

Art. 51
Extension of authorisation for minor uses

REGISTRATION REPORT

Part A

Risk Management

Product code: ARIANE C

Active Substances:

Clopyralid 80 g/L

Fluroxypyr 100 g/L (144,1 g/L Methyl-heptylester)

Florasulam 2,5 g/L

COUNTRY: Germany

Central Zone

Zonal Rapporteur Member State: Germany

NATIONAL ASSESSMENT

**Applicant: Bayerische Landesanstalt für Landwirtschaft -
Institut für Pflanzenschutz -**

Date: 2015-02-10

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PART A – Risk Management

This document describes the acceptable use conditions required for extension of the registration of ARIANE C containing Clopyralid, Fluroxypyr and Florasulam in Germany.

The risk assessment conclusions are based on the already existing registration of the PPP. The following sections of Registration Report, Part B were prepared on basis of new data:

- Section 4.

Assessments for the safe use of ARIANE C have been made using endpoints agreed in the EU reviews of Clopyralid, Fluroxypyr and Florasulam.

Appendix 1 of this document provides a copy of the final product authorisation in Germany.

1 Details of the application

Application to extend the authorisation of a plant protection product (PPP) already authorised in Germany to minor uses not yet covered by that authorisation.

The application is intended for use in Germany only.

1.1 Application background

Details on applicant and application

Plant protection product	ARIANE C
Type of application	Zonal application according to Article 51, ZRMS=DE, first application (GV1)
Registration number	006218-00/01
Applicant	Bayerische Landesanstalt für Landwirtschaft - Institut für Pflanzenschutz -, Lange Point 10, 85354 Freising-Weihenstephan, Deutschland
Authorisation holder	Dow AgroSciences GmbH, Truderinger Str. 15, 81677 München
Function	Herbicide
Type of formulation	Emulsifiable concentrate
Expiration of authorisation	2018-12-31

1.2 Annex I inclusion

The active substances included in the plant protection product are approved according Regulation (EC) No 1107/2009. The present application is in line with the provisions of the approvals.

Active substance (BVL Number)

Clopyralid (0446)

Content in PPP	80 g/L
Approval status	Approved according Regulation (EC) No 1107/2009
Approval	Regulation (EC) No 540/2011
Expiration of approval	30/04/2017

Fluroxypyr (0666)

Content in PPP	523,8 g/l
Approval status	Approved according Regulation (EC) No 1107/2009
Approval	Regulation (EC) No 540/2011
Expiration of approval	31/12/2021

Florasulam (0973)

Content in PPP	2,5 g/L
Approval status	Approved according Regulation (EC) No 1107/2009
Approval	Regulation (EC) No 540/2011
Expiration of approval	31/12/2015

1.3 Regulatory approach

The PPP is already registered in Germany according to Directive 91/414/EEC taking into account the uniform principles of Annex VI. Therefore the evaluation of the current application is limited to the points not covered by the existing registration.

1.3.1 Uses applied for and registration decision

Number of use	Plant/commodity/object	Harmful organism/purpose	decision
001	spelt	creeping thistle, annual dicotyledonous weeds	Authorize
002	spelt	creeping thistle, annual dicotyledonous weeds	Authorize
003	grasses	creeping thistle, annual dicotyledonous weeds	Authorize

1.3.2 Public interest and minor use

According to Article 51 (2) a and c of the Regulation (EC) No 1107/2009 extensions of authorisation are only possible if the intended use applied for is minor in nature and in public interest.

In Germany the cultivated area of spelt is about 8000 ha, of which approx. 6400 ha need to be controlled, the cultivated area of grasses is about 26656 ha, of which approx. 21325 ha need to be controlled. Calculation shows that authorisation holder will not profit from an authorisation of the requested uses. Upon this calculation and the examination of available alternative measures for the applied uses it can be stated that the applied uses is minor in nature and the authorisation is in the public interest.

1.4 Data protection claims

No new studies were submitted. Thus, there are no additional claims for data protection.

1.5 Letters of Access

Authorisation holder agrees to the current application to extend the authorisation.

2 Details of the authorisation

2.1 Product identity

Product name	ARIANE C
Authorisation number	006218-00
Composition	Clopyralid 80 g/L Fluroxypyr 100 g/L (144,1 g/L Methyl-heptylester) Florasulam 2,5 g/L
Type of formulation	Emulsifiable concentrate (EC)
Function	Herbicide
Authorisation holder	Dow AgroSciences GmbH, Truderinger Str. 15, 81677 München

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC or Regulation (EC) No 1272/2008

N	Dangerous for the environment
Xn	Harmful
RK017	R 36/38: Irritating to eyes and skin
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
RX020	R 20: Harmful by inhalation
SK015	S 36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
SX002	S 2: Keep out of the reach of children
SX013	S 13: Keep away from food, drink and animal feeding stuffs
SX026	S 26: In case of contact with the eyes, rinse thoroughly and seek medical advice
SX035	S 35: This material and its container must be disposed of in a safe way.
SX046	S 46: If swallowed, seek medical advice immediately and show this container or label
SX057	S 57 : Use appropriate container to avoid environmental contamination.

SP001 To avoid risks to man and the environment, comply with the instructions for use.

2.2.2 R and S phrases under Regulation (EC) No 547/2011

None

2.2.3 Other phrases

2.2.3.1 Restrictions linked to the PPP

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

Operator protection

- SB001 Avoid any unnecessary contact with the product. Misuse can lead to health damage.
- SS110 Wear standard protective gloves (plant protection) when handling the undiluted product.
- 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.
- SS210 Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.

Ecosystem protection

- NW262 The product is toxic for algae.
- NW264 The product is toxic for fish and aquatic invertebrates.
- NW265 The product is toxic for higher aquatic plants.
- NW468 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.

Honeybee

Integrated Pest Management (IPM)

- WH951 The risk of resistance has to be indicated on the package and in the instructions for use. Particularly measures for an appropriate risk management have to be declared.

Mode of action (HRAC-Group): O, B

WP711 Damage is possible to replanted dicotyledonous intermediate crops.

Active substance

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

Honeybee

- 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)

Integrated Pest Management (IPM)

- NN130 The product is classified as harmless for populations of the species Pardosa amentata and palustris (lycosid spiders).
- NN165 The product is classified as harmless for populations of the species Poecilus cupreus (ground beetle).
- NN170 The product is classified as harmless for populations of the species Chrysoperla carnea (lacewing).
- NN1842 The product is classified as harmless for populations of the species Aphidius rhopalosiphi (braconid wasp).

2.2.3.2 Specific restrictions linked to the intended uses

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

Ecosystem protection

- NW642-1 The product may not be applied in or in the immediate vicinity of surface or coastal waters. Irrespective of this, the minimum buffer zone from surface waters stipulated by state law must be observed. Violations may be punished by fines of up to 50 000 EUR
- NT103 In a strip at least 20 m wide which is adjacent to other areas, the product must be applied using loss reducing equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended, and be registered in at least drift reducing class 90 % (except agriculturally or horticulturally used areas, roads, paths and public places). Loss reducing equipment is not required if the product is applied with portable plant protection equipment or if adjacent areas (field boundaries, hedges, groups of woody plants) are less than 3 m wide or the product is applied in an area which has been declared by the Biologische Bundesanstalt in the "Index of regional proportions of ecotones" of 7 February 2002 (Federal Gazette no. 70 a of 13 April 2002), as amended, as agrarian landscape with a sufficient proportion of natural and semi-natural structures.

2.3 Product uses

PPP (product name/code) ARIANE C (006218-00)

active substance 1 Clopyralid

active substance 2 Fluroxypyr

active substance 3 Florasulam

Formulation type:

EC

80 g/L

Conc. of as 1:

100 g/L (144,1 g/L Methyl-heptylester)

Conc. of as 2:

2,5 g/L

Conc. of as:

safener -
synergist -

Conc. of safener:
-
Conc. of synergist:
-

Applicant: Bayerische Landesanstalt für Landwirtschaft -
Institut für Pflanzenschutz -

Zone(s): central EU

professional use
non professional use

Verified by MS: j

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	Spelt (TRZSP)	F	creeping thistle (CIRAR), annual dicotyledonous weeds (TTTDS)	spraying	BBCH 13 - 31; after emergence, spring	a) 1 b) 1	a) 1,5 L/ha b) 1,5 L/ha	a1) 0,12 kg as/ha a2) 0,15 kg as/ha a3) 0,0375 kg as/ha b1) 0,12 kg as/ha b2) 0,15 kg	200 – 400	F	Restrictions (see 2.2.3.2) NT103, NW642-1

									as/ha b3) 0,0375 kg as/ha			
002	DE	Spelt (TRZSP)	F	creeping thistle (CIRAR), annual dicotyledonous weeds (TTTDS)	spraying	BBCH 32 - 39; spring - late treatment	a) 1 b) 1	a) 1,5 L/ha b) 1,5 L/ha	a1) 0,12 kg as/ha a2) 0,15 kg as/ha a3) 0,0375 kg as/ha b1) 0,12 kg as/ha b2) 0,15 kg as/ha b3) 0,0375 kg as/ha	200-400	F	NT103, NW642-1
003	DE	Grasses (GGGGG)	F	creeping thistle (CIRAR), annual dicotyledonous weeds (TTTDS)	spraying	BBCH 13 - 29; after emergence, spring	a) 1 b) 1	a) 1,5 L/ha b) 1,5 L/ha	a1) 0,12 kg as/ha a2) 0,15 kg as/ha a3) 0,0375 kg as/ha b1) 0,12 kg as/ha b2) 0,15 kg as/ha b3) 0,0375 kg as/ha	200-400	N	NT103, NW642-1

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

Not relevant for extension of authorisation according article 51.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Not relevant for extension of authorisation according article 51.

3.1.2.2 Analytical methods for residues

Analytical methods for dry commodities such as spelt are available and acceptable for enforcing all compounds given in the residue definition of clopyralid, florasulam and fluroxypyr.

3.1.3 Mammalian Toxicology

The PPP is already registered in Germany according to Directive 91/414/EEC.

If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected.

3.1.4 Residues and Consumer Exposure

The residue behaviour of the active substances clopyralid, florasulam and fluroxypyr have been evaluated within the EU review process.

3.1.4.1 Residues

The available residue information is sufficient to perform an adequate assessment. Residues that are expected from the intended use of the plant protection product will not exceed the MRL set in Regulation (EC) No 396/2005 for clopyralid, florasulam and fluroxypyr.

3.1.4.2 Consumer exposure

An assessment of residue uptake by consumers (TMDI calculation, EFSA PRIMo) results in the following maximum ADI consumptions:

Clopyralid (0.15 mg/kg bw/d) – 27.6 % (DK child)

Florasulam (0.05 mg/kg bw/d) – 1.4 % (FR toddler)

Fluroxypyr (0.08 mg/kg bw/d) – 0.5 % (FR toddler)

Long-term dietary intake of residues of clopyralid, florasulam and fluroxypyr is unlikely to present a public health concern for European consumers.

No acute risk is expected from the consumption of spelt treated according to the intended use.

3.1.5 Environmental fate and behaviour

No new studies are presented; all data were reviewed within the EU review and approval of the national authorisation 006218-00/00 according the uniform principles of directive 91/414/EEC.

The specific German assessment scheme for groundwater contamination considers the entry paths direct leaching and bank filtration from adjacent ditches after surface run-off and drainage.

According to modelling results considering use patterns as laid down in 2.3 entries into groundwater of the active substance above 0.1 µg/L can be excluded. Special risk mitigation measures to protect the environment are not necessary.

3.1.6 Ecotoxicology

No new studies are presented; all data were reviewed within the EU review and approval of the national authorisation 006218-00/00 according the uniform principles of directive 91/414/EEC.

The PPP ARIANE C and the active substances Fluroxypyr and Florasulam are toxic to the aquatic environment (Fluroxypyr: *Navicula pelliculosa* E_bC₅₀ = 74,7 µg/L *Oncorhynchus mykiss* NOEC= 190 µg/L, *Daphnia magna* EC₅₀ = 9 µg/L; Florasulam: *Selenastrum capricornutum* E_bC₅₀ = 8,94 µg/L, *Lemna gibba* NOEC = 0,62 µg/L; PPP: *Pseudokirchneriella subcapitata* NOEC = 0,18 mg/L, *Oncorhynchus mykiss* LC₅₀ = 7,1 mg/L, *Daphnia magna* EC₅₀ = 6,9 µg/L, *Lemna gibba* NOEC = 0,032 mg/L).

Subsequently no additional entries as those according to the evaluated use pattern and good agricultural practise are acceptable. Therefore the safety phrases and conditions of use NW262, NW264, NW265, NW468 and NW 642-1 are assigned, see also 2.2.

The PPP Ariane C and the active substances are toxic to terrestrial non-target plants (Vegetative Vigour: ER₅₀ **Fluroxypyr:** 71,1 g/ha (*Vicia faba*), Clopyralid: 25,4 g/ha (*Glycine max*), **Florasulam:** 1,0 g/ha (*Daucus carota*), PPP: 21 mL/ha (*Lactuca sativa*). The resulting TER values will only exceed the relevant trigger of 10, if spraying equipment with 90 % drift reduction is used. Therefore the condition of use NT103 (90 % drift reduction) is assigned.

Risk Assessment for Honeybees

The honeybee risk assessment for the main application covers the use(s) in accordance with Article 51 of regulation (EC) No 1107/2009 (see also point 2.2).

3.1.7 Efficacy

Labelling in accordance with the requirements of ANNEX III General principles of integrated pest management under directive 2009/128/EC (see also point 2.2):

- The classification of effects on beneficial arthropods for the main application covers the uses applied for under the terms of Article 51 of regulation (EC) No 1107/2009.
- The categories and labelling for mode of action for the main application cover the uses applied for under the terms of Article 51 of regulation (EC) No 1107/2009.

According to Article 51 of the regulation (EC) No 1107/2009 the requirements for approval concerning the sufficient effect and any unacceptable effects on plants and plant products not need to be checked.

3.2 Conclusions

PPP ARIANE C is already registered in Germany according to Directive 91/414/EEC taking into account the uniform principles of Annex VI.

The intended use is minor in nature and the extension of authorisation is in public interest. Effects on bees and other beneficials were evaluated in the frame of the already authorised uses. No additional effects are anticipated because of the extension of uses.

The intended use in spelt will not result in residues above the MRLs set in Regulation (EC) No 396/2005 for clopyralid, florasulam and fluroxypyr. A risk for consumers through the consumption of food with

these residues is not expected. The use in grasses is not relevant for consumer health protection. There is no special risk mitigation necessary which deviate from the existing registration.

Considering an application in accordance with the evaluated use pattern and good agricultural practise 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 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

None

Appendix 1 – Copy of the product authorisation

See below.

Appendix 2 – Copy of the product label

No product label available. Not mandatory according to Article 51 (5)

Appendix 3 – Letter of Access

The access to the data or the data protection of the studies used for the assessment is yet to be clarified. The applicant did not submit new studies. Authorisation holder agrees to the current application to extend the authorisation.

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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22200.006218-00/01.81807
(bitte bei Antwort angeben)

DATUM 10. Februar 2015

GV1 006218-00/01

ARIANE C

**Verfahren zur Erweiterung einer Zulassung nach Artikel 51 Abs. 1 der Verordnung (EG)
Nr. 1107/2009**

Bescheid

Die Zulassung des oben genannten Pflanzenschutzmittels

mit den Wirkstoffen: 100 g/l Fluroxypyr (als 1-Methyl-heptylester 144 g/l)
80 g/l Clopyralid
2,5 g/l Florasulam

Zulassungsnummer: 006218-00

Versuchsbezeichnungen: DOW-81691-H-0-EC

Antrag vom: 11. April 2013

wird wie in Anlage 1 beschrieben auf der Grundlage von Art. 51 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) um folgende Anwendungsbiete bzw. Anwendungen erweitert:

Anwendungsnummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
006218-00/01-001, 006218-00/01-002	Acker-Kratzdistel, Einjährige zweikeim- blättrige Unkräuter	Dinkel	
006218-00/01-003	Acker-Kratzdistel, Einjährige zweikeim- blättrige Unkräuter	Gräser	

Festgesetzte Anwendungsbestimmungen

Es werden folgende Anwendungsbestimmungen gemäß § 36 Abs. 1 S. 1 des Gesetzes zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz - PflSchG) vom 6. Februar 2012 (BGBl. I S. 148, 1281), zuletzt geändert durch Artikel 4 Absatz 87 des Gesetzes vom 7. August 2013 (BGBl. I S. 3154) festgesetzt:

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

Auflagen

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

Siehe Anlage 1, jeweils unter Nr. 2.

Vorbehalt

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

Abgelehnte Anwendungsgebiete bzw. Anwendungen

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

- keine -

Rechtsbehelfsbelehrung

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

Mit freundlichen Grüßen
im Auftrag

gez. Dr. Karsten Hohgardt
kommissarischer Abteilungsleiter

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

Anlage

Anlage 1 zugelassene Anwendung: 006218-00/01-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Acker-Kratzdistel, Einjährige zweikeimblättrige Unkräuter

Pflanzen/-erzeugnisse/Objekte: Dinkel

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Ackerbau

Anwendungsbereich: Freiland

Anwendung im Haus- und

Kleingartenbereich: Nein

Stadium der Kultur: 13 bis 31

Anwendungszeitpunkt: Nach dem Auflaufen, Frühjahr

Maximale Zahl der Behandlungen

- in dieser Anwendung: 1

- für die Kultur bzw. je Jahr: 1

Anwendungstechnik: spritzen

Aufwand:

- 1,5 l/ha in 200 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)

Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zu widerhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

2.3 Wartezeiten

(F) Freiland: Dinkel

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

(NT103)

Die Anwendung des Mittels muss in einer Breite von mindestens 20 m zu angrenzenden Flä-

chen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) mit einem verlustmindernden Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung, mindestens in die Abdriftminderungsklasse 90 % eingetragen ist. Bei der Anwendung des Mittels ist der Einsatz verlustmindernder Technik nicht erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind oder die Anwendung des Mittels in einem Gebiet erfolgt, das von der Biologischen Bundesanstalt im "Verzeichnis der regionalisierten Kleinstrukturanteile" vom 7. Februar 2002 (Bundesanzeiger Nr. 70a vom 13. April 2002) in der jeweils geltenden Fassung, als Agrarlandschaft mit einem ausreichenden Anteil an Kleinstrukturen ausgewiesen worden ist.

Begründung:

Das o.g. Pflanzenschutzmittel weist ein hohes Gefährdungspotenzial für terrestrische Nichtzielpflanzen auf. Bewertungsbestimmend ist hier die ER50 von 21 ml/ha für Lactuca sativa im Wachstumstest mit dem Präparat. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 5 ist nach dem Stand der wissenschaftlichen Erkenntnisse die o.g. Anwendungsbestimmung erforderlich, um einen ausreichenden Schutz von terrestrischen Nichtzielpflanzen in Saumbiotopen zu gewährleisten.

Anlage 1 zugelassene Anwendung: 006218-00/01-002

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Acker-Kratzdistel, Einjährige zweikeimblättrige Unkräuter

Pflanzen/-erzeugnisse/Objekte: Dinkel

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Ackerbau

Anwendungsbereich: Freiland

Anwendung im Haus- und

Kleingartenbereich: Nein

Stadium der Kultur: 32 bis 39

Anwendungszeitpunkt: Frühjahr-Spätbehandlung

Maximale Zahl der Behandlungen

- in dieser Anwendung: 1

- für die Kultur bzw. je Jahr: 1

Anwendungstechnik: spritzen

Aufwand:

- 1,5 l/ha in 200 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)

Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zu widerhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

2.3 Wartezeiten

(F) Freiland: Dinkel

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

(NT103)

Die Anwendung des Mittels muss in einer Breite von mindestens 20 m zu angrenzenden Flä-

chen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) mit einem verlustmindernden Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung, mindestens in die Abdriftminderungsklasse 90 % eingetragen ist. Bei der Anwendung des Mittels ist der Einsatz verlustmindernder Technik nicht erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind oder die Anwendung des Mittels in einem Gebiet erfolgt, das von der Biologischen Bundesanstalt im "Verzeichnis der regionalisierten Kleinstrukturanteile" vom 7. Februar 2002 (Bundesanzeiger Nr. 70a vom 13. April 2002) in der jeweils geltenden Fassung, als Agrarlandschaft mit einem ausreichenden Anteil an Kleinstrukturen ausgewiesen worden ist.

Begründung:

Das o.g. Pflanzenschutzmittel weist ein hohes Gefährdungspotenzial für terrestrische Nichtzielpflanzen auf. Bewertungsbestimmend ist hier die ER50 von 21 ml/ha für Lactuca sativa im Wachstumstest mit dem Präparat. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 5 ist nach dem Stand der wissenschaftlichen Erkenntnisse die o.g. Anwendungsbestimmung erforderlich, um einen ausreichenden Schutz von terrestrischen Nichtzielpflanzen in Saumbiotopen zu gewährleisten.

Anlage 1 zugelassene Anwendung: 006218-00/01-003

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Acker-Kratzdistel, Einjährige zweikeimblättrige Unkräuter

Pflanzen/-erzeugnisse/Objekte: Gräser

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Ackerbau

Anwendungsbereich: Freiland

Anwendung im Haus- und

Kleingartenbereich: Nein

Erläuterung zur Kultur: In Beständen zur Saatguterzeugung

Stadium der Kultur: 13 bis 29

Anwendungszeitpunkt: Nach dem Auflaufen, Frühjahr

Maximale Zahl der Behandlungen

- in dieser Anwendung: 1

- für die Kultur bzw. je Jahr: 1

Anwendungstechnik: spritzen

Aufwand:

- 1,5 l/ha in 200 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)

Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zu widerhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

2.3 Wartezeiten

(N) Freiland: Gräser

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

(NT103)

Die Anwendung des Mittels muss in einer Breite von mindestens 20 m zu angrenzenden Flächen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) mit einem verlustmindernden Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils gel-

tenden Fassung, mindestens in die Abdriftminderungsklasse 90 % eingetragen ist. Bei der Anwendung des Mittels ist der Einsatz verlustmindernder Technik nicht erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind oder die Anwendung des Mittels in einem Gebiet erfolgt, das von der Biologischen Bundesanstalt im "Verzeichnis der regionalisierten Kleinstrukturanteile" vom 7. Februar 2002 (Bundesanzeiger Nr. 70a vom 13. April 2002) in der jeweils geltenden Fassung, als Agrarlandschaft mit einem ausreichenden Anteil an Kleinstrukturen ausgewiesen worden ist.

Begründung:

Das o.g. Pflanzenschutzmittel weist ein hohes Gefährdungspotenzial für terrestrische Nichtzielpflanzen auf. Bewertungsbestimmend ist hier die ER50 von 21 ml/ha für *Lactuca sativa* im Wachstumstest mit dem Präparat. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 5 ist nach dem Stand der wissenschaftlichen Erkenntnisse die o.g. Anwendungsbestimmung erforderlich, um einen ausreichenden Schutz von terrestrischen Nichtzielpflanzen in Saumbiotopen zu gewährleisten.

DRAFT REGISTRATION REPORT

Part B

Section 4: Metabolism and Residues

Detailed summary of the risk assessment

Product code: ARIANE C

Active Substances:

80 g/L Clopyralid
2.5 g/L Florasulam
100 g/L Fluroxypyr
(Fluroxypyr-1-methyl heptyl 144.1 g/L)

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Dow AgroSciences GmbH

Date: July/2014

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4 METABOLISM AND RESIDUES DATA

4.1 Evaluation of the active substances

For an evaluation of the active substance **clopyralid** please refer to the draft assessment report of the RMS (FIN, 2003 / [ASB2010-10318](#)) and to EFSA's conclusions regarding the peer review of the pesticide risk assessment of the active substance (EFSA Scientific Report (2005) 50, 1–65, [ASB2012-2729](#)).

For an evaluation of the active substance **florasulam** please refer to the draft renewal assessment report of the RMS (PL, 2013, [ASB2013-15291](#)). Further to this, it is referred to EFSA's reasoned opinion on the review of the existing maximum residue levels for florasulam according to Article 12 of Regulation (EC) No 396/2005 (EFSA Journal 2012;10(3):2626, [ASB2013-5917](#)).

For an evaluation of the active substance **fluroxypyr** please refer to the draft assessment report of the RMS (IRL, [ASB2010-10386](#)) and to EFSA's conclusions regarding the peer review of the pesticide risk assessment of the active substance (EFSA Journal 2011;9(3):2091, [ASB2012-3294](#)). Further to this, it is referred to EFSA's reasoned opinion on the review of the existing maximum residue levels for fluroxypyr according to Article 12 of Regulation (EC) No 396/2005 (EFSA Journal 2013;11(12):3495, [ASB2014-140](#)).

4.2 Evaluation of the intended uses

4.2.1 Selection of critical use and justification

The GAPs 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: Critical Uses (worst case) used for consumer intake and risk assessment

1	2	3	4	5	6	7	8	9	10	11	12	13
Use-No.	Member state(s)	Crop and/or situation (crop destination / purpose of crop) (a)	F G or I (b)	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group) (c)	Application			Application rate			PHI (days) (i)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures (j)
					Method / Kind (d-f)	Timing / Growth stage of crop & season (g)	Max. number (min. interval between applications) a) per use b) per crop/season (h)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	Spelt (0500090)	F	Creeping thistle, Annual dicotyledonous weeds	spraying	BBCH 13-31, after emergence, spring	a) 1 b) 1	a) 1.5 L/ha	a) clopyralid: 0.12 kg/ha florasulam: 0.0038 kg/ha fluroxypyr: 0.15 kg/ha	200-400	F	
002	DE		F		spraying	BBCH 32-39, spring, late treatment	a) 1 b) 1	a) 1.5 L/ha	a) clopyralid: 0.12 kg/ha florasulam: 0.0038 kg/ha fluroxypyr: 0.15 kg/ha	200-400		
003	DE	Grasses, in crops for seed production	F	Creeping thistle, Annual dicotyledonous weeds	spraying	BBCH 13-29, after emergence, spring	a) 1 b) 1	a) 1.5 L/ha	a) clopyralid: 0.12 kg/ha florasulam: 0.0038 kg/ha fluroxypyr: 0.15 kg/ha	200-400	N	

- 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 sucking 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 Spelt

4.2.2.1 *Residues in primary crops*

The following table presents an overview of the supervised residue trials selected for the assessment of **clopyralid** in wheat and barley grain and straw.

In addition, a comparable GAP on cereals was subject to evaluation as one of the representative uses in the framework of the peer review of clopyralid, supported by a set of eight supervised residue trials on wheat and nine trials on barley ([ASB2012-2729](#)). The existing EU MRL derived for cereal grains at 2 mg/kg is based thereupon.

For more details on the crop field trials summarized in table 4.2-2 it is referred to Appendix 2.

Table 4.2-2: Overview of the selected supervised residue trials for clopyralid

Commodity	Region ^(a)	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) ^(b)	HR (mg/kg) ^(c)	Existing MRL (mg/kg)	Median CF ^(d)
			Enforcement (clopyralid)	Risk assessment (clopyralid its salts and conjugates, expressed as clopyralid *)				
wheat grain barley grain	NEU	Outdoor	0.14; 0.24; 0.34; 0.37; 0.38; 0.47; 0.61; 0.79; 0.82; 0.83; 0.95; 1.1; 1.1; 1.3	0.14; 0.24; 0.34; 0.37; 0.38; 0.47; <u>0.61</u> ; <u>0.79</u> ; 0.82; 0.83; 0.95; 1.1; 1.1; 1.3	0.70	1.3	2	1.0
wheat straw barley straw	NEU	Outdoor	0.22; 0.28; 0.30; 0.31; 0.32; 0.33; 0.40; 0.43; 0.50; 0.58; 0.81; 0.87; 2 x 1.1;	0.22; 0.28; 0.30; 0.31; 0.32; 0.33; <u>0.40</u> ; <u>0.43</u> ; 0.50; 0.58; 0.81; 0.87; 2 x 1.1;	0.42	1.1	n.a.	1.0

* proposed also for enforcement ([ASB2012-3220](#))

(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.

Residue data gained on wheat may be used also for spelt by means of extrapolation. Likewise data gained on barley may be used, since they refer to growth stage of application prior to formation of generative organs. It is noted that applications were made later than envisaged. Nevertheless, the data were considered acceptable for purposes of the intended use, as residues were still clearly below the existing MRL for clopyralid in cereal grains.

A sufficiently validated analytical method is available to monitor all compounds given in the enforcement residue definition, currently established in Reg (EU) No 322/2012 as clopyralid only. It is noted that in the framework of the peer review, EFSA concluded that a sufficiently validated analytical method would be available to also monitor all compounds of a proposed enforcement residue definition including besides clopyralid its salts and conjugates, expressed as clopyralid equivalents.

The following table presents a brief overview of the supervised residue trials selected for the assessment of **florasulam** in wheat grain and straw.

In addition, a GAP on cereals was subject to evaluation in the framework of the peer review of existing MRLs for florasulam involving an application rate at 7.5 g as/ha ([ASB2012-2729](#)). The MRL currently being established at 0.01* mg/kg is based thereupon.

For more details on the crop field trials summarized in Table 4.2-3 it is referred to Appendix 2.

Table 4.2-3: Overview of the selected supervised residue trials for florasulam

Commodity	Region ^(a)	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) ^(b)	HR (mg/kg) ^(c)	Existing MRL (mg/kg)	Median CF ^(d)
			Enforcement (florasulam)	Risk assessment (florasulam)				
wheat grain	NEU	Outdoor	4 x <0.010	4 x < <u>0.010</u>	0.010	0.010	0.01	1.0
wheat straw	NEU	Outdoor	4 x <0.010	4 x < <u>0.010</u>	0.010	0.010	n.a.	1.0

(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.

Residue data gained on wheat may be used also for spelt by means of extrapolation.

Analytical methods for dry commodities such as spelt are available and acceptable for enforcing all compounds given in the residue definition of florasulam.

The following table presents a brief overview of the supervised residue trials selected for the assessment of fluroxypyr in wheat grain and wheat straw.

In addition, a GAP on cereals was subject to evaluation in the framework of the peer review of existing MRLs for fluroxypyr involving a single application rate spanning from 150 to 250 g as/ha from BBCH 37 to BBCH 45 ([ASB2012-3294](#)). A total of 25 trials were performed on wheat, barley and rye in support of that cGAP. The MRL currently being established in EU residue legislation at 0.1 mg/kg is based thereupon.

For more details on the crop field trials summarized in table 4.2-4 it is referred to Appendix 2.

Table 4.2-4: Overview of the selected supervised residue trials for fluroxypyr

Commodity	Region ^(a)	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) ^(b)	HR (mg/kg) ^(c)	Existing MRL (mg/kg)	Median CF ^(d)
			Enforcement (fluroxypyr, including its esters, expressed as fluroxypyr)*	Risk assessment (sum of fluroxypyr, its esters, its salts and its conjugates, expressed as fluroxypyr)				
wheat grain	NEU	Outdoor	2 x <0.010; 5 x <0.050	2 <0.010; 5 x < <u>0.050</u>	0.050	0.050	0.1	1.0
wheat straw	NEU	Outdoor	<0.2; 0.27; ; 0.71; 0.93; 4.9	<0.2; 0.27; 0.71; 0.93; 4.9	0.71	4.9	n.a.	1.0

* EFSA proposal from MRL review: sum of fluroxypyr, its esters, its salts and its conjugates, expressed as fluroxypyr

(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.

Residue data gained on wheat may be used also for spelt by means of extrapolation.

Analytical methods for dry commodities such as spelt are available and acceptable for enforcing all compounds given in the residue definition for fluroxypyr.

4.2.2.2 Distribution of the residue in peel/pulp

Not relevant for intended uses.

4.2.2.3 Residues in processed commodities

No new studies investigating the effects of processing on the magnitude of residues have been submitted on the crops under consideration. It is not expected that such studies would affect the outcome of the risk assessment.

4.2.2.4 Proposed pre-harvest intervals, withholding periods

No specific pre-harvest intervals are required.

4.2.3 Grass (for seed production)

4.2.3.1 Residues in primary crops

Grass was evaluated as one of the representative uses for **clopyralid** in the framework of the peer review of the active ingredient ([ASB2012-2729](#)) involving a cGAP of 1 x 80-120 g as/ha and a PHI of 7 days. The intended use under consideration is however limited to grass for seed production. Hence it is assumed that it is not fed to farm animals as forage or silage. No supervised residue trials are therefore necessary for clopyralid.

Grass was evaluated in the framework of the peer review of existing MRLs for **florasulam** ([ASB2013-5917](#)) with a cGAP involving 1 x 7.5 g as/ha and a PHI of 7 days. The intended use under consideration is however limited to grass for seed production. Hence it is assumed that it is not fed to farm animals as forage or silage. No supervised residue trials are therefore necessary for florasulam.

Grass was evaluated in the framework of the peer review of existing MRLs for **fluroxypyr** ([ASB2014-140](#)) with a cGAP involving 2 applications at 100-360 g as/ha and a PHI 4 days. The intended use under consideration is however limited to grass for seed production. Hence it is assumed that it is not fed to farm animals as forage or silage. No supervised residue trials are therefore necessary for fluroxypyr.

The envisaged use on grass is not relevant in terms of consumer health protection. The impact of residues in grass on potential residues of the substances in products of animal origin was considered in the framework of the aforementioned reports.

4.2.3.2 Distribution of the residue in peel/pulp

Not relevant for intended use.

4.2.3.3 Residues in processed commodities

Not relevant for intended use.

4.2.3.4 Proposed pre-harvest intervals, withholding periods

No specific pre-harvest interval is required.

4.3 Consumer intake and risk assessment

4.3.1 Clopyralid

The key data for consumer intake assessment, which have been derived from residue and/or processing studies for the intended uses, are summarized in Table 4.3-1.

Table 4.3-1: Key data for consumer intake assessment derived for the intended uses

Commodity	Long-term intake		Short-term intake	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
all commodities	variable	MRL (as laid down in Reg. (EU) No 322/2012	No ARfD was allocated for clopyralid. Thus, a calculation of the short-term intake of clopyralid residues was not undertaken	

The toxicological reference values and all input values used for consumer risk assessment are stated in

Table 4.3-2. To illustrate the results of the chronic risk assessment, a screenshot of the TMDI results obtained with EFSA PRIMO (rev. 2) is displayed in Appendix 3.

The clopyralid residues in grain and straw are within the envelope of a recent dietary burden calculation issued by EFSA (EFSA Journal 2011;9(10):2418, [ASB2012-3220](#)). Hence, the existing MRLs for commodities of animal origin need not to get amended from the intended use.

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

Chronic risk assessment	
ADI	0.15 mg/kg bw/day
TMDI (% ADI) according to EFSA PRIMO	27.6 % (based on DK child).
NTMDI (% ADI) according to German NVS II	22.1 % (based on DE child, mean body weight)
IEDI (% ADI) according to EFSA PRIMO rev.2	not necessary (TMDI < 100% ADI)
NEDI (% ADI) according to German NVS II	not necessary (NTMDI < 100% ADI)
Factors included in IEDI and NEDI	none
Acute risk assessment	
ARfD	not required due to low acute toxicity
IESTI (% ARfD) according to EFSA PRIMO rev.2	not applicable
NESTI (% ARfD) according to German NVS II	not applicable
Factors included in IESTI and NESTI	none

4.3.2 Florasulam

The key data for consumer intake assessment, which have been derived from residue and/or processing studies for the intended uses, are summarized in Table 4.3-3.

Table 4.3-3: Key data for consumer intake assessment derived for the intended uses

Commodity	Long-term intake		Short-term intake	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
all commodities	variable	MRL (as laid down in Reg. (EU) No 1317/2013)	No ARfD was allocated for florasulam. Thus, a calculation of the short-term intake of florasulam residues was not undertaken.	

The toxicological reference values and all input values used for consumer risk assessment are stated in Table 4.3-4. To illustrate the results of the chronic risk assessment, a screenshot of the TMDI results obtained with EFSA PRIMO is displayed in Appendix 3.

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

Chronic risk assessment	
ADI	0.05 mg/kg bw/day
TMDI (% ADI) according to EFSA PRIMO	1.4 % (based on FR toddler, mean body weight)
NTMDI (% ADI) according to German NVS II	1.3 % (based on DE child, individual consumption/body weight ratio)
IEDI (% ADI) according to EFSA PRIMO rev.2	not necessary (TMDI < 100% ADI)

NEDI (% ADI) according to German NVS II	not necessary (NTMDI < 100% ADI)
Factors included in IEDI and NEDI	none
Acute risk assessment	
ARfD	not required due to low acute toxicity
IESTI (% ARfD) according to EFSA PRIMo rev.2	not applicable
NESTI (% ARfD) according to German NVS II	not applicable
Factors included in IESTI and NESTI	none

The florasulam residues in grain and straw are within the envelope of a recent dietary burden calculation issued by EFSA (EFSA Journal 2012;10(3):2626, [ASB2013-5917](#)). Hence, the existing MRLs for commodities of animal origin need not to get amended from the intended use.

4.3.3 Fluroxypyr

The key data for consumer intake assessment, which have been derived from residue and/or processing studies for the intended uses, are summarized in Table 4.3-5.

Table 4.3-5: Key data for consumer intake assessment derived for the intended uses

Commodity	Long-term intake		Short-term intake	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
all commodities	variable	MRL (as laid down in Reg. (EU) No 822/2009	No ARfD was allocated for fluroxypyr. Thus, a calculation of the short-term intake of fluroxypyr residues was not undertaken.	

The toxicological reference values and all input values used for consumer risk assessment are stated in Table 4.3-6. To illustrate the results of the chronic risk assessment, a screenshot of the TMDI results obtained with EFSA PRIMO is displayed in Appendix 3.

Table 4.3-6: Consumer risk assessment for fluroxypyr (Annex IIA, point 6.9, Annex IIIA, point 8.8)

Chronic risk assessment	
ADI	0.8 mg/kg bw/day
TMDI (% ADI) according to EFSA PRIMo	0.5 % (based on FR toddler).
NTMDI (% ADI) according to German NVS II	0.4 % (based on DE child, mean body weight)
IEDI (% ADI) according to EFSA PRIMo rev.2	not necessary (TMDI < 100% ADI)
NEDI (% ADI) according to German NVS II	not necessary (NTMDI < 100% ADI)
Factors included in IEDI and NEDI	none
Acute risk assessment	
ARfD	not required due to low acute toxicity
IESTI (% ARfD) according to EFSA PRIMo rev.2	not applicable
NESTI (% ARfD) according to German NVS II	not applicable
Factors included in IESTI and NESTI	none

The fluroxypyr residues in grain and straw are within the envelope of a recent dietary burden calculation

issued by EFSA (EFSA Journal 2013;11(12):3495, [ASB2014-140](#)). Hence, the existing MRLs for commodities of animal origin need not to be amended for the intended use.

4.4 Proposed maximum residue levels (MRLs)

No new MRLs are required.

4.5 Conclusion

The available data are sufficient for dietary risk assessment. The supervised trials available adequately addressed the characteristics of the GAP on cereals. The periods of sample storage were within the range for which sufficient stability was demonstrated.

An exceedance of the MRLs as currently established in EU residue legislation of clopyralid (2.0 mg/kg), florasulam (0.01 mg/kg) and fluroxypyr (0.1 mg/kg) in wheat/spelt is not anticipated to occur from the intended use on spelt.

No MRLs are yet set out in EU residue legislation for grass straw.

No consumption data were available on spelt from any of the diets in EFSA PRIMo. It can be reasonably assumed, however, that intake is not higher than that of wheat or already covered by the wheat figures. Consequently, it can be concluded that both long-term and short-term intake of clopyralid, florasulam and fluroxypyr residues in spelt are unlikely to present a public health concern.

The intended use on grass for seed production is not considered relevant for consumer health. Grass straw is normally not fed to livestock animals. Moreover, residues in grass straw would be adequately covered by residues in cereal straw considered in the dietary burden calculations done in the framework of evaluations of each of the components of the product on cereal grains. No label instruction on not feeding grass straw treated with the product to farm animals is therefore deemed necessary.

As far as consumer health protection is concerned, Germany agrees with the authorization of the intended uses.

Appendix 1 List of data submitted in support of the evaluation

Table A 1: List of data submitted in support of the evaluation

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
OECD KIIA 6.3	Clements, B.; Brett, R.	1996	Residues of fluroxypyr-BPE in winter wheat at intervals following a single application of EF-1354, EF-1355 and EF-1312, UK-1995 GHE-P-4676 ! R95-129 ! CEMR-481 ! CEMS-481 GLP: Yes Published: No RIP9700148	Yes	DOW NUD	Add
	EFSA	2005	Conclusion regarding the peer review of the pesticide risk assessment of the active substance Clopyralid EFSA Scientific Report (2005) 50, 1-65 ASB2012-2729	No	publ.	Add
	EFSA	2011	European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance fluroxypyr EFSA Journal 2011;9(3):2091, 1-91 ASB2012-3294	No	publ.	Add

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
	EFSA	2011	Reasoned Opinion - Modification of the existing MRLs for Clopyralid in various commodities EFSA Journal 2011;9(10):2418, 1-40 ASB2012-3220	No	publ.	Add
	EFSA	2012	Reasoned opinion on the review of the existing maximum residue levels (MRLs) for Florasulam according to Article 12 of Regulation (EC) No 396/2005 EFSA Journal 2012;10(3):2626 ASB2013-5917	No	publ.	Add
	EFSA	2013	Reasoned opinion on the review of the existing maximum residue levels (MRLs) for Fluroxypyr according to Article 12 of Regulation (EC) No 396/2005 EFSA Journal 2013;11(12):3495 ASB2014-140	No	publ.	Add
OECD KIIA 6.3	Freeman, J. M. H.	1982	Effect of length of period between application of CYRONAL* and harvest on residues of 3,6 Dichloropicolinic acid (DOWCO 290**) in winter wheat, winter barley and maize - Belgium 1981 Derbi 30041 ! GHE-P-943 GLP: No Published: No BVL-1879443, BVL-1953927, BVL-2073685, ASB2010-7654	Yes	DOW	Add
OECD KIIA 6.3	Freeman, J. M. H.	1984	Residues of fluroxypyr in summer barley, summer wheat and winter wheat following application with a STARANE 250 g/litre Formulation - Holland 1983 GHE-P-1205 ! N12 GLP: No Published: No BVL-1680917, BVL-1692315, BVL-2347849, BVL-2347849, BVL-2347849, BVL-2347849, RIP9500509	Yes	DOE DOW NUD	Add
OECD: KIIA 6.3	Freeman, J. M. H. et al.	1982	Effect of length of period between application of Cyronal* and harvest on residues of 3,6-Dichloropicolinic Acid (DOWCO 290**) in winter wheat, winter barley and maize - Belgium 1981. GHE-P-943 ! N38 ! 30041 GLP: No Published: No BVL-1678832, BVL-1678843, BVL-1953670, BVL-2201121, RIP2002-1518	Yes (4) Open (1) No (1)	DOW	Add
OECD KIIA 6.3	Freeman, J. M. H.; Atterwill, L.	1986	Fluroxypyr residues in winter barley, winter rye and winter wheat grain and straw treated with STARANE 360 (HOE 2701-H) in comparative growth stage trials - Germany 1985 GHE-P 1447 ! DOW 00986 ! DOW 00985 ! DOW 00988 ! DOW 00987 ! DOW 00981 ! DOW 00980 ! DOW 00989 ! DOW 00982 ! DOW 00975 ! DOW 00979 ! DOW 00984 ! DOW 00983 ! N11 GLP: No Published: No BVL-1680916, BVL-1692303, BVL-2347842, BVL-2347842, BVL-2347842, BVL-2347842, RIP9500508	Yes (10) Open (2)	DOE DOW NUD	Add
	Germany	1996	Fluroxypyr (Draft Assessment Report), August 1996 GLP: not applicable Published: Yes ASB2010-10386	Open		Add
	Finland	2003	Clopyralid (Draft Assessment Report) November 2003 GLP: not applicable Published: Yes ASB2010-10318	Open		Add
	Poland	2013	Florasulam: Draft Renewal Assessment Report, Vol. 1-3 ASB2013-15291	No	publ.	Add

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
OECD KIIA 6.3	Pronier, I.	2011	Residues of Fluroxypyr and Florasulam in spring and winter cereals (wheat and barley) at harvest and at intervals following a single application of EF-1512 and EF-1343 mixture. Northern and Southern Zone - 2010. GHE-P-12647 ! 14SRX10R05 GLP: Yes Published: No BVL-2382390, BVL-2382390, ASB2013-1195	Yes	DOW	Add
OECD: KIIA 6.3	Rawle, N. W.	2002	Residues of Clopyralid in wheat at intervals under open field conditions following a single application of LONTREL (EF-1136), UK and Germany - 2000 GHE-P-9358 ! N181 ! 112403 GLP: Yes Published: No BVL-1678836, BVL-1879445, BVL-1953625, BVL-2073687, BVL-2201106, RIP2002-1530	Yes	DOW	Add
OECD KIIA 6.3	Rawle, N. W.	2002	Residues of Clopyralid in barley at harvest under open field condition following a single application of LONTREL 100 (EF-1136), UK - 2000 GHE-P-9359 ! N188 ! 104597 GLP: Yes Published: No BVL-1678845, BVL-1879461, BVL-1953644, BVL-2073702, BVL-2201111, RIP2002-1541	Yes	DOW	Add
OECD KIIA 6.3	Rawle, N. W.	2002	Residues of Clopyralid in barley at intervals under open field condition following a single application of LONTREL 100 (EF-1136), UK - 2000 GHE-P-9360 ! N185 ! 112414 GLP: Yes Published: No BVL-1678846, BVL-1879451, BVL-1953649, BVL-2073692, BVL-2201112, RIP2002-1542	Yes	DOW	Add
OECD KIIA 6.3	Rawle, N. W.	2002	Residues of Clopyralid in barley at intervals and at harvest following a single application of LONTREL 100 (EF-1136), EU Northern Zone - 2000 GHE-P-9383 ! N187 GLP: Yes Published: No BVL-1678844, BVL-1879450, BVL-1953637, BVL-2073691, BVL-2201110, RIP2002-1540	Yes	DOW	Add
OECD KIIA 6.3	Rawle, N. W.	2002	Residues of Clopyralid in wheat at intervals following a single application of LONTREL 100 (EF-1136), EU Northern Zone - 2001 GHE-P-9385 ! N182 ! 104434 GLP: Yes Published: No BVL-1678837, BVL-1879446, BVL-1953626, BVL-2073688, BVL-2201107, RIP2002-1533	Yes	DOW	Add
OECD KIIA 6.3	Teasdale, R.	1995	Residues of Fluroxypyr in winter wheat at intervals following a single application of Starane 400EW (EF-1312), UK-1994 GHE-P-4651 ! R94-012 ! CEMR-437 ! CEMS437 GLP: Yes Published: No BVL-1795835, BVL-1945069, BVL-1945069, BVL-2012553, BVL-2054117, BVL-2054117, BVL-2054117, RIP9700141	Yes	DOW NUD	Add

* 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 primary crops submitted/needed.

A 2.2.2 Magnitude of residues

Reference: OECD KIIA 6.3

Report see authority registration numbers cited in the remarks columns of the tables below (and study identification as laid down in the reference list)

Guideline(s): in accordance with agreed guidance unless stated otherwise in the commenting box

Deviations: no relevant deviations unless stated otherwise in the commenting box

GLP: see reference list

Acceptability: acceptable unless stated otherwise in the commenting box

Table A 2: Residues of clopyralid in wheat

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY) (Application on agricultural and horticultural crops)									
Federal Institute for Risk Assessment, Berlin Federal Republic of Germany					Active ingredient : clopyralid	Crop / crop group : Winter Soft Wheat	Crop Code : TRZAW		
					Submission date : 2002-08-09				
Content of a.i. (g/kg or g/l) : 100 g/L (133 g/L clopyralid monoethanolamine salt)					Indoors / Outdoors : Outdoors (European North)	Other a.i. in formulation (content and common name) :	Residues calculated as : clopyralid		
Formulation (e.g. WP) : SL (Soluble concentrate)									
Commercial product (name) : LONTREL 100									
Applicant : Dow AgroSciences GmbH									

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	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)
report No. GHE-P-9385, study No. CEMS-1544, trial CEMS-1544 A France (north) 37110 Le Boulay 2002-04-23	wheat / Apache	1) 2000-10-25 2) 3) 2001-07	0.15	300	0.050	2001-05-17	BBCH 49	whole plant whole plant whole plant whole plant grain straw	2.1 1.3 1.1 1.6 <u>1.1</u> 0.58	0 15 29 46 60 60	spraying analyt. method: GRM 01.16 (GC/NCI-MS) LOQ: 0.01 mg/kg max. sample storage time in month(s): 9 RIP2002-1533

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	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)
report No. GHE-P-9385, study No. CEMS-1544, trial CEMS-1544 B Germany 21739 Dollern 2002-04-23	wheat / Ritmo	1) 2000-10-07 2) 2001-06-17 - 2001-06-24 3) 2001-08	0.15	300	0.050	2001-05-31 ⁴⁾	BBCH 49	whole plant whole plant whole plant whole plant whole plant grain straw	2.1 1.2 0.94 1.2 <u>1.3</u> <u>0.81</u>	0 20 39 56 77 77	spraying analyt. method: GRM 01.16 (GC/NCI-MS) LOQ: 0.01 mg/kg max. sample storage time in month(s): 8 RIP2002-1533
report No. GHE-P-9358, study No. CEMS-1287, trial CEMS-1287 A United Kingdom NZ355 598 West Boldon 2002-03-01	wheat / Claire	1) 1999-09-11 2) 3) 2000	0.15	290	0.051	2000-06-09	BBCH 47- 51	whole plant whole plant whole plant whole plant whole plant grain straw	1.9 1.4 1.1 1.2 <u>0.79</u> <u>0.43</u>	0 14 28 42 61 61	spraying analyt. method: GRM 01.16 (GC/NCI-MS) LOQ: 0.01 mg/kg max. sample storage time in month(s): 20 RIP2002-1530
report No. GHE-P-9358, study No. CEMS-1287, trial CEMS-1287 B Germany Loevelingloh 2002-03-01	wheat / Flair	1) 1999-10-05 2) 3) 2000-07	0.15	300	0.051	2000-05-26 ⁴⁾	BBCH 49- 54	whole plant whole plant whole plant whole plant whole plant grain straw	2.8 1.2 1.6 1.1 <u>1.1</u> <u>0.33</u>	0 14 28 42 61 61	spraying analyt. method: GRM 01.16 (GC/NCI-MS) LOQ: 0.01 mg/kg max. sample storage time in month(s): 21 RIP2002-1530

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) : 100 g/L (133 g/L clopyralid monoethanolamine salt)
 Formulation (e.g. WP) : SL (Soluble concentrate)
 Commercial product (name) : LONTREL 100
 Applicant : Dow AgroSciences GmbH

Active ingredient : clopyralid
 Crop / crop group : Winter Soft Wheat
 Crop Code : TRZAW
 Submission date : 2002-08-09
 Indoors / Outdoors : Outdoors (European North)
 Other a.i. in formulation (content and common name) :
 Residues calculated as : clopyralid

1	2	3	4			5	6	7	8	9	10	
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks	
	(a)	(b)	kg a.i./ha	Water l/ha	kg a.i./hl	(c)		(a)		(d)	(e)	
report No. GHE-P-943, trial RT/142/81, plot 2 Belgium, Alleur 1982-04-01	wheat / Fidel	1) 1980-11-10 2) 3) 1981-08-15	0.15	360	0.042	1981-05-20	BBCH not reported	grain straw	0.73 0.32	96 96	spraying analyt. method: ERC 75.1 (GC-ECD) LOQs: 0.05 mg/kg (grain), 0.1 mg/kg (straw), max. sample storage time in month(s): 9 RIP2002-1518 ASB2010-7654 (final report)	
report No. GHE-P-943, trial RT/143/81, plot 2			0.30	360	0.083	1981-05-20		controls > LOQ				
report No. GHE-P-943, trial RT/142/81, plot 3			0.15	360	0.042	1981-06-01		grain straw	1.5 0.67	96 96		
report No. GHE-P-943, trial RT/143/81, plot 3			0.30	360	0.083	1981-06-01		grain straw	0.93 0.12	84 84		
								grain straw	1.6 0.24	84 84		

- 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:	The mean of residues from both parallel trials was used as both were considered not independent.
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RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
 (Application on agricultural and horticultural crops)

Active ingredient : Clopyralid
 Crop / crop group : Winter Barley

Submission date : 09.08.2002

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

Federal Institute for Risk Assessment, Berlin
 Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 100 g/l

Formulation (e.g. WP) : SL

Commercial product (name) : LONTREL 100 (EF-1136)

Applicant : Dow AgroSciences GmbH

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
		(a)	(b)				(c)	(a)		(d)	(e)
GHE-P-9383, CEMS-1542A (AF/5649/DE/1) France (north) 45300 Yevre la Ville 13.03.2002	barley / Drisma	1) 29.10.2000 2) -- 3) 19.07.2001	0.14	291	0.049	15.05.2001	BBCH 49	whole plant grain straw	3.1 0.58 0.71 0.31 <u>0.24</u> <u>0.32</u>	0 35 45 55 65 65	spraying analytical method: GRM 01.16 (GC/NCI-MS), LOQ: 0.01 mg/kg, max. sample storage: 6 months RIP2002-1540
GHE-P-9383, CEMS-1542B (AF/5649/DE/2) United Kingdom Stainsby, Chesterfield 13.03.2002	barley / Vanessa	1) 14.09.2000 2) -- 3) 27.07.2001	0.15	297	0.050	21.05.2001	BBCH 49	whole plant grain straw	2.5 1.9 1.2 0.89 <u>0.37</u> 1.1	0 36 45 55 67 67	spraying analytical method: GRM 01.16 (GC/NCI-MS), LOQ: 0.01 mg/kg, max. sample storage: 6 months RIP2002-1540
GHE-P-9383, CEMS-1542E (AF/5649/DE/3) United Kingdom Morley, Derbyshire 13.03.2002	barley / Pearl	1) 17.10.2000 2) -- 3) 27.07.2001	0.15	299	0.050	24.05.2001	BBCH 49	grain straw	<u>0.61</u> <u>1.1</u>	64 64	spraying analytical method: GRM 01.16 (GC/NCI-MS), LOQ: 0.01 mg/kg, max. sample storage: 6 months RIP2002-1540

GHE-P-9383, CEMS-1542E (AF/5649/DE/4) United Kingdom Draycott, Derbyshire 13.03.2002	barley / Regina	1) 17.10.2000 2) -- 3) 26.07.2001	0.15	303	0.050	21.05.2001	BBCH 49	grain straw	<u>0.34</u> <u>0.87</u>	66 66	spraying analytical method: GRM 01.16 (GC/NCI-MS), LOQ: 0.01 mg/kg, max. sample storage: 6 months RIP2002-1540
GHE-P-9383, CEMS-1542C Germany 75248 Dürren 13.03.2002	barley / Camera	1) 20.09.2000 2) -- 3) 12.07.2001	0.15	206	0.075	11.05.2001	BBCH 49	whole plant	2.4 0.91 1.6 1.6	0 35 45 53	spraying analytical method: GRM 01.16 (GC/NCI-MS), LOQ: 0.01 mg/kg, max. sample storage: 6 months RIP2002-1540
GHE-P-9383, CEMS-1542D Germany 27449 Mulsum 13.03.2002	barley / Hannah	1) 20.09.2000 2) -- 3) 12.07.2001	0.15	300	0.050	19.05.2001	BBCH 51	grain straw	<u>0.82</u> <u>0.28</u>	54 54	spraying analytical method: GRM 01.16 (GC/NCI-MS), LOQ: 0.01 mg/kg, max. sample storage: 6 months RIP2002-1540
GHE-P-9359, CEMS-1288A United Kingdom Carlton Hustwaite, North Yorkshire 09.04.2002	barley / Hanna	1) 29.10.1999 2) -- 3) 02.08.2000	0.15	294	0.050	24.05.2000	BBCH 49-55	grain straw	<u>0.47</u> <u>0.31</u>	70 70	spraying analytical method: GRM 01.16 (GC/NCI-MS), LOQ: 0.01 mg/kg, max. sample storage: 7 months RIP2002-1541
GHE-P-9360, CEMS-1289A United Kingdom Brearton, North Yorkshire 28.02.2002	barley / Halcyon	1) 05.10.1999 2) -- 3) 04.08.2000	0.15	301	0.050	24.05.2000	BBCH 49	whole plant	3.1 0.92 0.77 0.46	0 14 28 42	spraying analytical method: GRM 01.16 (GC/NCI-MS), LOQ: 0.01 mg/kg, max. sample storage: 7 months RIP2002-1542

Table A 3: **Residues of clopyralid in barley**

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

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 100 g/L (133 g/L clopyralid monoethanolamine salt)
Formulation (e.g. WP) : SL (Soluble concentrate)
Commercial product (name) : LONTREL 100
Applicant : Dow AgroSciences GmbH

Active ingredient : clopyralid
Crop / crop group : Winter Barley
Crop Code : HORVW
Submission date : 2002-08-09
Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) :
Residues calculated as : clopyralid

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl			(a)		(d)	(e)
report No. GHE-P-943, trial RT/140/81, plot 2 Belgium, Gembleux 1982-04-01	barley / Mammut	1) 1980-09-27 2) 3) 1981-08-05	0.15	360	0.042	1981-04-21	BBCH not reported	grain straw	<0.05 <0.10	106 106	spraying analyt. method: ERC 75.1 (GC-ECD) LOQ: 0.05 mg/kg (grain), 0.1 mg/kg (straw), max. sample storage time in month(s): 9 RIP2002-1518 ASB2010-7654 (final report)
report No. GHE-P-943, trial RT/143/81, plot 3			0.15	360	0.042	1981-05-11		grain straw	0.11	106	
report No. GHE-P-943, trial RT/142/81, plot 4			0.15	360	0.042	1981-05-18		grain straw	0.17 0.10	86 86	
report No. GHE-P-943, trial RT/143/81, plot 5			0.15	360	0.042	1981-05-25		grain straw	0.15 0.30	79 79	
								grain straw	0.38 0.17	72 72	

- 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:	The studies were considered acceptable.
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Table A 4: **Residues of florasulam in wheat**

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY) (Application on agricultural and horticultural crops)											
Federal Institute for Risk Assessment, Berlin Federal Republic of Germany											
Content of a.i. Formulation Commercial product Applicant	(g/kg or g/l) (e.g. WP) (name)	: 50 g/L : SC (Suspension concentrate (= flowable concentrate)) : PRIMUS : Dow AgroSciences GmbH			Active ingredient : florasulam Crop / crop group : Winter Soft Wheat Crop Code : TRZAW						
						Indoors / Outdoors : Outdoors (European North) Other a.i. in formulation (content and common name) : Residues calculated as : florasulam					
1	2	3	4		5	6	7	8	9	10	
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl			(a)		(e)	
GHE-P-12647, 14SRX10R05, trial SRHU10-004-14HR, plot 3 Hungary 9761 Taplans-zentkereszt 2011-08-05	wheat / Marshall	1) 2009-10-20 2) 2010-05 3) 2010-07-15	0.0066	320	0.0021	2010-04-29	BBCH 39	whole plant whole plant whole plant whole plant grain straw	0.12 <0.010 <0.010 <0.010 <0.010 <u><0.010</u>	0 7 14 28 77 77	tank mix with formulation EF-1512 (fluroxypyr-1-methylheptylester), analytical method: GRM 04.13 (adapted) (HPLC-MS/MS), LOQ: 0.01 mg/kg (whole plant, grain, straw), max. sample storage time in month(s): 9 ASB2013-1195
GHE-P-12647, 14SRX10R05, trial SRHU10-004-14HR, plot 4 Hungary 9761 Taplans-zentkereszt 2011-08-05	wheat / Marshall	1) 2009-10-20 2) 2010-05 3) 2010-07-15	0.0064	310	0.0021	2010-05-05	BBCH 45	whole plant whole plant whole plant whole plant grain straw	0.12 0.019 <0.010 <0.010 <0.010 <u><0.010</u>	0 8 15 29 71 71	tank mix with formulation EF-1512 (fluroxypyr-1-methylheptylester), analytical method: GRM 04.13 (adapted) (HPLC-MS/MS), LOQ: 0.01 mg/kg (whole plant, grain, straw), max. sample storage time in month(s): 8 ASB2013-1195
GHE-P-12647, 14SRX10R05, trial SRAT10-006-14R, plot 3 Austria 2471 Rohrau 2011-08-05	wheat / Tiger	1) 2009-09-30 2) 2010-06 3) 2010-07-01	0.0066	320	0.0021	2010-05-10	BBCH 39	grain straw	<0.010 <u><0.010</u>	72 72	tank mix with formulation EF-1512 (fluroxypyr-1-methylheptylester), analytical method: GRM 04.13 (adapted) (HPLC-MS/MS), LOQ: 0.01 mg/kg (grain, straw), max. sample storage time in month(s): 6 ASB2013-1195

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
(a)	(b)	(c)	(d)	(e)							
GHE-P-12647, 14SRX10R05, trial SRAT10-006-14R, plot 4 Austria 2471 Rohrau 2011-08-05	wheat / Tiger	1) 2009-09-30 2) 2010-06 3) 2010-07-01	0.0062	300	0.0021	2010-05-24	BBCH 45	grain straw	<u><0.010</u> <u><0.010</u>	58 58	tank mix with formulation EF-1512 (fluroxypyr-1-methylheptylester), analytical method: GRM 04.13 (adapted) (HPLC-MS/MS), LOQ: 0.01 mg/kg (grain, straw), max. sample storage time in month(s): 6 ASB2013-1195

- 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: The studies were considered acceptable.

Table A 5: **Residues of fluroxypyr in wheat**

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

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 360 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : STARANE 360
Applicant : Dow AgroScience

Active ingredient : fluroxypyr
Crop / crop group : Winter Wheat

Submission date : 1995-03-02

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

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	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)
GHE-P-1447, RT/4/85, DOW 00983 Germany Aligse 1986-03-01	wheat / Kanzler	1) 1983-10-02 2) 3) 1984-08-27	0.18	400	0.045	1984-06-08	BBCH 39	grain straw	<u><0.050</u> <u><0.2</u>	80 80	analytical method: ERC 83.16 (GC-ECD), LOQ: grain/straw 0.05/0.2 mg/kg, max. sample storage: 16 months RIP9500508

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

Active ingredient : fluroxypyr
 Crop / crop group : Winter Wheat

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) : EF 381
 Applicant : Dow AgroScience

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

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
		1) Sowing 2) Flowering 3) Harvest	kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
GHE-P-1205, RT/547-548/83 The Netherlands Zuider Wagenseplein, Leystad 1984-10-01	wheat / Arminda	1) 1982-10-11 (sowing) 2) 3) 1983-08-03	0.25 0.25 0.25			1982-12-08 1983-04-13 1983-04-21 ⁴⁾	BBCH 37	grain straw	<u><0.050</u> <u><0.050</u> <u><0.050</u> <u><0.050</u> <u>0.90/0.76/0.63/0.55</u> <u>0.45/0.44/0.42/0.42</u> <u><0.20</u> <u><0.20</u>	75 91 104 112 75 91 104 112	analytical method: ERC 83.16 (GC-ECD) 4 replicate samples, LOQ: grain/straw 0.05/0.2 mg/kg, max. sample storage: not reported RIP9500509

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 (288.1 g/L fluroxypyrr-1-methylheptylester)
 Formulation (e.g. WP) : EC (Emulsifiable concentrate)
 Commercial product (name) : EF-689 (STARANE 2)
 Applicant : Dow AgroSciences GmbH

Active ingredient : fluroxypyrr
 Crop / crop group : Winter Soft Wheat
 Crop Code : TRZAW
 Submission date : 1996-06-18
 Indoors / Outdoors : Outdoors (European North)
 Other a.i. in formulation (content and common name) :
 Residues calculated as : fluroxypyrr

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	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)
report No. GHE-P-4651, trial R94-012, plot 2 (EF-689) Bridging trial United Kingdom Ayot St Lawrence, Hertfordshire 1995-12-18	wheat / Hunter	1) 1993-10-12 2) 3) 1994-08	0.20	200	0.10	1994-06-01	BBCH 37-41	whole plant whole plant whole plant whole plant grain straw	5.9 2.3 1.8 2.2 <u><0.050</u> 4.9	0 19 40 62 76 76	analytical method: ERC 92.1 (GC-ECD) LOQ: 0.05 mg/kg (grain), 0.2 mg/kg (whole plant, straw), max. sample storage time 14 months RIP9700141

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) : 400 g/L (579.1 g/L fluroxypyrr-butoxypropylester)
 Formulation (e.g. WP) : EW (Emulsion, oil in water)
 Commercial product (name) : EF-1312 (STARANE 400 EW)
 Applicant : Dow AgroSciences GmbH

Active ingredient : fluroxypyrr
 Crop / crop group : Winter Soft Wheat
 Crop Code : TRZAW
 Submission date : 1996-06-18
 Indoors / Outdoors : Outdoors (European North)
 Other a.i. in formulation (content and common name) :
 Residues calculated as : fluroxypyrr

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	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)
report No. GHE-P-4651, trial R94-012, plot 3 (EF-1312)	wheat / Hunter	1) 1993-10-12 2) 3) 1994-08	0.20	200	0.10	1994-06-01	BBCH 37-41	whole plant whole plant whole plant whole plant grain straw	4.7 1.4 1.2 1.5 <0.050 2.5	0 19 40 62 76 76	analytical method: ERC 92.1 (GC-ECD), LOQ(s): 0.05 mg/kg (grain), 0.2 mg/kg (whole plant, straw), max. sample storage time 14 months RIP9700141
United Kingdom (UK) Ayot St Lawrence, Hertfordshire 1995-12-18											
report No. GHE-P-4676, trial R95-129 A, plot 2 (EF-1312)	wheat / Hussar	1) 1994-09-25 2) 3) 1995-08	0.40	200	0.20	1995-05-22	BBCH 39-41	whole plant whole plant whole plant whole plant whole plant grain straw	6.3 1.3 1.3 0.94 0.97 <0.050 1.2	0 7 14 28 56 72 72	analytical method: ERC 92.1 (GC-ECD), LOQ: 0.05 mg/kg (grain), 0.2 mg/kg (whole plant, straw), max. sample storage time 6 months RIP9700148
United Kingdom Filkins, Oxon 1996-02-22											

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 (290 g/L fluroxypyr-1-methylheptylester)
 Formulation (e.g. WP) : EC (Emulsifiable concentrate)
 Commercial product (name) : EF-1512
 Applicant : Dow AgroSciences GmbH

Active ingredient : fluroxypyr
 Crop / crop group : Winter Soft Wheat
 Crop Code : TRZAW
 Submission date : 2013-01-08
 Indoors / Outdoors : Outdoors (European North)
 Other a.i. in formulation (content and common name) :
 Residues calculated as : fluroxypyr

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	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)
GHE-P-12647, 14SRX10R05, trial SRHU10-004-14HR Hungary 9761 Taplanszentkereszt 2011-08-05	wheat / Marshall	1) 2009-10-20 2) 2010-05 3) 2010-07-15	0.21	320	0.066	2010-04-29	BBCH 39	whole plant whole plant whole plant whole plant grain straw	4.9 2.3 2.0 1.1 <u><0.010</u> <u>0.27</u>	0 7 14 28 77 77	tankmix with formulation PRIMUS (florasulam), analytical method: ERC 97.10 (adapted) (HPLC-MS/MS), LOQ: 0.01 mg/kg (whole plant, grain, straw) max. sample storage time 9 months ASB2013-1195
GHE-P-12647, 14SRX10R05, trial SRAT10-006-14R Austria 2471 Rohrau 2011-08-05	wheat / Tiger	1) 2009-09-30 2) 2010-06 3) 2010-07-01	0.21	320	0.067	2010-05-10	BBCH 39	grain straw	<u><0.010</u> <u>0.93</u>	72 72	tankmix with formulation PRIMUS (florasulam), analytical method: ERC 97.10 (adapted) (HPLC-MS/MS), LOQ: 0.01 mg/kg (grain, straw) max. sample storage time 6 months ASB2013-1195

- 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:	The studies are considered acceptable
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A 2.3 Residues in processed commodities

No new study on residues in processed commodities has been submitted.

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 (EFSA PRIMo, rev.2)

Screenshots of TMDJ calculations based on PRIMo rev.2

CLOPYRALID				Prepare workbook for refined calculations	
Status of the active substance:		Code no.:			
LOQ (mg/kg bw):		proposed LOQ:			
Toxicological end points					
ADI (mg/kg bw/dag):	0,15	ARfD (mg/kg bw):	n.n.		
Source of ADI:	EFSA 2005	Source of ARfD:	EFSA 2005		
Year of evaluation:		Year of evaluation:			
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		
			4 - 28		
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)	3rd contributor to MS diet (in % of ADI)
27,6	DK child	14,7	Rye	7,3	Wheat
27,0	UK Toddler	15,2	Sugar beet (root)	5,2	Wheat
26,6	VHO Cluster diet B	11,4	Wheat	3,3	Maize
21,7	IE adult	3,1	Maize	3,1	Maize
20,7	DE child	5,5	Wheat	4,2	Pome fruit
19,9	NL child	6,3	Wheat	2,3	Pome fruit
19,0	UK Infant	6,7	Sugar beet (root)	3,6	Wheat
17,0	VHO cluster diet D	8,7	Wheat	1,4	Potatoes
15,7	VHO cluster diet E	5,3	Wheat	1,4	Rye
14,1	FR toddler	3,5	Wheat	1,7	Potatoes
14,1	VHO Cluster diet F	4,8	Wheat	2,5	Rye
14,0	IT kids/toddler	8,9	Wheat	2,0	Other cereal
13,1	SE general population 90th percentile	4,3	Wheat	1,4	Potatoes
12,7	PT General population	5,2	Wheat	1,8	Potatoes
11,9	ES child	5,8	Wheat	0,8	Citrus fruit
11,1	VHO regional European diet	4,0	Wheat	1,3	Potatoes
9,3	IT adult	5,5	Wheat	0,9	Other cereal
9,2	LT adult	3,8	Rye	1,4	Wheat
9,1	UK vegetarian	2,7	Wheat	2,5	Sugar beet (root)
8,9	NL general	2,8	Wheat	0,9	Potatoes
8,5	FR all population	4,4	Wheat	1,4	Table and wine grapes
8,4	FR infant	1,4	Potatoes	1,1	Wheat
8,0	UK Adult	2,7	Sugar beet (root)	2,2	Wheat
8,0	DK adult	2,7	Wheat	2,3	Rye
7,7	ES adult	3,1	Wheat	0,7	Barley
6,2	FI adult	2,3	Rye	1,3	Wheat
4,1	PL general population	1,1	Potatoes	0,8	Pome fruit

Florasulam				Prepare workbook for refined calculations	
Status of the active substance:		Code no.			
LOQ (mg/kg bw):		proposed LOQ:			
ADI (mg/kg bw/day):	0,05	ARID (mg/kg bw):	n.a.		
Source of ADI:	EFSA	Source of ARID:	EFSA		
Year of evaluation:	2012	Year of evaluation:	2012		

Main choice of toxicological reference values.

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).

pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment					
		TMDI (range) in % of ADI minimum - maximum			
		0	1		
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
1,4	FR toddler	0,8	Milk and cream,	0,2	FRUIT (FRESH OR FROZEN)
1,4	UK Infant	0,8	Milk and cream,	0,2	SUGAR PLANTS
1,3	UK Toddler	0,5	SUGAR PLANTS	0,4	Milk and cream,
1,3	NL child	0,6	Milk and cream,	0,3	FRUIT (FRESH OR FROZEN)
1,1	DE child	0,5	FRUIT (FRESH OR FROZEN)	0,3	Milk and cream,
1,1	FR infant	0,5	Milk and cream,	0,3	FRUIT (FRESH OR FROZEN)
1,0	WHO Cluster diet B	0,2	CEREALS	0,1	CEREALS
0,8	DK child	0,3	Milk and cream,	0,2	CEREALS
0,8	SE general population 90th percentile	0,2	Milk and cream,	0,1	FRUIT (FRESH OR FROZEN)
0,8	ES child	0,3	Milk and cream,	0,1	FRUIT (FRESH OR FROZEN)
0,7	IE adult	0,2	FRUIT (FRESH OR FROZEN)	0,1	CEREALS
0,6	WHO cluster diet E	0,1	CEREALS	0,1	FRUIT (FRESH OR FROZEN)
0,6	WHO cluster diet D	0,2	CEREALS	0,1	Milk and cream,
0,6	WHO regional European diet	0,1	Milk and cream,	0,1	Root and tuber vegetables
0,6	WHO Cluster diet F	0,1	CEREALS	0,1	Root and tuber vegetables
0,4	NL general	0,1	Milk and cream,	0,1	FRUIT (FRESH OR FROZEN)
0,4	ES adult	0,1	Milk and cream,	0,1	Root and tuber vegetables
0,4	UK vegetarian	0,1	SUGAR PLANTS	0,1	FRUIT (FRESH OR FROZEN)
0,4	FR all population	0,1	FRUIT (FRESH OR FROZEN)	0,1	Milk and cream,
0,4	UK Adult	0,1	SUGAR PLANTS	0,1	FRUIT (FRESH OR FROZEN)
0,4	PT General population	0,1	FRUIT (FRESH OR FROZEN)	0,1	Brassica vegetables
0,3	DK adult	0,1	Milk and cream,	0,1	CEREALS
0,3	IT kids/toddler	0,2	CEREALS	0,1	Fruiting vegetables
0,3	LT adult	0,1	Milk and cream,	0,1	CEREALS
0,3	FI adult	0,1	Milk and cream,	0,1	CEREALS
0,2	IT adult	0,1	CEREALS	0,1	Fruiting vegetables
0,2	PL general population	0,1	Root and tuber vegetables	0,1	Fruiting vegetables

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.

A long-term intake of residues of Florasulam is unlikely to present a public health concern.

Fluroxypyr (fluroxypyr including its esters expressed as fluroxypyr) (R)						Prepare workbook for refined calculations	
Status of the active substance:		Code no.					
LOQ (mg/kg bw):		proposed LOQ:					
ADI (mg/kg bw/day):	0,8	ARID (mg/kg bw):	n.a.				
Source of ADI:	EFSA	Source of ARID:	EFSA				
Year of evaluation:	2011	Year of evaluation:	2011				

Main choice of toxicological reference values.

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).

pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment					
		TMDI (range) in % of ADI minimum - maximum			
		0	1		
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
0,5	FR toddler	0,2	Milk and cream,	0,1	FRUIT (FRESH OR FROZEN)
0,5	NL child	0,2	Milk and cream,	0,1	Wheat
0,5	UK Infant	0,2	Milk and cream,	0,1	FRUIT (FRESH OR FROZEN)
0,4	UK Toddler	0,1	SUGAR PLANTS	0,1	Wheat
0,4	DE child	0,1	FRUIT (FRESH OR FROZEN)	0,1	Wheat
0,4	FR infant	0,2	Milk and cream,	0,1	FRUIT (FRESH OR FROZEN)
0,4	WHO Cluster diet B	0,1	Wheat	0,0	Root and tuber vegetables
0,3	DK child	0,1	Milk and cream,	0,1	Rye
0,3	ES child	0,1	Milk and cream,	0,1	FRUIT (FRESH OR FROZEN)
0,2	IE adult	0,1	FRUIT (FRESH OR FROZEN)	0,0	Root and tuber vegetables
0,2	SE general population 90th percentile	0,1	Milk and cream,	0,0	FRUIT (FRESH OR FROZEN)
0,2	WHO cluster diet D	0,1	Wheat	0,0	Root and tuber vegetables
0,2	WHO cluster diet E	0,0	Wheat	0,0	Root and tuber vegetables
0,2	WHO Cluster diet F	0,0	Wheat	0,0	Milk and cream,
0,2	WHO regional European diet	0,0	Wheat	0,0	Root and tuber vegetables
0,2	NL general	0,0	Milk and cream,	0,0	Wheat
0,1	ES adult	0,0	Milk and cream,	0,0	FRUIT (FRESH OR FROZEN)
0,1	IT kids/toddler	0,1	Wheat	0,0	Fruiting vegetables
0,1	PT General population	0,0	Wheat	0,0	Brassica vegetables
0,1	FR all population	0,0	Wheat	0,0	Milk and cream,
0,1	UK vegetarian	0,0	Wheat	0,0	FRUIT (FRESH OR FROZEN)
0,1	DK adult	0,0	Milk and cream,	0,0	Milk and cream,
0,1	UK Adult	0,0	SUGAR PLANTS	0,0	FRUIT (FRESH OR FROZEN)
0,1	DE child	0,0	Milk and cream,	0,0	FRUIT (FRESH OR FROZEN)
0,1	LT adult	0,0	Milk and cream,	0,0	FRUIT (FRESH OR FROZEN)
0,1	IT adult	0,1	Wheat	0,0	Fruiting vegetables
0,1	FI adult	0,0	Milk and cream,	0,0	Wheat
0,1	PL general population	0,0	Root and tuber vegetables	0,0	Fruiting vegetables

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.

A long-term intake of residues of Fluroxypyr (fluroxypyr including its esters expressed as fluroxypyr) (R) is unlikely to present a public health concern.