 mg/kg, max. sample storage: 5 months
								rest of plant	0.41	0.11	0.52	35	
								ears of grain	0.14	0.06	0.19	35	
								grain	0.04	0.01	0.05	58	
								straw	0.47	0.08	0.56	58	ASB2009-5991

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)
RA-2039/07, R 2007 0427/5, 0427-07 Germany 51399 Burscheid 2008-02-25	Annabell	1) 2007-04-10 (sowing) 2) 2007-06-18 - 2007-06-24 3) 2007-08-06	0.075 0.075	300 300	0.025 0.025	2007-05-31 2007-06-18[4)]	BBCH 61	green forage grain straw	0.51 3.0 0.07 0.06 1.1 0.67	0.08 0.09 0.02 0.02 0.15 0.15	0.60 3.1 0.09 0.08 1.2 0.82	0[5)] 0 35 49 35 49	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI-) LOQ 0.01 mg/kg, max. sample storage: 5 months, ASB2009-5991
RA-2328/06, R 2006 0457/2, 0457-06 France 95510 St. Cyr en Arthies 2007-11-19	Carafe	1) 2006-03-18 (sowing) 2) 2006-06-18 - 2006-06-24 3) 2006-07-20 - 2006-08-10	0.075 0.075	300 300	0.025 0.025	2006-05-24 2006-06-20[4)]	BBCH 61	green forage grain straw	0.46 2.0 0.05 3.3	0.05 0.06 0.01 0.19	0.51 2.0 0.06 3.5	0[5)] 0 34 34	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI-) LOQ 0.01 mg/kg, max. sample storage: 6 months. ASB2009-5976
RA-2328/06, R 2006 0458/0, 0458-06 Sweden 24593 Staffanstorp 2007-11-19	Prestige	1) 2006-04-28 (sowing) 2) 2006-06-29 - 2006-07-05 3) 2006-08-08 - 2006-08-09	0.075 0.075	300 300	0.025 0.025	2006-06-15 2006-06-29[4)]	BBCH 61	green forage grain straw	2.6 2.0 1.3 1.5 0.05 5.1	0.06 0.17 0.16 0.22 0.01 0.56	2.6 2.2 1.4 1.8 0.06 5.7	0 7 14 28 40 40	4) spraying analytical method: 01013 (electrospray ionization, ESI+ and ESI-) LOQ 0.01 mg/kg, max. sample storage: 6 months, ASB2009-5976

Table A 22: Residues of bixafen in spring 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) : 50 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : FAR 01285-00, EC,treated with formulation FAR 01285-00, EC (100 g/l Prothioconazole, JAU 6476; 250 g/l Spiroxamin, KWG 4168 + 50 g/l Bixafen, BYF 00587)
Applicant : Bayer CropScience Deutschland GmbH

Active ingredient : Bixafen (BYF 00587)
Crop / crop group : Spring Barley

Submission date : 2008-10-15

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) : 100 g/l Prothioconazole, 250 g/l Spiroxamine

Residues calculated as :
8.1 Bixafen (BYF 00587)
8.2 Bixafen-desmethyl
8.3 Sum of Bixafen and bixafen-desmethyl, calculated as bixafen

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)
RA-2042/07, R 2007 0448/8, 0448-07 France 95510 St Cyr en Arthies (Ile-de-France) 2008-02-26	Heinley	1) 2007-03-12 (sowing) 2) 2007-05-28 - 2007-06-07 3) 2007-07-25 - 2007-08-04	0.075 0.075	300 300	0.025 0.025	2007-05-10 2007-05-29[4)]	BBCH 61	green forage	0.29	0.06	0.35	0[5)]	4) spraying 5) before last treatment
								green forage	1.9	0.06	1.9	0	analytical method: 01013 (electrospray ionization, ESI+ and ESI- (HPLC-MS/MS)), LOQ 0.01 mg/kg, max. sample storage: 7 months
								rest of plant	0.35	0.14	0.49	35	
								ears of grain	0.12	0.07	0.19	35	
								grain	0.05	0.02	0.07	58	
								straw	0.39	0.10	0.49	58	ASB2008-6491

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)
RA-2042/07, R 2007 0527/1, 0527-07 United Kingdom CB2 5EU Little Shelford 2008-02-26	Cocktail	1) 2007-01-24 (sowing) 2) 2007-05-25 - 2007-06-09 3) 2007-08-15 - 2007-08-31	0.075 0.080	300 300	0.025 0.027	2007-05-09 2007-05-25[4)]	BBCH 61	green forage green forage rest of plant ears of grain grain straw	0.33 2.6 0.27 0.03 <0.01 0.22	0.03 0.03 0.05 0.01 <0.01 0.03	0.35 2.7 0.32 0.05 <0.02 0.25	0[5)] 0 34 34 96 96	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI- (HPLC-MS/MS)), LOQ 0.01 mg/kg, max. sample storage: 7 months ASB2008-6491
RA-2042/07, R 2007 0529/8, 0529-07 Netherlands 1681 ND Zwaagdijk-Oost 2008-02-26	Prestige	1) 2007-04-06 (sowing) 2) 2007-06-12 - 2007-06-24 3) 2007-08-20 - 2007-09-02	0.075 0.075	300 300	0.025 0.025	2007-05-30 2007-06-13[4)]	BBCH 61	green forage green forage grain straw 	0.57 2.2 0.03 0.03 0.26 0.23	0.11 0.10 0.02 0.01 0.13 0.07	0.68 2.3 0.04 0.04 0.38 0.30	0[5)] 0 35 71 35 71	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI- (HPLC-MS/MS)), LOQ 0.01 mg/kg, max. sample storage: 7 months ASB2008-6491

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Acceptable.

Reference:	OECD KIIA 6.3
Report	ASB2009-5946, ASB2008-6491, ASB2009-5976
Guideline(s):	Yes, EC Guidance 7029/VI/95 rev.5, 7035/VI/95 rev. 5 (1997-07-22), IVA-Richtlinie: Rückstandsversuche, Teil I-III (1992)
Deviations:	No mention
GLP:	Yes
Acceptability:	Yes

Table A 23: Residues of bixafen in winter 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)	:	119.4 g/l
Formulation	(e.g. WP)	:	EC
Commercial product	(name)	:	BYF 000587 EC 125, treated with formulation BYF000587 EC 125 (119.4 g/l Bixafen, BYF 00587)
Applicant		:	Bayer CropScience AG

Active ingredient	:	Bixafen (BYF 00587)
Crop / crop group	:	Winter Barley
Submission date	:	2008-12-16
Indoors / outdoors	:	Outdoors (European North)
Other a.i. in formulation (content and common name)	:	
Residues calculated as	:	8.1 Bixafen (BYF 00587) 8.2 Bixafen-desmethyl 8.3 Sum of Bixafen and bixafen-desmethyl, calculated as bixafen

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)
RA-2322/06, R 2006 0435/1, 0435-06 United Kingdom IP21 5DB Hoxne / Nr Eye (Suffolk) 2007-09-13	Sequel	1) 2005-09-29 (sowing) 2) 2006-05-14 - 2006-05-25 3) 2006-07-18 - 2006-07-19	0.13 0.13	300 300	0.042 0.042	2006-05-05 2006-05-17[4]	BBCH 61	green forage grain straw	0.42 2.1 0.80 0.59 0.38 0.04 1.1	0.03 0.04 0.05 0.06 0.05 <0.01 0.08	0.45 2.1 0.85 0.65 0.43 0.05 1.2	0[5] 0 8 14 28 62 62	4) spraying 5) before last treatment analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg, max sample storage: 6 months ASB2009-5946
RA-2322/06, R 2006 0433/5, 0433-06 France 37210 Chambourg sur Indre 2007-09-13	Vanessa	1) 2005-10-31 (sowing) 2) 2006-05-10 - 2006-05-18 3) 2006-06-30	0.13 0.13	300 300	0.042 0.042	2006-04-28 2006-05-11[4]	BBCH 61	green forage grain straw	1.0 3.9 0.08 3.7	0.03 0.04 0.02 0.20	1.0 3.9 0.10 3.9	0[5] 0 49 49	4) spraying 5) before last treatment analytical method: 01012 (HPLC-MS/MS) LOQ 0.01 mg/kg, max sample storage: 6 months ASB2009-5946

Table A 24: Residues of bixafen in winter 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) : 50 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : FAR 01285-00, EC, treated with formulation FAR 01285-00, EC (100 g/l Prothioconazole, JAU 6476; 250 g/l Spiroxamin, KWG 4168 + 50 g/l Bixafen, BYF 00587)
Applicant : Bayer CropScience Deutschland GmbH

Active ingredient : Bixafen (BYF 00587)
Crop / crop group : Winter Barley

Submission date : 2008-10-15

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) : 100 g/l Prothioconazole, 250 g/l Spiroxamine

Residues calculated as :
8.1 Bixafen (BYF 00587)
8.2 Bixafen-desmethyl
8.3 Sum of Bixafen and bixafen-desmethyl, calculated as bixafen

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)
RA-2042/07, R 2007 0449/6, 0449-07	Naomi	1) 2006-09-25 (sowing)	0.075	300	0.025	2007-04-18	BBCH 61	green forage	0.83	0.02	0.84	0[5)]	4) spraying 5) before last treatment
		2) 2007-05-03 - 2007-05-14	0.075	300	0.025	2007-05-04[4)]			2.3	0.02	2.4	0	
Germany 53913 Swisttal		3) 2007-06-20 - 2007-06-28						rest of plant	0.86	0.065	0.93	35	analytical method: 01013 (electrospray ionization, ESI+ and ESI- (HPLC-MS/MS)), LOQ 0.02 mg/kg, max sample storage: 7 months
								ears of grain	0.14	0.03	0.17	35	
2008-02-26								grain	0.07	<0.01	0.08	55	
								straw	1.3	0.06	1.3	55	ASB2008-6491

Table A 25: Residues of bixafen in winter 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) : 75 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : BAY 18530 F, treated with formulation FAR 01282-00, 225 EC (150 g/l Prothioconazole, JAU 6476 + 75 g/l Bixafen, BYF 00587)
Applicant : Bayer CropScience Deutschland GmbH

Active ingredient : Bixafen
Crop / crop group : Winter Barley

Submission date : 2009-03-02

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) : 150 g/l Prothioconazole (JAU 6476)

Residues calculated as : 8.1 Bixafen (BYF 00587)
8.2 bixafen-desmethyl, calculated as Bixafen (BYF 00587)
8.3 Sum of Bixafen (BYF 00587) and bixafen-desmethyl, calculated as bixafen

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)
RA-2328/06, R 2006 0459/9, 0459-06 United Kingdom IP21 5DB Hoxne / Nr Eye 2007-11-19	Sequel	1) 2005-09-29 (sowing) 2) 2006-05-14 - 2006-05-25 3) 2006-07-18 - 2006-07-19	0.075 0.075	300 300	0.025 0.025	2006-05-05 2006-05-17[4)]	BBCH 61	green forage grain straw	0.28 1.5 0.04 1.2	0.02 0.02 0.01 0.12	0.30 1.6 0.06 1.3	0[5)] 0 62 62	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI-) LOQ 0.01 mg/kg, max. sample storage: 6 months ASB2009-5976

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)
RA-2328/06, R 2006 0460/2, 0460-06 Germany 59514 Welver-Flerke 2007-11-19	Duet	1) 2005-09-20 (sowing) 2) 2006-05-13 - 2006-05-23 3) 2006-07-05 - 2006-07-15	0.075 0.075	300 300	0.025 0.025	2006-04-28 2006-05-15[4)]	BBCH 61	green forage grain straw	0.45 1.7 0.63 0.29 0.41 <u><0.01</u> <u>0.56</u>	0.04 0.04 0.06 0.06 0.06 <0.01 0.12	0.49 1.8 0.69 0.34 0.47 <u><0.02</u> <u>0.68</u>	0[5)] 0 7 28 75 51 51	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI-) LOQ 0.01 mg/kg, max. sample storage: 6 months ASB2009-5976

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Acceptable.

Reference:	OECD KIIA 6.3
Report	RIP2004-735Source_Y_RIP2002_1060, RIP2002-1068, RIP2002-1069, ASB2008-6491, ASB2009-5976, ASB2009-5991
Guideline(s):	Yes, EC Guidance 7029/VI/95 rev.5 (1997-07-22)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 26: Residues of prothioconazole in spring 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) : 160 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : Input
Applicant : Bayer CropScience Deutschland GmbH

Active ingredient : Prothioconazole (JAU 6476)
Crop / crop group : Spring Barley

Submission date : 2004-09-03

Indoors / outdoors : Outdoors (European North)
Other a. i. in formulation (common name and content) : 300 g/l Spiroxamine
Residues calculated as : Prothioconazole-desthio

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2092/00, 0083-00 D-51399 Burscheid 2001-12-07	Baronesse	1) 2000-03-23 (sowing) 2) 2000-06-09 - 2000-06-12 3) 2000-08-14	0.20 0.20	300 300	0.067 0.067	2000-05-16 2000-06-09[4)]	BBCH 61	rest of plant ears of grain grain straw	2.6 0.17 0.06 3.0 0.01 0.01 <0.01 <0.01 <0.05 0.05	0 28 34 0 28 34 42 61 42 61	4) spraying analytical method: 00647 (RP-HPLC-ESI-MS/MS) LOQ 0.01 mg/kg (grain , ear) 0.05 mg/kg (rest of plant, straw), max. sample storage: 15 months RIP2004-735

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2092/00, 0425-00 D-40789 Monheim 2001-12-07	Alexis	1) 2000-03-23 (sowing) 2) 2000-06-09 - 2000-06-13 3) 2000-08-03	0.20 0.20	300 300	0.067 0.067	2000-05-16 2000-06-09[4)]	BBCH 61	rest of plant ears of grain grain straw	3.0 0.50 0.19 2.1 0.06 0.02 <0.01 <0.01 0.21 0.08	0 28 34 0 28 34 42 55 42 55	4) spraying analytical method: 00647 (RP-HPLC-ESI-MS/MS) LOQ 0.01 mg/kg (grain , ear) 0.05 mg/kg (rest of plant, straw), max. sample storage: 15 months RIP2004-735
RA-2096/00, 0426-00 France 27700 Fresne `l Archeveque 2001-12-07	Nevada	1) 2000-03-10 (sowing) 2) 2000-06-15 - 2000-06-21 3) 2000-08-11	0.20 0.20	300 300	0.067 0.067	2000-05-31 2000-06-16[4)]	BBCH 61	rest of plant ears of grain grain straw	1.9 0.13 0.12 0.06 3.1 0.01 <0.01 <0.01 <0.01 0.10	0 28 35 42 0 28 35 42 56 56	4) spraying analytical method: 00647 (RP-HPLC-ESI-MS/MS) LOQ 0.01 mg/kg (grain , ear) 0.05 mg/kg (rest of plant, straw), max. sample storage: 15 months RIP2004-735
RA-2096/00, 0427-00 United Kingdom IP31 3SH Thurston, Bury St. Edmunds 2001-12-07	Optic	1) 2000-03-23 (sowing) 2) 2000-06-15 - 2000-07-01 3) 2000-08-16	0.20 0.20	300 300	0.067 0.067	2000-06-05 2000-06-20[4)]	BBCH 61	rest of plant ears of grain grain straw	3.2 0.33 0.32 0.45 2.8 0.04 0.02 0.02 <0.01 0.28	0 29 35 43 0 29 35 43 57 57	4) spraying analytical method: 00647 (RP-HPLC-ESI-MS/MS) LOQ 0.01 mg/kg (grain , ear) 0.05 mg/kg (rest of plant, straw), max. sample storage: 15 months RIP2004-735

Table A 27: Residues of prothioconazole in spring barley

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Prothioconazole (JAU 6476)
Crop / crop group : Spring barley

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : September 2003

Content of a.i. (g/kg or g/l) : 200 g/l and 250 g/l
Formulation (e.g. WP) : FS and EC
Commercial product (name) : JAU 6476 FS 200 and JAU 6476 EC 250 Proline
Applicant : Bayer CropScience

Indoors / outdoors : Outdoors (European North)
Other a. i. in formulation (common name and content) :
Residues calculated as : Prothioconazole-desthio

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2140/98, R 1998 1247 1 1247-98 D-51399 Burscheid, Versuchsgut Höfchen 2002-05-08	Scarlett	1) 1998-03-26 2) 1998-06-16- 1998-06-20 3) 1998-08-12	15.0 g/100 kg seed 0.20 0.20	 300 300	 0.067 0.067	1998-03-26 (FS) seed 1998-06-04 1998-06-16 (EC) spraying	BBCH 61	seed green material ears of grain rest of plant straw grain	120 <0.05 2.2 0.01 2.7 0.08 0.13 <0.01	-89 -12 0 36 0 36 57 57	 analytical method: 00647 (RP-HPLC-ESI-MS/MS) LOQ: 0.01 mg/kg (grain, ear), 0.05 mg/kg (forage, straw) max. sample storage: 34 months RIP2002-1068
RA-2140/98, R 1998 1580 2 1580-98 D-40789 Monheim, Versuchsgut Laacherhof 2002-05-08	Scarlett	1) 1998-03-25 2) 1998-06-08- 1998-06-13 3) 1998-08-06	15.0 g/100 kg seed seed 0.20 0.20	 300 300	 0.067 0.067	1998-03-25 (FS) seed 1998-06-04 1998-06-08 (EC) spraying	BBCH 61	seed green material ears of grain rest of plant straw grain	130 <0.05 1.8 <0.01 3.2 0.06 0.14 <0.01	-81 -4 0 36 0 36 59 59	 analytical method: 00647 (RP-HPLC-ESI-MS/MS) LOQ: 0.01 mg/kg (grain, ear), 0.05 mg/kg (forage, straw) max. sample storage: 29 months RIP2002-1068

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2140/98, R 1998 1581 0 1581-98 FR-27700 Frense L'Archeveque Northern France 2002-05-08	Prisma	1) 1998-03-26 2) 1998-06-24- 1998-07-03 3) 1998-08-05	15.0 g/100 kg seed 0.20 0.20	 280 280	 0.072 0.072	1998-03-26 (FS) seed 1998-06-24 1998-06-24 (EC) spraying	BBCH 61	seed green material ears of grain rest of plant straw grain	140 <0.05 2.6 0.01 2.2 0.07 0.13 <0.01	-90 -16 0 35 0 35 48 48	analytical method: 00647 (RP-HPLC-ESI-MS/MS) LOQ: 0.01 mg/kg (grain, ear), 0.05 mg/kg (forage, straw) max. sample storage: 32 months RIP2002-1068
RA-2140/98, R 1998 1582 9 1582-98 GB-IP31 3SH Thurston, Bury St. Edmunds 2002-05-08	Alexis	1) 1998-03-24 2) 1998-06-17- 1998-07-01 3) 1998-08-07	15.0 g/100 kg seed 0.20 0.20	 300 300	 0.067 0.067	1998-03-24 (FS) seed 1998-05-29 1998-06-17 (EC) spraying	BBCH 61	seed green material ears of grain rest of plant straw grain	120 <0.05 3.3 0.01 2.3 0.07 0.10 <0.01	-85 -19 0 35 0 35 51 51	analytical method: 00647 (RP-HPLC-ESI-MS/MS) LOQ: 0.01 mg/kg (grain, ear), 0.05 mg/kg (forage, straw) max. sample storage: 33 months RIP2002-1068

Table A 28: Residues of prothioconazole in spring 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) : 250 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : JAU 6476 EC 250 = BAY 14120 F Proline
Applicant : Bayer CropScience

Active ingredient : Prothioconazole (JAU 6476)
Crop / crop group : Spring barley

Submission date : September 2003

Indoors / outdoors : Outdoors (European North)
Other a. i. in formulation (common name and content) :
Residues calculated as : Prothioconazole-desthio

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2101/00 R 2000 0452 4 0452-00 SE-24561 Staffanstorp 2002-05-08	Henni	1) 2000-03-22 2) 2000-06-19- 2000-06-28 3) 2000-08-09	0.20 0.20	300 300	0.067 0.067	2000-06-01 2000-06-21	BBCH 59	ears of grain rest of plant straw grain	0.01 3.2 0.86 0.12 0.33 1.3 0.60 0.33 0.12 0.14 <0.01 0.01	-0 0 7 14 -0 0 7 14 35 49 35 49	 analytical method: 00647 (RP-HPLC-ESI-MS/MS) LOQ: 0.01 mg/kg (grain, ear), 0.05 mg/kg (rest of plant, straw) max. sample storage. 8 months RIP2002-1069

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2101/00 R 2000 0456 7 0456-00 DE-51399 Burscheid, Versuchsgut Höfchen 2002-05-08	Baronesse	1) 2000-03-23 2) 2000-06-09- 2000-06-12 3) 2000-08-14	0.20 0.20	300 300	0.067 0.067	2000-05-16 2000-06-09	BBCH 61	ears of grain rest of plant straw grain	<0.01 1.5 0.35 0.05 <0.01 0.05 1.8 1.6 0.84 0.07 <u>0.05</u> <u><0.01</u>	-0 0 7 14 34 -0 0 7 14 34 61 61	 analytical method: 00647 (RP-HPLC-ESI-MS/MS) LOQ: 0.01 mg/kg (grain, ear), 0.05 mg/kg (rest of plant, straw) max. sample storage. 8 months RIP2002-1069
RA-2101/00 R 2000 0462 1 0462-00 FR-27700 Fresne L'Archeveque Northern France 2002-05-08	Nevada	1) 2000-03-10 2) 2000-06-15- 2000-06-21 3) 2000-08-11	0.20 0.20	300 300	0.067 0.067	2000-05-31 2000-06-16	BBCH 61	ears of grain rest of plant straw grain	<0.01 2.2 0.26 0.13 0.01 0.44 1.7 1.2 0.82 0.10 <u>0.10</u> <u><0.01</u>	-0 0 7 14 35 -0 0 7 14 35 56 56	 analytical method: 00647 (RP-HPLC-ESI-MS/MS) LOQ: 0.01 mg/kg (grain, ear), 0.05 mg/kg (rest of plant, straw) max. sample storage. 8 months RIP2002-1069

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2101/00 R 2000 0464 8 0464-00 GB-IP31 3SH Thurston, Bury St. Edmunds 2002-05-08	Optic	1) 2000-03-23 2) 2000-06-15- 2000-07-01 3) 2000-08-16	0.20 0.20	300 300	0.067 0.067	2000-06-05 2000-06-20	BBCH 63	ears of grain rest of plant straw grain	0.02 2.0 0.74 0.17 0.02 0.66 2.5 2.0 0.75 0.26 0.30 <0.01	-0 0 7 15 35 -0 0 7 15 35 57 57	 analytical method: 00647 (RP-HPLC-ESI-MS/MS) LOQ: 0.01 mg/kg (grain, ear), 0.05 mg/kg (rest of plant, straw) max. sample storage. 8 months RIP2002-1069
RA-2101/00 R 2000 0465 6 0465-00 DE-40789 Monheim, Versuchsgut Laacherhof 2002-05-08	Alexis	1) 2000-03-23 2) 2000-06-09.- 2000-06-13 3) 2000-07-31	0.20 0.20	300 300	0.067 0.067	2000-05-16 2000-06-09	BBCH 61	ears of grain rest of plant straw grain	0.02 1.5 0.41 0.09 0.02 0.16 1.9 1.7 1.2 0.28 0.08 <0.01	-0 0 7 14 34 -0 0 7 14 34 55 55	 analytical method: 00647 (RP-HPLC-ESI-MS/MS) LOQ: 0.01 mg/kg (grain, ear), 0.05 mg/kg (rest of plant, straw) max. sample storage. 8 months RIP2002-1069

Table A 29: Residues of prothioconazole in spring barley

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Prothioconazole
Crop / crop group : Spring Barley

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2008-10-15

Content of a.i. (g/kg or g/l) : 100 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : FAR 01285-00, EC, treated with formulation FAR 01285-00, EC (100 g/l Prothioconazole, JAU 6476; 250 g/l Spiroxamine, KWG 4168 + 50 g/l Bixafen, BYF 00587)
Applicant : Bayer CropScience Deutschland GmbH

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) : 50 g/l Bixafen (BYF 00587), 250 g/l Spiroxamine
Residues calculated as : Prothioconazole-desthio

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2042/07, R 2007 0448/8, 0448-07 France 95510 St Cyr en Arthies (Ile-de-France) 2008-02-26	Heinley	1) 2007-03-12 (sowing) 2) 2007-05-28 - 2007-06-07 3) 2007-07-25 - 2007-08-04	0.15 0.15	300 300	0.050 0.050	2007-05-10 2007-05-29[4)]	BBCH 61	green forage green forage rest of plant ears of grain grain straw	0.13 1.3 0.02 <0.01 <0.01 0.02	0[5)] 0 35 35 58 58	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI- (HPLC-MS/MS)) LOQ: 0.01 mg/kg, max. sample storage: 7 months ASB2008-6491

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2042/07, R 2007 0527/1, 0527-07 United Kingdom CB2 5EU Little Shelford 2008-02-26	Cocktail	1) 2007-01-24 (sowing) 2) 2007-05-25 - 2007-06-09 3) 2007-08-15 - 2007-08-31	0.15 0.16	300 300	0.050 0.053	2007-05-09 2007-05-25[4)]	BBCH 61	green forage green forage rest of plant ears of grain grain straw	0.07 1.3 0.02 <0.01 <0.01 0.02	0[5)] 0 34 34 96 96	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI- (HPLC-MS/MS)) LOQ: 0.01 mg/kg, max. sample storage: 7 months ASB2008-6491
RA-2042/07, R 2007 0529/8, 0529-07 Netherlands 1681 ND Zwaagdijk-Oost 2008-02-26	Prestige	1) 2007-04-06 (sowing) 2) 2007-06-12 - 2007-06-24 3) 2007-08-20 - 2007-09-02	0.15 0.15	300 300	0.050 0.050	2007-05-30 2007-06-13[4)]	BBCH 61	green forage green forage grain straw	0.21 1.2 <0.01 <0.01 0.02 0.02	0[5)] 0 35 71 35 71	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI- (HPLC-MS/MS)) LOQ: 0.01 mg/kg, max. sample storage: 7 months ASB2008-6491

Table A 30: Residues of prothioconazole in spring barley

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Prothioconazole
Crop / crop group : Spring Barley

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2009-03-02

Content of a.i. (g/kg or g/l) : 150 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : treated with formulation FAR 01282-00, 225 EC (150 g/l Prothioconazole, JAU 6476 + 75 g/l Bixafen, BYF 00587)
Applicant : Bayer CropScience Deutschland GmbH

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) : 75 g/l Bixafen (BYF 00587)
Residues calculated as : 8.1 Prothioconazole
8.2 Protioconazole-desthio

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)
RA-2328/06, R 2006 0457/2, 0457-06 France 95510 St. Cyr en Arthies 2007-11-19	Carafe	1) 2006-03-18 (sowing) 2) 2006-06-18 - 2006-06-24 3) 2006-07-20 - 2006-08-10	0.15 0.15	300 300	0.050 0.050	2006-05-24 2006-06-20[4)]	BBCH 61	green forage green forage grain straw	<0.01 1.2 <0.01 0.03	0.06 0.84 <u><0.01</u> <u>0.36</u>	0[5)] 0 34 34	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI-) LOQ: 0.01 mg/kg, max. sample storage 7 months ASB2009-5976

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)
RA-2328/06, R 2006 0458/0, 0458-06 Sweden 24593 Staffanstorp 2007-11-19	Prestige	1) 2006-04-28 (sowing) 2) 2006-06-29 - 2006-07-05 3) 2006-08-08 - 2006-08-09	0.15 0.15	300 300	0.050 0.050	2006-06-15 2006-06-29[4)]	BBCH 61	green forage grain straw	1.6 0.03 0.01 0.01 <0.01 0.04	1.8 1.5 0.59 0.53 <u><0.01</u> <u>0.56</u>	0 7 14 28 40 40	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI-) LOQ: 0.01 mg/kg, max. sample storage 7 months <u>ASB2009-5976</u>

Table A 31: Residues of prothioconazole in spring 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) : 150 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : treated with formulation FAR 01282-00, 225 EC (150 g/l Prothioconazole, JAU 6476 + 75 g/l Bixafen, BYF 00587)
Applicant : Bayer CropScience Deutschland GmbH

Active ingredient : Prothioconazole
Crop / crop group : Spring Barley

Submission date : 2009-03-02

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) : 75 g/l Bixafen (BYF 00587)
Residues calculated as : Protioconazole-desthio

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2039/07, R 2007 0426/7, 0426-07 France 95510 St. Cyr en Arthies 2008-02-25	Heinley	1) 2007-03-12 (sowing) 2) 2007-05-28 - 2007-06-07 3) 2007-07-25 - 2007-08-04	0.15 0.15	300 300	0.050 0.050	2007-05-10 2007-05-29[4)]	BBCH 61	green forage green forage rest of plant ears of grain grain straw	0.27 1.3 0.03 <0.01 <u><0.01</u> <u>0.03</u>	0[5)] 0 35 35 58 58	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI-), LOQ: 0.01 mg/kg max. sample storage: 5 months ASB2009-5991

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2039/07, R 2007 0427/5, 0427-07 Germany 51399 Burscheid 2008-02-25	Annabell	1) 2007-04-10 (sowing) 2) 2007-06-18 - 2007-06-24 3) 2007-08-06	0.15 0.15	300 300	0.050 0.050	2007-05-31 2007-06-18[4)]	BBCH 61	green forage green forage grain straw	0.21 <u>0.82</u> <u><0.01</u> <0.01 <u>0.11</u> 0.04	0[5)] 0 35 49 35 49	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI-), LOQ: 0.01 mg/kg max. sample storage: 5 months ASB2009-5991

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Acceptable.

Reference:	OECD KIIA 6.3
Report	ASB2008-6491, ASB2009-5976
Guideline(s):	Yes, EC Guidance 7029/VI/95 rev.5 (1997-07-22)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 32: Residues of prothioconazole in winter 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)	:	150 g/l
Formulation	(e.g. WP)	:	EC
Commercial product	(name)	:	treated with formulation FAR 01282-00, 225 EC (150 g/l Prothioconazole, JAU 6476 + 75 g/l Bixafen, BYF 00587)
Applicant		:	Bayer CropScience Deutschland GmbH

Active ingredient	:	Prothioconazole
Crop / crop group	:	Winter Barley
Submission date	:	2009-08-11
Indoors / outdoors	:	Outdoors (European North)
Other a.i. in formulation (content and common name)	:	75 g/l Bixafen (BYF 00587)
Residues calculated as	:	8.1 Prothioconazole 8.2 Prothioconazole-desthio

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)
RA-2328/06, R 2006 0459/9, 0459-06 United Kingdom IP21 5DB Hoxne / Nr Eye 2007-11-19	Sequel	1) 2005-09-29 (sowing) 2) 2006-05-14 - 2006-05-25 3) 2006-07-18 - 2006-07-19	0.15 0.15	300 300	0.050 0.050	2006-05-05 2006-05-17[4)]	BBCH 61	green forage grain straw	<0.01 0.83 <0.01 0.02	0.21 0.71 <u><0.01</u> <u>0.12</u>	0[5)] 0 62 62	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI-) LOQ: 0.01 mg/kg, max. sample storage 7 months ASB2009-5976
RA-2328/06, R 2006 0460/2, 0460-06 Germany 59514 Welver-Flerke 2007-11-19	Duet	1) 2005-09-20 (sowing) 2) 2006-05-13 - 2006-05-23 3) 2006-07-05 - 2006-07-15	0.15 0.15	300 300	0.050 0.050	2006-04-28 2006-05-15[4)]	BBCH 61	green forage grain straw	<0.01 1.3 0.02 <0.01 0.01 <0.01 <0.01	0.15 0.81 0.38 0.06 0.17 <u><0.01</u> <u>0.04</u>	0[5)] 0 7 28 75 51 51	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI-) LOQ: 0.01 mg/kg, max. sample storage 7 months ASB2009-5976

Table A 33: Residues of prothioconazole in winter barley

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Prothioconazole
Crop / crop group : Winter Barley

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2008-10-15

Content of a.i. (g/kg or g/l) : 100 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : FAR 01285-00, EC, treated with formulation FAR 01285-00, EC (100 g/l Prothioconazole, JAU 6476; 250 g/l Spiroxamin, KWG 4168 + 50 g/l Bixafen, BYF 00587)
Applicant : Bayer CropScience Deutschland GmbH

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) : 50 g/l Bixafen (BYF 00587)
250 g/l Spiroxamine
Residues calculated as : Prothioconazole-desthio (SXX 0665)

1	2	3	4			5	6	7	8	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)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
RA-2042/07, R 2007 0449/6, 0449-07 Germany 53913 Swisttal 2008-02-26	Naomi	1) 2006-09-25 (sowing) 2) 2007-05-03 - 2007-05-14 3) 2007-06-20 - 2007-06-28	0.15 0.15	300 300	0.050 0.050	2007-04-18 2007-05-04[4)]	BBCH 61	green forage rest of plant ears of grain grain straw	0.31 1.4 0.16 0.01 <0.01 0.06	0[5)] 0 35 35 55 55	4) spraying 5) before last treatment analytical method: 01013 (electrospray ionization, ESI+ and ESI- (HPLC-MS/MS)), LOQ: 0.01 mg/kg, max sample storage: 7 months ASB2008-6491

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Acceptable.

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)

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.

Prothioconazole (Prothioconazole-desthio) (R)			
Status of the active substance:		Code no.	1035
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:	EU Comm.	Source of ARfD:	EU Comm.
Year of evaluation:	2007	Year of evaluation:	2007

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	
3	87
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)
86,7	UK Toddler	68,6	Sugar beet (root)	8,2	PULSES, DRY	3,9	Wheat	
47,3	UK Infant	30,2	Sugar beet (root)	4,9	PULSES, DRY	3,9	Milk and cream,	
26,0	WHO Cluster diet B	8,5	Wheat	3,1	PULSES, DRY	2,0	Sugar beet (root)	
22,1	IE adult	5,5	PULSES, DRY	3,7	Barley	2,3	Wheat	
20,2	UK vegetarian	11,3	Sugar beet (root)	4,3	PULSES, DRY	2,0	Wheat	
20,2	FR toddler	4,0	Milk and cream,	3,4	PULSES, DRY	2,6	Wheat	
18,4	NL child	4,7	Wheat	3,0	FRUIT (FRESH OR FROZEN)	2,9	Milk and cream,	
18,3	UK Adult	12,0	Sugar beet (root)	2,4	PULSES, DRY	1,7	Wheat	
16,7	WHO cluster diet E	3,9	Wheat	2,4	Barley	1,2	PULSES, DRY	
16,2	ES child	4,7	PULSES, DRY	4,4	Wheat	1,3	Milk and cream,	
16,1	DK child	5,5	Wheat	4,4	Rye	1,4	Carrots	
15,9	WHO cluster diet D	6,5	Wheat	2,2	PULSES, DRY	0,8	Potatoes	
15,2	DE child	4,6	FRUIT (FRESH OR FROZEN)	4,1	Wheat	1,4	Milk and cream,	
14,9	FR infant	3,0	FRUIT (FRESH OR FROZEN)	2,7	PULSES, DRY	2,6	Carrots	
14,6	WHO Cluster diet F	3,6	Wheat	1,8	Barley	1,4	PULSES, DRY	
13,2	WHO regional European diet	3,0	Wheat	1,6	PULSES, DRY	1,0	Barley	
10,5	PT General population	3,9	Wheat	2,3	PULSES, DRY	1,3	FRUIT (FRESH OR FROZEN)	
10,3	IT kids/toddler	6,6	Wheat	1,5	PULSES, DRY	0,7	FRUIT (FRESH OR FROZEN)	
10,2	ES adult	2,3	Wheat	2,2	PULSES, DRY	1,5	Barley	
10,0	SE general population 90th percentile	3,2	Wheat	1,2	Milk and cream,	1,2	FRUIT (FRESH OR FROZEN)	
9,0	NL general	2,1	Wheat	1,1	Barley	1,0	FRUIT (FRESH OR FROZEN)	
7,6	FR all population	3,3	Wheat	1,2	FRUIT (FRESH OR FROZEN)	0,3	Poultry: Meat	
6,9	IT adult	4,1	Wheat	1,0	PULSES, DRY	0,6	FRUIT (FRESH OR FROZEN)	
6,1	LT adult	1,1	Rye	1,1	Wheat	0,6	Potatoes	
5,9	DK adult	2,0	Wheat	0,7	Rye	0,7	FRUIT (FRESH OR FROZEN)	
4,3	FI adult	1,0	Wheat	0,7	Rye	0,6	Milk and cream,	
3,3	PL general population	0,7	Potatoes	0,7	FRUIT (FRESH OR FROZEN)	0,5	PULSES, DRY	

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) (R) is unlikely to present a public health concern.

REGISTRATION REPORT
Part B

Section 5 Environmental Fate

Detailed summary of the risk assessment

Product code: 102000013869/ Aviator Xpro

Active Substance(s): Bixafen: 75 g/L
Prothioconazol: 150 g/L

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Bayer CropScience

Date: 19 April 2016

Table of Contents

Sec 5 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 Aviator Xpro containing the active substances Bixafen and .Prothioconazole in its intended uses in cereals according to Appendix 3. 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 Aviator Xpro

Code	102000013869		
plant protection product	Aviator Xpro		
applicant	BCS		
date of application	30.03.2012		
Formulation type (WP, EC, SC, …; density)	EC		
active substance	Bixafen	Prothioconazole	
Concentration of as	75 g/L	150 g/L	

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 zone for Aviator Xpro. A list of all intended uses within the zone is given in Appendix 4.

Table 5.2-1: Critical use pattern of Aviator Xpro

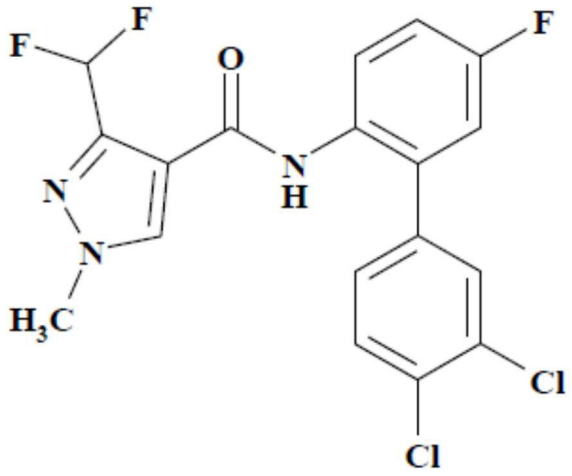
Group	Crop/growth stage	Application method / Drift scenario	Number of applications, Minimum application interval, interception, application time (season)	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
A	Wheat, Rye, Triticale / BBCH 30-69	spraying /	2 x, 14 d,spring 1. 70 % 2. 70 % Winter cereals: 1. Appl.: 19.4.=>169d and 183d after emergence Spring cereals: 1. Appl: 28.4.= >27 d and 41d after emergence	Bixafen: 2 x 93.75 = 187,5 Prothioconazol: 2 x 187.5= 375	Bixafen: 1. 28.125 2 28.125 Prothioconazol: 1. 56.25 2 56.25
B	Barley / BBCH 30-61	spraying /	2 x, 14d, spring 1. 70%, 14d 2. 70%, 10 d	Bixafen: 2 x 75=150 Prothioconazol: 2 x 150 = 300	Bixafen: 1. 22.5 2. 22.5 Prothioconazol: 1. 45 2. 45

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	
Date of approval	01/10/2013
Conditions of approval	
Confirmatory data	
RMS	United Kingdom
Minimum purity of the active substance as manufactured (g/kg)	950
Molecular formula	C18H12Cl2F3N3O
Molecular mass	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; 10 (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; 10 (11):2917
Henry's law constant (Pa × m^3 × mol^{-1})	3.89 x 10-5 Pa m3 mol-1	

Solubility in water (at 25 °C in mg/L)	0.00049 g/l at 20°C (5-9 pH) (99.2%)	
Partition co-efficient (at 25 °), log Pow	Log Pow = 3.3 at 40C	
Dissociation constant, pKa	No dissociation constant was found in the pH range 1 to 12.	
Hydrolytic degradation	pH 4: hydrolytically stable at 50ºC (96.5% remaining after 5 d). No further testing performed. No major metabolites.	
Photolytic degradation	DT50 : 82 experimental days No major (>10%) metabolites	
Quantum yield of direct phototransformation in water > 290 nm	Φ = 0.0000218	
Photochemical oxidative degradation in air (calculation according to Atkinson)	DT50 of 10.4 hours derived by the Atkinson model (AOPWIN version 1.91). OH (12 h) concentration assumed = 1.5x106 cm3	

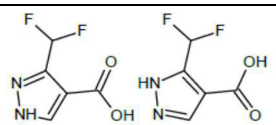
5.3.1.3 Metabolites of Bixafen

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 Aviator Xpro has been performed. Hence no potentially new metabolites need to be considered.

The leaching potential into groundwater of the soil metabolite 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

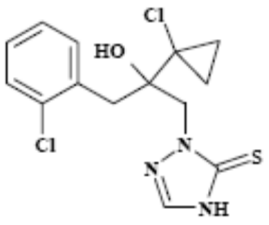
			active substance fluxapyroxad (BAS 700 F) (EFSA 2012): LC50/EC50 on fish, daphnia: >100 mg/L, EC50 on algae 22.44- 26.52 mg/L Groundwater: risk assessed as low to the aquatic environment

[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

5.3.2 Prothioconazole

5.3.2.1 *Identity, further information of Prothioconazole*

Table 5.3-4: 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	aproved
Date of approval	01/08/2008
Conditions of approval	
Confirmatory data	
RMS	United Kingdom
Minimum purity of the active substance as manufactured (g/kg)	≥ 970
Molecular formula	C14 H15 Cl2 N3 O S
Molecular mass	344.26 g/mol
Structural formula	

5.3.2.2 Physical and chemical properties of Prothioconazole

Physical and chemical properties of Prothioconazole as agreed at EU level (see EFSA Journal 2012; 10 (11):2917) and considered relevant for the exposure assessment are listed in Table 5.3-2.

Table 5.3-5: EU agreed physical chemical properties of Prothioconazole relevant for exposure assessment

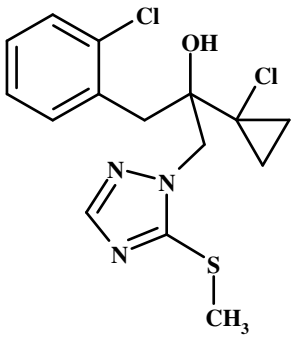
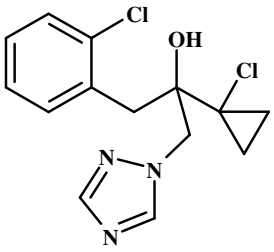
	Value	Reference
Vapour pressure (at 20 °C) (Pa)	<< 4 x 10-7 Pa at 20 °C << 4 x 10-7 Pa at 25 °C	LoEP, 2006
Henry's law constant (Pa × m³ × mol⁻¹)	<< 3 x 10-5 Pa x m3 / mole at 20 °C	
Solubility in water (at 25 °C in mg/L)	0.005 g/L at 20 °C at pH 4 0.3 g/L at 20 °C at pH 8 2.0 g/L at 20 °C at pH 9	
Partition co-efficient (at 25 °), log Pow	log Pow unbuffered 4.05 pH 4 4.16 pH 7 3.82 pH 9 2.00 all at 20 °C	
Dissociation constant, pKa	pKa = 6.9	
Hydrolytic degradation	DT50 at 50°C: pH 9 and 7: > 1 year pH 4: 120 days DT50 at 25°C: pH 9, 7 and 4: > 1 year	
Photolytic degradation	DT50 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	
Quantum yield of direct phototransformation in water > 290 nm	The mean quantum yield was calculated to be Φ = 0.0638 (pH 4) and 0.0047 (pH 9).	

5.3.2.3 Metabolites of Prothioconazole

Environmental occurring metabolites of Prothioconazole 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 Prothioconazole or Aviator Xpro has been performed. Hence no potentially new metabolites need to be considered.

Table 5.3-6: 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	occurrence in compartments (Max. at day/	Status of Relevance
JAU 6476-S-methyl (M01)		Soil: max. 14.6% day 7 . Sediment: max. 9.6%	Risk assessment not necessary. Toxicity covered by mothersubstance.
JAU 6476-desthio (M04)		Soil: max. 49.4% day 7 / 57% field Water: max. 32.3% day 7 Sediment: max. 26.9% day 14	Risk assessment required and provided..
1,2,4-triazole (M13)		water: max. 37.2% da 121	Risk assessment not necessary. Toxicity covered by mothersubstance.

[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

5.4 Summary on input parameter 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**	**Kinetic, Fit**	**Reference**
Sandy loam		6.0	>1y		
Silt loam		6.4	>1y		
loam		5.4	>1y		
Silt loam		6.1	>1y		
Aggregated DT_{50} (n=4)	**Coefficient of variation (%)**				
	Geometric mean (d)		>1y		

Table 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**	**Kinetic, 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 Conclusion
LUFA 2.2 – Sand – pyrazole label	5.9	20	40% MWHC	147/ >1000		147	FOMC, 1.9	
				120/ 567 overall; 4.86 DT50 fast; 193 DT50 slow		120 overall; 4.86 fast; 193 slow	DFOP, 2.1	
Wisconsin – Loamy sand – pyrazole label	5.9	20	40% MWHC	76.6/ >1000		70.4	FOMC, 2.2	
				83.1/ 454 – overall; 5.06 DT50 fast; 161 DT50 slow		76.3 overall; 4.65 fast; 148 slow	DFOP, 2.5	
	7.4	20	40% MWHC	197/ >1000		134	FOMC, 2.0	

Bruch West – Sandy loam – pyrazole label	7.4	20	40% MWHC	158/ 636 – overall; 9.94 DT50 fast; 204 DT50 slow		- 108 overall; 6.78 fast; 139 slow	DFOP; 2.2	
Aggregated DT_{50} (n=4, slow phase of DFOP kinetic was used,)		**Coefficient of variation (%)**				16		
		Geomean (d)				168.1		
		90th perzentil				193		

Prothioconazole

No new studies have been submitted regarding route and rate of degradation in soil of Prothioconazole.

The degradation behaviour of prothioconazole under laboratory conditions, in the dark, has been studied in a number of soils at temperatures of 20°C. The calculated DT50 values of prothioconazole determined in the laboratory soil degradation studies were in the range of 0.07 to 1.3 days. No studies were performed at 10°C and the DT50 calculated from the studies performed at 20°C were in the range of 0.2 to 2.9 days.

The DT50 values of the two major metabolites JAU 6476-S-methyl (M01) and JAU 6476-desthio (M04) determined in the laboratory trials were in the range of 5.9 to 46.0 days and 7.0 to 34.0 days, respectively.

Table 5.4-3: Summary of aerobic degradation rates metabolite JAU 6476-S-methyl (M01) - laboratory studies

Soil type	**pH**	DT_{50} (d) 20 °C, 40% MWHC	DT_{50} (d) 20 °C pF2/10 kPa	**Kinetic**	**Reference**
Loamy silt	7.3	5.9	3.4	SFO	Gilges 2001
Loamy silt	7.9	27.2	16.6	SFO	Gilges 2001
Sandy loam	7.2	8.2	5.5	SFO	Gilges 2001
Silty clay	6.3	46	25.9	SFO	Gilges 2001
Aggregated DT_{50} (n=4)	**Coefficient of variation (%)**		81		
	Geometric mean (d)		9.5		

The DT_{50} value of 9.5 days (geometric mean of 4 laboratory studies) of the metabolite M01 is used for PEC_{GW} calculations. For the a.i. and the metabolite M04 results of field studies were considered.

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 Table 5.4-4.

Table 5.4-4: Field degradation studies of Bixafen

soil / location	**pH**	**depth (cm)**	**DT_{50} (d)**	**DT_{90} (d)**	**Fit, Kinetic, Parameters**	**DT_{50} (d) 20 °C, pF2**	**Fit, Kinetic**	**Reference**
Silt loam Germany	6.3	0-30	>1235	>1000	HS	320.1	SFO	EFSA Conclusion 2012
Sandy loam UK	7.4		316	>1000	HS	196.8	SFO	
Silt loam Sweden	7.4		541	>1000	HS	247.8	SFO	
Silt loam N. France	6.7		395	>1000	HS	231.4	SFO	
Loam Spain	6.1		105	>1000	HS	145.6	SFO	
Silt loam Italy	8.3		30.6	>1000	HS	122.4	SFO	
Silt loam Germany	6.3		>1000	>1000	HS	320.1	SFO	
Geom. mean						**200.2**		

Table 5.4-5: 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 Conclusion 2012
Silt Loam – bare soil	6.4	0 - 40				23.1	SFO	
Silt Loam – bare soil	7.7	0 - 70				44.1	SFO	
Loam – bare soil	5.5	0 - 60				24.6	SFO	
Geom. mean						**25.9**		

Prothioconazole

The field dissipation rates of Prothioconazole were evaluated during EU assessment. After the evaluation the terrestrial field dissipation data for prothioconazole and its metabolites JAU 6476-desthio (M04) were re-evaluated kinetically according to FOCUS kinetic guidance and taking the new Q10 of 2.58 into account. This report is summarised in KIIA 7.1.1.2.2/1. In addition a kinetic evaluation and calculation of non-referenced DT50 were done for both compounds (see KIIA 7.1.1.2.2/12).

These DT50 values are summarised in Table 5.4-6 for prothioconazole and for JAU 6476-desthio (M04).

Table 5.4-6: Field degradation studies of Prothioconazole, 20 °C, pF2

soil / location	pH	Prothioconazole DT_{50} (d) 20 °C, pF2	Fit, Kinetic	M04 DT_{50} (d) 20 °C, pF2	Fit, Kinetic	ff	Reference
Germany	6.2	1.34	0.9, SFO	8.8	10.8, SFO	0.8	Recalculation Hardy 2009
Great Britain	7.6	0.55	1.8, SFO	28.2	12.9, SFO	0.52	
France, North	6.4	0.78	3.0, SFO	29.6	17.0, SFO	0.38	
Great Britain	7.5	0.70	2.7, SFO	25.1	20.2, SFO	0.56	
France, North	6.4	0.72	0.7, SFO	24.4	8.2, SFO	0.35	
France, South	7.6	0.75	2.2, SFO	36.4	12.6, SFO	0.59	
Italy	7.5	0.92	1.2, SFO	27.6	9.1, SFO	0.43	
Germany	6.3	0.78	1.0	18.1	7.3, SFO	0.66	
GEOMETRIC MEAN		0.79		23.1		0.54	

The DT_{50} of 0.79 days (geometric mean of 8 field studies) is used for PEC_{GW} calculations.

Table 5.4-7: Field degradation studies of Prothioconazole, non-referenced

soil / location	pH	Prothioconazole DT_{50} (d)	Fit, Kinetic	M04 DT_{50} (d)	Fit, Kinetic	Reference
Germany	6.2	2.0	1.47, SFO	17.1	9.5, SFO	Recalculation Schad, Zerbe 2008
Great Britain	7.6	1.8	1.70, SFO	57.0	10.1, SFO	

France, North	6.4	1.5	3.87, SFO	49.8	12.7, SFO	
Great Britain	7.5	2.4	2.08, SFO	50.8	13.4, SFO	
France, North	6.4	1.5	1.51, SFO	35.2	13.7, SFO	
France, South	7.6	1.9	2.68, SFO	50.8	10.1, SFO	
Italy	7.5	1.5	2.57, SFO	31.7	6.2, SFO	
Germany	6.3	1.7	1.47, SFO	28.7	7.7, SFO	
MAXIMUM		**2.4**		**57**		

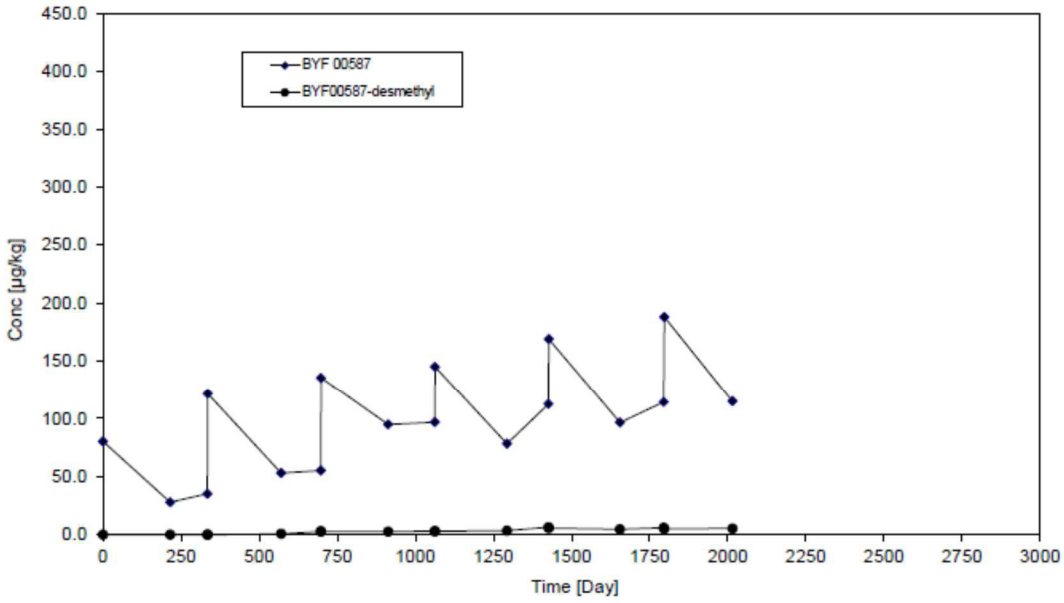
The DT_{50} of 2.4 days (worst case of 8 field studies) is used for PEC_{soil} calculations.

5.4.1.3 Soil accumulation study of Bixafen

A concern was raised during the peer review (EFSA Journal 2012;10(11):2917.) with regard to the persistency and accumulation potential of bixafen. After finalization of the DAR the final report of the soil accumulation study of Heinemann, Weuthen (2013) was available and is presented in Appendix 3 of this document.

The residues after annual treatments in 6 consecutive years at Monheim site (Germany) were already presented in Addendum 2 of the Bixafen DAR. The final report of Heinemann, Weuthen (2013) shows the results following eight consecutive annual treatments at site Monheim.

Figure 2: Dissipation of Bixafen and Formation of Bixafen-desmethyl Residues in Soil after Application of BYF 00587 SC 450, 09-2801-02 (Tarascon, France)



The factor between the low concentration of 340µg/kg from the Monheim trial in Germany and the concentration in soil resulting from one application of 91.8 µg/kg is 3.7. However, no plateau was reached at the end of the study.

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 5.4-8

Table 5.4-8: 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	
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 5.4-9: 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	

Location	Soil type (USDA)	Residue Level	Residues of Bixafen in Soil Layers Virtual[1] 0-10 cm [µg/kg]
Monheim Germany 09-2801-01 VG08	Sandy loam (0-50 cm) / Loamy Sand (50-100 cm)	High[2]	410 (Day 2526)
		Low[3]	340 (Day 2720)
Tarascon France 09-2801-02 FR08	Silt loam (0-100 cm)	High[4]	179 (Mean of days 1427 and 1797)
		Low[5]	106 (Mean of days 1655 and 2015)

1) total residues in soil, recalculated for a 10-cm soil layer (density 1.5 g/cm³)
2) residue determined after the last application
3) residue determined at the last sampling interval (prior to winter dormancy)
4) upper limit of the "saw teeth" curve (mean value, calculated from residues determined at days 1427 and 1797)
5) lower limit of the "saw teeth" curve (mean value, calculated from residues determined at days1655 and 2015)

Prothioconazole

No new studies have been submitted regarding adsorption/desorption in soil of Prothioconazole.

Kd and Koc values of prothioconazole could not be determined in 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. The EU agreed KOC value is 1765 determined on the basis of

this aged soil column leaching study. The 1/n value is set to 1 by zRMS, as this value replaced the old default value of 0.9.

Table 5.4-10: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite M01

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
Sandy loam	2.02	7.2	56.0	2772	0.87	
Silt	2.14	7.1	64.1	2995	0.88	
Silty clay loam	1.66	5.9	41.2	2482	0.91	
Loamy sand	0.79	6.8	15,6	1975	0.85	
Arithmetic mean				2556.3	0.88	LoEP

The EU agreed KOC value for the metabolite M01/ JAU-6476-S-methyl of 2556.3 together with the 1/n value of 0.88 is used for PEC_{GW}.

Table 5.4-11: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite M04

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	616.8	0.79	
Silt	2.14	7.1	13.38	625.3	0.83	
Silty clay loam	1.66	5.9	8.9	536.4	0.83	
Loamy sand	0.79	6.8	4.13	523.0	0.80	
Arithmetic mean				575.4	0.81	LoEP

The EU agreed KOC value for the metabolite M04/ JAU-6476-desthio of 575.4 together with the 1/n value of 0.81 is used for PEC_{GW}.

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.The DT_{50} values of the water/sediment study are summarized in Table 5.4-12.

Table 5.4-12: Degradation in water/sediment of Bixafen

Water/sediment system	$DegT_{50}$ / $DegT_{90}$ whole system	Kinetic, Fit	$DissT_{50}$ water	Kinetic, Fit	$DissT_{50}$ sed.	Kinetic, Fit	Reference

clay	1000		27.4	SFO, 9.1	1000		LoEP 2012
sand	1000		25.5	SFO, 12.2	1000		

Because of the DegT50 of over 1000 days the accumulation of Bixafen in the sediment has to be considered.

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,Oi 2001 and recalculation Schad 2001b) reviewed in the DAR.

The DT_{50} values of the water/sediment study are summarized in Table 5.4-13.

Table 5.4-13: 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**
Hönninger Weiher, loam	2.8/ 76.4 24.8	HS, 0.953 1st	0.8/ 2.7	1st, 0.947			Brumhard Schad
Angler Weiher, loamy sand	1.6/ 23.6 1.8	HS, 0.998 1st	1/ 3.4	1st, 0.999			Brumhard Schad
Geometric mean	6.7	1st					

Table 5.4-14: Degradation in water/sediment of metabolite prothioconazole-desthio (M04)

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**
Hönninger Weiher, loam	49.9	1st					Brumhard
Angler Weiher, loamy sand	39.2	1st					Brumhard
Geometric mean	44.2						

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: Input parameters related to application for PEC_{Soil} calculations

Plant protection product	Aviator Xpro
group	**A.**
Crop:	cereals
Application rate:	2x 1.25 L product/ha, 2x 93.75 g Bixafen/ha, 2x 187.5 g Prothioconazole/ha
Number of application/interval:	2, 14d
Crop interception:	70%

Table 5.5-2: Input parameter for active substance for PEC_{soil} calculation

Active substance	**DT_{50}**	**value in accordance to EU endpoint**
Prothioconazole	2.4d (worst case field studies non normalised)	
Metabolite M01, JAU 6476-S-methyl	46 d worst case lab. studies, non normalised),	
Metabolite M04, JAU 6476-desthio	57 d (worst case field studies non normalised)	
Product Aviator Xpro	cumulative	

Beside PEC_{act} values also PEC_{twa}, 21 d values are required for risk assessment. PEC_{twa},21 d values are also presented in Table 5.5-3

Table 5.5-3: Results of PEC_{soil} calculation for application of Aviator Xpro in cereals (soil bulk density 1.5 g/cm^{-3}, soil depth 5 cm) according to group 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)**
Prothioconazole	2 x 56,25 g/ha M:344.3	0.0763 on day 14	0.0250	-	-	-
Metabolite M01, JAU 6476-S-methyl	Ff=0.14, M: 358.3	0.0175 on day 23	0.0164	-	-	-
Metabolite M04, JAU 6476-desthio	Ff=0.8, M: 312.2	0.0901 on day 23	0.0856	20	0.0003	0.0904
Product Aviator Xpro	Density 1.01, 1x 2525 g/ha	3.3667				

PECaccu- Accumulation of Bixafen in soil

Due to the slow degradation of the active substance Bixafen in soil (DT_{90} > 365 d, field data) the accumulation potential 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 presented in Appendix 3) 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), presented in Appendix 3.

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 (see comment of zRMS to Heinemann, Weuthen 2013 in Appendix 3).

As the soils were ploughed, the background concentration was calculated for a soil depth of 20cm, although the residues in the soil accumulation study were found in 0-10 cm dephth.

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.

Results of PECaccu $_{soil}$ calculation for Bixafen

plant protection product:		Aviator Xpro				
group:		A				
Number of applications/intervall		2/ 14d				
application rate:		93.75 g/ha				
crop interception:		70%				
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	1x 56.25 g/ha	5	0.0750			
		20	0.0188	3.7	0.0694	0.0833
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	1x 56.25 g/ha	5				0.908
		20	10	0.833		

plant protection product:		Aviator Xpro				
group:		B				
Number of applications/intervall		2/ 14d				
application rate:		75 g/ha				
crop interception:		70%				
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	1x 45 g/ha	5	0.0600			
		20	0.015	3.7	0.055	0.066
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	1x 45 g/ha	5				0.721
		20	10	0.661		

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.

5.6.1 Bixafen

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)	4.6x 10-8	Yes	
Water solubility (mg/L)	0.49	Yes	
Kf,oc (mL g-1)	3869	Yes	Arithmetic mean
Freundlich Exponent 1/n	0.88	Yes	Arithmetic mean
DT_{50},soil (d)	200.2	Yes	Geomean (1st order, pF2,20°C) Laboratory data (see …)
DT_{50},water (d)	1000	Yes	Geomean of whole system (1st order, 20°C) (see …)
DT_{50},sed (d)	1000	Yes	Default value
DT_{50},whole system (d)	1000	Yes	

Table 5.6-2: Input parameters related to application for $PEC_{sw/sed}$ calculations

Plant protection product	Aviator Xpro
Use No.	**Group A**
Crop:	**Cereals, spring / winter**
Application rate:	0.09375 kg/ha
Number of application/interval:	2/ 14d
Application method:	Ground spray
Crop interception:	Average crop cover (Step 2)

Results of FOCUS SW calculations for the worst-case application scenario of Aviator Xpro are summarized in the tables below.

Table 5.6-3: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of Bixafen for the application of Aviator Xpro, single use

Bixafen	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/kg)**
		11.87	403.19
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/L)**
	North Europe Mar-May.	1.32 on day 18	47.27 on day 19
	South Europe, Mar-May	2.3 on day 18	85.06 on day 19

Table 5.6-4: Global maximum FOCUS Step 3 PEC_{sw} and PEC_{sed} values for Bixafen for the application of Aviator Xpro in cereals, spring according to use group A

	FOCUS STEP 3 Scenario	Water Body	PEC_{sw} global max (µg/L)	PEC_{SED} global max (µg/kg)
Bixafen	D1	ditch	0.543	2.023
	D1	stream	0.436	1.054
	D3	ditch	0.515	0.519
	D4	pond	0.0272	0.572
	D4	stream	0.379	0.108
	D5	pond	0.0248	0.399
	D5	stream	0.400	0.0158
	R4	stream	0.618	6.661

Table 5.6-5: FOCUS Step 3 Scenario related input parameters for $PEC_{SW/sed}$ calculations for the application in winter cereals in spring (113 d before harvest)

Scenario	Emergence date	Harvest date	Possible window of application
D1	25/9	26/8	5/5 – 18/6
D2	25/10	7/8	16/4 – 30/5
D3	21/11	15/8	24/4 – 7/6
D4	22/9	21/8	30/4 - 13/6
D5	10/112	15/7	24/5 – 7/5
D6	30/11	30/6	9/3 – 22/4
R1	12/11	31/7	9/4 – 23/5
R3	1/12	1/7	10/3- 23/4
R4	10/11	15/7	24/3 – 7/5

Table 5.6-6: Global maximum FOCUS Step 3 PEC_{sw} and PEC_{sed} values for Bixafen for the application of Aviator Xpro in cereals, winter according to use group A

	FOCUS STEP 3 Scenario	Water Body	PEC_{sw} global max (µg/L)	PEC_{SED} global max (µg/kg)
Bixafen	D1	ditch	0.643	4.988
	D1	stream	0.452	0.447
	D2	ditch	0.544	3.882

	D2	stream	0.463	1.669
	D3	ditch	0.516	0.580
	D4	pond	0.0280	0.458
	D4	stream	0.440	0.128
	D5	pond	0.0281	0.425
	D5	stream	0.448	0.0404
	D6	ditch	0.522	1.787
	R1	pond	0.0859	2.388
	R1	stream	0.455	6.611
	R3	stream	0.472	4.522
	R4	stream	0.703	8.650

5.6.1.1 Calculation of PEC sediment, accumulation

Calculation of PECsed,plateau

$$PEC_{sed,plateau} = \frac{PEC_{sed,max}}{1 - e^{-k \cdot t}} \cdot e^{-k \cdot t}$$

where PECsed,plateau Plateau concentration at steady state [µg/kg]

PECsed,max Highest global maximum concentration at Step 3 [µg/kg]

k Degradation rate in sediment (ln(2)/DT50) [d-1]

t Time interval between growing seasons (365 days) [d]

DT_{50} = 1000d

Table 5.6-7: PECsed,accu values of Bixafen after multi-year use of the substance on winter and spring cereals

	Worst-case scenario, water body	**PECsed,plateau (µg/kg)**	**PECsed,max (µg/kg)**	**PECsed,accu,overall (= PECsed,plateau + PECsed,max) (µg/kg)**
Spring cereals	R4 stream	23.11	6.661	29.77
Winter cereals	R4 stream	30.01	8.650	38.66

5.6.2 Prothioconazole

Table 5.6-8: 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)	344.26	Yes	
Water solubility (mg/L)	300 at pH 8	Yes	
Kf,oc (mL g-1)	1765	Yes	
Freundlich Exponent 1/n	1	Yes	
DT_{50},soil (d)	0.79		Geomean
$DegT_{50}$,water (d)	6.7		
DT_{50},sed (d)	1000		Default value
DT_{50},whole system (d)	6.7		Geomean
Metabolite	Prothioconazole-desthio (M04)		
Molecular weight (g/mol)	312.2	Yes	
Kf,oc (mL g-1)	575.4	Yes	
Freundlich Exponent 1/n		Yes	
DT_{50},soil (d)	23-1		Geomean
$DegT_{50}$,water (d)	44.2		
DT_{50},sed (d)	1000		Default value
DT_{50},whole system (d)	44.2		Geomean
Max. occurrence water	54% (whole system)		
Max. occurrence soil	49%		

Table 5.6-9: Input parameters related to application for $PEC_{sw/sed}$ calculations

Plant protection product	Aviator Xpro	
Use A.	**Group A**	
Crop:	**Cereals, spring / winter**	
Application rate:	187.5 g/ha	
Number of application/interval:	2/ 14d	
Application method:	Ground spray	
Crop interception:	Average crop cover (Step 2)	

Results of FOCUS SW calculations for the worst-case application scenario of Aviator Xpro are summarized in the tables below.

Table 5.6-10: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of Prothioconazole for the application of Aviator Xpro in spring and cereals

Prothioconazole	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/L)**
		40.73	657.93
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/L)**
	North Europe, Mar.-May	1.83	12.61
	South Europe, Mar.-May	1.93	10.51

Table 5.6-11: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of metabolite Prothioconazole-desthio (M04) for the application of Aviator Xpro in spring and winter cereals

Prothioconazole-desthio (M04)	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/L)**
		33.13	183.49
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/L)**
	North Europe Mar.-May	5.5 on day 18	30.9 on day 19
	South Europe Mar.-May	5.5 on day 18	30.9 on day 19

5.7 Risk assessment ground water (KIIIA1 9.6)

5.7.1 Predicted environmental concentration in groundwater (PEC_{GW}) calculation for active substance and its 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.

5.7.2 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 5.7-1: Input parameters related to application for PEC_{GW} modelling

plant protection product	Aviator Xpro
use.	**A**
application rate (kg as/ha)	0.028125
crop (crop rotation)	Winter cereals/ spring cereals
relative application date	169d and 183 d after emergence/ 27d and 41d after emergence

interception (%)	considered
soil moisture	100 % FC
Q10-factor	2.58
moisture exponent	0.7
simulation period (years)	26

Table 5.7-2: Input parameters related to active substance for PEC_{GW} modelling

Parent	**Bixafen**	**Remarks/Reference**
molecular weight (g/mol)	414.2	
DT_{50} in soil (d)	200.2	
K_{foc}	3869	
1/n	0.88	
plant uptake factor	0	

Table 5.7-3: Input parameters related to metabolites of Bixafen for PEC_{GW} modelling

Metabolite 1	**M 44**	**Remarks/Reference**
molecular mass	162.1	
Formation fraction	1	The formation fraction was set to 1
DT_{50} in soil (d)	25.9	
K_{foc}	7.7	
1/n	0.964	
plant uptake factor	0	

Table 5.7-4: PEC_{GW} at 1 m soil depth for Bixafen and its metabolites for the application of Aviator Xpro in winter cereals (based on geom. mean for DT_{50} value and arithm. mean for K_{foc})

Crop/Group	**Szenario**	**80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUSPELMO 5.5.3**		
		Bixafen	**Metabolit M44**	
Winter cereals, A	**Châteaudun**	<0.001	0.469	
	Hamburg	<0.001	1.596	
	Jokioinen	<0.001	2.083	
	Kremsmünster	<0.001	1.000	
	Okehampton	<0.001	1.077	
	Piacenza	<0.001	0.833	

	Porto	<0.001	0.781	
	Sevilla	<0.001	0.263	
	Thiva	<0.001	0.372	

No calculation for Group B is required, as the application rate of group B is lower then the application rate of group A.

Table 5.7-5: PEC_{GW} at 1 m soil depth for Bixafen and its metabolites for the application of Aviator Xpro in spring cereals (based on geom. mean for DT_{50} value and arithm. mean for K_{foc})

Crop/Group	**Szenario**	**80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUS PELMO 5.5.3**		
		Bixafen	**Metabolit M44**	
Spring cereals, A	**Châteaudun**	<0.001	0.400	
	Hamburg	<0.001	1.575	
	Jokioinen	<0.001	1.850	
	Kremsmünster	<0.001	0.972	
	Okehampton	<0.001	1.012	
	Porto	<0.001	0.710	

According to the PEC_{GW} modelling with FOCUS PELMO 5.5.3 a groundwater contamination of the active substance Bixafen at a concentration of ≥ 0.1 µg/L is not expected for all FOCUS groundwater scenarios for use in winter and spring cereals. For the metabolite M44 a groundwater concentration of ≥ 0.1 µg/L can not be excluded in all FOCUS groundwater scenarios.

5.7.3 Prothioconazole

The PEC of Prothioconazole and its metabolites in ground water have been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PELMO

Table 5.7-6: Input parameters related to application for PEC_{GW} modelling

plant protection product	Aviator Xpro
use	A
application rate (kg as/ha)	2x 0.05625
crop (crop rotation)	Winter cereals/ spring cereals
relative application date	169 d and 183 d after emergence/ 27d and 41d after emergence
interception (%)	considered
soil moisture	100 % FC
Q10-factor	2.58
moisture exponent	0.7

simulation period (years)	26

Table 5.7-7: Input parameters related to active substance for PEC_{GW} modelling

Parent	**Prothioconazole**	**Remarks/Reference**
molecular weight (g/mol)	344.3	
DT_{50} in soil (d)	0.79	To M04: 1.5 d, to M01: 5.6 d, to sink: 2.5 d
K_{foc}	1765	
1/n	1	the previous default value of 0.9 was used in the LoEP
plant uptake factor	0	

Table 5.7-8: Input parameters related to metabolites of Prothioconazole for PEC_{GW} modelling

Metabolite B1 and A2	**M04, JAU 6476-Desthio**	**Remarks/Reference**
molecular mass	312.2	
Formation fraction	0.54	
DT_{50} in soil (d)	23.1	To sink
K_{foc}	575.4	
1/n	0.81	
plant uptake factor	0	
Metabolite A1	**M01, JAU-6476-S-methyl**	**Remarks/Reference**
molecular mass	358.3	
Formation fraction	0.14	
DT_{50} in soil (d)	9.5	To metabolite M04
K_{foc}	2556.3	
1/n	0.88	
plant uptake factor	0	

Table 5.7-9: PEC_{GW} at 1 m soil depth for Prothioconazole and its metabolites for the application of Aviator Xpro in winter cereals (based on geom. mean for DT_{50} value and arithm. mean for K_{foc})

Crop/Group	Szenario	80^{th} Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUS PELMO 5.5.3		
		Prothioconazole	Metabolite M01/ JAU-6476-S-methyl	Metabolite M04/ JAU 6476-Desthio
Winter cereals/ A	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

Table 5.7-10: PEC_{GW} at 1 m soil depth for Prothioconazole and its metabolites for the application of Aviator Xpro in spring cereals (based on geom. mean for DT_{50} value and arithm. mean for K_{foc})

Crop/Group	**Szenario**	**80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUS PELMO 5.5.3**		
		Prothioconazole	**Metabolite M01/ JAU-6476-S-methyl**	**Metabolite M04/ JAU 6476-Desthio**
Spring cereals/ A	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
	Porto	<0.001	<0.001	<0.001

5.7.4 Summary of risk assessment for ground water

Results of modelling with FOCUSPELMO 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 and spring cereals.

For the metabolite M44 of Bixafen concentrations of ≥ 0.1 µg/L in groundwater can not be excluded in the FOCUS groundwater scenarios in the intended uses.

An assessment of metabolite M44 regarding its relevance for groundwater is necessary (see Section 8).

Results of modelling with FOCUSPELMO 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 uses in winter and spring cereals.

For the metabolites M01/ JAU-6476-S-methyl and M04/ JAU 6476-Desthio concentrations of ≥ 0.1 µg/L in groundwater can be excluded in the FOCUS groundwater scenarios in the intended uses.

5.8 Potential of active substances 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.

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.

Appemdix 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*
KIIA 7.1.1.2.2 /01	Hardy, I.	2009	Kinetic modelling analysis of prothioconazole from field soil residue studies conducted in europe normalised to 20ºC and pF2 Battelle UK Ltd., Ongar, Essex, United Kingdom BCS, Report No.: VC/08/038, Edition Number: M-345442-01-1 Date: 2009-03-25 Non GLP, unpublished	Yes	Bayer Crop Science	1)
KIIA 7.1.1.2.2	Schad, T.;	2008	Dissipation of prothioconazole and JAU6476-desthio under field conditions in Europe Kinetic evaluation and calculation of Non-referenced DT50 BCS, Report No.: MEF-08/114, Edition Number: M-298575-01-1 Date: 2008-02-20 Non GLP, unpublished	Yes	Bayer Crop Science	1)
KIIA 7.3.3	Heineman	2013	Determination of the residues of BYF 00587 in/on soil after spraying of BYF 00587 SC450 in the field in Germany and France (South) Date: 2013-04-26	Yes	Bayer Crop Science	4)

*

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).

Present the authority's evaluation of the study below each individual study.

KIIA 7 Fate and Behaviour in the Environment – Active Substance

KIIA 7.1.1.2. 2/1 Hardy I.A.J.; 2009

Reference:	KIIA 7.1.1.2. 2/ 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 20°C and pF2
Date:	25.03.2009
Guideline(s):	Not applicable
Deviations:	-
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 DT50 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 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.

Results and discussions

This evaluation led to the temperature and moisture normalised first-order DT50 values of prothioconazole and JAU 6476-desthio (M04) shown in Table A-2-1. Referenced DT50 values of prothioconazole range from 0.55 to 1.34 days, with a geometric mean of 0.79 days, referenced DT50 values of JAU 6476-desthio range from 8.8 to 36.4 days, with a geometric mean of 23.1 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 2-1: DT_{50} of active substance Prothioconazole and metabolite M04, 20 °C, pF2

Location	Prothioconazole	M04	ff
Germany	1.34	8.8	0.8
Great Britain	0.55	28.2	0.52
France, North	0.78	29.6	0.38
Great Britain	0.70	25.1	0.56
France, North	0.72	24.4	0.35
France, South	0.75	36.4	0.59

Italy	0.92	27.6	0.43

Conclusion

Field normalised DT50 values for use in environmental modelling have been calculated. The geometric mean normalised DT50 values are 0.79 days for prothioconazole and 23.1 days for JAU 6476-desthio (M04), along with an average formation fraction of 0.54.

Comments of zRMS

acceptable

KIIA 7.1.1.2.2./2 Schad T., Zerbe P.; 2008

Reference:	KIIA 7.1.1.2. 2/ KIIIA 9.2.1
Author:	Schad T., Zerbe P.;
Report:	Dissipation of prothioconazole and JAU6476-desthio under field conditions in Europe - Kinetic evaluation and calculation of non-referenced DT50
Date:	20.02.2008
Guideline(s):	Not applicable
Deviations:	-
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, chi2 statistic, significance T-test, and correlation analysis. The Simple First Order (SFO) model and a biphasic model (First Order Multi Compartment, FOMC) were employed.

Results and discussions

This evaluation led to non-referenced single first-order DT50 values of prothioconazole and JAU 6476-desthio (M04) shown in Table A 2-2 . Non-referenced DT50 values of prothioconazole range from 1.5 to 2.4 days, with a geometric mean of 1.8 days. Non-referenced DT50 of the metabolite JAU 6476-desthio (M04) ranged from 17.1 to 57.0 days, geometric mean of 37.6 days (Table 9.2.1- 5).

Table A 2-2: DT_{50} of active substance Prothioconazole and metabolite M04, non normalised

Location	DT_{50} Prothioconazole (days)	DT_{50} metabolite M04 (days)
Germany	2.0	17.1
Great Britain	1.8	57.0
France, North	1.5	49.8
Great Britain	2.4	50.8
France, North	1.5	35.2
France, South	1.9	50.8

Italy	1.5	31.7
Germany	1.7	28.7

Comments of zRMS

acceptable

KIIA 7.3.3 Heinemann, Weuthen 2013

Reference:	KIIA 7.1.1.2. 2/ KIIIA 9.2.1
Author:	Heinemann, Weuthen
Report:	Determination of the residues of BYF 00587 in/on soil after spraying of BYF 00587 SC450 in the field in Germany andFrance (South)
Date:	2013-04-26
Guideline(s):	Not avaiable
Deviations:	
GLP:	Yes
Acceptability:	With restrictions: plateau was not reached during the study, because of increasing trend of the residues accumulation can not be excluded

After finalization of the DAR the final report of the soil accumulation study (Heinemann, Weuthen 2013, see Appendix 2) was available.

The residues after annual treatments in 6 consecutive years at Monheim site (Germany) were already presented in Addendum 2. The final report shows the results following eight consecutive annual treatments at site Monheim.

The graph for the Monheim site (Germany) site shows that concentrations in soil have not yet reached a plateau.

The concentration for Bixafen immediately after the eighth application at site Monheimwas 410 µg/kg soil (overall maximum). At the termination of the study, the maximum plateau concentration at site Tarascon was 179 µg/kg soil (Tarascon, mean of days1427 and 1797). At site Monheim, no plateau concentration was reached in the courseof the study but the study was terminated due to technical reasons (test plot completelysampled, i.e. no further samplings possible on originally treated area). The results are presented in more detail in the following table.

Location	Soil type (USDA)	Residue Level	Residues of Bixafen in Soil Layers Virtual[1] 0-10 cm [µg/kg]
Monheim Germany 09-2801-01 VG08	Sandy loam (0-50 cm) / Loamy Sand (50-100 cm)	High[2]	410 (Day 2526)
		Low[3]	340 (Day 2720)
Tarascon France 09-2801-02 FR08	Silt loam (0-100 cm)	High[4]	179 (Mean of days 1427 and 1797)
		Low[5]	106 (Mean of days 1655 and 2015)

1) total residues in soil, recalculated for a 10-cm soil layer (density 1.5 g/cm^3)
2) residue determined after the last application
3) residue determined at the last sampling interval (prior to winter dormancy)
4) upper limit of the "saw teeth" curve (mean value, calculated from residues determined at days 1427 and 1797)
5) lower limit of the "saw teeth" curve (mean value, calculated from residues determined at days1655 and 2015)

Considering an application rate of 137.7 g/ha Bixafen, distributed in the top 10 cm of soil

and assuming a soil density of 1.5 kg/L, this results in a nominal Bixafen concentration

of 91.8 µg/kg soil after a single application. The factor between the low concentration of 340µg/kg from the Monheim trial in Germany and the concentration in soil resulting from one application of 91.8 µg/kg is 3.7. However, the plateau was at the end of the study not reached.

Comments of zRMS

Because of the increasing trend at the measured residues concentrations of Bixafen there is an uncertainty, if the plateau will ever be reached and if the concentrations after more than eight annual applications in following years will increase more than expected. For reason of precaution an uncertainty factor is used in the calculation of PECaccu soil (see chapter 5.5).

KIIIA1 9 Fate and Behaviour in the Environment – Plant protection product

Appendix 3 Table of Intended Uses justification and GAP tables

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		
1	Germany	wheat TRZSS	F	Powdery mildew *Erysiphe graminis* ERYSGR	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
2	Germany	wheat TRZSS	F	Leaf spot wheat *Septoria tritici* SEPTTR	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	**a)** 2 (14 - 21days) **b)** 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
3	Germany	wheat TRZSS	F	tan spot of cereals *Drechslera tritici-repentis* PYRNTR	spraying	From spring at beginning of infestation and/or when first symptoms become	a) 2 (14 - 21days)	a) 1.25 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha	150 - 400		

						visible BBCH 30 - 61	b) 2	b) 2.5 L/ha	b) 1: 187.6 g as/ha 2: 375 g as/ha			
4	Germany	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 BBCH 30 - 69	a) 2 (14 - 21days) b) 2	a) 1.25 L/ha b) 2.5L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
5	Germany	wheat TRZSS	F	stem break of cereals *Pseudocercosporella herpotrichoides* PSDCHE	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 37	a) 1 b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
6	Germany	wheat TRZSS	F	Stripe rust of grasses *Puccinia striiformis* PUCCST	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	a) 2 (14 - 21days) **b)** 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
7	Germany	wheat TRZSS	F	*Septoria* leaf spot wheat *Septoria nodorum* LEPTNO	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	**a)** 2 (14 - 21days) **b)** 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
8	Germany	barley HORVX	F	Powdery mildew *Erysiphe graminis* ERYSGR	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	**a)** 2 (14 - 21days) **b)** 2	a) 1 L/ha b) 2 L/ha	a) 1: 75 g as/ha 2: 150 g as/ha b) 1: 150 g as/ha	150 - 400		

									2: 300 g as/ha			
9	Germany	barley HORVX	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1 L/ha b) 2 L/ha	a) 1: 75 g as/ha 2: 150 g as/ha b) 1: 150 g as/ha 2: 300 g as/ha	150 - 400		
10	Germany	barley HORVX	F	net blotch *Pyrenophora teres* PYRNTE	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1 L/ha b) 2 L/ha	a) 1: 75 g as/ha 2: 150 g as/ha b) 1: 150 g as/ha 2: 300 g as/ha	150 - 400		
11	Germany	barley HORVX	F	brown rust of barley *Puccinia hordei* PUCCHD	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1 L/ha b) 2 L/ha	a) 1: 75 g as/ha 2: 150 g as/ha b) 1: 150 g as/ha 2: 300 g as/ha	150 - 400		
12	Germany	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 BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1 L/ha b) 2 L/ha	a) 1: 75 g as/ha 2: 150 g as/ha b) 1: 150 g as/ha 2: 300 g as/ha	150 - 400		
13	Germany	barley HORVX	F	decrease of non-parasitic leaf spots	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	a) 2 (14 - 21days) **b)** 2	a) 1 L/ha b) 2 L/ha	a) 1: 75 g as/ha 2: 150 g as/ha b) 1: 150 g as/ha 2: 300 g as/ha	150 - 400		

14	Germany	rye SECCE	F	Powdery mildew *Erysiphe graminis* ERYSGR	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	**a)** 2 (14 - 21days) **b)** 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
15	Germany	rye SECCE	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	**a)** 2 (14 - 21days) **b)** 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
16	Germany	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 BBCH 30 - 69	a) 2 (14 - 21days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
17	Germany	triticale TTLSS	F	Powdery mildew *Erysiphe graminis* ERYSGR	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
18	Germany	triticale TTLSS	F	*septoria*-species *Septoria* spp. SEPTSP	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		

19	Germany	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 BBCH 30 - 69	a) 2 b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		

REGISTRATION REPORT
Part B

Section 5 Environmental Fate

Detailed summary of the risk assessment

Product code: 102000013869/ Aviator Xpro

Active Substance(s): Bixafen: 75 g/L
Prothioconazol: 150 g/L

Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ADDENDUM – Germany

Applicant: Bayer CropScience

Date: 19 April 2016

Table of Contents

Sec 5 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)

The exposure assessment of the plant protection product Aviator Xpro in its intended uses in cereals is documented in detail in the core assessment of the plant protection product Aviator Xpro dated from 2013 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 Aviator 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 Aviator Xpro

Code	102000013869		
plant protection product	Aviator Xpro		
applicant	Bayer CropScience		
date of application	30.03.2012		
Formulation type (WP, EC, SC, …; density)	EC		
active substances (as)	Bixafen	Prothioconazole	
Concentration of as	75 g/L	150 g/L	

Data pool/task force	
letter of access/cross reference	
existing authorisations in DE	

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 are covered by the core assessment performed by Germany.

Table 5.2-1: Classification of intended uses in Germany for Aviator Xpro

Group	Crop/growth stage	Application method / Drift scenario	Number of applications, Minimum application interval, interception, application time (season)	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)

A	Wheat, Rye, Triticale / BBCH 30-69	spraying /	2 x, 14 d,spring 1. 70 % 2. 70 % Winter cereals: 1. Appl.: 19.4.=>169d and 183d after emergence Spring cereals: 1. Appl: 28.4.= >27 d and 41d after emergence	Bixafen: 2 x 93.75 = 187,5 Prothioconazol: 2 x 187.5= 375	Bixafen: 1. 28.125 2 28.125 Prothioconazol: 1. 56.25 2 56.25
B	Barley / BBCH 30-61	spraying /	2 x, 14d, spring 1. 70%, 14d 2. 70%, 10 d	Bixafen: 2 x 75=150 Prothioconazol: 2 x 150 = 300	Bixafen: 1. 22.5 2. 22.5 Prothioconazol: 1. 45 2. 45

* 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 (2013), part B, section 5, point 5.3.1.

5.3.2 Prothioconazole

Please refer to the core assessment (2013), part B, section 5, point 5.3.1.

5.4 Summary on input parameters for environmental exposure assessment

5.4.1 Rate of degradation in soil

Bixafen

Please refer to the core assessment (2013)part B, section 5, point 5.4.1.

Accumulation of Bixafen in soil

After finalization of the DAR the final report of the soil accumulation study (Heinemann, Weuthen 2013, see Appendix 2) was available.

The residues after annual treatments in 6 consecutive years at Monheim site (Germany) were already presented in Addendum 2. The final report shows the results following eight consecutive annual treatments at site Monheim.

The graph for the Monheim site (Germany) site shows that concentrations in soil have not yet reached a plateau.

The concentration for Bixafen immediately after the eighth application at site Monheimwas 410 µg/kg soil (overall maximum). At the termination of the study, the maximum plateau concentration at site Tarascon was 179 µg/kg soil (Tarascon, mean of days1427 and 1797). At site Monheim, no plateau concentration was reached in the courseof the study but the study was terminated due to technical reasons (test plot completelysampled, i.e. no further samplings possible on originally treated area). The results are presented in more detail in the following table.

Location	Soil type (USDA)	Residue Level	Residues of Bixafen in Soil Layers Virtual[1] 0-10 cm [µg/kg]
Monheim Germany 09-2801-01 VG08	Sandy loam (0-50 cm) / Loamy Sand (50-100 cm)	High[2]	410 (Day 2526)
		Low[3]	340 (Day 2720)
Tarascon France 09-2801-02 FR08	Silt loam (0-100 cm)	High[4]	179 (Mean of days 1427 and 1797)
		Low[5]	106 (Mean of days 1655 and 2015)

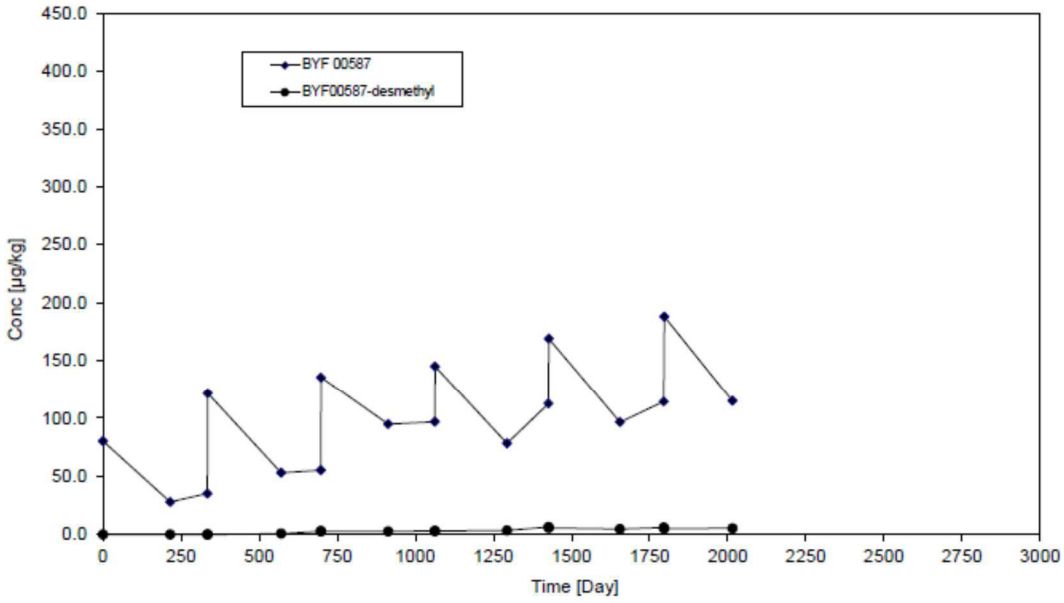
1) total residues in soil, recalculated for a 10-cm soil layer (density 1.5 g/cm^3)
2) residue determined after the last application
3) residue determined at the last sampling interval (prior to winter dormancy)
4) upper limit of the "saw teeth" curve (mean value, calculated from residues determined at days 1427 and 1797)
5) lower limit of the "saw teeth" curve (mean value, calculated from residues determined at days1655 and 2015)

Considering an application rate of 137.7 g/ha Bixafen, distributed in the top 10 cm of soil

and assuming a soil density of 1.5 kg/L, this results in a nominal Bixafen concentration

of 91.8 µg/kg soil after a single application. The factor between the low concentration of 340µg/kg from the Monheim trial in Germany and the concentration in soil resulting from one application of 91.8 µg/kg is 3.7. However, the plateau was at the end of the study not reached.

Figure 2: Dissipation of Bixafen and Formation of Bixafen-desmethyl Residues in Soil after Application of BYF 00587 SC 450, 09-2801-02 (Tarascon, France)



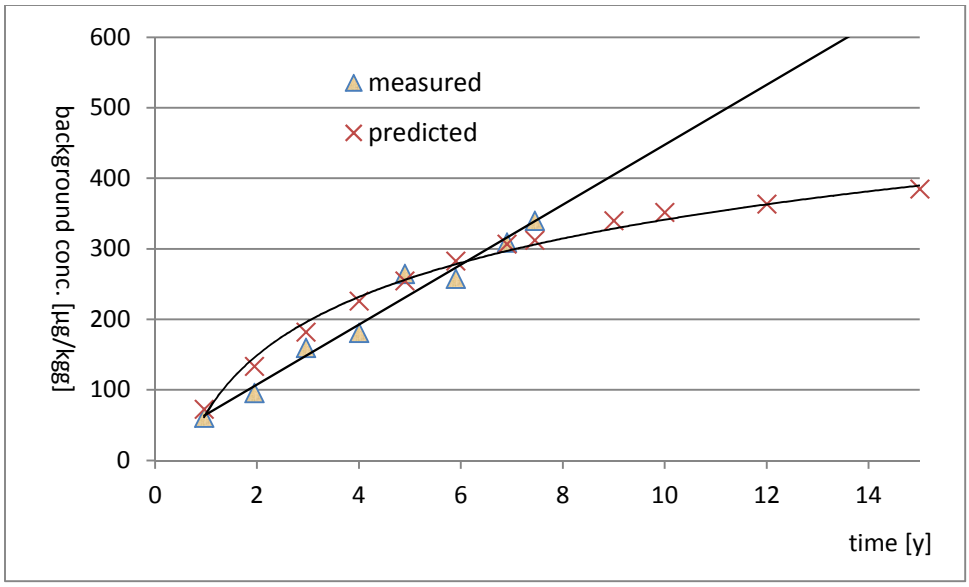
Comment ZRMs:

A comparison by zRMS of measured residues against predicted values considering a simplifying DT_{50} of 1235d shows, that the background residues residues at the end of the study are higher than predicted. For the prediction of the residues the factor f accu plateau was applied to the resulting concentration in soil after one application of 91.8 µg/kg. Because of the increasing trend of the measured residues of Bixafen there is an uncertainty, if the plateau will be ever reached and if the actual concentrations after annual applications of more than 8 following years will increase further. For reason of precaution an uncertainty factor will be applied for PECaccu soil calculation (see chapter 5.5).

time d	time y	measured	predicted	faccuplateau
353	0.96	60.6	72.522	0.79
710	1.95	95.8	133.11	1.45
1082	2.96	159.7	181.764	1.98
1460	4	180.9	225.828	2.46
1797	4.9	264.7	254.286	2.77
2161	5.9	257.6	282.744	3.08
2524	6.9	309.1	306.612	3.34
2720	7.45	340	312.12	3.4
	9		339.66	3.7

10	351.594	3.83
12	363.528	3.96
15	384.642	4.19
17	391.068	4.26
20	395.658	4.31

Figure 1: Measured residues of Bixafen in virtal 10 cm soil layer at Mohnheim site resulting from applications over 8 following years and predicted residues



5.4.2 Adsorption/desorption

Bixafen

Please refer to the core assessment (2013) part B, section 5, point 5.4.2.

5.4.3 Rate of degradation in water/sediment

Bixafen

Please refer to the core assessment (2013), 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, t = 356 d

5.5 Estimation of concentrations in soil (KIIIA1 9.4)

Results of PECsoil calculation for Aviator Xpro according to EU assessment considering 5 cm soil depth are given in the core assessment 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 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.

Due to the slow degradation of the active substance Bixafen in soil (DT_{90} > 365 d, field data) the accumulation potential needs to be considered. Therefore PEC_{soil} used for risk assessment comprises background concentration in soil (PEC_{accu}) deducated from the soil accumulation study given for a depth of 10 cm and the maximum annual soil concentration PEC_{act} considering the relevant soil depth of 1.0 cm. .

The PEC_{soil} calculation for Prothioconazole was performed with ESCAPE 2.0 based on the input parameters of Prothioconazole as presented in Table 5.5-1.

Table 5.5-1: Input parameters for Aviator Xpro for PEC_{soil} calculation

Active substance	**DT_{50}**
Bixafen	DT50 (D): K1 = 0.00810; K2 = 0.00023 BREAKPOINT (TB) = 53 D (DT50 = 1235 D) KINETICS: HS MODEL worst case, non-normalised DT50 from field dissipation studies (German trial).
Prothioconazole	2.4d (worst case field studies non normalised)
Metabolite M01, JAU 6476-S-methyl	25.9 d (worst case. lab. studies, normalised),
Metabolite M04, JAU 6476-desthio	57 d (worst case field studies non normalised)

Additional $PEC_{soil,act}$ was calculated for the formulation Aviator 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 Prothioconazole and for the formulation Aviator Xpro are summarized in Table 5.5-2.

Table 5.5-2: Results of PEC_{soil} calculation for the intended use used for German risk assessment

plant protection product:	Aviator Xpro

group:		A				
Number of applications/intervall		2/ 14d				
application rate:		93.75 g/ha				
crop interception:		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)**
Prothioconazole	2 x 56,25 g/ha M:344.3	1	0.3816 on day 14	-	-	-
Metabolite M01, JAU 6476-S-methyl	Ff=0.14, M: 358.3	1	0.072 on day 21	-	-	-
Metabolite M04, JAU 6476-desthio	Ff=0.8, M: 312.2	1	0.4506 on day 23	20	0.0003	0.4509

PEC$_{soil}$Accu Bixafen

Due to the slow degradation of the active substance Bixafen in soil (DT_{90} > 365 d, field data) the accumulation potential needs to be considered. Therefore PEC$_{soil}$ used for risk assessment comprises background concentration in soil (PEC$_{accu}$) deducted from the soil accumulation study (see also chapter 5.4.1, Accumulation of Bixafen in soil) given for a depth of 10 cm and the maximum annual soil concentration PEC$_{act}$ considering the relevant soil depth of 1.0 cm. .

A factor of 3.7 between the concentration resulting from one application and the low plateau concentration is derived from the soil accumulation study. As the plateau was not reached during the 8 years of the study, an extrapolation was performed. The after the study time of 8 years, measured background concentration of Bixafen represents only 80% of the for an active substance with a DT_{50} of 1235 calculated low plateau concentration. Therefore, the remaining 20% were added to the amount for the calculation of the background concentration.

Further, as no plateau was reached, a uncertainty factor of 10 for the background concentration was used additionally. It cannot be excluded that the background concentration will be higher than calculated.

As the soils were ploughed, the background concentration was calculated for a soil depth of 20cm, although the residues in the soil accumulation study were found in 0-10 cm dephth.

The overall accumulation PEC in soil is the sum PEC act + PECbackground.

Results of $PEC_{Accu\ soil}$ used for German risk assessment

plant protection product:		Aviator Xpro					
group:		A					
Number of applications/intervall		2/ 14d					
application rate:		93.75 g/ha					
crop interception:		70%					
active substance	**soil relevant application rate (g/ha)**	**soil $depth_{act}$ (cm)**	**PEC_{act} (mg/kg)**	**PEC_{bkgd} x3.7* (mg/kg)**	**PEC_{bkgd} +20%** (mg/kg -**	**PEC_{bkgd} x10 *** (mg/kg)**	**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg**
Bixafen	1x 56.25 g/ha	1	0.375	-			1.21
	PEC_{bkgd}	20	0.0188	0.0694	0.0833	0.833	-

*) factor deduced from soil accumulation study,
**) only 80% of the low plateau can be reched during 8 years, based on the DT_{50} value of 1235days for Bixafen
***) uncertainty factor, if no plateau was reached during the study

plant protection product:		Aviator Xpro					
group:		B					
Number of applications/intervall		2/ 14d					
application rate:		75 g/ha					
crop interception:		70%					
active substance	**soil relevant application rate (g/ha)**	**soil $depth_{act}$ (cm)**	**PEC_{act} (mg/kg)**	**PEC_{bkgd} x3.7* (mg/kg)**	**PEC_{bkgd} +20%** (mg/kg -**	**PEC_{bkgd} x10 *** (mg/kg)**	**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg**
Bixafen	1x 45 g/ha	1	0.300	-			0.961
	PEC_{bkgd}	20	0.015	0.055	0.066	0.661	-

*) factor deduced from soil accumulation study,
**) only 80% of the low plateau can be reched during 8 years, based on the DT_{50} value of 1235days for Bixafen
***) uncertainty factor, if no plateau was reached during the study

5.6 Estimation of concentrations in surface water and sediment (KIIIA1 9.7)

Results of PECsw calculation of Bixafen for the intended for uses of Aviator Xproin cereals using FOCUS Surface Water are given in the core assessment, 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 models 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 deposition following volatilisation

5.6.1.1 Bixafen

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.

The calculation of PECsw after exposure via spray drift is performed using the model EVA . 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 surface water exposure via spray drift and volatilization with subsequent deposition with EVA 2.1 are summarized in Table 5.6-1.

Table 5.6-1 Endpoints of Bixafen used for the PEC_{SW} calculations with EVA 2.1

Parameter	Bixafen	Reference
vapour pressure at 20 °C (Pa)	4.6 x 10^{-8}	See core assessment, section 5, point 5.3.1.1
Solubility in water (mg/L)	0.49	
$DissT_{50}$ water (d)	27.4	
DT_{50} hydrolysis/photolysis (d)	1000 (default)	

The calculated PECsw values after exposure via spray drift for the active substance Bixafen for the intended use in cereals (worst case application rate) are summarized in Table 5.6-2.

Table 5.6-2 PEC_{SW} for the active substance Bixafen after exposure via spray drift and volatilization with subsequent deposition modelled with EVA 2.1

active substance	Bixafen
use pattern/gap:	group A
application rate/number of applications / interval	93.75 g/ha/ 2, 14d(worst case)
$DissT_{50}$ (SFO) in water	27.4
relevant PEC if applicable twa-interval	
scenario/percentile:	82

distance (m)	PECsw via drift		PECsw via volatilisation		PECsw (via drift and volatilisation) (µg/L) depending on application technique (drift reduction)			
	(%)	(µg/L)	(%)	(µg/L)	common	90% red.	75% red.	50% red.
0	100.00	53.18	-	-	53.18	5.32	13.30	26.59
1	2.38	1.27	-	-	1.266	0.13	0.32	0.63
5	0.47	0.25	-	-	0.250	0.02	0.06	0.12
10	0.24	0.13	-	-	0.128	0.01	0.03	0.06
15	0.16	0.09	-	-	0.085	0.01	0.02	0.04
20	0.12	0.06	-	-	0.064	0.01	0.02	0.03

5.6.1.2 Accumulation of Bixafen in sediment

The concentration of Bixafen was calculated for a water body with 30L water and 10L sediment (1 cm sediment depth). A maximum amount of 88.3% Bixafen in the sediment phase was considered.

PEC sed. max= (53.18 µg/L x 300L x 0.833) / (10 L x 1.3 kg/L)= 1022.3 µg/kg

The plateau concentration PEC sed, plateau is PEC sed.max x faccu.

$f_{accu} = e^{-kt}/(1 - e^{-kt}) = 3.47$

k=degradation rate in sediment (ln(2) / DT_{50}), DT_{50} whole system: 1000d

t= time between growing seasons (365d)

1022.3 µg/kg x 3.47= 3547.4 µg/kg

The overall accumulation PEC in sediment is

PEC sed, accu. overall= PEC sed, plateau + PECsed, max

3547.4 µg/kg +1022.3 µg/kg = 4569.7 µg/kg

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 Prothioconazole is < 10^{-5} Pa. Hence the active substance Prothioconazole is regarded as non-volatile.

The calculation of PECsw after exposure via spray drift is performed using the model EVA . 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.

However, for the active substance Prothioconazole the thus calculated peak PECsw for multiple applications is lower than for one application. Thus, PECsw for one single application are used as highest PECsw here.

The endpoints used for modelling surface water exposure via spray drift and volatilization with subsequent deposition with EVA 2.1 are summarized in Table 5.6-3.

Table 5.6-3 Endpoints of Prothioconazole used for the PEC_{SW} calculations with EVA 2.1

Parameter	Prothioconazole	Reference
vapour pressure at 20 °C (Pa)	<< 4 x 10^{-7}	See core assessment, section 5, point 5.3.1.1
Solubility in water (mg/L)	300	
$DissT_{50}$ water (d)	1	
DT_{50} hydrolysis/photolysis (d)	1000 (default)	

5.6.1.3 Prothioconazole

The calculated PECsw values after exposure via spray drift for the active substance Prothioconazole for the intended use in cereals (worst case application rate) are summarized in

Table 5.6-4 PEC_{SW} for the active substance Prothioconazole after exposure via spray drift and volatilization with subsequent deposition modelled with EVA 2.1

active substance			Prothioconazole					
use pattern/gap:			group A					
application rate/number of applications / interval			187.5g/ha/ / 2 / 14d					
$DissT_{50}$ (SFO) in water			1					
relevant PEC if applicable twa-interval								
scenario/percentile:			Agriculture, single application/ 90					
distance (m)	PECsw via drift		PECsw via volatilisation		PECsw (via drift and volatilisation) (µg/L) depending on application technique (drift reduction)			
	(%)	(µg/L)	(%)	(µg/L)	common	90% red.	75% red.	50% red.
0	100.00	62.50	-	-	62.50	6.25	15.63	31.25
1	2.77	1.73	-	-	1.731	0.17	0.43	0.87
5	0.57	0.36	-	-	0.356	0.04	0.09	0.18
10	0.29	0.18	-	-	0.181	0.02	0.05	0.09
15	0.20	0.13	-	-	0.125	0.01	0.03	0.06
20	0.15	0.09	-	-	0.094	0.01	0.02	0.05

5.6.2 PEC_{SW} after exposure by surface run-off and drainage

5.6.2.1 Bixafen

The concentration of the active substance Bixafen in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.0.

The parameters for Bixafen used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.0 are summarized in Table 5.6-5.

Table 5.6-5 Input parameters for Bixafen used for PEC_{SW} calculations with EXPOSIT 3.0

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	see core assessment, section 5, point 5.3.1.1
Reduction by bank filtration (only relevant for PECgw see 5.7.2)	100%	

The calculated PEC_{SW} in an adjacent ditch due to surface run-off and drainage for the active substance Bixafen for the intended for use in cereals (worst case application rate) are summarized in Table 5.6-6**Fehler! Verweisquelle konnte nicht gefunden werden.**.

As Bixafen is very persistent – no plateau was reached in soil after applications over 8 following years- it was assumed that the rainfall event occurs after perennial application of Bixafen. The application rates of 93.75 g/ha for group A and 75g/ha for group B were corrected in order to consider run off of a part of the background concentrations in soil, too.

Table 5.6-6 PEC_{SW} of Bixafen in an adjacent ditch due to surface run-off and drainage

Active substance:	Bixafen	
Use pattern/GAP:	group A	
Application rate:	2x 160 g/ha (worst case considering background plateau), 14d interval, 70% interception	
Exposure by surface runoff		
vegetated buffer strip (m)	**PECsw in adjacent ditch ($PEC_{ini\ Runoff}$) (µg/L)**	**PECsw in adjacent ditch ($PEC_{ini\ Gesamtaustrag}$) (µg/L)**
0	0.31	0.64
5	0.27	0.56
10	0.23	0.32
20	0.16	0.2
Exposure by drainage		
time of application	**PECsw in adjacent ditch (µg/L)**	
autuum/winter/early spring	0.05	
Spring/summer	0.01	

Active substance:	Bixafen	
Use pattern/GAP:	group B	
Application rate:	2x 130 g/ha (worst case considering background plateau), 14d interval, 70% interception	
Exposure by surface runoff		
vegetated buffer strip (m)	**PECsw in adjacent ditch ($PEC_{ini\ Runoff}$) (µg/L)**	**PECsw in adjacent ditch ($PEC_{ini\ Gesamtaustrag}$) (µg/L)**
0	0.25	0.52

5	0.22	0.45
10	0.19	0.27
20	0.13	0.17
Exposure by drainage		
time of application	**PECsw in adjacent ditch (µg/L)**	
autuum/winter/early spring	0.04	
Spring/summer	0.01	

5.6.2.2 Prothioconazole

The concentration of the active substance Prothioconazole in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.0.

The parameters for Prothioconazole used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.0 are summarized in Table 5.6-7.

Table 5.6-7 Input parameters for Prothioconazole used for PEC_{SW} calculations with EXPOSIT 3.0

Parameter	**Prothioconazole**	**Reference**
$K_{foc, Runoff}$	1765	arithm. mean (see core assessment, section 5, chapter 5.4.2)
$K_{foc, mobility\ class}$	1765	arithm. mean (see core assessment, section 5, chapter 5.4.2)
DT_{50} soil (d)	2.4	
Solubility in water (mg/L)	300	see core assessment, section 5, point 5.3.1.1
Reduction by bank filtration (only relevant for PECgw see 5.7.2)	100%	

The calculated PEC_{SW} in an adjacent ditch due to surface run-off and drainage for the active substance Prothioconazole for the intended for use in cereals (worst case application rate) are summarized in Table 5.6-8.

Table 5.6-8 PEC_{SW} of Prothioconazole in an adjacent ditch due to surface run-off and drainage

Active substance:	Prothioconazole	
Use pattern/GAP:	group A	
Effective Application rate:	56.25 g/ha (worst case), 14d interval	
Exposure by surface runoff		
vegetated buffer strip (m)	**PECsw in adjacent ditch ($PEC_{ini\ Runoff}$) (µg/L)**	**PECsw in adjacent ditch ($PEC_{ini\ Gesamtaustrag}$) (µg/L)**

0	0.12	0.16
5	0.11	0.14
10	0.09	0.10
20	0.06	0.07
Exposure by drainage		
time of application	**PECsw in adjacent ditch (µg/L)**	
autuum/winter/early spring	0.01	
Spring/summer	<0.01	

5.7 Risk assessment for groundwater (KIIIA1 9.6)

Results of PECgw calculation of Bixafenfor the intended uses of Aviator Xpro in cerealsaccording to EU assessment using FOCUS PELMO are given in the core assessment 2013 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 4.4.3.

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 Aviator Xpro in cereals according to Table 5.2-1.

Table 5.7-1 Input parameters related to application for PEC_{GW} modelling with FOCUS PELMO 5.5.3

use evaluated	Group A
application rate (kg as/ha)	0.028125
crop (crop rotation)	Winter cereals/ spring cereals
date of application	169d and 183 d after emergence/ 27d and 41d after emergence

interception (%)	Considered in application rate
soil moisture	100 % FC
Q10-factor	2.58
moisture exponent	0.7
plant uptake	0
simulation period (years)	26

Bixafen

The endpoints used for groundwater modelling for Bixafen and its metabolite M44 according to INPUT DECISION 3.1 are summarized in Table 5.7-2.

Table 5.7-2 Input parameters for PEC_{GW} modelling

Parent	**Bixafen**	**Remarks/Reference to core assessment, part B, section 5**
molecular weight (g/mol)	414.2	
DT_{50} in soil (d)	200.2	
K_{foc}	3869	
1/n	0.88	
metabolite	**M 44**	
molecular weight (g/mol)	162.1	
Formation fraction	1	
DT_{50} in soil (d)	134.6	
K_{foc}	7.7	
1/n	0.964	

The results of the groundwater simulation are presented in Table 5.7-3.

Table 5.7-3 PEC_{GW} at 1 m soil depth of Bixafenand its metabolite M44 considered relevant for German exposure assessment

Use No.	**Szenario**	**80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 4.4.3**		
		Bixafen	**Metabolite M44**	
Group A	Hamburg, winter cereals	<0.001	1.596	
Group A	Hamburg, spring cereals	<0.001	1.575	

Prothioconazole

The endpoints used for groundwater modelling for Prothioconazole and its metabolite M44 according to INPUT DECISION 3.1 are summarized in Table 5.7-4.

Table 5.7-4 Input parameters for PEC_{GW} modelling

Parent	**Prothioconazole**	**Remarks/Reference to core assessment, part B, section 5**
molecular weight (g/mol)	344.26	
DT_{50} in soil (d)	300 at pH 8	
K_{foc}	1765	
1/n	1	
Metabolite	**M04, JAU 6476-Desthio**	
molecular weight (g/mol)	312.2	
Formation fraction	0.54	
DT_{50} in soil (d)	23.1	
K_{foc}	575.4	
1/n	0.81	
Metabolite	**M01, JAU-6476-S-methyl**	
molecular weight (g/mol)	358.3	
Formation fraction	0.14	
DT_{50} in soil (d)	9.5	
K_{foc}	2556.3	
1/n	0.88	

The results of the groundwater simulation are presented in Table 5.7-5.

Table 5.7-5 PEC_{GW} at 1 m soil depth of Prothioconazole its metabolites Metabolite M01/ JAU-6476-S-methyl and Metabolite M04/ JAU 6476-Desthio considered relevant for German exposure assessment

Use No.	**Szenario**	**80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 4.4.3**		
		Prothioconazole	Metabolite M01/ JAU-6476-S-methyl	Metabolite M04/ JAU 6476-Desthio
Group A	Hamburg, winter cereals	<0.001	<0.001	<0.001

Group A	Hamburg, spring cereals	<0.001	<0.001	<0.001

According to the results of the groundwater simulation with FOCUS-PELMO 4.4.3, a groundwater contamination of the active substance Bixafen in concentrations of ≥ 0.1 µg/L is not expected for the intended uses in winter and spring cereals.

For the metabolite M44 of Bixafen a groundwater concentration of ≥ 0.1 µg/L can not be excluded for the application in winter and spring cereals according to the results of the groundwater simulation with FOCUS-PELMO 5.5.3.

According to the results of the groundwater simulation with FOCUS-PELMO 5.5.3, a groundwater contamination of the active substance Prothioconazole and the metabolites M01/ JAU-6476-S-methyl and M04/ JAU 6476-Desthio in concentrations of ≥ 0.1 µg/L is not expected for the intended uses in winter and spring cereals.

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 3.0 are summarized in Table 5.7-6.

Table 5.7-6 Input parameters for Bixafenused for PEC_{GW} calculations with EXPOSIT 3.0

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%	

The calculated PECgw for Bixafen after surface run-off and drainage with subsequent bank filtration are summarized in Table 5.7-7.

Table 5.7-7 PEC_{gw} for Bixafen after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Active substance		**Bixafen**			
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)**
Group A	93.75 g/ha/ 70%	0	<0.001	autumn/winter/ early spring	<0.001
		5	<0.001		
		10	<0.001	spring/summer	<0.001
		20	<0.001		
required labelling		-			

According modelling with EXPOSIT 3, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance Bixafen due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

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 3.0 are summarized in Table 5.7-8

Table 5.7-8 Input parameters for Prothioconazole used for PEC_{GW} calculations with EXPOSIT 3.0

Parameter	**Prothioconazole**	**Reference**
$K_{foc, Runoff}$	1765	(see core assessment, section 5, chapter 5.4.2)
$K_{foc, mobility class}$	1765	(see core assessment, section 5, chapter 5.4.2)
DT_{50} soil (d)	2.4	
Solubility in water (mg/L)	300	
Mobility class	1	
Reduction by bank filtration	100%	

The calculated PECgw for Prothioconazole after surface run-off and drainage with subsequent bank filtration are summarized in Table 5.7-9.

Table 5.7-9 PEC_{gw} for Prothioconazole after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Active substance		**Prothioconazole**	
Use No.	**application rate**	**PECgw due to**	
		run-off	**drainage**

	interception	**vegetated buffer strip (m)**	**bank filtrate (µg/L)**	**Time of application**	**bank filtrate (µg/L)**
Group A	2x 187.5 g/ha, 70%	0	<0.001	autumn/winter/ early spring	<0.001
		5	<0.001		
		10	<0.001	spring/summer	<0.001
		20	<0.001		
required labelling		-			

According modelling with EXPOSIT 3, 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.

The authorization of the plant protection product Aviator Xprois linked with following labeling:

Use No. - NG -

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*
KIIA 7.1.1.2.2 /01	Hardy, I.	2009	Kinetic modelling analysis of prothioconazole from field soil residue studies conducted in europe normalised to 20ºC and pF2 Battelle UK Ltd., Ongar, Essex, United Kingdom BCS, Report No.: VC/08/038, Edition Number: M-345442-01-1 Date: 2009-03-25 Non GLP, unpublished	Yes	Bayer Crop Science	1)
KIIA 7.1.1.2.2 /02	Schad, T.; Zerbe, P.	2008	Dissipation of prothioconazole and JAU6476-desthio under field conditions in Europe Kinetic evaluation and calculation of Non-referenced DT50 BCS, Report No.: MEF-08/114, Edition Number: M-298575-01-1 Date: 2008-02-20 Non GLP, unpublished	Yes	Bayer Crop Science	1)
KIIA 7.3.3	Heinemann, Weuthen	2013	Determination of the residues of BYF 00587 in/on soil after spraying of BYF 00587 SC450 in the field in Germany and France (South) Date: 2013-04-26	Yes	BAY	4)

*

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

see CA

Appendix 3 Table of Intended Uses justification and GAP tables

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		
1	Germany	wheat TRZSS	F	Powdery mildew *Erysiphe graminis* ERYSGR	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
2	Germany	wheat TRZSS	F	Leaf spot wheat *Septoria tritici* SEPTTR	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	**a)** 2 (14 - 21days) **b)** 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
3	Germany	wheat TRZSS	F	tan spot of cereals *Drechslera tritici-repentis*	spraying	From spring at beginning of infestation and/or	a) 2	a) 1.25 L/ha	a) 1: 93.8 g as/ha	150 - 400		

				PYRNTR		when first symptoms become visible BBCH 30 - 61	(14 - 21days) b) 2	b) 2.5 L/ha	2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha			
4	Germany	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 BBCH 30 - 69	a) 2 (14 - 21days) b) 2	a) 1.25 L/ha b) 2.5L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
5	Germany	wheat TRZSS	F	stem break of cereals *Pseudocercosporella herpotrichoides* PSDCHE	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 37	a) 1 b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
6	Germany	wheat TRZSS	F	Stripe rust of grasses *Puccinia striiformis* PUCCST	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
7	Germany	wheat TRZSS	F	*Septoria* leaf spot wheat *Septoria nodorum* LEPTNO	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	**a)** 2 (14 - 21days) **b)** 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
8	Germany	barley HORVX	F	Powdery mildew *Erysiphe graminis*	spraying	From spring at beginning of infestation and/or	**a)** 2	a) 1 L/ha	a) 1: 75 g as/ha	150 - 400		

				ERYSGR		when first symptoms become visible BBCH 30 - 61	(14 - 21days) **b)** 2	b) 2 L/ha	2: 150 g as/ha b) 1: 150 g as/ha 2: 300 g as/ha			
9	Germany	barley HORVX	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1 L/ha b) 2 L/ha	a) 1: 75 g as/ha 2: 150 g as/ha b) 1: 150 g as/ha 2: 300 g as/ha	150 - 400		
10	Germany	barley HORVX	F	net blotch *Pyrenophora teres* PYRNTE	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1 L/ha b) 2 L/ha	a) 1: 75 g as/ha 2: 150 g as/ha b) 1: 150 g as/ha 2: 300 g as/ha	150 - 400		
11	Germany	barley HORVX	F	brown rust of barley *Puccinia hordei* PUCCHD	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1 L/ha b) 2 L/ha	a) 1: 75 g as/ha 2: 150 g as/ha b) 1: 150 g as/ha 2: 300 g as/ha	150 - 400		
12	Germany	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 BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1 L/ha b) 2 L/ha	a) 1: 75 g as/ha 2: 150 g as/ha b) 1: 150 g as/ha 2: 300 g as/ha	150 - 400		
13	Germany	barley HORVX	F	decrease of non-parasitic leaf spots	spraying	From spring at beginning of infestation and/or	a) 2	a) 1 L/ha	a) 1: 75 g as/ha	150 - 400		

						when first symptoms become visible BBCH 30 - 61	(14 - 21days) b) 2	b) 2 L/ha	2: 150 g as/ha b) 1: 150 g as/ha 2: 300 g as/ha			
14	Germany	rye SECCE	F	Powdery mildew *Erysiphe graminis* ERYSGR	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
15	Germany	rye SECCE	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	**a)** 2 (14 - 21days) **b)** 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
16	Germany	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 BBCH 30 - 69	a) 2 (14 - 21days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
17	Germany	triticale TTLSS	F	Powdery mildew *Erysiphe graminis* ERYSGR	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
18	Germany	triticale TTLSS	F	*septoria*-species *Septoria* spp.	spraying	From spring at beginning of infestation and/or	a) 2	a) 1.25 L/ha	a) 1: 93.8 g as/ha	150 - 400		

				SEPTSP		when first symptoms become visible BBCH 30 - 61	(14 - 21days) b) 2	b) 2.5 L/ha	2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha			
19	Germany	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 BBCH 30 - 69	a) 2 b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		

REGISTRATION REPORT
Part B

Section 6: Ecotoxicological studies

Detailed summary of the risk assessment

Product code: **102000013869/ Aviator Xpro**

Active Substances: **Bixafen: 75 g/L**
Prothioconazole: 150 g/L

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: **Bayer Crop Science**

Date: **19 April 2016**

Table of Contents

Sec 6 ECOTOXICOLOGICAL STUDIES (MIIIA 10)

6.1 GAP and overall conclusions

6.1.1 Table of intended uses

Please refer to GAP-table in Annex 4.

6.1.2 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.

The critical GAPs used for risk assessment is presented in the table below. It has been selected from the individual GAPs in the zone for Aviator Xpro. A list of all intended uses within the zone is given in Appendix 4.

Table 6.1-1: Critical use pattern of Aviator Xpro

Group	Crop/growth stage	Application method / Drift scenario	Number of applications, Minimum application interval, interception, application time (season)	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
A	Wheat, Rye, Triticale / BBCH 30-69 Uses: 007, 015, 016, 019, 004, 003, 014, 017, 001, 006, 005, 018, 002	spraying /	2 x, 14 d,spring 1. 70 % 2. 70 % Winter cereals: 1. Appl.: 19.4.=>169d and 183d after emergence Spring cereals: 1. Appl: 28.4.= >27 d and 41d after emergence	Bixafen: 2 x 93.75 = 187,5 Prothioconazol: 2 x 187.5= 375	Bixafen: 1. 28.125 2 28.125 Prothioconazol: 1. 56.25 2 56.25
B	Barley / BBCH 30-61 Uses: 008, 013, 010, 009, 012, 011	spraying /	2 x, 14d, spring 1. 70%, 14d 2. 70%, 10 d	Bixafen: 2 x 75=150 Prothioconazol: 2 x 150 = 300	Bixafen: 1. 22.5 2. 22.5 Prothioconazol: 1. 45 2. 45

Consideration of metabolites

The metabolites which require an ecotoxicological assessment according to the endpoint list are given below.

Table 6.1-2: Metabolites assessed of bixafen

Metabolite	Maximum occurrence in compartments	Risk assessment required and provided
M44 that consists of the tautomers 3-(difluoromethyl)-1*H*-pyrazole-4-carboxylic acid and 5-(difluoromethyl)-1*H*-pyrazole-4-carboxylic acid	groundwater	N 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: risk assessed as low to the aquatic environment

Table 6.1-3: Metabolites assessed of Prothioconazole

Metabolite	Maximum occurrence in compartments	Risk assessment required and provided
JAU 6476-S-methyl (M01)	Soil: max. 14.6% day 7 . Sediment: max. 9.6%	N, not necessary. Toxicity covered by mothersubstance.
JAU 6476-desthio (M04)	Soil: max. 49.4% day 7 / 57% field Water: max. 32.3% day 7 Sediment: max. 26.9% day 14	Y
1,2,4-triazole (M13)	water: max. 37.2% da 121	N, not necessary. Toxicity covered by mothersubstance.

6.2 Effects on birds (MIIIA 10.1, KPC 10.1, KPC 10.1.1)

Avian acute oral and long-term reproduction studies have been carried out with bixafen (BYF 00587), prothioconazole (JAU 6476) (and the metabolite prothioconazole-desthio (JAU 6476-desthio). Full details of avian toxicity studies are provided in the respective EU DAR as well as in Appendix 2 of this document (new studies). The studies with the relevant acute and long-term endpoints were agreed during EU review process and are used for the risk assessment.

Effects on birds of Aviator Xpro were not evaluated as part of the EU review of either the active substance bixafen or prothioconazole. However, the provision of further data on the formulation Aviator Xpro is not considered essential as the available data on the active substances are deemed to be sufficient to assess the risk of birds exposed to Aviator Xpro.

Table 6.2-1: Endpoints used for risk assessment for birds

Test system	Species	Results	Reference	Internal code
Bixafen				
Acute toxicity	*Colinus virginianus*	LD_{50} > 2000 mg/kg bw	List of endpoints Bixafen, EFSA Journal 2012;10(11):2917 **XXX** 20.12.2005 E 204 2937-7	69475
Reproductive toxicity	*Colinus virginianus*	NOEL: 24.5 mg/kg bw [1] Number of surviving juveniles/hen; endpoint less reliable,see below*	List of endpoints Bixafen, EFSA Journal 2012;10(11):2917 **XXX** 2007 E 205 3014-5	69623
	Colinus virginianus	**NOAEL: 30 mg/kg bw/d** *	List of endpoints Bixafen, EFSA Journal 2012;10(11):2917 **XXX** 17.06.2009 EBDRL003 1)	75490
Prothioconazole (JAU 6476)				
Acute toxicity	*Colinus virginianus*	LD_{50} > 2000 mg/kg bw	EFSA conclusion (2007) 106, 1-98 Prothioconazole **XXX** 17.06.1999 BAR/LD028	46062
Reproductive toxicity	*Anas platyrhynchos*	NOEC: 78 mg/kg bw/d (according to LoEP)	EFSA conclusion (2007) 106, 1-98 Prothioconazole **XXX** 07.11.2000 259919	46105
JAU 6476-desthio				
Acute toxicity	*Colinus virginianus*	LD_{50} > 2000 mg/kg bw	EFSA conclusion (2007) 106, 1-98 Prothioconazole **XXX** 1990/ LoEP 2007	46070
Reproductive toxicity	*Colinus virginianus*	NOEL: 14.8 mg/kg bw/d Reproduction	EFSA conclusion (2007) 106, 1-98 Prothioconazole **XXX** 2002 BAR/REP006	46106

* As required for the registration of bixafen a reproductive toxicity study has been conducted with Bobwhite quail (Barfknecht, 2007). This study was a 22-week reproduction study (acc. to OECD 206). The study considered here is a second study

(Christ and Lam, 2009), which was performed since technical problems in the first study (increased mortality due to aggression) raised concern in regard of robustness of the results. The second study should answer the question whether the observed problems of the first study were technically induced or treatment related, and to verify or modify the results of the first study. It was decided not to repeat a 22-week study, but to perform a study with proven breeders (acc. to OECD draft 2006) since this type of study has increased statistical power compared with the old design and is therefore better suitable to find relevant changes.

6.2.1 Justification for new endpoints

No deviation from the EU agreed endpoints.

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 uses groups A and B (see Table 6.1-1).

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 potential 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 toxicty

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 of Aviator Xpro is not an assessment of the formulation toxicity as such, but an assessment of 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:

$$LD_{50}(mix) = \left(\sum_i \frac{X(a.s._i)}{LD_{50}(a.s._i)} \right)^{-1}$$

where:

X(a.s. *i*) = fraction of active substance (i) in the mixture expressed as e.g.:
0.333 (Bixafen) = 75 g Bixafen/L / 225 g total a.i./L

0.666 (Prothioconazole) = 150 g Prothioconazole/L / 225 g total a.i./L

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

The results of the acute and reproductive screening risk assessments are summarized in the following tables.

Table 6.1.2.1-1: Acute screening assessment for birds

Intended use [g/ha]	Indicator species	Endpoint [mg/kg bw]	SV	MAF_{90}	DDD	TER
Bixafen						
Group A (93.75 g a.s./ha)	Small omnivorous bird	>2000	158.8	1.2	17,87	111.9
Prothioconazole						
Group A (187.5 g a.s./ha)	Small omnivorous bird	>2000	158.8	1.2	35.73	55.9
Prothioconazole-desthio						
Group A (187.5 g a.s./ha)*	Small omnivorous bird	>2000	158.8	1.2	35.73	55.9
Combined toxicity TER Mix						
Group A	Bixafen, Prothioconazole, Prothioconazole-desthio					22.4

* worst case scenario assuming that the active substance is totally converted into the metabolite

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.

Based on the highly conservative presumptions of the screening step, the acute risk of exposure of birds to the active ingredients bixafen, prothioconazole and its relevant metabolite protioconazole-desthio is considered acceptable as all TER values are above the relevant trigger value TER ≥ 10 for acute effects. Thus, further refinement is not necessary.

Due to the direct proportionality of the TER to the LD_{50}, it is possible, to calculate a TER(mix) with the following formula:

$$\mathrm{TER(mix)} = \left(\sum_i \frac{1}{\mathrm{TER(a.s._i)}} \right)^{-1}$$

With:

$TER_{(a.s.i)=}$ calculated TER for the active $substance_i$

According to this formula the TER(mix) is calculated to be 22.4, thus the predicted toxicity of the formulation does not achieve the acceptability criteria TER ≥ 10.

Table 6.2-2: Reproductive screening assessment for birds

Intended use [g/ha]	Indicator species	Endpoint [mg/kg bw]	SV	MAF x twa	DDD	TER
Bixafen						
Group A (93.75 g a.s./ha)	Small omnivorous bird	30	64.8	1.4xx 0.53	4.50	6.7
Prothioconazole						
Group A (187.5 g a.s./ha)	Small omnivorous bird	78	64.8	1.4 x 0.53	9.01	8.7
Prothioconazole-desthio						
Group A (187.5 g a.s./ha)*	Small omnivorous bird	14.8	64.8	1.4 x 0.53	64.8	1.64
Combined toxicity TER Mix						
Group A	Bixafen, Prothioconazole, Prothiocoanzole-desthio					1.14

* worst case scenario assuming that the active substance is totally converted into the metabolite

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.

Based on the highly conservative presumptions of the screening step, the calculated TER values for the long-term risk resulting from an exposure of birds to the active substances bixafen and prothioconazole according to the GAP of the formulation AviatorXpro 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.

For the metabolite Prothioconazole-desthio the TER values does not pass the Trigger ≥ 5 for long-term effects. Thus, Tier 1 assessment is necessary.

According to EFSA/2009/1438, the calculation of a combined toxicity is not applicable to the risk assessment of reproductive effects. 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.

6.2.2.2 Tier 1 risk assessment

The results of the reproductive Tier 1 risk assessments are summarized in the following tables.

Table 6.2-3: Reproductive tier 1 risk assessment for birds for Aviator Xpro.

Intended use	Generic focal species	Generic diet composition	Endpoint [mg/kg bw/d]	SV	MAF x twa	DDD_A [mg/kg bw/d]	TER
Group A Bixafen (93.75 g a.s./ha)							
cereals BBCH 30 - 69	Small omnivorous bird "lark" Woodlark *(Lullula arborea)*		30	5.4	1.4 x 0.53	0.38	79
Group A Prothioconazole (187.5 g a.s./ha)							
cereals BBCH 30 - 69	Small omnivorous bird "lark" Woodlark *(Lullula arborea)*		78	5.4	1.4 x 0.53	0.75	104
Group A Prothioconazole-desthio (187.5 g a.s./ha)*							
cereals BBCH 30 - 69	Small omnivorous bird "lark" Woodlark *(Lullula arborea)*		14.8	5.4	1.4 x 0.53	0.75	19.7
Combined toxicity TER Mix							
Group A	Bixafen, Prothioconazole, Prothiocoanzole-desthio						13.7

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.

* worst case scenario assuming that the active substance is totally converted into the metabolite

6.2.2.3 Drinking water exposure

In case of early post-emergence uses as intend for the product Aviator Xpro, birds might be exposed via drinking water from puddles.

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals (see below), 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 and Prothioconazole is presented below.

Table 6.2-4: Application rate to endpoint ratios for birds exposed to bixafen, prothioconazole and JAU 6476-desthio

Compound	Koc [L/kg]	Application rate * MAF [g as/ha]	NO(A)EL [mg as/ kg bw/d]	Ratio (Application rate * MAF) / NO(A)ED	"Escape clause" No concern if ratio	Conclusion
bixafen	3869	93.75 x 1.4	30	4.38	≤ 3000	No concern
prothioconazole	1765	187.5 x 1.4	78	3.37	≤ 3000	No concern
JAU 6476-desthio	575	187.5* x 1.4	14.8	17.7	≤ 3000	No concern

* Application rate from parent compound = worst-case

6.2.2.4 Effects of secondary poisoning (MIIIA 10.1.9)

Risk assessment for earthworm-eating birds via secondary poisoning

Dry soil approach

The EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) states that a log K_{ow} ≥3 is used to indicate that there might be a potential for bioaccumulation (see Section 5.6 Bioaccumulation and food chain behaviour). Bioaccumulation of bixafen and prothioconazole has to be assessed since the log P_{OW} is 3.3 and 3.82 respectively. For the prothiconazole metabolite JAU6476-desthio the log P_{OW} is greater 3, thus an assessment is needed for the metabolite. As the active ingredient prothioconazole is transformed rapidly into JAU 6476-desthio in soil and water, the assessment is done only for the metabolite. As the metabolite is of equal or even higher toxicity, the assessment based on the metabolite covers also the risk posed by the active substance. Risk assessment is based on earthworm eating birds (100 g bw, Food intake rate (FIR) = 104.6 g/d (freshweight)). The calculation is done for the worst case indication group A with the maximal soil relevant amount of the preparation.

Table 6.2-5: Assessement of the risk for earthworm eating birds from an exposure to bixafen through secondary poisoning for the intended use group A

Parameter	Bixafen	comments
PEC_{soil} (twa = 21 d) [mg/kg soil]	0.908	2 applications with 93.75 g a.i./ha
K_{ow}	1995	Log POW= 3.3
K_{oc}	3869	
F_{oc}	0.02	Default
BCF_{worm}	0,320	$BDF_{worm} = (PEC_{worm}/PEC_{soil})$ $= (0.84 + 0.12 \times K_{ow})/ f_{oc} \times K_{oc}$
PEC_{worm}	0.291	$PEC_{worm} = PEC_{soil} \times BCF$
Daily dietara dose (mg/kg bw/d)	0.305	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	30	Relevant reproductive endpoint
TER_{lt}	98.3	Acceptable TER>= 5

TER values shown in bold fall below the relevant trigger.

As the active ingredient prothioconazole is transformed rapidly into JAU 6476-desthio in soil and water, the assessment is done only for the metabolite. As the metabolite is of equal or even higher toxicity, the assessment based on the metabolite covers also the risk posed by the active substance.

Table 6.2-6: Assessement of the risk for earthworm eating birds from an exposure to JAU 6476-desthio (metabolite prothioconazole) through secondary poisoning for the intended use group A

Parameter	JAU 6476-desthio	comments
PEC_{soil} (twa = 21 d) [mg/kg soil]	0.131	2 applications with 187.5 g a.i./ha
K_{ow}	1096	Log POW= 3.04
K_{oc}	575	
F_{oc}	0.02	Default
BCF_{worm}	0.638	$BDF_{worm} = (PEC_{worm}/PEC_{soil})$ $= (0.84 + 0.12 \times K_{ow})/ f_{oc} \times K_{oc}$
PEC_{worm}	0.084	$PEC_{worm} = PEC_{soil} \times BCF$
Daily dietara dose (mg/kg bw/d)	0.088	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	14.7	Relevant reproductive endpoint
TER_{lt}	166.9	Acceptable TER>= 5

Risk assessment for fish-eating birds via secondary poisoning

Table 6.2-7: Assessement of the risk for fish eating birds from an exposure to Bixafen through secondary poisoning for the intended use group A

Parameter	Bixafen	comments
RAC-aq	0.000460	Based on a NOEC of 0.0046 mg/L with SF of 10
BCF_{fish}	523	DAR (2011)
PEC_{fish}	0.241	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietara dose (mg/kg bw/d)	0.038	$DDD = PEC_{fish} \times 0.159$
NOAEL (mg/kg bw/d)	30	Relevant reproductive endpoint
TER_{lt}	784.3	Acceptable TER>= 5

TER values shown in bold fall below the relevant trigger.

Table 6.2-8: Assessement of the risk for fish eating birds from an exposure to JAU 6476-desthio (metabolite prothioconazole) through secondary poisoning for the intended use group A

Parameter	JAU 6476-desthio	comments

PEC_{sw} (twa = 21 d) [mg/L]	0.001020	Based on a NOEC of 0.00334 mg/L with SF of 10
BCF_{fish}	65	LOEP (2007)
PEC_{fish}	0.066	$PEC_{fish} = PEC_{water}$ x BCF_{fish}
Daily dietara dose (mg/kg bw/d)	0.011	DDD = PEC_{fish} x 0.159
NOAEL (mg/kg bw/d)	14.7	Relevant reproductive endpoint
TER_{lt}	1395	Acceptable TER>= 5

TER values shown in bold fall below the relevant trigger.

6.2.3 Risk assessment (MIIIA 10.1.3, MIIIA 10.1.4, MIIIA 10.1.5) for baits, pellets, granules, prills or treated seed

Aviator Xpro is not formulated as baits, pellets, granules, prills or treated seeds.

6.2.4 Overall conclusions

Based on the screening/tier 1 assessment step, the calculated TER values for the acute and long-term risk resulting from an exposure of birds to bixafen, prothioconazole and JAU 6476-desthio (oral exposure and exposure via drinking water and secondary poisoning) according to the GAP of the formulation Aviator 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 Aviator Xpro in crops according to the label.

Based on the calculation of the risk arising from the uptake of bixafen, prothioconazole and JAU 6476-desthio via drinking water , the calculated TER values for birds exposed to the active substances bixafen, prothioconazole and JAU 6476-desthio according to the GAP of the formulation Aviator 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, further refinement is not necessary.

Based on the calculation of the risk arising from secondary poisoning , the calculated TER values for birds exposed to the active substances bixafen and JAU 6476-desthio according to the GAP of the formulation Aviator 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, further refinement is not necessary.

6.2.4.1 Risk characterisation and weight of evidence assessment

6.3 Effects on Terrestrial Vertebrates Other Than Birds (MIIIA 10.3, KPC 10.1, KPC 10.1.2)

Acute oral and long-term reproduction studies with mammals have been carried out with bixafen and prothioconazole. Full details of mammalian toxicity studies are provided in the respective EU DAR as well as in Appendix 2 of this document (new studies). The studies with the relevant acute and long-term endpoints were agreed during EU review process and are used for the risk assessment.

Effects on terrestrial vertebrates other than birds for Aviator Xpro were not evaluated as part of the EU review of bixafen and prothioconazole. Data on Aviator Xpro have been submitted by the applicant and are evaluated here. They are considered adequate to assess the risk for terrestrial vertebrates other than birds following the use of Aviator Xpro according to the intended uses.

Table 6.3-1: EU agreed endpoints and new endpoints

Test system	Species	Results	Reference	Internal code
Aviator Xpro				
Acute toxicity	rat	LD_{50} >2000 mg/kg bw/day	**XXX** 14.09.2007 AT04095	82323
Bixafen				
Acute toxicity	rat	$LD_{50} \geq$ 5000 mg/kg bw/day	List of endpoints Bixafen, EFSA Journal 2012;10(11):2917 **XXX** 01.08.2005 AT02236 ; T 7075636	64681
Reproductive toxicity	rat	NOAEL = 34.6 mg/kg bw/day	List of endpoints Bixafen, EFSA Journal 2012;10(11):2917 **XXX** 31.08.2007 201537	75551
Prothioconazole				
Acute toxicity	rat	LD_{50} >6200 mg/kg bw/day	EFSA conclusion (2007) 106, 1-98 Prothioconazole **XXX** 1998 T7062252	74190
Reproductive toxicity	rat	$NOAEL_{repro}$ = 95.6 mg/kg bw/day	EFSA conclusion (2007) 106, 1-98 Prothioconazole; **XXX** 2001 98-612-VH	56605
JAU 6476-desthio				
Acute toxicity	rat	LD_{50} = 2235 mg a.i./kg bw/day	EFSA conclusion (2007) 106, 1-98 Prothioconazole	79512

			XXX 20097 ;	
Reproductive toxicity	rat	NOAEL= 10 mg/kg bw/day offspring: dystocia, decreased neonatal viability NOAEL : 2.5 mg/kg bw/d parental: histopathological alterations in the liver	EFSA conclusion (2007) 106, 1-98 Prothioconazole **XXX** 2001 109835 ! M-036130-01-1	79513

6.3.1 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 groups A covers the risk for mammals from group A and B (see Table 6.1-1).

6.3.1.1 Screening assessment

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**
Aviator Xpro						
Group A	Small herbivorous mammal	>2000	118.4	1.2	177.6	>11.3

Bixafen						
Group A (93.75 g a.s./ha)	Small herbivorous mammal	>5000	118.4	1.2	13.32	>375
Prothioconazole						
Group A (187.5 g a.s./ha)	Small herbivorous mammal	>6200	118.4	1.2	26.64	>233
Prothioconazole-desthio						
Group A (187.5 g a.s./ha)*	Small herbivorous mammal	2235	118.4	1.2	26.64	>83.9

* worst case assumption that the active substance is completely converted into the metabolite

based on an application rate of 1.25 L/ha (group A)

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.

Based on the highly conservative presumptions of the screening step, the acute risk of exposure of birds to the active ingredients bixafen, prothioconazole and its metabolite JAU6476-desthio following the application of Aviator Xpro according to the intended uses achieves the relevant trigger value TER ≥ 10 for acute effects. Thus, further refinement is not necessary. For the formulation the criterion is not met for acute effects. However the risk seems to be acceptable as the worst case screening assessment nearly reached the TER value of 10 and would met with further refinement.

Table 6.3-3: Reproductive screening assessment for mammals

Intended use [g/ha]	**Indicator species**	**Endpoint [mg/kg bw/d]**	**SV**	**MAF_m x ftwa**	**DDD [mg/kg bw/d]**	**TER**
Bixafen						
Group A (93.75 g a.s./ha)	Small herbivorous mammal	34.6	48.3	1.4x0.53	3.359	10.3
Prothioconazole						
Group A (187.5 g a.s./ha)	Small herbivorous mammal	95.6	48.3	1.4x0.53	6.719	14.2
Prothioconazole-desthio						
Group A (187.5 g a.s./ha)*	Small herbivorous mammal	10	48.3	1.4x0.53	6.719	**1.49**

SV: shortcut value; MAF_m: multiple application factor (mean); DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Based on the highly conservative presumptions of the screening step, the long term risk of exposure of mammals to bixafen and prothioconazole when applied according to the GAP achieves the relevant trigger value TER ≥ 5 for long term effects. For the prothioconazole metabolite JAU6476-desthio the trigger value is not met in the screening step, thus a further refined assessment is necessary

6.3.1.2 Tier-1 risk assessment

The results of the reproductive Tier 1 risk assessments are summarized in the following tables.

Table 6.3-4: Reproductive Tier-1 risk assessment for terrestrial vertebrates other than birds for Prothioconazole and Prothioconazole-desthio (JAU6476-desthio)

Intended use [g/ha]	**Generic focal species**	**Endpoint [mg/kg bw/d]**	**SV**	**MAF**	**DDD_A**	**TER**
Group A (2x 187.5 g a.i./ha* Prothioconazole-desthio (JAU6476-desthio), interval 14 days)						
BBCH > 40	Small herbivorous mammal "vole" Common vole *(Microtus arvalis)*	10	21.7	1.4x 0.53	3.02	**3.31**
BBCH 30 - 39	Small omnivorous mammal "mouse" Wood mouse *(Apodemus sylvaticus)*	10	3.9	1.4x 0.53	0.54	18.5
BBCH >40	Small omnivorous mammal "mouse" Wood mouse *(Apodemus sylvaticus)*	10	2.3	1.4x 0.53	0.32	31.3

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.

* worst case assumption that the active substance is completely converted into the metabolite

Based on the tier 1 risk assessment, the long term risk of exposure of mammals to the metabolite JAU6476-desthio following the use of Aviator Xpro according to the intended uses achieves the relevant trigger value TER ≥ 5 for long term effects for the small insectivorous and small omnivorous indicator mammal but not for the small herbivorous mammal. Thus a further refinement is needed for the worst case indicator species.

6.3.1.3 Higher tier risk assessment for Prothioconazole-desthio (JAU6476-desthio) in cereals (KPC 10.1.2.2)

The applicant provided a study on the formation of Prothioconazole-desthio (JAU6476-desthio) on crops after an application of prothioconazole (Neumann, P. 2009, KIIIA 10.3.3). This study showed that the maximum residue concentration of the metabolite formed on the crop after application of prothioconazole (application rate was 3 x 0.200 kg a.s./ha) corresponded with a mean conversion factor of 29.9% of the initial total residues. Considering this conversion factor the application rate for JAU6476-desthio corresponds to 0.056 kg/ha instead of the worst case assumption of 0.1875 kg/ha (based on the assumption that the active substance is completely converted into the metabolite). The conversion factor was included in the refined risk assessment. The applicant stated that most of the evaluated results were

generated after at least 2 applications and thus there is no need for an additional multi-application factor (MAF) in the exposure estimation. As the applicant stated that most of the results were generated after at least two applications but did not really describe the method of the test, the ZRMS considered a MAF in the tier 2 assessment. The result of the further refined risk assessment for the worst case indicator mammal is presented in the following table.

Table 6.3-5: Refinement of reproductive risk assessment for small herbivorous mammal "vole" Common vole *(Microtus arvalis)* exposed to Prothioconazole-desthio (JAU6476-desthio) according to EFSA Journal (2009) in crops (BBCH >40). For details see text

indicator mammal (worst case)	scenario (worst cases)	shortcut value	PT	MAF × twa	DDD (mg/kg bw)	NOEL (mg as/kg bw/d)	TERLT
Group B (2x 0.056 g a.i./ha # Prothioconazole-desthio (JAU6476-desthio), interval 14 days)							
small herbivorous *Microtus arvalis* BBCH > 40	BBCH ≥ 40	21.7	1	1.4 x 0.53	0.90	10	11.1

29.9% of application rate of 0.1875 kg/ha based on the assumption that the active substance is completely converted into the metabolite, refer to text above the table

TERs shown in bold are above the relevant trigger.

FIR: Food intake rate; MAF: multiple application factor; RUD: Residue unit dose; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Based on the tier 2 risk assessment, the long term risk of exposure of mammals to the metabolite JAU6476-desthio following the use of Aviator Xpro according to the intended uses achieves the acceptability criteria TER ≥ 5 for long term effects. Thus no further refinement is needed.

6.3.1.4 Drinking water exposure

In case of early post-emergence uses as intend for the product Aviator Xpro, birds might be exposed via drinking water from puddles.

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals (see below), 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 and Prothioconazole and the metabolite JAU 6476-desthio is presented below.

Table 6.3-6: Application rate to endpoint ratios for birds exposed to bixafen, prothioconazole and JAU 6476-desthio

Compound	Koc [L/kg]	Application rate * MAF [g as/ha]	NO(A)EL [mg as/ kg bw/d]	Ratio (Application rate * MAF) / NO(A)ED	"Escape clause" No concern if ratio	Conclusion
bixafen	3869	93.75 x 1.4	34.6	3.79	≤ 3000	No concern
prothioconazole	1765	187.5 x 1.4	95.6	2.74	≤ 3000	No concern
JAU 6476-desthio	575	187.5* x 1.4	10	26.25	≤ 3000	No concern

* Application rate from parent compound = worst-case

This evaluation confirms that the risk for birds from drinking water that may contain residues from the use of the product is considered acceptable.

6.3.1.5 Effects of secondary poisoning (MIIIA 10.3.2.3)

Risk assessment for earthworm-eating birds via secondary poisoning

Dry soil approach

The EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) states that a log K_{ow} ≥3 is used to indicate that there might be a potential for bioaccumulation (see Section 5.6 Bioaccumulation and food chain behaviour). Bioaccumulation of bixafen and prothioconazole has to be assessed since the log P_{OW} is 3.3 and 3.82 respectively. For the prothiconazole metabolite JAU6476-desthio the log P_{OW} is greater 3, thus an assessment is needed for the metabolite. As the active ingredient prothioconazole is transformed rapidly into JAU 6476-desthio in soil and water, the assessment is done only for the metabolite. As the metabolite is of equal or even higher toxicity, the assessment based on the metabolite covers also the risk posed by the active substance. Risk assessment is based on earthworm eating birds (100 g bw, Food intake rate (FIR) = 104.6 g/d (freshweight)). The calculation is done for the worst case indication group A with the maximal soil relevant amount of the preparation.

Table 6.3-7: Assessement of the risk for earthworm eating mammals from an exposure to bixafen through secondary poisoning for the intended use group A

Parameter	Bixafen	comments
PEC_{soil} (twa = 21 d) [mg/kg soil]	0.908	2 applications with 93.75 g a.i./ha
K_{ow}	1995	Log POW= 3.3
K_{oc}	3869	
F_{oc}	0.02	Default
BCF_{worm}	0.320	$BDF_{worm} = (PEC_{worm}/PEC_{soil})$ $= (0.84 + 0.12 \times K_{ow})/ f_{oc} \times K_{oc}$
PEC_{worm}	0.291	$PEC_{worm} = PEC_{soil} \times BCF$
Daily dietara dose (mg/kg bw/d)	0.372	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	34.6	Relevant reproductive endpoint

TER_{lt}	93.0	Acceptable TER>= 5

TER values shown in bold fall below the relevant trigger.

As the active ingredient prothioconazole is transformed rapidly into JAU 6476-desthio in soil and water, the assessment is done only for the metabolite. As the metabolite is of equal or even higher toxicity, the assessment based on the metabolite covers also the risk posed by the active substance

Table 6.3-8: Assessement of the risk for earthworm eating mammal from an exposure to JAU 6476-desthio (metabolite prothioconazole) through secondary poisoning for the intended use group A

Parameter	**JAU 6476-desthio**	**comments**
PEC_{soil} (twa = 21 d) [mg/kg soil]	0.131	2 applications with 187.5 g a.i./ha
K_{ow}	1096	Log POW= 3.04
K_{oc}	575	
F_{oc}	0.02	Default
BCF_{worm}	0.638	$BDF_{worm} = (PEC_{worm}/PEC_{soil})$ $= (0.84 + 0.12 \times K_{ow})/ f_{oc} \times K_{oc}$
PEC_{worm}	0.084	$PEC_{worm} = PEC_{soil} \times BCF$
Daily dietara dose (mg/kg bw/d)	0.088	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	10	Relevant reproductive endpoint
TER_{lt}	93.2	Acceptable TER>= 5

Risk assessment for fish-eating mammal via secondary poisoning

Table 6.3-9: Assessement of the risk for fish eating mammal from an exposure to bixafen through secondary poisoning for the intended use group A

Parameter	**Bixafen**	**comments**
RAC-aq	0.000460	Based on a NOEC of 0.0046 mg/L with SF of 10
BCF_{fish}	523	DAR (2011)
PEC_{fish}	0.241	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietara dose (mg/kg bw/d)	0.034	$DDD = PEC_{fish} \times 0.159$
NOEL (mg/kg bw/d)	34.6	Relevant reproductive endpoint
TER_{lt}	1012.8	Acceptable TER>= 5

TER values shown in bold fall below the relevant trigger.

Table 6.3-10: Assessement of the risk for fish eating mammal from an exposure to JAU 6476-desthio (metabolite prothioconazole) through secondary poisoning for the intended use group A

Parameter	JAU 6476-desthio	comments
PEC_{sw} (twa = 21 d) [mg/L]	0.001020	Based on a NOEC of 0.00334 mg/L with SF of 10
BCF_{fish}	65	LOEP (2007)
PEC_{fish}	0.066	$PEC_{fish} = PEC_{water}$ x BCF_{fish}
Daily dietara dose (mg/kg bw/d)	0.011	DDD = PEC_{fish} x 0.159
NOAEL (mg/kg bw/d)	10	Relevant reproductive endpoint
TER_{lt}	1062	Acceptable TER>= 5

TER values shown in bold fall below the relevant trigger.

6.3.2 Risk assessment (MIIIA 10.3.1) for baits, pellets, granules, prills or treated seed

Aviator Xpro is not formulated as baits, pellets, granules, prills or treated seeds.

6.3.3 Overall conclusions

Based on the higher tier assessment step, the calculated TER values for the acute and long-term risk resulting from an exposure of mammals to bixafen, prothioconazole and JAU 6476-desthio (oral exposure and exposure via drinking water and secondary poisoning) according to the GAP of the formulation Aviator 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 Aviator Xpro in crops according to the label.

Based on the calculation of the risk arising from the uptake of bixafen, prothioconazole and JAU 6476-desthio via drinking water , the calculated TER values for mammals exposed to the active substances bixafen, prothioconazole and JAU 6476-desthio according to the GAP of the formulation Aviator 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 , further refinement is not necessary.

Based on the calculation of the risk arising from secondary poisoning , the calculated TER values for mammals exposed to the active substances bixafen, prothioconazole and JAU 6476-desthio according to the GAP of the formulation Aviator 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, further refinement is not necessary.

6.4 Effects on aquatic organisms (MIIIA 10.2, KPC 10.2, KPC 10.2.1)

The following EU agreed endpoints for aquatic organisms exposed to the active substances bixafen and prothioconazole are reported in the lists of endpoints of Bixafen (EFSA Journal 2012;10(11):2917) and EFSA conclusion (2007) 106, 1-98 Prothioconazole.

The applicant provides further studies on the risk for aquatic organisms with the formulation Aviator Xpro and for the active substance bixafen, prothioconazole and its major metabolites. Detailed study summaries for the studies performed with the formulated product Aviator Xpro as well as the Annex II data are presented in Appendix 2.

Table 6.4-1: Endpoints used for risk assessment for aquatic organisms for Bixafen

Test item	Species	Time scale	Results [mg a.s./L]	Reference	Internal code
Bixafen technical	*Oncorhynchus mykiss*	96 h, s	LC50 : 0,095 mg a.i./L mortality	DAR Bixafen – Addendum 1, Feb. 2012 **XXX** 2006 E 280 2990-0	69481
BYF 00587 tech (Bixafen, 95.8 % ai	*Pimephales promelas*	28 d, flow threw	NOEC : 0.0046 mg/L Growth measured	DAR Bixafen – Addendum 1, Feb. 2012 **XXX** 2006 E 284 2960-1	69484
BYF 00587 techn. (96.8% pure)	*Daphnia magna*	48 h static	EC50 : 1.2 mg/L Immobilisation nominal	DAR Bixafen – Volume 3, Annex B.9 ; Ecotoxicology, July 2011 Bruns, E. 2006 E 320 2952-3	69534
BYF 00587 techn. (96.8% pure)	*Daphnia magna*	21 d semistatic	NOEC : 0.05 mg/L * Number offspring NOEC : >=0.312 mg/L Immobilisation Nominal	DAR Bixafen – Volume 3, Annex B.9 ; Ecotoxicology, July 2011 Bruns, E. 2007 E 321 3124-6	69536
BYF 00587 tech (Bixafen, 95.8 % ai)	*Chironomus riparius*	28 d Water/sediment	NOEC : 0.0156 mg/L Emergence initial	DAR Bixafen – Volume 3, Annex B.9 ; Ecotoxicology, July 2011 Dorgerloh, M. 2007 EBDRP088	69485
BYF 00587 (95.5% pure)	*Pseudokirchneriella subcapitata*	3 d static	ErC50 : 0.0965 mg/L	DAR Bixafen – Volume 3, Annex B.9	69535

			Growth rate EbC50 : 0.0657 mg/L Biomass EyC50 : 0.0598 mg/L Biomass (Increase) nominal	; Ecotoxicology, July 2011 Dorgerloh, M. 2006 E 323 2932-4	
Aquatic higher plants					**-**
Higher tier studies (micro- or mesocosm studies)					**-**

s…static, ss…semi-static, f…flow-through

nom…nominal, mm…mean measured

* Study author established a reproductive NOEC ≥ 0.125 mg bixafen/L but RMS UK concluded that the NOEC shoul be 0.05 mg a.s./L. In Agreement with the EU review of the active substance and with the information given by the applicant, the lower value was considered here.

Relevant toxicity endpoint for bixafen

For the active ingredient bixafen the most sensitive acute endpoint divided by the corresponding safety factor is **NOEC = 0.0046 mg a.s./L (*Pimephales promelas*)**. As the assessment performed for the chronic fish endpoint covers the risk for other aquatic organisms, the risk assessment is based on this endpoint. Since Bixafen accumulates in the sediment, additionally an assessment for the sediment organisms, presented by ***Chironomus riparius***, was performed.

Table 6.4-2: Endpoints used for risk assessment for aquatic organisms for prothioconazole

Test item	**Species**	**Time scale**	**Results [mg a.s./L]**	**Reference**	**Internal code**
Prothioconazole (JAU 6476)	*Oncorhynchus mykiss*	96 h, s	LC50 : 1.83 mg/L Mortality nominal	EFSA conclusion (2007) 106, 1-98 Prothioconazole **XXX** 1999 DOM 99076	45863
	Oncorhynchus mykiss	91 d, flowthrou	NOEC : 0.49 mg/L Mortality (Juvenile) nominal	2 **XXX** 2007 EBJAX313	70485
	Oncorhynchus mykiss	97 d Durchfluss	NOEC : 0.308 mg/L Development nominal	1 **XXX** 2001 DOM 20028	45872
	Daphnia magna	2 d static	LC50 : 1.3	EFSA conclusion (2007) 106, 1-98	45837

			mg/L Immobilisation nominal	Prothioconazole Heimbach, F. 1999 HBF/DM 212	
	Daphnia magna	21 d semistatic	NOEC : 0.56 mg/L Reproduction nominal	EFSA conclusion (2007) 106, 1-98 Prothioconazole Hendel, B.; Sommer, H. 2001 HDB/RDM 67	45855
	Chironomus riparius	28 d	NOEC : 9.14 mg/L Emergence / Development nominal	EFSA conclusion (2007) 106, 1-98 Prothioconazole Hendel, B. 2000 HDB/CH 42	45953
	Skeletonema costatum	3 d static	EbC50 : 0.018 mg/L [12)] Biomass EbC50 : 0.0171 mg/L Biomass (Increase) ErC50 : 0.0456 mg/L Growth rate nominal	3 Kern, M.E.; De Haan R.A. 2004 EBJAX076 (J6883601)	69032
	Lemna gibba	7 d static	EbC50 : 0.404 mg/L Biomass EC50 : 0.074 mg/L Dryweight (Fronds) NOEC : 0.00334 mg/L Biomass measured	5 Kern, M. E.; Banman, C. S.; Lam, C. V. 2004 EBJAY002 (J6883701)	69854
JAU 6476-Desthio	*Oncorhynchus mykiss*	4 d static	LC50 : 6.63 mg/L Mortality Nominal	EFSA conclusion (2007) 106, 1-98 Prothioconazole **XXX** 1990 FF-298	45882
	Oncorhynchus mykiss	96 d Durchfluss	**NOEC : 0.00334 mg/L Deformations Nominal** NOEC : 0.053 mg/L Reproduction Nominal	EFSA conclusion (2007) 106, 1-98 Prothioconazole **XXX** 2002 1022.013.321	45888
	Daphnia magna	2 d	EC50 : > 10	EFSA conclusion (2007)	45936

		static	mg/L Immobilisation Nominal	106, 1-98 Prothioconazole Heimbach, F. 1990 HBF/DM 95	
	Daphnia magna	21 d semistatic	NOEC : 0.1 mg/L Number offspring Nominal	EFSA conclusion (2007) 106, 1-98 Prothioconazole Dorgerloh, M.; Sommer, H. 2001 DOM 21036	45686
	Chironomus riparius	28 d	EC50 : 8.46 mg/L Developmentrate EC10 : 3.77 mg/L Emergencerate NOEC : 2 mg/L Developmentrate Nominal	EFSA conclusion (2007) 106, 1-98 Prothioconazole Hendel, B. 2000 HDB/CH 43	45976
	Scenedesmus subspicatus	3 d static	EbC50 : 0.073 mg/L Biomass ErC50 : 0.55 mg/L Growth Nominal	EFSA conclusion (2007) 106, 1-98 Prothioconazole Heimbach, F. 1990 HBF/AL 78; E 323 0401-3	45945
	Lemna gibba	7 d semistatic	EC50 : 0.0394 mg/L Biomass ErC50 : 0.0809 mg/L Frondnumber EbC50 : 0.0568 mg/L Biomass EC50 : 0.0411 mg/L Dryweight NOEC : 0.0058 mg/L Frondnumber Measured	5 Kern, M. E.; Banman, C. S.; Lam, C. V. 2003 200469; EBJAX084 (J6883702)	65917
JAU 6476-S-Methyl	*Oncorhynchus mykiss*	4 d static	LC50 : 1.79 mg/L Mortality Real	EFSA conclusion (2007) 106, 1-98 Prothioconazole **XXX** 2001 DOM 21047	45633
	Daphnia magna	2 d static	EC50 : 2.8 mg/L Immobilisation Nominal	EFSA conclusion (2007) 106, 1-98 Prothioconazole Dorgerloh, M.,	45939

				Sommer, H. 2001 DOM 21055	
	Chironomus riparius	28 d static	NOEC : 0.1 mg/L EC50 : 1.41 mg/L Emergence NOEC : 0.1 mg/L EC50 : > 10 mg/L Developmentrate Nominal	Study not available for DAR preparation, since of newer date Bruns, E. 2006 EBJAX303	70238
	Selenastrum capricornutum	3 d static	EbC50 : 3.77 mg/L Biomass ErC50 : 47.4 mg/L Growth NOEC : < 1.03 mg/L Growth Measured	EFSA conclusion (2007) 106, 1-98 Prothioconazole Dorgerloh, M.; Sommer, H. 2001 DOM 21028; E 323 2061-7	45946
1,2,4-Triazol (CGA 98032)	*Oncorhynchus mykiss*	4 d static	LC50 : 498.3 mg/L Mortality Measured	EFSA conclusion (2007) 106, 1-98 Prothioconazole **XXX** 1983 821418	41737
	Oncorhynchus mykiss	28 d semistatic	NOEC : 3.2 mg/L sublethale Effects NOEC : 100 mg/L Growth Nominal	EFSA conclusion (2007) 106, 1-98 Prothioconazole **XXX** 2002 DOM 21060	45802
	Daphnia magna	2 d static	EC50 : >100 mg/L Immobilisation Nominal	Endpoint value according to agreement in PRAPeR expert meeting on triazole metabolites (PRAPeR 13, January 2007) Bell, G. 1995 ENVIR/95/52	48025
	Selenastrum capricornutum	3 d static	ErC50 : 22.5 mg/L Growth rate EbC50 : 8.2 mg/L Biomass NOEC : 4.6 mg/L Biomass/Growth	EFSA conclusion (2007) 106, 1-98 Prothioconazole Bell, G. 1995 AGV 50(b)952196	74250

			Nominal		
Prothioconazole-triazolylketone (JAU 6476-triazolylketone)	*Oncorhynchus mykiss*	4 d static	LC50 : > 100 mg/L Mortality Nominal	EFSA conclusion (2007) 106, 1-98 Prothioconazole **XXX** 2006 E 280 3090-2	70491
	Daphnia magna	2 d static	LC50 : > 100 mg/L) Immobilisation Nominal	Endpoint value according to agreement in PRAPeR expert meeting on triazole metabolites (PRAPeR 13, January 2007) Bruns, E. 2006 E 320 3104-3	70489
	Pseudokirchneriella subcapitata	3 d static	EbC50 : > 100 mg/L Biomass ErC50 : > 100 mg/L Growth rate NOEbC : > 100 mg/L Biomass NOErC : > 100 mg/L Growth rate Nominal	4 Dorgerloh, M. 2006 E 323 3084-3	70487
Higher tier studies (micro- or mesocosm studies)					**-**

1 This endpoint was included in the list of endpoints for prothioconazole. According to the assessment of Germany the study is not valid due to the insufficient emergence in the control (only 57 instead of 66 % given as validity criterion in the test guideline). After the peer review process a second ELS study was provided (see 6), which also was formally not valid as the emergence was 63 % and thus again did not reach the required 66 %. Taken into account that the problem with the insufficient emergence appears more often for the test species Oncorhynchus mykiss and considering the fact, that the established endpoints were in the same magnitude in both ELS tests for prothioconazole, it seems to be justifiable to consider the NOEC for O. mykiss given in the list of endpoints although the validity criteria are not fully met.

2 This study has been demanded by Germany, since the study included in the list of endpoints for prothioconazole (Dorgerloh, M., Sommer, H. 11.12.2001; DOM 20028) is not valid according to the assessment of Germany, due to the insufficient emergence in the control (only 57 instead of 66 %). Since this study also does not reach the validity criterion for emergence, however the endpoints are within the same magnitude the study listed in the LoEP for prothioconazole is considered. This study is only listed here for information and overview.

3 This endpoint is not included in the list of endpoints for prothioconazole but the study is known at German authority and was also cited as new study in the draft registration report provided by the applicant for the PPP Variano Xpro EC 190. As this endpoint is lower than the EU agreed endpoint it was considered here.

4 The metaboliote JAU 6476 triazolylketone was not considered as relevant metabolite in the EU evaluation of prothioconazole (please refer to the list of endpoints 2007), thus no data on the metabolite are presented on EU level. As the applicant presented the data for the metabolite in his overview on further toxicity studies for the active substance and the data is known to the zRMS, the existing studies are considered here as additional information as they were not essential for the assessment.

5 No data on aquatic macrophytes were included in the list of endpoints for prothioconazole. Data on aquatic plants are not required in this case but a study for the active ingredient and for the metabolite JAU 6476-desthio was provided by the applicant. For completeness both studies are presented here.

s…static, ss…semi-static, f…flow-through

nom…nominal, mm…mean measured

For the active ingredient **prothioconazole** the most sensitive endpoint, given by the lowest ratio of endpoint divided by the corresponding safety factor, is **EbC_{50} = 0.018 mg a.s./L (*Skeletonema costatum*).** As prothioconazole belongs to the triazoles, the potential for endocrine effects on fish has to be addressed in the risk assessment. Two ELS studies were provided for the active ingredient, both are not fully valid however the established endpoints seem to be reliable. Based on the lower endpoint of the ELS study by Dorgerloh and Sommer (2001) and an additional safety factor of 5 (because the standard ELS test does not address endocrine effects sufficiently) the ratio of endpoint divided by safety factor is still lower for the algae endpoint. Thus an assessment based on the algae endpoint covers the risk of endocrine effects for prothiconazole. However an assessment based on the prothioconazol algae endpoint does not cover the potential risk of endocrine effects caused by the metabolite JAU 6476-desthio, which is structurally very smiliar to the active substance. An ELS study was provided for the metabolite **JAU 6476-desthio** and the **NOEC = 0.00334 mg/L *(Oncorhynchus mykiss)*** presents the worst case for the ratio of endpoint divided by the corresponding safety factor (as also a FLC test is known for the metabolite, possible endocrine effects are sufficiently addressed and no further assessment factor is needed). **As the active ingredient prothioconazole degrades very fast in water (DT50 = 0.9 days) the assessment for prothioconazole is based on the main metabolite JAU 6476-desthio.**

Prothioconazole has three furthe relevant metabolites, JAU6476-S-methyl, 1,2,4-Triazol and JAU 6476-triazolylketone (for details please refer to the core assessment section 5). As the metabolites show a comparable or lower toxicity for fish, daphnids and algae as the active substance, no quantitative risk assessment was performed for these metabolites.

Table 6.4-3: Endpoints used for risk assessment for aquatic organisms for Aviator Xpro

Test item	Species	Time scale	Results [mg/L]	Reference	Internal code
Aviator Xpro	*Oncorhynchus mykiss*	96 h, static	LC_{50} = 1.55	**XXX** 04.10.2007 E 280 3259-9	69483
Aviator Xpro	*Daphnia magna*	48 h, static	EC_{50} = 3.0	Bruns, E. 30.05.2007 E 320 3196-4	69530

Aviator Xpro	*Pseudokirchneriella subcapitata*	72 h, static	E_rC_{50} = 0.549 E_bC_{50} = 1.53	Dorgerloh, M. 22.06.2007 E 323 3173-2	69529
Higher tier studies (micro- or mesocosm studies)					**-**

Table 6.4-4: Bioconcentration in fish

Bioconcentration in fish			
Test conditions	**Results**	**Reference: Author Date Code**	**ICS-Nr.**
BYF 00587 Bixafen OECD 305 Bluegill sunfish (Lepomis macrochirus) 7.98 % (d 0-28) 28 d 14 d	Steday state BCF: 695 Whole fish total radioactivity CT50: 1.33 d BCF: 523 Normalised to 6 % lipid	**XXX** 2007 E 244 3155-4 [8)]	69810
JAU6476 (Prothioconazol) [phenyl-UL-14C] OECD 305 Bluegill sunfish (Lepomis macrochirus) 6.1 % (Day 0-28) 28 d *14 d*	BCF: 19.7 Parent Whole fish total radioactivity CT_{50} : 0.8 d 50 µg/L	**XXX** 2001 E 244 2023-7 ; DOM 21003 [2)]	69372
JAU 6476-desthio [phenyl-UL-14C] OECD 305 Bluegill sunfish Lepomis macrochirus 8.5 % (Day 0-28) 28 d *14 d*	BCF : 65 Parent CT_{50} : 1.76 d Whole fish total radioactivity	**XXX** 2001 E 244 1731-2 ; DOM 20006 [2)]	69373

Relevant toxicity endpoints for the active ingredients Bixafen and Prothioconazole

For the active ingredient **Bixafen** the most sensitive acute endpoint divided by the corresponding safety factor is **NOEC = 0.0046 mg a.s./L (*Pimephales promelas*)**. As the assessment performed for the chronic fish endpoint covers the risk for other aquatic organisms, the risk assessment is done only for this endpoint.

For the active ingredient **Prothioconazole** the most sensitive endpoint, given by the lowest ratio of endpoint divided by the corresponding safety factor, is **EbC_{50} = 0.0171 mg a.s./L (*Skeletonema costatum*).** As Prothioconazole belongs to the triazoles, the potential for endocrine effects on fish has to be addressed in the risk assessment. Two ELS studies were provided for the active ingredient; both are not fully valid however the established endpoints seem to be reliable. Based on the lower endpoint of the

ELS study by Dorgerloh and Sommer (2001) and an additional safety factor of 5 (because the standard ELS test does not address endocrine effects sufficiently) the ratio of endpoint divided by safety factor is still lower for the algae endpoint. Thus an assessment based on the algae endpoint covers the risk of endocrine effects for Prothiconazole. However an assessment based on the Prothioconazole algae endpoint does not cover the potential risk of endocrine effects caused by the metabolite JAU 6476-desthio, which is structurally very similar to the active substance. An ELS study was provided for the **metabolite JAU 6476-desthio** and the **NOEC = 0.00334 mg/L (*Oncorhynchus mykiss*)** presents the worst case for the ratio of endpoint divided by the corresponding safety factor (as also a FLC test is known for the metabolite, possible endocrine effects are sufficiently addressed and no further assessment factor is needed). **As the active ingredient Prothioconazole degrades very fast in water (DT_{50} = 0.9 days) the assessment for Prothioconazole is based on the main metabolite JAU 6476-desthio.**

Prothioconazole has three further relevant metabolites, JAU6476-S-methyl, 1,2,4-Triazol and JAU 6476-triazolylketone (for details please refer to the core assessment section 5). As the metabolites show a comparable or lower toxicity for fish, daphnids and algae than the active substance, no quantitative risk assessment was performed for these metabolites.

6.4.1 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).

Aviator Xpro is a fungicide formulation containing Bixafen and Prothioconazole as active substances. According to the GAP table of intended uses (Appendix 3) the applications are considered to take place at two applications with a minimum 14 days between applications. It will be used as a fungicide against stem and leaf diseases in cereals.

For risk assessment purposes, a risk envelope approach was used. Hence, intended use group A covers the risk for aquatic organisms from all intended uses (see Table 6.1-1).

Aquatic organisms may be exposed to plant protection products as a result of emission from treated fields. When Aviator Xpro is applied according to good agricultural practice, the active ingredients can reach surface waters unintentionally by spraydrift during application, by run-off and drainage.

The predicted environmental concentrations in surface water (PEC_{SW}) have been calculated based on the application rates of 93.75 g/ha Bixafen and 187.5 g/ha Prothioconazole. For details on the FOCUS modeling, see dRR CA Part B, Section 5.5.

The relevant global maximum FOCUS Step 1 and 2 PEC_{SW} for risk assessments covering all proposed use patterns are summarized in the following table.

Table 6.4-5: Summary of highest global maximum FOCUS surface water PECsw and PECsed values for Bixafen – Step 1 and 2

Plant protection product	Aviator Xpro
Use No.	**Group A**

.			
Crop:		**Cereals, spring / winter**	
Application rate:		0.09375 kg/ha	
Number of application/interval:		2/ 14d	
Application method:		Ground spray	
Crop interception:		Average crop cover (Step 2)	
Bixafen	FOCUS Step 1	PECsw (µg/L)	PECsed (µg/kg)
		11.87	403.19
	FOCUS Step 2	PECsw (µg/L)	PECsed (µg/L)
	North Europe Mar-May.	1.32 on day 18	47.27 on day 19
	South Europe, Mar-May	2.3 on day 18	85.06 on day 19

Table 6.4-6: Global maximum FOCUS Step 3 PEC_{sw} and PEC_{sed} values for Bixafen for the application of Aviator Xpro in cereals, spring according to use group A

	FOCUS STEP 3 Scenario	**Water Body**	**PECsw global max (µg/L)**	**PECSED global max (µg/kg)**
Bixafen	D1	ditch	0.543	2.023
	D1	stream	0.436	1.054
	D3	ditch	0.515	0.519
	D4	pond	0.0272	0.572
	D4	stream	0.379	0.108
	D5	pond	0.0248	0.399
	D5	stream	0.400	0.0158
	R4	stream	0.618	6.661

Table 6.4-7: FOCUS Step 3 Scenario related input parameters for $PEC_{SW/sed}$ calculations for the application in winter cereals in spring (113 d before harvest)

Scenario	**Emergence date**	**Harvest date**	**Possible window of application**
D1	25/9	26/8	5/5 – 18/6
D2	25/10	7/8	16/4 – 30/5
D3	21/11	15/8	24/4 – 7/6
D4	22/9	21/8	30/4 - 13/6
D5	10/112	15/7	24/5 – 7/5
D6	30/11	30/6	9/3 – 22/4
R1	12/11	31/7	9/4 – 23/5

R3	1/12	1/7	10/3- 23/4
R4	10/11	15/7	24/3 – 7/5

Table 6.4-8: Global maximum FOCUS Step 3 PEC_{sw} and PEC_{sed} values for Bixafen for the application of Aviator Xpro in cereals, winter according to use group A

	FOCUS STEP 3 Scenario	**Water Body**	**PEC_{sw} global max (µg/L)**	**PEC_{SED} global max (µg/kg)**
Bixafen	D1	ditch	0.643	4.988
	D1	stream	0.452	0.447
	D2	ditch	0.544	3.882
	D2	stream	0.463	1.669
	D3	ditch	0.516	0.580
	D4	pond	0.0280	0.458
	D4	stream	0.440	0.128
	D5	pond	0.0281	0.425
	D5	stream	0.448	0.0404
	D6	ditch	0.522	1.787
	R1	pond	0.0859	2.388
	R1	stream	0.455	6.611
	R3	stream	0.472	4.522
	R4	stream	0.703	8.650

Table 6.4-9: PECsed,accu values of Bixafen after multi-year use of the substance on winter and spring cereals

	Worst-case scenario, water body	**PECsed,plateau (µg/kg)**	**PECsed,max (µg/kg)**	**PECsed,accu,overall (= PECsed,plateau + PECsed,max) (µg/kg)**
Spring cereals	R4 stream	23.11	6.661	29.77
Winter cereals	R4 stream	30.01	8.650	38.66

Table 6.4-10: Summary of highest global maximum FOCUS surface water PECsw and PECsed values for Prothioconazole and the metabolite Prothioconazole-desthio – Step 1 and 2

Plant protection product	Aviator Xpro

Use No. .		**Group A**	
Crop:		**Cereals, spring / winter**	
Application rate:		187.5 g/ha	
Number of application/interval:		2/ 14d	
Application method:		Ground spray	
Crop interception:		Average crop cover (Step 2)	
Prothioconazole	FOCUS Step 1	PECsw (µg/L)	PECsed (µg/L)
		40.73	657.93
	FOCUS Step 2	PECsw (µg/L)	PECsed (µg/L)
	North Europe, Mar.-May	1.83	12.61
	South Europe, Mar.-May	1.93	10.51
Prothioconazole-desthio (M04)	FOCUS Step 1	PECsw (µg/L)	PECsed (µg/L)
		33.13	183.49
	FOCUS Step 2	PECsw (µg/L)	PECsed (µg/L)
	North Europe Mar.-May	5.5 on day 18	30.9 on day 19
	South Europe Mar.-May	5.5 on day 18	30.9 on day 19

6.4.1.1 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 6.4-11: Aquatic organisms: PEC_{sw} for for Bixafen and relevant ecotoxicological endpoints for each organism' group.

Scenario	PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrates acute	Invertebrates prolonged	Algae	Sed. dweller prolonged	Mesocosm	PEC global max (µg/kg)	Sed. dweller prolonged
		Oncorhynchus mykiss	*P. promelas*	*Daphnia magna*	*Daphnia magna*	*Pseudokirchn. subcapitata*	*Chironomus riparius*	*Invertebrates*		*Chironomus riparius*
		LC_{50} (µg/L) **95**	NOEC (µg/L) **4,6**	EC_{50} (µg/L) **1200**	NOEC (µg/L) **125**	E_bC_{50} (µg/L) **66**	NOEC (µg/L) **15,6**	NOEC (µg/L) **0**		NOEC (µg/kg) **20000**
FOCUS Step 1										
	11.87	8	0.4	101.1	10.5	5.6	1.3	<0.1	403.19	49.6
FOCUS Step 2										
N.Europe	1.32	72	3.5	909.1	94.7	50	11.8	<0.1	47.27	423.1
S.Europe	2.3	41.3	2	521.7	54.3	28.7	6.8	<0.1	85.06	235.1
Step 3										
D1/ditch	0.543	175	8.5	2209.9	230.2	121.5	28.7	<0.1	2.023	9886.3
D1/stream	0.436	217.9	10.6	2752.3	286.7	151.4	35.8	<0.1	1.054	18975.3
D3/ditch	0.515	184.5	8.9	2330.1	242.7	128.2	30.3	<0.1	0.519	38535.6
D4/pond	0.0272	3492.6	169.1	44117.6	4595.6	2426.5	573.5	<0.1	0.572	34965
D4/stream	0.379	250.7	12.1	3166.2	329.8	174.1	41.2	<0.1	0.108	185185.2
D5/pond	0.0248	3830.6	185.5	48387.1	5040.3	2661.3	629	<0.1	0.399	50125.3
D5/stream	0.4	237.5	11.5	3000	312.5	165	39	<0.1	0.0158	1265822.8
R4/stream	0.618	153.7	7.4	1941.7	202.3	106.8	25.2	<0.1	6.661	3002.6

D1/ditch	0.643	147.7	7.2	1866.3	194.4	102.6	24.3	<0.1	4.988	4009.6
D1/stram	0.452	210.2	10.2	2654.9	276.5	146	34.5	<0.1	0.447	44742.7
D2/ditch	0.544	174.6	8.5	2205.9	229.8	121.3	28.7	<0.1	3.882	5152
D2/stream	0.463	205.2	9.9	2591.8	270	142.5	33.7	<0.1	1.669	11983.2
D3/ditch	0.516	184.1	8.9	2325.6	242.2	127.9	30.2	<0.1	0.58	34482.8
D4//pond	0.028	3392.9	164.3	42857.1	4464.3	2357.1	557.1	<0.1	0.458	43668.1
D4/stream	0.44	215.9	10.5	2727.3	284.1	150	35.5	<0.1	0.128	156250
D5/pond	0.0281	3380.8	163.7	42704.6	4448.4	2348.8	555.2	<0.1	0.425	47058.8
D5/stream	0.448	212.1	10.3	2678.6	279	147.3	34.8	<0.1	0.0404	495049.5
D6/ditch	0.522	182	8.8	2298.9	239.5	126.4	29.9	<0.1	1.787	11191.9
R1/pond	0.0859	1105.9	53.6	13969.7	1455.2	768.3	181.6	<0.1	2.388	8375.2
R1/stream	0.455	208.8	10.1	2637.4	274.7	145.1	34.3	<0.1	6.611	3025.3
R3/stream	0.472	201.3	9.7	2542.4	264.8	139.8	33.1	<0.1	4.522	4422.8
R4/stream	0.703	135.1	**6.5**	1707	177.8	93.9	22.2	<0.1	8.65	2312.1
		100	10	100	10	10	10	10		10

Scenario in bold: spring, in bold italic: winter

Table 6.4-12: Aquatic organisms: PEC_{sw} for for Prothioconazole and relevant ecotoxicological endpoints for each organism' group.

Scenario	**PEC global max**	**Fish acute**	**Fish prolonged**	**Invertebrates acute**	**Invertebrates prolonged**	**Algae**	**Sed. dweller prolonged**
		O. mykiss	***P. promelas***	***D. magna***	***D. magna***	***S. costatum***	***C. riparius***
FOCUS	**(µg/L)**	**LC_{50} (µg/L) 1830**	**NOEC (µg/L) 490**	**EC_{50} (µg/L) 1300**	**NOEC (µg/L) 560**	**E_bC_{50} (µg/L) 17,1**	**NOEC (µg/L) 9140**
Step 1							
	40.73	44.9	12	31.9	13.7	0.4	224.4
Step 2							
N.Europe	1.83	1000	267.8	710.4	306	9.3	4994.5
S.Europe	1.93	948.2	253.9	673.6	290.2	**8.9**	4735.8

TER criterion		100	10	100	10	10	10

Table 6.4-13: Aquatic organisms: PEC_{sw} for for Prothioconazole-metabolithe Prothioconazole-desthio and relevant ecotoxicological endpoints for each organism' group.

Scenario	**PEC global max**	**Fish acute**	**Fish prolonged**	**Invertebrates acute**	**Invertebrates prolonged**	**Algae**	**Sed. dweller prolonged**
		O. mykiss	***O. mykiss***	***D. magna***	***D. magna***	***P. subcapitata***	***C. riparius***
FOCUS	**(µg/L)**	**LC_{50} (µg/L) 6630**	**NOEC (µg/L) 3.34**	**EC_{50} (µg/L) 10000**	**NOEC (µg/L) 100**	**E_bC_{50} (µg/L) 73**	**NOEC (µg/L) 2000**
Step 1							
	33.13	200.1	0.1	301.8	3	2.2	60.4
Step 2							
N.Europe	5.5	1205.5	**0.6**	1818.2	18.2	13.3	363.6
S.Europe	5.5	1205.5	**0.6**	1818.2	18.2	13.3	363.6
TER criterion		100	10	100	10	10	10

Based on the calculated concentrations of the active substances Bixafen (PEC_{SW} FOCUS Step 3) and Prothioconazole with its metabolite Prothioconazole-Desthio in surface water (PEC_{SW} FOCUS Step 1and 2), the calculated TER values for the long-term risk resulting from an exposure of aquatic organisms to the active substances Bixafen and Protioconazole as well as the metabolite Prothioconazole-Desthio according to the GAP of the formulation Aviator Xpro **does not achieve** the acceptability criteria 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 unacceptable risk for aquatic organisms due to the intended use of Aviator Xpro in cereals according to the label.**

For the intended uses, further refinement is necessary.

According to the results of the TER-values calculations based on $FOCUS_{SW}$ Step 2 (Prothioconazole and Prothioconazole-Desthio) respective Step 3 (Bixafen) PEC values for the intended uses, the implementation of management practices will be necessary to reduce the exposure of aquatic organisms to Aviator Xpro. Management practices relevant for Germany are given in the respective Addendum.

With regard to the potential 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. 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).

6.4.1.2 Risk assessment for the product

Please refer to Annex 2 for a summary of the provided studies on the effects of Aviator Xpro on aquatic organisms. Section 4, gives the details of the risk assessment for aquatic organisms on the basis of all available data.

6.4.1.3 Consideration of Metabolites

Please refer to section 6.4, for the assessment of the metabolites of the active substances that was performed during peer review of the active substance in view of its approval.

Please refer to section 6.4 for a summary of the provided studies on the effects of the metabolites of the active substances on aquatic organisms. Next section gives the details of the risk assessment for aquatic organisms on the basis of all available data.

Prothioconazole forms these major metabolites in surface water: Prothioconazole-Desthio (32.3 %), 1,2,4-Triazole (37.2 %).

These metabolites are also formed in sediment (26.9 %, 6.1 % respectively). Moreover Prothioconazole-S-Methyl is formed in sediment (9.6 %).

In addition, the metabolite Prothioconazole-S-Methyl and Prothioconazole-Desthio are formed in soil with 14.6 % and 57 %, respectively.

Contamination via run-off and drainage cannot be excluded. Ecotoxicological studies are available for these metabolites. Please see section 6.4 for studies and discussion of risk for aquatic organisms resulting from an exposure to Aviator Xpro.

6.4.2 Overall conclusions

Based on the calculated concentrations of Bixafen, Prothioconazole and the metabolite Prothioconazole-Desthio in surface water (PEC_{SW} FOCUS Step 1,2,3), the calculated TER values for the acute and long-term risk resulting from an exposure of aquatic organisms to Bixafen, Prothioconazole and the metabolite Prothioconazole-Desthio according to the GAP of the formulation Aviator Xpro does 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 an unacceptable risk for aquatic organisms due to the intended use of Aviator Xpro in cereals according to the label. According to the results of the TER-values calculations based on $FOCUS_{SW}$ Step 2 and 3 PEC values for the intended uses, the implementation of management practices will be necessary to reduce the exposure of aquatic organisms to Aviator Xpro. Management practices relevant for Germany are given in the respective Addendum.

6.5 Effects on bees (MIIIA 10.4, KPC 10.3.1)

Table 6.5-1 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. Other data submitted in support of the evaluation are not considered adequate and are not reported here.

Table 6.5-1: Results of laboratory bee toxicity studies

Test substance	Exposure route	LD_{50}	Reference
BIX+PTZ EC 225	oral 48 h	> 106.2 µg product/bee	Schmitzer (2007) 31203035 KIIIA 10.4.2.1/01
	contact 48 h	> 100 µg product/bee	
bixafen tech.	oral 48 h	> 121.4 µg/bee	Schmitzer (2005); 24481035
	contact 48 h	> 100 µg/bee	
prothioconazole	oral 48 h	> 71 µg/bee *	EFSA Scientific Report (2007)

tech.	contact 48 h	> 200 µg/bee *	106, 1-98 Wilhelmy (1999); IBA64051

* EU agreed endpoint

Exposure

The recommended use pattern for BIX+PTZ EC 225 includes application in cereals at a maximum application rate of up to 1.25 L/ha. This maximum single application rate is equivalent to 1258 g/h.
Bees may be exposed to 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] / LD50 [µg product/bee]

Table 6.5-2: Hazard quotients for honeybees

Test substance	Max. single application rate [µg product/ha]	Exposure route	LD_{50} [µg product/bee]	Hazard quotient (HQ)	HQ trigger
BIX+PTZ EC 225	1258	oral	> 106.2 µg	< 12	50
		contact	> 100 µg	< 13	

Risk assessment

Due to the results of laboratory tests BIX+PTZ EC 225 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 BIX+PTZ EC 225 will not adversely affect bees or bee colonies when used as recommended.

6.6 Effects on arthropods other than bees (MIIIA 10.5, KPC 10.3.2)

Effects on arthropods other than bees for Aviator Xpro were not evaluated as part of the EU review of bixafen and prothioconaole. Data on Aviator Xpro have been submitted by the applicant and are evaluated here. They are considered adequate to assess the risk for non-target arthropods following the use of Aviator Xpro according to the intended uses.

Table 6.6-1: Toxicity of the product Aviator Xpro to non-target arthropods

Species **(exposed life stage)**	**Test substance, test substrate**	**Toxicity endpoints** **[g/ha]**	**Source**	**ICS-No.**
-				
Extended laboratory studies				
Typhlodromus pyri	**Ext. lab., bean leafs, 2D**	**LR50 =. 1.296 L Pr./ha** **mortality** ER50 > 1.00 L Pr./ha reproduction	Moll, M. 17.11.2006 31205062 ICS 69513	69513
Coccinella septempunctata	Ext. Lab, bean leafs 2D	LR50 =. 3.39 L Pr./ha ER50 > 2.17 L Pr./ha	Moll, M. 30.04.2007 31206012 ICS 69514	659514
Chrysoperla carnea	Ext. Lab, bean leafs, 2D	LR50 > 3.75 L Pr./ha ER50 > 3.75 L Pr./ha	Rosenkranz, B. 18.07.2007 312067047 ICS 69515	69515
Aphidius rhopalosiphi	**Ext. Lab, barley seedlings, 3D**	LR50 ca. 3.75 L Pr./ha ER50 > 3.75 L Pr./ha mortality reproduction	Moll, M. 22.01.2007 31204002 ICS 69512	69512
Aged residue studies for refinement of risk assessment				
Typhlodromus pyri	Ext. Lab., bean leafs, aged residues, 3D	LR50 > 3x 1.25 L Präp./ha ER50 > 3x 1.25 L Präp./ha	Rosenkranz, B. 12.09.2008 38631060 ICS 69516	69516
Field or semi-field tests				
-				

Studies submitted by the applicant

6.6.1 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 cover the risk for non-target arthropods from all intended uses (see Table 6.1-1). For risk assesset results from extended 2D test on *Typhlodromus pyri* with LR50 =. 1.296 L Pr./ha (mortality) is used.

Typhlodromus pyri	**Ext. lab., bean leafs, 2D**	**LR50 = 1.30 L Pr./ha** **mortality** ER50 > 1.00 L Pr./ha reproduction	Moll, M. 17.11.2006 31205062 ICS 69513	69513

6.6.1.1 Exposure

In field

Non-target arthropods living in the crop can be exposed to residues from Aviator Xpro by direct contact either as a result of overspray or through contact with residues on plants and soil or in food items.

Aviator Xpro is a fungicide formulation containing Bixafen, and Prothioconazole as active substances.. According to the GAP table of intended uses (Appendix 3) the applications are considered to take place at two applications with a minimum 14 days between applications. The formulation is intended for the use as a fungicide against stem and leaf diseases in cereals.

The in-field exposure, given as predicted environmental rates, PER, for non-target arthropods resulting from the intended uses of Aviator Xpro is calculated according to published agreement after ESCORT 2 workshop (Candolfi et al. 2001[1] -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

[1] 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.

Default MAF values for given numbers of applications are listed in the Guidance Document. Since Aviator Xpro will be applied in 2 application schemes, the worst case application scheme was identified and chosen for the risk assessment (MAF= 1.7).

The maximum predicted environmental rate (PER) occurring in the field after application of Aviator Xpro at the maximum application rate is presented in the following table.

The product is applied worst-case at a rate of 2 x 1250 mL product/ha in cereals (wheat, rye, triticale) at BBCH 30-69, with an interval of 14 days. The risk assessment for the lower application rate of 2 x 1000 mL product/ha in cereals (barley, BBCH 30-61, interval 14 days) is covered with the risk assessment for the higher rate.

Table 6.6-2: In-field predicted environmental rates (PER) for Aviator Xpro, intended use Group A

Substance	Application rate (L Product/ha)	in-field PER (L Product/ha)
Aviator Xpro	2 x 1.25	2.125

Off-field

Exposure of non-target arthropods living in non-target off-field areas to Aviator 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[2]) as shown in the following equation:

$$Off-field\ PER = \frac{Maximum\ in-field\ PER\ x \left(drift\ percentile / 100 \right)}{vegetation\ distribution\ factor\ (vdf)}$$

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 dilution factor of 10 is recommended by the Guidance Document, but has been questioned. The risk assessment procedure here considers a dilution factor of 5 more appropriated. For endpoint resulting from 3-dimensional studies, i.e. where spray treatment is applied onto whole plants, the dilution factor is not used.

[2] BBA (Biologische Bundesanstalt für Land- und Forstwirtschaft) (2000): Abtrifteckwerte für Flächen- und Raumkulturen sowie für den gewerblichen Gemüse-, Zierpflanzen- und Beerenobstanbau. Bundesanzeiger 100, 26. Mai 2000, Köln, pp. 9879.

The drift rate at 1 m distance is 2.38% of the application rate (82nd percentile drift).

For the results of study with *T. pyri* exposed in a 2 D extended lab-test to Aviator Xpro, a vegetation distribution factor has to be considered (study conducted in 2D environment, bean leaves).

The resulting PERoff-field values are shown in the following table.

Table 6.6-3: Off-field predicted environmental rates (PER) resulting from the intended uses of Aviator Xpro

Study type	Max. rate (ml Prod./ha)	MAF	Maximum in-field PER (ml Prod./ha)	Drift rate (% appl. rate)	Vegetation distribution factor	Off-field PER (ml Prod./ha)
3-dimensional	2 x 1250	1.7	2125	2.38%	5	10.12

Reduction of the amount of drift reaching the off-field areas can be achieved by implementing a in-field buffer strip of a given width. The resulting drift values (according also to spray-drift predictions of Ganzelmeier & Rautmann (2000)[3]) are given in the table below.

Table 6.6-4: Maximum off-field PER (predicted environmental rates) of Aviator Xpro at increasing distances from the sprayed areas following intended uses

Maximum intended in-field rate	Maximum PERoff-field at 1m (2.38% drift)	Maximum PERoff-field at 5m (0.47% drift)	Maximum PERoff-field at 10m (0.24% drift)
(mL Aviator Xpro/ha)			
2 x 1250	10.12	1.99	1.02

Risk assessment –overall conclusions

The outcome of the risk assessment for non-target arthropods exposed to Aviator Xpro is given in the table below.

Higher tier

[3] Ganzelmeier H., Rautmann D. (2000) Drift, drift-reducing sprayers and sprayer testing. Pesticide Application, Aspects of Applied Biology 57

Table 6.6-5: Acceptability criteria for higher tier data and minimal TER values for arthropod species other than bees after use of Aviator Xpro

Test substance	Species	Test type	Endpoint L(E)R50 (ml Prod./ha)	PER in-field (ml Prod./ha)	effects <50% at calc. rate?	TER in-field	PER off-field (1 m) (ml Prod./ha)	PER off-field x correction factor 5	effects <50% at calc. rate?	TER Off-field
Aviator Xpro	*Typhlo-dromus pyri*	ext Lab. 2D	1300	2125	no	0.62	10.12	252.9	yes	128.5

Based on the calculated rates of Aviator Xpro in in-field areas, the calculated HQ and TER values describing the potential risk resulting from an exposure of non-target arthropods to Aviator Xpro according to the GAP of the formulation. Aviator Xpro achieve not the acceptability criteria of less than 50% effects at calculated drift rates resp. TER ≥ 5 (higher Tier), according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.

Colonisation processes from off field to recolonise the infield areas by arthropods should be possible as shown in next step.

6.6.2 Risk assessment for Arthropods other than Bees

6.6.2.1 In-field

Higher Tier

The potential risk for non-target arthropods exposed in-field to Aviator Xpro was assessed by comparing the environmental rate (PER in-field) to the lowest lethal rate (LR50) 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.

Table 6.6-6: Risk assessment for non-target arthropods other than bees and acceptability criteria for higher tier data

Species	LR50 (mL Product/ha)	PER in-field (mL Product/ha)	effects < 50% at calc. rate?
Typhlodromus pyri	1300	2125	no

The results indicate that Aviator Xpro poses high risk to non-target arthropods in-field following application according to the intended uses. Refinement is necessary.

The applicant presented an refinement for in-field risk assessment by performing an **extended laboratory aged residues study** on the predatory mite *Typhlodromus pyri* (**Rosenkranz, 2008; M-307529-01-1, filed at KIIIA 10.5.2/05).**

The predatory mites 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. Five 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 28 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.

In the 1st, 2nd and 3rd bioassay (0, 7 and 14 days after application the effect of Aviator Xpro on mortality was below the trigger value of 50 % and statistically significant compared to the control.

Reproduction of *T. pyri* was tested in the 1st and 2nd bioassay (0 or 7 days after the last application, respectively). In both bioassays no unacceptable effects on reproduction (effects < 50%) after the use of 3 x 1.25 L product/ha were observed.

This aged residues study, gives indications that directly after the last application of 3 x 1.25 L Aviator Xpro, acceptable effects (< 50%) on both mortality and reproduction are observed on the most sensitive species, *Typhlodromus pyri*. Therefore, a recovery of the in-field NTA population/ a recolonization of the treated area can be expected on a short term and an acceptable in-field risk can be concluded.

6.6.2.2 Off field

HQ approach

In order to assess the potential risk of Aviator Xpro to non-target arthropods in off-field areas, the predicted environmental rate in the Off-field (see chapter below) is compared to the toxicity endpoints according to the following formula:

$$Off-field\ \ HQ = \frac{Off-field\ PER}{LR_{50}} \times correction\ factor$$

where:

Correction factor (also 'safety factor') = amounts to 10 in conjunction with Tier I data from tests on glass plates; amounts to 5 for Tier II data from extended laboratory tests/field tests. The factor accounts for extrapolation from testing few representative species to the species diversity expected in off-crop areas.

Higher Tier

With regard to extended laboratory tests and semi-field tests, lethal and sublethal effects of less than 50 % at the calculated deposition rates are considered acceptable provided that the tests covered the appropriate field rate.

Table 6.6-7: Acceptability criteria for higher tier non-target arthropods data

Species	Test type	L/ER50 (mL product/ha)	PER in-field (mL product/ha)	Distance (m)	PER off-field	PER off-field x correction factor 5 (mL product/ha)	effects <50% at calc. rate?
Typhlodromus pyri	2 D extended lab	1300	2125	1	10.12	50.6	yes

At the calculated deposition rates, the effects in the extended laboratory tests are lower than 50%, indicating that Aviator Xpro does not poses an unacceptable risk to non-target arthropods in off-field areas.

TER approach

Additionally to the HQ-approach, the assessment of the risk to non-target arthropods due to an exposure to Aviator 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 when the data were obtained in higher tier test (extended lab or field tests).

Table 6.6-8: Calculated TER values for non-target arthropods exposed to Aviator Xpro in off-field areas according to intended uses

Species	Test type	Correction factor	L/ER50 (mL product/ha)	PER in-field (mL product/ha)	Distance (m)	PERoff-field x correction factor (mL product/ha)	TER
Typhlodromus pyri	2-D extended lab	5	1300	2125	1	50.6	25.7

TER values in bold are below the trigger

Based on the calculated rates of Aviator Xpro in off-field areas, the calculated TER values for the risk resulting from an exposure of non-target arthropods to Aviator Xpro according to the GAP of the formulation Aviator Xpro achieve the acceptability criteria of 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 arthropods due to the intended use of Aviator Xpro in cereals according to the label.**

6.7 Effects on non-target soil meso- and macrofauna (MIIIA 10.6, KPC 10.4, KPC 10.4.1, KPC 10.4.2)

Effects on earthworms and other soil non-target organisms resulting from an exposure to bixafen, prothioconazole and Aviator Xpro were not evaluated as part of the EU review of bixafen and prothioconazole All relevant study data for the assessment of the risk to earthworm and other soil non-target macro-and mesofauna from the intended uses of Aviator Xpro are provided here. New data are listed in Appendix 1 and summarized in Appendix 2 (new studies).

Table 6.7-1: EU agreed endpoints and new endpoints for earthworms and other soil macro- and mesofauna

Test substance	Species	Time scale	Results [mg/kg soil dw]	Reference	Internal code
Laboratory studies					
Bixafen	*Eisenia fetida*	Acute 14 d 5% peat	LC_{50} > 1000 mg a.i./kg sdw	Lührs, U. 18.10.2006 29612021	69540
Bixafen	*Eisenia fetida*	56 d chronic 5 % peat	NOEC = 100 mg/kg dw reproduction	Lührs, U. 23.08.2006 29611022	69541
Bixafen	*Folsomia candida*	28 d chronic, 5% peat	NOEC: 7.74 mg/kg dw reproduction	Lührs, U. 10.08.2007 36952016	69542
Bixafen EC 125 (122.5 g/L)	*Hypoaspis aculeifer*	14 d	NOEC : 6.15 mg a.s./kg substrate reproduction nominal 5% peat	Kratz, M.-A. 2007 E 428 3292-0	69543
prothioconazole	*Eisenia fetida*	14 d	LC_{50} > 1000 mg/kg	Meisner, P.	45889

(JAU 6476)		acute 10 % peat	dw * **$LC_{50\ corr.}$ > 500 mg/kg dw**	10.04.2000 E 310 1769-7	
prothioconazole (JAU 6476)	*Eisenia fetida*	chronic	NOEC: 1.33 mg/kg dw* **$NOEC_{corr.}$: 0.67 mg/kg dw**	Loep 2007	-
prothioconazole (JAU 6476)	*Folsomia candida*	28 d chronic 10% peat	NOEC: 64 mg/kg dw $NOEC_{corr.}$: 32 mg/kg dw [1)]	Loep 2007	-
prothioconazole (JAU 6476)	*Folsomia candida*	28 d chronic	NOEC >= 1000 mg a.i./kg sdw	Frommholz, U. 12.04.2011 FRM-COLL-118/11	82310
prothioconazole (JAU 6476)	*Hypoaspis aculeifer*	14 d Lab extended test with natural standard soil (LUFA 2.1) (ca. 0.9% organic carbon)	NOEC ≥ 100 mg/kg soil dw reproduction nominal	Hoogendoorn, G.M. 06.09.2000 B060HAE	45923
JAU 6476-desthio	*Eisenia fetida*	14 d acute 10 % peat	LC_{50} > 1000 mg/kg dw* **$LC_{50\ corr.}$ > 500 mg/kg dw**	Meisner, P. 29.06.2000 MPE/Rg 338/00 ; E 310 1844-1	45898
JAU 6476-desthio	*Eisenia fetida*	56 d chronic 10 % peat	NOEC: 1 mg/kg dw* **$NOEC_{corr}$: 0.5 mg/kg dw**	Meisner, P. 31.10.2000 E 312 1799-2 ; MPE/Rg 332/00	45902
JAU 6476-desthio	*Folsomia candida*	28 d chronic 10% peat	NOEC: 62.5 mg/kg dw $NOEC_{corr.}$: 31.3 mg/kg dw [1)]	Loep 2007	-
JAU 6476-S-methyl	*Eisenia fetida*	14 d acute 10 % peat	LC_{50} > 1000 mg/kg dw* **$LC_{50\ corr.}$ > 500 mg/kg dw**	Heimbach, F. 25.01.2000 E 310 1743-9 ; HBF/Rg 321	45900
JAU 6476-S-methyl	*Eisenia fetida*	56 d chronic 10 % peat	NOEC: 100 mg/kg dw* **$NOEC_{corr.}$: 50 mg/kg dw**	Heimbach, F. 01.02.2000 E 312 1713-8 ; HBF/Rg 317	45903

Aviator Xpro	*Eisenia fetida*	Acute 14 d 5% peat	LC50 >1000 mg pr./kg sdw	Luehrs (2006) 31201021 M-280033-01-1	69524
Aviator Xpro	*Eisenia fetida*	56 d Chronic 5% peat	NOEC = 75 L pr/ha NOEC= 9.375 L pr/ha reproduction[1]	Luehrs (2006) 31202022 M-281333-01-1	69525
Aviator Xpro	*Folsomia candida*	28 d	NOEC= 104 mg/kg dw Reproduction NOEC= 208 mg kg/dw	Lührs, U. 10.08.2007 31209016	69527
Field studies					
Schulz, L. (23.07.2014): Bixafen + Prothioconazole + Tebuconazole EC 275 (75+100+100) G: Effects on **earthworms** under field conditions, 13 10 48 008 F, M-477174-02-1 Application rates : 1.25 L/ha, 2.50 L/ha and 3.75 L/ha No statistically significant effects on total earthworm abundance and biomass 1, 4 and 10 months after 1st test item application NOEC > 2 x 3.75 L Prod/ha					87040
Schulz, L. (12.05.2015): Bixafen + Prothioconazole + Tebuconazole EC 275 (75+100+100) G: Effects on **Collembola** under field conditions, Study No. 131048009F Natural collembola community, Application rates: Application rates : 1.25 L/ha, 2.50 L/ha and 3.75 L/ha Results: NOEC > 2 x 3.75 L/ha (analysed with ANOVA)** or NOEC < 2 x 1.25 L/ha (analysed with CP-CAT)**					86768
Lechelt-Kunze (02.02.2005): JAU 6476 EC 250: Effects on the earthworm fauna of grassland area in one year, LKC/RGF 58, M-040814-03-1 Field test with prothioconazole mono formulation JAU 6476 EC 250, 3 X 200g a.i./ha (3 X 803,4 g Prod./ha) EC 50= 200 g a.i./ha					76463
Litter bag test					
-					

*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).

**Please refer to point 6.8.3 below or to Appendix 2 for full evaluation of the study. The study of Schulz (2015) is considered sufficient for legislation of the product in Germany but due to a lot of shortcommings a further monitoring study is required to relieve remaining uncertainities regarding the risk iedntified for non-target soil meso- and macrofauna.

[1] Lower endpoint is used for risk assessment by UBA. Recalculation of test showed that reproduction rates were different compared to the control in treatment group 18.75 L/ha (statistic evaluation was done with Williams-test, with Tox-Rat). Thus NOEC for reproduction effects is 9.375 L/ha. That endpoint is used in risk assessment.

6.7.1 Justification for new endpoints

Not relevant.

6.7.2 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 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 all intended uses (see Table 6.1-1).

According to the GAP, Aviator Xpro is intended to be applied 2 times in early spring with a maximum application rate of 1.250 L formulation/ha (i.e. 93.75 g Bixafen/ha and 187.5 g Prothioconazole/ha). It will be used against a wide range of pests.

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.

Moreover, two additional higher tier studies for earthworms and other soil macro- and mesofauna have been submitted in the course of the current evaluation:

- Schulz, L. (23.07.2014) Bixafen + Prothioconazole + Tebuconazole EC 275 (75+100+100) G: Effects on earthworms under field conditions

- Schulz, L. (12.05.2015): Bixafen + Prothioconazole + Tebuconazole EC 275 (75+100+100) G: Effects on Collembola under field conditions, Study No. 131048009F, Lit Nr. 86768

These studies have been submitted after the phase II of the zonal assessment and were therefore not included in the commenting phase. However, these studies have been evaluated by the zRMS DE. A full description and evaluation is presented in Appendix 2.

For risk assessment purposes, a risk envelope approach was used. Hence, intended use groups A and B cover the risk for earthworms and other soil macro- and mesofauna.

The acute risk for earthworms and other non-target soil macro- and mesofauna resulting from an exposure to bixafen, prothioconazole, prothioconazole metabolite JAU 6476-desthio and the formulation Aviator Xpro was assessed by comparing the maximum PECSOIL with the 14-day LC50 value to generate acute TER values. The TERA 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 was assessed by comparing the maximum PECSOIL of the relevant substances (see above) with the NOEC value to generate chronic TER values. The TERLT 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 6.7-2: Results of PEC_{soil} calculation for application of Aviator Xpro in cereals (soil bulk density 1.5 g/cm^{-3}, soil depth 5 cm) according to group A

Plant protection product	Aviator Xpro					
group	A					
Crop:	cereals					
Application rate:	2x 1.25 L product/ha, 2x 93.75 g Bixafen/ha, 2x 187.5 g Prothioconazole/ha					
Number of application/interval:	2, 14d					
Crop interception:	70%					
active substance/ preparation	**soil relevant application rate (g/ha)**	**PECact (mg/kg)**	**PECtwa 21 d (mg/kg)**	**tillage depth (cm)**	**PECbkgd (mg/kg)**	**PECaccu = PECact + PECbkgd (mg/kg)**
Prothioconazole	2 x 56,25 g/ha M:344.3	0.0763 on day 14	0.0250	-	-	-
Metabolite M01, JAU 6476-S-methyl	Ff=0.14, M: 358.3	0.0175 on day 23	0.0164	-	-	-
Metabolite M04, JAU 6476-desthio	Ff=0.8, M: 312.2	0.0901 on day 23	0.0856	20	0.0003	0.0904
Product Aviator Xpro	Density 1.01, 1x 2525 g/ha	3.3667				
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	1x 56.25 g/ha	5	0.0750			
		20	0.0188	3.7	0.0694	0.0833
active substance/ formulation	**soil relevant application rate (g/ha)**	**soil $depth_{act}$ (cm)**	**Factor for uncertainity**	**PECbkgd after 8 years +20% x 10 (mg/kg)**		**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg**
Bixafen	1x 56.25 g/ha	5				**0.908**

		20	10	0.833	

Table 6.7-3: Results of PEC_{soil} calculation for application of Aviator Xpro in cereals (soil bulk density 1.5 g/cm^{-3}, soil depth 5 cm) according to group B (presented only for Bixafen, other active substance is covered by results of table above)

plant protection product:		Aviator Xpro				
group:		B				
Number of applications/intervall		2/ 14d				
application rate:		75 g/ha				
crop interception:		70%				
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	1x 45 g/ha	5	0.0600			
		20	0.0300	3.7	0.055	0.066
active substance/ formulation	**soil relevant application rate (g/ha)**	**soil $depth_{act}$ (cm)**	**Factor for uncertainity**	**PECbkgd after 8 years +20% x 10 (mg/kg)**		**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg**
Bixafen	1x 45 g/ha	5				**0.721**
		20	10	0.661		

Metabolites of bixafen

Bixafen forms no major metabolites in soil. For details please refer to the environmental fate section (Part B, Section 5) of this submission.

Metabolites of prothioconazole

Prothioconazole forms two major soil metabolites, JAU 6476-desthio and JAU 6476-S-methyl. For details please refer to the environmental fate section (Part B, Section 5) of this submission. For both metabolites an acute and a chronic test with *Eisenia fetida* was provided. According to the provided data both metabolites show an acute toxicity comparable to the active substance. Regarding the chronic toxicity, the metabolite JAU 6476-desthio is more toxic as the active substance while the other metabolite (JAU 6476-S-methyl) is less toxic. No risk assessment was performed for JAU 6476-S-methyl as the assessment for the active substance covers the effects of the metabolite. The second soil metabolite JAU 6476-desthio was included in the risk assessment due to its high chronic toxicity.

The results of the risk assessment are summarized in the following table.

Table 6.7-4: TER values for earthworms (Tier-1), Group A, 2x 1.25 L product/ha, 2x 93.75 g Bixafen/ha, 2x 187.5 g Prothioconazole/ha, 14d interval

Test substance	Worst-case use pattern	Timescale	Endpoint (mg/kg dw soil)	PEC (mg/kg dw soil	TER	TER risk assessment trigger
bixafen	**1 x 1.25 L product/ha in cereals**	**Acute**	> 1000	0.908	**> 1101**	**10**
		Long-term	100		**110.1**	**5**
prothioconazole		**Acute**	> 500	0.0763	**> 6553**	**10**
		Long-term	0.67		**8.78**	**5**
JAU 6476-desthio		**Acute**	> 500	0.0901	**>5549**	**10**
		Long-term	0.5		**5.5**	**5**
Aviator Xpro		**Acute**	>1000	3.3667	**>297**	**10**
		Long-term	9.375 L/ha	0.168 L/ha*	**74.4**	**5**

*consists of application rate 1.25 L/ha with 70% interception: 2x28.125 g a.i./ha bixafen and 2x56.25 g a.i./ha prothioconazole = 0.168 L/ha

Table 6.7-5: TER values for earthworms (Tier-1), Group B, 2x 75 g Bixafen/ha

Test substance	Worst-case use pattern	Timescale	Endpoint (mg/kg dw soil)	PEC (mg/kg dw soil	TER	TER risk assessment trigger
bixafen	**1 x 1.0 L product/ha in cereals**	**Acute**	> 1000	0.721	**> 1367**	**10**
		Long-term	100		**139**	**5**

A risk assessment for earthworms was performed, which resulted in acceptable TER values for acute and long-term effects of bixafen, prothioconazole and the product Aviator Xpro.

6.7.3 Higher tier risk assessment

A field study (Lechelt-Kunze, 2005, LKC/RGF 58, M-040814-03-1, ICS: 76463) with JAU 6476 EC 250 (monoformulation of prothioconazole) was presented by applicant. Results of the study: after application of 3 times 200 g a.i./ha with 2-3 week distance a investigation in earthworms was carried out after 162 days and after 11 month of first application. No unacceptable risk for soil organisms due to the intended use of prothioconazole was found. Thus the results of the assessment indicate an acceptable risk for earth worms due to the intended use of Aviator Xpro in cerals according to the label.

The notifyer submitted a earthworm field study (Schulz, 2015) looking at the effects of bixafen + prothioconazole + tebuconazole EC 275 (75 + 100 + 100) G on natural earthworm community. Please refer to Appendix 2 for complete evaluation of the study.

No statistically significant reduction in total earthworm abundance and biomass could be observed for all test item application rates tested up to a rate of 2 x 3.75 L (7 days interval) test item/ha about 1, 4 and 10 months after 1st test item application.

6.7.4 Effects on other non-target macro-organisms

Toxicity data **on other non-target meso- and macro-organisms** were evaluated on EU level for all active substances and their major soil metabolites. As bixafen does not form major metabolites in soil the assessment has to be done only for the active substance. For the major soil metabolites of prothioconazole JAU6476-desthio and JAU6476-S-methyl data on the toxicity against **collembolans** was provided, showing a higher toxicity of the metabolites compared to the active substance. Thus a risk assessment was performed for prothioconazole and its two major soil metabolites.

For assessment of PECaccu-accumulation of bixafen in soil please refer to Part B Section 5 CA chapter 5.5. to: Due to the slow degradation of the active substance Bixafen in soil (DT_{90} > 365 d, field data) the accumulation potential needs to be considered. Therefore PEC_{soil} used for risk assessment comprises background concentration in soil (PEC_{accu}) deducted 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 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. Therefore, the remaining 20% had to be taken intoaccunt for the calculation of the background concentration. Further, as no plateau was reached, we used additionally an uncertainity factor of 10 for the background concentration (see comment of zRMS to Heinemann, Weuthen 2013 in Appendix 3 of Section 5). As the soils were ploughed, the background concentration was calculated for a soil depth of 20cm, although the residues in the soil accumulation study were found in 0-10 cm dephth. The calculated background concentration was added to the the maximum annual soil concentration PEC_{act} in a soil depth of 5 cm.

Based on all informations about the degradation of Bixafen in soil 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. We seek the Member States to consider the persistence of Bixafen when addressing the risks of intended uses of "Aviator Xpro" for the soil compartment**.

The toxicity endpoints and worst-case initial PECsoil estimates for the relevant substances are summarized above in table 6.7-3 and the risk assessments are provided in the following Table:

Table 6.7-6: TER values for other non target soil macro-organisms: *Folsomia candida* and *Hypoaspis aculeifer* (Tier-1), Group A, 2x 1.25 L product/ha, 2x 93.75 g Bixafen/ha, 2x 187.5 g Prothioconazole/ha, 14d interval with PEC_{soil} values for application of Aviator Xpro in cereals (soil bulk density 1.5 g/cm^{-3}, soil depth 5 cm) according to group A, chronic tests

Test substance	NOEC [mg/kg soil]	Maximum instantaneous PEC_{soil} /PEC accu) [mg/kg soil]	TER
Folsomia candida			
bixafen	7.74	0.908	**8.5**
prothioconazole	32	0.0763	**419**
JAU 6476-desthio	31.3	0.0901	**347**
JAU 6476-S-methyl	≥ 15.8	0.0175	**≥ 903**
Aviator Xpro	104	3.3667	**30.9**
Hypoaspis aculeifer			
bixafen	6.15	0.908	**6.8**
TERs shown in bold are above the relevant trigger.			

Table 6.7-7: TER values for other non target soil macro-organisms *Folsomia candida* and *Hypoaspis aculeifer* (Tier-1), Group B, 2x 75.0 g Bixafen/ha, chronic tests

Test substance	NOEC [mg/kg soil]	Maximum instantaneous PEC_{soil} /PEC accu) [mg/kg soil]	TER
Folsomia candida			
bixafen	7.74	0.721	**10.7**
Hypoaspis aculeifer			
bixafen	6.15	0.721	**8.5**
TERs shown in bold are above the relevant trigger.			

6.7.5 Higher tier risk assessment

The notifyer submitted a collembolan field study (Schulz, 2015) looking at the effects of bixafen + prothioconazole + tebuconazole EC 275 (75 + 100 + 100) G on natural collembola community. Please refer to Appendix 2 for complete evaluation of the study.

The ZRMS DE has some concerns about i) the design and accomplishment of the study ii) the statistical analyses.

i) Design and accomplishment of the study

Following deficiencies were identified:

- Insufficient recording of collembolans: the start of the study was too late in the year to detect the active spring peak of the collembolans community. Due to the choice of sampling dates in August and in December, also the reproduction peak in autumn was not detected.

- High variability of plots: since the plots of the middle and the highest test concentration had much higher abundances of collembolans in the soil cores before application of the test substance, a robust comparison of the plots was not possible.

- Insufficient distribution of the test substance: the calculation of the plateau concentration for the risk assessment does include the incorporation of the active substance within the first 15 cm – 20 cm of the soil surface. However, the study design did not include the incorporation of the active substance into the soil. Due to the high KOC of the bixafen it can be assumed that no shift towards the deeper soil layers took place and the active substance Bixafen did remain within the first centimeter of the soil surface. A "real" plateau concentration in the field is distributed through tillage into the first 20 cm and therefore available for animals that do not reside directly on the soil surface. Therefore, the PEC plateau concentration should be incorporated into the soil for substances with high Koc values, like Bixafen. Further, a plateau concentration of tebuconazole was not applied. As tebuconazole shows a DT90field of 355 d, which is close to the trigger value of 365 d, a plateau concentration should also be applied for tebuconazole.

ii) Statistical analyses

- Insufficient evaluation of effects: the univariate analysis was performed with regard to reduction of numbers of collembolans compared to the control; increases compared to the control were not analyzed.

- Setting of the NOEC: the setting of the NOEC critically depends upon the statistical method used for calculation: ANOVA versus CP-CAT (Lehmann et al., 2015 , please refer to Appendix 2 CA for full evaluation). Whereas the ANOVA method proposed by the notifyer could not detect any significant effects at the highest tested concentration of 2 x 3.75 L Product /ha, the CP-CAT method used by the zRMS already identified significant effects in the lowest test concentration at the sixth sampling date after one year in soil cores as well as pitfall traps (i.e significant increase compared to the control for the species Ceratophysella denticulate, genus Ceratophysella as well as the family Hypogastruridae and the order Poduromorpha). Based on the CP-CAT method the setting of a NOEC is not possible (i.e. NOEC < lowest tested rates).

Conclusions:

The submitted field study (Schulz, 2015) shows effects on the observed population of soil macroorganisms (collembolans) already at the lowest tested concentration of 2 x 1.25 L/ha, which corresponds to the GAP of the use group A. Therefore, a 2 years monitoring study is also required for the use group A.

Based on the deficiencies identified in the study design and execution and since the setting of the NOEC is depending on which statistical method is used, the authorization of the product "Aviator Xpro" in Germany has to be linked with a 2 years monitoring study on collembolans treated with the granted product.

Due to shortcomings of the conducted field study from Schulz (2015) the 2 years monitoring study must consider the following recommendations:

- The application of the plateau concentration (bixafen + tebuconazole) should take place in autumn before application of the test item in the following spring. The active substances should be incorporated into the soil (20 cm depth).

- The first pre-sampling date should take place immediately before application of the plateau concentration.

- The application of the test item should be conducted in April to record the active spring peak of collembolans. Samplings should be taken just before as well as just after application of the test item (i.e. 2nd presampling before, 1st post sampling after application).

- The reproduction peak in autumn should be recorded by sampling dates.

- The last sampling date should be done one year after application of the test item – preferably in April.

- The sampling dates of collembolans should be combined with analytical measurements of the active substances – preferably in different soil layers (1 cm, 5 cm and 10 cm).

- The comparability of the plots should be possible (regarding the mean numbers of individuals as well as the composition of detected species).

- The statistical analysis must include the CP-CAT method (Lehmann et al., 2015).

6.7.6 Overall conclusions

Based on the predicted concentrations of prothioconazole and formulation Aviator Xpro in soils, the TER values describing the acute and longterm risk for earthworms and other soil- macro organisms following exposure to active substances and the formulation Aviator Xpro according to the GAP 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.

Based on the predicted concentration **of bixafen in** soils, the TER values describing the longterm risk for other non-target soil organisms following exposure to active substance bixafen according to the GAP of the formulation Aviator Xpro do achieve the acceptability criterion TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.

The submitted field study (Schulz, 2015) shows effects on the observed population of soil macroorganisms (collembolans) already at the lowest tested concentration of 2 x 1.25 L/ha, which corresponds to the GAP of the use group A. Therefore, a 2 years monitoring study is also required for the use group A. Therefore, the authorization of the product "Aviator Xpro" in Germany for the use group A

has to be linked with a 2 years monitoring study on collembolans treated with the granted product for all indications.

6.8 Effects on soil microbial activity (MIIIA 10.7, KPC 10.5)

Effects on soil microorganisms resulting from an exposure to Aviator Xpro were not evaluated as part of the EU review of bixafen and prothioconazole. All relevant study data for the assessment of the risk to soil microorganisms from the intended uses of Aviator Xpro are provided here. New studies are listed in Appendix 1and summarized in Appendix 2.

Table 6.8-1: EU agreed endpoints and new endpoints for soil microorganisms

Substance	Test design	Results	Source	Internal code
BYF 00587 (Bixafen tech.)	C-Transformation	Inhibition : 5 % [1)] 0.17 mg/kg soil dw Inhibition : 6 % 1.67 mg/kg soil dw	Lechelt-Kunze, C. 2005 E 330 2916-4	69808
BYF 00587 (Bixafen tech.)	N-Transformation	Inhibition : 5 %[1)] 0.17 mg/kg soil dw Inhibition : 3 % 1.67 mg/kg soil dw	Lechelt-Kunze, C. 2005 E 337 2915-0	69807
JAU 6476 tech. (Prothioconazol) 98.3 % Purity	N-Transformation	Inhibition : 1 % [2)] 0.27 mg/kg soil dw (= 203 g ai/ha) Inhibition : 4 % 2.71 mg/kg soil dw (= 2030 g ai/ha)	Anderson, J. P. E. 1999 AJO/203199	69374
JAU 6476 tech. (Prothioconazol) 98.3 % Purity	C-Transformation	Inhibition : 3 % [2)] 0.27 mg/kg soil dw (= 203 g ai/ha) Inhibition : 5 % 2.71 mg/kg soil dw (= 2030 g ai/ha)	Anderson, J. P. E. 1999 AJO/203099	69379
JAU 6476-Desthio	C-Transformation	Inhibition : < 25 % [3)] 0.2 kg /ha (=0.27 mg/kg soil) Inhibition : < 25 % 1 kg /ha (=1.33 mg/kg soil)	Leicher, T. 2007 E 330 3322-6	68729
JAU 6476-Desthio (97.7 % Purity)	N-Transformation	Inhibition : 19 %[2)] 0.27 mg/kg soil dw (= 205 g/ha) Stimulation : 20 % 0.27 mg/kg soil dw (= 205 g/ha)	Anderson, J. P. E. 2000 AJO/209400	69375
JAU 6476-S-methyl (99.1 % Purity)	C-Transformation	Stimulation : 5 % [2)] 0.27 mg/kg soil dw (= 202 g/ha)	Anderson, J. P. E. 1999 AJO/203299	69378

		Stimulation : 3 % 2.69 mg/kg soil dw (= 2020 g/ha)		
JAU 6476-S-methyl (99.1 % Purity)	N-Transformation	Stimulation : 3 % [2)] 0.27 mg/kg soil dw (= 202 g/ha) Stimulation : 4.5 % 2.69 mg/kg soil dw (= 2020 g/ha)	Anderson, J. P. E. 1999 AJO/203399	69377
1,2,4-Triazol	C-Transformation	Stimulation : +5.5 % [4)] 0.0353 mg/kg dry soil Stimulation : +8.3 % 0.353 mg/kg dry soil	Völkel, W. 2000 763367	65556
1,2,4-Triazol	N-Transformation	Inhibition : -5.2 % [4)] 0.035 mg/kg dry soil Inhibition : -1.5 % 0.353 mg/kg dry soil	Völkel, W. 2000 763367	65556
Aviator Xpro	N-Transformation	no influence (deviation <25%), 12.5 L prod./ha5	Reis (2006) M-281135-01-15	69523
Aviator Xpro	C-Transformation	no influence (deviation <25%), 12.5 L prod./ha5	Reis (2006) M-281135-01-15	69523

1) DAR Bixafen – Volume 3, Annex B.9; Ecotoxicology, July 2011

2) EFSA conclusion (2007) 106, 1-98 Prothioconazole

3) Study handed in to another PPP

4) Endpoint value according to agreement in PRAPeR expert meeting on triazole metabolites (PRAPeR 13, January 2007).

5) Study provided by the applicant

6.8.1 Justification for new endpoints

-

6.8.2 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).

Table 6.8-2: Maximum calculated PECSOIL values

Please refer to section 5 and to chapter **Fehler! Verweisquelle konnte nicht gefunden werden.** for the predicted environmental concentrations in soil (PEC_{SOIL}) of bixafen, prothioconazole, prothioconazole metabolite JAU 6476-desthio and the formulation Aviator Xpro.

The results of the risk assessment are summarized in the following table as a risk envelope (group A covers group B).

Table 6.8-3: Results of PEC_{soil} calculation for application of Aviator Xpro in cereals (soil bulk density 1.5 g/cm^{-3}, soil depth 5 cm) according to group A (covers group B)

Plant protection product		Aviator Xpro				
group		**A.**				
Crop:		cereals				
Application rate:		2x 1.25 L product/ha, 2x 93.75 g Bixafen/ha, 2x 187.5 g Prothioconazole/ha				
Number of application/interval:		2, 14d				
Crop interception:		70%				
active substance/ preparation	**soil relevant application rate (g/ha)**	**PECact (mg/kg)**	**PECtwa 21 d (mg/kg)**	**tillage depth (cm)**	**PECbkgd (mg/kg)**	**PECaccu = PECact + PECbkgd (mg/kg)**
Prothioconazole	2 x 56,25 g/ha M:344.3	0.0763 on day 14	0.0250	-	-	-
Metabolite M01, JAU 6476-S-methyl	Ff=0.14, M: 358.3	0.0175 on day 23	0.0164	-	-	-
Metabolite M04, JAU 6476-desthio	Ff=0.8, M: 312.2	0.0901 on day 23	0.0856	20	0.0003	0.0904
Product Aviator Xpro	Density 1.01, 1x 2525 g/ha	3.3667				
active substance/ formulation	**soil relevant application rate (g/ha)**	**soil $depth_{act}$ (cm)**	**Factor for uncertainity**	**PECbkgd after 8 years +20% x 10 (mg/kg)**		**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg**
Bixafen	1x 56.25 g/ha	5				0.908
		10	10	0.833		

Metabolites of bixafen

Bixafen forms no major metabolites in soil. For details please refer to the environmental fate section (Part B, Section 5) of this submission.

Metabolites of prothioconazole

Prothioconazole forms two major soil metabolites, JAU 6476-desthio and JAU 6476-S-methyl. For details please refer to the environmental fate section (Part B, Section 5) of this submission. For both metabolites studies determining effects on soil microorganisms were provided. According to the provided data both metabolites do not affect soil microorganisms at relevant test concentrations were shown.

The results of the risk assessment are summarized in the following table.

Table 6.8-4: Risk assessment for effects on soil micro-organisms (Group A covers Group B)

Test substance	Test concentration (adverse effects < 25%) [mg /kg]	PEC_{SOIL} [mg /kg]	Risk acceptable yes/no
bixafen	**1.67***	**0.908**	**yes**
prothioconazole	**2.71**	**0.0763**	**yes**
JAU 6476-Desthio	**0.27** **1.33**	**0.0901** **0.0901**	**yes**
Aviator Xpro	**12.5 L/ha**	**3.3667**	**yes**

*After 28 days of treatment 6% difference to control in carbon dioxide production and 3 % difference to control in nitrogen transformation

According to current regulatory requirements the risk is acceptable, if the effect of the recommended application rate of a product on nitrogen or carbon mineralisation is < 25% after 100 days. In no case, deviations from the control exceeded 25% after 28 days, thus it could be concluded that Aviator Xpro does not pose an unacceptable risk to soil microorganisms when applied according to the intended uses.

6.8.3 Overall conclusions

Based on the predicted concentrations of bixafen and prothioconazole in soils, the risk to soil microbial processes following exposure to bixafen and prothioconazole according to the GAP of the formulation Aviator 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.

6.9 Effects on non-target plants (MIIIA 10.8, KPC 10.6)

6.9.1 Effects on non-target terrestrial plants (MIIIA 10.8.1)

Effects on non-target plants resulting from an exposure to Aviator Xpro were not evaluated as part of the EU review.

As the data for the active substances were already evaluated on EU level and the data on the formulated product are most relevant for the risk assessment, only the data for the formulation are considered here.

Table 6.9-1: EU-agreed endpoints and new endpoints for non-target terrestrial plants

Test species	Test system	ER_{50} emergence [g/ha]	ER_{50} plant weight [g/ha]	ER_{50} plant height [g/ha]	Reference	Internal code
Aviator Xpro						
7 dicotyledonae and 3 monocotyledonae): cucumber (*Cucumis sativus*), oilseed rape (*Brassica napus*), soybean (*Glycine max*), sugar beet (*Beta vulgaris*), sunflower (*Helianthus annuus* L.), tomato (*Lycopersicon esculentum*), buckwheat (*Fagopyrum esculentum*), corn (*Zea mays*), oat (*Avena sativa*), and ryegrass (*Lolium perenne* L.). 7 dikotyle und 3 monokotyle Pflanzen-Spezies, 21 d	Vegetative vigour	ER50>1.25 L/ha (dry weight)			Gosch, G.; Nguyen, D.H. 14.08.2007 VV07/10	69519
7 dicotyledonae and 3 monocotyledonae): cucumber (*Cucumis sativus*), oilseed rape (*Brassica napus*), soybean (*Glycine max*), sugar beet (*Beta vulgaris*), sunflower (*Helianthus annuus*	Seedling emergence	ER50>1.25 L/ha (dry weight)			Gosch, G.; Nguyen, D.H. 14.08.2007 SE07/10	69521

L.), tomato (*Lycopersicon esculentum*), buckwheat (*Fagopyrum esculentum*), corn (*Zea mays*), oat (*Avena sativa*), and ryegrass (*Lolium perenne* L.).				

6.9.1.1 Justification for new endpoints

-

6.9.1.2 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)[4] from the spray-drift predictions of Ganzelmeier & Rautmann (2000)[5]. 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. For the calculation of the maximum in-field PER a multiple application factor (MAF) of 1.7 (according to ESCORT 2) was considered to account for the two time application of Aviator Xpro in cereals.

PECoff-field= Maximum in-field PER x (%DRIFT/100)

The exposure assessment for the intended use, due to the ground-directed application of Aviator Xpro, is most appropriately addressed by the drift values for field crops. The highest application rate of Aviator Xpro is 2 x 1,25 L product/ha in cereals (group A, covering all intended uses). The resulting maximum off-field predicted environmental rate (PERoff-field) is shown in the following Table:

Table 6.9-2: Maximum off-field predicted environmental rates of Aviator Xpro

Maximum intended in-field rate (PECin-field)	Maximum PERoff-field at 1m (2.**38**% drift)	Maximum PERoff-field at 5m (0.**47**% drift)	Maximum PERoff-field at 10m (0.24% drift)
2.125 L/ha	**0.05 L/ha**	**0.010 L/ha**	**0.0051 L/ha**

[4] BBA (2000) Bundesanzeiger Jg. 52 (Official Gazette), Nr 100, S. 9879-9880 (25.05.2000) Bekanntmachung über die Abtrifteckwerte, die bei der Prüfung und Zulassung von Pflanzenschutzmitteln herangezogen werden. Public domain.
[5] Ganzelmeier H., Rautmann D. (2000) Drift, drift-reducing sprayers and sprayer testing. Aspects of Applied Biology 57, 2000, Pesticide Application. Public domain.

Table 6.9-3: Risk assessment for terrestrial non-target plants exposed to Aviator Xpro

Effect endpoint	Effect rate **ER50** [L product/ha]	PERin-field [L product/ha]	Distance	Exposure PERoff-field [L product/ha]	TER
Seedling emergence	**> 1.25**	**2.125**	**1**	**0.05**	**> 25**
Vegetative vigour	**>1.25**		**1**	**0.05**	**>25**

Figures in bold indicate acceptable risk.

6.9.1.3 Risk assessment

For risk assessment purposes, a risk envelope approach was used. Hence, intended use group A cover the risk for non-target terrestrial plants from all intended uses.

The applicant provided a seedling emergence and a vegetative vigour test for the formulation Aviator Xpro. The risk assessment based on the overall lowest effect endpoint for seedling emergence and vegetative vigour for the actual formulation Aviator Xpro and the relevant predicted environmental rates in the off-field area after treatment with Aviator Xpro in accordance to the maximum proposed use rate of 2 x 1.25 L product/ha is presented in the following Table:

Table 6.9-4: Risk assessment for non-target plants after applications of Aviator Xpro in wheat BBCH 30-69 (worst case, covers all intended uses)

Study type	Critical endpoint (L/ha)	Distance (m)	Drift reducing nozzles	max. Off-field PER (L/ha)	TER
Vegetative vigour	**> 1.25**	**1**	**0%**	**0.05**	**>25**
Seedling emergence	**>1.25**	**1**	**0%**	**0.05**	**>25**
TERs shown in bold are above the relevant trigger.					

TER values based on the most sensitive species identified in the seedling emergence and the vegetative vigour test for Aviator Xpro are above the relevant trigger of TER ≥ 5 at a distance of 1 m from the treated field without drift reducing nozzles used during applications. Thus Aviator Xpro applied according to the intended uses poses an acceptable risk to non-target plants without risk mitigation measures.

6.9.1.4 Overall conclusions

Based on the predicted rates of formulation Aviator Xpro in off-field areas, the TER values describing the risk for non-target plants following exposure to formulation Aviator Xproaccording to the GAP of the

formulation Aviator Xpro achieve the acceptability criteria TER ≥ 10 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 Aviator Xpro in corn according to the label.

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
KIIA 8.2.1.2	**XXX**	2006	Acute toxicity of JAU 6476-triazolylketone (tech.) to fish (Oncorhynchus mykiss) under static conditions Bayer CropScience, Report No.: EBJAX306, Edition Number: M-266572-01-1 Date: 2006-02-23 GLP/GEP: yes, unpublished	Yes	Bayer Crop Science	1
KIIA 8.2.4	**XXX**	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, Edition Number: M-291414-01-1 Date: 2007-08-06 GLP/GEP: yes, unpublished	Yes	Bayer Crop Science	3
KIIA 8.3.1	Bruns, E.	2006	Acute toxicity of JAU 6476-triazolylketone (tech.) to the waterflea Daphnia magna in a static laboratory test system Bayer CropScience, Report No.: EBJAX305, Edition Number: M-266597-01-1 Date: 2006-02-23 GLP/GEP: yes, unpublished	Yes	Bayer Crop Science	1
KIIA 8.4	Dorgerloh, M.	2006	Pseudokirchneriella subcapitata: growth inhibition test with prothioconazole-triazolylketone Bayer CropScience, Report No.: EBJAX304, Edition Number: M-266567-01-1 Date: 2006-02-23 GLP/GEP: yes, unpublished	Yes	Bayer Crop Science	1
KIIA 8.4	Kern, M. E.; De Haan, R. A.; Lam, C.	2004	Toxicity of JAU 6478 Technical to the Saltwater Diaton *Skeletonema Costatum*	Yes	Bayer Crop Science	4

	V.		Bayer CropScience, Report No.: EBJAX076 (J6883601), Edition Number: M-000954-01-1 Date: 2004-03-10 GLP/GEP: yes, unpublished			
KIIA 8.5.2	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, Edition Number: M-266605-01-1 Date: 2006-03-14 GLP/GEP: yes, unpublished	Yes	Bayer Crop Science	1
KIIA 8.6	Kern, M. E.; Banman, C. S.; Lam, C. V.	2004	Toxicity of JAU 6476 technical to duckweed (Lemna gibba G3) under static-renewal conditions Bayer CropScience, Report No.: EBJAY0002, Edition Number: M-000532-01-1 Date: 2004-03-03 GLP/GEP: yes, unpublished	Yes	Bayer Crop Science	1
KIIA 8.6	Kern, M. E.; Banman, C. S.; Lam, C. V.	2003	Toxicity of JAU 6476-Desthio to duckweed (Lemna gibba G3) under static-renewal conditions Bayer CropScience, Report No.: EBJAX084, Edition Number: M-104599-01-1 Date: 2003-12-18 GLP/GEP: yes, unpublished	Yes	Bayer Crop Science	1
KIIA 8.7.1 KIIA 8.7.2	Schmitzer, S.	2005	Effects of BYF 00587 (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory 24481035 ! M-259639-01-1 266955 GLP/GEP: yes, unpublished	Yes	Bayer Crop Science	1
KIIA 8.9.3	Frommholz, U.	2011	Prothioconazole a.s.: Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil Bayer CropScience, Report No.: FRM-COLL-118/11, Edition Number: M-405273-01-1 Date: 2011-04-12 GLP/GEP: yes, unpublished	Yes	Bayer Crop Science	1
KIIA 8.10.2	Leicher, T.	2007	Metabolite JAU 6476-Desthio: Determination of effects on carbon transformation in soil Bayer CropScience, Report No.: LRT-C-74/07, Edition Number: M-290596-01-1 Date: 2007-07-20 GLP/GEP: yes, unpublished	Yes	Bayer Crop Science	4

KIIA 8.2.1.2	**XXX**	2006	Acute toxicity of JAU 6476-triazolylketone (tech.) to fish (Oncorhynchus mykiss) under static conditions Bayer CropScience, Report No.: EBJAX306, Edition Number: M-266572-01-1 Date: 2006-02-23 GLP/GEP: yes, unpublished	Yes	Bayer Crop Science	1
KIIA 8.2.4	**XXX**	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, Edition Number: M-291414-01-1 Date: 2007-08-06 GLP/GEP: yes, unpublished	Yes	Bayer Crop Science	3
KIIA 8.3.1	Bruns, E.	2006	Acute toxicity of JAU 6476-triazolylketone (tech.) to the waterflea Daphnia magna in a static laboratory test system Bayer CropScience, Report No.: EBJAX305, Edition Number: M-266597-01-1 Date: 2006-02-23 GLP/GEP: yes, unpublished	Yes	Bayer Crop Science	1
KIIIA 10.2 /01	Matlock, D.; Lam, C. V.	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, Edition Number: M-291414-01-1 Date: 2007-08-06 GLP, unpublished	Yes	Bayer Crop Science	1
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, Edition Number: M-266605-01-1 Date: 2006-03-14 GLP, unpublished	Yes	Bayer Crop Science	1
KIIIA 10.2 /03	**XXX**	2006	Acute toxicity of JAU 6476-triazolylketone (tech.) to fish (Oncorhynchus mykiss) under static conditions Bayer CropScience, Report No.: EBJAX306,	Yes	Bayer Crop Science	1

			Edition Number: M-266572-01-1 Date: 2006-02-23 GLP, unpublished			
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, Report No.: EBJAX305, Edition Number: M-266597-01-1 Date: 2006-02-23 GLP, unpublished	Yes	Bayer Crop Science	1
KIIIA 10.2 /05	Dorgerloh, M.	2006	Pseudokirchneriella subcapitata: growth inhibition test with prothioconazole-triazolylketone Bayer CropScience, Report No.: EBJAX304, Edition Number: M-266567-01-1 Date: 2006-02-23 GLP, unpublished	Yes	Bayer Crop Science	1
KIIIA 10.2.2.1 /01	**XXX**	2007	Acute toxicity of BIX+PTZ EC 225 (75+150) G to fish (Oncorhynchus mykiss) under static conditions Bayer CropScience, Report No.: EBDRP048, Edition Number: M-293311-02-1 Date: 2007-10-04 **Amended: 2007-11-28** GLP, unpublished	Yes	Bayer Crop Science	1
KIIIA 10.2.2.2 /01	Bruns, E.	2007	Acute toxicity of BYF 00587 & Prothioconazole EC 075+150 to the waterflea Daphnia magna in a static laboratory test system Bayer CropScience, Report No.: EBDRP049, Edition Number: M-288432-01-1 Date: 2007-05-30 GLP, unpublished	Yes	Bayer Crop Science	1
KIIIA 10.2.2.3 /01	Dorgerloh, M.	2007	Pseudokirchneriella subcapitata growth inhibition test with bixafen & prothioconazole EC 225 (75 + 150) G Bayer CropScience, Report No.: EBDRP050, Edition Number: M-289495-01-1 Date: 2007-06-22 GLP, unpublished	Yes	Bayer Crop Science	1
KIIIA 10.3.3 /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, Edition Number: M-348996-01-1 Date: 2009-06-24 Non GLP, unpublished	Yes	Bayer Crop Science	3

KIIIA 10.4.2.1 /01	Schmitzer, S.	2006	Effects of BYF 00587 + PTZ EC 75 + 150 G (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 31203035, Edition Number: M-284887-01-1 Date: 2006-11-17 GLP, unpublished	Yes	Bayer Crop Science	1
KIIIA 10.5.2 /01	Moll, M.	2007	Effects of BYF 00587 + PTZ EC 75 + 150 G on the parasitoid Aphidius rhopalosiphi, extended laboratory study - dose response test - IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 31204002, Edition Number: M-282592-01-1 Date: 2007-01-22 GLP, unpublished	Yes	Bayer Crop Science	1
KIIIA 10.5.2 /02	Moll, M.	2006	Effects of BYF 00587 + PTZ EC 75 + 150 G on the predatory mite Typhlodromus pyri, extended laboratory study - dose response test - IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 31205062, Edition Number: M-280528-01-1 Date: 2006-11-17 GLP, unpublished	Yes	Bayer Crop Science	1
KIIIA 10.5.2 /03	Rosenkranz, B.	2007	Effects of BYF 00587 + PTZ EC 75 + 150 G on the lacewing Chrysoperla carnea, extended laboratory study - dose response test - IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 31207047, Edition Number: M-290530-01-1 Date: 2007-07-18 GLP, unpublished	Yes	Bayer Crop Science	1
KIIIA 10.5.2 /04	Moll, M.	2007	Effects of BYF 00587 + PTZ EC 75 + 150 G on the ladybird beetle Coccinella septempunctata, extended laboratory study - dose response test - IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 31206012, Edition Number: M-287283-01-1 Date: 2007-04-30 GLP, unpublished	Yes	Bayer Crop Science	1
KIIIA 10.5.2 /05	Rosenkranz, B.	2008	Effects of BYF 00587 + PTZ EC 75 + 150 G on the predatory mite Typhlodromus pyri, extended	Yes	Bayer Crop Science	1

			laboratory study - aged residue test - IBACON GmbH, Rossdorf, Germany Report No.: 38631060, Edition Number: M-307529-01-1 Date: 2008-09-12 GLP, unpublished			
KIIIA 10.6.2 /01	Luehrs, U.	2006	BYF 00587 + PTZ EC 75 + 150: Acute toxicity (14 days) to the earthworm Eisenia fetida in artificial soil with 5% peat IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 31201021, Edition Number: M-280033-01-1 Date: 2006-11-07 GLP, unpublished	Yes	Bayer Crop Science	1
KIIIA 10.6.3 /01	Luehrs, U.	2006	BYF 00587 + PTZ EC 75 + 150: Effects on reproduction and growth of earthworms Eisenia fetida in artificial soil with 5% peat IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 31202022, Edition Number: M-281333-01-1 Date: 2006-12-18 GLP, unpublished	Yes	Bayer Crop Science	1
KIIIA 10.6.4 /01	Lechelt-Kunze, C.	2002	JAU 6476 EC 250: Effects on the earthworm fauna of grassland area in one year Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: LKC/RGF 58, Edition Number: M-040814-03-1 Date: 2002-02-28 **Amended: 2005-02-02** GLP, unpublished	Yes	Bayer Crop Science	3
KIIIA1 10.6.4 /03	Schulz, L.	2014	Bixafen + Prothioconazole + Tebuconazole EC 275 (75+100+100) G: Effects on earthworms under field conditions	Yes	Bayer Crop Science	1
KIIIA 10.6.6 /01	Luehrs, U.	2007	BYF 00587 + PTZ EC 75 + 150: effects on reproduction of the collembola Folsomia candida in artificial soil with 5% peat IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 31209016, Edition Number: M-291632-01-1 Date: 2007-08-10 GLP, unpublished	Yes	Bayer Crop Science	1
KIIIA 10.6.6 /02	Frommholz, U.	2011	Prothioconazole a.s.: Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil Bayer CropScience,	Yes	Bayer Crop Science	1

			Report No.: FRM-COLL-118/11, Edition Number: M-405273-01-1 Date: 2011-04-12 GLP, unpublished			
KIIIA1 10.6.6 /03	Schulz, L.	2015	Bixafen + Prothioconazole + Tebuconazole EC 275 (75+100+100) G: Effects on Collembola under field conditions	Yes	Bayer Crop Science	1
KIIIA 10.7.1 /01	Reis, K. H.	2006	Effects of BYF 00587 + PTZ EC 75 + 150 G on the activity of the soil microflora in the laboratory IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 31208080, Edition Number: M-281135-01-1 Date: 2006-12-12 GLP, unpublished	Yes	Bayer Crop Science	1
KIIIA 10.8.1.2 /01	Gosch, H.; Nguyen, D. H.	2007	Non-target terrestrial plants: an evaluation of the effects of BYF 00587 + Prothioconazole EC 75 + 150 g/L in the vegetative vigour test (Tier 1) Bayer CropScience, Report No.: VV07/10, Edition Number: M-291578-01-1 Date: 2007-08-14 Non GLP, unpublished	Yes	Bayer Crop Science	1
KIIIA 10.8.1.3 /01	Gosch, H.; Nguyen, D. H.	2007	Non-target terrestrial plants: an evaluation of the effects of BYF 00587 + Prothioconazole EC 75 + 150 g/L in the seedling emergence and growth test (Tier 1) Bayer CropScience, Report No.: SE07/10, Edition Number: M-291576-01-1 Date: 2007-08-14 Non GLP, unpublished	Yes	Bayer Crop Science	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

Reports only studies, which

(a) have not previously been evaluated within a peer reviewed process at EU level (Annex I inclusion of active substance) or

(b) have been evaluated in a peer reviewed process at EU level but where in exceptional cases derived endpoints have to be revised in the light of current scientific and technical knowledge.

Study evaluations are ordered according to OECD code numbers. For the report of study summaries, the applicant should use the OECD study evaluation templates. Indicate if original study evaluation from the notifier is acceptable or not acceptable without revision.

A2-1 Prothioconazole (generally only relevant in the case that new annex II data is provided after Prothioconazole approval)

IIA 8.2 Fish toxicity

Reference:	KIIA 8.2.1.3
Report	**XXX** Acute Toxicity of JAU 6476-triazolylketone (tech.) to Fish (*Oncorhynchus mykiss*) under Static Conditions, report No: EBJAX306, document No: M-266572-01-1 ICS No. 70491
Guideline(s):	Yes (OECD Guideline 203 (rev. 1992) EU Directive 92/69/EEC, C.1 (1992))
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No [No indicates that original study evaluation of the applicant was acceptable without any correction by the zRMS and therefore no commenting box is necessary]

Objective

A limit test at 100 mg/L was performed in order to show that fish (Rainbow trout) were not affected at this test level by the metabolite.

Materials 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.

Results and discussions

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.

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.

Comments of zRMS

Study Comments:	
Agreed Endpoints:	NOEC (4 d) = 100 mg a.s./L LC50 (4 d) > 100 mg a.s./L

Reference:	KIIA 8.2.4
Report	**XXX** Early life stage toxicity of prothioconazole technical to the rainbow trout (Oncorhynchus mykiss) under flow through conditions, report No: EBJAX313, document No: M-291414-01-1 ICS No. 70485
Guideline(s):	Yes (FIRA Guideline 72-4 OPPTS Guideline 850.1400 (draft) OECD Guideline 210)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	Yes [Yes indicates that study evaluation was corrected. In this case the relevant corrections of the original study evaluation by the applicant should be indicated in the commenting box.]

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.

Results and discussions

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/ollembolan effects)			

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/ollembolan effects. The maximum acceptable toxicant concentration (MATC) was 0.68 mg as/L.

Comments of zRMS

Study Comments:	Formally this test is not valid, due to non-compliance with the validity criteria for hatching (> 66%). Hatching in controls has only been 63 %. Since this problem seems to be species specific for rainbow trout this study is even though considered as valid.

Agreed Endpoints:	NOEC (91 d) = 0.49 mg a.s./L LOEC (91 d) = 0.94 mg a.s./L

IIA 8.3 Toxicity to aquatic species other than fish and aquatic species field testing

Reference:	KIIA 8.3.1
Report	Bruns, E., 2006, Acute Toxicity of JAU 6476-Triazolylketone (tech.) to the Waterflea *Daphnia magna* in a Static Laboratory Test System, report No: EBJAX305, document No: M-266597-01-1 ICS No. 70489
Guideline(s):	Yes (OECD Guideline 202 (1984) and corresponding revised draft proposal, dated February 01, 2004)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	Yes [Yes indicates that study evaluation was corrected. In this case the relevant corrections of the original study evaluation by the applicant should be indicated in the commenting box.]

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 ollembolanon.

Materials and methods

JAU 6476-triazolylketone (tech.), purity 99.5%, identified as batch HSRM 595; *Daphnia magna* (1^{st} 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.

Results and discussions

During 48 hours of static exposure, no immobilities occurred at or below the highest tested concentration of 100 mg pure metabolite/L.

Only 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.

Conclusion

Acute 48 hours static exposure of juvenile *Daphnia magna* to JAU 6476-triazolylketone (tech.) in aqueous solution revealed no ollembolanon 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 ollembolanon after 48 hours of static exposure were located above 100 mg pure metabolite/L.

Comments of zRMS [Commenting box]

Study Comments:	zRMS does not agree with the derived NOEC.
Agreed Endpoints:	NOEC (2 d) = 45.2 mg a.s./L (behaviour) LOEC (2 d) = 100 mg a.s./L (immobilisation and behaviour) LC50 (2 d) > 100 mg a.s./L (immobilisation)

IIA 8.4 Effects on algal growth and growth rate

Reference:	KIIA 8.4
Report	Dorgerloh, M, 2006, *Pseudokichneriella subcapitata:* Growth Inhibition Test with Prothioconazole-triazolylketone, report No: EBJAX304, document No: M-266567-01-1 ICS No. 70487
Guideline(s):	Yes (Draft Proposal for Updating OECD Guideline 201 (October 22, 2004))
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No [No indicates that original study evaluation of the applicant was acceptable without any correction by the zRMS and therefore no commenting box is necessary]

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).

Materials 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.

Results and discussions

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.

Conclusion

JAU 6476-triazolylketone has no significant toxic effects at concentrations up to nominal 100 mg/L to *Pseudokirchneriella subcapitata.*

Comments of zRMS

Study Comments:	
Agreed Endpoints:	NOErC (3 d) > 100 mg a.s./L NOEbC (3 d) > 100 mg a.s./L ErC50 (3 d) > 100 mg a.s./L EbC50 (3 d) > 100 mg a.s./L

Reference:	KIIA 8.4
Report	Kern, M.E., De Haan, R.A., 2004, Toxicity of JAU 6478 Technical to the Saltwater Diaton *Skeletonema Costatum*, report No: EBJAX076 (J6883601), document No: M-000954-01-1 ICS No. 69032
Guideline(s):	Yes (FIFRA Guideline 123-2)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	Yes [Yes indicates that study evaluation was corrected. In this case the relevant corrections of the original study evaluation by the applicant should be indicated in the commenting box.]

Materials and methods

JAU 6476 technical, Batch Number 6233*0031, 98.2% a.i. purity. *Skeletonema costatum* were exposed under static conditions (shaken cultures) for approximately 96 hours to the following nominal concentrations (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 (ppb).

Results and discussions

Toxicity to algae:

Test substance	JAU 6476
Test objectcontrol	*Skeletonema costatum*
Exposure	96 hour, static
96-h – cell density 96-h – cumulative biomass 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 – cumulative biomass 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 (cumulative biomass)
96-h Highest Concentration without Toxic Effect (NOEC)	7.3 µg a.i./L (cumulative biomass)
96-h Toxic Threshold Effect Concentration, TEC(Geometric mean of NOEC and LOEC)	11.3 µg a.i./L (cumulative biomass)

No physical abnormalities were observed in the controls or treatment groups during the study. The lowest NOEC, LOEC and TEC were determined wit hthe cumulative biomass end point.

Conclusion

Based on regression calculat5ions, cumulative biomass is the most sensitive endpoint to exposure to JAU 6476. The 96-hour EC50 and EC25 values for biomass were 20.1 µg a.i./L and 13.8 µg a.i./L, respectively, based on cumulative biomass. The 96-hour toxic threshold effect concentration (TEC – the geometric mean of the NOEC and LOEC) is 11.3 µg a.i./L.

Comments of zRMS

Study Comments:	zRMS only considers the 72-h (3d) values relevant.
Agreed Endpoints:	EbC50 (72 h) = 0.018 mg a.i./L, based on cell density EbC50 (72 h) = 0.0171 mg a.i./L, based on biomass ErC50 (72 h) = 0.0456 mg a.i./L, based on growth rate

IIA 8.5 Effects on sediment dwelling organisms

Reference:	KIIA 8.5.2
Report	Bruns, E., 2006, *Chironomus riparius* 28-day Chronic Toxicity Test with JAU 6476-S-Methyl in a Water-Sediment System using Spiked Water, report No: EBJAX303, document No: M-266605-01-1 ICS No. 70238
Guideline(s):	Yes (OECD Guideline 219 (adopted 13 April 2004))
Deviations:	No

GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No [No indicates that original study evaluation of the applicant was acceptable without any correction by the zRMS and therefore no commenting box is necessary]

Materials 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.

Results and discussions

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.

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.

Conclusion

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

Comments of zRMS

Study Comments:	
Agreed Endpoints:	NOEC (28 d) = 0.1 mg a.s./L (emergence and development) EC50 (28 d, emergence) = 1.41 mg a.s./L EC50 (28 d, development) = > 10 mg a.s./L

IIA 8.6 Effects on aquatic plants. Analytical data on concentrations in the test media

Reference:	KIIA 8.6
Report	Kern, M.E., Banman, C.S., Lam, C.V., 2004, Toxicity of JAU 6476 Technical to Duckweed (*Lemna gibba* G3) Under Static-Renewal Conditions, report No: EBJAY002 (J6883701), document No: M-000532-01-1 ICS No. 69854
Guideline(s):	Yes (U.S. EPA 1996. Series 850 – Ecological Effects test Guideslines (*draft*), OPPTS Number 850.4400)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No [No indicates that original study evaluation of the applicant was acceptable without any correction by the zRMS and therefore no commenting box is necessary]

Materials and methods

JAU 6476 Technical: 98.2% a.i., Batch number 6233/0031; the duckweed *Lemna gibba* G3 was exposed for 7 days under static-renewal conditions (solutions were renewed on day 3 and day 5). Nominal concentrations (mean measured of Day 0 and Day 5) were control (<0.5), solvent control (<0.5), 0.97 (1.01), 3.24 (3.34), 10.8 (10.4), 36.0 (35.1), 120 (106.4) and 400 (404.0) µg a.i./L. Growth was determined by frond counts on days 0, 3, 5, and 7.

Results and discussions

Observations made on Day 5 and Day 7 showed treatment related effects with regards to frond size at the 35.1, 106.4 and 404.0 µg a.i./L treatment levels. Observations on Day 7 showed treatment related effects with regard to frond color at the 35.1, 106.4 and 404.0 µg a.i./L.

Conclusion

The NOEC and LOEC in the 7-day exposure of *Lemna gibba* G3 to JAU 6476 technical were 3.34 and 10.4 µg a.i./L, respectively for the standing crop and cumulative biomass endpoints. Based on the EC50

values, the most sensitive endpoint was standing crop. The EC25 and EC50 for this endpoint were 15.6 and 74.0 µg a.i./L, respectively.

Comments of zRMS [Commenting box]

Study Comments:	
Agreed Endpoints:	NOEC (7 d) = 0.00334 mg a.s./L (biomass) EC50 (7 d) = 0.074 mg a.s./L (dry weight) EbC50 (7 d) = 0.404 mg a.s./L (biomass)

Reference:	KIIA 8.6
Report	Kern, M.E., Banman, C.S., Lam, C.V., 2003, Toxicity of JAU 6476-Desthio to Duckweed (*Lemna gibba* G3) Under Static-Renewal Conditions, report No: EBJAX084 (J6883702), document No: M-104599-01-1 ICS No. 65917
Guideline(s):	Yes (U.S. EPA 1996. Series 850 – Ecological Effects test Guideslines (*draft*), OPPTS Number 850.4400)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No [No indicates that original study evaluation of the applicant was acceptable without any correction by the zRMS and therefore no commenting box is necessary]

Materials and methods

JAU 6476-Desthio, purity 97.0% metabolite, Batch number RUX76-105/a; the duckweed *Lemna gibba* G3 was exposed for 7 days under static-renewal conditions (solutions were renewed on day 3). Nominal concentrations (mean measured of Day 0, Day 3 and Day 7 solutions) were control (<0.5), solvent control (<0.5), 2.56 (2.42), 6.40 (5.78), 16.0 (14.3), 40.0 (35.6), and 100 (89.8) µg metabolite/L. Growth was determined by frond counts on days 0, 3, 5, and 7.

Results and discussions

Effects on aquatic plants:

Test substance	JAU 6476-Desthio
Test Object	*Lemna gibba* G3
Exposure	7-day, static-renewals
7-day EC50 – standing crop	39.4 µg metabolite/L
7-day EC50 – growth rate	80.9 µg metabolite /L
7-day EC50 – cumulative biomass	56.8 µg metabolite /L
7-day EC50 – frond dry weight	41.1 µg metabolite /L
Lowest Concentration With an Effect (LOEC)	14.3 µg metabolite /L (All Endpoints)
Highest Concentration Without Toxic Effect (NOEC)	5.8 µg metabolite /L (All Endpoints)
Toxic Threshold Effect Concentration, TEC (Geometric mean of NOEC and LOEC)	9.1 µg metabolite /L (All Endpoints)

Observations made on Day 0 and Day 3 showed no treatment related effects in terms of plant appearance. Reduced frond size was observed at the 16.0 µg metabolite/L on Day 7 and on Days 5 and 7 at 40.0, and 100 µg metabolite/L levels.

Conclusion

The NOEC and LOEC in the 7-day exposure of *Lemna gibba* G3 to JAU 6476-Desthio were 5.8 and 14.3 µg metabolite/L, respectively for all endpoints. Based on the EC50 values, the most sensitive endpoint was standing crop. The EC25 and EC50 for this endpoint were 17.1 and 39.4 µg metabolite/L, respectively.

Comments of zRMS

Study Comments:	
Agreed Endpoints:	NOEC (7 d) = 0.0058 mg a.s./L (all endpoints) EC50 (7 d) = 0.0411 mg a.s./L (dry weight) EbC50 (7 d) = 0.0568 mg a.s./L (biomass) ErC50 (7 d) = 0.0809 mg a.s./L (growth rate)

IIA 8.9 Effects on earthworms and other soil macro-organims

Reference:	KIIA 8.9.3
Report	Frommholz, U., 2011, Prothioconazole a.s.: Influence on the reproduction of the collembolan species *Folsomia candida* tested in artificial soil., report No: FRM-COLL-118/11, document No: M-405273-01-1 ICS No. 41072
Guideline(s):	Yes (OECD 232, September 7, 2009)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No [No indicates that original study evaluation of the applicant was acceptable without any correction by the zRMS and therefore no commenting box is necessary.]

Materials 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.

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 (Will'am'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.

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 %

All validity criteria were met. Therefore this study is valid.

Conclusion

$NOEC_{reproduction}$ ≥1000 mg test item/kg artificial soil dry weight.

$LOEC_{reproduction}$ >1000 mg test item/kg artificial soil dry weight.

Comments of zRMS [Commenting box]

Study Comments:	
Agreed Endpoints:	NOEC (28 d) ≥ 1000 mg a.s./kg soil dw, related to reproduction

A2-2 Formulation

IIIA 10.2 Effects on aquatic organisms

IIIA 10.2.2.1 Fish acute toxicity LC_{50}, freshwater, cold-water species

Report:	**KIIIA 10.2.2.1/01, XXX; 2007**
Title:	Acute toxicity of BIX+PTZ EC 225 (75+150) G to fish *Oncorhynchus mykiss* under static conditions
Document No:	M-293311-02-1
Guidelines:	EPA-FIFRA § 72-1/SEP-EPA-540/9-85-006 (1982/1985); OPPTS 850.1075 (Public Draft, 1996); EU Directive 92/69/EEC, C.1 (1992); OECD No. 203 (rev.1992)
GLP:	Yes (certified laboratory)

Objective:
The aim of the study was to determine the acute toxicity of the test item to Rainbow trout (*Oncorhynchus mykiss*), expressed as 96h-LC_{50} for mortality.

Material and methods:
Test item: BIX+PTZ EC 225 (75+150) G, product code: BIX+PTZ EC 225 (75+150) G); analyzed a.s. contents: Bixafen 7.7% (77.2 g/L, 75 g/L nominal); Prothioconazole 14.7% (147 g/L; 150 g/L nominal) specified by batch no.: 2007-002622, tox no.: 07852-00, specification no.: 102000013869.
Test organism: Rainbow trout (*Oncorhynchus mykiss*), mean body length 4.3 cm, mean body weight 0.7 g. Lot F 10/07 was delivered on July 20, 2007. The biomass loading during testing was 0.18 g fish/ L test medium.
Ten fish in each test level were exposed for 96 h under static conditions to nominal concentrations of 0, 0.313, 0.625, 1.25, 2.50 and 5.00 mg test item / L. Dissolved oxygen concentrations ranged from 91.4 to 98.4 % oxygen saturation, the pH values ranged from 6.8 to 7.2 and the water temperature ranged from 11.6°C to 12.3°C in all aquaria over the whole testing period. Bixafen was analyzed in all test levels after 0 h, on day 2 and on day 4 of the exposure period to confirm nominal concentrations. In the event that 100% mortality was observed in test concentrations prior to the end of the test, the analytical determinations were made at those times.

Findings:
The test conditions met all validity criteria, given by the mentioned guidelines: Less than 5% mortality within the 48-hour settling-in period and < 10% mortality in the control(s) (or one fish if less than ten are used). Dissolved oxygen saturation > 60% throughout the test (see) and pH variation < 1.0 units.
Accompanying chemical analysis of bixafen revealed recoveries between 83% and 107% (mean) of nominal values over the entire test period of 96 hours. As the toxicity has to be attributed to the tested formulation as a whole, all results are related to nominal test concentrations of the formulated product.

Observations:
There were neither any sub-lethal effects nor any mortality in the control group. There were no behavioural observations on fish caused by the test item over the whole exposure period in all test levels < 0.313 mg test item / L. At the test level of 0.625 mg test item / L fish showed the following symptoms after 96h:
• remained for unusually long periods on the bottom of the aquarium
• turned dark in coloration

Conclusions:

Based on nominal concentrations, the 96 h LC_{50} was calculated by probit analysis to be 1.55 mg test item / L (C.I. 95%: 1.29 - 1.87 mg / L). The NOEC (highest concentration without sub-lethal effects) is considered to be 0.313 mg test item / L.

The minimum concentration causing 100% mortality (96 h) is 2.50 mg test item / L. The maximum concentration, which did not cause any mortality (no-observed-lethal-effect concentration = NOLEC) after 96h, is 0.625 mg test item / L.

Comments of zRMS

Study Comments:	
Agreed Endpoints:	96 h LC_{50}= 1.55 mg test item / L

IIIA 10.2.2.2 Acute toxicity (24 & 48 h) for Daphnia preferably Daphnia magna

Report:	**KIIIA 10.2.2.2/01, Bruns E.; 2007**
Title:	Acute toxicity of BYF 00587 & Prothioconazole EC 075+150 to the waterflea *Daphnia magna* in a static laboratory test system
Document No:	M-288432-01-1
Guidelines:	OECD guideline 202,(2004); EEC Directive 92/69/EWG, part C.2 (1992); U.S. EPA Pesticide Assessment Guidelines, Subdivision E, § 72 2 (1982); OPPTS Guideline 850.1010 public draft 1996 (modified); JMAFF 12 Nousan No. 8147 (2000)
GLP:	yes (certified laboratory)

Objective:
The objective of the study was a determination of possible effects of the test item on the mobility of Daphnia magna caused by 48 hours of exposure in a static laboratory test system, expressed as EC50 for immobilisation.

Material and methods:
Test item: BYF 00587 & Prothioconazole EC 075+150; batch 2006-001178, specification No.: 102000013869), a.s. content: 7.49% w/w BYF00587, 14.8% w/w JAU6476 (TOX 07660-00).
Test organism: *Daphnia magna*, 1st instars < 24 h old.
6 x 5 daphnids per concentration were exposed in a static test system for 48 hours to nominal concentrations of 0, 1, 2, 4, 8 and 16 mg formulation/L without feeding. Contents of BYF 00587 in the exposure media were measured for verification of the exposed test item concentrations.
Findings:
The test conditions met all validity criteria, given by the mentioned guidelines: ≤ 10.0% mortality in the control(s).
The chemical analysis of BYF00587 in the freshly prepared test solutions at test initiation revealed concentrations between 103% and 107% (mean: 105%) of the corresponding nominal concentrations. The corresponding concentrations of the aged test solutions at the end of the 48 hours exposure period ranged between 92% and 103% (mean: 101%) of nominal. No contaminations of BYF00587 were detected in

samples from untreated water control. As the toxicity has to be attributed to the tested formulation as a whole, all results are related to nominal test concentrations of the formulated product.

Conclusions:
Based on nominal concentrations of BYF 00587 + Prothioconazole EC 075+150, the following EC_{50} for immobilisation after 24 and 48 hours of static exposure were found:

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	7.7	n.d.	n.d.
48 hours	3.0	n.d.	n.d.

n.d.= not determined due to mathematical reasons

Comments of zRMS

Study Comments:	
Agreed Endpoints:	EC_{50}= 7.7mg test item / L (24 h) EC_{50}= 3.0mg test item / L (48 h)

IIIA 10.2.2.3 Effects on algal growth and growth rate

Report:	**KIIIA 10.2.2.3/01, Dorgerloh M.; 2007**
Title:	*Pseudokirchneriella subcapitata* growth inhibition test with bixafen & prothioconazole EC 225 (75 + 150) G
Document No:	M-289495-01-1
Guidelines:	OECD Guideline 201: "Freshwater Alga and Cyanobacteria, Growth Inhibition Test" (March 23, 2006)
GLP:	yes (certified laboratory)

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 EC_x for growth rate of algal biomass (cells per volume).

Material and methods:
Test item: Bixafen + Prothioconazole EC 75 + 150; analysed a.s. contents: Bixafen: 7.49% and Prothioconazole: 14.8% was tested, specified by batch ID: 2006-001178, sample description: TOX07660-00 and specification no.: 102000013869.
Test organism: *Pseudokirchneriella subcapitata* (freshwater microalgae, formerly known as *Selenastrum capricornutum*).

Algae were exposed in a chronic multigeneration test for 3 days under static exposure conditions to the nominal concentrations of 0, 0.162, 0.404, 1.01, 2.53 and 6.32 mg formulation/L. The pH values ranged

from 7.9 to 8.1 in the controls and the incubation temperature ranged from 21.7°C to 22.2°C (measured in an additional incubated glass vessel) over the whole period of testing at a continuous illumination of 6956 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: Biomass increased in the control more than 16-fold within the evaluation period, the percent coefficient of variation of sectional growth rates from day 0-1, day 1-2, and day 2-3 in the control did not exceed 35%, the percent coefficient of variation of the average growth rate in each control replicate did not exceed 7% and pH values in the control did not increase by more than 1.5 units.

The analytical findings of bixafen in the treatment levels found on day 0 were 94 to 100% of nominal (average 98.2%). On day 3 analytical findings of 93 to 101% of nominal (average 98.4%) were found. Given that the toxicity cannot be attributed to anyone of the a.s. compounds but to the formulation as a whole, all results are based on nominal test concentrations of the formulation.

Conclusions:
The (0 - 72h)-E_rC_{50} for Bixafen + Prothioconazole EC 75 + 150 is 1.52 mg formulation/L (95% CI: 1.07-2.21 mg form./L). The (0 - 72h)-E_bC_{50} for Bixafen + Prothioconazole EC 75 + 150 is 0.549 mg formulation/L.

Comments of zRMS

Study Comments:	
Agreed Endpoints:	EbC_{50}= 0.549 mg test item / L

IIIA 10.3.3 Supervised cage or field trials or other appropriate studies

Report:	**KIIIA 10.3.3/01, Neumann P.; 2009**
Title:	JAU 6476-desthio: Residue formation and dissipation rate as determined in plant residue studies for use in ecotoxicological risk assessments
Document No:	M-348996-01-1
Guidelines:	Not applicable
GLP:	No

Prothioconazole (JAU 6476) is applied up to 3 times with single application rates of 0.2 kg a.s./ha in cereals. After the application the metabolite JAU 6476-desthio (M04) is formed in a substantial amount on plants. Due to this formation a risk assessment for exposure of herbivorous birds and mammals to JAU 6476-desthio is required in dossiers for plant protection products that contain the active ingredient prothioconazole.

The aim of this evaluation was to review results from plant residue studies conducted under field conditions after application of prothioconazole, in order to derive the following parameter for use in refined risk assessments on herbivorous birds and mammals:

- Formation of JAU 6476-desthio: the maximum residue concentration of the metabolite formed on the crop after application of prothioconazole corresponded with a mean **conversion factor of 29.9% of the initial total residues.**
- Dissipation of JAU 6476-desthio on plants: a **mean DT_{50} of 3.2 d** was determined.
- Since most of the evaluated results were generated after at least 2 applications, there is **no need for an additional multi-application factor (MAF)** in the exposure estimation

IIIA 10.4 Effects on bees

IIIA 10.4.2 Acute toxicity of the preparation to bees

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. (2007): Effects of BYF 00587 + PTZ EC 75 + 150 (Acute Contact and Oral) on Honey Bees (*Apis mellifera* L.) in the Laboratory. Project: 31203035. IBACON GmbH, Rossdorf, Germany.
Document No:	31203035
Guidelines:	OECD 213 and 214
GLP	Yes

Materials and Methods

Test species:	worker honey bees *Apis mellifera* L.
Test substance:	BYF 00587 + PTZ EC 75 + 150; Batch ID.: 2006-001178, a.s. content: BYF 00587: 75 g/L (nominal), 75.3 g/L (7.49% w/w) (analytical), prothioconazole (JAU 6476): 150 g/L (nominal), 149 g/L (14.8% w/w) (analytical)
Control:	contact test: tap water + Adhasit treated control (applied after anesthetization with CO2) oral test: 50% aqueous sugar solution (in tap water)
Toxic standard:	Perfekthion EC (BAS 152111); dimethoate: 400 g/L
Doses:	oral: 100 µg test substance/bee contact: 100 µg test substance/bee
Bees per dose:	10
Replicates:	5

Exposure: 48 h

Oral toxicity study:
In a limit test, five replicates of 10 bees per group were fed with a sugar/water solution containing BYF 00587 + PTZ EC 75 + 150 at a measured level of 106.2 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, temperature was 24-25°C and humidity between 68 and 81%. Biological observations including mortality and behavioural changes were recorded at 4, 24 and 48 hours after dosing. Results are based on measured concentrations of the product per bee.

Contact toxicity study:
In a limit test, five replicates of 10 bees per group were exposed to BYF 00587 + PTZ EC 75 + 150 (dissolved in tap water + 0.5 % Adhaesit), administered topically in a 5 □L-droplet to the thorax of each bee, at a nominal level of 100 µg a.s./bee. For the control tap water containing 0.5 % Adhaesit was used. Dimethoate made up in tap water containing 0.5 % Adhaesit was used as toxic standard. The test was conducted in darkness; temperature was 24-25°C and humidity between 68 and 81%. Biological observations, including mortality and behavioural changes were recorded at 4, 24 and 48 hours after application. Results are based on nominal concentrations of the product per bee.

Findings

At the end of the contact toxicity test (48 hours after application), there was 6.0% mortality at 100.0 µg product/bee. No mortality occurred in the control (water + 0.5 % Adhaesit).
During the 4-hours assessment in the contact test up to 13 bees (26%) were behaving abnormal (uncoordinated movement). Thereafter, during the other assessments no more behavioural impairments occurred.
In the oral toxicity test the maximum nominal test level of BYF 00587 + PTZ EC 75 + 150 (100 µg product/bee) corresponded to an actual intake of 106.2 µg product/bee. This dose level led to 2.0% mortality after 48 hours. No mortality occurred in the control (50% sugar solution). 4 hours following the test item treatment, some of the bees showed uncoordinated movements or they were apathetic. These behavioural abnormalities could not be observed during the 24 and 48-hours assessment.

The results can be considered as valid, as all validity criteria of the test were met: control mortality is 0% for both tests, LD50 (24 h) of the toxic standard in the oral test equals 0.13 µg as/bee, LD50 (24 h) of the toxic standard in the contact test equals 0.12 µg as/bee.

Conclusions

The LD50 (48 h) was > 100.0 µg product/bee in the contact toxicity test and > 106.2 µg product/bee in the oral toxicity test.

IIIA 10.4.2.1 Oral

Refer to IIIA 10.4.2.

IIIA 10.4.2.2 Contact

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 into 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 tests

Not required.

IIIA 10.5.2 Effects on non-target terrestrial arthropods in extended laboratory tests

Report:	**KIIIA 10.5.2/01, Moll M.; 2007**
Title:	Effects of BYF 00587 + PTZ EC 75 + 150 G on the Parasitoid *Aphidius rhopalosiphi*, Extended Laboratory Study – Dose Response Test
Document No:	M-282592-01-1
Guidelines:	Mead-Briggs et al. 2000, Mead-Briggs et al. 2006
GLP:	yes (certified laboratory)

Objective:
The aim of the study was to determine the effects of freshly dried residues of BYF 00587 + PTZ EC 75 + 150 G applied onto barley seedlings to the parasitoid wasp *Aphidius rhopalosiphi*.

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%.

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).

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 to *Aphidius rhopalosiphi* is 4288 mL product/ha (95% confidence limits were not determinable due to mathematical reasons) according to the Probit-Analysis. This result might be a mathematical artefact, because the data are not really suitable for a dose response calculation. An estimation of the LR_{50} directly from the mortality results would lead to the assumption that this value should be close to, but not be greater than 3750 mL product/ha, where the corrected mortality was 53.3 % at this dose rate.

Comments of zRMS

Study Comments:	
Agreed Endpoints:	LR50 ca. 3,75 L Pr./ha ER50 > 3,75 L Pr./ha

Report:	**KIIIA 10.5.2/02, Moll, M.; 2006**
Title:	Effects of BYF 00587 + PTZ EC 75 + 150 G on the Predatory Mite *Typhlodromus pyri*, Extended Laboratory Study – Dose Response Test
Document No:	M-280528-01-1
Guidelines:	Bluemel *et al*., 2000: Laboratory residual contact test with the predatory mite *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae) for regulatory testing of plant protection products; Oomen 1988: Guideline for the evaluation of side-effects of pesticides on *Phytoseiulus persimilis* A.-H.
GLP:	yes (certified laboratory)

Objective:
The aim of the study was to determine the toxicity of freshly dried residues of BYF 00587 + PTZ EC 75 + 150 G applied onto detached bean leaves, to the predatory mite *Typhlodromus pyri*.

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.

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).

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).

Comments of zRMS

Study Comments:	
Agreed Endpoints:	LR50 =. 1,30 L Pr./ha ER50 > 1,00 L Pr./ha Mortality Reproduction

Report:	**KIIIA 10.5.2/03, Rosenkranz B.; 2007**
Title:	Effects of BYF 00587 + PTZ EC 75 + 150 G on the Lacewing *Chrysoperla carnea*, Extended Laboratory Study
Document No:	M-290530-01-1
Guidelines:	Vogt *et al*., 2000: Laboratory method to test effects of plant protection products on larvae of *Chrysoperla carnea* (Neuroptera: Chrysopidae)
GLP:	yes (certified laboratory)

Objective:
The aim of the study was to determine the toxicity of freshly dried residues of BYF 00587 + PTZ EC 75 + 150 G applied onto detached bean leaves, to the Lacewing *Chrysoperla carnea.*

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.

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).

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.

Comments of zRMS

Study Comments:	
Agreed Endpoints:	LR50 > 3,75 L Pr./ha ER50 > 3,75 L Pr./ha

Report:	**KIIIA 10.5.2/04, Moll M.; 2007**
Title:	Effects of BYF 00587 + PTZ EC 75 + 150 G on the Ladybird Beetle *Coccinella septempunctata*, Extended Laboratory Study - Dose Response Test
Document No:	M-287283-01-1
Guidelines:	Schmuck et al. 2000; this guideline was modified for exposure of *Coccinella septempunctata* on natural substrate
GLP:	yes (certified laboratory)

Objective:
The aim of the study was to determine the toxicity of freshly dried residues of BYF 00587 + PTZ EC 75 + 150 G applied onto detached bean leaves, to the Ladybird Beetle *Coccinella septempunctata.*

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.

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).

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 et 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).

Comments of zRMS

Study Comments:	
Agreed Endpoints:	LR50 =. 3,39 L Pr./ha ER50 > 2,17 L Pr./ha

Report:	**KIIIA 10.5.2/05, Rosenkranz B.; 2008**
Title:	Effects of BYF 00587 + PTZ EC 75 + 150 G on the predatory mite *Typhlodromus pyri*, Extended Laboratory Study – Aged residue test
Document No:	M-307529-01-1
Guidelines:	Bluemel *et al.*, 2000, Oomen, 1988
GLP:	yes (certified laboratory)

Objective:
The purpose of this study was to determine the duration and extend of effects of fresh dried or field aged residues of BYF 00587+PTZ EC 75+150G applied to bean plants on the predatory mite *Typhlodromus pyri* Scheuten in the laboratory. Therefore, different bioassays were started after different aging intervals of the residues on the bean plants. Additionally, an assessment for significant sub-lethal effects (reproduction assessment) was done.

Materials and methods:
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 (< 24 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 per 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.

Findings:
The results can be considered as valid, as all validity criteria of the test were met. The control mortality was ≤ 20%, the corrected mortality in the reference item was > 50% (75.3% in this study) and the number of eggs per female in the control group was ≥ 4.

Conclusion:

The duration and the extent of effects of fresh dried and aged residues of BYF 00587+PTZ EC 75+150G applied on oil seed rape 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.

Comments of zRMS

Study Comments:	
Agreed Endpoints:	LR50 > 3x 1,25 L Präp./ha

	ER50 > 3x 1,25 L Präp./ha

IIIA 10.5.3 Effects on non-target terrestrial arthropods in semi-field tests

IIIA 10.6 Effects on earthworms and other soil macro-organisms

Report:	**KIIIA 10.6.2/01, Luehrs U.; 2006**
Title:	BYF 00587 + PTZ EC 75 + 150: Acute Toxicity (14 Days) to the Earthworm *Eisenia fetida* in Artificial Soil with 5% Peat
Document No:	M-280033-01-1
Guidelines:	OECD No. 207 "Earthworm, Acute Toxicity Tests" (adopted April 4, 1984); ISO-Guideline 11268-1: 1993 "Soil quality - Effects of pollutants on earthworms (*Eisenia fetida*)- Part 1: Determination of acute toxicity using artificial soil substrate"
GLP:	yes

Objective:
The aim of the study was to determine the acute toxicity of BYF 00587 + PTZ EC 75 + 150 to the earthworm *Eisenia fetida*.

Materials and Methods:
Test item: BYF 00587 + PTZ EC 75 + 150, Batch ID: 2006-001178; a.s. contents: BYF 00587: 75 g/L (nominal), 75.3 g/L (7.49 % w/w) (analytical); Prothioconazole (JAU 6476): 150 g/L (nominal), 149 g/L (14.8 % w/w) (analytical).
Reference Item: 2-Chloroacetamide is tested at least once a year in a dose response study.
Control: untreated and moistened with deionised water.
Test organism: adult earthworms (*Eisenia fetida)*, 11-12 months old and with clitellum.

BYF 00587 + PTZ EC 75 + 150 was mixed into the soil at 62.5, 125, 250, 500 and 1000 mg test item/kg artificial soil (dry weight) (containing approx.74.8% quartz sand, 20% kaolinite clay, 5% sphagnum peat and approx. 0.2% CaCO3) to which earthworms (4 replicates with 10 worms per treatment group) were exposed for 14 days at 19 - 21°C and continuous illumination with a light intensity of 420 - 800 lux. The worms were not fed during the study.
The test vessel size was 1 L; containing about 500 g dry artificial soil. The initial soil water content was 54.3% to 57.5% of the maximum water holding capacity, the water content at experimental termination 50.3% to 53.5% of the maximum water holding capacity. The initial pH was 5.5 to 5.6 and the pH at experimental termination5.6 to 5.7.
Mortality and behavioural abnormalities were assessed at day 7 and 14 and body weight at day 0 and 14.

Findings:
The results can be considered as valid, as all validity criteria of the test were met. Mortality in the control was ≤ 10% (0% in this study) and mean loss of biomass in the control was ≤ 20% (9.4% in this study).

Observations:

Short termed behavioural effects were observed at the concentration of 1000 mg test item/kg soil dry weight as worms were lethargic after 7 days of exposure but this effect could not be observed after 14 days of exposure.
Mortality was zero or not significantly different compared to the control up to and including the highest concentration of 1000 mg test item/kg soil.
Additionally, body weight changes of the earthworms were also not significantly different compared to the control up to and including the highest concentration of 1000 mg test item/kg soil.

Conclusion:
In a 14-days toxicity study with BYF 00587 + PTZ EC 75 + 150 to earthworms (*Eisenia fetida*) the LC_{50} was determined to be greater than 1000 mg test item/kg soil dry weight.
The No Observed Effect Concentration (NOEC) related to mortality and biomass was determined to be 1000 mg test item/kg soil dry weight.
The study is considered to represent worst case laboratory conditions.

Comments of zRMS

Study Comments:	
Agreed Endpoints:	NOEC = 1000 mg test item/kg soil dry weight

Report:	**KIIIA 10.6.3/01, Luehrs U.; 2006**
Title:	BYF 00587 + PTZ EC 75 + 150: Effects on Reproduction and Growth of Earthworms *Eisenia fetida* in Artificial Soil with 5% Peat
Document No:	M-281333-01-1
Guidelines:	OECD, Nr. 222 "Earthworm, Reproduction Test" (adopted April 13, 2004); ISO-Guideline 11268-2, "Soil quality - Effects of pollutants on earthworm (*Eisenia fetida*) - Part 2: Determination of effects on reproduction", 1998
GLP:	Yes

Objective: The aim of the study was to determine the effects of BYF 00587 + PTZ EC 75 + 150 on the reproduction and growth of the earthworm *Eisenia fetida*.

Materials and Methods: Test item: BYF 00587 + PTZ EC 75 + 150, Batch ID: 2006-001178; a.s. contents: BYF 00587: 75 g/L (nominal), 75.3 g/L (7.49 % w/w) (analytical); Prothioconazole (JAU 6476): 150 g/L (nominal), 149 g/L (14.8% w/w) (analytical).
Reference Item: Brabant Carbendazim Flowable (500 g/L) (active ingredient carbendazim) is tested at least once a year in a dose response study.
Control: sprayed with deionised water.
Test organism: adult earthworms (*Eisenia fetida)*, approximately 11 months old and with clitellum

BYF 00587 + PTZ EC 75 + 150 was sprayed onto artificial soil (dry weight) (containing approx.74.8% quartz sand, 20% kaolinite clay, 5% sphagnum peat and approx. 0.2% $CaCO_3$) at rates corresponding to 4.688, 9.375, 18.75, 37.5 and 75 L test item/ha to which earthworms were exposed at 19°C - 23°C, a photoperiod of 16 h light: 8 h dark and a light intensity of 540 - 800 lux. Four replicates with

10 earthworms were used per treatment group and 8 replicates with 10 earthworms for the control. Earthworms were fed weekly with dried cattle manure.
The test vessel size was 18.3 cm x 13.6 cm x 6 cm; containing about 500 g dry artificial soil.
The initial soil water content was 51.8% to 52.8% of the maximum water holding capacity; the water content at experimental termination 58.8% to 63.8% of the maximum water holding capacity. The initial was pH 5.8, the pH at experimental termination 5.8 -6.1.
Assessed endpoints were mortality (at day 28), body weight change (at day 28), feeding activity and reproduction (after 8 weeks).

Findings: The results can be considered as valid, as all validity criteria of the test were met. Mortality in the control was ≤ 10% (0% in this study), reproduction of the control was ≥ 30 worms per container (203-391 worms in this study) and the coefficient of variation of reproduction in the control was ≤ 30% (18.3% in this study).

Observations: No mortality and no behavioural abnormalities were observed in any treatment group and none of the body weight changes of the test item treated groups were significantly different compared to the control (Dunnett test, $\alpha = 0.05$, two sided).

But in UBA test evaluation the reproduction rates were different compared to the control in treatment group 18.75 L/ha (statistic evaluation was done with Williams-test, with Tox-Rat). Thus NOEC for reproduction effects is 9.375 L/ha.

Conclusion: In this study the lowest-observed-effect-concentration (LOEC) of BYF 00587 + PTZ EC 75 + 150 for mortality and growth and reproduction of the earthworm *Eisenia fetida* was estimated to be 75 L/ha.
The no-observed-effect-concentration (NOEC) of BYF 00587 + PTZ EC 75 + 150 for reproduction of the earthworm *Eisenia fetida* was determined to be 9.375 L/ha, i.e. the highest tested rate.

Comments of zRMS

Study Comments:	
Agreed Endpoints:	NOEC = 9.375 L/ha

Report:	**KIIIA 10.6.4/01, Lechelt-Kunze C.; 2002**
Title:	JAU 6476 EC 250: Effects on the earthworm fauna of grassland area in one year
Document No.:	M-040814-03-1 (amended report)
Guidelines:	BBA Part VI, 2-3 (1994): Effects of PPP on Earthworms in the Field ISO Draft Guideline CD 11268-3 (E), 1999
GLP:	Yes

Material and methods: JAU 6476 EC 250 was applied three times (May 14, May 29, and June 19, 2001) onto four plots with an application rate 3 x 803.4 g formulation/ha (= 3 x 200 g a.s./ha) onto an area that had been used for many years as grassland. As a reference substance, Benomyl 50 WP was applied once (May 14, 2001) on four plots of this grassland area at 8 kg product/ha.

The test was performed in order to determine whether effects of JAU 6476 EC 250 to earthworm populations under field conditions occur. The earthworm abundance was determined by use of the "formalin method" seven weeks after the first application (July 2-3, 2001) 5 months after the first application (autumn 2001: October 10-18, 2001) and 11 months after the first application (spring 2002: April 18-30, 2002). At each sampling time 16 samples per treatment were taken. In the control, seven weeks after the first application earthworm abundance was 60 earthworms/m2; 5 months after the first application, 201 earthworms/m2 and 11 months after the first application, 145 earthworms/m^2 were sampled.
Five different species were identified: the tanylobous species *Lumbricus terrestris, L. rubellus* and *L. castaneus,* the epilobous species *Aporrectodea caliginosa* and *Aporrectodea terrestris longa.*

Soil samples from the control and from the treated plots were taken one (May 30, 2001) and seven days (June 5, 2001) after the second and one (June 20, 2001) and seven days (June 26, 2001) after the third application. Soil samples were analysed according to method 00610 (described in the conjunct study MR-435/01) for the presence of JAU 6476 and the metabolite JAU6476-desthio.

Findings: The application of JAU 6476 EC 250 did not cause a statistically significant reduction of total adult & juvenile earthworm species seven weeks after the first application. Only the number of juvenile *A. caliginosa* was reduced by 47% leading to a statistically significant reduction of juvenile epilobous species by 48%. However, taking into account the variability of earthworm abundance in natural soils and the lack of significant effects in the total abundance of epilobous species, this reduction is not considered to be a biologically significant effect.
Five months after the first application (autumn 2001), no significant reduction of any earthworm species was observed.
Eleven months after the first application (spring 2002), the number and biomass of adult and juvenile *A. caliginosa* was significantly increased by 45 and 69% leading to a significant increase of total epilobous species by 47 and 71% (based on a significant increase of the adult earthworms). The number of adult *L. castaneus* was significantly reduced by 50%.

In Benomyl 50 WP treated plots, the number of earthworms (adult and juvenile) was significantly reduced by 56 % and the biomass by 74 % seven weeks after the first application. Five months after the first application (autumn 2001), the number and biomass of adult and juvenile earthworms were not significantly reduced. However the number of *L. terrestris* was significantly reduced by 38 % and the biomass by 59 %, leading to a biomass reduction of total tanylobous species of 49 %. Eleven months after the first application (spring 2002), the number and biomass of *A. caliginosa* was significantly increased by 43 and 86 % leading to a significant increase of total epilobous species by 42 and 85 % for the adult and juvenile earthworms (based on a significant increase of the adult earthworms). The number and biomass of L. *terrestris* was significantly reduced by 49 and 44 % leading to a significant reduction of total tanylobous species by 43 and 44 % for the adult and juvenile earthworms (based on a significant reduction of the juvenil *L. terrestris* and the adult *L. castaneus).* This pattern of earthworm population dynamics after application of Benomyl corresponds to similar studies reported in literature.

The conjunct study MR-435/01 shows the results of soil analysis after the second and third application:
One day after the **second** application the mean plot concentrations of JAU 6476 ranged from 40.3 - 53.2 ug/kg, the mean plot concentrations of JAU 6476-desthio ranged from 85.6-106.0 ug/kg.
Seven days after the **second** application the mean plot concentrations of JAU 6476 ranged from < LOQ (LOQ 6 ug/kg) to 9.87 ug/kg, the mean plot concentrations of JAU 6476-desthio ranged from 64.2 - 95.0 ug/kg.

One day after the **third** application the mean plot concentrations of JAU 6476 ranged from 18.6 - 22.8 ug/kg, the mean plot concentrations of JAU 6476-desthio ranged from 59.4 - 67.3 ug/kg.
Seven days after the **third** application the mean plot concentrations of JAU 6476 ranged from < LOQ (LOQ 6 ug/kg) to 5.19 ug/kg, the mean plot concentrations of JAU 6476-desthio ranged from 56.2 - 69.4 ug/kg.

Conclusion: This study indicates that earthworm populations were not adversely affected by application rates of JAU 6476 EC 250 (3 x 200 g a.s./ha) seven weeks, 5 months and 11 months after the first application.

Report:	**KIIIA 10.6.4/02, Schulz L.; 2015**
Title:	Bixafen + Prothioconazole + Tebuconazole EC 275 (75+100+100) G: Effects on Collembola under field conditions,
Document No.:	131048009F
Guidelines:	ISO 23611-2 (2006) Technical Recommendations to ISO 11268-3 (1999), Kula et al. (2006)
GLP:	Yes

Material and methods: The objective of this field study was to investigate potential effects and the potential recovery of natural field populations of earthworms after the application of the test item bixafen + prothioconazole + tebuconazole EC 275 (75+100+100) G. A field experiment lasting about one year was performed and the effects of the test items at application rates of 2 x 1.25 L, 2 x 2.50 L and 2 x 3.75 L/ha (7 days interval) with regard to species composition, biomass and abundance were compared to an untreated control and to a reference item (toxic standard; Nutdazim 50 FLOW®).
The study design was based on the ISO guidance document (ISO 11268-3, 1999: Soil quality – Effects of pollutants on earthworms. Part 3: Guidance on the determination of effects in field situations (Anonymous, 1999)). The following recommendations were taken into account: KULA et al. (2006): Technical recommendations for the update of the ISO earthworm field test guideline (ISO 11268-3).
The mean abundance of earthworms of the test field at trial start was 160.7 ind./m^2, thus fulfilling the guideline recommendation (100 ind./m² for grassland soils).
At least one representative of endogeic and anecic earthworms was present at the field site in a sufficient number (>10 % of total earthworms or 10 - 15 ind./m^2), with abundances of 84.8 ind./m2 for *Aporrectodea caliginosa* (endogeic) and 58.5 ind./m² for *Lumbricus terrestris* (anecic; pre-sampling values).
The trial was placed on **grassland** near Machern in Saxony/Germany.
The selection of the test field was based on an earthworm pre-sampling (12.06.2013) conducted prior to the plateau application in June 2013. Results of this sampling confirmed the suitability of the test field.
Bixafen EC 125 G (bixafen (BYF 00587) 125 g/L (nominal)) was applied once to all plots of the different test item treatment groups at a rate of 2.84 L/ha corresponding to 0.355 kg bixafen/ha (nominal) about 2 weeks (date: 20.06.2013) before the 1st test item application to simulate a plateau concentration of 0.237 mg bixafen/kg soil (nominal).
The test item bixafen + prothioconazole + tebuconazole EC 275 (75+100+100) G (bixafen (BYF 00587) 75 g/L (nominal), prothioconazole (JAU 6476) 100 g/L (nominal), tebuconazole (HWG 1608) 100 g/L (nominal)) was applied twice (dates: 08.07.2013, 22.07.2013) at rates of 1.25 L/ha, 2.50 L/ha and 3.75 L/ha, corresponding to 0.094 kg, 0.188 kg and 0.281 kg bixafen/ha (nominal), 0.125 kg, 0.250 kg and 0.375 kg propiconazole/ha (nominal) as well as 0.125 kg, 0.250 kg and 0.375 kg tebuconazole/ha (nominal).
Nutdazim 50 FLOW® (carbendazim 500 g/L, nominal) was applied once to the plots as reference item at a rate of 10 kg nominal a.s./ha (20 L product/ha). Tap water was applied once as a control.

Twenty plots, each 10 m x 10 m, were arranged in a 5 x 4 formation, each plot surrounded by a 2 m wide pathway between the plots. The set-up was a randomised block design. The assignment of the treatment groups to the plots was based on the results of a pre-sampling. The pre-sampling was conducted to determine the density, diversity and homogeneity of earthworm populations at the site. Defined areas were sampled to assess earthworm populations before application and 3 times after application, i.e about 1, 4 and 10 months after 1st test item application (sampling dates: 31.07.2013, 30.10.2013, 28.04.2014). Earthworms were sampled from four 0.125 m² sampling areas per plot per sampling occasion.
Earthworms were sampled from four 0.125 m² samples (replicates) were taken exclusively from the central area (6 x 6 m) of each plot per sampling occasion by combining hand sorting with formalin extraction in the excavated hole. The mean earthworm abundance in the control plots was 158.0 ind./m² at pre-sampling, 51.0 ind./m² at 1st sampling, 127.0 ind./m^2 at 2nd sampling and 118.0 ind./m^2 at 3rd sampling. The presence of the dominant species *Aporrectodea caliginosa* (endogeic, 52.8 % of total earthworms) and *Lumbricus terrestris* (anecic, 36.4 % of total earthworms). The abundance of earthworms was recorded and the weight (biomass) determined with a precision balance for each sample separately.

Results:

Surface monitoring on days 1-3 after each application showed that there was no acute primary effect on earthworms by bixafen EC 125 G and bixafen + prothioconazole + tebuconazole EC 275 (75+100+100) G. No alive, moribund or dead earthworms were found on the soil surface neither in the test item nor in the control monitoring areas.
In the reference item treatment group the total earthworm abundance and biomass was reduced by 45.1 % and 68.1 % at 1st sampling (about 1 month after 1st test item application, guideline recommendation are fulfilled: reduction of the earthworm abundance and / or biomass of > 50 % compared to the control).
Endogeic (*Aporrectodea caliginosa, Aporrectodea rosea, Aporrectodea spec.*) and anecic *(Aporrectodea longa, Lumbricus terrestris)* species were found and determined. The age stage of the test organisms was variable based on natural climatic and environmental conditions.

Total abundance and total biomass

None of the test item application rates tested up to a rate of 2 x 3.75 L test item/ha caused statistically significant effects on total earthworm abundance and biomass about 1, 4 and 10 months after 1st test item application.

Abundance and biomass of total adult and total juvenile

None of the test item application rates tested up to a rate of 2 x 3.75 L test item/ha caused statistically significant effects **on total adult and juvenile earthworm abundance and biomass** about 1, 4 and 10 months after 1st test item application.

Abundance and biomass of endogeic species

A. caliginosa and *A. rosea* were the two endogeic species present on the test field. *A. rosea* comprised only a small portion of the earthworm population (1.9 % of the total abundance at presampling). Therefore, statistical analyses were carried out for total abundance of *A. rosea* only. None of the test item application rates tested up to a rate of 2 x 3.75 L test item/ha caused statistically significant effects on endogeic abundance and biomass about 1, 4 and 10 months after 1st test item application.

Abundance and biomass of anecic species

L. terrestris and *A. longa* were the two anecic species present on the test field. The second anecic species *A. longa* comprised only a small portion of the earthworm population (5.4 % of the total abundance at pre-sampling). Therefore, statistical analyses were carried out for total abundance of *A. longa* only. None of the test item application rates tested up to a rate of 2 x 3.75 L test item/ha caused statistically significant effects on anecic abundance and biomass about 1, 4 and 10 months after 1st test item application. None of the test item application rates tested up to a rate of 2 x 3.75 L test item/ha caused statistically significant effects on abundance and biomass (total, adult, juvenile) of *L. terrestris* and *A. longa* about 1, 4 and 10 months after 1st test item application. Only for juvenile abundance of *Lumbricus terrestris* a statistically significant reduction of 20 % could be observed in the treatment group of the highest tested application rate of 2 x 3.75 L test item/ha about 10 months after 1st test item application. Recalculations on subsamples niveau done by RMS show no significant findings in juvenile abundance of *Lumbricus terrestris*.

Statistics: With the Shapiro-Wilk's-test data were analysed for normal distribution and with the Levene's test data were analysed for homogeneity in variance. Data were reasonably normal in distribution and variances were reasonably equal. Post-treatment sampling: data were analysed by a one-sided Dunnett-test with treatment group < control at the 5 % significance level. Test item and reference item were analysed in separate analyses.

Summary: No statistically significant reduction in total earthworm abundance and biomass could be observed for all test item application rates tested up to a rate of 2 x 3.75 L test item/ha about 1, 4 and 10 months after 1st test item application.
Furthermore, no statistically significant reductions in abundance and biomass of the earthworm species present on the field (*Aporrectodea caliginosa, Aporrectodea rosea, Aporrectodea longa, Lumbricus terrestris*) and ecological groups (endogeic and anecic earthworms) could be observed for all test item application rates about 1, 4 and 10 months after 1st test item application. Only for juvenile abundance of *Lumbricus terrestris* a statistically significant reduction of 20 % could be observed in the treatment group of the highest tested application rate of 2 x 3.75 L test item/ha about 10 months after 1st test item application.
Surface monitoring on days 1-3 after each application showed that there was no acute primary effect on earthworms by bixafen EC 125 G and bixafen + prothioconazole + tebuconazole EC 275 (75+100+100) G. No alive, moribund or dead earthworms were found on the soil surface neither in the test item nor in the control monitoring areas.

Conclusions: No statistically significant reduction in total earthworm abundance and biomass could be observed for all test item application rates tested up to a rate of 2 x 3.75 L (7 days interval) test item/ha about 1, 4 and 10 months after 1st test item application.

Comments of zRMS

Study Comments:	Based on the some concerns on the appropriatness and the reliability of the ANOVA approach, the zRMS DE used the CTCAP method (Lehman et al. 2015) to recalculate the NOEC. Please refer to the evaluation for more details. The study of Schulz (2015) is considered sufficient for legislation of the product in Germany but due to a lot of shortcommings a further monitoring study is required to relieve remaining uncertainities regarding the risk iedntified for non-target soil meso- and macrofauna.
Agreed Endpoints:	**No agreed endpoints:** NOEC > 2 x 3.75 L Product /ha (ANOVA) NOEC < 2 x 1.25 L Product /ha (CP-CAT)

Report:	KIIIA 10.6.4/03, Schulz, L.; 2014
Title:	Bixafen + prothioconazole + tebuconazole EC 275 (075 + 100 + 100) G: Effects on earthworms under field conditions
Document No:	Report-No.: 13 10 48 008 F
Guidelines:	ISO/DIS 11268, Freilandstudie nach ISO 11268-3 und Kula (2006)
GLP:	yes (certified laboratory)

Materia and Methods:
The objective of this field study was to investigate potential effects and the potential recovery of natural field populations of earthworms after the application of the test item bixafen + prothioconazole + tebuconazole EC 275 (75+100+100) G. A field experiment lasting about one year was performed and the effects of the test items at application rates of 2 x 1.25 L, 2 x 2.50 L and 2 x 3.75 L/ha (7 days interval) with regard to species composition, biomass and abundance were compared to an untreated control and to a reference item (toxic standard; Nutdazim 50 FLOW®).
The study design was based on the ISO guidance document (ISO 11268-3, 1999: Soil quality – Effects of pollutants on earthworms. Part 3: Guidance on the determination of effects in field situations (Anonymous, 1999)). The following recommendations were taken into account: KULA et al. (2006): Technical recommendations for the update of the ISO earthworm field test guideline (ISO 11268-3).
The mean abundance of earthworms of the test field at trial start was 160.7 ind./m^2, thus fulfilling the guideline recommendation (100 ind./m² for grassland soils).
At least one representative of endogeic and anecic earthworms was present at the field site in a sufficient number (>10 % of total earthworms or 10 - 15 ind./m^2), with abundances of 84.8 ind./m2 for *Aporrectodea caliginosa* (endogeic) and 58.5 ind./m² for *Lumbricus terrestris* (anecic; pre-sampling values).
The trial was placed on **grassland** near Machern in Saxony/Germany.
The selection of the test field was based on an earthworm pre-sampling (12.06.2013) conducted prior to the plateau application in June 2013. Results of this sampling confirmed the suitability of the test field.
Bixafen EC 125 G (bixafen (BYF 00587) 125 g/L (nominal)) was applied once to all plots of the different test item treatment groups at a rate of 2.84 L/ha corresponding to 0.355 kg bixafen/ha (nominal) about 2 weeks (date: 20.06.2013) before the 1st test item application to simulate a plateau concentration of 0.237 mg bixafen/kg soil (nominal).
The test item bixafen + prothioconazole + tebuconazole EC 275 (75+100+100) G (bixafen (BYF 00587) 75 g/L (nominal), prothioconazole (JAU 6476) 100 g/L (nominal), tebuconazole (HWG 1608) 100 g/L (nominal)) was applied twice (dates: 08.07.2013, 22.07.2013) at rates of 1.25 L/ha, 2.50 L/ha and 3.75 L/ha, corresponding to 0.094 kg, 0.188 kg and 0.281 kg bixafen/ha (nominal), 0.125 kg, 0.250 kg and 0.375 kg propiconazole/ha (nominal) as well as 0.125 kg, 0.250 kg and 0.375 kg tebuconazole/ha (nominal).
Nutdazim 50 FLOW® (carbendazim 500 g/L, nominal) was applied once to the plots as reference item at a rate of 10 kg nominal a.s./ha (20 L product/ha). Tap water was applied once as a control.
Twenty plots, each 10 m x 10 m, were arranged in a 5 x 4 formation, each plot surrounded by a 2 m wide pathway between the plots. The set-up was a randomised block design. The assignment of the treatment groups to the plots was based on the results of a pre-sampling. The pre-sampling was conducted to determine the density, diversity and homogeneity of earthworm populations at the site. Defined areas were sampled to assess earthworm populations before application and 3 times after application, i.e about 1, 4 and 10 months after 1st test item application (sampling dates: 31.07.2013, 30.10.2013, 28.04.2014). Earthworms were sampled from four 0.125 m² sampling areas per plot per sampling occasion.
Earthworms were sampled from four 0.125 m² samples (replicates) were taken exclusively from the central area (6 x 6 m) of each plot per sampling occasion by combining hand sorting with formalin extraction in the excavated hole. The mean earthworm abundance in the control plots was 158.0 ind./m² at pre-sampling, 51.0 ind./m² at 1st sampling, 127.0 ind./m^2 at 2nd sampling and 118.0 ind./m^2 at 3rd sampling. The presence of the dominant species *Aporrectodea caliginosa* (endogeic, 52.8 % of total earthworms) and *Lumbricus terrestris* (anecic, 36.4 % of total earthworms). The abundance of

earthworms was recorded and the weight (biomass) determined with a precision balance for each sample separately.

Results:
Surface monitoring on days 1-3 after each application showed that there was no acute primary effect on earthworms by bixafen EC 125 G and bixafen + prothioconazole + tebuconazole EC 275 (75+100+100) G. No alive, moribund or dead earthworms were found on the soil surface neither in the test item nor in the control monitoring areas.
In the reference item treatment group the total earthworm abundance and biomass was reduced by 45.1 % and 68.1 % at 1st sampling (about 1 month after 1st test item application, guideline recommendation are fulfilled: reduction of the earthworm abundance and / or biomass of > 50 % compared to the control).
Endogeic (*Aporrectodea caliginosa, Aporrectodea rosea, Aporrectodea spec.*) and anecic *(Aporrectodea longa, Lumbricus terrestris)* species were found and determined. The age stage of the test organisms was variable based on natural climatic and environmental conditions.
Total abundance and total biomass
None of the test item application rates tested up to a rate of 2 x 3.75 L test item/ha caused statistically significant effects on total earthworm abundance and biomass about 1, 4 and 10 months after 1st test item application.
Abundance and biomass of total adult and total juvenile
None of the test item application rates tested up to a rate of 2 x 3.75 L test item/ha caused statistically significant effects **on total adult and juvenile earthworm abundance and biomass** about 1, 4 and 10 months after 1st test item application.
Abundance and biomass of endogeic species
A. caliginosa and *A. rosea* were the two endogeic species present on the test field. *A. rosea* comprised only a small portion of the earthworm population (1.9 % of the total abundance at presampling). Therefore, statistical analyses were carried out for total abundance of *A. rosea* only. None of the test item application rates tested up to a rate of 2 x 3.75 L test item/ha caused statistically significant effects on endogeic abundance and biomass about 1, 4 and 10 months after 1st test item application.
Abundance and biomass of anecic species
L. terrestris and *A. longa* were the two anecic species present on the test field. The second anecic species *A. longa* comprised only a small portion of the earthworm population (5.4 % of the total abundance at pre-sampling). Therefore, statistical analyses were carried out for total abundance of *A. longa* only. None of the test item application rates tested up to a rate of 2 x 3.75 L test item/ha caused statistically significant effects on anecic abundance and biomass about 1, 4 and 10 months after 1st test item application. None of the test item application rates tested up to a rate of 2 x 3.75 L test item/ha caused statistically significant effects on abundance and biomass (total, adult, juvenile) of *L. terrestris* and *A. longa* about 1, 4 and 10 months after 1st test item application. Only for juvenile abundance of *Lumbricus terrestris* a statistically significant reduction of 20 % could be observed in the treatment group of the highest tested application rate of 2 x 3.75 L test item/ha about 10 months after 1st test item application. Recalculations on subsamples niveau done by RMS show no significant findings in juvenile abundance of *Lumbricus terrestris*.

Statistics: With the Shapiro-Wilk's-test data were analysed for normal distribution and with the Levene's test data were analysed for homogeneity in variance. Data were reasonably normal in distribution and variances were reasonably equal. Post-treatment sampling: data were analysed by a one-sided Dunnett-test with treatment group < control at the 5 % significance level. Test item and reference item were analysed in separate analyses.

Summary: No statistically significant reduction in total earthworm abundance and biomass could be observed for all test item application rates tested up to a rate of 2 x 3.75 L test item/ha about 1, 4 and 10 months after 1st test item application.
Furthermore, no statistically significant reductions in abundance and biomass of the earthworm species present on the field (*Aporrectodea caliginosa, Aporrectodea rosea, Aporrectodea longa, Lumbricus*

terrestris) and ecological groups (endogeic and anecic earthworms) could be observed for all test item application rates about 1, 4 and 10 months after 1st test item application. Only for juvenile abundance of *Lumbricus terrestris* a statistically significant reduction of 20 % could be observed in the treatment group of the highest tested application rate of 2 x 3.75 L test item/ha about 10 months after 1st test item application.
Surface monitoring on days 1-3 after each application showed that there was no acute primary effect on earthworms by bixafen EC 125 G and bixafen + prothioconazole + tebuconazole EC 275 (75+100+100) G. No alive, moribund or dead earthworms were found on the soil surface neither in the test item nor in the control monitoring areas.

Conclusions: No statistically significant reduction in total earthworm abundance and biomass could be observed for all test item application rates tested up to a rate of 2 x 3.75 L (7 days interval) test item/ha about 1, 4 and 10 months after 1st test item application.

Comments of zRMS:	-
Agreed Endpoints:	NOEC > 2 x 3.75 L Product /ha

IIIA 10.6.6 Effects of other soil non-target macro-organisms

Report:	**KIIIA 10.6.6/01, Luehrs U.; 2007**
Title:	BYF 00587 + PTZ EC 75 + 150: Effects on Reproduction of the Collembola *Folsomia Candida* in Artificial Soil with 5% Peat
Document No:	M-291632-01-1
Guidelines:	ISO 11267 Soil Quality - Inhibition of reproduction of Collembola (*Folsomia Candida*) by soil pollutants, 1999
GLP:	yes (certified laboratory)

Objective:
The purpose of the study was to determine the effects of BYF 00587 + PTZ EC 75 + 150 on mortality and reproduction of the collembola *Folsomia candida* in artificial soil.

Materials and methods:
Test item: BYF 00587 + PTZ EC 75 + 150, Sample Description: TOX07660-00, Work order No.: 06013765, Batch No.: 2006-001178; a.s. contents: BYF 00587: 75 g/L (nominal), 75.3 g/L (7.49% w/w) (analytical); Prothioconazole (JAU 6476): 150 g/L (nominal), 149 g/L (14.8% w/w) (analytical).
Reference Item: Betosip (a.s. phenmedipham) is tested at least once a year in a dose response study.
Test organism: the collembola *Folsomia candida.*

BYF 00587 + PTZ EC 75 + 150 was mixed into soil (containing approx.74.8% quartz sand, 20% kaolinite clay, 5% sphagnum peat and approx. 0.2% $CaCO_3$) at 26, 52, 104, 208 and 416 mg BYF 00587 + PTZ EC 75 + 150/ kg d.wt.s., to which collembola *Folsomia Candida* (50 individuals per treatment group) were exposed for 28 days at 18 - 20°C and a photoperiod of 16 h light : 8 h dark with a light intensity of 410 to 540 lux. The initial soil water content was 21.9 % to 22.7 % equivalent to 53.5% to 55.3% of the maximum water holding capacity and the water content at experimental termination was 20.2% to 21.8%

equivalent to 49.2% to 53.2%. The initial pH was 5.7 to 5.8 and the pH at experimental termination 5.5. Collembola were fed with dry yeast at start and after 14 days.
Endpoints were mortality and reproduction after 28 days.

Findings:
The results can be considered as valid, as all validity criteria of the test were met. The mean mortality in the control was ≤ 20% (12% in this study), the number of juvenile collembola per replicate was ≥ 100 (692-831 in this study) and the coefficient of variation of the control reproduction was ≤ 30% (7.6% in this study).

Observations:
In this study BYF 00587 + PTZ EC 75 + 150 caused statistically significant effects on mortality of *Folsomia candida* at 416 mg test item/kg soil dry weight.
A statistically significant reduction of reproduction occurred at 208 mg test item/kg soil dry weight.

Conclusion:
The overall NOEC was determined to be 104 mg test item/kg soil dry weight.
The overall LOEC was determined to be 208 mg test item/kg soil dry weight.

Comments of zRMS

Study Comments:	
Agreed Endpoints:	NOEC = 104 mg test item/kg soil dry weight

Report:	**KIIIA 10.6.6/02, Frommholz U.; 2011**
Title:	Prothioconazole a.s.: Influence on the reproduction of the collembolan species *Folsomia candida* tested in artificial soil.
Document No:	M-405273-01-1
Guidelines:	OECD 232 adopted (September 07, 2009)
GLP:	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.

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 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.

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 %

All validity criteria were met. Therefore this study is valid.

Conclusions:

$NOEC_{reproduction}$ ≥1000 mg test item/kg artificial soil dry weight.
$LOEC_{reproduction}$ >1000 mg test item/kg artificial soil dry weight.

Comments of zRMS

Study Comments:	
Agreed Endpoints:	$NOEC_{reproduction}$ ≥1000 mg test item/kg artificial soil dry weight.

IIIA 10.6.7 Effects on organic matter breakdown

Report:	**KIIIA 10.7.1/01, Reis K.H.; 2006**
Title:	Effects of BYF 00587 + PTZ EC 75 + 150 G on the Activity of the Soil Micro flora in the Laboratory
Document No:	M-281135-01-1
Guidelines:	OECD No. 217, Soil Microorganisms: Carbon Transformation Test, 2000, OECD No. 216, Soil Microorganisms: Nitrogen Transformation Test, 2000
GLP:	Yes (certified laboratory)

Objectives:
The objective of the test was to determine the influence of 1.68 and 16.77 mg of BYF 00587 + PTZ EC 75 + 150 G /kg d.wt.s. on carbon and nitrogen transformation in an agricultural soil.

Materials and Methods:
Test item: BYF 00587 + PTZ EC 75 + 150 G; Batch No.: 2006-001178; analysed a.s. contents: BYF 00587: 75.3 g/L, JAU 6476 (Prothioconazole): 149 g/L.

Carbon transformation:
A loamy sand soil was exposed for 28 d to concentrations of 1.68 mg and 16.77 mg BYF 00587 + PTZ EC 75 + 150 G /kg d.wt.s (application rates were equivalent to 1x and 10x recommended field rate, respectively). Glucose was added to the soil samples (4 g/kg dry weight soil) to induce maximum respiration rate. The test was conducted in 3 replicates per concentration. Untreated soil served as a control.
Endpoint was the O_2-consumption after 28 days of exposure.

Nitrogen transformation:
A loamy sand soil was exposed for 42 d to concentrations of 1.68 mg and 16.77 mg BYF 00587 + PTZ EC 75 + 150 G /kg d.wt.s (application rates were equivalent to 1x and 10x recommended field rate, respectively). Lucerne meal was added to the soil (5 g/kg dry weight soil) to stimulate nitrogen transformation.
Endpoint was the NO_3-nitrogen production after 42 days of exposure.

Findings:
The variation between the replicate control samples clearly matched the validity criterion of 15% for both the carbon and nitrogen transformation test (OECD test guidelines 216/217). The validity of the test system was further confirmed by the sensitivity established in positive control experiments.

Observations:

Carbon transformation:
The differences in soil respiration rates among the different treatments were clearly below the OECD guideline 217 trigger value of 25% throughout the test.
At day 28 after application, the differences between the respiration rates of BYF 00587 + PTZ EC 75 + 150 G treated soils and the control soil were 10.04 % and 9.52 % at 1.68 mg/kg and 16.77 mg/kg d.wt.s., respectively. The differences from control were not statistically significant ($p>0.05$).

Nitrogen transformation:
At the dose rate of 1.68 mg/kg d.wt.s. the soil nitrate content deviated more than ±25% from the control on day 28 (-28.99%) but felt below the trigger value at all following sampling date day 42 (-19.23%). At

the higher dose rate of 16.77 mg/kg d.wt.s. the nitrate content was less than the trigger level on day 28 (-8.62% of the control) and was within the trigger value at day 42 with -7.49% of the control. Even the deviations on day 42 were below the 25% trigger value given by the OECD 216 test guideline. The differences were statistically significant (Student-t-test, a = 0.05).
The soil nitrate formation rates were calculated incremental (i.e. between sampling dates). At the lower dose rate of 1.68 mg/kg d.wt.s. the soil nitrate formation rate was higher than the 25% trigger value given by the OECD 216 test guideline at the interval of 7 - 14 days. At the interval between days 28 and 42, the difference from control was -8.5%. At the higher dose rate of 16.77 mg/kg d.wt.s., the difference in nitrate formation rate was below the 25% trigger value within the test. On time interval between days 28 and 42, the difference was -6.2%. A statistically significantly difference of treated groups from control was found at the lower test concentration but not at the higher test concentration.
The soil mineral nitrogen content (as required by the EPPO and SETAC guidelines) at the dose rate of 1.68 mg/kg d.wt.s. was higher than the 25% trigger value on days 14 and 28 and felt below 25% difference from control on day 42 (-19.11%). At the dose rate of 16.77 mg/kg d.wt.s. the mineral nitrogen content was continuously within the ±25% difference from control. On day 42, the difference from control was -7.61%. Even the deviations on day 42 were below the 25% trigger value given by the OECD 216 test guideline. The differences were statistically significant (Student-t-test, a = 0.05).

Conclusions:
Based on the results of this study, BYF 00587 + PTZ EC 75 + 150 G has no impact on respiration activities, soil nitrate content and soil nitrate formation rate of soil microflora when applied up to 16.77 mg/kg soil dry weight (corresponding to 10 times the maximum recommended application rate of 1.25 L BYF 00587 + PTZ EC 75 + 150 G per ha).
It can be concluded that BYF 00587 + PTZ EC 75 + 150 G does not have long term influence on soil microflora.

Comments of zRMS

Study Comments:	
Agreed Endpoints:	It can be concluded that BYF 00587 + PTZ EC 75 + 150 G does not have long term influence on soil microflora.

III 10.8.1 Effects on non-target terrestrial plants

Report:	**KIIIA 10.8.1.2/01, Gosch H. & Nguyen D.H.; 2007**
Title:	Non-target terrestrial plants: an evaluation of the effects of BYF 00587 + Prothioconazole EC 75 + 150 g/L in the vegetative vigour test (Tier 1).
Document No:	M-291578-01-1
Guidelines:	OECD 227 (July 2006): vegetative vigour test (Tier 1)
GLP:	No

Objective:

The purpose of the study was to evaluate the phytotoxic effects of 1.25 L/ha BYF 00587 + Prothioconazole EC 75 + 150 g/L on ten species representing non-target terrestrial plant species during vegetative vigour test following a post emergence application of the product onto the foliage of plants at the 2 to 4 -leaf growth stage.

Materials and Methods:
Test item: BYF 00587 + Prothioconazole EC 75+150 g/L (BIX + PTZ 75+150 G), Sample description: TOX 07852-00, Batch ID: 2007-002622, Specification No.: 102000013869; a.s. contents: 7.7% w/w BYF 00587, 14.7% w/w Prothioconazole.
Test organisms: Ten species of terrestrial non-target plants (7 dicotyledonae and 3 monocotyledonae): cucumber (*Cucumis sativus*), oilseed rape (*Brassica napus*), soybean (*Glycine max*), sugar beet (*Beta vulgaris*), sunflower (*Helianthus annuus* L.), tomato (*Lycopersicon esculentum*), buckwheat (*Fagopyrum esculentum*), corn (*Zea mays*), oat (*Avena sativa*), and ryegrass (*Lolium perenne* L.).

Plants were treated at the 2-4-leaf stage with a foliar spray application of 1.25 L product/ha. Spray treatments were applied once, at test initiation, with a sprayer set at the nominal spray volume of 200 L/ha. Control pots were sprayed with deionized water. Four to five replicates with four to five plants per pot for each species were tested. All pots were individually contained in saucers and retained on benches within a greenhouse.
Plants were assessed for survival and phytotoxicity on days 7, 14 and 21. At study termination, endpoint determinations were performed for plant dry weights.
Statistical analysis was carried out using the Pairwise Mann-Whitney-U-test (one sided smaller).

Findings:
Observations:
There was no adverse effect of 1.25 L BIX + PTZ 75+150 G/ha on the survival of the ten species tested.
Slight to total phytotoxicity, visualized as chlorosis, necrosis, leaf deformation and stunting was observed in cucumber, oilseed rape, soybean, sugar beet, sunflower, tomato and buckwheat.
Biomass was increased in corn and oat by 15.7% and 26.4%, respectively. Biomass was reduced in cucumber, oilseed rape, soybean, sugar beet, sunflower, tomato, buckwheat and ryegrass by 31.9%, 30.9%, 35.3%, 12.7%, 24.7%, 35.9%, 37.2 and 5.1%, respectively. Differences were significant for cucumber, oilseed rape, soybean, tomato and buckwheat at the 95% confidence limits. None of these differences reached or exceeded 50% to trigger further testing.

Conclusion:
Applied at the nominal application rate of 1.25 L product/ha, BYF 00587 + Prothioconazole EC 75 + 150 g/L showed no adverse effect (i.e. greater than 50%) for all the tested species in the vegetative vigour test.

Comments of zRMS

Study Comments:	
Agreed Endpoints:	Applied at the nominal application rate of 1.25 L product/ha, BYF 00587 + Prothioconazole EC 75 + 150 g/L showed no adverse effect (i.e. greater than 50%) for all the tested species in the vegetative vigour test.

A 10.8.1.3 Seedling emergence

Report:	**KIIIA 10.8.1.3/01, Gosch H. & Nguyen D.H.; 2007**
Title:	Non-target terrestrial plants: an evaluation of the effects of BYF 00587 + Prothioconazole EC 75 + 150 g/L in the seedling emergence and growth test (Tier l)
Document No:	M-291576-01-1
Guidelines:	OECD 208 (July 2006): seedling emergence and growth test (Tier 1)
GLP:	No

Objective:
The purpose of the study was to evaluate the phytotoxic effects of 1.25 L BIX + PTZ 75+150 G/ha on ten species representing non-target terrestrial plant species during seedling emergence and growth following a pre-emergence application of the product.

Materials and Methods:
Test item: BYF 00587 + Prothioconazole EC 75+150 g/L (BIX + PTZ 75+150 G), Sample description: TOX 07852-00, Batch ID: 2007-002622, Specification No.: 102000013869; a.s. contents: 7.7% w/w BYF 00587, 14.7% w/w Prothioconazole.
Test organisms: Ten species of terrestrial non-target plants (7 dicotyledonae and 3 monocotyledonae): cucumber (*Cucumis sativus*), oilseed rape (*Brassica napus*), soybean (*Glycine max*), sugar beet (*Beta vulgaris*), sunflower (*Helianthus annuus* L.), tomato (*Lycopersicon esculentum*), buckwheat (*Fagopyrum esculentum*), corn (*Zea mays*), oat (*Avena sativa*), and ryegrass (*Lolium perenne* L.).

The terrestrial non-target plants were treated at an application rate of 1.25 L product/ha.
All seeds were sown one day before application and test duration was 14 days after 70% emergence of the seedling in the controls for each species. Spray treatments were applied once, at test initiation, with a sprayer set at the nominal spray volume of 200 L/ha. Control pots were sprayed with deionised water. Four replicates with five seeds per pot for each species were tested. All pots were individually contained in saucers and retained on benches within a greenhouse. Plants were assessed for emergence, survival and rated for phytotoxicity on days 7 and 14.
At study termination, biomass endpoint determinations were performed for plant dry weights. Statistical analysis was carried out using the Pairwise Mann-Whitney-U-test (one sided smaller).

Findings:
Observations:
Germination was increased in cucumber and tomato by 25.0% and 5.3% respectively. Germination was reduced in oilseed rape, soybean, sugar beet, sunflower, buckwheat, oat and ryegrass by 5.0%, 21.1%, 13.3%, 5.3%, 5.6%, 5.0% and 16.7%, respectively.
Survival of emerged plants was not effected in any of the treated plant species. Slight to severe phytotoxicity, visualized as chlorosis, necrosis, leaf deformation and stunting was observed in oilseed rape, soybean, sugar beet and sunflower.
Biomass was increased in corn by 7.1%. Biomass was reduced in cucumber, oilseed rape, soybean, soybean, sugar beet, sunflower, tomato, buckwheat, oat and ryegrass at 19.8%, 38.5%, 24.8%, 42.6%, 21.0%, 32.7%, 10.8%, 15.3% and 36.7%, respectively. The differences in biomass were significant at the

95% confidence limits for oilseed rape, tomato and ryegrass. None of these differences reached or exceeded the 50% trigger for further testing.

Conclusion:
Applied at the nominal application rate of 1.25 L product/ha, BYF 00587 + Prothioconazole EC 75 + 150 g/L showed no adverse effects (i.e. greater than 50%) for all tested species in the seedling emergence test.

Comments of zRMS

Study Comments:	
Agreed Endpoints:	1.25 L product/ha, BYF 00587 + Prothioconazole EC 75 + 150 g/L showed no adverse effects (i.e. greater than 50%) for all tested species in the seedling emergence test

REGISTRATION REPORT
Part B

Section 6: Ecotoxicological studies
Detailed summary of the risk assessment

Product code: 102000013869/ Aviator Xpro
Active Substances: Bixafen: 75 g/L
Prothioconazol: 150 g/L

Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ADDENDUM

Applicant: Bayer Crop Science
Date: 19 April 2016

Table of Contents

Sec 6 ECOTOXICOLOGICAL STUDIES (MIIIA 10)

A full risk assessment according to Uniform Principles for the plant protection product Aviator Xpro in its intended uses in cereals is documented in detail in the core assessment of the plant protection product Aviator Xpro dated from February 2016 performed by zRMS Germany.

This document comprises specific risk assessment for some annex points for authorization of the plant protection product Aviator Xpro in Germany according to the uses listed in Appendix 2.

6.1.1 GAP and overall conclusions

Please refer to GAP-table in CA Annex 4.

6.1.2 ECOTOXICOLOGICAL STUDIES (MIIIA 10)

6.1.3 GAP and overall conclusions

Please refer to the GAP-table in Annex 4 in the core assessment section 6.

6.1.4 Table of intended uses

6.1.5 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.

The critical GAPs used for risk assessment is presented in the table below. It has been selected from the individual GAPs in the zone for Aviator Xpro. A list of all intended uses within the zone is given in Appendix 4.

Table 6.2-1: Critical use pattern of Aviator Xpro

Group	Crop/growth stage	Application method / Drift scenario	Number of applications, Minimum application interval, interception, application time (season)	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)

A	Wheat, Rye, Triticale / BBCH 30-69 Uses: 007, 015, 016, 019, 004, 003, 014, 017, 001, 006, 005, 018, 002	spraying /	2 x, 14 d,spring 1. 70 % 2. 70 % Winter cereals: 1. Appl.: 19.4.=>169d and 183d after emergence Spring cereals: 1. Appl: 28.4.= >27 d and 41d after emergence	Bixafen: 2 x 93.75 = 187,5 Prothioconazol: 2 x 187.5= 375	Bixafen: 1. 28.125 2 28.125 Prothioconazol: 1. 56.25 2 56.25
B	Barley / BBCH 30-61 Uses: 008, 013, 010, 009, 012, 011	spraying /	2 x, 14d, spring 1. 70%, 14d 2. 70%, 10 d	Bixafen: 2 x 75=150 Prothioconazol: 2 x 150 = 300	Bixafen: 1. 22.5 2. 22.5 Prothioconazol: 1. 45 2. 45

Consideration of metabolites

Please refer to the core assessment section 6.

6.1.6 Effects on birds (MIIIA 10.1, KPC 10.1, KPC 10.1.1)

Please refer to the core assessment section 6.

6.1.7 Effects on Terrestrial Vertebrates Other Than Birds (MIIIA 10.3, KPC 10.1, KPC 10.1.2)

Please refer to the core assessment.

6.1.8 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KPC 10.1.3)

Please refer to the core assessment.

6.1.9 Effects on aquatic organisms (MIIIA 10.2, KPC 10.2, KPC 10.2.1)

6.1.10 Overview and summary

Effects on aquatic organisms of Aviator Xpro were not evaluated as part of the EU review of either bixafen or prothioconazole. Data on Aviator Xpro is evaluated here, and risk assessments with the proposed use pattern are provided here. 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. Hence, aquatic risk assessment differs from the FOCUS based evaluations in the core assessment.

The risk assessment for aquatic organism for authorization of Aviator Xpro is outlined in the following chapters.

6.1.10.1 Toxicity

The endpoints for aquatic organisms relevant for the risk assessment are indicated in the following table. For better readability only studies relevant for the risk assessment are presented here. For studies on other aquatic organisms please refer to section 6 core assessment.

Table 6.2-2: Ecotoxicological endpoints of bixafen

Species	Test substance	Timescale (test type)	Endpoint Toxicity (mg/L)	Reference Author code	ICS-No.
Fish, acute toxicity					
Oncorhynchus mykiss	**bixafen**	**4 d static**	**LC50: 0.095 (nom.)**	**XXX 11.01.2006 E 280 2990-0**	**69481**
Fish, long-term toxicity					
Pimephales promelas	**bixafen**	**28 d flow-trough**	**NOEC: 0.0046 (nom.)**	**XXX 24.01.2006 E 284 2960-1**	**69484**
Invertebrates, acute toxicity					
Daphnia magna	**bixafen**	**2 d static**	**EC50: 1.2 (nom.)**	**Bruns, E. 10.08.2006 E 320 2952-3**	**69534**
Invertebrates, long-term toxicity					
Daphnia magna	**bixafen**	**21 d static**	**NOEC: 0.05 * (nom.)**	**Bruns, E. 21.08.2007 E 321 3124-6**	**69536**
Sediment dwelling organisms					
Chironomus riparius	**bixafen**	**28 d static spiked water**	**NOEC: 0.0156 (nom.)**	**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**

Species	Test substance	Timescale (test type)	Endpoint Toxicity (mg/L)	Reference Author code	ICS-No.
Algae					
Pseudokirchneriella subcapitata	**bixafen**	**3 d static**	**EbC50 : 0.0657 (nom.)** **ErC50: 0.0965 (nom.)**	**Dorgerloh, M. 04.04.2006 E 323 2932-4**	**69535**
Aquatic higher plants					
No data					
Mesocosm study					
No data					

1) indicate with bold letters if endpoint deviates from EU agreed endpoint or represents new data e.g. study with new formulation

2) indicate whether based on nominal (nom = analytically confirmed), mean measured (mm) or time-weighted concentrations (twa). In the case of preparations indicate whether endpoints are presented as units of preparation or as. No indication means effects related to compound indicated in column ”Test substance”.

* Study author established a reproductive NOEC ≥ 0.125 mg bixafen/L but RMS UK concluded that the NOEC should be 0.05 mg a.s./L. In Agreement with the EU review of the active substance and with the information given by the applicant, the lower value was considered here.

Relevant toxicity endpoint for bixafen

For the active ingredient bixafen the most sensitive acute endpoint divided by the corresponding safety factor is **NOEC = 0.0046 mg a.s./L (*Pimephales promelas*).** As the assessment performed for the chronic fish endpoint covers the risk for other aquatic organisms, the risk assessment is based on this endpoint. Since Bixafen accumulates in the sediment, additionally an assessment for the sediment organisms, presented by *Chironomus riparius*, was performed.

Table 6.2-3: Ecotoxicological endpoints of prothioconazole and its metabolites

Species	Test substance	Timescale (test type)	Endpoint Toxicity (mg/L)	Reference Author code	ICS-No.
Fish, acute toxicity					
Oncorhynchus mykiss	**prothioconazol (JAU 6476)**	**4 d static**	**LC_{50}: 1.83 (nom.)**	**XXX 01.09.1999 DOM 99076**	**45863**
Oncorhynchus mykiss	**JAU 6476-desthio**	**4 d static**	**LC_{50}: 6.63 (nom.)**	**XXX 26.10.1990**	**45882**

Species	Test substance	Timescale (test type)	Endpoint Toxicity (mg/L)	Reference Author code	ICS-No.
				FF-298	
Oncorhynchus mykiss	**JAU 6476-S-methyl**	**4 d semi-static**	**LC_{50}: 1.79 (m.)**	**XXX 25.09.2001 DOM 21047**	**45633**
Oncorhynchus mykiss	**1,2,4-triazole**	**4 d static**	**LC_{50}: 498.3 (m.)**	**XXX 30.08.1983 821418**	**41737**
Oncorhynchus mykiss	**JAU 6476-triazolylketone**	**4 d static**	**LC_{50} >100 (nom.)**	**XXX 23.02.2006 E 280 3090-2**	**70491**

Species	Test substance	Timescale (test type)	Endpoint Toxicity (mg/L)	Reference Author code	ICS-No.
Fish, long-term toxicity					
Oncorhynchus mykiss	**prothioconazol (JAU 6476)**	**97 d ELS**	**NOEC: 0.308 *[1] (emergence in control only 57 instead of re-quired 66 %)**	**XXX 11.12.2001 DOM 20028**	**45872**
Oncorhynchus mykiss	**JAU 6476-desthio**	**96 d ELS**	**NOEC: 0.00334**	**XXX 15.02.2002 1022.013.321**	**45888**
Oncorhynchus mykiss	**1,2,4-triazole**	**28 d static**	**NOEC: 3.2 (nom.)**	**XXX 14.01.2002 DOM 21060**	**45802**
Invertebrates, acute toxicity					
Daphnia magna	**prothioconazol (JAU 6476)**	**2 d static**	**EC_{50}: 1.3 (nom.)**	**Heimbach, F. 13.08.1999 HBF/DM 212**	**45837**
Daphnia magna	**JAU 6476-desthio**	**2 d static**	**EC_{50} > 10 (nom.)**	**Heimbach, F. 16.05.1990 HBF/DM 95**	**45936**
Daphnia magna	**JAU 6476-S-methyl**	**2 d static**	**EC_{50}: 2.8 (nom.)**	**Dorgerloh, M., Sommer, H. 03.09.2001 DOM 21055**	**45939**
Daphnia magna	**1,2,4-triazole**	**2 d static**	**EC_{50} > 100 *[2] (nom.)**	**Bell, G. 29.11.1995 ENVIR/95/52**	**48025**
Daphnia magna	**JAU 6476-triazolylketone**	**2 d static**	**EC_{50} > 100 (nom.)**	**Bruns, E. 23.02.2006 E 320 3104-3**	**70489**
Invertebrates, long-term toxicity					
Daphnia magna	**prothioconazol (JAU 6476)**	**21 d static**	**NOEC: 0.56 (nom.)**	**Hendel, B.; Sommer, H. 11.04.2001 HDB/RDM 67**	**45855**
Daphnia magna	**JAU 6476-desthio**	**21 d semi-static**	**NOEC: 0.10 (nom.)**	**Dorgerloh, M.; Sommer, H. 10.09.2001 DOM 21036**	**45686**
Sediment dwelling organisms					
Chironomus ripa-rius	**prothioconazol (JAU 6476)**	**28 d**	**NOEC: 9.14 (nom.)**	**Hendel, B. 14.09.2000 HDB/CH 42**	**45953**
Chironomus ripa-rius	**JAU 6476-desthio**	**28 d**	**NOEC: 2.0 mg/L**	**Hendel 2000 Loep 2007**	**-**
Algae					

Species	Test substance	Timescale (test type)	Endpoint Toxicity (mg/L)	Reference Author code	ICS-No.
Skeletonema costatum	**prothioconazol (JAU 6476)**	**3 d static**	**EbC_{50}: 0.018 *[3] (nom.) ErC_{50}: 0.046 (nom.)**	**Kern, M.E.; De Haan R.A. 10.03.2004 EBJAX076 (J6883601)**	**69032**
Desmodesmus subspicatus	**JAU 6476-desthio**	**3 d static**	**EbC_{50}: 0.073 (nom.) ErC_{50}: 0.55 (nom.)**	**Heimbach, F. 20.06.1990 HBF/AL 78**	**45945**
Pseudokirchneriella subcapitata	**JAU 6476-S-methyl**	**3 d static**	**EbC_{50}: 3.77 (m.) ErC_{50}: 47.4 (m.)**	**Dorgerloh, M.; Sommer, H. 20.07.2001 DOM 21028**	**45946**
Pseudokirchneriella subcapitata	**1,2,4-triazole**	**3 d static**	**EbC_{50}: 8.2 *[4] (nom.) ErC_{50}: 22.5 (nom.)**	**Bell, G. 29.11.1995 AGV 50(b)952196**	**74250**
Pseudokirchneriella subcapitata	**Prothioconazole-triazolylketone (JAU 6476-Triazolylketone)**	**3 d statisch**	**EbC_{50} > 100 (nom.) ErC_{50} > 100 (nom.)**	**Dorgerloh, M. 23.02.2006 E 323 3084-3**	**70487**
Aquatic higher plants					
Lemna gibba	**prothioconazol (JAU 6476)**	**7 d static**	**EC_{50}: 0.074 *[5] (m.) EbC_{50}: 0.404 (m.) NOEC: 0.00334 (m.)**	**Kern, M. E.; Banman, C. S.; Lam, C. V. 03.03.2004 EBJAY002 (J6883701)**	**69854**
Lemna gibba	**JAU 6476-desthio**	**7 d, semi**	**EC_{50}: 0.0394 *[6] biomass standing crop (m.) EbC_{50}: 0.0568 (m.) ErC_{50}: 0.0809 (m.) NOEC: 0.0058 (m.)**	**Kern, M.E., Banman, C.S.; Lam, C.V. 18.12.2003 MO-04-000837, 200469**	**65917**
Mesocosm study					
No data					

1) indicate with bold letters if endpoint deviates from EU agreed endpoint or represents new data e.g. study with new formulation

2) indicate whether based on nominal (nom = analytically confirmed), measured (m), mean measured (mm) or time-weighted concentrations (twa). In the case of preparations indicate whether endpoints are presented as units of preparation or as. No indication means effects related to compound indicated in column "Test substance".

*[1] This endpoint was included in the list of endpoints for prothioconazole. According to the assessment of Germany the study is not valid due to the insufficient emergence in the control (only 57 instead of 66 % given as validity criterion in the test guideline). After the peer review process a second ELS study was provided, which also was not formally valid as the emergence was 63 % and thus again did not reach the required 66 %. Taken into account that the problem with the insufficient emergence appears more often for the test species *Oncorhynchus mykiss* and considering the fact, that the established endpoints were in the same magnitude in both ELS tests for prothioconazole, it seems to be justifiable to consider the NOEC for *O. mykiss* given in the list of endpoints although the validity criteria are not fully met.

*[2] Endpoint value according to agreement in PRAPeR expert meeting on triazole metabolites (PRAPeR 13, January 2007).

*[3] This endpoint is not included in the list of endpoints for prothioconazole but the study is known at German authority and was also cited as new study in the draft assessment report provided by the applicant. As this endpoint is lower than the EU agreed endpoint it was considered here.

*[4] Endpoint value according to agreement in PRAPeR expert meeting on triazole metabolites (PRAPeR 13, January 2007)

*[5+6] No data on aquatic macrophytes were included in the list of endpoints for prothioconazole. Data on aquatic plants are not required in this case but a study for the active ingredient and for the metabolite JAU 6476-desthio was provided by the applicant. For completeness both studies are presented here.

Relevant toxicity endpoint for prothioconazole

For the active ingredient **prothioconazole** the most sensitive endpoint, given by the lowest ratio of endpoint divided by the corresponding safety factor, is **EbC50 = 0.018 mg a.s./L *(Skeletonema costatum).*** As prothioconazole belongs to the triazoles, the potential for endocrine effects on fish has to be addressed in the risk assessment. Two ELS studies were provided for the active ingredient, both are not fully valid however the established endpoints seem to be reliable. Based on the lower endpoint of the ELS study reported by Dorgerloh and Sommer (2001) and an additional safety factor of 5 (because the standard ELS test does not address endocrine effects sufficiently) the ratio of endpoint divided by safety factor is still lower for the algae endpoint. Thus an assessment based on the algae endpoint covers the risk of endocrine effects for prothioconazole.

However an assessment based on the prothioconazol algae endpoint does not cover the potential risk of endocrine effects caused by the **metabolite JAU 6476-desthio,** which is structurally very similar to the active substance. An ELS study was provided for the metabolite JAU 6476-desthio and the **NOEC = 0.00334 mg/L *(Oncorhynchus mykiss)*** presents the worst case for the ratio of endpoint divided by the corresponding safety factor (on the national level also a FFLC test is known for the metabolite, thus possible endocrine effects are sufficiently addressed and no further assessment factor is needed here).

As the active ingredient prothioconazole degrades very fast in water (DT50 = 0.9 days) the assessment for **prothioconazole is based on the main metabolite JAU 6476-desthio, this assessment covers also the risk posed by the active substance.**

Prothioconazole has three furthe relevant metabolites, JAU6476-S-methyl, 1,2,4-Triazol and JAU 6476-triazolylketone (for details please refer to the core assessment section 5). As the metabolites show a com-

parable or lower toxicity for fish, daphnias and algae as the active substance, no quantitative risk assessment was performed for these metabolites.

Table 6.2-4: Ecotoxicological endpoints of Aviator Xpro

Species	Test substance	Timescale (test type)	Endpoint Toxicity (mg/L)	Reference Author code	ICS-No.
Fish, acute toxicity					
Oncorhynchus mykiss	Aviator Xpro	96 h, static	LC50 = 1.55	**XXX** 04.10.2007 E 280 3259-9	69483
Fish, long-term toxicity					
No data					
Invertebrates, acute toxicity					
Daphnia magna	Aviator Xpro	48 h, static	EC50 = 3.0	Bruns, E. 30.05.2007 E 320 3196-4	69530
Invertebrates, long-term toxicity					
No data					
Sediment dwelling organisms					
No data					
Algae					
Pseudokirchneriella subcapitata	Aviator Xpro	72 h, static	ErC50 = 0.549 EbC50 = 1.53	Dorgerloh, M. 22.06.2007 E 323 3173-2	69529
Aquatic higher plants					
No data					
Mesocosm study					
No data					

For the formulation the most sensitive endpoint divided by the safety factor is EC_{50} = 3.0 mg/L (*Daphnia magna*).

6.1.10.2 Exposure

Following the dilution and spraying of the formulated product, much of the formulation constituents are likely to be lost by volatilisation. Therefore, shortly after application of a formulated product, aquatic organisms are mainly exposed to the single active substances present in the formulation. An evaluation of the risk posed by the intact formulation is therefore relevant only for the acute assessment. As the assessments based on the endpoints for the active substances present the worst case here, no separate assess-

ment was performed for the formulation. The risk was assessed considering data for the active substances in the formulation.

Bixafen forms no major metabolites in surface water and there are no major metabolites in soil. But there is the metabolite M44 which occurs in groundwater. According to European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance fluxapyroxad (BAS 700 F) (EFSA 2012): Groundwater: risk assessed as low to the aquatic environment

Prothioconazole forms four major metabolites in surface water and/or sediment which also appear in soil: JAU6476-S-methyl (sediment 2 x > 5 %, soil 14.6 %), JAU 6476-desthio (water 32.3 %, sediment 26.9 %, soil 57 %), 1,2,4-triazole (water 37.2 %) and JAU 6476-triazolylketone (water 2 x > 5 %). Contamination via run-off and drainage can also not be excluded. The risk posed by these metabolites to aquatic organisms was assessed. For the metabolite JAU6476-desthio a quantitative assessment was performed as the metabolite shows a higher chronic toxicity to fish and daphnias as the active substance. Within the EU-review of the active substance prothioconazole toxicity data on fish, invertebrates and algae were also assessed for the metabolites JAU6476-S-methyl and 1,2,4-triazole and it was concluded that both metabolites pose a low risk to aquatic organisms. The metabolite JAU 6476-triazolylketone was not assessed within the EU review process but toxicity data on fish, invertebrates and algae show that this metabolite also poses a low risk to aquatic organisms.

Within this national addendum the calculations of PECsw were performed with EVA 2.1 and Exposit 3.01. Deposition of the active substances bixafen, and prothioconazole in surface water following volatisation is generally not expected as all substances have a vapour pressure below 10^{-5} Pa (20°C) and hence are not volatile. Therefore a calculation of exposure, resulting from volatisation and deposition, with the model EVA 2.1 is not necessary. For details please refer to Part B, Section 5 national addendum.

Table 6.2-5: Endpoints of Bixafen and Prothioconazole used for the PEC_{SW} calculations with EVA 3.0

Parameter	**Bixafen**	**Reference**
vapour pressure at 20 °C (Pa)	4.6 x 10-8	See Table 5.6-1 of the Section 5 core assessment
Solubility in water (mg/L)	0.49 at pH5-9	See Table 5.6-1 of the Section 5 core assessment
DissT50 water (d)	25.5-27.4	See Table 5.6-1 of the Section 5 core assessment
DT50 water/sediment study, total system (d)	1000*	See Table 5.6-1 of the Section 5 core assessment
hydrolysis/photolysis	1000	Default
Parameter	**Prothioconazole**	**Reference**
vapour pressure at 20 °C (Pa)	<< 4x 10-7 Pa	See Table 5.6-8 of the Section 5 core assessment

Solubility in water (mg/L)	300 at pH 8	See Table 5.6-8 of the Section 5 core assessment
DissT50 water (d)	0.8-3.4	See Table 5.6-8 of the Section 5 core assessment
DT50 water/sediment study, total system (d)	6.7	See Table 5.6-8 of the Section 5 core assessment
hydrolysis/photolysis	1000	Default

*SFO, worst case

6.1.10.3 Risk assessment –overall conclusions

The risk to aquatic organisms following exposure to Aviator Xpro via spray drift and for the entry routes run-off and drainage is not acceptable without drift reducing measures or without buffer zones.

6.1.11 Toxicity to Exposure ratio

6.1.11.1 TER values for the entry into surface water via spraydrift

The calculation of PECsw after exposure via spray drift and volatilisation is performed using the model EVA 2.1. The resulting PECsw and TER-values for the intended uses group A and B are given in the following tables. TER-values in bold are above the relevant trigger.

Table 6.2-5: TER-values for the active substance Bixafen after exposure via spray drift and volatilization with subsequent deposition modeled with EVA 3.0

Compound:			Bixafen					
Use no:			Group A, BBCH 30-39 wheat, rye					
Growth stage and season			70 % interception					
Application rate / number of applications / interval			93.75g/ha Bixafen/ 2 applications/ 14d intervall (worst case)					
DT50 water (SFO):			27.4 d					
PEC-selection:			Actual					
Scenario / Drift-Percentile:			Agriculture / 82nd percentile of drift probabilities					
Buffer zone	Entry via spraydrift		Entry via deposition following volatilization		PECsw [µg as/L]; conventional and drift reducing technique			
[m]	[%]	[µg/L]	[%]	[µg/L]	0% conv.	50% red.	75% red.	90% red.
0	100.00	53.18	-	-				
1	2.38	1.266	-	-	1.266	0.633	0.316	0.127
5	0.47	0.250	-	-	0.250	0.125	0.062	0.025

10	0.24	0.128	-	-	0.128	0.064	0.032	0.013
15	0.16	0.085	-	-	0.085	0.043	0.021	0.009
20	0.12	0.064	-	-	0.064	0.032	0.016	0.006
Relevant toxicity endpoint: NOEC = 0.0046 mg a.s./L (*P. promelas*) Relevant TER: 10								
Buffer zone [m]					TER			
0					-	-	-	-
1					3.6	7.3	**14.5**	**36.3**
5					**18.4**	**36.8**	**73.6**	**184.0**
Risk mitigation measures			NW 605/606 (5 m conv. and 50 % drift red.; 0 m 90 resp. 75 % drift red.)					

Compound:			Bixafen					
Use no:			Group B, BBCH 30-39 wheat, rye					
Growth stage and season			70 % interception					
Application rate / number of applications / interval			75g/ha Bixafen/ 2 applications/ 14d intervall (worst case)					
DT50 water (SFO):			27.4d					
PEC-selection:			Actual					
Scenario / Drift-Percentile:			Agriculture / 82nd percentile of drift probabilities					
Buffer zone	Entry via spraydrift		Entry via deposition following volatilization		PECsw [µg as/L]; conventional and drift reducing technique			
[m]	[%]	[µg/L]	[%]	[µg/L]	0% conv.	50% red.	75% red.	90% red.
0	100.00		-	-				
1	2.38	1.013	-	-	1.013	0.506	0.253	0.101
5	0.47	0.200	-	-	0.200	0.100	0.050	0.020
10	0.24	0.102	-	-	0.102	0.051	0.026	0.010
15	0.16	0.068	-	-	0.068	0.034	0.017	0.007
20	0.12	0.051	-	-	0.051	0.026	0.013	0.005
Relevant toxicity endpoint: NOEC = 0.0046 mg a.s./L (*P. promelas*) Relevant TER: 10								
Buffer zone [m]					TER			
0						-	-	-
1					4.5	9.1	**18.2**	**45.4**
5					**23.0**	**46.0**	**92.0**	**230.0**
Risk mitigation measures			NW 605/606 (5 m conv. and 50 % drift red.; 0 m 90 % resp. 75 % drift red.)					

Since Bixafen accumulates in the sediment, PECsw and PECsed as well as PECsed,accu after application of Aviator Xpro have been calculated for the entry path drift (for further details see section 5 national addendum Germany). This calculation has been conducted in accordance with the calculation on EU level for the DAR of Bixafen, except with a sediment depth of 1 cm. The PEC values are then used in combination with the sediment organisms' endpoints to calculate the respective TER values. The results are documented in the following table.

The concentration of Bixafen was calculated for a water body with 30L water and 10L sediment (1 cm sediment depth). A maximum amount of 88.3% Bixafen in the sediment phase was considered.

PEC sed. max= (53.18 µg/L x 300L x 0.833) / (10 L x 1.3 kg/L)= 1022.3 µg/kg

The plateau concentration PEC sed, plateau is PEC sed.max x faccu.

f_{accu} = e-kt/(1 – e-kt)= 3.47

k=degradation rate in sediment (ln(2) / DT_{50}), DT_{50} whole system: 1000d

t= time between growing seasons (365d)

1022.3 µg/kg x 3.47= 3547.4 µg/kg

The overall accumulation PEC in sediment is

PEC sed, accu. overall= PEC sed, plateau + PECsed, max

3547.4 µg/kg +1022.3 µg/kg = **4569.7 µg/kg**

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. Please refer to Section 5.6.1.2 of national addendum of Section 5.

Table 6.2-6: TER-values for the active substance Bixafen after exposure via spray– based on accumulation in sediment (PEC sed, accu. overall)

Compound:		Bixafen	
Use no:		Group A, BBCH 30-39 wheat, rye	
Growth stage and season		70 % interception	
Application rate / number of applications / interval		93.75g/ha Bixafen/ 2 applications/ 14d intervall (worst case)	
DT50 water (SFO):		27.4 d	
PEC-selection:		Actual	
Scenario / Drift-Percentile:		Agriculture / 82nd percentile of drift probabilities	
Buffer zone	Entry via spraydrift	Entry via deposition following volatilization	PECsed,accu (via drift and volatilisation) (µg/kg) depending on application technique (drift reduction)

[m]	[%]	[µg/kg]	[%]	[µg/L]	0% conv.	50% red.	75% red.	90% red.
0	100.00	4569.7	-	-	4569.7	456.9	1142.4	2284.8
1	2.38	108.76	-	-	108.76	10.88	27.19	54.38
5	0.47	21.48	-	-	21.48	2.15	5.37	10.74
10	0.24	10.97	-	-	10.97	1.10	2.74	5.48
15	0.16	7.31	-	-	7.31	0.731	1.83	3.65
20	0.12	5.48	-	-	5.48	0.548	1.37	2.74
Relevant toxicity endpoint: NOEC = 20.0 mg a.s./kg sediment (*C. riparus*) /spiked sediment test Relevant TER: 10								
Buffer zone [m]					TER			
0					4.4	-	-	-
1					**183.9**	**1838.2**	**735.6**	**367.8**
Risk mitigation measures		none						

Based on the $PEC_{sed\ accu\ overall}$ the assessment for sediment dwelling organisms, presented by *Chironomus riparius,* results in acceptable TER-values without risk mitigation measures (for PECsed).

However the worst case assumption (as presented in the DAR and LOEP for bixafen and as considered here) that the active ingredient accumulates in the sediment and then is remobilized completely into the water phase within one single event seems to very unlikely. Additionally it should be taken into account that the assessment based on the Chironomus endpoint from the spiked-sediment test and the $PEC_{sed\ accu\ overall}$ shows acceptable TER-values without risk mitigation measures. Overall the assessment for the exposure via surface water and the chronic fish endpoint for bixafen seems to cover also the assessment for sediment organisms. There is some uncertainty regarding the possibility that bixafen may could be remobilized from sediment. However the risk mitigation measures which have to be implemented for Aviator Xpro are triggered by the results for the prothiconazole metabolite prothioconazole-desthio and it could be assumed that this approach covers also the risk posed by bixafen via remobilistaion from sediment.

Table 6.2-7: TER-values for the active substance Prothioconazole-Desthio after exposure via spray drift and volatilization with subsequent deposition modeled with EVA 3.0

Compound:		Prothioconazole-Desthio	
Use no:		Group A, BBCH 30-39 wheat, rye	
Growth stage and season		70 % interception	
Application rate / number of applications / interval		187.5g/ha Prothioconazole-Desthio/ 2 applications/ 14d intervall (worst case)	
DT50 water (SFO):		23.1 d	
PEC-selection:		Actual	
Scenario / Drift-Percentile:		Agriculture / 82nd percentile of drift probabilities	
Buffer	Entry via spraydrift	Entry via deposition	PECsw [µg as/L]; conventional and drift reducing

zone			following volatilization		technique			
[m]	[%]	[µg/L]	[%]	[µg/L]	0% conv.	50% red.	75% red.	90% red.
1	2.38	2.465	-	-	2.465	1.232	0.616	0.246
5	0.47	0.487	-	-	0.487	0.243	0.122	0.049
10	0.24	0.249	-	-	0.249	0.124	0.062	0.025
15	0.16	0.166	-	-	0.166	0.083	0.041	0.017
20	0.12	0.124	-	-	0.124	0.062	0.031	0.012
Relevant toxicity endpoint: NOEC = 0.00344 mg a.s./L *(O.mykiss)* Relevant TER: 10								
Buffer zone [m]					TER			
1					1.4	2.8	5.6	**14.0**
5					7.1	**14.1**	**28.3**	**70.7**
10					**13.8**	**27.7**	**55.4**	**138.4**
Risk mitigation measures			NW 605/606 (10 m conv., 5 m 75% and 50 % drift red.; 0 m 90 % drift red.)					

Compound:	Prothioconazole-Desthio
Use no:	Group B, BBCH 30-39 wheat, rye
Growth stage and season	70 % interception
Application rate / number of applications / interval	150g/ha Prothioconazole Desthio/ 2 applications/ 14d intervall (worst case)
DT50 water (SFO):	23.1d
PEC-selection:	Actual
Scenario / Drift-Percentile:	Agriculture / 82nd percentile of drift probabilities

Buffer zone	Entry via spraydrift		Entry via deposition following volatilization		PECsw [µg as/L]; conventional and drift reducing technique			
[m]	[%]	[µg/L]	[%]	[µg/L]	0% conv.	50% red.	75% red.	90% red.
0	100.00		-	-				
1	2.38	1.972	-	-	1.972	0.986	0.493	0.197
5	0.47	0.389	-	-	0.389	0.195	0.097	0.039
10	0.24	0.199	-	-	0.199	0.099	0.050	0.020
15	0.16	0.133	-	-	0.133	0.066	0.033	0.013
20	0.12	0.099	-	-	0.099	0.050	0.025	0.010
Relevant toxicity endpoint: NOEC = 0.0046 mg a.s./L (*P. promelas*) Relevant TER: 10								
Buffer zone [m]					TER			
1					1.7	3.5	7.0	**17.4**
5					8.8	**17.7**	**35.3**	**88.3**

10	**17.3**	**34.6**	**69.2**	**173.0**
Risk mitigation measures	NW 605/606 (10 m conv. , 5 m 50 % and 75% drift red., 0m 90 % drift red.)			

6.1.11.2 TER values for the entry into surface waters via run-off and drainage

For details on the EXPOSIT modelling, see dRR NA Part B, Section 5.6. The input parameters for the active substances and the metabolite Prothioconazole-Desthio used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.01 are summarised in the following table.

Table 6.2-8: Input parameters for Bixafen and Prothiocaonazole used for PEC_{SW} 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	see core assessment, section 5, point 5.3.1.1
Reduction by bank filtration (only relevant for PECgw see 5.7.2)	100%	
Parameter	**Prothioconazole**	**Reference**
K foc, Runoff	1765	arithm. mean (see core assessment, section 5, chapter 5.4.2)
Kfoc, mobility class	1765	arithm. mean (see core assessment, section 5, chapter 5.4.2)
DT50 soil (d)	2.4	
Solubility in water (mg/L)	300	see core assessment, section 5, point 5.3.1.1
Reduction by bank filtration (only relevant for PECgw see 5.7.2)	100%	
Parameter	**Prothioconazole-Desthio**	**Reference**
K foc, Runoff	575	arithm. mean (see core assessment, section 5, chapter 5.4.2)
Kfoc, mobility class	575	arithm. mean (see core assessment, section 5, chapter 5.4.2)
DT50 soil (d)	23.1	
Solubility in water (mg/L)	300	see core assessment, section 5, point 5.3.1.1

The resulting PECsw and TER-values for the intended use-groups A and B are given in the following tables. TER-values in bold are above the relevant trigger.

As Bixafen is very persistent – no plateau was reached in soil after applications over 8 following years- it was assumed that the rainfall event occurs after perennial application of Bixafen. The application rate of 93.75 g/ha was corrected to 160 g/ha in order to consider the PECaccu concentration in soil. Please refer to Sec 5 chapter 5.6.2.

Table 6.2-9: EXPOSIT 3.01 calculation for Bixafen

Active substance	Bixafen	
Use no:	Group A	
Application rate / no. of applications / interval	160g/ha Bixafen/ 2 applications/ 14d intervall (worst case)- please refer to explanation above.	
Interception	70 %	
Relevant toxicity endpoint:	NOEC = 0.0046 mg a.s./L (*P. promelas*)	
Relevant TER:	10	
Run-off		
Buffer zone [m]	**PEC [µg/L]**	**TER**
0	0.31	14.91
5	0.27	17.21
Drainage		
Time of application	**PEC [µg/L]**	**TER**
Autumn/winter/early spring	0.05	**100.23**
Spring/summer	0.01	**308.39**
Risk mitigation measures	**none**	

Due to the accumulation of Bixafen in sediment, PECsw and PECsed accu overall after application of Aviator Xpro have been calculated for the entry paths surface runoff and drainage (for further details see section 5 national addendum Germany). This calculation has been conducted in accordance with the calculation on EU level for the DAR of Bixafen, except with a sediment depth of 1 cm. The PEC values are then used in combination with the sediment organisms' endpoints to calculate the respective TER values. The results are documented in the following table.

Table 6.2-10: TER calculation for Bixafen based on sediment PEC

Active substance	Bixafen
Use no:	Group A
Application rate / no. of applications	160g/ha Bixafen/ 2 applications/ 14d intervall (worst case)

/ interval		
Interception	70 %	
Relevant toxicity endpoint:	NOEC = 20.0 mg a.s./kg sediment (*C. riparus*)	
Relevant TER:	10	
Run-off		
Buffer zone [m]	**PECsed accu overall [µg/kg]**	**TER**
0	26.37	**758**
Drainage		
Time of application	**PECsed [µg/kg]**	**TER**
Autumn/winter/early spring	4.29	**4662**
Spring/summer	0.86	**23256**
Risk mitigation measures	**none**	

Table 6.2-11: EXPOSIT 3.01 calculation for Prothioconazole

Active substance	Prothioconazole	
Use no:	Group A	
Application rate / no. of applications / interval	187.5 g/ha Prothioconazole / 2 applications / 14 d interval (worst case)	
Interception	70 %	
Relevant toxicity endpoint:	E_bC_{50} = 0.018 mg a.s./L (*S. costatum*)	
Relevant TER:	10	
Run-off		
Buffer zone [m]	**PEC [µg/L]**	**TER**
0	0.12	**146.2**
Drainage		
Time of application	**PEC [µg/L]**	**TER**
Autumn/winter/early spring	0.01	**1555.8**
Spring/summer	0.00	**4787.0**
Risk mitigation measures	**none**	

Table 6.2-12: EXPOSIT 3.01 calculation for Prothioconazole-Desthio

Active substance	Prothioconazole-Desthio
Use no:	Group A
Application rate / no. of applications	187.5 g/ha Prothioconazole / 2 applications / 14 d interval (worst case)

/ interval		
Interception	70 %	
Relevant toxicity endpoint:	NOEC = 0.00334 mg a.s./L (*O. mykiss*)	
Relevant TER:	10	
Run-off		
Buffer zone [m]	**PEC [µg/L]**	**TER**
0	0.60	5.54
5	0.52	6.39
10	0.45	7.46
20	0.31	**10.65**
Drainage		
Time of application	**PEC [µg/L]**	**TER**
Autumn/winter/early spring	0.82	4.08
Spring/summer	0.27	**12.55**
Risk mitigation measures	**NW 706 (20 m vegetated buffer strip) (NW 800 - Application not allowed on drained areas between 1 November and 15 March.)**	

Table 6.2-13: EXPOSIT 3.01 calculation for Prothioconazole-Desthio

Active substance	Prothioconazole-Desthio	
Use no:	Group B (covers group B)	
Application rate / no. of applications / interval	150g/ha Prothioconazole Desthio/ 2 applications/ 14d intervall (worst case)	
Interception	70 % interception	
Relevant toxicity endpoint:	NOEC = 0.00334 mg a.s./L (*O. mykiss*)	
Relevant TER:	10	
Run-off		
Buffer zone [m]	**PEC [µg/L]**	**TER**
0	0.48	6.93
5	0.42	7.99
10	0.36	9.32
20	0.25	**13.32**
Drainage		
Time of application	**PEC [µg/L]**	**TER**
Autumn/winter/early spring	0.66	5.10
Spring/summer	0.21	**15.68**
Risk mitigation measures	**NW 706 (20 m vegetated buffer strip)**	

	(NW 800 - Application not allowed on drained areas between 1 November and 15 March.)

An application of Aviator Xpro on drained areas between 1 November and 15 March is not applied by the applicant, thus an assignment of NW 800 is not necessary.

Regarding the exposure via run-off and drainage the TER values are greater than the relevant TER trigger of 10 for the worst case assessment of the metabolite JAU 6476-desthio (covers the active substances) considering risk mitigation measures. It could be concluded that the formulation Aviator Xpro does not pose an unacceptable risk if it is not applied on drained fields between November and March.

Due to the toxicity of the active ingredients as well as the formulation, the following labels must be indicated:

Group A and group B

NW 262 The product is toxic for algae.

Bixafen: *Pseudokirchnerilla subcapitata* EbC50 : 0.0657 mg/L
Prothioconazole: *Skeletonema costatum* EbC50: 0.018 mg/L

NW 264 The product is toxic for fish and aquatic invertebrates.

Bixafen: *Daphnia magna* NOEC: 0.05 mg/L
Prothioconazole *Daphnia magna* NOEC: 0.56 mg/L

NW 265 The product is toxic for higher aquatic plants.

Prothioconazole-Desthio: *Lemna gibba*, EC50 = 0.0394 mg/L

Prothioconazole: *Lemna gibba*, EC50= 0.074 mg/L

Group A and B (caused by Prothioconazole Desthio):

NW 605/606 Drift reduction 90 % 0 m; 75 % 5°m; 50 % 5 m, con. 10 m

Group A and B

NW 706 20 m vegetated buffer strip

NW 800 Application not allowed on drained areas between 1 November and 15 March

6.1.12 Overall conclusions

Based on the calculated concentrations of bixafen, prothioconazole and prothioconazole-desthio 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, prothioconazole and prothioconazole-desthio according to the GAP of the formulation Aviator 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 Aviator Xpro in cereals according to the label.

6.2 Effects on bees (MIIIA 10.4, KPC 10.3.1)

Please refer to the core assessment.

6.3 Effects on arthropods other than bees (MIIIA 10.5, KPC 10.3.2)

The applicant has submitted data on the effect of Aviator Xpro on non-target arthropods.

Please refer to the core assessment.

6.4 Effects on non-target soil meso- and macrofauna (MIIIA 10.6, KPC 10.4, KPC 10.4.1, KPC 10.4.2)

Earthworms, other soil non-target macro and mesofauna as well as soil organisms involved in the breakdown of dead organic matter will be exposed to plant protection products containing Bixafen and Prothioconazole whenever contamination of soil may occur as a result of the intended uses of Aviator Xpro.

Effects on earthworms and other soil non-target organisms resulting from an exposure to Aviator Xpro were not evaluated as part of the EU review of any of the active substances. All relevant study data for the assessment of the risk to earthworm and other soil non-target macro-and mesofauna from the intended uses of Aviator Xpro are provided here.

For the choices of relevant endpoints, please refer to the core assessment.

Table 6.4-1: EU agreed endpoints and new endpoints for earthworms and other soil macro- and mesofauna

Test substance	Species	Time scale	Results [mg/kg soil dw]	Reference	Internal code
Laboratory studies					
Bixafen	*Eisenia fetida*	Acute	LC_{50} > 1000 mg	Lührs, U.	69540

		14 d 5% peat	a.i./kg sdw	18.10.2006 29612021	
Bixafen	*Eisenia fetida*	56 d chronic 5 % peat	NOEC =100 mg/kg dw reproduction	Lührs, U. 23.08.2006 29611022	69541
Bixafen	*Folsomia candida*	28 d chronic, 5% peat	NOEC: 7.74 mg/kg dw reproduction	Lührs, U. 10.08.2007 36952016	69542
Bixafen EC 125 (122.5 g/L)	*Hypoaspis aculeifer*	14 d	NOEC : 6.15 mg a.s./kg substrate reproduction nominal 5% peat	Kratz, M.-A. 2007 E 428 3292-0	69543
prothioconazole (JAU 6476)	*Eisenia fetida*	14 d acute 10 % peat	LC_{50} > 1000 mg/kg dw * **$LC_{50\ corr.}$ > 500 mg/kg dw**	Meisner, P. 10.04.2000 E 310 1769-7	45889
prothioconazole (JAU 6476)	*Eisenia fetida*	chronic	NOEC: 1.33 mg/kg dw* **NOEC $_{corr.}$: 0.67 mg/kg dw**	Loep 2007	-
prothioconazole (JAU 6476)	*Folsomia candida*	28 d chronic 10% peat	NOEC: 64 mg/kg dw NOEC $_{corr.}$: 32 mg/kg dw [1)]	Loep 2007	-
prothioconazole (JAU 6476)	*Folsomia candida*	28 d chronic	NOEC >= 1000 mg a.i./kg sdw	Frommholz, U. 12.04.2011 FRM-COLL-118/11	82310
prothioconazole (JAU 6476)	*Hypoaspis aculeifer*	14 d Lab extended test with natural standard soil (LUFA 2.1) (ca. 0.9% organic carbon)	NOEC ≥ 100 mg/kg soil dw reproduction nominal	Hoogendoorn, G.M. 06.09.2000 B060HAE	45923
JAU 6476-desthio	*Eisenia fetida*	14 d acute 10 % peat	LC_{50} > 1000 mg/kg dw* **$LC_{50\ corr.}$ > 500 mg/kg dw**	Meisner, P. 29.06.2000 MPE/Rg 338/00 ; E 310 1844-1	45898
JAU 6476-desthio	*Eisenia fetida*	56 d chronic	NOEC: 1 mg/kg dw*	Meisner, P.	45902

		10 % peat	**NOEC corr: 0.5 mg/kg dw**	31.10.2000 E 312 1799-2 ; MPE/Rg 332/00	
JAU 6476-desthio	*Folsomia candida*	28 d chronic 10% peat	NOEC: 62.5 mg/kg dw NOEC corr.: 31.3 mg/kg dw 1)	Loep 2007	-
JAU 6476-S-methyl	*Eisenia fetida*	14 d acute 10 % peat	LC_{50} > 1000 mg/kg dw* **$LC_{50\ corr.}$ > 500 mg/kg dw**	Heimbach, F. 25.01.2000 E 310 1743-9 ; HBF/Rg 321	45900
JAU 6476-S-methyl	*Eisenia fetida*	56 d chronic 10 % peat	NOEC: 100 mg/kg dw* **NOEC corr.: 50 mg/kg dw**	Heimbach, F. 01.02.2000 E 312 1713-8 ; HBF/Rg 317	45903
Prothioconazol-Metab. (JAU 6476-S-Methyl)	*Folsomia candida*	28 d Lab log Pow = 4.19	NOEC : >= 31.6 mg/kg d.w. soil 2) Mortality/reproduction NOECcorr : >= 15.8 mg/kg d.w. soil reproduction	Moser, T.; Scheffczyk, A. 2001 P35CR	45922
Aviator Xpro	*Eisenia fetida*	Acute 14 d 5% peat	LC50 >1000 mg pr./kg sdw	Luehrs (2006) 31201021 M-280033-01-1	69524
Aviator Xpro	*Eisenia fetida*	56 d Chronic 5% peat	NOEC = 75 L pr/ha NOEC= 9.375 L pr/ha reproduction[1]	Luehrs (2006) 31202022 M-281333-01-1	69525
Aviator Xpro	*Folsomia candida*	28 d	NOEC= 104 mg/kg dw Reproduction: NOEC= 208 mg kg/dw	Lührs, U. 10.08.2007 31209016	69527
Field studies					
Field test with prothioconazole mono formulation JAU 6476 EC 250 EC 50= 200 g a.i./ha					76463
Litter bag test					
-					

*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).

[1] Lower endpoint is used for risk assessment by UBA. Recalculation of test showed that reproduction rates were different compared to the control in treatment group 18.75 L/ha (statistic evaluation was done with Williams-test, with Tox-Rat). Thus NOEC for reproduction effects is 9.375 L/ha.

6.4.1 Justification for new endpoints

Please refer to the core assessment.

6.4.2 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. The resulting maximum PECsoil values for the active substances bixafen, prothioconazole and the major soil degradation products are presented in the table below. Calculations considered the maximum application rate of 1.250 L formulation/ha and a minimum of 70 % foliar interception for applications to cereals at BBCH growth stage 30-69. PEC values for the soil metabolites were calculated considering the maximum percentage of their formation observed in either the aerobic or anaerobic soil degradation studies and correcting for molecular weight.

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.

For risk assessment purposes, a risk envelope approach was used. Hence, intended use groups A and B cover the risk for earthworms and other soil macro- and mesofauna from all intended uses .

For assessment of PECaccu-accumulation of bixafen in soil please refer to Part B Section 5 CA chapter 5.5. to: Due to the slow degradation of the active substance Bixafen in soil ($DT_{90} > 365$ d, field data) the accumulation potential needs to be considered. Therefore PEC_{soil} used for risk assessment comprises background concentration in soil (PEC_{accu}) deducted 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 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 DT50 of 1235 days represents only 80% of the calculated background concentration for a substance with such a long DT50 value. Therefore, the remaining 20% had to be taken intoaccunt for the calculation of the background concentration. Further, as no plateau was reached, we used additionally an uncertainity factor of 10 for the background concentration (see comment of zRMS to Heinemann, Weuthen 2013 in Appendix 3 of Section 5). As the soils were ploughed, the background concentration was calculated for a

soil depth of 20cm, although the residues in the soil accumulation study were found in 0-10 cm dephth. Based on all informations about the degradation of Bixafen in soil 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.**

The toxicity endpoints and worst-case initial PECsoil estimates for the relevant substances are summarized in the following Table:

Table 6.4-2: Maximum calculated PEC_{SOIL} values for grop A

plant protection product:		Aviator Xpro				
group:		A				
Number of applications/intervall		2/ 14d				
application rate:		93.75 g/ha				
crop interception:		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)**
Prothioconazole	2 x 56,25 g/ha M:344.3	1	0.3816 on day 14	-	-	-
Metabolite M01, JAU 6476-S-methyl	Ff=0.14, M: 358.3	1	0.072 on day 21	-	-	-
Metabolite M04, JAU 6476-desthio	Ff=0.8, M: 312.2	1	0.4506 on day 23	20	0.0003	0.4509
Product Aviator Xpro	Density 1.01, 1x 2525 g/ha	1	16.8335			
active substance/ formulation	**soil relevant application rate (g/ha)**	**soil dept-h_{act} (cm)**	**PEC_{act} (mg/kg)**	**PEC_{bkgd} x3.7* +20%** (mg/kg)**	**PEC_{bkgd} x10 ** (mg/kg)**	**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg**
Bixafen	1x 56.25 g/ha	1	0.375			1.21
		20	0.0188	0.0694 +20% = 0.0833	0.833	

*) factor deduced from soil accumulation study,
**) only 80% of the low plateau can be reched during 8 years, based on the DT_{50} value of 1235days for Bixafen

Table 6.4-3: Maximum calculated PEC_{SOIL} values for group B

plant protection product:		Aviator Xpro				
group:		B				
Number of applications/intervall		2/ 14d				
application rate:		75g/ha				
crop interception:		70%				
active substance/ formulation	**soil relevant application rate (g/ha)**	**soil depth$_{act}$ (cm)**	**PEC_{act} (mg/kg)**	**PEC_{bkgd} x3.7*+20% ** (mg/kg)**	**PEC_{bkgd} x10 ** (mg/kg)**	**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg**
Bixafen	1x 45 g/ha	1	0.300	-		0.961
	PEC_{bkgd}	20	0.015	0.055 +20% =0.066	0.661	-

*) factor deduced from soil accumulation study,
**) only 80% of the low plateau can be reched during 8 years, based on the DT_{50} value of 1235days for Bixafen

The acute risk for earthworms and other non-target soil macro- and mesofauna resulting from an exposure to 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 breackdown resulting from an exposure to bixafen and prothioconazole as well as the major soil degradation products of prothioconazole 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 6.4-4: TER values for earthworms and other soil macro- and mesofauna (Tier-1): *Folsomia candida* and *Hypoaspis aculeifer* , Group A, 2x 1.25 L product/ha, 2x 93.75 g Bixafen/ha, 2x 187.5 g Prothioconazole/ha, 14d interval

Test substance	Worst-case use pattern	Timescale	Endpoint (mg/kg dw soil)	PEC (mg/kg dw soil	TER	TER risk assessment trigger
Earthworms *(Eisenia fetida)*						
bixafen	**1 x 1.25 L product/ha in cereals**	**Acute**	> 1000	1.21	**> 826**	**10**
		Long-term	100		**82.6**	**5**
prothioconazole		**Acute**	> 500	0.3816	**> 1310**	**10**
		Long-term	0.67		1.8	**5**
JAU 6476-desthio		**Acute**	> 500	0.4509	**>1109**	**10**
		Long-term	0.5		1.1	**5**
JAU 6476-S-methyl		**Acute**	>500	0.072	**>6944**	**10**
		Long-term	50		**6944**	**5**
Aviator Xpro		**Acute**	>1000	16.8335	**>59.4**	**10**
		Long-term	9.375 L/ha	0.168 L/ha*	**55.4**	**5**
Other soil meso- and macrofauna Collembola *(Folsomia candida)*						
bixafen		**Long-term**	7.74	1.21	**6.3**	**5**
prothioconazole		**Long-term**	32	0.3816	**83.8**	**5**
JAU 6476-desthio		**Long-term**	31.3	0.4509	**69.4**	**5**
JAU 6476-S-methyl		**Long-term**	15.8	0.072	**219.0**	**5**
Aviator Xpro		**Long-term**	104	16.8335	**6.2**	**5**
Hypoaspis aculeifer						
bixafen		**Long-term**	6.15	1.21	**5.1**	**5**

*consists of application rate 1.25 L/ha with 70% interception: 2x28.125 g .ai./ha bixafen and 2x56.25 g a.i./ha prothioconazole/2 = 0.084 L/ha

Table 6.4-5: TER values for earthworms and other soil macro- and mesofauna (Tier 1): *Folsomia candida* and *Hypoaspis aculeifer* , Group B, 2x 10 L product/ha, 2x 75.0 g Bixafen/ha, 2x 187.5 g Prothioconazole/ha, 14d interval

Test substance	Worst-case use pattern	Timescale	Endpoint (mg/kg dw soil)	PEC (mg/kg dw soil	TER	TER risk assessment trigger
Earthworms *(Eisenia fetida)*						
bixafen	**1 x 1.25 L**	**Acute**	> 1000	0.961	**>1040**	**10**

	product/ha in cereals	**Long-term**	100		**61.3**	**5**
Other soil meso- and macrofauna Collembola *(Folsomia candida)*						
bixafen		**Long-term**	7.74	0.961	**8.1**	**5**
Hypoaspis aculeifer						
bixafen		**Long-term**	6.15	0.961	**6.4**	**5**

For prothioconazole and the its metabolite JAU 6476-desthio the TER_{LT} is in *Eisenia fetida* below the trigger 5, thus further refinement is needed.

6.4.3 Higher tier risk assessment

Refinement of TER_{LT} for prothioconazole and prothioconazole-desthio for earthworms:

An earthworm field study has been performed by the applicant with the formulation Prothioconazole EC 250 (Lechelt-Kunze, 2002 – document M-040814-03-1, KIIIA 10.6.4/01). 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, this 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.

Furthermore the notifyer submitted a collembolan field study (Schulz, 2015) looking at the effects of bixafen + prothioconazole + tebuconazole EC 275 (75 + 100 + 100) on natural collembola community. Please refer to Appendix 2 for complete evaluation of the study. The submitted field study (Schulz, 2015) shows effects on the observed population of soil macroorganisms (collembolans) already at the lowest tested concentration of 2 x 1.25 L/ha, which corresponds to the GAP of the use group A. Therefore, a 2 years monitoring study is required for the use group A.

6.4.4 Overall conclusions

With the formulation prothioconazole EC 250 a field study has been conducted (Lechelt-Kunze, C. 2002, Rep.-No.: E 311 2093-9, ICS-No. 46030). Here 3 x 200 g a.s./ha have been applied, which is considerably more than for the present indication for Aviator Xpro. The results of this study back up the risk of the ac-

tive substance prothioconazole and its metabolites to earthworms even for long-term exposure. But for risk asessement of bixafen in collembola no further refinement was presented.

Based on the predicted concentrations of bixafen, prothioconazole and its metabolites and the formulation Aviator Xpro in soils, the TER values describing the acute and longterm risk for earthworms following exposure to prothioconazole and bixafen and its metabolites according to the GAP of the formulation Aviator Xpro do achieve the acceptability criteria TER ≥ 10 resp. TER ≥ 5 after refinement according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2.

Based on the predicted concentrations of bixafen, prothioconazole and its metabolites and the formulation Aviator Xpro the TER values describing the acute and longterm risk for other non-target soil organisms as collembolans following exposure to bixafen, prothioconazole and its according to the GAP of the formulation Aviator Xpro dos 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. too.

The results of the assessment indicate an acceptable risk for soil organisms due to the intended use of Aviator Xpro in cereals according to the label. However, the submitted field study (Schulz, 2015) shows effects on the observed population of soil macroorganisms (collembolans) already at the lowest tested concentration of 2 x 1.25 L/ha, which corresponds to the GAP of the use group A. Therefore, a 2 years monitoring study is also required for the use group A.

Consequences for authorization:

A 2 years monitoring study of soil macroorganisms (collembolans) is required for the use group A.

6.5 Effects on soil microbial activity (MIIIA 10.7, KPC 10.5)

Please refer to the core assessment.

Please refer to the core dossier for the central zone. All effects were below the trigger value < 25 % after 28 days exposure, indicating that the proposed use of Aviator Xpro poses an acceptable risk to soil micro organisms.

6.6 Effects on non-target plants (MIIIA 10.8, KPC 10.6)

6.6.1 Effects on non-target terrestrial plants (MIIIA 10.8.1)

Please refer to the core assessment.

REGISTRATION REPORT

Part B

Section 7: Efficacy Data and Information

Detailed Summary

Product Code: Aviator Xpro

Reg. No.: ZV1 026764-00/00

Active Substance: Prothioconazole 150 g/L + Bixafen 75 g/L

Central Zone

Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Bayer CropScience

Date: 2012-03-27

Table of Contents

IIIA1 6 Efficacy Data and Information on the Plant Protection Product

General information

The present Registration Report (RR) is prepared to support the registration of the fungicide Aviator Xpro for the control of fungal diseases in cereals in the Central Registration Zone (Zone B). Aviator Xpro is formulated as a suspension concentrate (EC) containing 75 g/L bixafen and 150 g/L prothiocoanzole.

The application is a request for the first authorisation according to Art. 29 Reg. (EC) No 1107/2009. Germany (DE) is zonal rapporteur member state (zRMS). Other member states are not concerned (Table 6.0-1).

Table 6.0-1: Zonal rapporteur member state (zRMS) and concerned member states (cMS).

zRMS	Germany	DE
cMS	-	-

According to EPPO PP1/241 (zones of comparable climate in the EPPO region) Germany is part of the maritime EPPO zone.

Recent registration situation/history of the PPP

Bixafen is a new fungicidal active substance with the chemical code BYF 0587. In March 2008, an Annex II dossier for the active substance was submitted to PSD of the United Kingdom acting as rapporteur for the EU. In that dossier, the use of the compound was supported in cereals (spray application with an EC 125).
Bixafen is included on Annex I of Directive 91/41/EEC. The Rapporteur Member state for bixafen is the United Kingdom. The draft Review Report for bixafen and the EFSA Reasoned Opinion (2009) 7 (12) are considered to provide the relevant scientific information for the review of the product.

Prothioconazole (JAU 6476) was included in Annex I to Directive 91/414/EEC by Directive 2008/44/EC of 04 April 2008. Relevant information about this active substance may be found in the Annex II dossier and its supplements submitted by Bayer CropScience in March 2002 and 2006, respectively, in the draft assessment report (DAR) issued by the rapporteur member state UK in October 2004, and in the conclusions regarding the peer review of prothioconazole finalised by EFSA on 12 July 2007 (EFSA Scientific Report (2007) 106, 1-98).
For the implementation of the uniform principles of Annex VI, the conclusions of the review report on the active substance 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.

The Annex I Inclusion Directive for prothioconazole provides no specific provisions under Part B which need to be considered by the applicant in the preparation of this section and by the MS prior to granting an authorisation.

Information on the active ingredients (Uptake and mode of action)

Prothiocoanzole 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, Ustilago 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.

Prothioconazole is used for foliar application and seed treatment.

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 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 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 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.

Information on crops and pests

Diseases controlled by the plant protection product are: eyespot caused by *Oculimacula acuformis* and *O. yallundae*, leaf spot caused by *Mycosphaerella graminicola*, leaf spot & glume blotch caused by *Leptosphaeria nodorum*, powdery mildew caused by *Blumeria graminis*, yellow or stripe rust caused by *Puccinia striiformis*, brown rusts caused by *Puccinia recondita* in wheat, rye and triticale, *Puccinia hordei* in barley, tan spot caused by *Drechslera tritici-repentis* in wheat, leaf blotch caused by *Rhynchosporium secalis* in barley and rye, net blotch caused by *Pyrenophora (Drechslera) teres*, Ramularia leaf spot caused by *Ramularia collo-cygni*.

Table 6.0-2: Classification of crops and pests in the rapporteur member states (zRMS)

crop / pathogen	EPPO-Code	Classification of crop/situation		Classification of pest/disease	
		major	minor	major	minor
1	2	3		4	
Wheat / *Erysiphe graminis*	TRZAW / ERYSGR	DE		DE	
Wheat / *Septoria tritici*	TRZAW / SEPTTR	DE		DE	
Wheat / *Drechslera tritici-repentis*	TRZAW / PYRNTR	DE		DE	
Wheat / *Puccinia recondita*	TRZAW / PUCCRE	DE		DE	
Wheat / Oculimacula herpotrichoides	TRZAW / PDSCHE	DE		DE	
Wheat / *Puccinia striiformis*	TRZAW / PUCCST	DE		DE	
Wheat / *Septoria nodorum*	TRZAW / LEPTNO	DE		DE	
Barley / Erysiphe graminis	HORVX / ERYSGR	De		DE	
Barley / *Rhynchosporium secalis*	HORVX / RHYNSE	DE		DE	
Barley / *Pyrenophora teres*	HORVX / PYRNTE	DE		DE	
Barley / *Puccinia hordei*	HORVX / PUCCHD	DE		DE	
Barley / *Ramularia collo-cygni*	HORVX / RAMUCC	DE		DE	
Barley / *Physiological leaf spots*	HORVX / MEHITE	DE		DE	
Rye / *Erysiphe graminis*	SECCE / ERYSGR	DE		DE	
Rye / *Rhynchosporium secalis*	SECCE / RHYNSE	DE		DE	
Rye / *Puccinia recondita*	SECCE / PUCCRE	DE		DE	
Triticale / *Erysiphe graminis*	TTLWI / ERYSGR	DE		DE	
Triticale / *Septoria sp.*	TTLWI / SEPTSP	DE		DE	
Triticale / *Puccinia recondita*	TTLWI / PUCCRE	DE		DE	

Controlled pathogens:

Eyespot caused by *Oculimucula species O. acuformis* – anamorph: *Ramulispora yallundae* and *O. yallunda*e – 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 whiteheads. The risk of severe infection is increased in continual cereal cropping and early drilling.

Septoria leaf spot caused by *Mycosphaerella graminic*ola – anamorph: *Septoria tritici* is a major foliar disease problem for wheat growers. 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: *Stagonospora 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* 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. 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 and rye 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* 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. 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 secalis* in barley and rye is common in wet, cool maritime climates of Northern Europe. 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.

Information on the intended uses

(2012-07-11)

Use No.	**026764-00/00-001**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	wheat TRZSS
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)/aim(s)	powdery mildew *(Erysiphe graminis)* ERYSGR
Area of use	Outdoors
Time of treatment	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Interval between treatments	14 to 21 days
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1.25 L/ha in 150 to 400 L water/ha
additional requirements	
---	---
Use No.	**026764-00/00-002**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	wheat TRZSS
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)/aim(s)	Leaf spot of wheat (*Septoria tritici)* SEPTTR
Area of use	Outdoors
Time of treatment	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Interval between treatments	14 to 21 days
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1.25 L/ha in 150 to 400 L water/ha
additional requirements	
---	---
Use No.	**026764-00/00-003**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	wheat TRZSS
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)/aim(s)	tan spot of cereals *(Drechslera tritici-repentis)* PYRNTR
Area of use	Outdoors
Time of treatment	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Interval between treatments	14 to 21 days
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1.25 L/ha in 150 to 400 L water/ha
additional requirements	
---	---
Use No.	**026764-00/00-004**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	wheat TRZSS
Crop stage(s) (BBCH)	30 to 69
Pest(s)/target(s)/aim(s)	brown leaf rust of cereals *(Puccinia recondita)* PUCCRE
Area of use	Outdoors
Time of treatment	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Interval between treatments	14 to 21 days

Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1.25 L/ha in 150 to 400 L water/ha
additional requirements	
---	---
Use No.	**026764-00/00-005**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	wheat TRZSS
Crop stage(s) (BBCH)	29 to 32
Pest(s)/target(s)/aim(s)	eyespot of cereals *(Pseudocercosporella herpotrichoides)* PSDCHE
Area of use	Outdoors
Time of treatment	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	1
Max. number of treatments per crop or season	2
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1.25 L/ha in 150 to 400 L water/ha
additional requirements	
---	---
Use No.	**026764-00/00-006**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	wheat TRZSS
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)/aim(s)	stripe rust of cereals *(Puccinia striiformis)* PUCCST
Area of use	Outdoors
Time of treatment	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Interval between treatments	14 to 21 days
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1.25 L/ha in 150 to 400 L water/ha
additional requirements	
---	---
Use No.	**026764-00/00-007**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	wheat TRZSS
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)/aim(s)	leaf and glume blotch *(Septoria nodorum)* LEPTNO
Area of use	Outdoors
Time of treatment	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Interval between treatments	14 to 21 days
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1.25 L/ha in 150 to 400 L water/ha
additional requirements	
---	---
Use No.	**026764-00/00-008**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	barley HORVX
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)/aim(s)	powdery mildew *(Erysiphe graminis)* ERYSGR
Area of use	Outdoors
Time of treatment	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Interval between treatments	14 to 21 days
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1 L/ha in 150 to 400 L water/ha
additional requirements	

Use No.	**026764-00/00-009**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	barley HORVX
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)/aim(s)	leaf blotch of cereals *(Rhynchosporium secalis)* RHYNSE
Area of use	Outdoors
Time of treatment	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Interval between treatments	14 to 21 days
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1 L/ha in 150 to 400 L water/ha
additional requirements	

Use No.	**026764-00/00-010**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	barley HORVX
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)/aim(s)	net blotch *(Pyrenophora teres)* PYRNTE
Area of use	Outdoors
Time of treatment	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Interval between treatments	14 to 21 days
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1 L/ha in 150 to 400 L water/ha
additional requirements	

Use No.	**026764-00/00-011**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	barley HORVX
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)/aim(s)	brown rust of barley *(Puccinia hordei)* PUCCHD
Area of use	Outdoors
Time of treatment	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Interval between treatments	14 to 21 days
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1 L/ha in 150 to 400 L water/ha
additional requirements	

Use No.	**026764-00/00-012**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	barley HORVX
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)/aim(s)	Ramularia leaf spot disease *(Ramularia collo-cygni)* RAMUCC
Area of use	Outdoors
Time of treatment	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Interval between treatments	14 to 21 days
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1 L/ha in 150 to 400 L water/ha
additional requirements	

Use No.	**026764-00/00-013**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	barley HORVX

Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)/aim(s)	Physiologic leaf spots (PLS) MEHITE
Area of use	Outdoors
Time of treatment	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Interval between treatments	14 to 21 days
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1 L/ha in 150 to 400 L water/ha
additional requirements	
---	---
Use No.	**026764-00/00-014**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	rye SECCE
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)/aim(s)	powdery mildew *(Erysiphe graminis)* ERYSGR
Area of use	Outdoors
Time of treatment	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Interval between treatments	14 to 21 days
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1.25 L/ha in 150 to 400 L water/ha
additional requirements	
---	---
Use No.	**026764-00/00-015**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	rye SECCE
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)/aim(s)	leaf blotch of cereals *(Rhynchosporium secalis)* RHYNSE
Area of use	Outdoors
Time of treatment	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Interval between treatments	14 to 21 days
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1.25 L/ha in 150 to 400 L water/ha
additional requirements	
---	---
Use No.	**026764-00/00-016**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	rye SECCE
Crop stage(s) (BBCH)	30 to 69
Pest(s)/target(s)/aim(s)	brown leaf rust of cereals *(Puccinia recondita)* PUCCRE
Area of use	Outdoors
Time of treatment	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Interval between treatments	14 to 21 days
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1.25 L/ha in 150 to 400 L water/ha
additional requirements	
---	---
Use No.	**026764-00/00-017**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	triticale TTLSS
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)/aim(s)	powdery mildew *(Erysiphe graminis)* ERYSGR
Area of use	Outdoors
Time of treatment	From spring at beginning of infestation and/or when first symptoms become visible

Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Interval between treatments	14 to 21 days
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1.25 L/ha in 150 to 400 L water/ha
additional requirements	
---	---
Use No.	**026764-00/00-018**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	triticale TTLSS
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)/aim(s)	septoria-species *(Septoria spp.)* SEPTSP
Area of use	Outdoors
Time of treatment	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Interval between treatments	14 to 21 days
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1.25 L/ha in 150 to 400 L water/ha
additional requirements	
---	---
Use No.	**026764-00/00-019**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	triticale TTLSS
Crop stage(s) (BBCH)	30 to 69
Pest(s)/target(s)/aim(s)	brown leaf rust of cereals *(Puccinia recondita)* PUCCRE
Area of use	Outdoors
Time of treatment	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Interval between treatments	14 to 21 days
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1.25 L/ha in 150 to 400 L water/ha
additional requirements	
---	---

IIIA1 6.1 Efficacy data

IIIA1 6.1.1 Preliminary range-finding tests

Some studies for preliminary range finding tests have been submitted. The applicant describes that based on the results of field trials in cereals crops conducted in the years 2008 - 2010 in relevant cereal growing regions of North western and Central Europe (Germany, France and United Kingdom) the 1 / 1.25 / 2.0 / 3.5 ratio of the active substances (a.s.) bixafen and prothioconazole was justified.

Bixafen has been shown to exhibit a broad spectrum of activity against all important cereal diseases with a strong preventive and curative activity. Prothioconazole was demonstrated to be active against a wide range of fungal diseases including the most important foliar and stem base pathogens of cereals.

The co-formulated product Aviator Xpro EC 225 combines the spectrum of activity of a typical broad spectrum de-methylation-inhibitor (DMI) with that of a broad spectrum carboxamide and provides at the same time an efficient tool for resistance prevention by mixing products with different modes of action.

Table 6.1.1-1: Preliminary findings test with prothioconazole and bixafen

Disease	% disease	Mean % control (mean % relative for yield)					
	Untreated	Bixafen	Prothio.	Bixafen & Prothioconazole			Standard
g/ha bixafen		75		50	75	100	-
g/ha prothioconazole			150	175	150	125	
ratio		-	-	1:3.5	1:2	1:1.25	-
S. tritici (5 trials)	51.4	62.2	76.0	86.0	89.6	86.0	84.8
O. species (3 trials)	50.3	50.0	37.3	53.3	55.7	52.7	47.7
D. teres (2 trials)	56.0	89.5	90.5	90.0	92.5	91.5	89.0
Relative yield (4 trials)	[82.3 dt/ha]	131	136	140	142	140	137

Standard: prothioconazole & fluoxastrobin at 125+125 g/ha (*D. teres*)
prothioconazole & spiroxamine at 200+375 g/ha (*S. tritici*, *O.* species, yield)

Several ratios of bixafen & prothioconazole were evaluated under field conditions against *Septoria tritici* and *Puccinia recondita* on wheat and *Rhynchosporium secalis* and *Drechslera teres* on barley (Table 6.1.1-1). Results clearly indicate that the 1:2 ratio in the plant protection product bixafen & prothioconazole EC 225 achieved overall the best level of performance. Compared to the 2 other ratios and for the same total amount of active substances it gives the maximum and best additive effects.

IIIA1 6.1.2 Minimum effective dose tests

To determine the minimum effective dose, the applicant provided data from experiments in wheat, barley, rye and triticale with different fungal pathogens.

Wheat

In the minimum effective dose wheat trials Aviator Xpro applied at 1.25 L/ha gave an sufficient control of all tested wheat pathogens. A clear dose response could be seen for *Blumeria graminis*, *Septoria tritici, Drechslera tritici-repentis* and *Puccinia recondita*. Especially against *S. tritici, Drechslera tritici-repentis* and *P. recondita, as* two main wheat pathogens the dose reduction from 1.25 L/ha to 0.75 L/ha resulted in a decreased of disease control of about 11-14 % under a medium infection pressure. These results indicate that a dose rate of 1.25l/ha is necessary to control the main wheat pathogens under high disease pressure. Main data is shown in the table below (Table 6.1.2-1).

Table 6.1.2-1: Minimum effective dose trials in wheat

Disease	Untreated	Abbott (mean % control)			
	% severity	Aviator Xpro			Standards
		1.25 L/ha	1.0 L/ha	0.75 L/ha	N rate
B. graminis (4 trials)	21.7	80.6	74.6	66.4	81.2
S. tritici (10 trials)	32.6	80.8	74.9	68.2	73.9
D. tritici-repentis (4 trials)	17.8	90.5	86.1	79.9	90.9
P. recondita (6 trials)	16.9	97.7	96.7	93.6	94.8

Barley

In the minimum effective dose barley trials Aviator Xpro applied at 1.0 L/ha gave an sufficient control of all tested barley pathogens. A clear dose response against *Rhynchosporium secalis* and *Blumeria graminis* and Physiological leaf spot (PLS) with the reduction of efficacy by 4 % in the first step, while for *Pyrenophora teres*, *Ramularia* (*R. collo-cygni*) and *P. teres* only a slight effect was present, but always giving a better control at all dose rates compared to the standards. To give a sufficient control under a high disease pressure and unfavourable conditions the dose rate of 1.0 L/ha is necessary. Main data is summarized in the table below (Table 6.1.2-2).

Table 6.1.2-2: Minimum effective dose trials in barley

Disease		Untreated	Abbott (mean % control)			
		% severity	Aviator Xpro (L/ha)			Standards
			1.0	0.8	0.6	N rate
B. graminis	(4 trials)	5.9	93.7	90.0	81.4	94.7
R. secalis	(8 trials)	4.0	86.8	82.2	78.3	89.4
P. teres	(10 trials)	19.2	95.0	94.8	93.9	89.8
P. hordei	(3 trials)	29.3	99.8	99.1	97.8	99.8
R. collo-cygni	(3 trials)	37.2	98.4	97.3	94.6	99.4
PLS	(6 trials)	26.6	90.9	86.7	82	85.2

Rye

In the minimum effective dose barley trials Aviator Xpro applied at 1.25 L/ha gave a sufficient control of all tested rye pathogens. A clear dose response could be seen against both *Rhynchosporium secalis, Blumeria graminis* and *Puccinia recondita*. The dose reduction to 0.75 L/ha resulted in a decreased pathogen control of about 8-11 % under a medium infection pressure. These results indicate that a dose rate of 1.25 L/ha in rye is necessary to control the main rye pathogens under high disease pressure and unfavourable conditions. Main data is shown in the table below (Table 6.1.2-3).

Table 6.1.2-3: Minimum effective dose trials in rye

Disease		Untreated	Abbott (mean % control)			
		% severity	Aviator Xpro			Standards
			1.25 L/ha	1.0 L/ha	0.75 L/ha	N rate
B. graminis	(9 trials)	17.2	86.9	84.9	77.9	83.8
R. secalis	(7 trials)	33.2	83.1	78.9	72.9	78.4
P. recondita	(14 trials)	27.8	91.5	88.2	84.6	81.5

Triticale

In the minimum effective dose barley trials Aviator Xpro applied at 1.25 L/ha gave a sufficient control of all tested triticale pathogens. Especially against *Septoria spp*. and *Blumeria graminis* the dose reduction below 1.0 L/ha resulted in a decreased pathogen control of about 9-11 % under a medium infection pressure. These results indicate that a dose rate of 1.25 L/ha is necessary to control the main triticale pathogens under high disease pressure and unfavourable conditions. Main data is shown in the table below (Table 6.1.2-4).

Table 6.1.2-4: Minimum effective dose trials in triticale

Disease	Untreated	Abbott (mean % control)	
	% severity	Aviator Xpro	Standards

		1.25 L/ha	1.0 L/ha	0.75 L/ha	N rate
B. graminis	(7 trials)	27.3	75.8	75.9	64.5	80.9
Septoria spp.	(8 trials)	18.3	89.6	87.9	80.1	80.0
P. recondita	(5 trials)	10.3	87.0	85.7	78.2	82.3

IIIA1 6.1.3 Efficacy tests

According to the actual legislation for the registration of plant protection products in Europe and with special regard to the zonal approach, only results from field trials in Germany were compiled in this biological assessment dossier for the different indications.
Diseases, cultural practices, soil types and weather conditions are sufficiently similar and all trial sites were in typical crops growing areas in Germany. Trials covered a range of cultivars, soil types and environmental conditions.

Material and methods

Table 6.1.3-1: Number of efficacy trials

	2006	2007	2008	2009	2010	Total
Germany (DE)	170	131	3	1	10	
total						304

No data available for the trial distribution in different test years and different countries.

Table 6.1.3-2: Guidelines and trial design

GEP	Yes (135)
standards	EPPO PP 1/26(3), PP 1/28(3), 1/152(/3), PP1/181(3),
number of replications	4 (72)
plot design, plot size	RCBD (44), 20-45 m²
trials per crop	winter and spring wheat (108) winter and spring barley (97) winter rye (61) triticale (49)
trial per intended use	*Erysiphe graminis* – wheat (16 from 2006 and 2007) *Septoria tritici* – wheat (36 from 2006 and 2007) *Drechslera tritici-repentis* – wheat (12 from 2006 and 2007) *Puccinia recondita* – wheat (25 from 2006 and 2007) *Pseucocerc. herptr.* – wheat (15 from 2006, 2007, 2008 and 2010) *Puccinia striiformis* – wheat (8 from 2007, 2008 and 2009) Septoria nodorum – wheat (10 from 2007 and 2008) *Erysiphe graminis* – barley (13 from 2006 and 2007) *Rhynchosporium secalis* – barley (24 from 2006 and 2007) *Pyrenophora teres* – barley (23 from 2006 and 2007) *Puccinia hordei* – barley (14 from 2006 and 2007) *Ramularia collo-cygni* – barley (8 from 2006 and 2007) Physiological leaf spots – barley (15 from 2006 and 2007) *Erysiphe graminis – rye* (17 from 2006 and 2007) *Rhynchosporium secalis* – rye (15 from 2006 and 2007) *Puccinia recondita* – rye (29 from 2006 and 2007) *Erysiphe graminis – triticale* (17 from 2006 and 2007)

	Septoria spec. – triticale (18 from 2006 and 2007) *Puccinia recondita – triticale* (14 from 2006 and 2007)
crop stage (BBCH) at application	winter wheat: BBCH 30 - BBCH 69 barely: BBCH 30 - BBCH 61 rye: BBCH 30 - BBCH 69 triticale: BBCH 30 - BBCH 69

Products/formulation used for studies:

Product	Formulation type	Active ingredient	Content g/L or %w/w
BYF 00587	EC	bixafen	125
SP 102 0000 13869	EC	bixafen	75
		prothioconazole	150
Proline	EC	prothioconazole	250
Input	EC	prothioconazole	160
		spiroxamine	300
Prosaro	EC	prothioconazole	125
		tebuconazole	125
Horizon EW	EW	tebuconazole	250
Fandango	EC	fluoxastrobin	100
		prothioconazole	100
Opus	SC	epoxiconazole	125
Tracker	EC	epoxiconazole	67
		boscalid	233

Aviator Xpro was applied in 200-300 L/ha of water with field sprayers.

Intended use: 026764-00/00-001

The effectiveness of the fungicide was demonstrated in 16 trials. In the mean of the results the disease level of 12.2 % in untreated control was reduced by the test product to 2.0 %, which corresponds to an average efficiency of 82.3 % (Table 6.1.3-3).

Table 6.1.3-3: Disease level / Efficacy (%) of Aviator Xpro on *Erysiphe graminis* in wheat

disease	EPPO	n	disease level (UTC) [%]	test product		ref. product	
				mean	ABBOTT (%)	mean	ABBOTT (%)
Erysiphe graminis	ERYSGR	16	12.2	2.0	86	1.9	87

Intended use: 026764-00/00-002

The effectiveness of the fungicide was demonstrated in 36 trials. In the mean of the results the disease level of 24.1 % in untreated control was reduced by the test product to 3.1 %, which corresponds to an average efficiency of 85.0 % (Table 6.1.3-4).

Table 6.1.3-4: Disease level / Efficacy (%) of AviatorXpro on *Septoria tritici* in wheat

disease	EPPO	n	disease level (UTC) [%]	test product		ref. product	
				mean	ABBOTT (%)	mean	ABBOTT (%)
Septoria tritici	SEPTTR	36	24.1	3.1	85	4.6	80

Intended use: 026764-00/00-003

The effectiveness of the fungicide was demonstrated in 12 trials. In the mean of the results the disease level of 13.8 % in untreated control was reduced by the test product to 1.6 %, which corresponds to an average efficiency of 87 % (Table 6.1.3-5).

Table 6.1.3-5: Disease level / Efficacy (%) of Aviator Xpro on *Drechslera tritici-repentis* in wheat

disease	EPPO	n	disease level (UTC) [%]	test product		ref. product	
				mean	ABBOTT (%)	mean	ABBOTT (%)
Drechslera tritici-repentis	PYRNTR	12	13.8	1.6	87	1.8	88

Intended use: 026764-00/00-004

The effectiveness of the fungicide was demonstrated in 25 trials. In the mean of the results the disease level of 15.3 % in untreated control was reduced by the test product to 1.0 %, which corresponds to an average efficiency of 95 % (Table 6.1.3-6).

Table 6.1.3-6: Disease level / Efficacy (%) of Aviator Xpro on *Puccinia recondita* in wheat

disease	EPPO	n	disease level (UTC) [%]	test product		ref. product	
				mean	ABBOTT (%)	mean	ABBOTT (%)
Puccinia recondita	PUCCRE	25	15.3	1.0	95	3.1	88

Intended use: 026764-00/00-005

The effectiveness of the fungicide was demonstrated in 15 trials. In the mean of the results the disease level of 37.0 % in untreated control was reduced by the test product to 15.5 %, which corresponds to an average efficiency of 61.2 % (Table 6.1.3-7).

Table 6.1.3-7: Disease level / Efficacy (%) of Aviator Xpro on *Pseudocercosporella herpotrichoides (= Oculimacula herptr.)* in wheat

disease	EPPO	n	disease level (UTC) [%]	test product		ref. product	
				mean	ABBOTT (%)	mean	ABBOTT (%)
Pseudo-cerc. herpotr.	PDSCHE	15	37.0	15.5	61.2	20.1	47.7

Intended use: 026764-00/00-006

The effectiveness of the fungicide was demonstrated in 8 trials. In the mean of the results the disease level of 21.8 % in untreated control was reduced by the test product to 1.5 %, which corresponds to an average efficiency of 95.5 % (Table 6.1.3-8).

Table 6.1.3-8: Disease level / Efficacy (%) of Aviator Xpro on *Puccinia striiformis* in wheat

disease	EPPO	n	disease level (UTC) [%]	test product		ref. product	
				mean	ABBOTT (%)	mean	ABBOTT (%)
Puccinia striiformis	PUCCST	8	21.8	1.5	95.5	2.1	91.8

Intended use: 026764-00/00-007

The effectiveness of the fungicide was demonstrated in 10 trials. In the mean of the results the disease level of 34.3 % in untreated control was reduced by the test product to 2.8 %, which corresponds to an average efficiency of 92.7 % (Table 6.1.3-9).

Table 6.1.3-9: Disease level / Efficacy (%) of Aviator Xpro on *Leptosphaeria nodorum* in wheat

disease	EPPO	n	disease level (UTC) [%]	test product		ref. product	
				mean	ABBOTT (%)	mean	ABBOTT (%)
Lepto-sphaeria nodorum	PUCCST	10	34.3	2.8	92.7	6.3	79.8

Intended use: 026764-00/00-008

The effectiveness of the fungicide was demonstrated in 13 trials. In the mean of the results the disease level of 11.9 % in untreated control was reduced by the test product to 0.9 %, which corresponds to an average efficiency of 93.5 % (Table 6.1.3-10).

Table 6.1.3-10: Disease level / Efficacy (%) of Aviator Xpro on *Erysiphe graminis* in barley

disease	EPPO	n	disease level (UTC) [%]	test product		ref. product	
				mean	ABBOTT (%)	mean	ABBOTT (%)
Erysiphe graminis	ERYSGR	13	11.9	0.9	93.5	1.3	89.6

Intended use: 026764-00/00-009

The effectiveness of the fungicide was demonstrated in 15 trials. In the mean of the results the disease level of 13.1 % in untreated control was reduced by the test product to 1.1 %, which corresponds to an average efficiency of 91.9 % (Table 6.1.3-11).

Table 6.1.3-11: Disease level / Efficacy (%) of Aviator Xpro on *Rhynchosporium secalis* in barley

disease	EPPO	n	disease level (UTC) [%]	test product		ref. product	
				mean	ABBOTT (%)	mean	ABBOTT (%)
Rhyn-chosporium secalis	RHYNSE	15	13.1	1.1	91.9	1.8	86.5

Intended use: 026764-00/00-010

The effectiveness of the fungicide was demonstrated in 27 trials. In the mean of the results the disease level of 26.5 % in untreated control was reduced by the test product to 1.9 %, which corresponds to an average efficiency of 92.9 % (Table 6.1.3-12).

Table 6.1.3-12: Disease level / Efficacy (%) of Aviator Xpro on *Pyrenophora teres* in barley

disease	EPPO	n	disease level (UTC) [%]	test product		ref. product	
				mean	ABBOTT (%)	mean	ABBOTT (%)
Pyrenoph-ora teres	PYRNTE	27	26.5	1.9	92.9	4.6	81.6

Intended use: 026764-00/00-011

The effectiveness of the fungicide was demonstrated in 8 trials. In the mean of the results the disease level of 20.1 % in untreated control was reduced by the test product to 20.1 %, which corresponds to an average efficiency of 0.6 % (Table 6.1.3-13).

Table 6.1.3-13: Disease level / Efficacy (%) of Aviator Xpro on *Puccinia hordei* in barley

disease	EPPO	n	disease level (UTC) [%]	test product		ref. product	
				mean	ABBOTT (%)	mean	ABBOTT (%)
Puccinia hordei	PUCCHD	8	20.1	0.6	95.0	0.4	95.6

Intended use: 026764-00/00-12

The effectiveness of the fungicide was demonstrated in 9 trials. In the mean of the results the disease level of 40.7 % in untreated control was reduced by the test product to 1.4 %, which corresponds to an average efficiency of 96.0 % (Table 6.1.3-14).

Table 6.1.3-14: Disease level / Efficacy (%) of Aviator Xpro on *Ramularia collo-cygni* in barley

disease	EPPO	n	disease level (UTC) [%]	test product		ref. product	
				mean	ABBOTT (%)	mean	ABBOTT (%)
Ramularia collo-cygni	RAMUCC	9	40.7	1.4	96.0	13.4	70.0

Intended use: 026764-00/00-13

The effectiveness of the fungicide was demonstrated in 7 trials. In the mean of the results the disease level of 45.4 % in untreated control was reduced by the test product to 13.2 %, which corresponds to an average efficiency of 77.6 % (Table 6.1.3-15).

Table 6.1.3-15: Disease level / Efficacy (%) of Aviator Xpro on *Physiological leaf spots* in barley

disease	EPPO	n	disease level (UTC) [%]	test product		ref. product	
				mean	ABBOTT (%)	mean	ABBOTT (%)
Physiologi-cal leaf spots	MEHITE	7	45.4	13.2	77.6	22.8	59.7

Intended use: 026764-00/00-14

The effectiveness of the fungicide was demonstrated in 6 trials. In the mean of the results the disease level of 10.4 % in untreated control was reduced by the test product to 1.6 %, which corresponds to an average efficiency of 82.3 % (Table 6.1.3-16).

Table 6.1.3-16: Disease level / Efficacy (%) of Aviator Xpro on *Erysiphe graminis* in rye

disease	EPPO	n	disease level (UTC) [%]	test product		ref. product	
				mean	ABBOTT (%)	mean	ABBOTT (%)
Erysiphe graminis	ERYSGR	6	10.4	1.6	82.3	2.0	80.9

Intended use: 026764-00/00-15

The effectiveness of the fungicide was demonstrated in 12 trials. In the mean of the results the disease level of 23.9 % in untreated control was reduced by the test product to 7.7 %, which corresponds to an average efficiency of 80.0 % (Table 6.1.3-17).

Table 6.1.3-17: Disease level / Efficacy (%) of Aviator Xpro on *Rhynchosporium secalis* in rye

disease	EPPO	n	disease level (UTC) [%]	test product		ref. product	
				mean	ABBOTT (%)	mean	ABBOTT (%)
Rhyn-chosporium secalis	RHYNSE	12	23.9	7.7	80.0	7.9	75.4

Intended use: 026764-00/00-16

The effectiveness of the fungicide was demonstrated in 20 trials. In the mean of the results the disease level of 26.1 % in untreated control was reduced by the test product to 3.8 %, which corresponds to an average efficiency of 86.7 % (Table 6.1.3-18).

Table 6.1.3-18: Disease level / Efficacy (%) of Aviator Xpro on *Puccinia recondita* in rye

disease	EPPO	n	disease level (UTC) [%]	test product		ref. product	
				mean	ABBOTT (%)	mean	ABBOTT (%)
Puccinia re-condita	PUCCRE	20	26.1	3.8	86.7	6.9	78.9

Intended use: 026764-00/00-17

The effectiveness of the fungicide was demonstrated in 7 trials. In the mean of the results the disease level of 17.3 % in untreated control was reduced by the test product to 2.9 %, which corresponds to an average efficiency of 86.7 % (Table 6.1.3-19).

Table 6.1.3-19: Disease level / Efficacy (%) of Aviator Xpro on *Erysiphe graminis* in triticale

disease	EPPO	n	disease level (UTC) [%]	test product		ref. product	
				mean	ABBOTT (%)	mean	ABBOTT (%)
Erysiphe graminis	ERYSGR	7	17.3	2.9	86.7	1.5	92.9

Intended use: 026764-00/00-18

The effectiveness of the fungicide was demonstrated in 16 trials. In the mean of the results the disease level of 25.9 % in untreated control was reduced by the test product to 5.7 %, which corresponds to an average efficiency of 82.0 % (Table 6.1.3-20).

Table 6.1.3-20: Disease level / Efficacy (%) of Aviator Xpro on *Septoria species* in triticale

disease	EPPO	n	disease level (UTC) [%]	test product		ref. product	
				mean	ABBOTT (%)	mean	ABBOTT (%)
Septoria species	SEPTSP	16	25.9	5.7	82.0	6.5	78.2

Intended use: 026764-00/00-19

The effectiveness of the fungicide was demonstrated in 4 trials. In the mean of the results the disease level of 9.5 % in untreated control was reduced by the test product to 1.2 %, which corresponds to an average efficiency of 92.3 % (Table 6.1.3-21).

Table 6.1.3-21: Disease level / Efficacy (%) of Aviator Xpro on *Puccinia recondita* in triticale

disease	EPPO	n	disease level (UTC) [%]	test product		ref. product	
				mean	ABBOTT (%)	mean	ABBOTT (%)
Puccinia recondita	PUCCRE	14	2.6	1.6	90.0	2.4	85.0

IIIA1 6.1.4 Effects on yield and quality

IIIA1 6.1.4.1 Impact on the quality of plants and plant products

In parallel to the efficacy testing most trials were harvested and the yield was analyzed for hecto-liter weight (HLW) and thousand kernel weight (TKG). Due to the huge number of trials, all following results were conducted in Germany by Bayer CropScience Deutschland GmbH or at official trial sites (AMP) in 2006 and 2007.

Wheat

Aviator Xpro applied at 1.25 L/ha resulted in wheat in an average increase of thousand grain weight of 12.0 % g compared to untreated. The effect on the hecto-liter weight was for Aviator Xpro in average and median with +6.0 % slightly higher (0.6-0.9 kg) than for the comparison product. These results mostly reflect the better disease control of Aviator Xpro and some plant physiological benefits (Table 6.1.4.1-1).

Table 6.1.4.1-1: Quality analysis in wheat: hector-litre weight (HLW) and thousand grain weight (TKG) of Aviator Xpro (1.25 L/ha) and comparison product with one or two applications, trials conducted in Germany 2006-2007

	Thousand kernel weight (TKW)	Hecto-liter weight (HLW)

	Un-treated	Avia-tor Xpro [g]	Avia-tor Xpro [%rel]	CP* [g]	CP* [%rel]	Un-treated [kg]	Avia-tor Xpro [kg]	Avia-tor Xpro [%rel]	CP* [kg]	CP* [%rel]
Mean	40.6	45.3	112	44.2	109	71.0	74.4	106	73.8	105
Median	41.6	46.0	111	44.4	109	72.7	76.0	106	75.1	104
Max	58.2	58.2	148	58.2	132	77.3	80.5	113	79.7	111
Min	32.5	37.1	100	34.9	100	61.9	65.4	100	66.0	100
Count	35	35	35	35	35	12	12	12	12	12

* comparison product

Barley

Aviator Xpro applied at 1.0 L/ha resulted in barley in an average increase of thousand grain weight of 6.0 % compared to untreated. The effect on the hecto-liter of both, Aviator Xpro and the comparison product were very small for all parameters (Table. 6.1.4.1-2).

These results mostly reflect the disease control of Aviator Xpro and some plant physiological benefits.

Table 6.1.4.1-2: Quality analysis in barley: hecto-liter weight (HLW) and thousand grain weight (TKG) of Aviator Xpro (1.0 L/ha) and comparison product with one or two applications, trials conducted in Germany 2006-2007

	Thousand kernel weight (TKW)					Hecto-liter weight (HLW)				
	Un-treat. [g]	Avia-tor Xpro [g]	CP* [g]	Avia-tor Xpro [%rel]	CP* [%rel]	Un-treat. [kg]	Avia-tor Xpro [kg]	CP* [kg]	Avia-tor Xpro [%rel]	CP* [%rel]
Mean	49.3	51.9	51.5	106	105	63.5	64.9	65.0	102	103
Median	48.9	51.8	50.7	104	103	63.2	66.6	66.4	101	102
Max	72.0	73.0	74.0	134	132	72.0	73.0	74.0	113	114
Min	35.6	38.9	39.0	97	97	55.4	55.9	55.5	100	100
Count	32	32	32	32	32	9	9	9	9	9

* comparison product

Rye

Aviator Xpro applied at 1.25 L/ha resulted in rye in an average increase of thousand grain weight of 10.0 % compared to untreated. The effect on the hecto-liter weight was for Aviator Xpro in average higher only 2.0 % higher. These results mostly reflect the better disease control of Aviator Xpro and some plant physiological benefits (Table 6.1.4.1-3).

Table 6.1.4.1-3: Quality analysis in rye: hecto-liter weight (HLW) and thousand grain weight (TKG) of Aviator Xpro (1.25 L/ha) and comparison product with one or two applications, trials conducted in Germany 2006-2007

	Thousand kernel weight (TKW)					Hecto-liter weight (HLW)				
	Un-treated	Avia-tor Xpro [g]	Avia-tor Xpro [%rel]	CP* [g]	CP* [%rel]	Un-treated [kg]	Avia-tor Xpro [kg]	Avia-tor Xpro [%rel]	CP* [kg]	CP* [%rel]
Mean	33.6	36.8	110	36.0	108	71.7	73.1	102	72.7	101
Median	31.0	32.6	110	32.3	107	71.9	74.1	102	74.1	101
Max	100.0	112.6	126	110.5	133	75.3	78.2	105	77.2	105
Min	18.8	22.9	96	22.0	95	65.9	68.5	99	67.1	99

Count	29	29	29	29	29	17	17	17	17	17

* comparison product

Triticale

Aviator Xpro applied at 1.25 L/ha resulted in triticale in an average increase of thousand grain weight of 7.0 % compared to untreated. The effect on the hecto-liter weight for Aviator Xpro was in average, median and minimum higher (0.7-1.2 kg) than for the comparison product, while the both maxima were identical. These results mostly reflect the better disease control of Aviator Xpro and some plant physiological benefits (Table 6.1.4.1-4).

Table 6.1.4.1-4: Quality analysis in triticale: hecto-liter weight (HLW) and thousand grain weight (TKG) of Aviator Xpro (1.25 L/ha) and comparison product with one or two applications, trials conducted in Germany 2006-2007

	Thousand kernel weight (TKW)					Hecto-liter weight (HLW)				
	Un-treated	Aviator Xpro [g]	Aviator Xpro [%rel]	CP* [g]	CP* [%rel]	Un-treated [kg]	Aviator Xpro [kg]	Aviator Xpro [%rel]	CP* [kg]	CP* [%rel]
Mean	41.3	44.0	107	43.4	105	69.5	71.2	103	70.2	101
Median	43.4	44.8	106	44.7	103	69.3	71.8	102	70.6	101
Max	52.5	54.9	131	54.1	130	78.1	78.6	112	78.6	105
Min	28.1	31.3	99	29.6	97	57.2	60.1	98	59.4	97
Count	23	23	23	23	23	8	8	8	8	8

* comparison product

The tests applied by the applicant demonstrate that applications of Aviator Xpro at 1.25 L/ha in winter wheat, rye and triticale or at 1.0 L/ha in barley had a positive effect on thousand grain weight and hecto-liter grain weight, even though the differences to actual standards were not significant.

Therefore, it is concluded that spray applications of Aviator Xpro will not cause any adverse effect on the quality of harvested crop when used as recommended.

IIIA1 6.1.4.2 Effects on the processing procedure

Brewing – Bixafen & Prothioconazole

The applicant states that at the maximum proposed rates of use (2 x 1.0 litre / ha in barley), the plant protection product including the active ingredient bixafen & prothioconazole provides a wide safety margin for application.

Therefore, it can be concluded that commercial use of bixafen & prothioconazole EC 225, will most likely have no detrimental effect on quality of malt and beer and on the transformation processes of brewing.

Bread making – Bixafen & Prothioconazole

The applicant submitted results from two tests clearly show that bixafen & prothioconazole EC 225 had no significant impact on quality parameters which can influence bread making quality.

Results from the single active substance and the co-formulation provide evidence that a commercial use of bixafen & prothioconazole EC 225 will not have detrimental effects on the quality and the transformation processes of bread making.

IIIA1 6.1.4.3 Effects on the yield of treated plants and plant products

From 37 harvested wheat trials, Aviator Xpro showed not only a good disease control in wheat, but also no phototoxic effects, additional grain yield and improved grain quality (Table 6.1.4.3-1). In average the application resulted in an increased yield of 15.3 dt/ha (121 % rel.), which was 4 dt/ha more than the comparison products (+12.0 dt/ha / 117 % rel.).

Table 6.1.4.3-1: Mean Yield effects in wheat efficacy trials

	Yield				
	Untreated [dt/ha]	Aviator Xpro 1.25 [dt/ha]	Aviator Xpro 1.25 [%rel]	CP* [dt/ha]	CP* [%rel]
Mean	73.9	89.2	121	85.9	117
Median	72.8	89.0	120	86.5	116
Max	93.5	111.2	148	104.1	135
Min	50.4	64.6	108	62.9	107
Count	37	37	37	37	37

Table 6.1.4.3-2: Yield effect in efficacy trials in wheat diseases for each intended use

intended use	n	untreated	test product	ref. product
		yield (dt/ha)	yield rel. (%)	
-001: *Erysiphe graminis* – wheat	16	72.2	121.7	118.8
-002: *Septoria tritici* – wheat	36	74.6	120.4	116.1
-003: *Drechslera tritici-repentis* – wheat	12	70.3	120.1	117.8
-004: *Puccinia recondita* – wheat	25	71.2	120.9	117.1
-005: *Puccinia striiformis* –wheat	15	80.8	111.5	109.7
-006: *Pseudocerc. herptr.* – wheat	8	72.7	150.1	143.7
-007: *Septoria nodorum* – wheat	10	84.9	129.8	122.0
mean		**72.4**	**120.7**	**117.6**

Based on the results of the efficacy trials, the treatment of 1.25 L/ha Aviator Xpro leads to a yield increase of 20.7 % compared to the untreated control (Table 6.1.4.3-2).

From 46 harvested barley trials, Aviator Xpro showed not only a sufficient disease control in barley, but also no phototoxic effects and additional grain yield and improved grain quality (Table 6.1.4.3-3). In average a single or double application resulted in an increased yield of 10.3 dt/ha (115 % rel.), which was 1.9 dt/ha more than the comparison products (+8.4 dt/ha / 113 % rel.).

Table 6.1.4.3-3: Mean Yield effects in barley efficacy trials

	Yield				
	Untreated [dt/ha]	Aviator Xpro 1.0 [dt/ha]	Aviator Xpro 1.0 [%rel]	CP* [dt/ha]	CP* [%rel]
Mean	71.0	81.3	115	79.4	113
Median	72.5	81.9	113	79.3	111
Max	98.7	113.7	163	109.1	161
Min	38.7	43.1	95	47.1	95
Count	46	46	46	46	46

* comparison product

Table 6.1.4.3-4: Yield effect in efficacy trials in barley diseases for each intended use

intended use	n	untreated	test product	ref. product
		yield (dt/ha)	yield rel. (%)	
-008: *Erysiphe graminis* – barley	13	72.7	112.7	110.3
-009: *Rhynchosporium secalis* – barley	24	75.5	109.9	108.9
-010: *Pyrenophora teres* – barley	23	72.5	118.8	115.6
-011: *Puccinia hordei* – barley	12	62.6	118.4	115.0
-012: *Ramularia collo-cygni* – barley	8	75.7	109.9	107.4
-013: Physiological leaf spot – barley	15	73.4	112.8	110.2
mean		**73.6**	**113.8**	**111.6**

Based on the results of the efficacy trials, the treatment of 1.25 L/ha Aviator Xpro leads to a yield increase of 13.8 % compared to the untreated control (Table 6.1.4.3-4).

From 23 harvested rye trials Aviator Xpro showed a good disease control in rye, but also no phototoxic effects and additional grain yield and improved grain quality (Table 6.1.4.3-5). In average a single or double application resulted in an increased yield of 15.8 dt/ha (126 % rel.), which was 6.1 dt/ha more than the comparison products (+9.7 dt/ha / 116 % rel.).

Table 6.1.4.3-5: Mean Yield effects in rye efficacy trials

	Yield				
	Untreated [dt/ha]	Aviator Xpro 1.25 [dt/ha]	Aviator Xpro 1.25 [%rel]	CP* [dt/ha]	CP* [%rel]
Mean	67.5	83.3	126	77.2	116
Median	70.0	88.3	124	84.2	116
Max	100.2	111.5	152	108.8	141
Min	33.9	44.2	108	39.0	101
Count	23	23	23	23	23

* comparison product

Table 6.1.4.3-6: Yield effect in efficacy trials in rye diseases for each intended use

intended use	n	untreated	test product	ref. product
		yield (dt/ha)	yield rel. (%)	
-014: *Erysiphe graminis* – rye	17	72.4	121.4	111.3
-015: *Rhynchosporium secalis* – rye	15	78.2	117.3	110.6
-016: *Puccinia recondita* – rye	29	69.2	121.4	112.9
mean		**73.3**	**120.0**	**111.6**

Based on the results of the efficacy trials, the treatment of 1.25 L/ha Aviator Xpro leads to a yield increase of 20.2 % compared to the untreated control (Table 6.1.4.3-6).

For 27 harvested triticale trials, Aviator Xpro not only showed superior disease control in triticale, but also no phototoxic effects and additional grain yield and improved grain quality (Table 6.1.4.3-7). In average a single or double application resulted in an increased yield of 9.5 dt/ha (115 % rel.), which was 1.3 dt/ha more than the comparison products (+8.2 dt/ha / 112 % rel.).

Table 6.1.4.3-7: Mean Yield effects in triticale efficacy trials

	Yield				
	Untreated [dt/ha]	Aviator Xpro 1.25 [dt/ha]	Aviator Xpro 1.25 [%rel]	CP* [dt/ha]	CP* [%rel]
Mean	69.8	79.3	115	78.0	112
Median	71.7	81.5	112	81.9	111
Max	101.6	110.3	143	109.4	140
Min	38.3	47.8	105	48.3	103
Count	27	27	27	27	27

* comparison product

Table 6.1.4.3-8: Yield effect in efficacy trials in triticale diseases for each intended use

intended use	n	untreated	test product	ref. product
		yield (dt/ha)	yield rel. (%)	
-017: *Erysiphe graminis* – triticale	17	66.3	118.4	116.9
-018: Septoria sp.– triticale	18	77.7	111.1	109.5
-019: *Puccinia recondita* – triticale	14	67.0	116.7	112.8
mean		**70.3**	**115.4**	**113.1**

Based on the results of the efficacy trials, the treatment of 1.25 L/ha Aviator Xpro leads to a yield increase of 15.4 % compared to the untreated control (Table 6.1.4-8).

IIIA1 6.2 Adverse effects

IIIA1 6.2.1 Phytotoxicity to host crop

The applicant states that since 2006 the plant protection product bixafen & prothioconazole EC 225 has been applied to a wide range of cereal varieties at different geographical locations across Northern and Southern Europe (Austria, Belgium, Switzerland, Denmark, France, Germany, Italy, Netherlands, Sweden, United Kingdom) without any damage symptoms onto the crop.

Crop safety observations were made in all efficacy trials on a wide range of cultivars treated between growth stages BBCH 25 and BBCH 73 with a single or double spray applications of the plant protection product. No case of significant adverse effects were recorded on any cultivars at the proposed dose rates of 1.25 L/ha on wheat, triticale and rye and at 1.0 L/ha on barley and oats.

IIIA1 6.2.2 Adverse effects on health of host animals

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

IIIA1 6.2.3 Adverse effects on site of application

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

IIIA1 6.2.4 Adverse effects on beneficial organisms (other than bees)

Effects on relevant beneficial organisms

The toxicity of BYF 00587 + PTZ EC 75 + 150 G on beneficial organisms has been investigated by carrying out tests under extended laboratory conditions on *Aphidius rhopalosiphi*, *Chrysoperla carnea*, *Coccinella septempunctata* and *Typhlodromus pyri.*
With *Chrysoperla carnea*, unacceptable effects (≥ 25 %) on survival or fertility were not observed, when BYF 00587 + PTZ EC 75 + 150 G was applied 3 times the highest recommended field rate/ha and application (Table 6.2.4-2).
The results of the tests on *Aphidius rhopalosiphi* and *Coccinella septempunctata* are shown in Table 6.2.4-1 and 6.2.4-3.
One application of the highest recommended field rate/ha BYF 00587 + PTZ EC 75 + 150 G is not harmful for *Aphidius rhopalosiphi.* But, the recommended two applications of 1.25 L/ha product might reduce the population of *Aphidius rhopalosiphi* by up to 50 %.
With *Coccinella septempunctata*, effects ≥ 25 % up to 42 % on survival or fertility of the test animals were observed, when BYF 00587 + PTZ EC 75 + 150 G was applied at 1.0 times and 1.7 times highest recommended field rate/ha and application. 3.75 L/ha product (corresponding to 3 times highest recommended field rate/ha and application) led to lethal effects > 50 %.
Therefore, no effects ≥ 25 % are expected for populations of the relevant beneficial insect *Chrysoperla carnea*, when Aviator Xpro is applied according to the recommended use pattern, i.e. two applications of 1.0 L/ha to barley and two applications of 1.25 L/ha to wheat, rye and triticale. In comparison to *Chrysoperla carnea*, populations of the beneficial insect species *Aphidius rhopalosiphi* and *Coccinella septempunctata* might reduce up to 50 % by two applications of Aviator Xpro.

Table 6.2.4-1: Effects of BYF 00587 + PTZ EC 75 + 150 G on *Aphidius rhopalosiphi* (exposed stage: female) in an extended laboratory test (substrate: barley seedlings)

Application rate [L/ha]	Corrected mortality [%]	Effect on parasitisation rate [%]	Reference
0.0463	0	-4.5	Moll, M., 2007
0.1390	0	19.0	M-282592-01-1
0.4170	6.7	29.7	
1.2500	0	13.4	
3.7500*	53.3	31.9	

*The settling rate was statistically significantly lower compared to the control.

Table 6.2.4-2: Effects of BYF 00587 + PTZ EC 75 + 150 G on *Chrysoperla carnea* (exposed stage: larva) in an extended laboratory test (substrate: bean leaves)

Application rate [L/ha]	Corrected mortality [%]	Effect on fertility [%]	Reference
0.0463	11.4	-28.2	Rosenkranz, B., 2007
0.1390	2.3	45.8	M-290530-01-1
0.4170	6.8	22.2	
1.2500	4.5	-0.3	
3.7500	0	21.6	

Table 6.2.4-3: Effects of BYF 00587 + PTZ EC 75 + 150 G on *Coccinella septempunctata* (exposed stage: larva) in an extended laboratory test (substrate: bean leaves)

Application rate [L/ha]	Corrected mortality [%]	Effect on fertility [%]	Reference
0.417	-10.3	16.0	Moll, M., 2007
0.722	6.9	51.7	M-287283-01-1
1.250	0	42.2	
2.165	27.6	20.7	
3.750	55.2	-	
LR_{50}: 3.391 L/ha (95 % Confidence limits: 2.508 L/ha – 4.585 L/ha)			

Table 6.2.4-4 shows the results of the two tests on the predatory mite *Typhlodromus pyri*. The indicator test species *Typhlodromus pyri* is not relevant antagonist in fields with cereals. But, the results for *Typhlodromus pyri* (especially from the higher tier aged residue test) indicate that two applications of Aviator Xpro to cereals might reduce the populations of relevant predatory mites and spiders between 25 % and 50 %.

Table 6.2.4-4: Effects of BYF 00587 + PTZ EC 75 + 150 G on *Typhlodromus pyri* (exposed stage: protonym)

Application rate [L/ha]	Corrected mortality [%]	Effect on reproduction [%]	Reference
1 Laboratory test using bean leaves			
0.250	1.8	-35.0	Moll, M., 2006

0.500	12.3	35.9	M-280528-01-1
1.000	17.5	31.3	
2.000	87.7	-	
4.000	98.2	-	
LR_{50}: 1.296 L/ha (95 % Confidence limits: 0.424 L/ha – 2.348 L/ha)			
2 Laboratory test using leaves from treated bean plants (aged residue test) The test item was applied 3 times (T1, T2 and T3) under field conditions (spray interval: 2 weeks) on bean plants. 0, 7 and 14 days after T3 treatment leaves were collected from plants and returned to the laboratory.			
3 x 1.250	0 days after T3		Rosenkranz, B., 2008
	39.8	31.8	M-307529-01-1
	7 days after T3		
	32.2	27.7	
	14 days after T3		
	21.2	-	

Conclusions
Aviator Xpro is classified as not harmful for populations of *Chrysoperla carnea*.
Aviator Xpro is classified as slightly harmful for populations of *Aphidius rhopalosiphi* and *Coccinella septempunctata*.
Aviator Xpro is classified as slightly harmful for populations of relevant predatory mites and spiders.

Effects on soil quality

Effects on soil macro-organisms being used as indicators of soil quality

Effects on earthworms

Acute and chronic toxicity of bixafen to earthworms

To consider the sorption of the lipophilic substance bixafen (log P_{OW} = 3.31), the organic matter content of the test soil was reduced from 10 % to 5 % peat in the studies with the active substance.

Table 6.2.4-5: Effects of bixafen on soil macro-organisms – earthworms

Test species	Test design	Ecotoxicological endpoint			Reference
Eisenia fetida	acute, 14 d (5 % peat in test soil)	LC_{50}	**> 1000**	mg as/kg dws	Luehrs (2006) 29612021 M-279174-01-1
Eisenia fetida	reproduction, 56 d (5 % peat in test soil) mixing or sprayed	56d-NOE-C_{repro}	**100***	mg as/kg dws	Luehrs (2006) 29611022 M-276419-01-1

dws = dry weight soil
Bold values: Endpoints considered relevant for risk assessment

Metabolites of bixafen:

No major metabolites of bixafen were identified in the aquatic environment, in soil or plant material**.**

Acute and chronic toxicity of prothioconazole to earthworms

To consider the sorption of the lipophilic substances prothioconazole (log P_{OW} = 3.82), its metabolites JAU 6476-desthio (log P_{OW} = 3.04) and JAU 6476-S-methyl (log P_{OW} = 4.19), the organic matter content of the test soil was reduced from 10 % to 5 % peat in the study with the formulation. However, the older acute earthworm studies with the active substances and their metabolites were performed with 10 % peat within the artificial soil. Therefore, in the risk assessment for the active substances an additional assessment factor of 2 is applied on the respective endpoint.
The metabolite 1,2,4-triazole (log P_{OW} = 0.58) does not exceed this trigger value. Thus, no additional assessment factor needs to be considered for this metabolite.

Table 6.2.4-6: Effects of prothioconazole and relevant metabolites on soil macro-organisms – earthworms

Test species	Test design	Ecotoxicological endpoint			Reference
Prothioconazole					
Eisenia fetida	acute, 14 d (10 % peat in test soil) mixed into soil	LC_{50}	> 500	mg/kg dws [b)]	Meisner (2000) Report MPE/Rg 326/00 M-031137-02-1
Eisenia fetida [a)]	reproduction, 56 d (10 % peat in test soil) sprayed onto soil	NOEC NOEC NOEC	> 1000 ≥ 0.67 ≥ 1.98	g as/ha mg/kg dws [b)] mg/kg dws [c)]	Meisner (2000) Report MPE/Rg 325 M-033501-02-1
JAU 6476-desthio					
Eisenia fetida	acute, 14 d (10 % peat in test soil) mixed into soil	LC_{50}	> 500	mg/kg dws [b)]	Meisner (2000) Report MPE/Rg 338/00 M-038880-01-1
Eisenia fetida	reproduction, 56 d (10 % peat in test soil) mixed into soil	NOEC	0.5	mg/kg dws [b)]	Meisner (2000) Report MPE/Rg 332/00 M-026193-01-2
JAU 6476-S-methyl					
Eisenia fetida	acute, 14 d (10 % peat in test soil) mixed into soil	LC_{50}	> 500	mg/kg dws [b)]	Heimbach (2000) Report HBF/Rg 321 M-020680-01-1
Eisenia fetida	reproduction, 56 d (10 % peat in test soil) mixed into soil	NOEC	50	mg/kg dws [b)]	Heimbach (2000) Report HBF/Rg 317 M-021370-01-1

[a)] Sublethal effects were assessed with the lead formulation Prothioconazole EC 250
[b)] Adjusted by a factor of 2 to address the log P_{ow} > 2 and the organic matter content in the study
[c)] Study endpoint refined with the actual test conditions: area 198 cm^2 and 500 g dry weight soil
dws = dry weight soil
pm= pure metabolite
Bold values: Endpoints considered relevant for risk assessment

Metabolites of prothioconazole:

JAU 6476-desthio and JAU 6476-S-methyl were identified as major soil-metabolites of prothioconazole.

Acute and chronic toxicity of Aviator Xpro to earthworms

Table 6.2.4-7: Effects of BIX+PTZ EC 225 on soil macro-organisms - earthworms

Test species	Test design	Ecotoxicological endpoint			Reference
Eisenia fetida	acute, 14 d (5 % peat in test soil)	LC_{50}	> 1000	mg prod./kg dws	Luehrs (2006) M-280033-01-1 KIIIA 10.6.2/01
Eisenia fetida	chronic, 56 d (5 % peat in test soil)	NOECrepro	75 (≡ 373[#]	L prod./ha mg/kg dws)	Luehrs (2006) M-281333-01-1 KIIIA 10.6.3/01

[#] Endpoint was recalculated from L prod./ha into mg/kg dws assuming a product density of 1.011 g/mL

Exposure in soil

Predicted environmental concentrations in soil (PECsoil) values were calculated for the active ingredients and their respective metabolites as described in detail in Point 9.4 (active substances and formulated product) and 9.5 (metabolites) of the core assessment.
A soil layer of 5 cm with a bulk density of 1.5 g/cm^3 and 70 % interception were considered. The maximum PEC_{soil} values are summarised in following table (see also Section 5, IIIA 9.4 & 9.5).

Table 6.2.4-8: Maximum PEC_{soil} values after application of 1.25 L product/ha

		1.25 L product/ha	1.0 L product/ha
Compound	DT_{50} [days]	$PEC_{soil, max}$ [mg/kg]	$PEC_{soil, max}$ [mg/kg
BIX + PTZ EC 225	-	1.677 [A]	1.341 [A]
Bixafen	1235	1.069 [B]	n.c.
Prothioconazole	2.4	0.127	0.102
JAU 6476-desthio	57	0.119	0.095
JAU 6476-s-methyl	46	0.033	0.027

[A] If considering soil parameters as described above and a product density of 1.006 g/mL for 1.25 (1.0) L prod/ha

[B] $PEC_{soil, accu}$, taking potential accumulation into account; worst-case (minimum tillage)
Bold values were used for risk assessment

Toxicity exposure ratios, TER_A and TER_{LT}

Table 6.2.4-9: TER calculations for earthworms

Compound test design	Endpoint	[mg/kg dws]	PEC_{max} [mg/kg soil]	TER_A / TER_{LT}	Trigger
Aviator Xpro					

Compound test design	Endpoint	[mg/kg dws]	PEC_{max} [mg/kg soil]		TER_A / TER_{LT}	Trigger
BIX + PTZ EC 225 acute	LC_{50}	> 1000	1.677		> 596	10
BIX + PTZ EC 225 chronic	NOEC	373	1.677		222	5
Bixafen						
bixafen acute	LC_{50}	> 1000	1.069		> 935	10
bixafen chronic	NOEC	100	1.069		94	5
Prothioconazole and metabolites						
prothioconazole acute	LC_{50}	> 500 [a)]	0.127		> 3 937	10
prothioconazole chronic	NOEC	≥ 0.67 [a)] ≥ 1.98 [a) b)]	0.127		> 5.3 > 16	5
JAU 6476-desthio acute	LC_{50}	> 500 [a)]	0.119		> 4 202	10
JAU 6476-desthio chronic	NOEC	0.5 [a)]	1.25 L *	0.119	4.2	5
			1.0 L*	0.095	5.3	
JAU 6476-S-methyl acute	LC_{50}	> 500 [a)]	0.033		> 15 152	10
JAU 6476-S-methyl chronic	NOEC	50 [a)]	0.033		1 515	5

[a)] Endpoint divided by factor 2 to allow for log Pow > 2
[b)] Study endpoint refined with the actual test conditions: area 198 cm^2 and 500 g dry weight soil
* Application rate in L product/ha
Bold values do not meet the trigger

For an application of 1.25 L product/ha the TER_{LT} value for JAU 6476-desthio is slightly below the trigger, indicating a need for refinement.

Refined risk assessment for JAU 6476-desthio

An earthworm field study has been performed with the formulation Prothioconazole EC 250 (Lechelt-Kunze, 2002 – document M-040814-03-1, KIIIA 10.6.4/01). 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. These values are comparable to the maximum PEC_{soil} determined for this metabolite (i.e., 119 µg/kg, see Table 10.6- 6). 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, this 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.

Conclusion: The acute and chronic TER values for soil non-target macro-organisms are above the trigger of concern for bixafen, prothioconazole and JAU 6476-s-methyl, indicating an acceptable risk for earthworms and soil non-target macro-organisms from the use of the product according to the intended use pattern.
During an earthworm field study where the exposure to JAU 6476-desthio was analytically confirmed, no adverse effects on earthworm populations could be observed.
In conclusion, no unacceptable risk for earthworms and soil non-target macro-organisms is to be expected from the use of the product according to the intended use pattern in cereals.

Residue content of earthworms

According to the "Guidance Document on Risk Assessment for Birds and Mammals (EFSA, 2009) a log P_{OW} > 3 is used to indicate that there might be a potential for bioaccumulation. For information on the residue content of earthworms please refer to IIIA 10.1.9.

Effects on other non-target macro-organisms

Bixafen

Table 6.2.4-10: Effects on other soil non-target macro-organisms

Test species	Test design	Ecotoxicological endpoint			Reference
Folsomia candida	chronic, 28 d (5 % peat in test soil)	NOEC	7.74	mg as/kg dws	Luehrs (2007) 36952016 M-291636-01-1
Hypoaspis aculeifer	Chronic, 14 d (5 % peat in test soil)	NOEC	12.3	mg as/kg dws	Kratz (2007) KRA-HR-4/07 M-292249-01-1

dws = dry weight soil
Bold letters – Values are considered relevant for risk assessment

Prothioconazole

Table 6.2.4-11: Effects of prothioconazole on other soil non-target macro-organisms

Test species	Test item/ substance	Test design	Ecotoxicological endpoint			Reference
Prothioconazole						
Folsomia candida	Prothioconazole	chronic, 28 d (10 % peat in test soil)	NOEC $NOEC_{corr}$	≥64 ≥32 a)	mg/kg dws mg/kg dws	Nienstedt & Novent (2002) 1022.028.641 M-034235-01-1
Folsomia candida	Prothioconazole	chronic, 28 d (5 % peat in test soil)	NOEC	≥1000 b)	mg/kg dws	Frommholz (2011) FRM-Coll-118/11 M-405273-01-1 KIIIA 10.6.6/02
Hypoaspis aculeifer	Prothioconazole	chronic, 34 d (Lufa 2.1 test soil)	NOEC	≥100	mg/kg dws	Hoogendoorn (2000) Report B060HAE M-037786-02-1
JAU 6476-desthio						

Test species	Test item/ substance	Test design	Ecotoxicological endpoint			Reference
Folsomia candida	JAU 6476-desthio	chronic, 28 d (10 % peat in test soil)	NOEC $NOEC_{corr}$	62.5 31.3 [a]	mg/kg dws mg/kg dws	Moser & Roembke (2002) P1CR M-035070-03-1
Folsomia candida	JAU 6476-desthio	chronic, 28 d (10 % peat in test soil)	NOEC $NOEC_{corr}$	≥64 ≥32 [a]	mg/kg dws mg/kg dws	Nienstedt & Novent (2001) 1022.020.641 M-087946-02-1
JAU 6476-S-methyl						
Folsomia candida	JAU 6476-S-methyl	chronic, 28 d (10 % peat in test soil)	NOEC $NOEC_{corr}$	≥31.6 ≥15.8 [a]	mg/kg dws mg/kg dws	Moser & Scheffczyk (2001) P35CR M-087207-01-1

[a] Adjusted by a factor of 2 to address the log P_{OW} > 2 and the organic matter content in the study
[b] The NOEC of ≥32 mg/kg dws in the study M-034235-01-1was set above the highest test concentration of 64 mg/kg dws (not adjusted to the peat content). The new study (KIIIA 10.6.6/03) was conducted with test concentrations up to 1000 mg as/kg dws
dws = dry weight soil
Bold letters – Values are considered relevant for risk assessment

Aviator Xpro

Table 6.2.4-12: Effects of Aviator Xpro on other soil non-target macro-organisms

Test species	Test design	Ecotoxicological endpoint			Reference
Folsomia candida	chronic, 28 d (5 % peat in test soil)	NOECrepro	104	mg prod/kg dws	Luehrs (2007) M-291632-01-1 KIIIA 10.6.6/01

dws = dry weight soil

Chronic toxicity exposure ratios for soil non-target macro-organisms

Ecotoxicological endpoints and PEC_{soil} used for TER calculations for soil non-target macro-organisms are summarised below. TER values were calculated using the equation:

$TER = NOEC / PEC_{soil}$

The risk is considered acceptable, if the TER_{LT} is >5.

Table 6.2.4-13: TER_{LT} calculations for soil macro-organisms

Compound Test design	Endpoint	[mg/kg soil]	PEC_{max} [mg/kg soil]	TER_{LT}	Trigger
Folsomia candida					
Aviator Xpro chronic	NOEC	104	1.677 [b]	62	5
bixafen chronic	NOEC	7.74	1.069 [c]	7	5
prothioconazole chronic	NOEC	≥ 1000	0.127	≥ 7 874	5

Compound Test design	Endpoint	[mg/kg soil]	PEC_{max} [mg/kg soil]	TER_{LT}	Trigger
JAU 6476-desthio chronic	NOEC	31.3 [a)]	0.119	263	5
JAU 6476-s-methyl chronic	NOEC	≥ 15.8 [a)]	0.033	≥ 479	5
Hypoaspis aculeifer					
bixafen chronic	NOEC	12.3	1.069 [c)]	11	5
prothioconazole chronic	NOEC	> 100	0.127	> 787	5

[a)] Endpoint corrected by a factor 2 to allow for log Pow >2
[b)] If considering soil parameters as described above and a product density of 1.006 g/mL for 1.25 L prod/ha
[c)] $PEC_{soil,\ accu}$ for minimum tillage practice (worst-case)

Conclusion: The TER values are above the trigger of concern, indicating no unacceptable risk for soil non-target macro-organisms, i.e. collembola, soil mites.

Effects on organic matter breakdown

A study on the organic matter breakdown is not required based on the $DT90_f$ value of the active substances and acceptable TER values for earthworms, soil macro-organisms and/or soil micro-organisms.
Nevertheless, available litterbag studies on the lead formulations of the active ingredients are presented below:

Table 6.2.4-14: Summary of effects to non-target soil macro-organisms – litter bag studies

Test system	Test substance	Results – degradation [%]	References
Soil litter degradation (untreated wheat was sown and litter bags containing straw buried)	BYF 00587 EC 125 spray application applied at 272 + 140.5 g as/ha	after 26 days: test item: 16.7; control: 16.5 after 91 days: test item: 43.1; control: 42.0 after 181 days: test item: 64.0; control: 59.6	M-287186-01-1
Soil litter degradation (untreated wheat was sown and litter bags containing straw buried)	JAU 6476 EC 250 spray application applied at 3 x 200 g as/ha	after 34 days: test item: 51.7; control: 52.1 after 126 days: test item: 74.3; control: 78.4 after 126 days: test item: 92.0; control: 91.2	M-066463-01-1

According to these studies, bixafen and prothioconazole do not present any significant risk for organic matter breakdown.

Overall conclusion with respect to effects on soil macro-organisms

It is concluded that the proposed use of Aviator Xpro will not pose an unacceptable risk to populations of earthworms or other soil macro-organisms, when applied according to the recommended use pattern.

Instructions and information: None

Overall conclusion with respect to effects on soil quality

There is no indication of any unacceptable adverse effects on soil macro- or soil micro-organisms relevant for the maintenance of soil quality.

Effects on soil non-target micro-organisms exposed to Aviator Xpro

Table 6.2.4-15: Ecotoxicological endpoints for soil micro-organisms

Test item	Test design[1]	EU agreed endpoints	Reference
BYF 00587 + PTZ EC 75 + 150 G	C	No significant effect > 25 % at day 28 at 1.25 L or 12.5 L product/ha (1.68 mg or 16.77 mg/kg soil dw.)	Reis, K.-H. (2006) Final Report IBACON Project 31208080
	N	No significant effect > 25 % at day 42 at 1.25 L or 12.5 L product/ha (1.68 mg or 16.77 mg/kg soil dw.)	
JAU 6476-Des-thio (PTZ-Des-thio)	N	No significant effect > 25 % at day 42 at 0.20 kg a.s./ha (0.27 mg/kg soil dw.)	Anderson, J.P.E. (2000) Report No.: AJO/209400
	C	No significant effect > 25 % at day 28 at 0.27 kg a.s./ha (1.33 mg/kg soil dw.)	Leicher, Th. (2007) Bayer CropScience AG Report LRT-C-74/07
JAU 6476-S-Methyl	N	No significant effect > 25 % at day 42 at 0.20 kg and 2.0 kg a.s./ha (0.27 mg and 2.69 mg/kg soil dw.)	Anderson, J.P.E. (1999) Report No.: AJO/203399
	C	No significant effect > 25 % at day 28 at 0.20 kg and 2.0 kg a.s./ha (0.27 mg and 2.69 mg/kg soil dw.)	Anderson, J.P.E. (1999) Report No.: AJO/203299

[1] C = Carbon Mineralization, N = Nitrogen transformation.

Risk assessment for soil microflora functions

Based on the results of these studies, Aviator Xpro showed no effects of $\geq \pm$ 25 % compared to the control on soil microbial activity up to a maximum tested concentration of 16.77 mg/kg soil dry weight, after 28 days.
As the proposed use of Aviator Xpro an acceptable risk to soil microbial activity can be concluded.

IIIA1 6.2.5 Adverse effects on parts of plant used for propagating purposes

The data shows that germination (%) of harvested grain, defined as quotient of (normal seedlings x 100) / total number of seeds, was not affected when wheat and barley crops were treated with bixafen & prothioconazole EC 225 three times in wheat and twice in barley at 2 N application rates. No adverse effects were observed neither on the vigour, the final number of plants nor on plant weights. There were no significant differences in germination between the untreated control, standard treatments and the bixafen & prothioconazole treated plants, from the first assessment to the final crop stand score and seedling weight.

Thus, it can be concluded that bixafen & prothioconazole EC 225 when applied as recommended will not have any deleterious effect on the germination and the seedling development of the harvested grains.

IIIA1 6.2.6 Impact on succeeding crops

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/ha bixafen). Some minor damage could be observed on *Lolium perenne* and *Glycine max*, but 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 concludes that BYF 00587 (125 g/L bixafen), when used as proposed, will be safe to any succeeding crops.

IIIA1 6.2.7 Impact on other plants including adjacent crops

Over several years of field testing, no negative influence on adjacent crops was ever reported following bixafen & prothioconazole EC 225 applications.

Justification for the effects of bixafen & prothioconazole EC 225 on adjacent crops is based on data generated on BYF 00587 EC 125 and Proline EC 250, at higher rates of both active ingredients.
At the maximum proposed rates of use (2 x 1.25 litres / ha), the plant protection product bixafen & prothioconazole EC 225 delivers less of each active ingredient than the products BYF 00587 (bixafen) and Proline (prothioconazole), this provides a wide safety margin for applications of bixafen & prothioconazole EC 225.

Therefore, it can be concluded that commercial use of bixafen & prothioconazole EC 225, will be safe to any adjacent crops when used as recommended.

IIIA1 6.2.8 Possible development of resistance or cross-resistance

Generally, from the resistance risk evaluations available for both active ingredients reported within latest individual resistance risk statements or dossiers, no additional risk can be expected for products containing bixafen and prothioconazole. On the other hand, consequently, a reduced risk for each mixing partner is also not expected for the co-formulation bixafen & prothioconazole EC 225.

Bixafen

Mode of action and possible occurrence of resistance

Bixafen is, chemically, a carboxamide analogue. Its 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. As all carboxamide fungicides have the same target site in common, compounds inhibiting this enzyme are also called SDHI-fungicides. The SDHI target is encoded in nuclear DNA. Consequently, bixafen exhibits in general a positive cross-resistance pattern to other SDHI fungicides, although in regards to the pathogens for which sensitivity monitoring programmes were initiated no resistance cases in praxis have been reported up to now (www.frac.info).

Resistance to SDHI fungicides in field isolates of pathogens causing monocot diseases has until now only been reported for *Ustilago nuda* and carboxin 20 years ago. Thus, reports of cases of resistance to SDHI fungicides and cereal pathogens are very rare.
Due to recent reports concerning the detection of new mutations in dicot pathogens, the resistance risk classification of SDHI fungicides was changed by the FRAC SDHI Working Group in December 2009 from medium to medium-to-high (www.frac.info).

Sensitivity Profile
For all cereal pathogens investigated a quite narrow sensitivity profile of the studied populations has been observed with bixafen. The available sensitivity data give up to now no hint for an existing resistance issue in praxis.

Resistance Management
The current FRAC guidelines for bixafen resistance management in cereals are as follows:

- Apply SDHI fungicides always in mixtures. The mixture partner should provide satisfactory disease control when used alone on the target disease and must have a different mode of action.
- Apply a maximum of 2 SDHI fungicide containing sprays per cereal crop.
- Apply the SDHI fungicide preventively or as early as possible in the disease cycle. Do not rely only on the curative potential of SDHI fungicides.
- Strongly reduced rate programs including multiple applications must not be used. Refer to manufacturers' recommendations for rates.

The actual recommendations of the FRAC SDHI Working Group for the use of SDHI fungicides are yearly published on the internet (www.frac.info).

Summary of experimental studies

Sensitivity information and cross resistance studies are available for *Puccinia recondita*, *Septoria tritici*, *Oculimacula yallundae*, *Oculimacula acuformis*, *Puccinia hordei*, *Pyrenophora / Drechslera teres* and *Rhynchosporium secalis*. Overall, for most of the pathogens investigated a quite narrow sensitivity profile was observed with bixafen (table. 6.2.8-1).

Table 6.2.8-1: Sensitivity profile and cross resistance pattern of Bixafen

Pathogen	**Sensitivity profile with Bixafen**	**Cross resistance pattern**
Puccinia recondita	· narrow sensitivity distribution, with EC_{50}s: 0.3 - 2.35 mg/L · mean sensitivity of populations covers a very narrow range, with mEC_{50}s: 0.42 – 1.11 mg/L · overall stable situation	
Puccinia hordei	· narrow sensitivity distribution, with EC_{50}s: 0.26 – 0.95 mg/L · mean sensitivity of populations covers a very narrow range, with mEC_{50}s: 0.35 – 0.73 mg/L · overall stable situation	
Pyrenophora teres	· relatively broad sensitivity distribution, with low	

	EC_{50}s: 0.002 – 0.234 mg/L · mean sensitivity of populations covers a very narrow range, with mEC_{50}s: 0.003 – 0.009 mg/L · overall stable situation	
Septoria tritici	· low EC_{50} values · mean sensitivity of populations covers a very narrow range, with mEC_{50}s: 0.08 – 0.27 mg/L · overall stable situation	positive cross resistance to other carboxamide fungicide confirmed
Oculimacula acuformis	· quite broad sensitivity distribution, with low EC_{50} values · mean sensitivity of populations covers a narrow range, with mEC_{50}s: 0.018 – 0.145 mg/L · few isolates with EC_{50}s >0.5 mg/L detected, but overall stable situation	positive cross resistance to other carboxamide fungicide confirmed
Oculimacula yallundae	· quite broad sensitivity distribution, with low EC_{50} values · mean sensitivity of populations covers a narrow range, with mEC_{50}s: 0.019 – 0.146 mg/L · few isolates with EC_{50}s >0.5 mg/L detected, but overall stable situation	positive cross resistance to other carboxamide fungicide confirmed
Rhynchosporium secalis	· quite broad sensitivity distribution, but · mean sensitivity of populations covers a very narrow range, with mEC_{50}s: 0.007 – 0.055 mg/L (data 2006-2007) · data 2005 generated with different test conditions; 2007: only limited data due to dry weather and low disease incidence	positive cross resistance to other carboxamide fungicide confirmed

Prothioconazole

Mode of action and resistance

The mode of action of prothioconazole has been shown to rely on the inhibition of the demethylation at the C14 position in the fungal sterol biosynthesis. All fungicides with this mode of action are called DMI fungicides (from DeMethylation Inhibitors).

Overall, more than 30 DMI fungicides have entered the market stage meanwhile with prothioconazole being the latest introduction. Therefore, information on mode of action and resistance risk of this fungicide group is one of the most complete overall.

From a multitude of publications that are available on the resistance mechanism of DMI fungicides it becomes clear that resistance against DMI fungicides is mostly based on the accumulation of several mutations. Therefore, the resistance type characteristic for DMIs is often described as "continuous selection" or “shifting”.

The resistance risk of DMI fungicides is still classified as "medium" or “moderate”.

Sensitivity Profile

Overall, the sensitivity studies show for most pathogens that prothioconazole is a typical DMI fungicide although the measured resistance factors are usually lower than those of other triazoles. Several mutations within the target site of DMIs have been detected and it is now becoming clear that different mutations have varying impact on individual azoles. None of the studied mutations showed a significant effect on the efficacy of prothioconazole.

Resistance to DMI fungicides has been reported for several pathogens such as *Blumeria graminis*, *Mycosphaerella fijiensis*, *Venturia inaequalis* and *Erysiphe necator*. Nevertheless, although showing no longer the initial level of activity in all these cases DMIs are still widely used on the practical level.

In cereals, for several key pathogens sensitivity monitoring was performed by F.G. Felsenstein (EpiLogic) for wheat and barley powdery mildew and *Pyrenophora teres*, J.M Seng (Biotranfer) for eyespot (*Oculimacula spp.*) and Bayer CropScience for *Septoria tritici* and *Rhynchosporium secalis*.
Table 6.2.8-3 shows that mostly a stable sensitivity situation is given for prothioconazole. This is in good correlation with the yearly reports of the FRAC SBI Working Group (www.frac.info) which announces a generally stable situation for DMIs for more than 10 years.
Although important fluctuations can be found in DMI sensitivity studies over the years and regions no stable trend for a significant decrease of sensitivity could be identified with most pathogens.
Overall, the sensitivity studies show for most pathogens that prothioconazole is a typical DMI fungicide although the measured resistance factors are usually lower than with other triazoles. In the case of the cereal eyespot pathogens (*Oculimacula yallundae* and *O. acuformis*) prothioconazole reveals until now a unique profile as no cross resistance to other DMIs such as prochloraz can be detected until now.

Table 6.2.8-3: Comparison between the results of prothioconazole studies and those from other studies as published by the FRAC SBI Working Group

Pathogen	Sensitivity profile in this study with prothioconazole	Sensitivity trend reported by the FRAC SBI Working Group
Blumeria graminis f.sp. tritici	MRF ~ 6 Overall stable situation	overall stable situation
Blumeria graminis f.sp. hordei	MRF ~ 8-12 overall stable situation, with a slight tendency to increased sensitivity	overall stable situation
Pyrenophora teres	relatively high EC50 values; mean sensitivity of populations covers a narrow range of sensitivity; overall stable situation with a tendency for increased sensitivity	overall stable situation
Septoria tritici	low EC50 values; MRF variable relative to sensitive or medium sensitive standard isolates	positive cross resistance to other DMIs known* MRF ~ 4-10 relative to sensitive standard isolates
Oculimacula yallundae *Oculimacula acuformis*	narrow sensitivity distribution; very few isolates with EC50s > 1 ppm detected; no cross resistance to other DMIs found until now; overall stable situation	
Rhynchosporium secalis	narrow sensitivity distribution of mean EC50s; only 3 years of sensitivity monitoring available; trends not yet detectable	stable sensitivity, similar sensitivity all over Europe, control problems reported since many years from Northern UK but not from Germany and France

* published by the FRAC SBI Working Group; MRF = mean resistance factor

Resistance management
In regard to the specific risk of resistance of **bixafen** the following statements can be made:

- The a.m. study clearly indicates that the specific resistance risk of bixafen is mostly that of other carboxamide fungicides although the available sensitivity data give up to now no hint for an existing resistance issue.
- The resistance risk of the carboxamide group is compared to other groups of specific fungicides at the moment not completely understood. Due to the nuclear DNA encoded target of carboxamides the resistance risk can be expected to be lower than with fungicides with mitochondrial DNA encoded target. Mostly the resistance risk of carboxamides is regarded to be 'medium' (FRAC Code list 1).
- An acceptable resistance risk for bixafen is therefore most probably given when the approved resistance risk modifiers that are in use for other medium risk fungicide classes such as e.g. the DMIs are generally implemented for bixafen. It seems to be quite probable that the adaptation of these approved rules to bixafen will be effective and sufficient.

In addition to the specific fungicide risk the inherent pathogen risk is a second factor that determines the overall resistance risk of bixafen.

- All target pathogens effectively controlled with bixafen are classified either as low risk or medium risk pathogen, none as a high risk pathogen. Therefore, the fungicidal spectrum of bixafen reduces the overall resistance risk.
- Repeated applications of bixafen alone should not be used on the same crop in one season against pathogens that are known to bear a high resistance risk.
- Split/ reduced rate programmes using repeated applications which provide continuous selection pressure should be avoided.
- To ensure good performance in situations of high disease pressure it is of importance to adhere to dosages and spray timings as recommended on the label.
- Amine fungicides such as spiroxamine are effective non-cross-resistant partner fungicides for carboxamide fungicides on cereals for the control of powdery mildew.
- Effective fungicides from non-carboxamide classes should be used as partner fungicides for carboxamide fungicides on cereals for the control of leaf spot diseases and rusts.

For mixture products with strobilurins (e.g. fluoxastrobin or trifloxystrobin) as well as for mixture products with fungicides from the Amine group (e.g. spiroxamine) or DMI group (e.g. tebuconazole or prothioconazole) the specific recommendations for the use of QoI fungicides (as published by the FRAC QoI Working Group) and SBI fungicides (as published by the FRAC SBI Working Group) have to be followed in addition.

The resistance management for **prothioconazole** in cereals is coordinated for all DMI fungicides by the FRAC SBI Working Group where Bayer CropScience in an active member. All resistance management recommendations of the group (future changes included) are automatically applied for prothioconazole as well.

However, although an additional resistance risk for the use of bixafen and prothioconazole containing products in cereals is therefore not expected, possible sensitivity changes within the populations of pathogens effectively controlled with the mixture have to be regularly studied within future sensitivity monitoring programs.

IIIA1 6.3 Economics

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

IIIA1 6.4 Benefits

IIIA1 6.4.1 Survey of alternative pest control measures

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

IIIA1 6.4.2 Compatibility with current management practices including IPM

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

IIIA1 6.4.3 Contribution to risk reduction

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

IIIA1 6.5 Other/special studies

Spray tank washing

The product can be easily removed from spray tanks with water and 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 IIIA1 6.2.7.
It is concluded that bixafen & prothioconazole EC 225 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

The plant protection product Aviator Xpro (BAY 18530 F / 102000013869) has been developed by Bayer CropScience as a new foliar fungicide product for the control of diseases in cereals. It belongs to the carboxamides chemical class (complex II inhibitor) and the DMIs group of fungicides and has shown a broad spectrum of efficacy against the most economically important diseases of cereal crops caused by fungi from the classes of Basidiomycetes, Ascomycetes and Deuteromycetes.

Aviator Xpro has demonstrated excellent crop tolerance to all cereal varieties tested. It is an EC liquid formulation containing 75 g/L bixafen and 150 g/L prothioconazole. It has been shown to

achieve effective and reliable control of the main cereals diseases at the dose rate of 1.25 L/ha in wheat, rye and triticale resp. 1.0 L/ha in barley.

Field trials conducted in Europe have confirmed the following spectrum of efficacy:

Wheat	· powdery mildew	: *Blumeria graminis*
	leaf spot	: *Septoria tritici* / *Mycosphaerella graminis*
	· tan spot	: *Drechslera tritici-repentis*
	· brown rust	: *Puccinia recondita*
	eyespot	*: Pseudocercosporella herptroichoides (=Oculimacula sp.)*
	· stripe rust	: *Puccinia striiformis*
	glume blotch	*: Septoria nodorum (=Leptosphaeria nodorum)*
Barley	· powdery mildew	: *Blumeria graminis*
	· leaf blotch	: *Rhynchosporium secalis*
	· net blotch	: *Pyrenophora teres* / *Drechslera teres*
	· brown rust	: *Puccinia hordei*
	· ramularia	: *Ramularia collo-cygni*
	· physiological leaf spots	
Rye	· powdery mildew	: *Blumeria graminis*
	· leaf blotch	: *Rhynchosporium secalis*
	· brown rust	: *Puccinia recondita*
Triticale	. powdery mildew	: *Blumeria graminis*
	. leaf spot	: *Septoria tritici* / *Leptosphaeria nodorum*
	· brown rust	: *Puccinia recondita*

For the use of Aviator Xpro in cereals a maximum number of two applications per year and per crop in 150-400 litre water are recommended.

Applied from BBCH 30 up to the early flowering stage (BBCH 61) on barley and up to the end of flowering (BBCH 69) on wheat, rye and triticale it provides a broad spectrum of disease control and increased grain yields.

Field data have shown that Aviator Xpro, when used as recommended, is safe to winter and spring wheat, barley, rye and triticale.

Undesirable effects are not expected on succeeding crops, adjacent crops, part of plants used for propagating purposes and beneficial organisms.

Studies demonstrated that adverse effects on processing procedures are unlikely.

The prothioconazole and bixafen active substances provide built in resistance management.

IIIA1 6.7 List of test facilities including the corresponding certificates

TC code	Trial conductor	Country	GEP
ALR Kiel	Landwirtschaftskammer S-H Abt. 3, FB Pflanzenschutz Am Kamp 15-17 24768 Rendsburg	DEU	YES
Bayr. LfL	Bayerische Landesanstalt für Landwirtschaft Institut für Pflanzenschutz (IPS) Amtliche Mittelprüfung (1c) Lange Point 10 85354 Freising	DEU	YES
BCS AG	Bayer CropScience AG Alfred-Nobel-Str.50 6100 Monheim	DEU	YES
BCS BEL	Bayer CropScience SA – NV, Brussel J.E. Mommaertslaan 14, 1831 Diegem (Mache-len), België	BEL	YES
BCS DE	Bayer CropScience Deutschland GmbH Elisabeth-Selbert-Str. 4a 40764 Langenfeld	DEU	YES
BCS UK	Bayer CropScience Ltd 230 Cambridge Science Park Milton Road CB 40 WB Cambridge	GBR	YES
LALLF-PSD	Landesamt für Landwirtschaft, Lebensmittelsicherheit and Fischerei Mecklenburg-Vorpommern - Pflanzenschutzdienst - Graf-Lippe-Straße 1 18059 Rostock	MVP	YES
LfL Ref. PS	SÄCHSISCHES LANDESAMT FÜR UMWELT, LANDWIRTSCHAFT UND GEOLOGIE Referat 74 | Pflanzenschutz Stübelallee 2 | 01307 Dresden	SAC	YES
LLFG MD	Landesanstalt für Landwirschaft, Forsten and Gartenbau Dezernat Pflanzenschutz Strenzfelder Allee 22 06406 Bernburg	SAA	YES
LTZ BW	Landwirtschaftliches Technologiezentrum Au-gustenberg Außenstelle Stuttgart Reinsburgstraße 107 70197 Stuttgart	BAW	YES
LVLF VS Nuhnen	LVLF Brandenburg Buckower Straße 15236 Frankfurt (Oder)	BRB	YES
LWK H	Landwirtschaftskammer Niedersachsen Geschäftsbereich Landwirtschaft Wunstorfer Landstr.9 30453 Hannover	NSA	YES

LWK MS	Landwirtschaftskammer Nordrhein-Westfalen Referat 32 - Herbizidversuche im Ackerbau (Pflanzenschutz) Nevinghoff 40 48147 Münster	NRW	YES
LWK NRW	Landwirtschaftskammer Nordrhein-Westfalen Referat 32 – Pflanzenschutzdienst Siebengebirgsstraße 200 53229 Bonn	NRW	YES
LWK OL	Landwirtschaftskammer Weser-Ems Pflanzenschutzamt Sedanstr. 4, 26121 Oldenburg	NSA	YES

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

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6	Meyer, G.; Krieg, U.	Summary of the efficacy data and information on the plant protection product for Aviator Xpro - Bixafen & Prothioconazole 075 + 150 g/L - Emulsifible concentrate (EC) - BAY 18530 F	2012	M-427992-01-1 266830
KIIIA1 6	Meyer, G.; Krieg, U.	Summary of the efficacy data and information on the plant protection product for Aviator Xpro - Bixafen & Prothioconazole 075 + 150 g/L - Emulsifible concentrate (EC) - BAY 18530 F	2012	M-427992-01-1 266831
KIIIA1 6	Meyer, G.; Krieg, U.	Summary of the efficacy data and information on the plant protection product for Aviator Xpro - Bixafen & Prothioconazole 075 + 150 g/L - Emulsifible concentrate (EC) - BAY 18530 F	2012	M-427992-01-1 266832
KIIIA1 6.1.1	Dahmen, P.; Voerste, A.; Wachendorff-Neumann, U.	Results of bixafen in the primary and secondary screening against different fungal diseases in monocots and dicots	2007	DAP 001-2007 266833
KIIIA1 6.1.1	Kuck, K.H.; Mauler-Machnik, A.; Wachendorff-Neumann, U.	Results of JAU 6476 in the primary and secondary screening against different fungal diseases in monocots and dicots	2001	WDU 003/2001 266834
KIIIA1 6.1.1	Dutzmann, S.	Biological performance of bixafen (BIX) + prothioconazole (PTZ) EC 225 in cereal crops (field trials 2005-2007)	2007	AD-DUS-002/2007 266835
KIIIA1 6.1.2	Dutzmann, S.	Biological performance of bixafen (BIX) + prothioconazole (PTZ) EC 225 in cereal crops (field trials 2005-2007)	2007	AD-DUS-002/2007 266836
KIIIA1 6.1.2	Krieg, U.; Meyer, G.	KIIIA 6.1.2/02 - Dose response of Aviator Xpro against powdery mildew (ERYSGR) in wheat - BAY 18530 F	2012	M-426048-01-1 266837
KIIIA1 6.1.2	Krieg, U.; Meyer, G.	KIIIA 6.1.2/03 - Dose response of Aviator Xpro against Septoria leaf spot (SEPTTR) in wheat - BAY 18530 F	2012	M-426064-01-1 266839
KIIIA1 6.1.2	Krieg, U.; Meyer, G.	KIIIA 6.1.2/04 - Dose response of Aviator Xpro against tan spot (PYRNTR) in wheat - BAY 18530 F	2012	M-426075-01-1 266840
KIIIA1 6.1.2	Krieg, U.; Meyer, G.	KIIIA 6.1.2/05 - Dose response of Aviator Xpro against brown rust (PUCCRE) in wheat - BAY 18530 F	2012	M-426080-01-1 266841
KIIIA1 6.1.2	Krieg, U.; Meyer, G.	KIIIA 6.1.2/06 - Dose response of Aviator Xpro against powdery mildew (ERYSGH) in barley - BAY 18530 F	2012	M-426087-01-1 266842
KIIIA1 6.1.2	Krieg, U.; Meyer, G.	KIIIA 6.1.2/07 - Dose response of Aviator Xpro against leaf scald (RHYNSE) in barley - BAY 18530 F	2012	M-426092-01-1 266843
KIIIA1 6.1.2	Krieg, U.; Meyer, G.	KIIIA 6.1.2/08 - Dose response of Aviator Xpro against net blotch (PYRNTE) in barley - BAY 18530 F	2012	M-426095-01-1 266845

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.2	Krieg, U.; Meyer, G.	KIIIA 6.1.2/09 - Dose response of Aviator Xpro against dwarf rust (PUCCHD) in barley - BAY 18530 F	2012	M-426097-01-1 266846
KIIIA1 6.1.2	Krieg, U.; Meyer, G.	KIIIA 6.1.2/10 - Dose response of Aviator Xpro against Ramularia collo-cygni (RAMUCC) in barley - BAY 18530 F	2012	M-426100-01-1 266847
KIIIA1 6.1.2	Krieg, U.; Meyer, G.	KIIIA 6.1.2/11 - Dose response of Aviator Xpro against physiological leaf spot (PLS) in barley - BAY 18530 F	2012	M-426118-01-1 266849
KIIIA1 6.1.2	Krieg, U.; Meyer, G.	KIIIA 6.1.2/12 - Dose response of Aviator Xpro against powdery mildew (ERYSGR) in rye - BAY 18530 F	2012	M-426121-01-1 266850
KIIIA1 6.1.2	Krieg, U.; Meyer, G.	KIIIA 6.1.2/13 - Dose response of Aviator Xpro against leaf scald (RHYNSE) - in rye - BAY 18530 F	2012	M-426126-01-1 266851
KIIIA1 6.1.2	Krieg, U.; Meyer, G.	KIIIA 6.1.2/14 - Dose response of Aviator Xpro against brown rust (PUCCRE) in rye - BAY 18530 F	2012	M-426139-01-1 266852
KIIIA1 6.1.2	Krieg, U.; Meyer, G.	KIIIA 6.1.2/15 - Dose response of Aviator Xpro against powdery mildew (ERYSGR) in triticale - BAY 18530 F	2012	M-426142-01-1 266853
KIIIA1 6.1.2	Krieg, U.; Meyer, G.	KIIIA 6.1.2/16 - Dose response of Aviator Xpro against Septoria spp. (SEPTSP) in triticale - BAY 18530 F	2012	M-426145-01-1 266854
KIIIA1 6.1.2	Krieg, U.; Meyer, G.	KIIIA 6.1.2/17 - Dose response of Aviator Xpro against brown rust (PUCCRE) in triticale - BAY 18530 F	2012	M-426147-01-1 266855
KIIIA1 6.1.3	Krieg, U.; Meyer, G.	KIIIA 6.1.3/01 - Efficacy of Aviator Xpro against powdery mildew (ERYSGR) in wheat - BAY 18530 F	2012	M-426148-01-1 266856
KIIIA1 6.1.3	Krieg, U.; Meyer, G.	KIIIA 6.1.3/02 - Efficacy of Aviator Xpro against septoria leaf spot (SEPTTR) in wheat - BAY 18530 F	2012	M-426285-01-1 266857
KIIIA1 6.1.3	Krieg, U.; Meyer, G.	KIIIA 6.1.3/03 - Efficacy of Aviator Xpro against tan spot (PYRNTR) in wheat - BAY 18530 F	2012	M-426287-01-1 266858
KIIIA1 6.1.3	Krieg, U.; Meyer, G.	KIIIA 6.1.3/04 - Efficacy of Aviator Xpro against brown rust (PUCCRE) in wheat - BAY 18530 F	2012	M-426292-01-1 266859
KIIIA1 6.1.3	Krieg, U.; Meyer, G.	KIIIA 6.1.3/05 - Efficacy of Aviator Xpro against eye spot (PSDCHE) in wheat - BAY 18530 F	2011	M-408234-01-2 266860
KIIIA1 6.1.3	Krieg, U.; Meyer, G.	KIIIA 6.1.3/06 - Efficacy of Aviator Xpro against yellow rust (PUCCSI) in wheat - BAY 18530 F	2012	M-408236-01-2 266861
KIIIA1 6.1.3	Krieg, U.; Meyer, G.	KIIIA 6.1.3/07 - Efficacy of Aviator Xpro against glume blotch (LEPTNO) in wheat - BAY 18530 F	2012	M-408237-01-2 266862
KIIIA1 6.1.3	Krieg, U.; Meyer, G.	KIIIA 6.1.3/08 - Efficacy of Aviator Xpro against powdery mildew (ERYSGR) in barley - BAY 18530 F	2012	M-426296-01-1 266863

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.3	Krieg, U.; Meyer, G.	KIIIA 6.1.3/10 - Efficacy of Aviator Xpro against net blotch (PYRNTE) in barley - BAY 18530 F	2012	M-426301-01-1 266864
KIIIA1 6.1.3	Krieg, U.; Meyer, G.	KIIIA 6.1.3/11 - Efficacy of Aviator Xpro against dwarf rust (PUCCHD) in barley - BAY 18530 F	2012	M-426305-01-1 266865
KIIIA1 6.1.3	Krieg, U.; Meyer, G.	KIIIA 6.1.3/12 - Efficacy of Aviator Xpro against ramularia collo-cygni (RAMUCC) in barley - BAY 18530 F	2012	M-426308-01-1 266866
KIIIA1 6.1.3	Krieg, U.; Meyer, G.	KIIIA 6.1.3/13 - Efficacy of Aviator Xpro against physiological leaf spot (PLS) in barley - BAY 18530 F	2012	M-426327-01-1 266867
KIIIA1 6.1.3	Krieg, U.; Meyer, G.	KIIIA 6.1.3/14 - Efficacy of Aviator Xpro against powdery mildew (ERYSGR) in rye - BAY 18530 F	2012	M-426328-01-1 266869
KIIIA1 6.1.3	Krieg, U.; Meyer, G.	KIIIA 6.1.3/15 - Efficacy of Aviator Xpro against leaf scald (RHYNSE) in rye - BAY 18530 F	2012	M-426331-01-1 266870
KIIIA1 6.1.3	Krieg, U.; Meyer, G.	KIIIA 6.1.3/16 - Efficacy of Aviator Xpro against brown rust (PUCCRE) in rye - BAY 18530 F	2012	M-426333-01-1 266871
KIIIA1 6.1.3	Krieg, U.; Meyer, G.	KIIIA 6.1.3/17 - Efficacy of Aviator Xpro against powdery mildew (ERYSGR) in triticale - BAY 18530 F	2012	M-426336-01-1 266872
KIIIA1 6.1.3	Krieg, U.; Meyer, G.	KIIIA 6.1.3/18 - Efficacy of Aviator Xpro against Septoria spp. (SEPTSP)in triticale	2012	M-426338-01-1 266873
KIIIA1 6.1.3	Krieg, U.; Meyer, G.	KIIIA 6.1.3/19 - Efficacy of Aviator Xpro against brown rust (PUCCRE) in triticale - BAY 18530 F	2012	M-426342-01-1 266874
KIIIA1 6.1.4.2	Baxter, D.	Malting and brewing trials with barley treated with BYF00587	2007	FD07GBRA 08 266875
KIIIA1 6.1.4.2	Baxter, D.	Report to BBPA of pesticide evaluation malting and brewing trials with barleys treated with UK756 and UK831	2002	CS 835 266876
KIIIA1 6.1.4.2	Bezet, B.	Resulats d'analyses de qualite sur ble tendre - Recolte 2006	2006	RACH-2006111699-97781068 266877
KIIIA1 6.1.4.2	Bezet, M.	Résultats d'analyses de qualité sur blé tendre - récolte 2007	2007	M-296593-01-1 266878
KIIIA1 6.2.5	Haeuser-Hahn, I.; Ebbinghaus, D.	Seed compatibility of wheat and barley after foliar spray application with bixafen / bixafen + prothioconazole	2007	HIS 2/2007 266879
KIIIA1 6.2.6	Hills, M.	Evaluation of the pre-emergence (PPI) biological activity of BYF 00587 EC 125 G	2007	PPI-07003 266880

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.2.6	Drewes, M.	Influence of JAU 6476 EC on non-target plants	2001	PF-F-HB_JAU6476_02 266881
KIIIA1 6.2.7	Hills, M.	Evaluation of the post-emergence biological activity of BYF 00587 EC 125 G	2007	PP07022 266882
KIIIA1 6.2.7	Drewes, M.	Influence of JAU 6476 EC on non-target plants	2001	PF-F-HB_JAU6476_02 266883
KIIIA1 6.2.8	Mehl, A.; Schlachtmeier, M.	Bixafen (BYF00587): Baseline sensitivity and anti-resistance strategy	2007	MHA BXF-01/2007 266884
KIIIA1 10.5.2	Moll, M.	Effects of BYF 00587 + PTZ EC 75 + 150 G on the parasitoid Aphidius rhopalosiphi, extended laboratory study - dose response test -	2007	31204002 266889
KIIIA1 10.5.2	Moll, M.	Effects of BYF 00587 + PTZ EC 75 + 150 G on the predatory mite Typhlodromus pyri, extended laboratory study - dose response test -	2006	31205062 266890
KIIIA1 10.5.2	Rosenkranz, B.	Effects of BYF 00587 + PTZ EC 75 + 150 G on the lacewing Chrysoperla carnea, extended laboratory study - dose response test -	2007	31207047 266891
KIIIA1 10.5.2	Moll, M.	Effects of BYF 00587 + PTZ EC 75 + 150 G on the ladybird beetle Coccinella septempunctata, extended laboratory study - dose response test -	2007	31206012 266892
KIIIA1 10.5.2	Rosenkranz, B.	Effects of BYF 00587 + PTZ EC 75 + 150 G on the predatory mite Typhlodromus pyri, extended laboratory study - aged residue test -	2008	38631060 266893
KIIIA1 10.6.2	Lührs, U.	BYF 00587 + PTZ EC 75 + 150: Acute toxicity (14 days) to the earthworm Eisenia fetida in artificial soil with 5% peat	2006	31201021 266894
KIIIA1 10.6.3	Lührs, U.	BYF 00587 + PTZ EC 75 + 150: Effects on reproduction and growth of earthworms Eisenia fetida in artificial soil with 5% peat	2006	31202022 266895
KIIIA1 10.6.4	Lechelt-Kunze, C.	JAU 6476 EC 250: Effects on the earthworm fauna of grassland area in one year	2005	LKC/RgF 58 266896
KIIIA1 10.6.6	Lührs, U.	BYF 00587 + PTZ EC 75 + 150: effects on reproduction of the collembola Folsomia candida in artificial soil with 5% peat	2007	31209016 266897
KIIIA1 10.6.6	Frommholz, U.	Prothioconazole a.s.: Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil	2011	FRM-COLL-118/11 266898
KIIIA1 10.7.1	Reis, K.H.	Effects of BYF 00587 + PTZ EC 75 + 150 G on the activity of the soil microflora in the laboratory	2006	31208080 266899
MIIIA1 Sec 6	BAY	Draft Registration Report - Part B - Aviator Xpro - DE - Section 6 - Ecotoxicology - National assessment	2012	M-425530-01-1 266911
MIIIA1 Sec 6	BAY	Draft Registration Report - Part B - Aviator Xpro - DE - Section 6 - Ecotoxicology - National assessment	2012	M-425530-01-1 266912

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
MIIIA1 Sec 7	BAY	Draft Registration Report - Part B - Aviator Xpro - DE - Section 7 - Efficacy Data and Information - National assessment	2012	M-428470-01-1 266914
MIIIA1 Sec 7	BAY	Draft Registration Report - Part B - Aviator Xpro - DE - Section 7 - Efficacy Data and Information - National assessment	2012	M-428470-01-1 266915
KIIA 8.9.1	Lührs, U.	BYF 00587: Acute toxicity (14 days) to the earthworm Eisenia fetida in artificial soil with 5% peat	2006	29612021 ! M-279174-01-1 266952
KIIA 8.9.2	Lührs, U.	BYF 00587: Effects on reproduction and growth of earthworms Eisenia fetida in artificial soil with 5% peat	2006	29611022 ! M-276419-01-1 266953
KIIA 8.9.2	Leicher, T.	BYF 00587 EC 125: Effects on soil litter degradation	2007	LRT-SLD-31/07 ! E 427 3116-4 266954
KIIA 8.8.1.1	Waltersdorfer, A.	Toxicity to the parasitoid wasp Aphidius rhopalosiphi (DESTEPHANI-PEREZ) (Hymenoptera: Braconidae) in the laboratory; BYF 00587 EC 125 G	2006	CW06/069 ! M-279853-01-1 266959
KIIA 8.8.1.2	Waltersdorfer, A.	Toxicity to the predatory mite Typhlodromus pyri SCHEUTEN (Acari, Phytoseiidae) in the laboratory BYF 00587 EC 125 G	2006	CW06/070 ! M-280351-01-1 266960
KIIA 8.9.2	Kratz, M. A.	Bixafen EC 125: Influence on mortality and reproduction on the soil mite species Hypoaspis aculeifer tested in artificial soil with 5 % peat	2007	KRA-HR-4/07 ! E 428 3292-0 266962
KIIA 8.9.2	Lührs, U.	BYF 00587 EC 125: effects on reproduction of the collembola Folsomia candida in artificial soil with 5% peat	2007	36952016 ! M-291636-01-1 266963
KIIA 8.9.2	Lechelt-Kunze, C.	JAU 6476 EC 250: Effects on the earthworm fauna of grassland area in one year	2005	LKC/RGF 58 266968
KIIA 8.9.2	Meisner, P.	Influence of JAU 6476 EC 250 on the reproduction of earthworms (Eisenia fetida)	2002	MPE/RG 325 ! M-033501-02-1 266970
KIIA 8.9.1	Meisner, P.	Acute toxicity of JAU 6476-Desthio to earthworms (Eisenia fetida)	2000	MPE/RG 338/00 ! M-038880-01-1 266975
KIIA 8.9.2	Heimbach, F.	Influence of JAU 6476-S-Methyl on the reproduction of earthworms (Eisenia fetida)	2000	HBF/RG 317 ! M-021370-01-1 266976
KIIA 8.8.1.1	Röhlig, U.	Acute toxicity of prothioconazole EC 250 to the cereal aphid parasitoid Aphidius rhopalosiphi (Destefani-Perez) under extended laboratory conditions	2002	021048050 ! M-078264-01-1 266977

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIA 8.8.1.4	Maus, C.	Effects of JAU 6476 EC 250 on the ladybird beetle (Coccinella septempunctata) under laboratory conditions - Amendment No. 1	2002	MAUS/CS 001 ! M-021332-02-1 266979
KIIA 8.8.1.2	Gossmann, A.	Effects of JAU 6476 250 EC on the predatory mite Typhlodromus pyri under extended laboratory conditions (aged residue test)	2001	10194062 ! M-089351-01-1 266980
KIIA 8.9.1	Heimbach, F.	Acute toxicity of JAU 6476-S-methyl to earthworms (Eisenia fetida)	2000	HBF/RG 321 ! M-020680-01-1 266982
KIIA 8.8.1.2	Gossmann, A.	Effects of JAU 6476 250 EC on the predatory mite Typhlodromus pyri - extended laboratory study (dose response test)	2001	10193062 ! M-073995-02-1 266983
KIIA 8.9.2	Meisner, P.	Influence of JAU 6476-desthio on the reproduction of earthworms (Eisenia fetida)	2000	MPE/RG 332/00 ! M-026193-01-1 266987
KIIA 8.8.1.1	Bruhnke, C.	JAU 6476 EC 250 - Acute effects on Typhlodromus pyri (Acari: Phytoseiidae) in coffin-cells	2001	IRC71732 ! M-079753-01-1 266988
KIIA 8.8.1.4	Drexler, A.	Effects of JAU 6476 EC 250 on the lacewing Chrysoperla carnea Steph. (Neuroptera, Chrysopidae) in the laboratory - multi dose test -	2001	10192046 ! M-066907-01-1 266994
KIIA 8.9.1	Meisner, P.	Acute toxicity of JAU 6476 (tech.) to earthworms (Eisenia fetida)	2000	MPE/RG 326/00 ! M-031137-02-1 267006
KIIA 8.8.1.1	Dechert, G.	JAU 6476 EC 250 - Laboratory test on Aphidius rhopalosiphi	2000	IWA73572 ! M-020412-01-1 267008

Appendix 2: GAP table

GAP rev. , date: 2012-07-11

PPP (product name/code) Aviator Xpro **Formulation: Type: EC**
active substance 1 Bixafen **Conc. of as 1: 75 g/L**
active substance 2 Prothioconazole **Conc. of as 2: 150 g/L**

Applicant: Bayer CropScience **professional use** ☒ **non professional use** ☐

Zone(s): central EU

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 ap-plications) 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	Wa-ter L/ha min / max		
1	DE	wheat TRZSS	F	powdery mildew *Ery-siphe graminis* ERYSGR	spraying	BBCH 30 – 61 From spring at beginning of in-festation and/or when first symp-toms become visi-ble	a) 2 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	as 1 a) 93.8 g/ha b) 187.6 g/ha as 2 a) 187.5 g/ha b) 375 g/ha	150 – 400		
2	DE	wheat TRZSS	F	Septoria leaf blotch of wheat *Septoria tritici* SEPTTR	spraying	BBCH 30 – 61 From spring at beginning of in-festation and/or	a) 2 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	as 1 a) 93.8 g/ha b) 187.6 g/ha as 2	150 – 400		

						when first symptoms become visible			a) 187.5 g/ha b) 375 g/ha			
3	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 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	as 1 a) 93.8 g/ha b) 187.6 g/ha as 2 a) 187.5 g/ha b) 375 g/ha	150 – 400		
4	DE	wheat TRZSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 – 69 From spring at beginning of infestation and/or when first symptoms become visible	a) 2 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	as 1 a) 93.8 g/ha b) 187.6 g/ha as 2 a) 187.5 g/ha b) 375 g/ha	150 – 400		
5	DE	wheat TRZSS	F	eyespot of cereals *Pseudocercosporella herpotrichoides* PSDCHE	spraying	BBCH 29 – 32 From spring at beginning of infestation and/or when first symptoms become visible	a) 2 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	as 1 a) 93.8 g/ha b) 187.6 g/ha as 2 a) 187.5 g/ha b) 375 g/ha	150 – 400		
6	DE	wheat TRZSS	F	stripe rust of cereals *Puccinia striiformis* PUCCST	spraying	BBCH 30 – 61 From spring at beginning of infestation and/or when first symptoms become visible	a) 2 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	as 1 a) 93.8 g/ha b) 187.6 g/ha as 2 a) 187.5 g/ha b) 375 g/ha	150 – 400		
7	DE	wheat TRZSS	F	leaf and glume blotch *Septoria nodorum (Stagonospora nodorum)* LEPTNO	spraying	BBCH 30 – 61 From spring at beginning of infestation and/or when first symptoms become visible	a) 2 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	as 1 a) 93.8 g/ha b) 187.6 g/ha as 2 a) 187.5 g/ha b) 375 g/ha	150 – 400		
8	DE	barley HORVX	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 – 61 From spring at beginning of infestation and/or	a) 2 (14 -21 days) b) 2	a) 1.0 L/ha b) 2.0 L/ha	as 1 a) 75 g/ha b) 150 g/ha as 2 a) 150 g/ha	150 – 400		

						when first symptoms become visible			b) 300 g/ha			
9	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) 2 (14 -21 days) b) 2	a) 1.0 L/ha b) 2.0 L/ha	as 1 a) 75 g/ha b) 150 g/ha as 2 a) 150 g/ha b) 300 g/ha	150 – 400		
10	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) 2 (14 -21 days) b) 2	a) 1.0 L/ha b) 2.0 L/ha	as 1 a) 75 g/ha b) 150 g/ha as 2 a) 150 g/ha b) 300 g/ha	150 – 400		
11	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) 2 (14 -21 days) b) 2	a) 1.0 L/ha b) 2.0 L/ha	as 1 a) 75 g/ha b) 150 g/ha as 2 a) 150 g/ha b) 300 g/ha	150 – 400		
12	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) 2 (14 -21 days) b) 2	a) 1.0 L/ha b) 2.0 L/ha	as 1 a) 75 g/ha b) 150 g/ha as 2 a) 150 g/ha b) 300 g/ha	150 – 400		
13	DE	barley HORVX	F	Physiologic leaf spots (PLS) MEHITE	spraying	BBCH 30 – 61 From spring at beginning of infestation and/or when first symptoms become visible	a) 2 (14 -21 days) b) 2	a) 1.0 L/ha b) 2.0 L/ha	as 1 a) 75 g/ha b) 150 g/ha as 2 a) 150 g/ha b) 300 g/ha	150 – 400		
14	DE	rye SECCE	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 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	as 1 a) 93.8 g/ha b) 187.6 g/ha as 2 a) 187.5 g/ha b) 375 g/ha	150 – 400		

15	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 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	as 1 a) 93.8 g/ha b) 187.6 g/ha as 2 a) 187.5 g/ha b) 375 g/ha	150 – 400		
16	DE	rye SECCE	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 – 69 From spring at beginning of infestation and/or when first symptoms become visible	a) 2 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	as 1 a) 93.8 g/ha b) 187.6 g/ha as 2 a) 187.5 g/ha b) 375 g/ha	150 – 400		
17	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 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	as 1 a) 93.8 g/ha b) 187.6 g/ha as 2 a) 187.5 g/ha b) 375 g/ha	150 – 400		
18	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 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	as 1 a) 93.8 g/ha b) 187.6 g/ha as 2 a) 187.5 g/ha b) 375 g/ha	150 – 400		
19	DE	triticale TTLSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 – 69 From spring at beginning of infestation and/or when first symptoms become visible	a) 2 (14 -21 days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	as 1 a) 93.8 g/ha b) 187.6 g/ha as 2 a) 187.5 g/ha b) 375 g/ha	150 – 400		

Remarks:
(a) In case of group of crops the Codex classification should be used
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil born insects, foliar fungi
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) Use CIPAC/FAO Codes where appropriate
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants
(i) g/kg or g/L
(j) Growth stage at last treatment
(k) PHI = Pre-harvest interval
(l) Remarks may include: Extent of use/economic importance/restrictions (e.g. feeding, grazing)/minimal intervals between applications

REGISTRATION REPORT
Part B

Section 8 Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: 102000013869/ Aviator Xpro

Active Substances: Bixafen: 75 g/L
Prothioconazol: 150 g/L

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT /
NATIONAL ADDENDUM – Germany

Applicant: Bayer CropScience

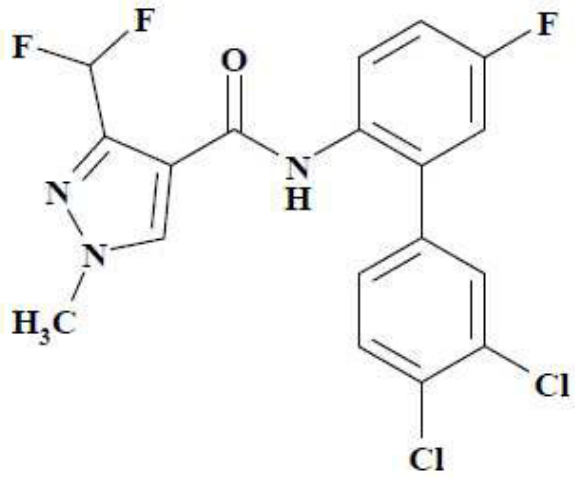
Date: **19 April 2016**

Table of Contents

Sec 8 ASSESSMENT OF THE RELEVANCE OF METABOLITES IN GROUNDWATER

8.1 Introduction

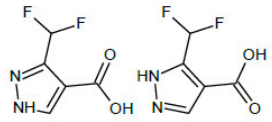
Table 8.1-1: Identity, further information on Bixafen

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	
Date of approval	01/10/2013
Conditions of approval	
Confirmatory data	
RMS	United Kingdom
Minimum purity of the active substance as manufactured (g/kg)	950
Molecular formula	C18H12Cl2F3N3O
Molecular mass	414.21 g/mol
Structural formula	

According to the EFSA Conclussion 2012 a data gap has been identified for a groundwater exposure assessment for M44. A consequent groundwater non-relevance assessment will be necessary addressing both pesticidal activity and toxicological relevance, including a consumer risk assessment.The soil metabolite M44 of Bixafen is described in Table 8.1-2.

Table 8.1-2: 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)

Metabolit	**Structural formula/Molecular formula**	**Maximum occurence in compartements**	**Status of relevance (according to SANCO 7593/VI/97 final -**

			14/08/2000)
M44		Soil Max. 2.9 % at the end of study	

[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)

8.2 Exclusion of degradation products of no concern

None.

8.3 Quantification of potential groundwater contamination (Step 2)

8.3.1 Bixafen

8.3.1.1 *Exposure assessment for the Central Zone*

Table 8.3-1: PEC_{GW} at 1 m soil depth for Bixafen and its metabolites

Use No /crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUS PELMO 5.5.3		
		Bixafen	**Metabolit M44**	
Winter cereals, A	Châteaudun	<0.001	0.469	
	Hamburg	<0.001	1.596	
	Jokioinen	<0.001	2.083	
	Kremsmünster	<0.001	1.000	
	Okehampton	<0.001	1.077	
	Piacenza	<0.001	0.833	
	Porto	<0.001	0.781	
	Sevilla	<0.001	0.263	
	Thiva	<0.001	0.372	

Crop/Group	**Szenario**	**80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUS PELMO 5.5.3**		
		Bixafen	**Metabolit M44**	
Spring cereals, A	**Châteaudun**	<0.001	0.400	
	Hamburg	<0.001	1.575	
	Jokioinen	<0.001	1.850	
	Kremsmünster	<0.001	0.972	
	Okehampton	<0.001	1.012	
	Porto	<0.001	0.710	

For the metabolite M44 a groundwater concentration of ≥ 0.1 µg/L can not be excluded in all FOCUS groundwater scenarios.

.

8.3.1.2 Exposure assessment for Germany

Since the metabolite was not measured in the laboratory soil study in relevant concentrations and it is additionally considered as not toxicologically relevant, no risk assessment of M 44 will be performed here.

8.4 Hazard Assessment: Identification of relevant metabolites (Step 3)

8.4.1 Screening for biological activity

8.4.1.1 *Bixafen-Metabolite*

During the Peer review of the pesticide risk assessment of bixafen a data gap was identified regarding the groundwater relevance assessment for the metabolite M44 (see EFSA Conclusion, EFSA-Juornal 2012, 10(11), 2917)

The relevance of the groundwater metabolite M44 has already been assessed and accepted at EU level (see „Conclusion on the peer review of the pesticide risk assessment of the active substance bixafen."EFSA Journal 2012;10(11):2917. M44 is not considered as relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10- final 25 February 2003. A summary of the relevance assessment is given in Table 8-.

8.4.2 Screening for genotoxicity

8.4.2.1 *Bixafen-Metabolite*

During the Peer review of the pesticide risk assessment of bixafen a data gap was identified regarding the relevance assessment for the metabolite M44 (see EFSA Conclusion, EFSA-Juornal 2012, 10(11), 2917)

The metabolite M44 is not genotoxic.

8.4.3 Screening for toxicity

8.4.3.1 *Bixafen-Metabolite*

During the Peer review of the pesticide risk assessment of bixafen a data gap was identified regarding the relevance assessment for the metabolite M44 (see EFSA Conclusion, EFSA-Juornal 2012, 10(11), 2917).

The relevance of the groundwater metabolite M44 has already been assessed and accepted at EU level (see „Conclusion on the peer review of the pesticide risk assessment of the active substance bixafen."EFSA Journal 2012;10(11):2917. M44 is not considered as relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10- final 25 February 2003. A summary of the relevance assessment is given in Table 8-.

Table 8-4.3 Summary of the relevance assessment for M44

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundw	STEP 2		Max PECgw Based on	1.596 µg/L Model Hamburg FOCUS PELMO 5.5.3
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	 Not classified
			Classification of metabolite	Not classified
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 Predicted exposure (% of ADI) ADI based on	acceptable 3.2 µg/d / 60 kg bw 0.05 µg/kg bw/d; ADI = 0.3 mg/kg bw/d => Exposure ~0.0167 % ADI ADI for M44; EFSA Journal 2012;10(11):2917 [ASB2012-14631]

8.5 Exposure assessment – threshold of concern approach (Step 4)

See 8.4.

8.6 Refined risk assessment for non-relevant metabolites (Step 5)

8.6.1 Refined toxicological risk assessment for non-relevant metabolites

None.

Appendix 1 GAP table

This document summarises the information related to country GAPs supported and cGAPs derived from the GAPs, followed by the rationale for the risk envelope approach used in the Ecotoxicological and Environemental Fate & behaviour risk assessment. The formulation covered in this document is:

Formulation Code	Type	Active Substance(s)
102000013869	EC	Bixafen, Prothioconazole

Table A 1: Detailed GAP for Aviator Xpro uses:

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		
1	Germany	wheat TRZSS	F	Powdery mildew *Erysiphe graminis* ERYSGR	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
2	Germany	wheat TRZSS	F	Leaf spot wheat *Septoria tritici* SEPTTR	spraying	From spring at beginning of infestation and/or when first symptoms become	**a)** 2 (14 - 21days)	a) 1.25 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha	150 - 400		

						visible BBCH 30 - 61	**b)** 2	b) 2.5 L/ha	b) 1: 187.6 g as/ha 2: 375 g as/ha			
3	Germany	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 BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
4	Germany	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 BBCH 30 - 69	a) 2 (14 - 21days) b) 2	a) 1.25 L/ha b) 2.5L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
5	Germany	wheat TRZSS	F	stem break of cereals *Pseudocercosporella herpotrichoides* PSDCHE	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 37	a) 1 b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
6	Germany	wheat TRZSS	F	Stripe rust of grasses *Puccinia striiformis* PUCCST	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
7	Germany	wheat TRZSS	F	*Septoria* leaf spot wheat *Septoria nodorum*	spraying	From spring at beginning of	**a)** 2 (14 -	a) 1.25 L/ha	a) 1: 93.8 g as/ha	150 - 400		

				LEPTNO		infestation and/or when first symptoms become visible BBCH 30 - 61	21days) **b)** 2	b) 2.5 L/ha	2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha			
8	Germany	barley HORVX	F	Powdery mildew *Erysiphe graminis* ERYSGR	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	**a)** 2 (14 - 21days) **b)** 2	a) 1 L/ha b) 2 L/ha	a) 1: 75 g as/ha 2: 150 g as/ha b) 1: 150 g as/ha 2: 300 g as/ha	150 - 400		
9	Germany	barley HORVX	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1 L/ha b) 2 L/ha	a) 1: 75 g as/ha 2: 150 g as/ha b) 1: 150 g as/ha 2: 300 g as/ha	150 - 400		
10	Germany	barley HORVX	F	net blotch *Pyrenophora teres* PYRNTE	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1 L/ha b) 2 L/ha	a) 1: 75 g as/ha 2: 150 g as/ha b) 1: 150 g as/ha 2: 300 g as/ha	150 - 400		
11	Germany	barley HORVX	F	brown rust of barley *Puccinia hordei* PUCCHD	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1 L/ha b) 2 L/ha	a) 1: 75 g as/ha 2: 150 g as/ha b) 1: 150 g as/ha 2: 300 g as/ha	150 - 400		

12	Germany	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 BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1 L/ha b) 2 L/ha	a) 1: 75 g as/ha 2: 150 g as/ha b) 1: 150 g as/ha 2: 300 g as/ha	150 - 400		
13	Germany	barley HORVX	F	decrease of non-parasitic leaf spots	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1 L/ha b) 2 L/ha	a) 1: 75 g as/ha 2: 150 g as/ha b) 1: 150 g as/ha 2: 300 g as/ha	150 - 400		
14	Germany	rye SECCE	F	Powdery mildew *Erysiphe graminis* ERYSGR	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	**a)** 2 (14 - 21days) **b)** 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
15	Germany	rye SECCE	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	**a)** 2 (14 - 21days) **b)** 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
16	Germany	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 BBCH 30 -	a) 2 (14 - 21days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g	150 - 400		

						69			as/ha 2: 375 g as/ha			
17	Germany	triticale TTLSS	F	Powdery mildew *Erysiphe graminis* ERYSGR	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
18	Germany	triticale TTLSS	F	*septoria*-species *Septoria* spp. SEPTSP	spraying	From spring at beginning of infestation and/or when first symptoms become visible BBCH 30 - 61	a) 2 (14 - 21days) b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		
19	Germany	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 BBCH 30 - 69	a) 2 b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 1: 93.8 g as/ha 2: 187.5 g as/ha b) 1: 187.6 g as/ha 2: 375 g as/ha	150 - 400		