

Art. 51 extension

REGISTRATION REPORT

Part A

Risk Management

Product code: Artist

Active Substances:

Metribuzin 175 g/kg and Flufenacet 240 g/kg

COUNTRY: Germany

Central Zone

Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

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

Date: 18/06/2012

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PART A – Risk Management

This document describes the acceptable use conditions required for extension of the registration of Artist containing metribuzin and flufenacet 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 Artist have been made using endpoints agreed in the EU reviews of metribuzin and flufenacet.

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	Artist
Type of application	Zonal application according to Article 51, ZRMS=DE, first application (GV1)
Registration number	024559-00/03
Applicant	Bayerische Landesanstalt für Landwirtschaft - Institut für Pflanzenschutz -, Lange Point 10, 85354 Freising-Weihenstephan, Deutschland
Authorisation holder	Bayer CropScience Deutschland GmbH, Registrierung & PGA Elisabeth-Selbert-Straße 4a, 40764 Langenfeld
Function	Herbicide
Type of formulation	Water dispersible granule (WG)
Expiration of authorisation	2016-12-31

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)

Metribuzin (0337)

Content in PPP	175 g/kg
Approval status	Approved according Regulation (EC) No 1107/2009
Approval	Regulation (EC) No 540/2011
Expiration of approval	30/09/2017

Flufenacet (0922)

Content in PPP	240 g/kg
Approval status	Approved according Regulation (EC) No 1107/2009
Approval	Regulation (EC) No 540/2011
Expiration of approval	31/12/2013

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
1	Soya bean	annual bluegrass, annual dicotyledonous weeds, weed millets	Authorise

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 soybean is about 3500 ha, thereof 2800 ha need to be controlled. Calculation shows that authorisation holder will not profit from authorisation in that use.

Upon this calculation and the examination of available alternative measures for the applied use(s) it can be stated that the applied use(s) is minor in nature and the authorisation is in the public interest.

1.4 Data protection claims

The authorisation holder is owner of the new studies submitted and claims data protection.

1.5 Letters of Access

The authorisation holder is owner of the new studies submitted.

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

2 Details of the authorisation

2.1 Product identity

Product name	Artist
Authorisation number	024559-00/03
Composition	Metribuzin 175 g/kg; Flufenacet 240g/kg
Type of formulation	Water dispersible granule (WDG)
Function	Herbicide
Authorisation holder	Bayer CropScience Deutschland GmbH, Registrierung & PGA Elisabeth-Selbert-Straße 4a, 40764 Langenfeld

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
RK021	R 48/22: Danger of serious damage to health by prolonged exposure if swallowed
RK050	R 50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
RX022	R 22: Harmful if swallowed
RX043	R 43: May cause sensitisation by skin contact
SK012	S 36/37 : Wear suitable protective clothing and gloves.
SP001	To avoid risks to man and the environment, comply with the instructions for use.
SX002	S 2: Keep out of the reach of children.
SX013	S 13: Keep away from food, drink and animal feeding stuffs.
SX024	S 24: Avoid contact with skin.
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.

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.
- 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.

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

Integrated Pest Management (IPM)

Mode of action (HRAC-Group): C1

Active substance

None.

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* und *palustris* (wolfspiders).
- NN165 The product is classified as harmless for populations of the species *Poecilus cupreus* (carabid beetle).
- NN160 The product is classified as harmless for populations of the species *Aleochara bilineata* (rove beetle).

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

- NW609-1 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 observing the minimum buffer zone stated below. It is not necessary to observe this buffer zone if the product is applied using equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended. Irrespective of this, 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. Violations may be punished by fines of up to 50 000 EUR.
- NW706 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.
- 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) **Artist (024559-00/03)**
active substance 1 **Metribuzin**
active substance 2 **Flufenacet**

Formulation type: **Water dispersible granule (WDG)**
Conc. of as 1: **175 g/kg**
Conc. of as 2: **240 g/kg**

Applicant: **Bayerische Landesanstalt für Landwirtschaft** professional use
Zone(s): **central EU** 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:
					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	Soya bean GLXMA	F	annual bluegrass POAAN, annual dicotyledonous weeds TTTDS, weed millets PPPPP	spraying	BBCH 00-07, before emergence	a) 1 b) 1	a) 2 kg/ha b) 2 kg/ha	a) Metribuzin 350 g/ha; Flufenacet 480 g/ha b) ditto	200 - 400	F	Restrictions (see 2.2.3.2) NW609-1 NW706 NT103

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

Soja beans belong to the group of high oil content commodities. Sufficiently validated analytical methods are available for enforcing flufenacet and metribuzin in soya beans.

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 flufenacet and metribuzin has been evaluated within the EU review process. Information about metabolism is sufficient to evaluate the intended use in soya beans.

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 both flufenacet and metribuzin.

3.1.4.2 Consumer exposure

Chronic risk:

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

Flufenacet (ADI = 0.005 mg/kg bw/d): 47 % (UK toddlers), 40 % (German children)

Metribuzin (ADI = 0.013 mg/kg bw/d): 55 % (French toddlers), 47 % (German children)

Long-term dietary intake of residues of flufenacet and metribuzin following treatment of soya beans according to the intended use is unlikely to present a public health concern for European consumers.

Acute risk:

An assessment of residue uptake by consumers (IESTI calculation, EFSA PRIMo and NESTI calculation, German VELs model) results in the following maximum ARfD consumptions:

Flufenacet (ARfD = 0.017 mg/kg bw/d): <1 % (German children)

Metribuzin (ADI = 0.02 mg/kg bw/d): <1 % (German children)

No acute risk is expected from the consumption of soya beans 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 025876-00/00 according the uniform principles of directive 91/414/EEC.

3.1.6 Ecotoxicology

No new studies are presented; all data were reviewed within the EU review and approval of the national authorisation 025876-00/00 according the uniform principles of directive 91/414/EEC.

Considering use patterns as laid down in 2.3 entries into the surface water of the active substances metribuzin and flufenacet can not be excluded. Taking into consideration the NOEAEC of 18 µg as/L for metribuzin and 12 µg as/L for flufenacet from mesocosm studies, risk management is necessary to avoid unacceptable effects on aquatic organisms (NW609-1, NW 706).

Considering use patterns as laid down in 2.3 effects on non-target terrestrial plants cannot be excluded (seedling emergence *Lolium perenne* ER₅₀ 80.20 g as/ha, vegetative vigor *Lactuca sativa* 53 g as/ha). Risk mitigation is necessary to avoid unacceptable effect on non-target terrestrial plants (NT 103).

Honeybee risk assessment

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

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.

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 use(s) 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 use(s) applied for under the terms of Article 51 of regulation (EC) No 1107/2009.

3.2 Conclusions

PPP Artist 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 beyond these are anticipated because of the extension of uses(s).

The intended use in soya beans will not result in residues above the MRLs set for flufenacet and metribuzin in Regulation (EC) No 396/2005. A risk for consumers through the consumption of food

containing residues at that level is not expected. 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.

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

No letter of access necessary. The authorisation holder is owner of the new studies submitted. Authorisation holder agrees to the current application to extend the authorisation.



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IHR ZEICHEN
IHRE NACHRICHT VOM
AKTENZEICHEN 200.22200.024559-00/03.56332
(bitte bei Antwort angeben)

DATUM 05. Juni 2012

GV1 024559-00/03

Artist

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

Bescheid

mit den Wirkstoffen: 240 g/kg Flufenacet; 175 g/kg Metribuzin

Zulassungsnummer 024559-00 in weiteren Anwendungsgebieten

Versuchsbezeichnung: BAY-11510-H-0-WG

Ihr Antrag vom 04. August 2011

Die Zulassung des oben genannten Pflanzenschutzmittels wird wie in Anlage 1 beschrieben auf der Grundlage von Art. 51 der Verordnung (EG) Nr. 1107/2009 um folgende Anwendungsgebiete erweitert:

Dienstszitz Braunschweig
Bundesallee 50, Geb. 247
38116 Braunschweig
Tel: +49 (0)531 21497-0
Fax: +49 (0)531 21497-299

Abt. Pflanzenschutzmittel
Messeweg 11/12
38104 Braunschweig
Tel: +49 (0)531 299-5
Fax: +49 (0)531 299-3002

Dienstszitz Berlin
Mauerstraße 39-42
10117 Berlin
Tel: +49 (0)30 18444-000
Fax: +49 (0)30 18444-89999

Referatsgr. Untersuchungen
Diedersdorfer Weg 1
12277 Berlin
Tel: +49 (0)30 18412-0
Fax: +49 (0)30 18412-2955

Schadorganismus/ Zweckbestimmung	Pflanzen/ -erzeugnisse/Objekte	Anwendungsnummer
Schadhirsen, Einjähriges Rispengras, Einjährige zweikeimblättrige Unkräuter	Sojabohne	024559-00/03-001

Es werden folgende Anwendungsbestimmungen gemäß § 36 Abs. 1 S. 1 PflSchG festgesetzt:

Für die Anwendung 024559-00/03-001:

(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 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:

Bei der Untersuchung der Auswirkungen des Präparates auf 6 Spezies erwies sich im Voraufauftest das Weidelgras (*Lolium perenne*) mit einer ER_{50} von 0.0802 kg/ha als empfindlichste Spezies und im Nachaufauftest war der Salat (*Lactuca sativa*) mit einer ER_{50} von 0.053 kg/ha die empfindlichste Spezies. Aus Berechnungen zur additiven Toxizität der Wirkstoffe im Mittel kann abgeleitet werden, dass sich die beiden Wirkstoffe im Präparat nicht gegenseitig verstärken, d.h. das Präparat ist nicht toxischer als aufgrund der Wirkstoffanteile zu erwarten wäre. Unter Beachtung dieses Sachverhaltes und dass für beide Wirkstoffe aufgrund der hohen Anzahl getesteter Arten (>10 sp.) eine Absenkung des TER von 10 auf 5 akzeptiert werden kann, sowie zum Mittel ein kompletter Grunddatensatz vorliegt, wird für die Bewertung des Präparates ebenso ein TER-Wert von 5 als ausreichend

angesehen, um mit an Sicherheit grenzender Wahrscheinlichkeit schädliche Auswirkungen auf Nichtzielpflanzen ausschließen zu können.

Ausgehend vom aktuellen Abdriftmodell errechnen sich wegen der Toxizität des Mittels gegenüber Pflanzen folgende Einträge in an die Behandlungsfläche angrenzende Areale mit den jeweils korrespondierenden TER-Werten:

Aufwandmenge / -häufigkeit / -abstand: 1 x 2 kg Präparat/ha						
Szenario / Perzentil: Feldbau, 90. Perzentil						
relevanter TER: 5						
Abstand [m]	Abdrift [%]	PEC _{ini} [g/ha]	TER-Werte zu ER ₅₀ : 53 g /ha (<i>Lactuca sativa</i> , NA)			
			konv. T.	90 % Reduz.	75 % Reduz.	50 % Reduz.
1	2,77	55,4	1,0	9,6	3,8	1,9

Eine Gefährdung von terrestrischen Nichtzielpflanzen infolge Abdrift ist bei einer sachgerechten und bestimmungsgemäßen Anwendung des Mittels für den Abstand von 1m von der behandelten Fläche erst bei Einsatz von driftreduzierender Technik mit 90%iger Driftreduktion auszuschließen.

Bei Nichteinhaltung der in Zusammenhang mit der NT103 definierten Maßgaben sind Einträge des Mittels in angrenzende Flächen zu erwarten, die zu einer Unterschreitung des einzustellenden Toxizitäts-/Expositionsverhältnisses (hier TER = 5) führen.

Für die Anwendung 024559-00/03-001:

(NW609-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mindestens mit unten genanntem Abstand erfolgen. Dieser Abstand muss nicht eingehalten werden, wenn die Anwendung mit einem Gerät erfolgt, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Unabhängig davon ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten. Zuwiderhandlungen können mit einem Bußgeld bis zu 50.000 Euro geahndet werden.

5 m

Begründung:

Zur Bewertung des Risikos werden die zum Mittel vorgelegten Untersuchungen herangezogen. Als bewertungsrelevanter Endpunkt für die Festsetzung der erforderlichen

Risikominderungsmaßnahmen wird die EAC von 12 µg/L (SF: 5) aus den Mikrokosmos-Untersuchungen mit Flufenacet eingestellt. Unter Berücksichtigung der aktuell geltenden Abdrifteckwerte und der bewertungsrelevanten Toxizität des o.g. Mittels errechnen sich folgende Initialkonzentrationen im Oberflächengewässer mit den jeweils korrespondierenden TER-Werten:

Wirkstoff: Flufenacet					
Aufwandmenge/-häufigkeit/-abstand: 2,0 kg Präparat/ha entspricht 480 g ai/ha Flufenacet					
Szenario / Perzentil: Feldbau / 90. Perzentil					
relevanter Endpunkt: EAC _{Mikrokosmos} =12 µg ai/L (TER: 5)					
		TER-Werte bezogen auf EAC_{Mikrokosm}=12 µg ai/L (TER: 5)			
Abstand	PEC _{ini}		Einsatz verlustmindernder Technik mit einer Driftrate von		
in m	in µg ai/L	konv. Technik	90 %	75 %	50 %
1	4,432	2,7	27,1	10,8	5,4
5	0,912	13,2			

Bei Nichteinhaltung der in Zusammenhang mit der Anwendungsbestimmung NW609-1 definierten Maßgaben führen die Einträge des o.g. Mittels bzw. seiner beiden Wirkstoffe in Oberflächengewässer und die hieraus resultierenden Konzentrationen auch bei sachgerechter und bestimmungsgemäßer Anwendung zu einer Unterschreitung des erforderlichen Toxizitäts-/Expositionsverhältnisses (hier TER = 5).

Für die Anwendung 024559-00/03-001:

(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:

Ausgehend vom aktuellen EXPOSIT-Modell (Version 2.0) wurden die zu erwartenden Einträge der Wirkstoffe Metribuzin und Flufenacet in Oberflächengewässer auf dem Wege des Oberflächenabflusses (Run-Off) berechnet. Als bewertungsrelevante Endpunkte für die Festsetzung der erforderlichen Risikominderungsmaßnahmen wurde für Metribuzin die NOEAEC von 18 µg a.i./L (mit SF: 10) und für Flufenacet die NOEAEC von 12 µg a.i./L (mit SF: 5) aus Mikrokosmos-Untersuchungen eingestellt.

Einträge in Oberflächengewässer via Run-off und Drainage (Modelling mit Exposit 2.0a):
Graben parallel zur Zielfläche (Breite: 100 cm, Ausgangswassertiefe: 30 cm), DT₅₀ Boden folgt Abbaukinetik 1. Ordnung, Zeitraum zwischen Applikation u. Niederschlagsereignis – 3 d, Niederschlagsereignis – 20 mm innerhalb von 24 h, Wasserabfluss – 50 % des Niederschlags, Austrag an PSM – 0,5 % der applizierten Wirkstoffmenge einer Anwendung, Reduktion von abfließendem Wasser durch Randstreifen, Wasserreduktion entspricht Verminderung des Wirkstoffeintrags

Inputparameter:

Flufenacet: Wasserlöslichkeit 56 mg/l, DT₅₀ Boden = 34 d, K_{OC} = 328 → geringe Mobilität, Gruppe II – Risikogruppe; AWM = 2 kg Präp./ha, 480 g a.i./ha (Vorauflauf); VA-Applikation auf Boden ohne Pflanzenbestand, Interzeption = 0 %;

Metribuzin: Wasserlöslichkeit 1.05 g/l, DT₅₀ Boden = 17,3 d, K_{OC} = 37 ml/g, Gefährdungsgruppe III – GW-Kontamination möglich, hohes Grundwassergefährdungspotenzial); AWM = 2 kg Präp./ha, 350 g a.i./ha (Vorauflauf); VA-Applikation auf Boden ohne Pflanzenbestand, Interzeption = 0 %;

Metaboliten: Nicht relevant, da weniger toxisch gegenüber Gewässerorganismen als die Wirkstoffe

Flufenacet mit AWM von 480 g/ha	Exposition	Interzeption [%]	Randstreifen [m]	PEC [µg/l]	TER (TER _{soll})
Flufenacet (NOEC Mikrokosmos: 12 µg ai/l)	Run-off (Randstr.)	0	0	8,7	1,4 (5)
			5	7,1	1,7 (5)
			10	2,8	4,2 (5)
			20	0,9	14 (5)
	Drainage	--	--	1,4 *4,3	8,5 (5) *2,8 (5)

* Anwendung im zeitigen Frühjahr – für die beantragte Anwendung als nicht relevant erachtet

Metribuzin mit AWM von 350 g/ha	Exposition	Interzeption [%]	Randstreifen [m]	PEC [µg/l]	TER (TER _{soll})	
Metribuzin (NOEC Mikrokosmos: 18 µg ai/l)	Run-off (Randstr.)	0	0	6,0	3,0 (10)	
			5	4,8	3,7 (10)	
			10	1,9	9,3 (10)	
			20	0,6	30 (10)	
	Drainage				1,0	19 (10)
					*3,0	*6,0 (10)

* Anwendung im zeitigen Frühjahr – für die beantragte Anwendung als nicht relevant erachtet

Bei Nichteinhaltung der in Zusammenhang mit der Anwendungsbestimmung NW706 definierten Maßgaben (hier: Anlage eines dauerhaft bewachsenen Randstreifens von 20 m Breite) führen die Einträge des o.g. Mittels in Oberflächengewässer und die hieraus resultierenden Konzentrationen auch bei sachgerechter und bestimmungsgemäßer Anwendung zu einer Unterschreitung der erforderlichen Toxizitäts-/Expositionsverhältnisse (hier: TER_{Metribuzin} = 10 und TER_{Flufenacet} = 5).

Folgende Auflage wird gemäß § 36 Abs. 3 S. 1 PflSchG erteilt:

Siehe anwendungsbezogene Auflage in Anlage 1, unter 3.

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

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.

Im Auftrag

gez.

Dr. Hans-Gerd Nolting
Abteilungsleiter

Anlage

Dieses Schreiben ist maschinell gefertigt und daher ohne Unterschrift gültig.

Anlage 1 genehmigte Anwendung: 024559-00/03-001

1 Anwendungsgebiet:

Schadorganismus/Zweckbestimmung	Schadhirsen, Einjähriges Rispengras, Einjährige zweikeimblättrige Unkräuter
Pflanzen/-erzeugnisse/Objekte	Sojabohne

2 Einsatzgebiet:

Ackerbau

3 Kennzeichnungsaufgaben:**3.1 Angaben zur sachgerechten****Anwendung:**

Anwendungsbereich	Freiland
Stadium der Kultur	00 bis 07
Anwendungszeitpunkt	Vor dem Auflaufen
Maximale Zahl der Behandlungen	
- in dieser Anwendung	1
- für die Kultur bzw. je Jahr	1
Anwendungstechnik	spritzen
Aufwand	2 kg/ha in 200 bis 400 l Wasser/ha

3.2 Sonstige Kennzeichnungsaufgaben:

- keine -

3.3 Wartezeiten:

(F) Freiland: Sojabohne

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.

4 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 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.
- NW609-1 Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mindestens mit unten genanntem Abstand erfolgen. Dieser Abstand muss nicht eingehalten werden, wenn die Anwendung mit einem Gerät erfolgt, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Unabhängig davon ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten. Zuwiderhandlungen können mit einem Bußgeld bis zu 50.000 Euro geahndet werden.
- 5 m

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.

REGISTRATION REPORT
Part B

Section 4: Metabolism and Residues
Detailed summary of the risk assessment

Product code: Artist

Active Substance: 175 g/kg Metribuzin
240 g/kg Flufenacet

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Bayrische Landesanstalt für
Landwirtschaft (MN1)

Date: 25/11/2011

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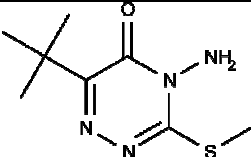
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IIIA 8 METABOLISM AND RESIDUES DATA

IIIA 8.1 Evaluation of the active substances

IIIA 8.1.1 Metribuzin

Table IIIA 8.1-1: Information on the active substance metribuzin

Structural formula	
Common Name	Metribuzin

IIIA 8.1.1.1 Storage stability

A brief summary of the storage stability data on metribuzin is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR (Germany, August 2004, [ASB2010-10278](#)). For the detailed evaluation of new/additional studies on storage stability it is referred to Appendix 2.

Table IIIA 8.1-2: Stability of residues (Annex IIA, point 6 Introduction, Annex IIIA, point 8 Introduction)

Stability of metribuzin and its metabolites DK-, DA- and DADK-metribuzin	<p>As reported in the DAR, the stability of metribuzin, DK- (tuber only) and DA- as well as DADK-metribuzin has been analyzed in several potato matrices (tuber, flakes, chips, wet peel, dry peel). The storage temperature was reported as -5°C, while from the original temperature protocols in the study -21°F to -4°F were obtained. Accordingly, potato matrices were stored at -29°C to -20°C. Stability in potato tubers has been shown for >28 months (metribuzin, DA-), >24 months (DK-) and >27 months (DADK-).</p> <p>Also stability of residues in tomato (fruit, juice, dry pomace, catsup), asparagus, wheat (bran, shorts, flour), soya bean (grain, forage, hay) and maize (forage, fodder, grain, meal, oil) has been investigated. In the framework of this §51 application, not all available data is evaluated, only that obtained for soybean matrices. Stability (in months) in soybean matrices during storage at -20°C is as follows:</p> <table border="1"> <thead> <tr> <th>Matrix</th> <th>as</th> <th>DA</th> <th>DK</th> <th>DADK</th> </tr> </thead> <tbody> <tr> <td>Grain</td> <td>7.5</td> <td>>37</td> <td>$<^1$</td> <td>>37</td> </tr> <tr> <td>Forage</td> <td>7.5</td> <td>>37</td> <td>$-^1$</td> <td>>37</td> </tr> <tr> <td>Hay</td> <td>≈ 3</td> <td>3</td> <td>$-^1$</td> <td>>23</td> </tr> </tbody> </table> <p>¹ not stable. The binding of DK-metribuzin to the sample matrix has been provided as an explanation for the poor recoveries. However, in other studies analysis of DK-metribuzin was possible and quantitation satisfactory. Since in the soybean metabolism study DADK-metribuzin has been shown to be the major metabolite ($\approx 50\%$TRR) and DK-metribuzin occurred with around 10%TRR, the conclusion might also be drawn that DK-metribuzin had degraded during storage to DADK-metribuzin. Both are part of the proposed DoR, so this partial degradation is not of importance for stability of the overall residue.</p>	Matrix	as	DA	DK	DADK	Grain	7.5	>37	$<^1$	>37	Forage	7.5	>37	$-^1$	>37	Hay	≈ 3	3	$-^1$	>23
Matrix	as	DA	DK	DADK																	
Grain	7.5	>37	$<^1$	>37																	
Forage	7.5	>37	$-^1$	>37																	
Hay	≈ 3	3	$-^1$	>23																	

IIIA 8.1.1.2 Metabolism in plants and plant residue definition(s)

A brief summary of the metabolism of metribuzin in plants is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR, Germany, August 2004 ([ASB2010-10278](#)).

Table IIIA 8.1-3: Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	<p>Potato (≈ 2.2 kg/ha), soya bean (0.34 kg/ha, both pre-emergence soil treatment) and wheat (0.17 kg/ha, foliar treatment)</p> <p>The metabolism of metribuzin resulted in the same metabolites in all investigated crops (DA-, DK- and DADK-metribuzin), but in different quantities. In potato tubers grown in treated soil the unchanged parent substance was the major residue, probably due to direct uptake into the tubers. In soya beans grown in treated soil the aerial parts contained nearly no metribuzin, but the more polar metabolite DADK-metribuzin. In wheat treated directly, metribuzin was quickly degraded, again leaving DADK-metribuzin as primary metabolite. Parent metribuzin seems to be only present in plant parts directly affected by the active substance (e.g. located in soil). Metribuzin itself is degraded relatively quickly, leaving the more polar metabolites DA-, DK- and DADK-metribuzin, which are also taken up by the roots from soil.</p> <p>On European level the metabolism was not considered comparable for all crops investigated due to different relative quantities of the metabolites.</p>
Rotational crops	Because of its fast decay and since metribuzin or its metabolites do not accumulate in plants no studies on rotational crops are necessary.
Metabolism in rotational crops similar to metabolism in primary crops? (yes/no)	Not applicable
Distribution of the residue in peel/ pulp	Not relevant
Processed commodities (nature of residue)	Due to residues being consistently below the trigger value of 0.1 mg/kg in RAC at harvest, no information about the effects of industrial processing is required for metribuzin.
Residue pattern in raw and processed commodities similar? (yes/no)	Not applicable
Plant residue definition for monitoring	<ul style="list-style-type: none"> - metribuzin (potatoes only) - other crops: not concluded yet, finalization of MRL review on EU level is pending <p>It has to be noted, that currently MRLs are set in Reg. (EC) No 396/2005 based on the (preliminary) DoR “metribuzin” for all commodities.</p> <p>DoR proposed by DE: sum of metribuzin and DA-, DK- and DADK-metribuzin, expressed as metribuzin</p>
Plant residue definition for risk assessment	<p>According to the EFSA Conclusion (ASB2012-1090):</p> <p>Potatoes only: sum of DA-, DK-, DADK-, and metribuzin, expressed as metribuzin.</p> <p>DE proposal: extend DoR to all plant commodities</p>

Conversion factor(s) (monitoring to risk assessment)	2 (potatoes) A final conclusion for other crops is postponed until the MRL review on EU level is finalized.
--	--

IIIA 8.1.1.3 Metabolism in livestock and animal residue definition(s)

A brief summary of the metabolism of metribuzin in livestock is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR, Germany, August 2004 ([ASB2010-10278](#)).

Table IIIA 8.1-4: Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Lactating goats Highest TRR levels were found in liver and kidney. Residues in muscle and fat were at comparable levels. In liver and kidney only a minor part of the radioactivity was unchanged parent, while in fat more than 70% were identified as metribuzin. Further metabolites of relevance were DA, DK and DADK, mostly conjugated. A study on laying hens became available after the DAR was finalized, but was not evaluated in the framework of this §51 application (no exposure envisaged).
Time needed to reach a plateau concentration in milk and eggs	3–5 days
Animal residue definition for monitoring	It has to be noted, that currently MRLs are set in Reg. (EC) No 396/2005 based on the (preliminary) DoR “metribuzin” for all commodities. EFSA Conclusion (ASB2012-1090): No DoR proposed. DoR proposed by BfR: sum of metribuzin and DA-, DK- and DADK-metribuzin, expressed as metribuzin. A final conclusion as well as the requirement of analytical methods for enforcement purposes based on this proposed DoR should be postponed until the MRL review on EU level is finalized.
Animal residue definition for risk assessment	EFSA Conclusion (ASB2012-1090): No DoR proposed. DoR proposed by BfR: sum of metribuzin and DA-, DK- and DADK-metribuzin, expressed as metribuzin A final conclusion should be postponed until the MRL review on EU level is finalized.
Conversion factor(s) (monitoring to risk assessment)	Not concluded yet. A final conclusion should be postponed until the MRL review on EU level is finalized.
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	no

IIIA 8.1.1.4 Residues in rotational crops

No study available

Table IIIA 8.1-5: Residues in rotational crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

Field studies	No study available and none required.
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IIIA 8.1.1.5 Residues in livestock

An actual calculation of the dietary burden (based on all relevant uses within the zone) is not deemed necessary, since in supervised field trials on potatoes and soya beans no residues above the LOQ of 0.05 mg/kg were found in potential feed items (see also EFSA Conclusion, [ASB2012-1090](#)). Livestock feeding studies have not been provided and are not required.

Table IIIA 8.1-6: Conditions of requirement of livestock feeding studies on metribuzin

	Ruminant:	Poultry:	Pig:
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	no	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)	no	--	--

IIIA 8.1.2 Flufenacet

Table IIIA 8.1-7: Information on the active substance flufenacet

Structural formula	
Common Name	Flufenacet

IIIA 8.1.2.1 Storage stability

A brief summary of the storage stability data on flufenacet is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR (France, August 1997, [ASB2010-10513](#)).

Table IIIA 8.1-8: Stability of residues (Annex IIA, point 6 Introduction, Annex IIIA, point 8 Introduction)

Stability of flufenacet	Maize (grain, forage), soybeans (seed, forage, straw), turnips (roots, leaves and tops): stable for > 28 months under deep freeze conditions ($-26 \pm 5^\circ\text{C}$)
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IIIA 8.1.2.2 Metabolism in plants and plant residue definition(s)

A brief summary of the metabolism of flufenacet in plants is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR (France, August 1997, [ASB2010-10513](#)).

Table IIIA 8.1-9: Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	<p><u>Maize</u>: [fluorophenyl-UL-¹⁴C] label, soil application, 1.37 kg/ha, 1.81 mg/kg soil <u>Cotton</u>: [fluorophenyl-UL-¹⁴C] label, soil application, 1.78 kg/ha, 2.73 mg/kg soil <u>Soybean</u>: [fluorophenyl-UL-¹⁴C] label and [thiadiazol-2-¹⁴C] label, soil application, 1.98 and 1.84 mg/kg soil, respectively Studies on <u>wheat</u> and <u>potatoes</u> are also available, but not relevant for the current application.</p> <p>The metabolism of flufenacet was comparable in all investigated crops. In the first step the thiadiazole ring was removed forming an oxalic acid derivative (M1, FOEOXALAT). Another pathway led to several -2-methylsulfinyl and -2-methylsulfonyl metabolites (FAMSOC, FASO3H, FAMSO, FAMSOL, FAMSO2). The thiadiazolone (thiadone, TH) itself was not observed but conjugates such as the quantitatively most important N-glucoside (M 25, THNG). In soybeans, the malonylalanine conjugate (M34, THNMALALA) predominated.</p> <p>Main residues in soybeans were THNMALALA and FAMSOC.</p>
Rotational crops	<p>Kale, turnips, wheat</p> <p>Application onto bare soil, [fluorophenyl-UL-¹⁴C] label and [thiadiazol-2-¹⁴C] label, 0.9 kg/ha, planting/sowing of rotational crops after PBI of 1, 4–5 and 12 months</p> <p>Highest residues were usually found in 1 month PBI samples. TRR in kale and turnip was very low, only wheat contained significant residues (main compound: M1, FOEOXALAT). No unchanged parent substance was identified in the rotational crops. Concerning reasons for high residues in cereals, please refer to the DAR.</p>
Metabolism in rotational crops similar to metabolism in primary crops? (yes/no)	yes
Distribution of the residue in peel/ pulp	No data, not relevant for the envisaged use
Processed commodities (nature of residue)	Due to low residues at harvest, no processing studies are required.
Residue pattern in raw and processed commodities similar? (yes/no)	Not applicable.
Plant residue definition for monitoring	<p>Sum of all compounds containing the N fluorophenyl-N-isopropyl moiety, expressed as flufenacet</p> <p>This is in line with Reg. (EC) No 396/2005.</p>
Plant residue definition for risk assessment	Sum of all compounds containing the N fluorophenyl-N-isopropyl moiety, expressed as flufenacet
Conversion factor(s) (monitoring to risk assessment)	None

IIIA 8.1.2.3 Metabolism in livestock and animal residue definition(s)

A brief summary of the metabolism of flufenacet in livestock is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR (France, August 1997, [ASB2010-10513](#)).

Table IIIA 8.1-10: Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Lactating goats, laying hens 5-5.1 mg/kg bw, 3 days, [fluorophenyl-UL- ¹⁴ C]- and [thiadiazol-2- ¹⁴ C]-labelled flufenacet, [phenyl-UL- ¹⁴ C]-labelled FOEOXALAT In animals, flufenacet as well as its oxalic acid derivative FOEOXALAT are degraded fast and nearly completely. Biotransformation seems to take the mercaptic acid pathway generating various methylsulfinyl and sulfonyl metabolites. Unchanged parent occurred in traces only.
Time needed to reach a plateau concentration in milk and eggs	3 days
Animal residue definition for monitoring	Sum of all compounds containing the N fluorophenyl-N-isopropyl moiety, expressed as flufenacet Note: Under Reg. (EC) No. 396/2005 no MRLs for flufenacet in animal commodities have been established yet.
Animal residue definition for risk assessment	Sum of all compounds containing the N fluorophenyl-N-isopropyl moiety, expressed as flufenacet
Conversion factor(s) (monitoring to risk assessment)	None
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No

IIIA 8.1.2.4 Residues in rotational crops

No respective studies are available.

Table IIIA 8.1-11: Residues in rotational crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

Field studies	No studies available. Consequent to rotational crop metabolism studies, significant residues are not expected in food and feed commodities obtained from succeeding crops (consequent to uses in compliance with cGAP).
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IIIA 8.1.2.5 Residues in livestock

An actual calculation of the dietary burden (based on all relevant uses in Germany) is provided in the following table.

Table IIIA 8.1-12: Calculation of the dietary burden (based on all relevant uses within the zone)

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 except Maize	86	70	40	0	40	0.050 ^a	0.041	0.023	0	0.023

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
Straw (Cereals)	86	0	20	40	0	0.100 ^b	0	0.023	0.047	0
Root and Tubers (e.g. Potatoes)	15	20	30	60	60	0.070 ^c	0.093	0.140	0.280	0.280
Oilseed	86	10	10	0	0	0.010 ^d	0.001	0.001	0	0
Intake (mg/kg dry weight feed)							0.135	0.188	0.327	0.303
Intake (mg/kg bw/d)							0.009	0.007	0.014	0.012
Intake (mg/animal/d)							0.016	3.753	4.898	0.910

a STMR, based on the following cGAP: 1x 0.25 kg as/ha, PHI: XF

b HR, based on the following cGAP: 1x 0.25 kg as/ha, PHI: XF

c HR, based on the following cGAP: 1x 0.6 kg as/ha, PHI: XF

d STMR, based on the following cGAP: 1x 0.48 kg as/ha, PHI: F

A brief summary of the available livestock feeding study is given in the following table. It has previously been evaluated at EU level and is described in detail in the DAR (France, August 1997, [ASB2010-10513](#)).

Table IIIA 8.1-13: Conditions of requirement of livestock feeding studies on flufenacet

	Ruminant:	Poultry:	Pig:
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	yes 0.327	yes 0.14	yes 0.303
Potential for accumulation (yes/no):	no	no	no
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	no	no	no

Table IIIA 8.1-14: Results of livestock feeding studies on flufenacet

	Ruminant:	Poultry:	Pig:
Feeding levels (mg/kg feed dry matter) in feeding studies	Dairy cattle: 7.8, 24.7 and 82.4 mg/kg DM; substance applied was FOEOXALAT	--	--
Relevant dosing levels in feeding study: 7.8 mg/kg DM (still largely overdosed) Expected residue levels in animal matrices (mg/kg):			
Muscle	<0.05 (<0.01 at 1N)	<0.01	<0.01
Liver	<0.05 (<0.01 at 1N)	<0.01	<0.01
Kidney	0.055 (<0.01 at 1N)	<0.01	<0.01
Fat	<0.05 (<0.01 at 1N)	<0.01	<0.01
Milk	<0.01 (<0.01 at 1N)		<0.01
Eggs		<0.01	

IIIA 8.2 Evaluation of the intended use(s)

IIIA 8.2.1 Selection of critical use and justification

The critical GAP used for the consumer intake and risk assessment is presented in the following Table. It is the only GAP reported for the central zone for soya beans.

Table IIIA 8.2-1: Critical Use (worst case) used for consumer intake and risk assessment

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) (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)	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	Soya bean	F	Annual bluegrass, Dicotyledonous weeds, Panicum-like plants	spraying	BBCH 00-07, before emergence	1	2 kg/ha	Metribuzin: 0.35 kg as/ha Flufenacet: 0.48 kg as/ha	200-400	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

IIIA 8.2.2 Soya beans

IIIA 8.2.2.1 Residues in primary crops

Metribuzin

The following table gives a brief overview of the supervised residue trials selected for the assessment of metribuzin in soya beans. For the detailed evaluation it is referred to Appendix 2.

Table IIIA 8.2-2: Overview of the selected supervised residue trials for metribuzin in soya beans

Commodity	Region ^(a)	Outdoor / Indoor	Individual trial results (mg/kg)		STMR (mg/kg) ^(b)	HR (mg/kg) ^(c)	Median CF ^(d)
			Enforcement (DoR: Metribuzin)	Risk assessment (DoR: sum of metribuzin and DA-, DK- and DADK-metribuzin, expressed as metribuzin)			
Soya bean	NEU	Outdoor	<0.01 (3)	<0.045, <u>0.06</u> (2)	0.06	0.06	6

Give trial results in increasing order of magnitude

Underline median values

- (a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.
 (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.

Analytical methods for commodities of high oil content such as soya beans are available and acceptable for enforcing metribuzin.

Flufenacet

The following table gives a brief overview of the supervised residue trials selected for the assessment of flufenacet in soya beans. For the detailed evaluation it is referred to Appendix 2.

Table IIIA 8.2-3: Overview of the selected supervised residue trials for flufenacet in soya beans

Commodity	Region ^(a)	Outdoor / Indoor	Individual trial results (mg/kg)		STMR (mg/kg) ^(b)	HR (mg/kg) ^(c)	Median CF ^(d)
			Enforcement (DoR: sum of all compounds containing the N fluorophenyl-N-isopropyl moiety, expressed as flufenacet)	Risk assessment (DoR: sum of all compounds containing the N fluorophenyl-N-isopropyl moiety, expressed as flufenacet)			
Soya bean	NEU	Outdoor	<0.01 (3)	< <u>0.01</u> (3)	0.01	0.01	1

Give trial results in increasing order of magnitude

Underline median values

- (a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.
 (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.

Analytical methods for commodities of high oil content such as soya beans are available and acceptable for enforcing flufenacet according to the DoR.

IIIA 8.2.2.2 Distribution of the residue in peel/pulp

Not relevant.

IIIA 8.2.2.3 Residues in processed commodities

Due to low residues at harvest, no processing studies are required.

IIIA 8.2.2.4 Proposed Pre-Harvest Intervals, Withholding Periods

Due to the early treatment, no specific PHI is required.

IIIA 8.3 Consumer intake and risk assessment

The consumer intake and risk assessment is based on the appropriate input values given in Table IIIA 8.3-1 and the toxicological reference values stated in Table IIIA 8.3-2. For the detailed calculation results it is referred to Appendix 3.

Table IIIA 8.3-1: 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
Soy bean	0.1 (metribuzin)	MRL For soya beans, the MRL (based on metribuzin only) is higher than HR/STMR based on DoR for risk assessment	0.06	STMR
Other commodities	0.1 (metribuzin)	MRLs have been set on the same level for all commodities Note: all MRLs based on parent only, no conversion factors derived yet (apart from soya beans and potatoes)	--	--
Soy bean	0.05 (flufenacet)	MRL	0.01	HR=STMR
Other commodities	various (flufenacet)	MRLs	--	--

Table IIIA 8.3-2: Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8) - metribuzin

ADI	0.013 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	55 % (based on French toddlers, 8.8 kg bw)
NTMDI (% ADI) according to VELs model	47 % (based on German children, 2-4 years, 16.15 kg bw)

IEDI (EFSA PRIMo) (% ADI)	Not required
NEDI (VELS model) (% ADI)	Not required
Factors included in IEDI and NEDI	Not applicable
ARfD	0.02 mg/kg bw
IESTI (EFSA PRIMo) (% ARfD)	Soya bean: <1 % (based on German children, 2-4 years , 16.15 kg bw)
NESTI (VELS model) (% ARfD)	Soya bean: <1 % (based on German children, 2-4 years, 16.15 kg bw)
Factors included in IESTI and NESTI	none

Table IIIA 8.3-3: Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8) - flufenacet

ADI	0.005 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	47 % (based on UK toddlers, 14.5 kg bw)
NTMDI (% ADI) according to VELS model	40 % (based on German children, 2-4 years, 16.15 kg bw)
IEDI (EFSA PRIMo) (% ADI)	Not required
NEDI (VELS model) (% ADI)	Not required
Factors included in IEDI and NEDI	none
ARfD	0.017 mg/kg bw
IESTI (EFSA PRIMo) (% ARfD)	Soya bean: <1 % (based on German children, 2-4 years, 16.15 kg bw)
NESTI (VELS model) (% ARfD)	Soya bean: <1 % (based on German children, 2-4 years, 16.15 kg bw)
Factors included in IESTI and NESTI	None

IIIA 8.4 Proposed maximum residue levels (MRLs)

The existing EU MRLs for soya beans are summarized in Table IIIA 8.4-1.

Table IIIA 8.4-1: Overview of the existing EC MRL(s) and new MRL proposals (if required)

Commodity (Code)	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal/ Comments
Soya bean	Metribuzin: 0.1*	Currently no new proposal	HR below MRL, no consumer risk identified; MRL review on EU level needs to be awaited
Soya bean	Flufenacet: 0.05*	Currently no new proposal	HR below MRL, no consumer risk identified

IIIA 8.5 Conclusion

The data available is considered sufficient for the risk assessment. An exceedance of the current MRLs (see Table 8.4-1) is not expected.

The three available residue trials are considered being sufficient since overall residues were very low (mostly below LOQ) and far below ADI and ARfD values.

The short-term intake of metribuzin or flufenacet residues is unlikely to present a public health concern.

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

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
OECD: KIIA 6.1	Lenz, CA	1995	Review of the storage stability data on Metribuzin and its metabolites in crops and processed products 102615-1! M 016691-03-1 ASB2011-6967		BAY	Used for assessment
OECD: KIIA 6.3	Noss, G	2009	Determination of the residues of flufenacet/ metribuzin in/on soybean after spraying of Flufenacet & Metribuzin WG 41.5 in the field in France (North) and Hungary. Incl. Amendment No. 2 und 3 09-2084 ASB2011-11905		BAY	Used for assessment

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Storage stability

A 2.1.1 Storage stability of residues in plant products

Reference: [ASB2011-6967](#)

Report Review of the storage stability data on Metribuzin and its metabolites in
crops and processed products
Lenz, CA
1995
102615-1! M-016691-03-1

Guideline(s): yes

Deviations: no

GLP: yes

Acceptability: yes

Note: Since only the data on soya beans is relevant in the framework of the current application only the soya bean related data from the study is reported here.

Materials and methods

No information was available concerning the preparation of the soya samples. Obviously they were supplied after having been processed by milling, chopping, etc. Spiking level was 1 mg/kg. After the solvent was given time to evaporate for 1 hour, the jars were sealed and frozen at ≈ -20 °C (range -23 °C

to -5°C). At one incident the storage temperature reached 5°C “for a brief period; however, the samples remained frozen.

Samples were refluxed in 4 : 1 acetonitrile : water, partitioned with hexane, and after removal of acetonitrile partitioned with chloroform. The chloroform fraction (metribuzin) was partitioned against 0.1 N NaOH. The aqueous fraction (metabolites) was subjected to clean-up with normal phase, the chloroform fraction (metribuzin) was cleaned up with a Florisil® column. The extracts were subjected to GC/PND. The method was validated at 0.3 mg/kg and 1 mg/kg. LOQ was 0.01 mg/kg.

Results and discussions

The analytical method is considered acceptable, albeit it has been stated, that the poor stability found especially for DK-metribuzin is likely due to “binding” of DK to the matrix. However, in other storage stability studies, similar extraction protocols have been used successfully. It is not clear whether DK is unstable or not. Possibly further investigations are needed to achieve certainty which extraction protocol to use.

Table A 2: Summary of recoveries of metribuzin and its metabolites in soya beans

Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Recoveries (%)	Mean
Metribuzin				
1 mg/kg	0	3	89, 106, 89	95%
1 mg/kg	38	2	78, 105	92%
1 mg/kg	86	2	76, 72	74%
1 mg/kg	225	2	85, 86	86%
1 mg/kg	365	2	51, 87	69%
1 mg/kg	549	2	40, 32	36%
1 mg/kg	708	2	85, 84	85%
1 mg/kg	1119	2	93, 104	99%
DA				
1 mg/kg	0	5	119, 125, 125, 116, 101	117%
1 mg/kg	29	3	110, 113, 115	113%
1 mg/kg	86	3	106, 109, 108	108%
1 mg/kg	225	3	92, 95, 96	94%
1 mg/kg	365	3	90, 87, 83	87%
1 mg/kg	549	3	72, 74, 89	78%
1 mg/kg	708	3	119, 114, 123	119%
1 mg/kg	1119	3	94, 97, 110	100%
DK				
1 mg/kg	0	5	67, 71, 78, 72, 51	68%
1 mg/kg	29	3	40, 49, 51	47%
1 mg/kg	59	3	37, 38, 46	40%
1 mg/kg	86	3	40, 38, 29	36%
1 mg/kg	1119	3	44, 33, 77	51%

Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Recoveries (%)	Mean
DADK				
1 mg/kg	0	3	82, 105, 96	94%
1 mg/kg	29	2	93, 86	90%
1 mg/kg	86	2	73, 70	72%
1 mg/kg	225	2	83, 84	84%
1 mg/kg	365	2	82, 88	85%
1 mg/kg	549	2	87, 91	89%
1 mg/kg	708	2	96, 116	106%
1 mg/kg	1119	2	98, 91	95%

Conclusion

Except for DK-metribuzin, residues are considered being stable in soya beans for at least 1119 d. The binding of DK-metribuzin to the sample matrix has been provided as an explanation for the poor recoveries. However, in other studies analysis of DK-metribuzin was possible and quantitation satisfactory. Since in the soybean metabolism study DADK-metribuzin has been shown to be the major metabolite ($\approx 50\%$ TRR) and DK-metribuzin occurred with around 10% TRR, the conclusion might also be drawn that DK-metribuzin had degraded during storage to DADK-metribuzin. Both are part of the proposed DoR, so this partial degradation is not of importance for the stability of the overall residue.

Comments of zRMS:	The study has some ambiguities. It is not clear, whether the extraction method or “real” decay leads to poor recovery of DK-metribuzin. Also, storage temperature varied considerably. For risk assessment in the context of the present application, the study was considered acceptable.
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A 2.1.2 Storage stability of residues in animal products

No further data

A 2.2 Residues in primary crops

A 2.2.1 Nature of residues

No further data

A 2.2.2 Magnitude of residues

Reference:	ASB2011-11905
Report	Determination of the residues of flufenacet/ metribuzin in/on soybean after spraying of Flufenacet & Metribuzin WG 41.5 in the field in France (North) and Hungary. Incl. Amendment No. 2 und 3 Noss, G.; Krusell, L. 2009 09-2084
Guideline(s):	yes
Deviations:	Method of calculation of sums for total metribuzin residues was not reported; calculations by the RMS gave different results than reported; Storage temperature was >-18 °C
GLP:	yes
Acceptability:	yes

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 Crop / crop group	: Metribuzin (DIC 1468) : Soya Bean
Content of a.i. (g/kg or g/l) Formulation (e.g. WP) Commercial product (name)	Submission date Indoors / outdoors Other a.i. in formulation (content and common name)	: 2011-10-06 : Outdoors (European North) : 240 g/kg Flufenacet
Applicant	Residues calculated as	: 8.1 Metribuzin 8.2 DK-Metribuzin 8.3 DA-Metribuzin 8.4 DADK-metribuzin 8.5 Sum of metribuzin and DA-, DK- and DADK-metribuzin, expressed as Metribuzin

Part B – Section 4 - Core Assessment

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	8.5	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl										
	(a)	(b)				(c)		(a)						(d)	(e)
Report No: 09-2084, trial 09-2084-01 Hungary 8143 Sarszentmihal y, Fejer 2010-07-02	PR91M10	1) 2009-04-22 (sowing) 2) 3) 2009-09-22	0.37	313	0.12	2009-04-24 ⁴⁾	BBCH 00	green forage seed(s)	0.06 <0.01	<0.01 <0.01	<0.01 <0.01	0.08 0.02	0.18 <u>0.06</u>	68 151	4) spraying analytical method: 00965/M003 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 4 months for green material, 2 months for seed(s) ASB2011-11905
Report No: 09-2084, trial 09-2084-03 France 71470 Menetreuil 2010-07-02	Essor	1) 2009-04-21 (sowing) 2) 3) 2009-09-01	0.36	307	0.12	2009-04-24 ⁴⁾	BBCH 03	green forage seed(s)	0.03 <0.01	<0.01 <0.01	<0.01 <0.01	0.31 0.02	0.45 <u>0.06</u>	52 130	4) spraying analytical method: 00965/M003 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 5 months for green material, 2 months for seed(s) ASB2011-11905
Report No: 09-2084, trial 09-2084-04 France 71590 Verjux 2010-07-02	Amphore	1) 2009-04-22 (sowing) 2) 3) 2009-09-01	0.36	310	0.12	2009-04-24 ⁴⁾	BBCH 03	green forage seed(s)	0.03 <0.01	<0.01 <0.01	<0.01 <0.01	0.05 <0.01	0.12 <u><0.045</u>	52 130	4) spraying analytical method: 00965/M003 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 5 months for green material, 2 months for seed(s) ASB2011-11905

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active ingredient : Flufenacet (FOE 5043)
Crop / crop group : Soya BeanFederal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2011-10-06

Content of a.i. (g/kg or g/l) : 240 g/kg
Formulation (e.g. WP) : WG
Commercial product (name) : Artist **024559-00** (submitted to *GI8 024559-00/03*)
treated with formulation WG41.5 (actual 175 g/kg Metribuzin and
240 g/kg Flufenacet)Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) : 175 g/kg Metribuzin

Applicant : Bayer CropScience Deutschland GmbH

Residues calculated as : Flufenacet (including metabolites
containing the fluoroaniline
moiety)

1 Report-No. Location incl. Postal code and date	2 Commodity/ Variety	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest	4 Application rate per treatment			5 Dates of treatments or no. of treatments and last date	6 Growth stage at last treatment or date	7 Portion analysed	8 Residues (mg/kg)	9 PHI (days)	10 Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
(a)	(a)	(b)			(c)		(a)		(d)	(e)	
Report No: 09-2084, trial 09-2084-01 Hungary 8143 Sarszentmihaly, Fejer 2010-07-02	PR91M10	1) 2009-04-22 (sowing) 2) 3) 2009-09-22	0.50	313	0.16	2009-04-24 ⁴⁾	BBCH 00	green forage seed(s)	0.030 <u><0.01</u>	68 151	4) spraying analytical method: 01100 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 7 months for green material, 5 months for seed(s) ASB2011-11905

Artist – 024559-00/03

Part B – Section 4 - Core Assessment

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)
Report No: 09-2084, trial 09-2084-03 France 71470 Menetreuil 2010-07-02	Essor	1) 2009-04-21 (sowing) 2) 3) 2009-09-01	0.49	307	0.16	2009-04-24 ⁴⁾	BBCH 03	green forage seed(s)	0.050 <u><0.01</u>	52 130	4) spraying analytical method: 01100 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 8 months for green material, 5 months for seed(s) ASB2011-11905
Report No: 09-2084, trial 09-2084-04 France 71590 Verjux 2010-07-02	Amphore	1) 2009-04-22 (sowing) 2) 3) 2009-09-01	0.50	310	0.16	2009-04-24 ⁴⁾	BBCH 03	green forage seed(s)	0.080 <u><0.01</u>	52 130	4) spraying analytical method: 01100 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 8 months for green material, 5 months for seed(s) ASB2011-11905

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
- Note: All entries to be filled in as appropriate

Comments of zRMS:	Acceptable, though the method of summation for total metribuzin residues was not reported. Calculations by the RMS gave deviating results. Storage stability for the metabolite DK-metribuzin was not shown in a storage stability study and storage conditions were not ideal (considerably often >-18°C). However, if the metabolite DK-metribuzin is unstable it is likely to be converted to DADK, which are both part of the DoR for risk assessment.
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A 2.3 Residues in processed commodities

No further data

A 2.4 Residues in rotational crops

No further data

A 2.5 Residues in livestock

No further data

A 2.6 Other studies/information

No further data

Appendix 3 Pesticide Residue Intake Model (PRIMo)

Metribuzin			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0,013	ARfD (mg/kg bw):	0,02
Source of ADI:	EFSA	Source of ARfD:	EFSA
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							
		8 55							
		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)	
55,3	FR toddler	33,3	PRODUCTS OF ANIMAL ORIGIN	9,0	FRUIT (FRESH OR FROZEN)	3,9	Potatoes		
54,3	UK Infant	32,3	PRODUCTS OF ANIMAL ORIGIN	7,8	SUGAR PLANTS	4,2	FRUIT (FRESH OR FROZEN)		
51,6	UK Toddler	18,1	PRODUCTS OF ANIMAL ORIGIN	17,6	SUGAR PLANTS	4,9	FRUIT (FRESH OR FROZEN)		
50,5	NL child	25,3	PRODUCTS OF ANIMAL ORIGIN	11,5	FRUIT (FRESH OR FROZEN)	4,5	Potatoes		
46,1	DE child	18,1	PRODUCTS OF ANIMAL ORIGIN	17,7	FRUIT (FRESH OR FROZEN)	4,3	CEREALS		
42,0	FR infant	21,1	PRODUCTS OF ANIMAL ORIGIN	11,7	FRUIT (FRESH OR FROZEN)	3,2	Potatoes		
35,5	WHO Cluster diet B	9,1	CEREALS	5,5	FRUIT (FRESH OR FROZEN)	5,5	FRUIT (FRESH OR FROZEN)		
34,4	DK child	16,8	PRODUCTS OF ANIMAL ORIGIN	8,0	CEREALS	3,9	FRUIT (FRESH OR FROZEN)		
29,5	SE general population 90th percentile	13,6	PRODUCTS OF ANIMAL ORIGIN	4,5	FRUIT (FRESH OR FROZEN)	3,8	CEREALS		
28,7	IE adult	8,2	FRUIT (FRESH OR FROZEN)	5,1	CEREALS	4,6	PRODUCTS OF ANIMAL ORIGIN		
27,2	ES child	13,6	PRODUCTS OF ANIMAL ORIGIN	4,3	FRUIT (FRESH OR FROZEN)	4,0	CEREALS		
23,2	WHO cluster diet E	5,1	PRODUCTS OF ANIMAL ORIGIN	4,7	CEREALS	4,4	FRUIT (FRESH OR FROZEN)		
22,1	WHO cluster diet D	6,5	CEREALS	5,5	PRODUCTS OF ANIMAL ORIGIN	3,1	Potatoes		
20,7	WHO regional European diet	7,2	PRODUCTS OF ANIMAL ORIGIN	3,1	Potatoes	2,8	CEREALS		
19,6	WHO Cluster diet F	5,6	PRODUCTS OF ANIMAL ORIGIN	4,2	CEREALS	2,9	FRUIT (FRESH OR FROZEN)		
18,1	PT General population	4,9	FRUIT (FRESH OR FROZEN)	4,1	CEREALS	4,1	Potatoes		
17,0	NL general	6,3	PRODUCTS OF ANIMAL ORIGIN	3,7	FRUIT (FRESH OR FROZEN)	2,1	CEREALS		
15,4	ES adult	6,1	PRODUCTS OF ANIMAL ORIGIN	3,1	FRUIT (FRESH OR FROZEN)	2,4	CEREALS		
15,0	UK vegetarian	2,9	SUGAR PLANTS	2,8	PRODUCTS OF ANIMAL ORIGIN	2,6	FRUIT (FRESH OR FROZEN)		
14,8	FR all population	4,7	FRUIT (FRESH OR FROZEN)	3,4	PRODUCTS OF ANIMAL ORIGIN	2,6	CEREALS		
13,9	UK Adult	3,4	PRODUCTS OF ANIMAL ORIGIN	3,1	SUGAR PLANTS	2,2	FRUIT (FRESH OR FROZEN)		
13,3	DK adult	5,8	PRODUCTS OF ANIMAL ORIGIN	2,6	FRUIT (FRESH OR FROZEN)	2,2	CEREALS		
13,0	IT kids/toddler	6,4	CEREALS	2,7	FRUIT (FRESH OR FROZEN)	1,5	Fruiting vegetables		
12,5	LT adult	4,6	PRODUCTS OF ANIMAL ORIGIN	2,4	Potatoes	2,1	CEREALS		
11,0	FI adult	5,3	PRODUCTS OF ANIMAL ORIGIN	1,9	FRUIT (FRESH OR FROZEN)	1,5	CEREALS		
9,8	IT adult	3,9	CEREALS	2,1	FRUIT (FRESH OR FROZEN)	1,4	Fruiting vegetables		
7,5	PL general population	2,6	Potatoes	2,6	FRUIT (FRESH OR FROZEN)	0,8	Fruiting vegetables		

Conclusion:
 The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
 A long-term intake of residues of Metribuzin is unlikely to present a public health concern.

Flufenacet			
Status of the active substance:	Included	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0,005	ARfD (mg/kg bw):	0,017
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Chronic risk assessment

	TMDI (range) in % of ADI minimum - maximum 9 - 47
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)
41,7	WHO Cluster diet B	11,9	CEREALS	7,2	FRUIT (FRESH OR FROZEN)	5,7	Fruiting vegetables	
39,0	DE child	23,0	FRUIT (FRESH OR FROZEN)	5,6	CEREALS	5,1	Potatoes	
38,6	NL child	15,0	FRUIT (FRESH OR FROZEN)	11,8	Potatoes	5,6	CEREALS	
33,7	FR toddler	11,8	FRUIT (FRESH OR FROZEN)	10,1	Potatoes	3,0	CEREALS	
33,6	IE adult	10,7	FRUIT (FRESH OR FROZEN)	6,6	CEREALS	4,6	Potatoes	
31,8	UK Infant	10,1	SUGAR PLANTS	6,5	Potatoes	5,5	FRUIT (FRESH OR FROZEN)	
31,3	FR infant	15,2	FRUIT (FRESH OR FROZEN)	8,3	Potatoes	3,0	Other root and tuber vegetables	
29,0	PT General population	10,7	Potatoes	6,4	FRUIT (FRESH OR FROZEN)	5,4	CEREALS	
27,4	WHO cluster diet E	7,7	Potatoes	6,1	CEREALS	5,8	FRUIT (FRESH OR FROZEN)	
25,6	WHO cluster diet D	8,4	CEREALS	8,1	Potatoes	2,8	FRUIT (FRESH OR FROZEN)	
25,3	DK child	10,4	CEREALS	5,1	FRUIT (FRESH OR FROZEN)	4,9	Potatoes	
25,2	SE general population 90th percentile	8,3	Potatoes	5,8	FRUIT (FRESH OR FROZEN)	5,0	CEREALS	
21,6	WHO Cluster diet F	6,8	Potatoes	5,5	CEREALS	3,8	FRUIT (FRESH OR FROZEN)	
21,5	WHO regional European diet	8,0	Potatoes	3,7	CEREALS	3,5	FRUIT (FRESH OR FROZEN)	
19,6	ES child	5,6	FRUIT (FRESH OR FROZEN)	5,2	CEREALS	3,7	Potatoes	
17,3	IT kids/toddler	8,4	CEREALS	3,5	FRUIT (FRESH OR FROZEN)	2,0	Fruiting vegetables	
17,2	UK vegetarian	3,8	SUGAR PLANTS	3,4	FRUIT (FRESH OR FROZEN)	2,7	Potatoes	
16,6	NL general	5,5	Potatoes	4,9	FRUIT (FRESH OR FROZEN)	2,8	CEREALS	
15,1	FR all population	6,2	FRUIT (FRESH OR FROZEN)	3,4	CEREALS	2,2	Potatoes	
15,0	UK Adult	4,0	SUGAR PLANTS	2,9	FRUIT (FRESH OR FROZEN)	2,8	Potatoes	
13,4	LT adult	6,3	Potatoes	2,7	CEREALS	2,3	FRUIT (FRESH OR FROZEN)	
13,1	PL general population	6,9	Potatoes	3,4	FRUIT (FRESH OR FROZEN)	1,1	Fruiting vegetables	
13,1	ES adult	4,1	FRUIT (FRESH OR FROZEN)	3,2	CEREALS	1,9	Potatoes	
12,7	IT adult	5,0	CEREALS	2,8	FRUIT (FRESH OR FROZEN)	1,8	Fruiting vegetables	
11,3	DK adult	3,3	FRUIT (FRESH OR FROZEN)	2,9	Potatoes	2,9	CEREALS	
8,7	FI adult	2,5	FRUIT (FRESH OR FROZEN)	2,5	Potatoes	1,9	CEREALS	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRls were below the ADI.
A long-term intake of residues of Flufenacet is unlikely to present a public health concern.