

Art. 51 amendment

REGISTRATION REPORT

Part A

Risk Management

Product code: ATLANTIS WG

Active Substances:

**Iodosulfuron 5.6 g/kg (Methylester-Na 6 g/kg) and
Mesosulfuron 29.2 g/kg (Methylester 30 g/kg)**

COUNTRY: Germany

Central Zone

Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

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

Date: 05/06/2012

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PART A – Risk Management

This document describes the acceptable use conditions required for extension of the registration of ATLANTIS WG containing Iodosulfuron 5.6 g/kg (Methylester-Na 6 g/kg) and Mesosulfuron 29.2 g/kg (Methylester 30 g/kg) in Germany.

The risk assessment conclusions are based on the already existing registration of the PPP. See

- Part B Section 4.

Assessments for the safe use of ATLANTIS WG have been made using endpoints agreed in the EU reviews of Iodosulfuron and Mesosulfuron.

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	ATLANTIS WG
Type of application	Zonal application according to Article 51, ZRMS=DE, first application (GV1)
Registration number	025094-00/01
Applicant	Bayerische Landesanstalt für Landwirtschaft - Institut für Pflanzenschutz -, Lange Point 10, 85354 Freising-Weihenstephan, Germany
Authorisation holder	Bayer CropScience Deutschland GmbH Registrierung & PGA, Elisabeth-Selbert-Straße 4a, 40764 Langenfeld, Germany
Function	Herbicide
Type of formulation	Combi-pack solid/liquid
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)

Iodosulfuron (0983)

Content in PPP	5.6 g/kg
Approval status	Approved according Regulation (EC) No 1107/2009
Approval	Regulation (EC) No 540/2011
Expiration of approval	31/12/2013

Mesosulfuron (1019)

Content in PPP	29.2 g/kg
Approval status	Approved according Regulation (EC) No 1107/2009
Approval	Regulation (EC) No 540/2011
Expiration of approval	31/03/2014

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

Number of use	Plant/commodity/object	Harmful organism/purpose	decision
1	Spelt TRZSP	slender foxtail ALOMY windgrass APESV common chickweed STEME annual bluegrass POAAN rough meadow grass POATR	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 cultivated area of Spelt is about 8.000 ha, there from worth to treat are 6.400 ha. Calculation shows that the authorisation holder will not profit from an authorisation of that requested 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

Not relevant. No studies submitted.

1.5 Letters of Access

No studies submitted.

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

2 Details of the authorisation

2.1 Product identity

Product name	ATLANTIS WG
Authorisation number	025094-00
Composition	Iodosulfuron 5.6 g/kg (Methylester-Na 6 g/kg) and Mesosulfuron 29.2 g/kg (Methylester 30 g/kg)
Type of formulation	Combi-pack solid/liquid (KK)
Function	Herbicide
Authorisation holder	Bayer CropScience Deutschland GmbH Registrierung & PGA, Elisabeth-Selbert-Straße 4a, 40764 Langenfeld, Germany

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
Xi	Irritant
RA122	Contains fatty alcohol ethoxylate-alkylether. May produce allergic reactions.
RK050	R 50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
RX041	R 41: Risk of serious damage to eyes.
SK015	S 36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
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
SX024	S 24: Avoid contact with skin.
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.

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.
- SE110 Wear tight fitting eye protection when handling the undiluted product.
- SS110 Wear standard protective gloves (plant protection) when handling the undiluted product.
- SS2101 Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.
- SS610 Wear a rubber apron 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.

Integrated Pest Management (IPM)

Mode of action: not yet labelled

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)

- NN1842 The product is classified as harmless for populations of the species *Aphidius rhopalosiph* (braconid wasp).
- NN1303 The product is classified as harmless for populations of the species *Pardosa agrestis* (lycosid spiders).
- NN130 The product is classified as harmless for populations of the species *Pardosa amentata* and *palustris* (lycosid spiders).
- NN170 The product is classified as harmless for populations of the species *Chrysoperla carnea* (lacewing).

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 The product is not authorised for use in or in the immediate vicinity of surface waters or coastal waters (§ 6 (2) 'PflschG' [Plant Protection Act]). Irrespective of this fact, the binding minimum buffer zone to be kept from surface waters, provided for by state law, must be observed. Violations may be punished by fines of up to Euro 50.000.

- (NW701)
- Between treated areas which have an incline of more than 2 % and surface waters - including periodically but excluding occasionally water-bearing surface waters - there must be a buffer zone under complete plant cover. The buffer zone's protective function must not be impaired by the use of implements. It must be at least 10 m wide. This buffer zone is not necessary if:
 - -sufficient catching systems are available for the water and soil transported by run-off, which do not flow into surface water or are not connected with the urban drainage system or
 - -the product is used for conservation or no-tillage methods.
- (NT108)
- A buffer zone of at least 5 m must be kept from adjacent areas (except agriculturally or horticulturally used areas, roads, paths and public places). In addition, in an adjoining strip of at least 20 m, 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 75 %. Neither loss reducing equipment nor a buffer zone of at least 5 m are 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. A buffer zone of at least 5 m is also unnecessary if 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, or if evidence can be shown that adjacent areas (e.g. field boundaries, hedges, groups of woody plants) were planted on agriculturally or horticulturally used areas.

2.3 Product uses

PPP (product name/code) **ATLANTIS WG (025094-00)** Formulation type: **Combi-pack solid/liquid (KK)**
 active substance 1 **Iodosulfuron** Conc. of as 1: **5.6 g/kg**
 active substance 2 **Mesosulfuron** Conc. of as 2: **29.2 g/kg**

Applicant: **Bayerische Landesanstalt für Landwirtschaft - Institut für Pflanzenschutz -, Lange Point 10, 85354 Freising-Weißenstephan, Germany** professional use
 non professional use
 Zone(s): **central EU**

Verified by MS:yes

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	DE	Spelt TRZSP	F	slender foxtail ALOMY windgrass APESV common chickweed STEME annual bluegrass POAAN rough meadow grass POATR	spraying	BBCH 13-32, Spring, after emergence	a) 1 b) 1	a) 0.3 kg/ha b) 0.3 kg/ha as tankmix with 0.6 l/ha surfactant	a) Iodosulfuron 1.68 g/ha Mesosulfuro n 8.76 g/ha b) ditto	200 - 400	F	Restrictions (see 2.2.3.2)

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

Cereals grain and straw belong to the group of dry commodities. Sufficiently validated analytical methods based on HPLC or LC/MS/MS are available for enforcing iodosulfuron-methyl-sodium and mesosulfuron-methyl in cereals grain and straw.

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 iodosulfuron-methyl-sodium and mesosulfuron-methyl in different cereals have been evaluated within the EU review process. Information about metabolism is sufficient to evaluate the intended use in spelt.

3.1.4.1 Residues

The available information on the residue situation of both active substances in winter wheat grain and straw is sufficient to perform an adequate assessment by extrapolation of the data to spelt. Residues that are expected from the intended use of the plant protection product will not exceed the MRLs set in Regulation (EC) No 396/2005 for iodosulfuron-methyl (0.02* mg/kg) and mesosulfuron-methyl (0.01* mg/kg). This includes the residue situation in unripe spelt grain.

3.1.4.2 Consumer exposure

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

Iodosulfuron-methyl-sodium (ADI = 0.03 mg/kg bw/d): 2.9 % (UK toddlers)

Mesosulfuron-methyl (ADI = 1 mg/kg bw/d): <1 % (UK toddlers)

Long-term dietary intake of residues of iodosulfuron-methyl and mesosulfuron-methyl is unlikely to present a public health concern for European consumers.

Due to the low acute toxicity no acute reference doses of both active substances have been allocated. Therefore, no acute risk is expected from the consumption of spelt grain 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 025094-00/00 according the uniform principles of directive 91/414/EEC.

Considering data on use, degradation and adsorption of actives and product, accumulation of actives and metabolites in soil and contamination of groundwater can be ruled out with almost absolute certainty

3.1.6 Ecotoxicology

No new studies are presented; all data were reviewed within the EU review and approval of the national authorisation 025094-00/00 according the uniform principles of directive 91/414/EEC.

Risk Assessment for Aquatic Species

The PPP ATLANTIS WG and the active substance Mesosulfuron are toxic to the aquatic environment (Mesosulfuron: *Lemna gibba* EC₅₀ 0.62 µg/L; „ATLANTIS WG“: *Lemna gibba* EC₅₀ 0.46 µg/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, NW265, NW468 and NW 642 are assigned, see also 2.2.

For the contamination by run-off, a calculation using the German model „EXPOSIT 2.0 a“ with the following input parameters was carried out.

Mesosulfuron-methyl: water solubility: 0.48 g/L (pH 7)

DT50 Soil = 73 d

KOC = 48 (Median)

Risk potential group III

Application rate : 9 g a.i./ha,

Cereals, post emergence application: 50 % Interception

Other parameters: Default

Relevant TER: 10

•

0 m buffer zone	0.08 µg/l in ditch	TER = 7.4
5 m buffer zone	0.07 µg/l in ditch	TER = 9.1
10 m buffer zone	0.03 µg/l in ditch	TER = 22.7

•

The relevant TER of 10 was not met without risk mitigation measures. A buffer zone of 10 m is needed to minimize the risk to aquatic species by run-off, resulting in the following restriction:

- (NW701)
- Between treated areas which have an incline of more than 2 % and surface waters - including periodically but excluding occasionally water-bearing surface waters - there must be a buffer zone under complete plant cover. The buffer zone's protective function must not be impaired by the use of implements. It must be at least 10 m wide. This buffer zone is not necessary if:
 - -sufficient catching systems are available for the water and soil transported by run-off, which do not flow into surface water or are not connected with the urban drainage system or
 - -the product is used for conservation or no-tillage methods.

Risk Assessment for other Non-target Organisms (Flora and Fauna)

Risk assessment for other Non-target Organisms (Flora and Fauna) is based on the ER₅₀ for *Raphanus sativus* (5.1 g/ha Atlantis WG“ + „Genapol LRO liquid“) from the growth test.

300 g Product/ha, Scenario field crops/ 90th Percentile; relevant TER: 10						
Buffer zone [m]	Drift [%]	PEC_{ini} [g/ha]	No drift reduction	90 % drift reduction.	75 % drift reduction.	50 % drift reduction.
			TER	TER	TER	TER
1	2.77	8.31	0.6	6.1	2.4	1.2
5	0.57	1.71	3.0	29.8	11.9	6.0

The necessary TER of 10 is reached only keeping a bufferzone of 5 m in combination with spray drift reduction of at least 75 %, resulting in the following restriction:

(NT108)

- A buffer zone of at least 5 m must be kept from adjacent areas (except agriculturally or horticulturally used areas, roads, paths and public places). In addition, in an adjoining strip of at least 20 m, 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 75 %. Neither loss reducing equipment nor a buffer zone of at least 5 m are 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. A buffer zone of at least 5 m is also unnecessary if 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, or if evidence can be shown that adjacent areas (e.g. field boundaries, hedges, groups of woody plants) were planted on agriculturally or horticulturally used areas.

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

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 ATLANTIS WG 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 spelt will not result in residues above the MRLs set for iodosulfuron-methyl and mesosulfuron-methyl according to Regulation (EC) No 396/2005. A risk for consumers through the consumption of food with these residues 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. Authorisation holder agrees to the current application to extend the authorisation. No Studies submitted.



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IHR ZEICHEN
IHRE NACHRICHT VOM
AKTENZEICHEN 200.22200.025094-00/01.56322
(bitte bei Antwort angeben)

DATUM 30. Mai 2012

GV1 025094-00/01

ATLANTIS WG

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

Bescheid

mit den Wirkstoffen: 5,6 g/kg Iodosulfuron (als Methylester-Na 6 g/kg); 29,2 g/kg
Mesosulfuron (als Methylester 30 g/kg)

Zulassungsnummer 025094-00 in weiteren Anwendungsgebieten

Versuchsbezeichnung: BAY-44750-H-2-KK

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
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Tel: +49 (0)30 18444-000
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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
Acker-Fuchsschwanz, Gemeiner Windhalm, Vogel-Sternmiere, Einjähriges Rispengras, Gemeines Rispengras, Kamille-Arten	Dinkel	025094-00/01-001

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

Für die Anwendung 025094-00/01-001:

(NT108)

Bei der Anwendung des Mittels muss ein Abstand von mindestens 5 m zu angrenzenden Flächen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) eingehalten werden. Zusätzlich muss die Anwendung in einer darauf folgenden Breite von mindestens 20 m 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 Abdriftminderungskategorie 75 % eingetragen ist. Bei der Anwendung des Mittels ist weder der Einsatz verlustmindernder Technik noch die Einhaltung eines Abstandes von mindestens 5 m erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind. Bei der Anwendung des Mittels ist ferner die Einhaltung eines Abstandes von mindestens 5 m nicht erforderlich, wenn 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 oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) nachweislich auf landwirtschaftlich oder gärtnerisch genutzten Flächen angelegt worden sind.

Begründung:

Das Gemisch „Atlantis WG“ + „Genapol LRO liquid“ bzw. die darin enthaltenen herbiziden Wirkstoffe Mesosulfuron-methyl und Iodosulfuron-methyl besitzen ein hohes Gefährdungspotenzial für terrestrische Nichtzielpflanzen. Für das Gemisch „Atlantis WG“ + „Genapol LRO liquid“ wurden Ergebnisse aus einem Wachstumstest mit 10 Spezies

vorgelegt. Empfindlichste und damit bewertungsrelevante Spezies ist *Raphanus sativus* mit einer ED₅₀(21 d) von 5.1 g/ha (bezogen auf „Atlantis WG“).

In Abhängigkeit von der verwendeten Technik und dem Abstand zu Nichtzielflächen errechnen sich folgende Einträge in an die Behandlungsfläche angrenzende Areale mit den jeweils korrespondierenden TER-Werten:

Aufwandmenge / -häufigkeit / -abstand: 1 x 300 g Präp./ha						
Szenario / Perzentil: Ackerbau / 90.						
relevanter TER: 10						
Abstand [m]	Abdrift [%]	PEC_{ini} [g/ha]	TER			
			konv.T.	90 % Reduz.	75 % Reduz.	50 % Reduz.
1	2.77	8.31	0.6	6.1	2.4	1.2
5	0.57	1.71	3.0	29.8	11.9	6.0

Die Einhaltung der in der Anwendungsbestimmung NT 108 aufgeführten Maßnahmen ist bei Einsatz des Mittels „Atlantis WG“ bzw. des Gemisches „Atlantis WG“ + „Genapol LRO liquid“ aufgrund der beschriebenen Effekte gegenüber terrestrischen Nichtzielpflanzen durchsetzbar vorzuschreiben, da andernfalls das unter Berücksichtigung der bestehenden Unsicherheiten zum Schutz terrestrischer Biozöten festgelegte Toxizitäts-/Expositionsverhältnis (hier: TER = 10) unterschritten wird, schädliche Auswirkungen auf den Naturhaushalt nicht auszuschließen sind und somit der Schutz der terrestrischen Biozöten nicht gewährleistet ist.

Trotz der Vielzahl der mit dem Gemisch getesteten Spezies (10) kann derzeit keine Reduzierung des erforderlichen Toxizitäts-/Expositionsverhältnisses (TER) von 10 auf 5 vorgenommen werden, da die in den Wirkstoffuntersuchungen ermittelten empfindlichsten Spezies bei der Gemischprüfung nicht berücksichtigt wurden.

Für die Anwendung 025094-00/01-001:

(NW701)

Zwischen behandelten Flächen mit einer Hangneigung von über 2 % und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - muss ein mit einer geschlossenen Pflanzendecke bewachsener Randstreifen vorhanden sein. Dessen Schutzfunktion darf durch den Einsatz von Arbeitsgeräten nicht beeinträchtigt werden. Er muss eine Mindestbreite von 10 m haben. Dieser Randstreifen ist nicht erforderlich, wenn: -

ausreichende Auffangsysteme für das abgeschwemmte Wasser bzw. den abgeschwemmten Boden vorhanden sind, die nicht in ein Oberflächengewässer münden, bzw. mit der Kanalisation verbunden sind oder - die Anwendung im Mulch- oder Direktsaatverfahren erfolgt.

Begründung:

Eingangsgroßen für die Simulationsrechnungen mit dem Modell „EXPOSIT 2.0 a“

Mesosulfuron-methyl: Wasserlöslichkeit: 0.48 g/L bei pH 7, DT_{50} Boden = 73 d, $K_{OC} = 48$ (Median), Gefährdungsgruppe III, AWM: von 4.5 – 15 g a.i./ha, (Ackerbau: Getreide); NA-Applikation, Interzeption: 50 %; Schlaggröße: 1 ha (100 m * 100 m), Graben parallel zur Zielfläche (Breite: 100 cm, Ausgangswassertiefe: 30 cm), Zeitraum zwischen Applikation u. Niederschlagsereignis: 3 d, Niederschlag: 20 mm innerhalb von 24 h, Wasserabfluss: 50 % des Niederschlags, während des Niederschlagsereignisses wird ein Fließen des Grabenwassers unterstellt (Einrechnung eines Verdünnungsfaktors von 4), Austrag an PSM: 0.5 % der applizierten Wirkstoffmenge einer Anwendung, Reduktion von abfließendem Wasser durch Randstreifen, Wasserreduktion entspricht Verminderung des Wirkstoffeintrags.

Bewertungsrelevant sind die Ergebnisse aus dem Toxizitätstests mit dem Wirkstoff Mesosulfuron-methyl an *Lemna gibba* mit einer EC_{50} (7 d) von 0.62 µg a.i./L.

Mit dem o.g. Modell errechnen sich unter den beschriebenen Annahmen als Folge der beantragten Anwendung die folgenden abschwemmungsbedingten und drainagebedingten Einträge von der Applikationsfläche in einen angrenzenden Graben für Mesosulfuron-methyl folgende Konzentrationen und TER-Werte:

Wirkstoff: Mesosulfuron-methyl		
Aufwandmenge: 9 g a.i./ha, Interzeption 50 %		
relevante Toxizität: <i>Lemna gibba</i> EC₅₀(7d)_{semi}: 0.62 µg Mesosulfuron-methyl/L		
relevanter TER: 10		
Breite des bewachsenen Randstreifens [m]	Konzentration im Graben [µg/L]	TER
0	0.08	7.4
5	0.07	9.1
10	0.03	22.7
Anwendungszeitpunkt	Konzentration im Graben [µg/L]	TER
Herbst/Winter/zeitiges Frühjahr	0.04	14.7

Die Einhaltung der in der Anwendungsbestimmung NW 701 aufgeführten Maßnahmen ist bei Einsatz des Mittels „Atlantis WG“ auf Grund der beschriebenen Effekte gegenüber höheren Wasserpflanzen vorzuschreiben, da andernfalls das unter Berücksichtigung der bestehenden Unsicherheiten zum Schutz aquatischer Biozöten festgelegte Toxizitäts-/Expositionsverhältnis (hier: TER = 10) unterschritten wird, schädliche Auswirkungen auf den Naturhaushalt nicht auszuschließen sind und somit der Schutz der aquatischen Biozöten nicht gewährleistet ist.

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 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: 025094-00/01-001

1 Anwendungsgebiet:

Schadorganismus/Zweckbestimmung	Acker-Fuchsschwanz, Gemeiner Windhalm, Vogel-Sternmiere, Einjähriges Rispengras, Gemeines Rispengras, Kamille-Arten
Pflanzen/-erzeugnisse/Objekte	Dinkel

2 Einsatzgebiet: Ackerbau**3 Kennzeichnungsauflagen:****3.1 Angaben zur sachgerechten****Anwendung:**

Anwendungsbereich	Freiland
Stadium der Kultur	13 bis 32
Anwendungszeitpunkt	Frühjahr, nach dem Auflaufen
Maximale Zahl der Behandlungen	
- in dieser Anwendung	1
- für die Kultur bzw. je Jahr	1
Anwendungstechnik	spritzen
Aufwand	0,3 kg/ha in 200 bis 400 l Wasser/ha
Sonstige Ergänzungen und Hinweise	Aufwand Kombinationspartner: in Verbindung mit 0,6 l/ha Netzmittel

3.2 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. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
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3.3 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.
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4 Anwendungsbezogene Anwendungsbestimmungen:

- NT108 Bei der Anwendung des Mittels muss ein Abstand von mindestens 5 m zu angrenzenden Flächen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) eingehalten werden. Zusätzlich muss die Anwendung in einer darauf folgenden Breite von mindestens 20 m 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 75 % eingetragen ist.
- Bei der Anwendung des Mittels ist weder der Einsatz verlustmindernder Technik noch die Einhaltung eines Abstandes von mindestens 5 m erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind. Bei der Anwendung des Mittels ist ferner die Einhaltung eines Abstandes von mindestens 5 m nicht erforderlich, wenn 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 oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) nachweislich auf landwirtschaftlich oder gärtnerisch genutzten Flächen angelegt worden sind.
- NW701 Zwischen behandelten Flächen mit einer Hangneigung von über 2 % und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - muss ein mit einer geschlossenen Pflanzendecke bewachsener Randstreifen vorhanden sein. Dessen Schutzfunktion darf durch den Einsatz von Arbeitsgeräten nicht beeinträchtigt werden. Er muss eine Mindestbreite von 10 m haben. Dieser Randstreifen ist nicht erforderlich, wenn: - ausreichende Auffangsysteme für das abgeschwemmte Wasser bzw. den abgeschwemmten Boden vorhanden sind, die nicht in ein Oberflächengewässer münden, bzw. mit der Kanalisation verbunden sind oder - die Anwendung im Mulch- oder Direktsaatverfahren erfolgt.

REGISTRATION REPORT
Part B

Section 4: Metabolism and Residues

Detailed summary of the risk assessment

Product code: Atlantis WG

**Active Substance: 5.6 g/kg Iodosulfuron-methyl-Na
and 29.2 g/kg Mesosulfuron-methyl**

Central Zone

Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

**Applicant: Bayerische Landesanstalt für
Landwirtschaft**

Date: 01/12/2011

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IIIA 8 METABOLISM AND RESIDUES DATA

IIIA 8.1 Evaluation of the active substances

IIIA 8.1.1 Iodosulfuron-methyl-sodium

Table IIIA 8.1-1: Information on the active substance iodosulfuron-methyl-sodium

Structural formula	
Common Name	Iodosulfuron-methyl-sodium

IIIA 8.1.1.1 Storage stability

A brief summary of the storage stability data on iodosulfuron-methyl-sodium is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR ([ASB2010-10562](#)).

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

Stability of iodosulfuron-methyl-sodium	<p>Wheat grain, fortified at 0.1 and 0.01 mg/kg, wheat straw (0.05 and 0.5 mg/kg) and forage (0.048 mg/kg) stored at about -18°C, stable for 24 months. Storage intervals of respective field samples were <24 months.</p> <p>Note: For forage and straw studies covering longer storage intervals exist, which have not been reported at EU level.</p>
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IIIA 8.1.1.2 Metabolism in plants and plant residue definition(s)

A brief summary of the metabolism of iodosulfuron-methyl-sodium in plants is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR ([ASB2010-10562](#)).

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>Wheat, leaf application, ^{14}C-U-phenyl and 2-^{14}C-triazinyl label, application rate 20 g/ha</p> <p>Parent was the principal residue. Furthermore, the three metabolites M-17, M-4 (metsulfuron-methyl) and M-7 (4-hydroxy-triazinyl-iodosulfuron-methyl acid) were characterised in straw at harvest and, at extremely low levels, in grain. Metabolite M-1 (2-amino-4-methoxy-6-methyl-1,3,5-triazine) was only detected in straw. All plant metabolites also occurred in livestock.</p>
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Rotational crops	Spinach, carrots, wheat, 2- ¹⁴ C-triazinyl label, 20 g/ha applied to bare soil, rotational crops planted 29, 120 and 365 DAT Total radioactive residues in wheat grain, carrot roots and spinach were very low. Higher residues were observed in wheat straw (all PBIs, highest with 30 day PBI), amounting to 0.52 mg/kg. For spinach and carrots no data could be obtained for the 29 (both) and 120 d (spinach) PBI due to phytotoxicity. None of the residue components in straw exceeded 0.05 g/kg (LOQ). The residue level in the soil was too low to obtain a clear metabolic pattern. Metabolites M-1 and M-17 were seen in the straw of directly treated and succeeding wheat. Except for cereal straw no detectable residues are likely to occur in rotated crops under normal agricultural conditions.
Metabolism in rotational crops similar to metabolism in primary crops? (yes/no)	Yes
Distribution of the residue in peel/ pulp	Not relevant
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	Iodosulfuron-methyl including salts, expressed as iodosulfuron-methyl This is in line with Reg. (EC) No. 396/2005.
Plant residue definition for risk assessment	Iodosulfuron-methyl including salts, expressed as iodosulfuron-methyl
Conversion factor(s) (monitoring to risk assessment)	None

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

A comment on the metabolism of iodosulfuron-methyl-sodium in livestock is given in the following table.

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	Metabolism studies with laying hens and lactating cows exist, but have not yet been reported on EU level. Since the residues in potential feed stuffs expected to arise from current GAP are below LOQ, no residues are to be expected in foodstuff of animal origin.
Time needed to reach a plateau concentration in milk and eggs	Not necessary
Animal residue definition for monitoring	Not necessary
Animal residue definition for risk assessment	Not necessary
Conversion factor(s) (monitoring to risk assessment)	None
Metabolism in rat and ruminant similar (yes/no)	Not necessary
Fat soluble residue: (yes/no)	No, log P _{OW} values were in the range of 1.96 (pH 4) and -1.22 (pH 9)

IIIA 8.1.1.4 Residues in rotational crops

A comment on field rotational crop studies on iodosulfuron-methyl-sodium is given in the following

table.

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

Field studies	<p>One study on the magnitude of residues in rotational crop exists, but has not yet been reported at EU level.</p> <p>Since the rotational crop metabolism studies indicate, that no significant residues are to be expected in succeeding or rotational crops, this study is also not reported here.</p>
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IIIA 8.1.1.5 Residues in livestock

Since no residues are expected in potential feed items (based on evaluation of cereals), consequently no residues are expected in animal matrices. No further evaluation is required.

IIIA 8.1.2 Mesosulfuron-methyl

Table IIIA 8.1-6: Information on the active substance mesosulfuron-methyl

Structural formula	
Common Name	Mesosulfuron-methyl

IIIA 8.1.2.1 Storage stability

A brief summary of the storage stability data on mesosulfuron-methyl is given in the following table. Data which has been previously evaluated at EU level is described in detail in the DAR ([ASB2010-10580](#)).

Table IIIA 8.1-7: Stability of residues (Annex IIA, point 6 Introduction, Annex IIIA, point 8 Introduction)

Stability of mesosulfuron-methyl	<p>Wheat grain (fortified at 0.1 mg/kg), wheat straw and wheat forage (fortified at 0.5 mg/kg)</p> <p>Residues were stable in wheat matrices for at least 13 months when stored frozen at about -18 °C.</p>
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IIIA 8.1.2.2 Metabolism in plants and plant residue definition(s)

A brief summary of the metabolism of mesosulfuron-methyl in plants is given in the following table. Data which has been previously evaluated at EU level is described in detail in the DAR ([ASB2010-10580](#)).

Table IIIA 8.1-8: Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Wheat, leaf application, ¹⁴ C-pyrimidyl and ¹⁴ C-phenyl label, 2x 10 g/ha (pyrimidyl), 2x 30 g/ha (phenyl) Residues were very low. Only three metabolites could be identified which occurred at absolute levels of <0.01 mg/kg. Most metabolites were very polar.
Rotational crops	Spinach, carrots, wheat, 2- ¹⁴ C-pyrimidyl and ¹⁴ C-phenyl label, 15 g/ha applied to bare soil, after 1, 4 and 12 months of ageing rotational crops were planted 30 d-spinach exhibited growth damages. TRR was very low in all plant matrices. Residues above 0.01 mg as-eq/kg were seen only in wheat straw (0.0219 mg/kg at PBI 30 days, 0.0125 at PBI 4 months; 0.0144 at PBI 12 months). No metabolite individually exceeded 0.01 mg/kg in straw. No residues above the LOQ are expected to occur in edible plant parts of rotational crops.
Metabolism in rotational crops similar to metabolism in primary crops? (yes/no)	Not applicable (residues mainly too low for identification)
Distribution of the residue in peel/ pulp	Not relevant
Processed commodities (nature of residue)	Not necessary
Residue pattern in raw and processed commodities similar? (yes/no)	Not applicable
Plant residue definition for monitoring	Mesosulfuron-methyl, expressed as mesosulfuron
Plant residue definition for risk assessment	Mesosulfuron-methyl, expressed as mesosulfuron
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 mesosulfuron-methyl in livestock is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR ([ASB2010-10580](#)).

Table IIIA 8.1-9: Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Lactating cow, ¹⁴ C-phenyl (0.417 mg/kg bw) Laying hens, ¹⁴ C-phenyl, 10 mg/kg feed (1.44 mg/bird) Residues in milk (0.004 mg/kg), eggs (0.012 mg/kg) and tissues (0.02–0.06 mg/kg) were low throughout the study. The largest part of residues was excreted rapidly. Main component of the residue was parent in all matrices.
Time needed to reach a plateau concentration in milk and eggs	Milk: not concluded (very low residues) Egg yolk: 10 d, egg white: 8 d
Animal residue definition for monitoring	Not necessary, no MRLs have been set
Animal residue definition for risk assessment	Not necessary, no exposure of livestock envisaged
Conversion factor(s) (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No, log P _{OW} between 1.90 at pH 4 and –2.10 at pH 10 (25°C)

IIIA 8.1.2.4 Residues in rotational crops

A comment on field rotational crop studies on mesosulfuron-methyl is given in the following table.

Table IIIA 8.1-10: Residues in rotational crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

Field studies	Metabolism studies on rotational crops have shown that no residues at or above the LOQ (0.01 mg/kg) are to be expected in succeeding crops. Therefore no field trials on representative crops are necessary.
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IIIA 8.1.2.5 Residues in livestock

Since no residues of mesosulfuron-methyl are expected in potential feed items (based on evaluation of cereals), consequently no residues are expected in animal matrices. No further evaluation is required.

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 Table IIIA 8.2-1. It is the only GAP reported for the central zone for spelt.

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	Spelt	F	Slender foxtail, Windgrass, Common chickweed, Annual bluegrass, Rough meadow grass, Chamomille spec.	spraying	BBCH 13-32, spring	1 1	0.30 kg/ha	a) Iodosulfuron-methyl: 0.0017 kg as/ha Mesosulfuron- methyl: 0.0088 kg as/ha b) Iodosulfuron-methyl: 0.0017 kg as/ha Mesosulfuron- methyl: 0.0088 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 Spelt

IIIA 8.2.2.1 Residues in wheat

The following tables give a brief overview of the supervised residue trials selected for the assessment of iodosulfuron-methyl-sodium and mesosulfuron-methyl in wheat, which can be extrapolated to spelt. Data, which has been previously evaluated at EU level is described in detail in the DARs for iodosulfuron ([ASB2010-10652](#)) and mesosulfuron ([ASB2010-10580](#)). For the detailed evaluation of new/additional residue trials it is referred to Appendix 2.

Table IIIA 8.2-2: Overview of the selected supervised residue trials for iodosulfuron-methyl-sodium in wheat

Commodity	Region ^(a)	Outdoor / Indoor	Individual trial results (mg/kg)		STMR (mg/kg) ^(b)	HR (mg/kg) ^(c)	Median CF ^(d)
			Enforcement (iodosulfuron-methyl including salts, expressed as iodosulfuron-methyl)	Risk assessment (iodosulfuron-methyl including salts, expressed as iodosulfuron-methyl)			
grain	NEU	Outdoor	<0.01 (17)	< <u>0.01</u> (17)	0.01	0.01	1
straw	NEU	Outdoor	<0.05 (17)	< <u>0.05</u> (17)	0.05	0.05	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 enforcement residue definition.
 (c): Highest value of the individual trial results according to the enforcement 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 dry commodities such as grains and straw are available and acceptable for enforcing all compounds given in the residue definition for iodosulfuron-methyl-sodium.

Table IIIA 8.2-3: Overview of the selected supervised residue trials for mesosulfuron-methyl in wheat

Commodity	Region ^(a)	Outdoor / Indoor	Individual trial results (mg/kg)		STMR (mg/kg) ^(b)	HR (mg/kg) ^(c)	Median CF ^(d)
			Enforcement (mesosulfuron-methyl expressed as mesosulfuron)	Risk assessment (mesosulfuron-methyl expressed as mesosulfuron)			
grain	NEU	Outdoor	<0.01 (21)	< <u>0.01</u> (21)	0.01	0.01	1
straw	NEU	Outdoor	<0.05 (20); 0.09	< <u>0.05</u> (20); 0.09	0.05	0.05	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 enforcement residue definition.
 (c): Highest value of the individual trial results according to the enforcement 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 dry commodities such as grains and straw are available and acceptable for enforcing all compounds given in the residue definition for mesosulfuron-methyl.

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

When application is made according to cGAP (BBCH 13–32), the waiting period is covered by the vegetation period.

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 (iodosulfuron-methyl-sodium) and Table IIIA 8.3-3 (mesosulfuron-methyl) as well as the toxicological reference values stated in Table IIIA 8.3-2 (iodosulfuron-methyl-sodium) and Table IIIA 8.3-4 (mesosulfuron-methyl), respectively. For the detailed calculation results it is referred to Appendix 3.

Table IIIA 8.3-1: Residue input values for iodosulfuron-methyl-sodium for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Spelt	0.02	MRL	0.01	HR=STMR

Table IIIA 8.3-2: Consumer risk assessment for iodosulfuron-methyl-sodium (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.03 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	2.9 % (based on UK toddlers, 14.5 kg bw)
NTMDI (% ADI) according to German VELs model	2.5 % (based on DE children, 2-4 years, 16.15 kg bw)
IEDI (EFSA PRIMo) (% ADI)	Not necessary
NEDI (German VELs model) (% ADI)	Not necessary
Factors included in IEDI and NEDI	Not applicable
ARfD	Not allocated
IESTI (EFSA PRIMo) (% ARfD)	Not necessary
NESTI (German VELs model) (% ARfD)	Not necessary
Factors included in IESTI and NESTI	Not applicable

Table IIIA 8.3-3: Residue input values for mesosulfuron-methyl for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Spelt	0.01	MRL	0.01	HR=STMR

Table IIIA 8.3-4: Consumer risk assessment for mesosulfuron-methyl (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	1 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	<1 % (based on UK toddlers, 14.5 kg bw)
NTMDI (% ADI) according to German VELs model	<1 % (based on DE children, 2-4 years, 16.15 kg bw)
IEDI (EFSA PRIMo) (% ADI)	Not necessary
NEDI (German VELs model) (% ADI)	Not necessary
Factors included in IEDI and NEDI	Not applicable
ARfD	Not allocated
IESTI (EFSA PRIMo) (% ARfD)	Not necessary
NESTI (German VELs model) (% ARfD)	Not necessary
Factors included in IESTI and NESTI	Not applicable

IIIA 8.4 Proposed maximum residue levels (MRLs)

The existing EU MRLs and proposals for new MRLs (if required) for the crops applied for in this dossier 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)	Result of OECD calculator	Justification for the proposal/ Comments
Wheat (Spelt, Triticale) (500090) Iodosulfuron-methyl including salts, expressed as iodosulfuron-methyl	0.02*	Not required	Not required	Data is sufficient, no residue above LOQ (0.01 mg/kg) detected
Wheat (Spelt, Triticale) (500090) Mesosulfuron-methyl, expressed as mesosulfuron	0.01*	Not required	Not required	Data is sufficient, no residue above LOQ (0.01 mg/kg) detected

IIIA 8.5 Conclusion

The data available is considered sufficient for risk assessment. An exceedance of the current MRLs of 0.02* mg/kg (iodosulfuron-methyl) and 0.01* mg/kg (mesosulfuron-methyl) for wheat including spelt as laid down in Reg. (EU) No 396/2005 is not expected, especially since all residue trials have been overdosed.

The short-term intake of iodosulfuron-methyl or mesosulfuron-methyl residues is unlikely to present a public health concern.

As far as consumer health protection is concerned, the RMS 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 Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR Study-Status / Usage
OECD: KIIA 6.3	Helgers, A.	1993	Decline of residues in wheat and triticale European Union (northern zone and Southern France) 1997; AE F075032, AE F115008 and AE F107892 water dispersible granule 12.5%, 1.25% and 12.5% w/w C000395, ER 97 ECN 511 RIP1999-360		BAY	used for evaluation
OECD: KIIA 6.3	Davies, P	2000	Decline of residues in wheat European Union northern Zone and southern France 1999; Iodosulfuron-methyl-sodium (AE F115008) 1%; Mesosulfuron-methyl (AE F130060) 3%; Mefenpyr-diethyl (AE F107892) 9%; Water dispersible granule, C009932, ER99ECN523 RIP2001-522		BAY	used for evaluation
OECD: KIIA 6.3	Davies, P	2000	Decline of residues in common wheat European Union northern Zone 1999; Iodosulfuron-methyl-sodium (AE F115008) 3%; Mesosulfuron-methyl (AE F130060) 3%; Mefenpyr-diethyl (AE F107892) 9%; Water dispersible granule, C009933, ER99ECN524 RIP2001-523		BAY	used for evaluation
OECD: KIIA 6.3	Helgers, A.	2000	Decline of residues in cereals European Union northern zone 1997 - AE F130060 and AE F107892 (Mefenpyr-diethyl) Oil Flowable 30 and 90 g/l, C006208, ER97ECN521, M-193491-01-1 RIP2001-511		BAY	used for evaluation
OECD: KIIA 6.3	Davies, P	2000	Residues at harvest in wheat European Union northern zone 1998; ; AE F130060 and Mefenpyr-diethyl Oil Flowable 30 + 90 g/l, C007152, ER98ECN521 RIP2001-512		BAY	used for evaluation
OECD: KIIA 6.3	Davies, P	2000	Decline of residues in wheat European Union northern Zone and southern France 1999; Iodosulfuron-methyl-sodium (AE F115008) 1%; Mesosulfuron-methyl (AE F130060) 3%; Mefenpyr-diethyl (AE F107892) 9%; Water dispersible granule, C009932, ER99ECN523 RIP2001-522		BAY	used for evaluation
OECD: KIIA 6.3	Davies, P	2000	Decline of residues in common wheat European Union northern Zone 1999; Iodosulfuron-methyl-sodium (AE F115008) 3%; Mesosulfuron-methyl (AE F130060) 3%; Mefenpyr-diethyl (AE F107892) 9%; Water dispersible granule, C009933, ER99ECN524 RIP2001-523		BAY	used for evaluation

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Storage stability

No further studies evaluated.

A 2.2 Residues in primary crops

A 2.2.1 Nature of residues

No further studies evaluated.

A 2.2.2 Magnitude of residues

Reference: RIP1999-360

Report: Decline of residues in wheat and triticale European Union (northern zone and Southern France) 1997; AE F075032, AE F115008 and AE F107892 water dispersible granule 12.5%, 1.25% and 12.5% w/w, Helgers, A., 1993, C000395, ER 97 ECN 511

Guideline(s): Yes

Deviations: Yes

GLP: Yes

Acceptability: Yes

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active ingredient : Iodosulfuron-Methyl-Na
Crop / crop group : Winter wheat

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 1999-04-16

Content of a.i. (g/kg or g/l) : 12.5 g/kg
Formulation (e.g. WP) : WG
Commercial product (name) : AE F075032 08 WG26 **004778-00**

Indoors / outdoors : Outdoors (European North)
Other a. i. in formulation (common name and content) : 125 g/kg Amidosulfuron, 125 g/kg Mefenpyr Diethylester

Applicant : Hoechst Schering AgrEvo GmbH (AVO)

Residues calculated as : Iodosulfuron-Methyl-Na

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)	
ER 97 ECN 511 DEU0101 D- 21357 Barum-Horburg 1999-03-19	Batis	1)07.10.1996 (sowing) 2)18.06.- 02.07.1997 3)15.08.1997	0.0030	300	0.0010	07.06.1997	BBCH 49	shoot straw grain	<0.05 <0.05 <0.05 <0.01	0 13 69 69	analytical methods: HPLC: grain AL 008/96-0 (Ref. 3), straw AL 121/96-0 (Ref. 4), shoots AL 120/96-0 (Ref. 5), LOQ: shoot, straw 0.05 mg/kg; grain 0.01 mg/kg, max. sample storage: 10 months, <u>RIP1999-360</u>

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)	(a)	(b)				(c)		(a)		(d)	(e)
ER 97 ECN 511 DEU0301 D- 86368 Gersthofen 1999-03-19	Tambor	1)26.10.1996 (sowing) 2)09.06.- 17.06.1997 3)19.08.1997	0.0030	300	0.0010	09.06.1997	BBCH 51	shoot straw grain	<0.05 <0.05 <0.05 <0.01	0 8 71 71	analytical methods: HPLC: grain AL 008/96-0 (Ref. 3), straw AL 121/96-0 (Ref. 4), shoots AL 120/96-0 (Ref. 5), LOQ: shoot, straw 0.05 mg/kg; grain 0.01 mg/kg, max. sample storage: 10 months RIP1999-360
ER 97 ECN 511 DEU0601 D- 04509 Kreuma 1999-03-19	Toronto	1)03.11.1996 (sowing) 2)14.06.- 21.06.1997 3)11.08.1997	0.0030	300	0.0010	04.06.1997	BBCH 49	shoot straw grain	0.06 <0.05 <0.05 <0.01	0 9 68 68	analytical methods: HPLC: grain AL 008/96-0 (Ref. 3), straw AL 121/96-0 (Ref. 4), shoots AL 120/96-0 (Ref. 5), LOQ: shoot, straw 0.05 mg/kg; grain 0.01 mg/kg, max. sample storage: 10 months RIP1999-360
ER 97 ECN 511 FRA0001 France F-91400 Gometz la Ville 1999-03-19	Rialto	1)08.10.1996 (sowing) 2)01.06.- 15.06.1997 3)04.08.1997	0.0030	250	0.0012	23.05.1997	BBCH 53	shoot straw grain	<0.05 <0.05 <0.05 <0.01	0 10 73 73	analytical methods: HPLC: grain AL 008/96-0 (Ref. 3), straw AL 121/96-0 (Ref. 4), shoots AL 120/96-0 (Ref. 5), LOQ: shoot, straw 0.05 mg/kg; grain 0.01 mg/kg, max. sample storage: 10 months RIP1999-360

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)	(a)	(b)				(c)		(a)		(d)	(e)
RIP 1999-360 ER 97 ECN 511 GBR0001 GB- SG8 8SS Chishill 1999-03-19	Riband	1)22.09.1996 (sowing) 2)01.06.- 30.06.1997 3)18.08.1997	0.0030	300	0.0010	04.06.1997	BBCH 49	shoot straw grain	<0.05 <0.05 <u><0.05</u> <u><0.01</u>	0 20 75 75	analytical methods: HPLC: grain AL 008/96-0 (Ref. 3), straw AL 121/96-0 (Ref. 4), shoots AL 120/96-0 (Ref. 5), LOQ: shoot, straw 0.05 mg/kg; grain 0.01 mg/kg, max. sample storage: 10 months RIP1999-360

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 as a worst case scenario (overdosed and application was made at a later growth stage than envisaged according to cGAP). Used in risk assessment, since residues were nevertheless below the LOQ.
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Reference: RIP2001-522
 Report Decline of residues in wheat European Union northern Zone and southern France 1999; Iodosulfuron-methyl-sodium (AE F115008) 1%; Mesosulfuron-methyl (AE F130060) 3%; Mefenpyr-diethyl (AE F107892) 9%; Water dispersible granule, Davies, P., 2000, C009932, ER99ECN523
 Guideline(s): Yes
 Deviations: Yes
 GLP: Yes
 Acceptability: Yes

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

Active ingredient : Iodosulfuron-methyl-Na
 Crop / crop group : Winter wheat

Federal Institute for Risk Assessment, Berlin
 Federal Republic of Germany

Submission date : 2003-02-06

Content of a.i. (g/kg or g/l) : 10 g/kg
 Formulation (e.g. WP) : WG
 Commercial product (name) : AE F130060 02 WG13 A202 0
 (submitted to "ATLANTIS WG" **005094-00**)
 Applicant : Bayer CropScience

Indoors / outdoors : Outdoors (European North)
 Other a. i. in formulation (common name and content) : 30 g/kg Mesosulfuron, 90 g/kg Mefenpyr-diethyl
 Residues calculated as : 8.1 Iodosulfuron-methyl-Na (AE F115008)
 8.2 AE F075736

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1)Sowing or planting 2)Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl							
C009932 DEU0301/02 D- 86368 Gerstofen 2000-11-15	Tambor	1) 30.09.1998 (sowing) 2) 14.06.- 25.06.1999 3) 26.08.1999	0.0050	300	0.0017	18.05.1999	BBCH 39	shoots straw grain	0.21 <0.05 <0.05 <0.01	<0.05 <0.05 <0.01	0 27 100 100	Analyt.l method: EMF 08/99-0 (LC-MS/MS), LOQ: shoots, straw 0.05 mg/kg; grain 0.01 g/kg, max. sample storage: 15 months <u>RIP2001-522</u>

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1)Sowing or planting 2)Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl							
	(a)	(b)				(c)		(a)			(d)	(e)
C009932 DEU0501/02 D- 53347 Alfter- Witterschlick 2000-11-15	Triso	1) 24.03.1999 (sowing) 2) 01.07.- 09.07.1999 3) 03.08.1999	0.0050	300	0.0017	14.06.1999	BBCH 49	shoots straw grain	0.11 <0.05 <0.05 <0.01	<0.05 <0.05 <0.01	0 21 50 50	Analyt. method: EMF 08/99-0 (LC-MS/MS), LOQ: shoots, straw 0.05 mg/kg; grain 0.01 g/kg, max. sample storage: 15 months <u>RIP2001-522</u>
C009932 FRAU0101/02 France F- 91400 Gometz la Ville 2000-11-15	Bourbon	1) 02.10.1998 (sowing) 2) 01.06.- 15.06.1999 3) 05.08.1999	0.0050	250	0.0020	12.05.1999	BBCH 39	shoots straw grain	0.07 <0.05 <0.05 <0.01	<0.05 <0.05 <0.01	0 15 85 85	Analyt. method: EMF 08/99-0 (LC-MS/MS), LOQ: shoots, straw 0.05 mg/kg; grain 0.01 g/kg, max. sample storage: 15 months <u>RIP2001-522</u>
C009932 DEU0301/03 D- 86368 Gerstofen 2000-11-15	Tambor	1) 30.09.1998 (sowing) 2) 14.06.- 25.06.1999 3) 26.08.1999	0.0050	300	0.0017	18.05.1999	BBCH 39	shoots straw grain	0.21 <0.05 <0.05 <0.01	<0.05 <0.05 <0.01	0 27 100 100	Addition of Mero, 1 l/ha Analyt. method: EMF 08/99-0 (LC-MS/MS), LOQ: shoots, straw 0.05 mg/kg; grain 0.01 g/kg, max. sample storage: 15 months <u>RIP2001-522</u>
C009932 DEU0501/03 D- 53347 Alfter- Witterschlick 2000-11-15	Triso	1) 24.03.1999 (sowing) 2) 01.07.- 09.07.1999 3) 03.08.1999	0.0050	300	0.0017	14.06.1999	BBCH 49	shoots straw grain	0.08 <0.05 <0.05 <0.01	<0.05 <0.05 <0.01	0 21 50 50	Addition of Mero, 1 l/ha Analyt. method: EMF 08/99-0 (LC-MS/MS), LOQ: shoots, straw 0.05 mg/kg; grain 0.01 g/kg, max. sample storage: 15 months <u>RIP2001-522</u>

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1)Sowing or planting 2)Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl							
C009932 FRA0101/03 France F- 91400 Gometz la Ville 2000-11-15	Bourbon	1) 02.10.1998 (sowing) 2) 01.06.- 15.06.1999 3) 05.08.1999	0.0050	250	0.0020	12.05.1999	BBCH 39	shoots straw grain	0.06 <0.05 <0.05 <0.01	<0.05 <0.05 <0.05 <0.01	0 15 85 85	Addition of Actirob B, 1 l/ha Analyt. method: EMF 08/99-0 (LC-MS/MS), LOQ: shoots, straw 0.05 mg/kg; grain 0.01 g/kg, max. sample storage: 15 months <u>RIP2001-522</u>
C009932 DEU0301/04 D- 86368 Gerstofen 2000-11-15	Tambor	1) 30.09.1998 (sowing) 2) 14.06.- 25.06.1999 3) 26.08.1999	0.0050	300	0.0017	18.05.1999	BBCH 39	shoots straw grain	0.23 <0.05 <0.05 <0.01	<0.05 <0.05 <0.05 <0.01	0 27 100 100	Addition of Genapol LRO fluid Analyt. method: EMF 08/99-0 (LC-MS/MS), LOQ: shoots, straw 0.05 mg/kg; grain 0.01 g/kg, max. sample storage: 15 months <u>RIP2001-522</u>
C009932 DEU0501/04 D- 53347 Alfter- Witterschlick 2000-11-15	Triso	1) 24.03.1999 (sowing) 2) 01.07.- 09.07.1999 3) 03.08.1999	0.0050	300	0.0020	14.06.1999	BBCH 49	shoots straw grain	0.08 <0.05 <0.05 <0.01	<0.05 <0.05 <0.05 <0.01	0 21 50 50	Addition of Genapol LRO fluid Analyt. method: EMF 08/99-0 (LC-MS/MS), LOQ: shoots, straw 0.05 mg/kg; grain 0.01 g/kg, max. sample storage: 15 months <u>RIP2001-522</u>

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1)Sowing or planting 2)Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl							
C009932 FRA0101/04 France F- 91400 Gometz la Ville 2000-11-15	Bourbon	1) 02.10.1998 (sowing) 2) 01.06.- 15.06.1999 3) 05.08.1999	0.0050	250	0.0020	12.05.1999	BBCH 39	shoots straw grain	0.05 <0.05 <0.05 <0.01	<0.05 <0.05 <0.01	0 15 85 85	Addition of Genapol LRO fluid Analyt. method: EMF 08/99-0 (LC-MS/MS), LOQ: shoots, straw 0.05 mg/kg; grain 0.01 g/kg, max. sample storage: 15 months <u>RIP2001-522</u>

- 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 as a worst case scenario (overdosed and application was made at a later growth stage than envisaged according to cGAP). Used in risk assessment, since residues were nevertheless below the LOQ.
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Reference: RIP2001-523

Report: Decline of residues in common wheat European Union northern Zone 1999; Iodosulfuron-methyl-sodium (AE F115008) 3%; Mesosulfuron-methyl (AE F130060) 3%; Mefenpyr-diethyl (AE F107892) 9%; Water dispersible granule, Davies, P., 2000, C009933, ER99ECN524

Guideline(s): Yes

Deviations: Yes

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

Content of a.i. (g/kg or g/l) : 30 g/kg
Formulation (e.g. WP) : WG
Commercial product (name) : AE F130060 02 WG15 A401
(submitted to "ATLANTIS WG" **005094-00**)
Applicant : Bayer CropScience

Active ingredient : Iodosulfuron-methyl-Na
Crop / crop group : Winter wheat

Submission date : 2000-11-15

Indoors / outdoors : Outdoors (European North))

Other a. i. in formulation (common name and content) : 30 g/kg Mesosulfuron, 90 g/kg Mefenpyr-diethyl
Residues calculated as : 8.1 Iodosulfuron-methyl-Na (AE F115008)
8.2 AE F075736

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1)Sowing or planting 2)Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl							
	(a)	(b)				(c)		(a)			(d)	(e)
C009933 DEU0601 D- 04821 Brandis 2000-11-15	Rialto	1) 28.09.1998 (sowing) 2) 20.06.- 30.06.1999 3) 29.07.1999	0.010	300	0.0033	14.05.1999	BBCH 39	shoot straw grain	0.17 <0.05 <0.05 <0.01	<0.05 <0.05 <0.01	0 17 76 76	LOQ: shoot, straw 0.05 mg/kg; grain 0.01 mg/kg RIP2001-523

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1)Sowing or planting 2)Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl							
	(a)	(b)				(c)		(a)			(d)	(e)
C009933 FRA0101 France F- 95510 Amenucourt 2000-11-15	Soissons	1) 15.10.1998 (sowing) 2) 29.05.- 10.06.1999 3) 27.07.1999	0.010	250	0.004	03.05.1999	BBCH 39	shoot straw grain	0.18 <0.05 <0.05 <0.01	<0.05 <0.05 <0.01	0 17 85 85	LOQ: shoot, straw 0.05 mg/kg; grain 0.01 mg/kg <u>RIP2001-523</u>
C009933 GBR0101 GB- PE321HN East Winch 2000-11-15	Riband	1) 29.10.1998 (sowing) 2) – 3) 16.08.1999	0.010	300	0.0033	01.06.1999	BBCH 39	shoot straw grain	0.19 <0.05 <0.05 <0.01	<0.05 <0.05 <0.01	0 7 76 76	LOQ: shoot, straw 0.05 mg/kg; grain 0.01 mg/kg <u>RIP2001-523</u>

- 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 as a worst case scenario (overdosed and application was made at a later growth stage than envisaged according to cGAP). Used in risk assessment, since residues were nevertheless below the LOQ.
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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)
C006208 DEU0401 DE- 65929 Unterliederbach 2000-11-15	Ritmo	1) 11.10.1996 (sowing) 2) 02.06.- 20.06.1997 3) 11.08.1997	0.015	300	0.005	23.05.1997	BBCH 47	shoot straw grain	0.16 0.11 <u><0.05</u> <u><0.01</u>	0 12 80 80	LOQ: grain 0.01 mg/kg; straw, shoot 0.05 mg/kg RIP2001-511
C006208 GBR0001 GB- PE321HN East Winch 2000-11-15	Riband	1) 11.10.1996 (sowing) 2) 11.06.- 30.06.1997 3) 19.08.1997	0.015	300	0.005	23.05.1997	BBCH 39	shoot straw grain	0.25 0.09 <u><0.05</u> <u><0.01</u>	0 12 88 88	LOQ: grain 0.01 mg/kg; straw, shoot 0.05 mg/kg RIP2001-511
C006208 GBR0002 GB- CB7 SUF Soham 2000-11-15	Consort	1) 10.10.1996 (sowing) 2) 01.06.- 30.06.1997 3) 12.08.1997	0.015	300	0.005	14.05.1997	BBCH 37	shoot straw grain	0.27 <0.05 <u><0.05</u> <u><0.01</u>	0 22 90 90	LOQ: grain 0.01 mg/kg; straw, shoot 0.05 mg/kg RIP2001-511
C006209 GRC0001 GR-60066 Methoni 2000-11-15	Mexicalli	1) 10.11.1996 (sowing) 2) – 3) 19.06.1997	0.015	300	0.005	08.05.1997	BBCH 39	shoot straw grain	0.16 0.05 <u>0.09</u> <u><0.01</u>	0 26 42 42	LOQ: grain 0.01 mg/kg; straw, shoot 0.05 mg/kg RIP2001-511

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 as a worst case scenario (overdosed and application was made at a later growth stage than envisaged according to cGAP). Used in risk assessment, since residues were nevertheless below the LOQ.
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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)	(a)	(b)				(c)		(a)		(d)	(e)
C007152 FRA0001 FR- 91940 Gometz le Chatel 2000-11-15	Rialto	1) 17.10.1997 (sowing) 2) 25.05.- 10.06.1998 3) 07.08.1998	0.015	250	0.006	15.05.1998	BBCH 39	shoot straw grain	0.24 <0.05 <0.01	0 84 84	LOQ: grain 0.01 mg/kg; straw, shoot 0.05 mg/kg <u>RIP2001-512</u>
C007152 FRA0002 FR- 95510 Amenucourt 2000-11-15	Soissons	1) 23.10.1997 (sowing) 2) 21.05.- 05.06.1998 3) 31.07.1998	0.015	250	0.006	12.05.1998	BBCH 39	shoot straw grain	0.30 <0.05 <0.01	0 80 80	LOQ: grain 0.01 mg/kg; straw, shoot 0.05 mg/kg <u>RIP2001-512</u>
C007152 GBR0001 GB- PE321HN East Winch 2000-11-15	Riband	1) 23.10.1997 (sowing) 2) 01.06.- 30.06.1998 3) 20.08.1998	0.015	300	0.005	19.05.1998	BBCH 39	shoot straw grain	0.36 <0.05 <0.01	0 93 93	LOQ: grain 0.01 mg/kg; straw, shoot 0.05 mg/kg <u>RIP2001-512</u>

- 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 as a worst case scenario (overdosed and application was made at a later growth stage than envisaged according to cGAP). Used in risk assessment, since residues were nevertheless below the LOQ.
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Reference: RIP2001-522
 Report: Decline of residues in wheat European Union northern Zone and southern France 1999; Iodosulfuron-methyl-sodium (AE F115008) 1%; Mesosulfuron-methyl (AE F130060) 3%; Mefenpyr-diethyl (AE F107892) 9%; Water dispersible granule, Davies, P., 2000, C009932, ER99ECN523
 Guideline(s): Yes
 Deviations: Yes
 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 : Mesosulfuron-methyl
Crop / crop group : Winter Wheat

Submission date : 2003-02-06

Content of a.i. (g/kg or g/l) : 30 g/kg
 Formulation (e.g. WP) : WG
 Commercial product (name) : AE F130060 02 WG13 A202 (submitted to ZN8 **005094-00**)

Indoors / outdoors : Outdoors (European North)
 Other a. i. in formulation (common name and content) : 10 g/kg Iodosulfuron-methyl
 90 g/kg Mefenpyr-diethyl

Applicant : Aventis CropScience Deutschland GmbH (AVD)
 Residues calculated as : Mesosulfuron

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						
C009932 DEU0301/02 DE- 86368 Gerstofen 2000-11-15	Tambor	1) 30.09.1998 (sowing) 2) 14.06.- 25.06.1999 3) 26.08.1999	0.015	300	0.005	18.05.1999	BBCH 39	shoots straw grain	0.38 <0.05 <0.05 <0.01	0 27 100 100	analytical method: EMF 08/99 (LC-MS/MS), LOQ: grain 0.01 mg/kg; straw, shoots 0.05 mg/kg, max. sample storage: 8 months RIP2001-522

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)
C009932 DEU0501/02 DE- 53347 Alfter- Witterschlick 2000-11-15	Triso	1) 24.03.1999 (sowing) 2) 01.07.- 09.07.1999 3) 03.08.1999	0.015	300	0.005	14.06.1999	BBCH 49	shoots straw grain	0.31 <0.05 <0.05 <0.01	0 21 50 50	analytical method: EMF 08/99 (LC-MS/MS), LOQ: grain 0.01 mg/kg; straw, shoots 0.05 mg/kg, max. sample storage: 8 months <u>RIP2001-522</u>
C009932 FRA0101/02 FR- 91400 Gometz la Ville 2000-11-15	Bourbon	1) 02.10.1998 (sowing) 2) 01.06.- 15.06.1999 3) 05.08.1999	0.015	250	0.006	12.05.1999	BBCH 39	shoots straw grain	0.24 <0.05 <0.05 <0.01	0 15 85 85	analytical method: EMF 08/99 (LC-MS/MS), LOQ: grain 0.01 mg/kg; straw, shoots 0.05 mg/kg, max. sample storage: 8 months <u>RIP2001-522</u>
C009932 DEU0301/03 DE- 86368 Gerstofen 2000-11-15	Tambor	1) 30.09.1998 (sowing) 2) 14.06.- 25.06.1999 3) 26.08.1999	0.015	300	0.005	18.05.1999	BBCH 39	shoots straw grain	0.43 <0.05 <0.05 <0.01	0 27 100 100	additional: Mero, 1 l/ha analytical method: EMF 08/99 (LC-MS/MS), LOQ: grain 0.01 mg/kg; straw, shoots 0.05 mg/kg, max. sample storage: 8 months <u>RIP2001-522</u>

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)
C009932 DEU0501/03 DE- 53347 Alfter- Witterschlick 2000-11-15	Triso	1) 24.03.1999 (sowing) 2) 01.07.- 09.07.1999 3) 03.08.1999	0.015	300	0.005	14.06.1999	BBCH 49	shoots straw grain	0.27 <0.05 <0.05 <0.01	0 21 50 50	additional: Mero, 1 l/ha analytical method: EMF 08/99 (LC-MS/MS), LOQ: grain 0.01 mg/kg; straw, shoots 0.05 mg/kg, max. sample storage: 8 months <u>RIP2001-522</u>
C009932 FRA0101/03 FR- 91400 Gometz la Ville 2000-11-15	Bourbon	1) 02.10.1998 (sowing) 2) 01.06.- 15.06.1999 3) 05.08.1999	0.015	250	0.006	12.05.1999	BBCH 39	shoots straw grain	0.23 <0.05 <0.05 <0.01	0 15 85 85	additional: Actirob B, 1 l/ha analytical method: EMF 08/99 (LC-MS/MS), LOQ: grain 0.01 mg/kg; straw, shoots 0.05 mg/kg, max. sample storage: 8 months <u>RIP2001-522</u>
C009932 DEU0301/04 DE- 86368 Gerstofen 2000-11-15	Tambor	1) 30.09.1998 (sowing) 2) 14.06.- 25.06.1999 3) 26.08.1999	0.015	300	0.005	18.05.1999	BBCH 39	shoots straw grain	0.46 <0.05 <0.05 <0.01	0 27 100 100	additional: Genapol LRO fluid analytical method: EMF 08/99 (LC-MS/MS), LOQ: grain 0.01 mg/kg; straw, shoots 0.05 mg/kg, max. sample storage: 8 months <u>RIP2001-522</u>

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)	(a)	(b)				(c)		(a)		(d)	(e)
C009932 DEU0501/04 DE- 53347 Alfter- Witterschlick 2000-11-15	Triso	1) 24.03.1999 (sowing) 2) 01.07.- 09.07.1999 3) 03.08.1999	0.015	300	0.005	14.06.1999	BBCH 49	shoots straw grain	0.28 <0.05 <0.05 <0.01	0 21 50 50	additional: Genapol LRO fluid analytical method: EMF 08/99 (LC-MS/MS), LOQ: grain 0.01 mg/kg; straw, shoots 0.05 mg/kg, max. sample storage: 8 months <u>RIP2001-522</u>
C009932 FRA0101/04 FR- 91400 Gometz la Ville 2000-11-15	Bourbon	1) 02.10.1998 (sowing) 2) 01.06.- 15.06.1999 3) 05.08.1999	0.015	250	0.006	12.05.1999	BBCH 39	shoots straw grain	0.24 <0.05 <0.05 <0.01	0 15 85 85	additional: Genapol LRO fluid analytical method: EMF 08/99 (LC-MS/MS), LOQ: grain 0.01 mg/kg; straw, shoots 0.05 mg/kg, max. sample storage: 8 months <u>RIP2001-522</u>

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 as a worst case scenario (overdosed and application was made at a later growth stage than envisaged according to cGAP). Used in risk assessment, since residues were nevertheless below the LOQ.
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Reference: RIP2001-523

Report: Decline of residues in common wheat European Union northern Zone 1999; Iodosulfuron-methyl-sodium (AE F115008) 3%; Mesosulfuron-methyl (AE F130060) 3%; Mefenpyr-diethyl (AE F107892) 9%; Water dispersible granule, Davies, P., 2000, C009933, ER99ECN524

Guideline(s): Yes

Deviations: No

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 : Mesosulfuron-methyl
Crop / crop group : Winter Wheat

Submission date : 15.11.2000

Content of a.i. (g/kg or g/l) : 30 g/kg
Formulation (e.g. WP) : WG
Commercial product (name) : AE F130060 02 WG15 A401 (submitted to ZN8 **005094-00**)

Indoors / outdoors : Outdoors (European North)
Other a. i. in formulation (common name and content) : 30 g/kg Iodosulfuron-methyl, 90 g/kg Mefenpyr-diethyl

Applicant : Aventis CropScience Deutschland GmbH (AVD)
Residues calculated as : Mesosulfuron

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)	
C009933 DEU0601 DE- 04821 Brandis 2000-11-15	Rialto	1) 28.09.1998 (sowing) 2) 20.06.- 30.06.1999 3) 29.07.1999	0.0099	300	0.0033	14.05.1999	BBCH 39	shoot straw grain	0.23 <0.05 <0.05 <0.01	0 17 76 76	LOQ: grain 0.01 mg/kg; straw, shoot 0.05 mg/kg <u>RIP2001-523</u>

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)	(a)	(b)				(c)		(a)		(d)	(e)
C009933 FRA0101 FR- 95510 Amenucourt 2000-11-15	Soissons	1) 15.10.1998 (sowing) 2) 29.05.- 10.06.1999 3) 27.07.1999	0.0099	250	0.004	03.05.1999	BBCH 39	shoot straw grain	0.21 <0.05 <u><0.05</u> <u><0.01</u>	0 17 85 85	LOQ: grain 0.01 mg/kg; straw, shoot 0.05 mg/kg <u>RIP2001-523</u>
C009933 GBR0101 GB- PE321HN East Winch 2000-11-15	Riband	1) 29.10.1998 (sowing) 2) – 3) 16.08.1999	0.0099	300	0.0033	01.06.1999	BBCH 39	shoot straw grain	0.26 <0.05 <u><0.05</u> <u><0.01</u>	0 7 76 76	LOQ: grain 0.01 mg/kg; straw, shoot 0.05 mg/kg <u>RIP2001-523</u>

- 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, slightly more critical than intended GAP. Used in risk assessment, since residues were nevertheless below the LOQ.
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A 2.3 Residues in processed commodities

No further studies evaluated.

A 2.4 Residues in rotational crops

No further studies evaluated.

A 2.5 Residues in livestock

No further studies evaluated.

A 2.6 Other studies/information

No further studies evaluated.

Appendix 3 Pesticide Residue Intake Modell (PRIMO)

Iodosulfuron-methyl (iodosulfuron-methyl including salts, expressed as iodosulfuron-methyl)			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0,03	ARfD (mg/kg bw):	Not allocated
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2003	Year of evaluation:	2003

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

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)	
2,9	UK Toddler	1,5	SUGAR PLANTS	0,4	FRUIT (FRESH OR FROZEN)	0,4	VEGETABLES										
2,6	WHO Cluster diet B	1,0	VEGETABLES	0,8	CEREALS	0,5	FRUIT (FRESH OR FROZEN)										
2,5	FR infant	1,4	VEGETABLES	1,0	FRUIT (FRESH OR FROZEN)	0,1	CEREALS										
2,5	DE child	1,5	FRUIT (FRESH OR FROZEN)	0,5	VEGETABLES	0,4	CEREALS										
2,2	NL child	1,0	FRUIT (FRESH OR FROZEN)	0,8	VEGETABLES	0,4	CEREALS										
2,2	FR toddler	1,2	VEGETABLES	0,8	FRUIT (FRESH OR FROZEN)	0,2	CEREALS										
1,9	UK Infant	0,7	SUGAR PLANTS	0,4	VEGETABLES	0,4	FRUIT (FRESH OR FROZEN)										
1,9	IE adult	0,7	FRUIT (FRESH OR FROZEN)	0,6	VEGETABLES	0,4	CEREALS										
1,6	WHO cluster diet E	0,6	VEGETABLES	0,4	CEREALS	0,4	FRUIT (FRESH OR FROZEN)										
1,5	DK child	0,7	CEREALS	0,5	VEGETABLES	0,3	FRUIT (FRESH OR FROZEN)										
1,4	WHO cluster diet D	0,6	VEGETABLES	0,6	CEREALS	0,2	FRUIT (FRESH OR FROZEN)										
1,4	SE general population 90th percentile	0,7	VEGETABLES	0,4	FRUIT (FRESH OR FROZEN)	0,3	CEREALS										
1,3	WHO Cluster diet F	0,5	VEGETABLES	0,4	CEREALS	0,3	FRUIT (FRESH OR FROZEN)										
1,2	ES child	0,4	FRUIT (FRESH OR FROZEN)	0,3	CEREALS	0,3	VEGETABLES										
1,2	PT General population	0,4	FRUIT (FRESH OR FROZEN)	0,4	VEGETABLES	0,4	CEREALS										
1,2	WHO regional European diet	0,6	VEGETABLES	0,2	CEREALS	0,2	FRUIT (FRESH OR FROZEN)										
1,1	IT kids/toddler	0,6	CEREALS	0,3	VEGETABLES	0,2	FRUIT (FRESH OR FROZEN)										
1,1	UK vegetarian	0,3	SUGAR PLANTS	0,3	VEGETABLES	0,2	FRUIT (FRESH OR FROZEN)										
0,9	FR all population	0,4	FRUIT (FRESH OR FROZEN)	0,2	VEGETABLES	0,2	CEREALS										
0,9	NL general	0,4	VEGETABLES	0,3	FRUIT (FRESH OR FROZEN)	0,2	CEREALS										
0,9	UK Adult	0,3	SUGAR PLANTS	0,2	VEGETABLES	0,2	FRUIT (FRESH OR FROZEN)										
0,8	ES adult	0,3	FRUIT (FRESH OR FROZEN)	0,3	VEGETABLES	0,2	CEREALS										
0,8	IT adult	0,3	CEREALS	0,3	VEGETABLES	0,2	FRUIT (FRESH OR FROZEN)										
0,7	LT adult	0,3	VEGETABLES	0,2	CEREALS	0,2	FRUIT (FRESH OR FROZEN)										
0,7	DK adult	0,2	VEGETABLES	0,2	FRUIT (FRESH OR FROZEN)	0,2	CEREALS										
0,6	PL general population	0,4	VEGETABLES	0,2	FRUIT (FRESH OR FROZEN)	0,0	PULSES, DRY										
0,5	FI adult	0,2	VEGETABLES	0,2	FRUIT (FRESH OR FROZEN)	0,1	CEREALS										

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Iodosulfuron-methyl (iodosulfuron-methyl including salts, expressed as iodosulfuron-methyl) is unlikely to present a public health concern.

Mesosulfuron-methyl expressed as mesosulfuron			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	1	ARfD (mg/kg bw):	Not necessary
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2003	Year of evaluation:	2003

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						
		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)
0,0	UK Toddler	0,0	SUGAR PLANTS	0,0	FRUIT (FRESH OR FROZEN)	0,0	VEGETABLES	
0,0	WHO Cluster diet B	0,0	VEGETABLES	0,0	CEREALS	0,0	FRUIT (FRESH OR FROZEN)	
0,0	FR infant	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	0,0	CEREALS	
0,0	DE child	0,0	FRUIT (FRESH OR FROZEN)	0,0	VEGETABLES	0,0	CEREALS	
0,0	NL child	0,0	FRUIT (FRESH OR FROZEN)	0,0	VEGETABLES	0,0	CEREALS	
0,0	FR toddler	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	0,0	CEREALS	
0,0	UK Infant	0,0	SUGAR PLANTS	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	
0,0	IE adult	0,0	FRUIT (FRESH OR FROZEN)	0,0	VEGETABLES	0,0	CEREALS	
0,0	WHO cluster diet E	0,0	VEGETABLES	0,0	CEREALS	0,0	FRUIT (FRESH OR FROZEN)	
0,0	DK child	0,0	CEREALS	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	
0,0	WHO cluster diet D	0,0	VEGETABLES	0,0	CEREALS	0,0	FRUIT (FRESH OR FROZEN)	
0,0	SE general population 90th percentile	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	0,0	CEREALS	
0,0	WHO Cluster diet F	0,0	VEGETABLES	0,0	CEREALS	0,0	FRUIT (FRESH OR FROZEN)	
0,0	PT General population	0,0	FRUIT (FRESH OR FROZEN)	0,0	VEGETABLES	0,0	CEREALS	
0,0	ES child	0,0	FRUIT (FRESH OR FROZEN)	0,0	CEREALS	0,0	VEGETABLES	
0,0	WHO regional European diet	0,0	VEGETABLES	0,0	CEREALS	0,0	FRUIT (FRESH OR FROZEN)	
0,0	IT kids/toddler	0,0	CEREALS	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	
0,0	UK Adult	0,0	SUGAR PLANTS	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	
0,0	FR all population	0,0	FRUIT (FRESH OR FROZEN)	0,0	VEGETABLES	0,0	CEREALS	
0,0	UK vegetarian	0,0	SUGAR PLANTS	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	
0,0	NL general	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	0,0	CEREALS	
0,0	ES adult	0,0	FRUIT (FRESH OR FROZEN)	0,0	VEGETABLES	0,0	CEREALS	
0,0	IT adult	0,0	CEREALS	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	
0,0	LT adult	0,0	VEGETABLES	0,0	CEREALS	0,0	FRUIT (FRESH OR FROZEN)	
0,0	DK adult	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	0,0	CEREALS	
0,0	PL general population	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	0,0	PULSES, DRY	
0,0	FI adult	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	0,0	CEREALS	

Conclusion:

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