

Draft Renewal Assessment Report
under Regulation (EC) 1107/2009



FORAMSULFURON
Active substance and Product data
Volume 1

Rapporteur Member State: Finland
Co-Rapporteur Member State: Slovakia

March 2015

Volume 1

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Version History

When	What
2001/April	Initial DAR (no addenda to Volume 1 could be identified)
2015/March	First draft RAR

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Level 1

FORAMSULFURON

1. STATEMENT OF SUBJECT MATTER AND PURPOSE FOR WHICH THIS REPORT HAS BEEN PREPARED AND BACKGROUND INFORMATION ON THE APPLICATION

1.1. CONTEXT IN WHICH THIS DRAFT ASSESSMENT REPORT WAS PREPARED

1.1.1. Purpose for which the draft assessment report was prepared

Foramsulfuron was originally included in Annex I of the EU Council Directive 91/414/EEC with Commission Directive 2003/23/EC (entry into force on 1 July 2003). The active substance was subsequently approved under Regulation (EC) 1107/2009 via Implementing Regulation (EU) 540/2011. In accordance with Commission Regulation (EU) 844/2012 of 18 September 2012, Bayer CropScience submitted dossier to support the renewal of the approval of foramsulfuron. Finland acting as the Rapporteur Member State (RMS) evaluated the renewal dossier together with the Co-Rapporteur (Co-RMS) Slovakia.

This DRAR provides a discussion of relevant studies submitted for the original EU evaluation for Annex I inclusion as well as relevant new studies and information generated since the Annex I inclusion of foramsulfuron in 2003. Where necessary, studies submitted for the original EU evaluation for Annex I inclusion have been re-evaluated to allow risk assessment along current standards, and to validate previous conclusions and/or calculations.

Foramsulfuron is subject to harmonised classification and the RMS did not find reasons to propose an amendment of this which would have any implications for the considerations of renewal of the approval under Commission Regulation (EC) No. 1107/2009. Therefore the RMS did not submit any such proposal to ECHA.

1.1.2. Arrangements between rapporteur Member State and co-rapporteur Member State

According to an agreement reached by the respective designated authorities, the Co-RMS Slovakia conducted the evaluation in the sections physical and chemical identity, analytical methods, efficacy and Vol4 Confidential. Fate and behavior as well as ecotoxicology were done in co-operation.

The first official version of the DRAR was submitted to the Commission and EFSA by the end of March 2015.

1.1.3. EU Regulatory history for use in Plant Protection Products

Foramsulfuron was included as a New Active Substance in Annex I of EU Council Directive 91/414/EEC on 1st July 2003 (Commission Directive 2003/23/EC of 25 March 2003).

The Commission presented a Review Report (SANCO/10324/2002-final 29 November 2003) in support to the consideration of Annex I inclusion. No EFSA Conclusion was prepared at that time.

Aventis Crop Science (later Bayer CropScience) was the main data submitter in support of Annex I inclusion. Germany acted as Rapporteur Member State (RMS). There was no request for confirmatory data to be submitted after the inclusion in Annex I of EU Council Directive 91/414/EEC.

EFSA has published a Reasoned opinion on the review of the existing maximum residue levels (MRLs) for foramsulfuron according to Article 12 of Regulation (EC) No 396/2005 (EFSA Journal 2012;10(11):2962)

1.1.4. Evaluations carried out under other regulatory contexts

The RMS is not aware of any other relevant EU-evaluations of foramsulfuron carried out in the framework of other relevant EU-legislation (e.g. biocides, flavourings, food additives, cosmetics).

Foramsulfuron was not included in the Inventory of Evaluations performed by the Joint Meeting on Pesticide Residues (JMPR).

In the US a Registration Review is on-going, with a Draft Risk Assessment estimated to be subject for public consultation in 2016 (Registration Review Case No 7252, Docket No EPA-HQ-OPP-2012-0387). The RMS did not find any recent (less than 5 years old) evaluation of foramsulfuron from PMRA, Canada.

1.2. APPLICANT INFORMATION

1.2.1. Name and address of applicant for approval of the active substance

Name: Bayer CropScience AG

Address: Alfred Nobel Str. 50
D-40789 Monheim
Germany

Contact:



Telephone
number



1.2.2. Producer or producers of the active substance

Address: Bayer CropScience AG
Product Supply
Alfred Nobel Str. 50
D-40789 Monheim
Germany

Contact:

**1.2.3. Information relating to the collective provision of dossiers**


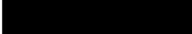


The RMS received an application for renewal of the approval of foramsulfuron only from Bayer CropScience AG. A collective provision of dossiers has therefore not been necessary.

1.3. IDENTITY OF THE ACTIVE SUBSTANCE

1.3.1. Common name proposed or ISO-accepted and synonyms	Foramsulfuron (no synonyms)
1.3.2. Chemical name (IUPAC and CA nomenclature)	
IUPAC	1-(4,6-dimethoxypyrimidin-2-yl)-3-(2-dimethylcarbamoyl-5-formamidophenylsulfonyl)urea
CA	2-[[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]-4-(formylamino)-N,N-dimethylbenzamide
1.3.3. Producer's development code number	AE F130360 (current company code) Hoe 130360 (former company code)
1.3.4. CAS, EEC and CIPAC numbers	
CAS	173159-57-4
EEC	not assigned
CIPAC	659

1.3.5. Molecular and structural formula, molecular mass	
Molecular formula	C ₁₇ H ₂₀ N ₆ O ₇ S
Structural formula	
Molecular mass	452.44 g/mol
1.3.6. Method of manufacture (synthesis pathway) of the active substance	Confidential information, see Volume 4 point C 1.1.2
1.3.7. Specification of purity of the active substance in g/kg	940 g/kg (first inclusion) 973 g/kg
1.3.8. Identity and content of additives (such as stabilizers) and impurities	
1.3.8.1. Additives	The active substance as manufactured does not contain any intentionally added additives
1.3.8.2. Significant impurities	For further information please refer to Volume 4 point C 1.2.2
1.3.8.3. Relevant impurities	The active substance as manufactured does not contain any impurities requiring toxicological/ecotoxicological relevance (e.g. nitrosamines, hexachlorobenzene, hydrazines, halogenated, dibenzodioxins and halogenated dibenzofurans, chlorinated biphenyls, oxygen analogs of organophosphates)
1.3.9. Analytical profile of batches	Confidential information, see Volume 4 point C 1.2.3

1.4. INFORMATION ON THE PLANT PROTECTION PRODUCT

1.4.1. Applicant	Name: Bayer CropScience AG Address: Alfred Nobel Str. 50 D-40789 Monheim Germany Contact:  Telephone number: 															
1.4.2. Producer of the plant protection product	Name: Bayer S.A.S. Bayer CropScience Address: 16, rue Jean-Marie Leclair CS 90106 69266 Lyon Cedex 09 France Contact:  Telephone number: 															
1.4.3. Trade name or proposed trade name and producer's development code number of the plant protection product	Trade names: Equip OD, Cubix, Option, Monsoon Code number: Specification 102000011304, UVP 06321801 FSN+IDF OD 22,5+22,5 Old codes: AE F130360 01 1K05 A3, A8, A9															
1.4.4. Detailed quantitative and qualitative information on the composition of the plant protection product																
1.4.4.1. Composition of the plant protection product	<table border="1"> <thead> <tr> <th colspan="5">Pure active substance</th> </tr> <tr> <th>Active substance</th><th>Declared content in pure [g/L]</th><th>FAO Limits [min-max]</th><th>Technical content* [g/L]</th><th>Technical content** [% w/w]</th></tr> </thead> <tbody> <tr> <td>Foramsulfuron</td><td>22.5</td><td>19.1-25.9</td><td>23.1</td><td>2.41</td></tr> </tbody> </table> <p>* Based on the minimum content of the active substance 97.3 % ** Based on the density value from the specification d = 0.960</p> <p>Safeners, synergists and co-formulants Confidential information, see Volume C point C 1.4</p>	Pure active substance					Active substance	Declared content in pure [g/L]	FAO Limits [min-max]	Technical content* [g/L]	Technical content** [% w/w]	Foramsulfuron	22.5	19.1-25.9	23.1	2.41
Pure active substance																
Active substance	Declared content in pure [g/L]	FAO Limits [min-max]	Technical content* [g/L]	Technical content** [% w/w]												
Foramsulfuron	22.5	19.1-25.9	23.1	2.41												

1.4.4.2. Information on the active substances	Type	Name/Code/Number
	ISO common name	Foramsulfuron
	CAS No.	173159-57-4
	EC No.	Not allocated
	CIPAC No.	659
	Salt, ester anion or cation present	None
1.4.4.3. Information on safeners, synergists and co-formulants	Confidential information, see Volume C point C 1.4	
1.4.5. Type and code of the plant protection product	Type: Code:	oil dispersion OD
1.4.6. Function	Herbicide	
1.4.7. Field of use envisaged	Post-emergence herbicide for the control of broadleaved weeds and grasses in maize (corn)	
1.4.8. Effects on harmful organisms	Effect	systemic
	mode of action	Amino acids synthesis inhibitors
	range of target organisms	broadleaved weeds and grasses in maize (corn)

1.5. DETAILED USES OF THE PLANT PROTECTION PRODUCT

1.5.1. Details of representative uses

There are two key use patterns for the formulation, Equip OD. The first consists of a single application at a maximum rate of approx. 2.6 L per hectare at growth stage 12-18. The second consists of split application, two applications at a max rate of 1L per application between BBCH 12-18 with an interval of 7-14 days. In the dossier the critical GAP is defined as the single application at approx. 2.6L per hectare (highlighted in grey in the table).

Crop and/or situation (a)	Zone / Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	g as/hL min max	water L/ha min max	g as/ha max		
maize (corn)	Various	Equip OD 45 22.5+22.5 g / L	F	Annual grasses and dicots	OD	22.5 g/L (1) 22.5 g/L (2)	Broadcast, overall spraying	BBCH 12-18	1-1	-	15-40 (1) 15-40 (2)	150-400	60 g//Ha (1) 60 g//Ha (2)	-	Single application of Equip OD at a maximum product rate of 2.6 L/ha
maize (corn)	Various	Equip OD 45 22.5+22.5 g / L	F	Annual grasses and dicots	OD	22.5 g/L (1) 22.5 g/L (2)	Broadcast, overall spraying	BBCH 12-18	2	7-14	7.5-20 (1) 7.5-20 (2)	150-400	30 g//Ha (1) 30 g//Ha (2)	-	Split application of Equip OD.

Remarks:	(a)	For crops, Codex (or other, e.g. EU) classifications should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)	(h)	Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants
	(b)	Outdoor or field use (F), glasshouse application (G) or indoor application(I)	(i)	- type of equipment used must be indicated g/kg or g/l
	(c)	e.g. biting and sucking insects, soil born insects, foliar fungi, weeds	(j)	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
	(d)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(k)	The minimum and maximum number of application possible under practical conditions of use must be provided
	(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989	(l)	PHI - minimum pre-harvest interval
	(f)	All abbreviations used must be explained	(m)	Remarks may include: Extent of use/economic importance/restriction
	(g)	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench		

1.5.2. Further information on representative uses

Foramsulfuron is a post-emergence herbicide for use in maize (corn) to control broad-leaved weeds and grasses. Foramsulfuron is used at a maximum application rate of 60 g of the active substance per hectare and is applied as a broadcast overall spray.

Foramsulfuron is very effective in controlling most annual and perennial grasses occurring in maize (corn), such as *Echinochloa crus-galli*, *Setaria* spp., *Panicum* spp., *Poa annua*, *Lolium* spp., *Sorghum* spp. and *Agropyron repens*. It also controls a broad spectrum of broad-leaved weeds, including *Amaranthus retroflexus*, *Solanum nigrum*, *Stellaria media*, *Mercurialis annua*, *Abutilon theophrasti*, and most agriculturally important crucifers.

1.5.3. Details of other uses applied for to support the setting of MRLs for uses beyond the representative uses

Not relevant.

1.5.4. Overview on authorisations in EU Member States

Foramsulfuron is widely authorised in European countries including Austria, Belgium, Bulgaria, Croatia, Czech Republic, Cyprus, France, Germany, Greece, Hungary, Italy, Luxembourg, Portugal, Romania, Slovakia, Slovenia, Spain.

The information on the authorized uses of representative formulations in the EU Member States.

Representative Uses (for application details see table 2)					Existing Authorisations								
Crop	Target	Situation of use (e.g. indoor...)	AI content & Formulation Type	Application method	Country	Zone	Since	Reg. No.	Product	Product Application rate per treatment Min and Max (L/ha)	Active Substance Application rate per treatment Min and Max (g a.s./ha)	Number of treatments per Season Min and Max	Active Substance Max total dose/ ha Min and Max
maize (corn)	Weeds (grasses and broad-leaved weeds)	outdoor	45 OD	Broadcast overall spray	Austria	C	11/26/2002	2826	MONSOON	Max 2.7	60.75	1	60.75
					Austria	C	11/26/2002	2826	MONSOON	Max 1.3	29.25	1-2	29.25 – 58.5
					Germany	C	10/5/2009	005806-00	MONSOON	2	45	1	45
					Belgium	C	1/13/2005	9395P/B	EQUIP	2.66	59.85	1	59.85
					Luxembourg	C	4/6/2005	L01643-017	EQUIP	2.66	59.85	1	59.85
					Czech Republic	C	2/5/2010	4635-0	EQUIP	2	45	1	45
					Romania	C	4/11/2001	2106	EQUIP	1-1.5	22.5 – 33.75	1	22.5 – 33.75
					Romania	C	4/11/2001	2106	EQUIP	1.75-2.5	39.37 – 56.25	1	39.37 – 56.25
					Romania	C	4/11/2001	2106	EQUIP	2.5	56.25	1	56.25

Representative Uses (for application details see table 2)					Existing Authorisations								
Crop	Target	Situation of use (e.g. indoor...)	AI content & Formulation Type	Application method	Country	Zone	Since	Reg. No.	Product	Product Application rate per treatment Min and Max (L/ha)	Active Substance Application rate per treatment Min and Max (g a.s./ha)	Number of treatments per Season Min and Max	Active Substance Max total dose/ ha Min and Max
					Slovakia	C	4/26/2012	12-11-1245	EQUIP	Max 2	45	1	45
					Slovenia	C	2/15/2006	327-02-290/2004/17	EQUIP	2-2.5	45 - 56.25	1	45 - 56.25
					Czech Republic	C	10/23/2011	4635-1	MONSOON	2	45	1	45
					Hungary	C	1/10/2002	11001/2002	MONSOON	1.8-2.5	40.5 – 56.25	1	40.5 – 56.25
					Slovakia	C	7/7/2011	11-11-1190	MONSOON	Max 2	45	1	45
					Slovakia	C	6/3/2013	13-11-1355	MUSKETEER PLUS	Max 2	45	1	45
					Bulgaria	S	12/28/2002	0039/5.02.2003	EQUIP	2-2.5	45-56.25	1	45-56.25
					Bulgaria	S	4/30/2009	01087/30.04.2010	EQUIP OD	2-2.5	45 - 56.25	1	45 - 56.25
					Cyprus	S	11/27/2009	2805	EQUIP OD	2-2.67	45 – 60.07	1	45 – 60.07
					Cyprus	S	11/27/2009	2805	EQUIP OD	1.3-1.3	29.25	2	29.25 – 58.5

Representative Uses (for application details see table 2)					Existing Authorisations								
Crop	Target	Situation of use (e.g. indoor...)	AI content & Formulation Type	Application method	Country	Zone	Since	Reg. No.	Product	Product Application rate per treatment Min and Max (L/ha)	Active Substance Application rate per treatment Min and Max (g a.s./ha)	Number of treatments per Season Min and Max	Active Substance Max total dose/ ha Min and Max
					Croatia	S	1/16/2002	UP/I-320-20/04-01/229	EQUIP	2-2.5	45 - 56.25	1	45 - 56.25
					France	S	11/8/2002	2000301	EQUIP	2.66	59.85	1	59.85
					France	S	11/8/2002	2000301	CUBIX	2.66	59.85	1	59.85
					Greece	S	8/16/2004	7734	EQUIP OD	2-2.67	45 – 60.07	1	45 – 60.07
					Greece	S	8/16/2004	7734	EQUIP OD	1.3-1.3	29.25	2	29.25 – 58.5
					Italy	S	12/14/2004	12452	EQUIP	2-2.7	45-60.75	1	45-60.75
					Italy	S	12/14/2004	12452	EQUIP	1.8-1.8	40.5	1	40.5
					Italy	S	12/14/2004	12452	EQUIP	0.9-0.9	20.25	1	20.25
					Spain	S	6/1/2007	23934/13	CUBIX	2-2.7	45 – 60.75	1	45 – 60.75
					Portugal	S	2/8/2007	AV n° 75	OPTION	2-2.5	45 – 56.25	1	45 – 56.25

Level 2

FORAMSULFURON

2. SUMMARY OF ACTIVE SUBSTANCE HAZARD AND OF PRODUCT RISK ASSESSMENT

2.1. IDENTITY

Foramsulfuron is the ISO common name of 1-(4,6-dimethoxypyrimidin-2-yl)-3-(2-dimethylcarbamoyl-5-formamidophenylsulfonyl)urea.

Acceptable information has been submitted to establish both the identity of foramsulfuron and the representative plant protection product. This includes new data on the technical material. The manufacturing process has changed in 2003/2004 when going to full industrial scale production. Thus a new material accountability study was performed in 2013, and the composition of five batches of technical material of foramsulfuron was analyzed. Based on the results of the new material accountability study, a new specification has been derived. With the new manufacturing process, foramsulfuron technical material of higher purity is obtained, so the purity of the active substance has increased from 940 g/kg (original EU specification) to 973 g/kg based on the new material accountability study.

The active substance as manufactured does not contain any impurities requiring toxicological / ecotoxicological relevance.

2.2. PHYSICAL AND CHEMICAL PROPERTIES

2.2.1. Summary of physical and chemical properties of the active substance

Foramsulfuron active substance as manufactured is a white solid (powder).

A melting point of 194.5°C was determined for the pure substance. After melting of the test substance only an exothermic reaction is observed. The substance decomposes before reaching the boiling point. Foramsulfuron is not explosive, flammable or oxidising. The relative density determined at 25.5°C is 1.44. Vapour pressures measured at 20 and 25 °C are $4.2 \cdot 10^{-11}$ Pa and $1.3 \cdot 10^{-10}$ Pa, respectively. The Henry's constant at 20°C was calculated to be $K_H = 5.8 \cdot 10^{-12}$ Pa·m³/mol. Solubilities in water are strongly influenced by pH and are between 37.2 mg/L at pH 5 and 94577 mg/L at pH 8. The test substance is slightly soluble (1 to 2 g/L) in acetone, acetonitrile and methanol. Lowest solubilities (<0.010 g/L) are observed in heptane and p-xylene. The K_{OW} values are in the range of 27.5 at pH 2 and 0.0106 at pH 9 ($\log_{POW} = -0.78$ at pH 7). At 21.5 °C, the pK_a value is 4.60.

2.2.2. Summary of physical and chemical properties of the plant protection product

Equip OD is a beige oil dispersion with weakly sweetish aromatic odour, It has neither explosive nor oxidising properties. The flash point is > 100°C and the auto-flammability is 350°C. 1% dilution in distilled water has a pH value of 5.6. The product is surface active. The preparation is stable throughout the test period of 8 weeks at 40 °C in HDPE/PA and HDPE/EVOH packagings. During shelf life storage stability tests at ambient temperature in

HDPE/PA packaging content of foramsulfuron decreased by 6.6%. No major changes in the tested physical properties were detectable.

New shelf life storage stability study at ambient temperature with current specification is running in HDPE/PA and HDPE/EVOH packagings. The applicant has been contacted and asked about the timetable of the test. According to the answer, the 2-year storage stability studies will be available by the end of 2015. Thus the shelf life test is considered as a data gap.

The technical properties of Equip OD indicate no particular problems when used as recommended.

Equip OD needs to be classified as an aspiration hazardous compound according to CLP, because one of its co-formulants is classified in Category 1, the formulation contains > 10% of it, and the kinematic viscosity of the formulation at 40 °C is < 20.5 mm²/s.

2.3. DATA ON APPLICATION AND EFFICACY

In accordance with the guidance document (SANCO/12592/2012) on the ‘Template Assessment Report’ only limited information for efficacy will be provided to address the requirements of Article 4(3) of Regulation (EC) No 1107/2009. Detailed consideration of efficacy will occur in the subsequent product authorisation process at Member State level when a full biological assessment dossier will be provided. Therefore only limited efficacy information is required for foramsulfuron and has been provided under the appropriate headings in line with the guidance for renewals - Guidance Document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No 844/2012 Appendix II (SANCO/2012/11251).

2.3.1. Summary of effectiveness

Foramsulfuron is effective in controlling most annual and perennial grasses occurring in maize, such as *Echinochloa crus-galli*, *Setaria* spp., *Panicum* spp., *Poa annua*, *Lolium* spp., *Sorghum* spp. and *Agropyron repens*. It also controls a broad spectrum of broad-leaved weeds, including *Amaranthus retroflexus*, *Solanum nigrum*, *Stellaria media*, *Mercurialis annua*, *Abutilon theophrasti*, and most agriculturally important crucifers.

2.3.2. Summary of information on the development of resistance

As with other herbicides of the sulfonylurea family, primary biochemical target site of foramsulfuron is the enzyme acetolactate synthase (ALS) in the aliphatic amino acid pathway. Hence the substance belongs to the mode of action group B according to the HRAC (Herbicide Resistance Action Committee) classification.

The notifier himself assesses the resistance risk as to be “moderate to high”, stating that the risk is reduced mainly by the facts, that (i) ALS-inhibiting herbicides have not been used in maize for a long time and (ii) as in maize a great number of products acting differently in the target plants than ALS-inhibitors is available, farmers have not necessarily to rely on ALS-inhibitor herbicides for weed control. The alternative herbicides belong to the mode of action groups C1 (inhibition of Photosynthesis II), C3 (C1 (inhibition of Photosynthesis II), F2 (4-hydroxyphenyl-pyruvate-dioxygenase -inhibition), K1 (microtubule assembly inhibition), K3 (inhibition of cell division) and O (action like indole acetic acid).

2.3.3. Summary of adverse effects on treated crops

Application of foramsulfuron during unfavourable conditions, i.e. (i) temperatures above 25 °C together with high light intensity and low water supply for the plant, (ii) high differences between day and night temperatures (> 20 °C) or (iii) periods with low temperature (below 10 °C) together with continuous rain, can cause phytotoxicity symptoms. Crop damage may also occur if maize plants are weakened by frost, waterlogging, dryness or insufficient nourishment.

Differences in the tolerance of commercially available maize varieties have been observed but the number of sensitive varieties is low. In all trials, comprising those showing higher levels of initial damage, symptoms were of temporary nature and remained without effect on subsequent maize growth. No thinning effects were found.

According to selectivity, foramsulfuron is incompatible with phosphoric acid esters. Insecticides of the organophosphate group when used before or after herbicide application may cause a risk of crop damage, for they delay the degradation of sulfonylurea herbicides in the crop plants. Therefore the use of Equip on maize fields treated with insecticides from the organophosphate group is not recommended just as these insecticides should not be applied on maize stand treated with Equip beforehand.

2.3.4. Summary of observations on other undesirable or unintended side-effects

Information about observations on other undesirable or unintended side-effects has not been supplied.

2.4. FURTHER INFORMATION

2.4.1. Summary of methods and precautions concerning handling, storage, transport or fire

Advice on safe handling	Use only in area provided with appropriate exhaust ventilation.
Advice on protection	Dust may form explosive mixture in air. Keep away from heat and sources of ignition
Personal protective equipment	Avoid contact with skin, eyes and clothing. Keep working clothes separately. Wash hands before breaks and immediately after handling the product. Remove soiled clothing immediately and clean thoroughly before using again. Garments that cannot be cleaned must be destroyed (burnt).

Storage:

Requirements for storage areas and containers	Store in original container. Keep containers tightly closed in a dry, cool and well-ventilated place. Store in a place accessible by authorized persons only. Keep away from direct sunlight.
Advice on common storage	Keep away from food, drink and animal feeding stuffs.

Transport:

Further information	According to ADN/ADR/RID/IMDG/IATA not classified as dangerous goods.
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Fire:

Suitable extinguishing media	Water spray, Carbon dioxide (CO ₂), Foam, Sand
Extinguishing media which must not be used for safety reasons	High volume water jet.
Specific hazards during fire fighting	In the event of fire the following may be released:, Hydrogen cyanide (hydrocyanic acid), Carbon monoxide (CO), Sulphur oxides, Nitrogen oxides (NO _x)
Special protective equipment for fire-fighters	In the event of fire and/or explosion do not breathe fumes. In the event of fire, wear self-contained breathing apparatus.
Further information	Contain the spread of the fire-fighting media. Do not allow run-off from firefighting to enter drains or water courses.

2.4.2. Summary of procedures for destruction or decontamination

Pyrolytic behaviour under controlled conditions at 800°C

Foramsulfuron contains no halogen atom, i.e. the halogen content is 0% (w/w).

Possible co-formulated active substances as well as the formulation additives have halogen contents considerably below 60 % (w/w) or contain no halogen at all. The total halogen content in formulated products is therefore below the trigger value of 60 % (w/w).

Consequently, additional studies on the pyrolytic behaviour, combustion products and contents of polyhalogenated dibenzo-p-dioxins and dibenzo-furanes in the products of pyrolysis are not required for foramsulfuron or for plant protection products (preparations, formulations) containing foramsulfuron.

No methods other than controlled incineration are recommended.

2.4.3. Summary of emergency measures in case of an accident

Inhalation	Move to fresh air. Keep patient warm and at rest. Call a physician or poison control center immediately.
Skin contact	Wash off thoroughly with plenty of soap and water, if available with polyethyleneglycol 400, subsequently rinse with water.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Do NOT induce vomiting. Call a physician or poison control center immediately.
General advice	Move out of dangerous area. Place and transport victim in stable position (lying sideways). Remove contaminated clothing immediately and dispose of safely.
Notes to physician:	
Symptoms	No symptoms known or expected.
Treatment	Treat symptomatically. In case of ingestion gastric lavage should be considered in cases of significant ingestions only within the first 2 hours. However, the application of activated charcoal and sodium sulphate is always advisable. There is no specific antidote.

2.5. METHODS OF ANALYSIS

2.5.1. Methods used for the generation of pre-authorisation data

2.5.1.1 Active substance

Analytical methodology is available for the determination of the active substance and the impurities in the technical material.

Foramsulfuron in the technical active substance is determined by a HPLC external standard method on a reversed phase column with UV detection.

Organic by-products in the technical active substance are determined by a HPLC method on a reversed phase column with UV detection. One impurity is determined by gas chromatography and two impurities by ion chromatography.

All methods are fully validated.

HPLC-MS/MS analytical method for determination of residues of foramsulfuron and metabolite AE F 153745 in maize is available with LOQ of foramsulfuron 0.01 mg/kg. Two MRM transitions are used, method is self-confirmatory. However, no ILV has been performed.

2.5.1.2 Product

An analytical method is available for the determination of the active substance foramsulfuron and the safener isoxadifen-ethyl in the representative formulation. Foramsulfuron and the safener are determined by a HPLC external standard method using UV detection.

An analytical method is available for the determination of 3 degradation products in the representative formulation. They are determined by HPLC on a reversed phase column using UV detection. The test has been performed in a GLP test facility but the test itself has not been performed according to GLP. However, as the validation is done in compliance with SANCO/3030/99 rev. 4, the missing GLP is considered as a minor data gap.

2.5.2. Methods for post control and monitoring purposes

HPLC-MS/MS analytical methods for determination of residues of foramsulfuron in plant material is available with LOQ 0.05 mg/kg of foramsulfuron in wheat straw and shoot and LOQ 0.01 mg/kg of foramsulfuron in wheat grain, lemon, tomato and maize kernel. Methods are validated.

Enforced multiresidual HPLC-MS/MS analytical method for determination of residues of foramsulfuron in plant materials is available with LOQ 0.01 of foramsulfuron in sugar beet body, sugar beet leaf, lemon (fruit), oilseed rape, cereal straw. Two MRM transitions are used, method is self-confirmatory. Method is fully validated.

Enforced multiresidual HPLC-MS/MS analytical method for determination of residues of foramsulfuron in food of animal origin is available with LOQ 0.01 mg/kg of foramsulfuron in animal tissues (meat, fat, liver, kidney), milk and egg. Two MRM transitions are used, method is self-confirmatory. Method is fully validated.

HPLC-MS/MS analytical method for monitoring purpose in soil is available with LOQ 0.1 µg/kg of foramsulfuron in silt soil and loam soil. Two MRM transitions are used, method is self-confirmatory.

Enforced HPLC-MS/MS analytical method for monitoring purpose in water is available with LOQ 0.05 µg/L in drinking and surface water. Two MRM transitions are used, method is self-confirmatory.

Updated analytical method for residues of foramsulfuron in air with LOQ 12 µg/m³ was revised during the course of the Annex I Listing process and is considered appropriate.

Analytical methods for residues of foramsulfuron in body fluids and tissues are not required.

2.6. EFFECTS ON HUMAN AND ANIMAL HEALTH

2.6.1. Summary of absorption, distribution and excretion in mammals

Biokinetics and metabolism of foramsulfuron were investigated in the rat.

Absorption

Approx. 20% of an orally administered dose of radiolabelled foramsulfuron (10 mg/kg bw) was absorbed from the gastrointestinal tract of bile-cannulated rats within 48 h.

Distribution

The radiolabel was initially distributed into almost all tissues. 30 h after application of a low dose, the highest residues were found in the liver and kidney, but by 72 h, levels of all tissues were near or below the level of detection. 30 h after high-dose treatment (1000 mg/kg bw), the thyroid, adrenals, female gonads, eyes and liver showed the highest residue levels. By 72 h, all tissue residues were below 0.5 mg/kg of tissue, except for the spleen, heart, and renal fat of males (0.653–1.608 mg equivalents/kg) and the liver and spleen of females (0.510–0.551 mg equivalents/kg). The elimination half-life in the plasma was 5.4–18.5 h at the low dose and 2.4–2.8 h at the high dose level.

Potential for accumulation

Upon repeated administration of radiolabelled foramsulfuron at 10 mg/kg bw/d, increases of residue concentration levels resulted in most tissues over the 14-d treatment period. These increases did not exceed 3-fold with the exception of the following male tissues: brain (20x increase), testes (15x), thyroid (10x), and heart (6.5x). The level of the radioactive residues in the tissues throughout the study was generally below 0.1 mg equivalent/kg. The liver was the only tissue exhibiting clearly increased radiolabel concentrations compared to plasma at both timepoints of investigation (24 and 48 h). This finding is considered to reflect redistribution of

the radiolabel prior to biliary/renal excretion and should not be interpreted as an indication of an accumulation potential of foramsulfuron. This view is further supported by the fact that the extent of elimination from the body was independent of dose and frequency of administration.

Elimination

A mean of 95% AD was present in the 0–48 h excreta at the low dose level. Faecal excretion predominated, with only 5.6% of the administered low dose found in the urine. Within 48 h after application of the high-dose, faecal and renal elimination amounted to 97% AD and 1.4% AD, respectively. There was no significant sex difference in the route of excretion and no significant excretion of radiolabelled carbon dioxide. Repeat dosing had no significant effect on the excretion profile.

Metabolism

The metabolism of foramsulfuron showed that at both dose levels the main excretion product was unchanged foramsulfuron, excreted mainly in the faeces. Two metabolic routes were identified leading to the formation of AE F130619, an amine (4-amino-2-[3-(4, 6-dimethoxypyrimidin-2-yl)-ureidosulfonyl]-N,N-dimethylbenzamide), and the cleavage product AE F153745 (4-formylamino-N, N-dimethyl-2-sulfamoyl-benzamide) as minor metabolites. A number of unidentified, minor (<4%), polar metabolites formed from both the phenyl or pyrimidyl ring-labelled compound were also excreted.

The comparative metabolism of [pyrimidine-2-¹⁴C]-foramsulfuron was investigated in animal *in-vitro* systems by incubating the test item separately with liver microsomes from male Wistar rats and humans in the presence of NADPH cofactor at $37 \pm 1^\circ\text{C}$. The results suggest that phase I metabolism is not involved in the biotransformation of Foramsulfuron in rat and human liver microsomes.

Dermal absorption

Dermal absorption in rats *in vivo* was evaluated with a suspension concentrate formulation that was applied both as the undiluted formulation and at the spray dilution concentration. In both cases, the 24-h absorption rate was very low (<2%).

2.6.2. Summary of acute toxicity

Foramsulfuron has been shown to have very low acute toxicity to mammals irrespective of the route of exposure. Only non-specific clinical signs were seen after oral administration of 5000 mg/kg bw/d to rats (piloerection, hunched posture and white soft to liquid faeces) and after inhalation exposure of rats to 5.04 mg/l (principally wet fur, hunched posture with increased respiratory rate and red/brown staining of the head and snout and, in one instance, of the eyes). These signs had completely resolved 4 days following oral treatment and by day 1 after inhalation exposure. There was no evidence of systemic toxicity following acute dermal exposure to 2000 mg/kg.

It was not irritant to rabbit skin (Primary Irritancy Index = 0) and only mildly irritating to rabbit eyes causing slight to moderate conjunctival reddening, slight chemosis and a slight to moderate discharge (Primary Irritancy Index = 6.3). These responses had resolved 48 hours post instillation.

Foramsulfuron did not induce delayed contact hypersensitivity (skin sensitisation) in a Magnusson and Kligman maximisation test.

Due to the data requirements (EU) No 283/2013 a phototoxicity study is required if the molar extinction coefficient is higher than $10 \text{ L} \times \text{mol}^{-1} \times \text{cm}^{-1}$. For foramsulfuron this is the case and a phototoxicity study was conducted and this showed that foramsulfuron does not possess any phototoxic potential.

The results of these studies are summarised in Table 2.6-1.

Table 2.6-1: Acute toxicity data of foramsulfuron

Test	Species	Result
Acute oral toxicity	Rat	LD ₅₀ : >5000 mg/kg bw
Acute dermal toxicity	Rat	LD ₅₀ : >2000 mg/kg bw
Acute inhalation toxicity	Rat	LC ₅₀ : >5.04 mg/l air (4-h nose-only, dust aerosol)
Skin irritancy	Rabbit	Not irritating
Eye irritancy	Rabbit	Not irritating
Skin sensitisation (M & K test)	Guinea pig	Not a skin sensitiser
Phototoxicity	<i>In vitro</i> assay with BALB/c 3T3 cells	No phototoxic potential

Classification is not required according to CLP Regulation (EC) No 1272/2008.

2.6.3. Summary of short-term toxicity

Rat: Continuous short-term (28-day) dietary exposure to 20,000 ppm of foramsulfuron reduced female body weight gain, slightly decreased food intake and increased water consumption. Food conversion was also lowered. No other treatment-related findings were seen. Dietary treatment for 90-days at dose levels up to 20,000 ppm, which approximated to the international regulatory limit dose, had no effects.

No systemic toxicity was seen after repeated dermal administration of up to the international regulatory limit dose, 1000 mg/kg bw/d. Only yellow staining of the treated skin site was observed after repeated exposure.

Mouse: No effects of treatment were seen after both 28-day and 90-day continuous dietary exposure to mice at dose levels of up to 6400 ppm, approximating to 1000 mg/kg bw/d.

Dog: Similarly, gavage treatment of dogs with up to 1000 mg/kg bw/d for 28-days caused no treatment-related findings. In the 90-day gavage study, the only findings at this same high dose level were occasional beige faeces, particularly in females. There were no findings at any other dose level. In dogs, the only finding following gavage administration of up to 1000 mg/kg bw/d for 1 year was slight increase in the incidence of beige faeces (beige being the colour of foramsulfuron) of females at the high dose level. Isolated incidents of beige vomit were also seen in both sexes at this dose level throughout the study.

Table 2.6-2: Data from short-term toxicity studies with foramsulfuron

Study and dose levels	NOAEL		LOAEL		Effects
	ppm	mg/kg bw/d	ppm	mg/kg bw/d	
Rat 28-d oral diet 0–1000–5000–20000 ppm Acceptable as a range-finding study	5000	m: 434 f: 490	20000	m: 1789 f: 1884	females only: ↓ bw gain, ↑ water intake
Rat 90-d oral diet 0–20–200–5000–20000 ppm	20000	m: 1568 f: 1786	–	–	No effects adverse observed
Mouse 28-d oral diet 0–400–1600–6400 ppm Acceptable as a range-finding study	6400	m: 1164 f: 1695	–	–	No adverse effects observed
Mouse 90-d oral diet 0–64–3200–6400 ppm	6400	m: 1002 f: 1178	–	–	No adverse effects observed
Dog 28-d oral gavage 0–40–200–1000 mg/kg bw/d Acceptable as a range-finding study	–	1000	–	–	No adverse effects observed
Dog 90-d oral gavage 0–10–250–1000 mg/kg bw/d	–	1000	–	–	No adverse effects observed
Dog 1-yr oral gavage 0–5–100–1000 mg/kg bw/d	–	1000	–	–	No adverse effects observed
Rat 28-d dermal 0–10–100–1000 mg/kg bw/d	–	1000	–	–	No adverse effects observed

m: male; f: female

2.6.4. Summary of genotoxicity

The genotoxic potential of foramsulfuron was evaluated in a battery of tests which examined gene mutation in bacteria and mammalian cells, chromosome damage *in vitro* and *in vivo* and DNA damage in mammalian cells *in vivo*. The only indication of genotoxicity was a slightly increased incidence of chromosomal aberrations observed in an *in vitro* assay with human lymphocytes. The increased incidences occurred only at the highest dose level tested, 2400 µg/ml, and only in the absence of exogenous metabolic activation. However, since there was no evidence of chromosomal damage *in vivo*, and in view of the negative test result obtained the *in vivo* assay for unscheduled DNA synthesis, this isolated positive test result is considered to be an *in vitro* specific effect. The micronucleus assay does not fulfil current data requirements. Only 1000 polychromatic erythrocytes

were examined for the number of micronuclei which is too little according to the current OECD Test Guideline 474 (1997) where testing on 2000 polychromatic erythrocytes is required. However, no increases in the number of micronuclei in polychromatic erythrocytes was observed. Taken together that no carcinogenic, reproductive toxic and teratogenic effects of foramsulfuron were observed, performing a new study is not considered necessary. Overall, the weight of evidence suggests that foramsulfuron is of no genotoxic concern. The results of the genotoxicity studies are summarised in Table 2.6-3.

Table 2.6-3: Data from genotoxicity studies with foramsulfuron

Study/test system	Result
Reverse mutation in bacteria (<i>S. typhimurium</i> and <i>E. coli</i>)	Negative
Chromosome aberrations <i>in vitro</i> (human lymphocytes)	Weakly positive in the absence of metabolic activation, negative with metabolic activation
Gene mutation in mammalian cells <i>in vitro</i> (Chinese hamster V79 cells, HPRT locus)	Negative
Mouse bone marrow erythrocyte micronucleus <i>in vivo</i>	Negative
Unscheduled DNA synthesis <i>in vivo</i> in rat hepatocytes	Negative

2.6.5. Summary of long-term toxicity and carcinogenicity

In a combined chronic toxicity and oncogenicity study, rats were subjected to continuous dietary treatment for 2 years with dose levels of up to 20000 ppm, corresponding to 849 mg/kg bw/d in males and 1135 mg/kg bw/d in females. Tumour incidences were slightly increased in some tissues/organs (brain, thyroid, uterus, malignant lymphoma), but the increases did not follow a dose-response relationship, were not significantly different when compared to control values and similar to historical control data of the test laboratory. Therefore, these effects were considered not to be related to treatment with foramsulfuron.

In mice, dietary treatment with up to 8000 ppm for 80 consecutive weeks provoked no evidence of oncogenic activity. This high dose level also approximated to the international regulatory limit dose.

Results obtained in these long-term studies are presented below.

Table 2.6-4: Data from long-term toxicity studies with foramsulfuron

Study and dose levels	NOAEL		LOAEL	Effects
	ppm	mg/kg bw/d		
Rat combined chronic toxicity/carcinogenicity 0–100–600–1000–20000 ppm	20000	Males: 849 Females: 1135	–	No effects
Mouse oncogenicity 0–40–800–8000 ppm	8000	Males: 1115 Females: 1358	–	No effects

2.6.6. Summary of reproductive toxicity

No effect on any parameter was seen in the rat two-generation reproduction toxicity study with dietary dose levels of up to 15000 ppm (equivalent to an achieved intake of 1038 mg/kg bw/d for F₀ and F₁ males and 1430 mg/kg bw/d for F₀ and F₁ females).

In developmental toxicity studies conducted with rats and rabbits, oral gavage administration of foramsulfuron during the period of organogenesis had no effect on the development of the conceptus (including no evidence of teratogenicity) of either rats or rabbits at dose levels up to 1000 mg/kg bw/d and 500 mg/kg bw/d, respectively. In rats, no indication of maternal toxicity could be detected at the international regulatory limit dose. In rabbits, however, maternal toxicity, as indicated by reduced body weight gain (only 1.8 g gained between Days 6 and 19 of gestation) and slightly decreased food intake (24% lower than controls) throughout the dosing period, was seen in rabbits at 500 mg/kg bw/d. The rat study deviates from the current OECD Test Guideline 414 in the sense that the exposure period was on days 7-16 and not days 5-15 as currently required. The rabbit study fulfils the current data requirements except that the number of 15 animals with implantation sites at necropsy is just under the required count (16-20 dams) mentioned in the current OECD Test Guideline. As the overall picture indicates no developmental toxic properties of foramsulfuron, the studies are considered to be acceptable despite of these deviations. The results of the reproduction and developmental toxicity studies are summarised in Table 2.6-5.

Table 2.6-5: Summary of reproduction and developmental toxicity studies with foramsulfuron

Study and dose levels	Target	NOAEL	LOAEL	Effects
Rat 2-generation study 0–100–1225–15000 ppm	Parental + reproductive tox.	15000 ppm m: 1038 mg/kg bw/d f: 1430 mg/kg bw/d	–	No effects observed
Rat teratogenicity 0–5–71–1000 mg/kg bw/d	Maternal + developmental toxicity	1000 mg/kg bw/d	–	No effects observed
Rabbit teratogenicity 0–5–50–500 mg/kg bw/d	Maternal toxicity	50 mg/kg bw/d	500 mg/kg bw/d	↓ body weight gain, ↓ food intake, reddish urine
	Developmental toxicity	500 mg/kg bw/d	–	No effects observed

m: male; f: female

2.6.7. Summary of neurotoxicity

Foramsulfuron, a sulfonylurea herbicide, has no structural relationship to neurotoxic substances. Moreover, its very low and non-specific toxicological profile shows no evidence of neurotoxic potential.

In a 28-day neurotoxicity study in rat, there were no treatment related effects on brain weights and no treatment related ophthalmic abnormalities were observed. There were no findings in FOB results related to treatment at any dietary level in either sex. Results of home cage observations, observations during handling, open field observations, reflex / physiologic observations as well as landing foot splay and grip strength measurements were not affected. For the overall 60-minute test session, motor and locomotor activity were not affected by

treatment at any dietary level in either sex. The NOAEL for neurotoxicologic endpoints in rats was 15000 ppm (1208 and 1415 mg/kg bw/day for males and females, respectively).

2.6.8. Summary of further toxicological studies on the active substance

In the studies performed, no evidence of an endocrine effect of foramsulfuron was obvious. No clinical signs, organ weight effects or morphological finding in endocrine organs or organ systems were seen in any sub chronic or chronic/carcinogenicity study which would indicate such an effect. Furthermore, the reproduction toxicity study in rats and the developmental toxicity studies in rats and rabbits did not indicate any impact of foramsulfuron on reproduction or developmental parameters indicating an endocrine effect. Furthermore, foramsulfuron does not fall under the interim definition for Endocrine Disruption.

2.6.9. Summary of toxicological data on impurities and metabolites

There are no significant plant or soil-specific metabolites. All significant metabolites detected in these systems have also been found in mammals. Therefore no studies with metabolites have been conducted.

2.6.10. Summary of medical data and information

There are no reports on poisoning in humans and no reports of any adverse effects on human health during manufacture and formulation.

2.6.11. Toxicological end point for assessment of risk following long-term dietary exposure - ADI

The potential health risk for consumers would result mainly from long-term exposure to residues of foramsulfuron in food. Therefore an evaluation of the consumer risk is normally based on long-term dietary toxicity studies. However, other repeated-dose studies will be taken into consideration if adverse effects are observed at lower dose levels than those obtained in long-term toxicity studies. In accordance with internationally accepted procedures, the Acceptable Daily Intake (ADI) for consumers is derived from the No Observable Adverse Effect Level (NOAEL) in the most sensitive species. A safety factor is applied which takes into consideration the type of effect seen in this study, its severity, reversibility and potential inter- and intra-species variability.

With respect to foramsulfuron, in the majority of studies the No Observable Adverse Effect Level (NOAEL) equates to the No Observable Effect Level (NOEL). These values for the long-term and reproduction toxicity studies are summarised in Table 2.6-6.

Table 2.6-6: Summary of relevant NOAELs/NOELs for deriving the ADI

Toxicity Studies	NOELs/NOAELs		LOAEL	
	ppm	mg/kg bw/d	ppm	mg/kg bw/d
Rat, 2-yr combined chronic tox./carcinogenicity oral diet	20000	849	–	–
Mouse, oncogenicity 80-wk oral diet	8000	1115	–	–
Dog, 1-yr oral toxicity	–	1000	–	–
Rat, two-generation reproduction toxicity	15000	1038	–	–
Rat, developmental oral gavage (maternal toxicity)		1000	–	–
Rabbit, developmental oral gavage (maternal toxicity)	–	50	–	500

Based on the achieved intakes, the rabbit is the most sensitive species and the overall lowest NOAEL was 50 mg/kg bw/d, based on adverse effects on body weight and food consumption observed in dams at the next higher dose (500 mg/kg bw/d) of the oral developmental toxicity study. Given the absence of any carcinogenicity, significant genotoxicity, reproduction toxicity, developmental toxicity or any other special hazard potential, and taking into consideration the low toxicity profile, poor absorption and rapid excretion (predominantly of parent compound), a safety factor of 100 is considered appropriate. Therefore the proposed Acceptable Daily Intake (ADI) is as follows:

$$\text{ADI} = 0.5 \text{ mg/kg bw/day.}$$

2.6.12. Toxicological end point for assessment of risk following acute dietary exposure - ARfD (acute reference dose)

An **ARfD is not allocated** because not necessary. On the basis of its toxicological profile, foramsulfuron is considered unlikely to present an acute hazard. The acute and short term oral toxicity of foramsulfuron is very low. No specific effects were observed up to the limit dose.

2.6.13. Toxicological end point for assessment of occupational, bystander and residents risks – AOEL

Health risks for operators relate to short-term rather than long-term exposure because of the proposed use patterns. Therefore, the NOAELs derived from short-term toxicity and developmental toxicity studies are most appropriate for deriving the Acceptable Operator Exposure (AOEL). In the majority of these studies, the NOAEL equates to the NOEL. These values are summarised in Table 2.6-7.

Table 2.6-7: Summary of relevant NOAELs/NOELs and LOAELs/LOELs for deriving the AOEL

Toxicity Studies	NOAELs		LOAEL	
	ppm	mg/kg bw/d	ppm	mg/kg bw/d
Rat, 28-day oral	5000	434	20000	1789
Mouse, 28-day oral diet	6400	1164	–	–
Dog, 28-day oral diet	–	1000	–	–
Rat, 90-day oral diet	20000	1568		–
Mouse, 90-day oral diet	6400	1002		–
Dog, 90-day oral capsule	–	1000		–
Dog, 1-year oral capsule	-	1000		-
Rat, developmental oral gavage	–	1000		–
Rabbit, developmental oral gavage	–	50		500
Rat, 28-day dermal	–	1000		–

From the above studies, the rabbit is the most sensitive species and the overall lowest NOAEL in this species was 50 mg/kg/day. Therefore, based on this the following Acceptable Operator Exposure Levels (AOELs) is proposed:

Systemic AOEL:

The systemic Acceptable Operator Exposure Level, $AOEL_{(ORAL)}$ is derived as follows from the NOAEL in a rabbit developmental toxicity (teratogenicity) study by applying a standard safety factor of 100. Since absorption was only 20% of the administered dose by the oral route, the AOEL is corrected:

$$AOEL_{(SYS)} = \frac{50 \text{ mg / kg bw / d}}{100} \times 20\% = 0.1 \text{ mg / kg bw / d}$$

The proposed systemic AOEL is as follows:

$$AOEL \text{ (sys.)} = 0.1 \text{ mg/kg bw/day.}$$

2.6.14. Summary of product exposure and risk assessment

Operator exposure to the product Equip was modelled with German model and UK-POEM. Systemic exposure was estimated to be under the AOEL of 0.1 mg/kg bw/day even if no personal protective equipment (PPE) is used. As the product is classified as Skin Irrit. 2 - H315 and needs to be labelled with the statement EUH208, gloves, respiratory protective equipment (RPE) and coverall are required during mixing and loading. The product presents an aspiration hazard (H304) and need to be stored locked up. Re-entry activities after spraying of Equip on the representative use on corn are not necessary. Bystander and resident are not anticipated to be exposed for unacceptably high levels of foramsulfuron.

Exposure of operator, worker, bystander and resident is estimated to be on acceptable level and no risk for health is anticipated when the product Equip is used according to the instructions under the recommended conditions of use.

2.7. RESIDUE

2.7.1. Summary of storage stability of residues

Approximately 20% of the residues representing parent have been lost after 70 days of storage. In contrast to parent, the metabolite AE F153745 has been shown by the present studies to be stable for 866 days, but the variance is high, and the lowest recoveries are less than 50%. The recoveries during storage show marked variation for the parent levels and it is difficult to interpret the results by statistical methods. For the metabolite AE F153745 the results are more coherent and it can be stated that the results show stability for this residue species.

It can be stated that method performance should be better. In spite of these uncertainties, the overall residues are considered to be stable during storage.

2.7.2. Summary of metabolism, distribution and expression of residues in plants, poultry, lactating ruminants, pigs and fish

2.7.2.1 Plants

The metabolism studies in the plant species belonging to one commodity group (i.e. maize) employing two labels were submitted as a part of the original EU dossier. In peer review the studies were considered to be valid and the original submission is regarded as being sufficient.

Since studies on three crop groups are expected and only one studied, the conclusions and definitions are not universal.

To sum up, two primary routes of degradation were found for foramsulfuron in maize (corn).

One pathway involves hydrolytic cleavage of the sulfonylurea bridge yielding N,N-dimethylated aminobenzenesulfonylamide (AE F153745) and the corresponding pyrimidyl metabolite, 4,6-dimethoxypyrimidin-2-amine (iAE F092944), which also is a common metabolite for a few other active substances. The said major metabolite in plants AE F153745 was identified in and thus covered by the rodent metabolism and toxicity studies.

In the other pathway foramsulfuron hydrolyses at the formamide moiety of the phenyl ring to yield aminobenzamide derivative (i.e. AE F130619), which is at the same time a minor metabolite in rodents thus the toxicological tests cover its properties.

All these metabolites are subjected to further degradation leading to the formation of highly polar water soluble components.

In spite of attempts with exaggerated application rate at different development stages only half of the pyrimidyl labeled residue species and one fifth of the phenyl labeled residue species were identified in forage and stover. This leaves some uncertainty in the residue burden evaluation for livestock animals.

The studies indicated low residue levels in all maize (corn) grain samples.

In the grain the residue levels were so low that further identification is not necessary and in this respect the study fulfills its objectives.

In the rodent studies approximately 20% of total radioactivity was absorbed and resulting foramsulfuron residues were rapidly and extensively cleared from the tissues with an elimination half-life in the plasma of 5.4–18.5 hours at the low and 2.4–2.9 hours at the high dose level.

As no new uses have been carried out since the first submission, and as maize (corn) – the AIR3 "safe use" – has already been tested, no new studies have been submitted for the Annex I Renewal by the notifier.

2.7.2.2 Animals

Based on the “non-residue situation” in treated maize studies on metabolism in domestic animals are not necessary. However, corresponding investigations have been undertaken on lactating cows and laying hens. The resulting data are not used for evaluation with respect to the inclusion of foramsulfuron in Annex I of the directive 91/414/EEC because they are not required according to document 7030/VI/95 rev.3.

Any studies to cover pigs, fish and bees were neither requested nor submitted.

2.7.3. Definition of the residue

For plants, the relevant residue definition in animal for monitoring and risk assessment is proposed as foramsulfuron as concluded earlier by EFSA (Nov. 2012; EFSA Journal 2012;10(11):2974).

For possible future uses, one must bear in mind that the residue definition is not universal and applies only for uses (see Appendix 3) covering the cereal crop group, i.e. those commodities, which can be extrapolated from the maize.

Since no metabolism data concerning livestock animals are required, any residue definition for products of animal origin is not considered necessary. Given the low dietary burden, the relevant residue definition in animal for monitoring and risk assessment is proposed as foramsulfuron as concluded earlier by EFSA (Nov. 2012; EFSA Journal 2012;10(11):2974).

Matrices		Residue definition	Reference
Food of plant origin	Risk assessment and Monitoring	Foramsulfuron	DAR (01 April 2001)
Food of animal origin	Risk assessment and Monitoring	Foramsulfuron	EFSA Journal 2012; 10(11):2962

2.7.4. Summary of residue trials in plants and identification of critical GAP

At normal harvest no residues were detected in forage, silage, and cob, as well as in grain above the LOQ of 0.05 mg/kg or 0.01 mg/kg, respectively.

2.7.5. Summary of feeding studies in poultry, ruminants, pigs and fish

Foramsulfuron is authorised for use on maize (corn) that might be fed to livestock. The median and maximum dietary burdens were therefore calculated for different groups of livestock using the agreed European methodology (EC, 1996). The input values for all relevant commodities have been selected according to the recommendations of JMPR (FAO, 2009).

The dietary burden has been calculated according to current requirements and this is provided below. It can be concluded that under the current requirements the calculated dietary burdens for different groups of livestock do not exceed the trigger value of 0.004 mg/kg bw/day.

2.7.6. Summary of effects of processing

As the chronic exposure does not exceed 10 % of the ADI, and of level of individual residue species have low levels, any studies on industrial and/or household processing are not triggered.

2.7.7. Summary of residues in rotational crops

The potential incorporation of soil residues into succeeding and rotational crops was investigated in radish, soya bean and wheat.

The study revealed similar metabolism in rotational crops as in primary (maize). Furthermore, the results show that significant residues in rotational crops are not expected. Thus the same residue definitions can be used for rotational crops and for primary uses. No relevant residues at or above the LOQ of 0.01 mg/kg are expected in succeeding crops.

Specific plant back restrictions related to the use of foramsulfuron are not required.

2.7.8. Summary of other studies

Other special studies have neither been submitted nor requested.

Foramsulfuron is applied on maize (corn) early in the growing season no residues are expected in pollen and bee products. Studies on honey, pollen or royal jelly have neither been submitted nor requested.

2.7.9. Estimation of the potential and actual exposure through diet and other sources

The consumer safety is acceptable, as can be seen from the resulting TMDI of 0.00036 mg/kg bw (German model) or 0.0002 mg/kg bw (WHO model). The values contribute respectively only 0.07% and 0.04% to the proposed ADI of 0.5 mg/kg bw/d (see point B.7.16).

2.7.10. Proposed MRLs and compliance with existing MRLs

Table 7.12.1-2: Current MRLs established by EFSA

Commodity	MRL (mg/kg)	Reference
Maize grain	0.01* (a)	Regulation (EC) No 149/2008 (29 January 2008) EFSA Journal 2012; 10(11):2962
Bovine meat, fat, liver, kidney	0.01*	Regulation (EC) No 149/2008 (29 January 2008) EFSA Journal 2012; 10(11):2962
Sheep meat, fat, liver, kidney	0.01*	Regulation (EC) No 149/2008 (29 January 2008) EFSA Journal 2012; 10(11):2962
Goat meat, fat, liver, kidney	0.01*	Regulation (EC) No 149/2008 (29 January 2008) EFSA Journal 2012; 10(11):2962
Cattle, sheep, goat milk	0.01*	Regulation (EC) No 149/2008 (29 January 2008) EFSA Journal 2012; 10(11):2962

2.7.11. Proposed import tolerances and compliance with existing import tolerances

There are no relevant import tolerances reported at EU level and any CXL have not been applied. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D) depending on the commodity in question.

2.7.12. Conclusion

The metabolism studies do not lend support to universal residue definitions. Storage stability is considered adequate (with some slight deficiencies). The studies have established a no-residue situation in maize (corn), and consequently there is no need to request feeding studies and processing studies. As the MRLs are set at LOQ and ADI is high, the chronic consumer exposure does not raise any concerns whatsoever. Evaluation of acute dietary exposure is not needed, as allocation of an aRfD was not considered necessary.

2.8. FATE AND BEHAVIOUR IN THE ENVIRONMENT

2.8.1. Summary of fate and behaviour in soil

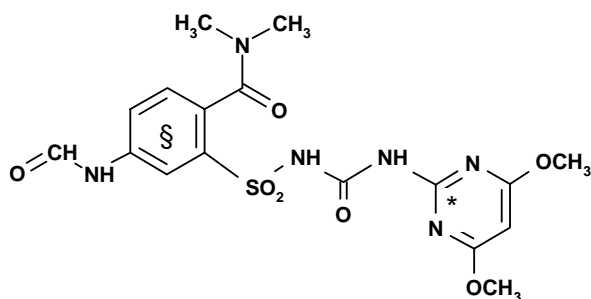
2.8.1.1. Route and rate of degradation of foramsulfuron in aerobic soil

For detailed information please see Volume 3 CA B.8.1.1.1.

The route of degradation in aerobic soil has been investigated under laboratory conditions in three studies following application of phenyl-UL-¹⁴C- and pyrimidyl-2-¹⁴C- labelled active substance to:

- 3 soils under standard conditions of 20°C and moisture at 40 % maximum water holding capacity, MWHC (Judge et al 2000a)
- 1 soil under sterile conditions (Judge et al 2000a)
- 2 soils at 25°C and moisture at 75% of field capacity at 0.33 bar (Judge 1999)
- 1 soil at 10°C and 40 % MWHC and application of phenyl-UL-¹⁴C- and pyrimidyl-2-¹⁴C- labeled active substance (Judge et al 2000b)

All the studies were evaluated during the Annex I inclusion and were considered acceptable by the RMS Germany. These studies were not re-evaluated, since the studies were performed according to the USEPA: 162-1 which is in line with OECD test guideline No. 307: Aerobic and Anaerobic Transformation in Soil. The studies investigating into the environmental fate of foramsulfuron were performed with the following positions of ¹⁴C-radiolabel in the active substance:

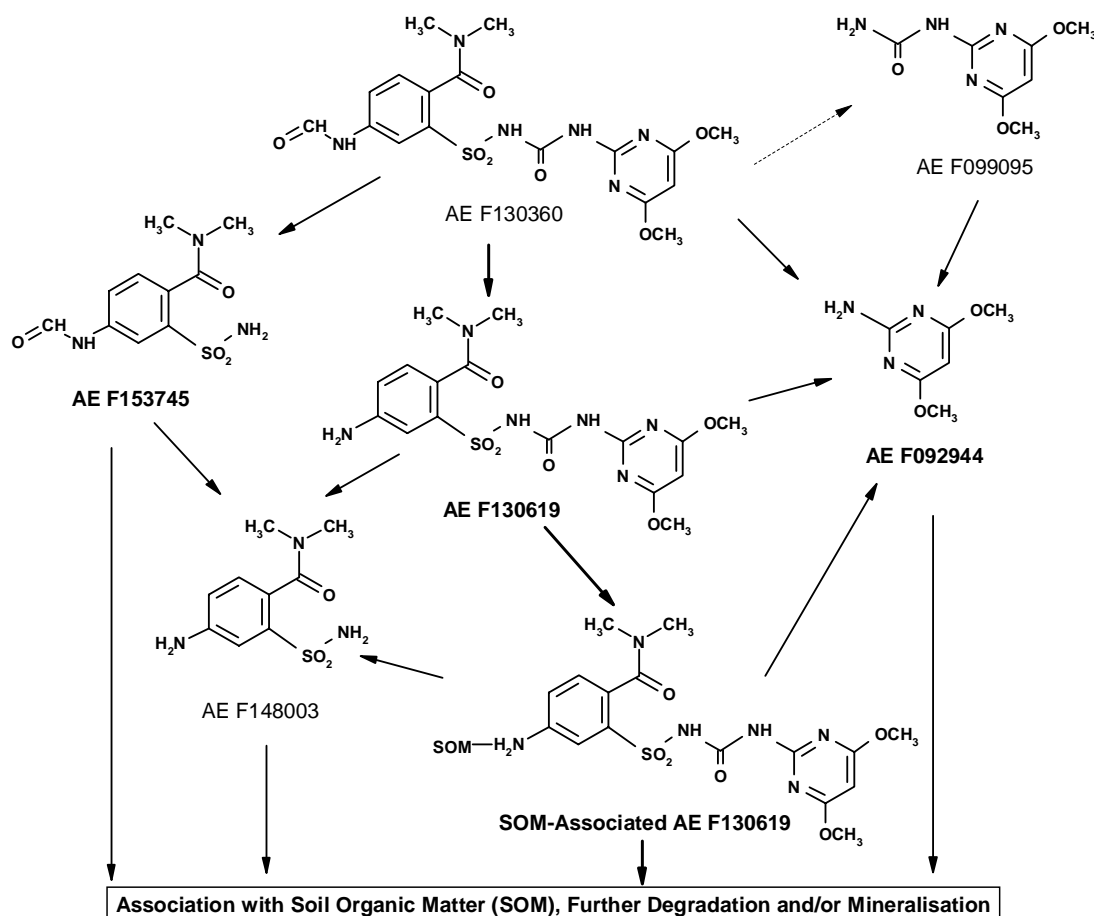


(§) Label 1: [phenyl-UL-¹⁴C]

(*) Label 2: [pyrimidyl-2-¹⁴C]

The degradation of foramsulfuron was found to proceed via two routes, i.e. firstly by hydrolysis of the formamide group of the parent compound to result in the formation of the amino-aryl derivative AE F130619 as the predominant pathway. The second pathway involved cleavage of the 'sulfonylurea bridge' to form AE F153745 and AE F092944. The basic metabolic pattern was identical for all soils tested with metabolites AE F092944, AE F130619 and AE F153745 being observed at maximum values of 17.8% AR, 30.8% and 7.8%, respectively at 20 °C (Table 2.8.1-1). Trace amounts of metabolites AE F099095 and AE F148003 were also found. The tests were amended by separate tests performed after application of ¹⁴C-labelled metabolites AE F092944, AE F130619 and AE F153745 to aerobic soil.

Figure 2.8.1-1. Proposed pathway of metabolism of foramsulfuron (AE F130360) in aerobic soil



The degradation of foramsulfuron and its metabolites was accompanied by the formation of non-extractable residues (NER) and mineralisation to $^{14}\text{CO}_2$. Dependent of radiolabel applied the level of NER reached 55% to 93% AR under aerobic conditions after 100 days of incubation (Table 2.8.1-1). As a consequence mineralisation ranged from 0.2 to 16.3% AR for the same incubation period. The formation of NER could be explained by the binding of the amino-aryl moiety of AE F130619 to soil organic matter. This was demonstrated by direct application of AE F130619 to soils resulting in the same levels of NER as observed from application of ^{14}C -foramsulfuron to soil. The clearly biotic nature of NER formation was underlined by tests with sterilized soils. This was significantly less than the levels observed under laboratory conditions. It clearly demonstrated that metabolism of NER was significant under actual use conditions with NER being part of the natural turnover within the carbon cycle in soil.

Table 2.8.1-1: Summary of studies on route of degradation of foramsulfuron under aerobic, dark conditions.

Study	Soil	Label	Temp	NER (%)	CO ₂ (%)	AE F130619 (%)	AE F153745 (%)	AE F092944 (%)
Judge 2000a	Shuttleworth	Phenyl	20 °C	73.8	0.4	5.5	7.8	
	Orainville	Phenyl	20 °C	85.0	0.5	27.3	1.7	
	Chantepie	Phenyl	20 °C	93.3	1.2	4.2	4.8	
Judge 1999	Iowa	Phenyl	25 °C	84.6	0.3	10.4	2.3	
	North Carolina	Phenyl	25 °C	83.3	0.4	10.0	4.9	
Judge 2000b	Shuttleworth	Phenyl	10 °C	67.5	0.2	4.6	12.9	
Judge 2000a	Shuttleworth	Pyrimidyl	20 °C	54.7	4.5	4.7		16.9
	Orainville	Pyrimidyl	20 °C	93.1	2.5	30.8		3.4
	Chantepie	Pyrimidyl	20 °C	73.1	16.3	5.5		7.9
Judge 1999	Iowa	Pyrimidyl	25 °C	75.0	6.2	9.9		4.9
	North Carolina	Pyrimidyl	25 °C	55.7	11.4	8.8		17.8
Judge 2000b	Shuttleworth	Pyrimidyl	10 °C	66.7	1.2	5.1		12.3

Rate of degradation of foramsulfuron in soil

The kinetic evaluation of the degradation behaviour of foramsulfuron in the three laboratory studies listed above were subject to kinetic evaluation in Schmitt & Mikolasch (2012) and it was conducted following the guidance given by the FOCUS report on kinetic evaluation (FOCUS, 2006).

Data Pre-processing

All radioactive residues in soil were used for the kinetic evaluation. For some of the studies performed for very long periods of up to one year the evaluations for deriving modelling endpoints used only data measured up to day 120 days which is the maximum recommended duration for laboratory studies according to OECD test guideline 307 (2002).

Temperature and Moisture Normalisation

The DT₅₀-values derived were normalised to standard reference temperature 20 °C and soil moisture 100 % field capacity in order to obtain standardised input parameters for predictions of environmental concentrations. This normalisation was conducted according to the standard approach by FOCUS.

Modelling approach

The degradation of foramsulfuron in aerobic soil resulted in the predominant formation (> 80%) of non-extractable residues (NER). Similar results were obtained for tests with metabolites AE F130619 and AE F153745 following their separate application to soil.

The results suggest that the amino group at the phenyl ring of AE F130619 is responsible for such irreversible binding to the soil matrix. The lower portion of bound residues found after application of pyrimidyl labelled AE F130619 can be explained by cleavage of the sulfonylurea bridge as structural element thus losing the respective amino-phenyl containing residues. Metabolite AE F148003 may result from the formation of AE F153745. By containing the same structural element responsible for

irreversible binding AE F148003 has a transient character. AE F148003 was not included into the kinetic evaluations since the compound was observed at trace level only.

The overall importance of bound residues was considered by introduction as a separate compartment into the kinetic evaluations for studies performed with the parent compound foramsulfuron. This resulted in compartmental models as shown in Figure 2.8.1-2 for the phenyl label and in Figure 2.8.1-3 for the pyrimidine label. The inclusion of bound residues into the model optimisation resulted in an improvement of certainty for the parameter determination since more experimental information had been considered.

Figure 2.8.1-2. Compartmental model for degradation of phenyl labelled foramsulfuron in aerobic soil.

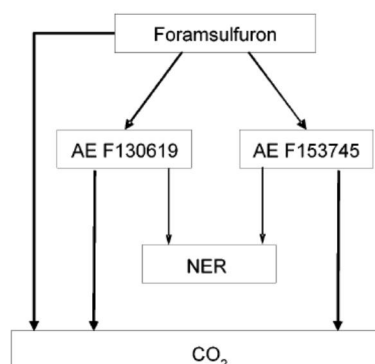
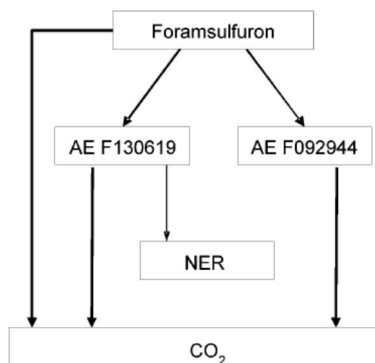


Figure 2.8.1-3. Compartmental model for degradation of pyrimidyl labelled foramsulfuron in aerobic soil.



Summary of calculation of non-normalised DT₅₀-values:

For the parent compound foramsulfuron the kinetic evaluation of soil degradation tests using the SFO approach did not result in acceptable fits to the experimental data. For all but two data sets the evaluation resulted in FOMC to be the optimal fit to describe the degradation data. Instead, the two tests failing the FOMC fit could be described best by the DFOP model. For modelling purposes and for use as non-normalised data prior to normalisation to reference conditions, the DT₅₀-values were back-calculated from the corresponding value of the DT₉₀ derived either by the FOMC or the DFOP fit. The results are summarised in Table 2.8.1-2.

Table 2.8.1-2: DT₅₀ and DT₉₀-values for parent compound foramsulfuron in aerobic soils under laboratory conditions for modelling evaluation and for trigger evaluation

Soil (Origin)	Label position	Non-normalised DT ₅₀ (days)	Non-normalised DT ₉₀ (days)	Non-normalised Pseudo-DT ₅₀ (days)	Normalised Pseudo-DT ₅₀ (days)	Model
		Best fit	Best fit	Modelling	Modelling	
Iowa, 25°C (Judge, 1999)	phenyl	7.1	143.8	43.3	53.0	FOMC
Iowa, 25°C (Judge, 1999)	pyrimidyl	9.2	222.4	67.0	82.0	FOMC
Mean (geometric)		8.1	178.8		65.9	
North Carolina, 25°C (Judge, 1999)	phenyl	7.0	102.6	30.9	29.8	FOMC
North Carolina, 25°C (Judge, 1999)	pyrimidyl	6.7	93.0	28.0	27.0	FOMC
Mean (geometric)		6.8	97.7		28.4	
Shuttleworth, 20°C (Judge, 2000a)	phenyl	7.3	51.8	15.6	10.5	FOMC
Shuttleworth, 20°C (Judge, 2000a)	pyrimidyl	11.5	65.1	19.6	13.1	FOMC
Shuttleworth, 10°C (Judge, 2000b)	phenyl			56.7	29.2	DFOP
Shuttleworth, 10°C (Judge, 2000b)	pyrimidyl			86.6	44.6	DFOP
Mean (geometric)		9.2	58.1		20.6	
Orainville, 20°C (Judge, 2000a)	phenyl	1.2	11.6	3.5	2.0	FOMC
Orainville, 20°C (Judge, 2000a)	pyrimidyl	1.0	10.3	3.1	1.8	FOMC
Mean (geometric)		1.1	10.9		1.9	
Chantepie, 20°C (Judge, 2000a)	phenyl	3.5	35.2	10.6	6.1	FOMC
Chantepie, 20°C (Judge, 2000a)	pyrimidyl	3.5	34.9	10.5	6.1	FOMC
Mean (geometric)		3.5	35.0		6.1	
Mean (geometric) for modelling		-	-		13.5	
Worst case for trigger evaluation (best fit)		9.2	178.8			
Shuttleworth, 10°C (Judge, 2000b)	phenyl	18.5	188.2	29.2		DFOP
Shuttleworth, 10°C (Judge, 2000b)	pyrimidyl	20.5	287.5	44.6		DFOP
Worst case for trigger evaluation		19.5	232.6			

For comparison with EU triggers the kinetic evaluation of degradation in aerobic soil at 20 to 25°C was performed according to FOCUS guidance to result in half-lives ranging from 1.1 to 9.2 days for foramsulfuron. The corresponding values for the DT₉₀ were 10.9 to 178.8 days. The worst case non-normalised half-life of 9.2 days and a DT₉₀ of 178.8 days were used against the persistence triggers. The half-life for foramsulfuron at 10°C was 19.5 days associated by a DT₉₀ of 232.6 days.

For use as modeling endpoints the kinetic evaluations resulted in geometric mean half-lives of 13.5 days for foramsulfuron. The corresponding formation fractions from foramsulfuron were estimated to 0.22 for AE F092944, 0.92 for AE F130619 and 0.22 for AE F153745.

Route of degradation of foramsulfuron in anaerobic soil

For detailed information please see Volume 3 CA B.8.1.2.

The route of degradation in anaerobic soil had been investigated under laboratory conditions in:

- 1 flooded soil at 20°C following application of phenyl-UL-¹⁴C- and pyrimidyl-2-¹⁴C- labeled active substance (Mayer & Pat 2000, amended 2002).

The data requirement was evaluated within the process of evaluation for Annex I inclusion and was considered acceptable by the RMS Germany. The study was not re-evaluated, since the study was performed according to the USEPA: 162-2 which is in line with OECD test guideline No. 307: Aerobic and Anaerobic Transformation in Soil. Degradation of foramsulfuron was slow under the conditions of anaerobic soil testing (DT₅₀ = 165 days). The degradation pathway was similar to that under aerobic conditions as indicated by the same pattern of metabolites formed as observed in aerobic soil degradation tests. However, the low level of metabolites formed resulting in scattering data did not allow for kinetic evaluation to determine degradation rates under anaerobic conditions.

Foramsulfuron is intended for use in corn where anaerobic conditions in soil do not prevail for extended time periods and usually not on a full field plot scale. Metabolites formed under anaerobic conditions will be degraded when the soil turns back to aerobic conditions after a period of low oxygen content. This will prevent accumulation of metabolites in the soil. For these reasons specific studies on anaerobic degradation of relevant metabolites, degradation and reaction products in soil are not required.

Photodegradation of foramsulfuron on soil surface

For detailed information please see Volume 3 CA B.8.1.3.

The route of degradation on irradiated soil surfaces has been investigated under laboratory conditions in:

- 1 soil under standard conditions (20°C, 75 % of field capacity at 0.33 bar) following application of pyrimidyl-2-¹⁴C-labeled active substance (Burri 2000).

The data requirement was evaluated within the process of evaluation for Annex I inclusion and was considered acceptable by the RMS Germany. The study was not re-evaluated, since it was performed according to the US EPA: 161-3. The evaluation revealed that pyrimidyl-2-¹⁴C-labeled foramsulfuron was stable towards photo-chemical transformation under the conditions of the test. Metabolite AE F099095 was observed as the only degradation product clearly below 10% AR in irradiated samples. This compound was also formed in dark control samples being therefore not specific to photolytic processes.

For Annex I Renewal the existing soil photolysis data was amended by a new study performed with phenyl-UL-¹⁴C-labeled active substance as the second position of radiolabel (Hall 2012). The study was considered acceptable by the RMS.

For irradiated samples, the occurrence of metabolites resulting from photo-degradation was generally low resulting in the formation of the hydrolysis product AE F153745 (foramsulfuron sulfonamide) as the only major product at 10.4% by DAT-4. All other transformation products occurred at trace level at or below 2.5% of AR in the course of the study. For dark controls, the predominance of biotical induced degradation is documented by the observation of AE F130619 (foramsulfuron amine) which is well in line with the results of aerobic soil degradation. AE F130619 was observed at maximum values of 38.7% of AR by DAT-2 to show a decline to 17.3% by DAT-10. The formation of other metabolites was low with none of the components observed at more than 1.9% of AR each in the course of the test.

The results were subject to kinetic evaluation. Tests performed with UL-¹⁴C-phenyl-labeled foramsulfuron resulted in an experimental SFO DT₅₀ of 15.9 days. This is equivalent to 47 environmental days for lower light conditions of Athens in the EU. Photolytically induced degradation is significantly slower when compared to biotic processes of degradation in dark control (experimental SFO DT₅₀ of 1.6 day).

Since both degradation processes can be expected to occur in parallel under conditions of the outdoor environment, microbial degradation of residues after application is significantly faster thus leaving low residues of active substance available for photolytic degradation. The contribution of photolytic transformation processes on soil surfaces to the elimination of foramsulfuron from the soil environment is thus regarded as negligible.

Field dissipation data

The data requirement was evaluated within the process of Annex I inclusion by the RMS Germany (2001). The study was not re-evaluated, since field dissipation studies with foramsulfuron are not triggered when following re-calculations of aerobic soil degradation rates in the laboratory. The worst case non-normalised half-life of 11.5 days and 20.5 days were obtained for foramsulfuron at 20 °C and 10 °C, respectively in the same soil.

2.8.1.2. Route and rate of degradation of metabolites in aerobic soil

For detailed information please see Volume 3 CA B.8.1.1.2.

Metabolite AE F130619

In the evaluations for Annex I inclusion information on rate of degradation of metabolite AE F130619 in aerobic soil was derived from the following laboratory test:

- 4 soils under standard conditions of 20°C and moisture at 40 % MWHC following application of phenyl-UL-¹⁴C- and pyrimidyl-2-¹⁴C- labeled metabolite AE F130619 (Judge et al. 2000c; Judge 2000a, amendment). Data sets from laboratory tests were kinetically re-evaluated (Schmitt & Mikolasch 2013).

This study was evaluated within the process of Annex I inclusion and was considered acceptable by RMS Germany. The study was not re-evaluated, since the study was performed according to the US EPA: 162-1 which is in line with OECD test guideline No. 307: Aerobic and Anaerobic Transformation in Soil.

In the study with direct application of AE F130619 to soil apart from the applied substance also potential degradation products (AE F148003, AE F092944 and AE F099095) were analysed. However, in most cases analysis of extractable residues was stopped after 14 days and due to the very short period no reliable information on the kinetics was derivable. In addition the residues observed for the metabolites were generally very low. An exception was given by the trial with soil Chantepie using pyrimidyl labelled substance. In this case considerable residues of AE F092944 were found and samples were analysed up to 120 days. This dataset was tried to be evaluated for deriving endpoints for the metabolite, but it was not possible to achieve an acceptable fit of the kinetic model. Therefore it was decided generally to evaluate only the degradation of the applied substance and to derive a reliable DT₅₀ values for AE F130619. The results for the degradation rate of the metabolite AE F130619 are presented in the Table 2.8.1-3.

Table 2.8.1-3: DT₅₀ and DT₉₀ -values for metabolite AE F130619 in aerobic soil under laboratory conditions for use as modelling input parameters in environmental exposure assessments and for trigger evaluation (values highlighted in green are obtained from studies with the active substance evaluated in Vol 3 under the Section B.8.1.1.1)

Soil	Label position	Non-Normalised DT ₅₀ (days) Modelling	Normalised DT ₅₀ (days) Modelling	Non-Normalised DT ₅₀ (days) Trigger	Non-Normalised DT ₉₀ (days) Trigger	Model
				Best fit	Best fit	
Shuttleworth (Study 1)	phenyl	6.5	4.4	6.5	21.6	SFO
Shuttleworth (Study 1)	pyrimidyl	-	-	-	-	-
Worst case		6.5	4.4	6.5	21.6	
Shuttleworth (Study 2)	phenyl	2.0	3.5	0.8	6.8	FOMC
Shuttleworth (Study 2)	pyrimidyl	1.8	3.1	0.6	6.0	FOMC
Mean (geometric)		1.9	3.6	0.7	6.4	
Orainville (Study 1)	phenyl	0.7	0.4	0.7	2.3	SFO
Orainville (Study 1)	pyrimidyl	0.9	0.5	0.9	3.0	SFO
Mean (geometric)		0.8		0.4	5.1	
Orainville (Study 2)	phenyl	1.4	1.3	0.5	4.6	FOMC
Orainville (Study 2)	pyrimidyl	1.7	1.6	0.4	5.6	FOMC
Mean (geometric)		1.5	0.8	1.5	5.1	
Chantepie (Study 1)	phenyl	0.2	0.1	0.2	0.7	SFO
Chantepie (Study 1)	pyrimidyl	-	-	-	-	-
Worst case		0.2		0.2	0.7	
Chantepie (Study 2)	phenyl	1.5	1.4	0.5	5.0	FOMC
Chantepie (Study 2)	pyrimidyl	1.6	1.4	0.6	5.2	FOMC
Mean (geometric)		1.5	0.6	0.5	5.1	
Illinois (Study 2)	phenyl	8.7	9.0	1.1	18.1	DFOP
Illinois (Study 2)	pyrimidyl	24.7	25.7	1.9	42.2	DFOP
Mean (geometric)		14.7	15.2	1.4	27.6	
Worst case for trigger evaluation				6.5	27.6	
Mean (geometric) for modelling:			2.3			

Study 1: KCA 7.1.2.1.1 /01; Study 2: KCA 7.1.2.1.2 /04

For comparison with EU triggers the kinetic evaluation of degradation in aerobic soil at 20 °C was performed according to FOCUS guidance to result in half-lives ranging from 0.2 to 6.5 days for AE F130619. The corresponding values for the DT₉₀ were from 0.7 to 27.6 days. The worst case non-normalised half-life of 6.5 days and a DT₉₀ of 27.6 days were used against the persistence triggers.

For use as modeling endpoints the kinetic evaluations resulted in geometric mean half-life of 2.3 days for AE F130619. The corresponding formation fraction from foramsulfuron was estimated to 0.92 for AE F130619.

Metabolite AE F153745

For the renewal process, a new study was submitted for the metabolite AE F153745. The route and rate of degradation of metabolite AE F153745 in aerobic soil was derived from the following laboratory test:

- 4 soils under standard conditions of 20°C and moisture at 55 % MWHC following application of [Phenyl-UL-14C] foramsulfuron sulfonamide (AE F153745) (Shepherd & Ripperger 2012). Data sets from laboratory tests were kinetically re-evaluated (Schmitt & Mikolasch 2013).

The study was evaluated by the RMS and was considered acceptable. In the study with direct application of AE F153745 to soil apart from the applied substance also the potential degradation product foramsulfuron aminosulfonamide (AE F148003) was analysed. The formation of AE F148003 was observed at maximum values from 30.7% AR to 67.2% AR in the course of the study in four soils. The degradation of foramsulfuron sulfonamide in aerobic soil is underlined by the formation of non-extractable (bound) residues. The biotic character of bound residue formation is supported by the results of separate samples indicating a lower level of formation for sterilized soils.

Metabolite AE F148003 was also observed at trace level in the studies on aerobic route performed with the parent substance. Considering its overall low occurrence in the total metabolic pathway, the compound was not triggered for take up into the residue definition for environmental risk assessment and therefore also no kinetic evaluation of the degradation of metabolite AE F148003 was performed. The results for the degradation rate of the metabolite AE F153745 are presented in the Table 2.8.1-4.

Table 2.8.1-4: DT₅₀ and DT₉₀ -values for metabolite AE F153745 in aerobic soil under laboratory conditions for use as modelling input parameters in environmental exposure assessments and for trigger evaluation

Soil	Label position	Non-Normalised DT ₅₀ /pseudoDT ₅₀ (days) Modelling	Normalised DT ₅₀ /pseudoDT ₅₀ (days) Modelling	Non-Normalised DT ₅₀ (days) Trigger	Non-Normalised DT ₉₀ (days) Trigger	Kinetic Model
				Best fit	Best fit	
Porterville (Study 1)	phenyl	3.5	3.7	3.3	11.6	SFO
Springfield (Study 1)	phenyl	0.2	0.2	0.8	0.7	SFO
Pikeville (Study 1)	phenyl	1.9	2.5	0.8	6.2	FOMC
Sanger (Study 1)	phenyl	0.3	0.3	0.2	1.0	SFO
Worst case for trigger evaluation				3.3	11.6	
Mean (geometric) for modelling:			0.85			

Study: KCA 7.1.2.1.2 /03

For comparison with EU triggers the kinetic evaluation of degradation in aerobic soil at 20°C was performed according to FOCUS guidance to result in non-normalised half-lives ranging from 0.2 to 3.3 days for AE F153745. The corresponding values for the DT₉₀ were 0.7 to 11.6 days. The non-normalised worst case half-life of 3.3 days associated with a DT₉₀ of 11.6 days from the same soil is used for comparison against trigger endpoints.

For use as modeling endpoints the kinetic evaluations resulted in geometric mean half-life of 0.85 days for AE F153745. The corresponding formation fraction from foramsulfuron was estimated to 0.22 for AE F153745.

Metabolite AE F092944

For the renewal process, a new study was submitted for the metabolite AE F092944. AE F092944 is a common metabolite of the active substances foramsulfuron and nicosulfuron. The submitted study has been subject to evaluation within the Annex I inclusion process of the active substance nicosulfuron and it was therefore included into the publicly available version of the DAR of this existing active substance prepared by RMS UK dated June 2006. The study was performed according to OECD test guideline No. 307: Aerobic and Anaerobic Transformation in Soil and was not re-evaluated by RMS.

The route and rate of degradation of metabolite AE F092944 in aerobic soil was derived as following:

- 3 soils under standard conditions of 20°C and moisture at 40 % MWHC following application of [pyrimidine-14C] AE F092944 (Voelkel 2006). Data sets from laboratory tests were kinetically re-evaluated (Schmitt & Mikolasch 2013).

Following 104 days of incubation, values of non-extractable radioactivity ranged from 29.6 to 39.4% AR accompanied by the formation of ¹⁴CO₂ amounting to 48.6 to 56.9%. While no values were reported for total extractable residues, the amount of AE F092944 extracted from soil declined from 90.8% of AR (soil Collombey), 93.7% (soil Speyer 2.2) and 91.4% (soil Les Evouettes) by day zero to 0.8%, 4.7% and 8.3% after 104 days of incubation. Small amounts of at least 7 other unidentified components were observed in soil extracts. The largest fraction was represented by two polar components being below 4.2% of AR in all soils. None of the other components exceeded 2.6% of AR in the course of the study.

The results for the degradation rate of the metabolite AE F092944 are presented in the Table 2.8.1-5.

Table 2.8.1-5: DT₅₀ and DT₉₀-values for metabolite AE F092944 in aerobic soil under laboratory conditions for use as modelling input parameters in environmental exposure assessments and for trigger evaluation (values highlighted in green are obtained from studies with the active substance evaluated in Vol 3 under the Section B.8.1.1.1)

Soil	Label position	Non-Normalised DT ₅₀ /pseudoDT ₅₀ (days) Modelling	Normalised DT ₅₀ / pseudoDT ₅₀ (days) Modelling	Non-Normalised DT ₅₀ (days) Trigger	Non-Normalised DT ₉₀ (days) Trigger	Model
Shuttleworth (Study 1)	pyrimidyl	141.7	94.9	141.7	470.4	SFO
Chantepie (Study 1)	pyrimidyl	254.4	147.6	254.4	844.6	SFO
Collombey (Study 3)	pyrimidyl	2.9	3.4	2.9	9.6	SFO
Speyer 2.2 (Study 3)	pyrimidyl	10.5	12.4	4.9	34.8	FOMC
Les Evouettes (Study 3)	pyrimidyl	21.8	19.6	9.0	72.4	FOMC
Geometric mean for modelling			25.9			
Overall worst case for trigger evaluation (Best fit)				254	845	

Study 1: KCA 7.1.2.1.1 /01; Study 3: KCA 7.1.2.1.2 /07

For comparison with EU triggers the kinetic evaluation of degradation in aerobic soil at 20 °C was performed according to FOCUS guidance to result in half-lives ranging from 2.9 to 254.4 days for AE F092944. The corresponding values for the DT₉₀ were 9.6 to 845 days. The non-normalised worst case half-life of 254 days associated with a DT₉₀ of 845 days from the same soil is used for comparison against trigger endpoints.

For use as modeling endpoints the kinetic evaluations resulted in geometric mean half-life of 25.9 days for AE F092944. The corresponding formation fraction from foramsulfuron was estimated to 0.22.

2.8.2. Assessment in relation to the P-criteria

The criteria for persistence in soil, as stated in Annex II to Regulation (EC) 1107/2009, are DT₅₀ 120 days (PBT) and 180 days (POP and vPvB). It is assumed that these criteria represent a constant rate of degradation over the decline curve, i.e. that single first order (SFO) kinetics has been assumed implicitly when the criteria were defined. To allow a comparison against the criteria also for results derived by other kinetic models than SFO the RMS has divided the FOMC/DFOP DT₉₀s by 3.3.2 (since SFO DT₅₀ x 3.3.2 = SFO DT₉₀).

All results for foramsulfuron from laboratory studies are clearly below these criteria. This is the case also for major soil metabolites AE F153745 and AE F130619. Only for one of the metabolites, AE F092944, did the DT₅₀s exceed the criterion for PBT in two soils and in one soil also the criterion for POP/vPvB.

2.8.3. Adsorption, desorption and mobility in soil

For detailed information please see Volume 3 CA B.8.2.1.

Adsorption/desorption of the foramsulfuron

This data requirement has been evaluated within the process of Annex I inclusion (2001) and was considered acceptable by RMS Germany. The study was not re-evaluated by RMS, since the OECD test guideline No.106: Adsorption -- Desorption Using a Batch Equilibrium Method has not been revised after Annex I inclusion. The adsorption of the active substance foramsulfuron to soil was investigated under conditions of the laboratory in:

- 5 soils under standard conditions of batch equilibrium tests at 20°C following application of phenyl-UL-¹⁴C- labeled active substance (Allan et al 2000).

Table 2.8.3-1: Sorption behaviour of foramsulfuron (AE F130360) in 5 soils

Soil	%OC	% Clay	pH (CaCl ₂)	CEC	Ads KF (mL/g)	Ads K _{OC} (mL/g)	Ads 1/n
Maquoketa, US (EFS-16)	1.73	29.2	7.2	16.2	2.61	151	0.96
Pikeville, US (EFS-21)	0.47	4.8	6.2	2.2	0.42	89	0.82
Münster, D (EFS-22)	1.80	6.0	5.5	5.6	0.91	51	0.86
Shuttleworth, UK (EFS-24)	0.81	6.0	6.4	3.7	0.31	38	0.86
Chantepie F (EFS-25)	1.84	40.0	5.4	10.0	1.17	63	0.87
Geometric mean Ads K_{OC} and arithmetic mean of 1/n						69.7	0.87

CEC = Cation Exchange Capacity

Adsorption/desorption of the metabolites

The adsorption/desorption studies with all the metabolites were evaluated within the process of Annex I inclusion (2001) and were considered acceptable by RMS Germany. Studies with the metabolites have not been re-evaluated by RMS, since the OECD test guideline No.106: Adsorption -- Desorption Using a Batch Equilibrium Method has not been revised after Annex I inclusion.

Metabolite AE F153745

The adsorption of the metabolite AE F153745 to soil was investigated under conditions of the laboratory in:

- 4 soils under standard conditions of batch equilibrium tests following application of phenyl-UL-¹⁴C-labeled test substance (Reynolds 1999).

Table 2.8.3-2: Sorption behaviour of AE F153745 in 4 soils

Soil	%OC	% Clay	pH (CaCl ₂)	CEC	Ads K _F (mL/g)	Ads K _{OC} (mL/g)	Ads 1/n
Shuttleworth, US	0.81	6.0	6.9	3.67	0.51	63	0.98
Chantepie, F	4.09	37.2	6.2	13.77	1.43	35	0.97
Wonderpark, US	3.0	6.0	7.7	19	1.49	50	0.92
Pikeville, US	2.07	19.8	5.1	10.61	0.99	48	1.00
Geometric mean Ads K_{OC} and arithmetic mean of 1/n						48	0.97

CEC = Cation Exchange Capacity

Metabolite AE F130619

The adsorption of the metabolite AE F130619 to soil was investigated under conditions of the laboratory in:

- 4 soils under standard conditions of batch equilibrium tests following application of phenyl-UL-¹⁴C-labeled test substance (Allan & Pate 2000).

Table 2.8.3-3: Sorption behaviour of AE F130619 in 4 soils

Soil	%OC	% Clay	pH (CaCl ₂)	CEC	Ads K _F (mL/g)	Ads K _{OC} (mL/g)	Ads 1/n
Wonderpark, US	3.0	6.0	7.2	19	1.90	63	0.93
Shuttleworth, US	0.81	6.0	6.4	3.67	0.36	44	0.93
Orainville, F	1.99	32.2	7.4	7.99	0.79	40	0.90
Pikeville, US	2.07	19.8	4.5	10.61	2.98	144	0.94
Geometric mean Ads K_{OC} and arithmetic mean of 1/n						63.2	0.93

CEC = Cation Exchange Capacity

Metabolite AE F092944

The adsorption of the metabolite AE F092944 to soil was investigated under conditions of the laboratory in:

- 8 soils under standard conditions of batch equilibrium tests following application of non-labeled test substance (Schollmeier & Eyrich 1992).

Table B.8.2.3-4: Sorption behaviour of AE F092944 in 8 soils

Soil	%OC	% Clay	pH (CaCl ₂)	CEC	Ads K _F (mL/g)	Ads K _{OC} (mL/g)	Ads 1/n
S 2.1, D	1.17	3.50	5.0	3.95	2.47	211	0.69
LS 2.2, D	2.91	5.70	5.0	10.59	2.59	89	0.86
SL 2.3, D	1.32	8.90	4.7	4.68	8.25	625	0.65
Arizona A, US	0.16	8.75	8.0	3.39	1.05	663	0.52
Arizona B, US	0.26	19.47	7.95	10.78	1.82	696	0.63
SLV, D	1.04	11.60	6.1	6.60	4.11	395	0.78
SL 2, US	0.72	18.10	5.6	16.10	81.30	11289	0.58
Kanada, Canada	1.80	56.47	7.7	39.54	16.50	917	0.62
Geometric mean Ads K_{OC} and arithmetic mean of 1/n						621.1	0.67

CEC = Cation Exchange Capacity

Column leaching studies

For detailed information please see Volume 3 CA B.8.2.2.

Column leaching studies with the foramsulfuron and its major metabolites AE F130619, AE F153745 and AE F092944 in soil were not performed as the data on their persistence under aerobic conditions (e.g. DT₅₀) and their adsorption coefficients determined in laboratory studies allow for full assessment of the mobility of these substances in different soils. Such data are sufficient enough for further environmental risk assessment and hence column leaching studies are therefore regarded as not necessary.

Field leaching/lysimeter studies

For detailed information please see Volume 3 CA B.8.2.3.

The leaching of foramsulfuron and its major metabolites AE F130619, AE F153745 and AE F092944 was investigated in two lysimeter studies. The study with application of pyrimidyl-2-¹⁴C-labeled active substance was evaluated within the process for Annex I inclusion and was considered acceptable by the RMS Germany. This study was not re-evaluated. This experiment revealed that even under the worst case realistic conditions for leaching, neither foramsulfuron nor any of its soil metabolites were found to leach at concentrations above the trigger 0.1 µg/L.

Another lysimeter study was submitted for the renewal process in which the fate and mobility of pyrimidyl-2-¹⁴C-labelled foramsulfuron ([¹⁴C]-AE F130360) was investigated in 3-year experiment in two lysimeters at a rate of 2 x 45 g/ha per season to maize, together with the non-labelled safener compound Isoxadifen (Burr & Mackenzie 2001). The study was evaluated and was considered acceptable by RMS.

The annual average concentrations of [¹⁴C]-AE F130360 residues in leachates after three experimental years was 4.91% and 3.85% AR. The highest annual average concentration of total radioactive residues in leachates was 0.678 µg a.s.-equiv./L. The radioactivity in leachates was separated by

HPLC/fraction collection/LSC into characteristic profiles. The mean annual concentration of foramsulfuron was 0.005 µg/L in the first year with none detected in subsequent years. AE F130619 was found to reach a maximum annual average concentration of 0.003 µg a.s.-equiv./L in each lysimeter. No other known metabolites were detected in any leachate sample. The remainder of radioactivity was composed of highly polar components or material that co-eluted with UV associated organic material.

2.8.4. Summary of fate and behaviour in water and sediment

2.8.4.1. Abiotic degradation in water

Hydrolysis

For detailed information please see Volume 3 CA B.8.4.1.1.

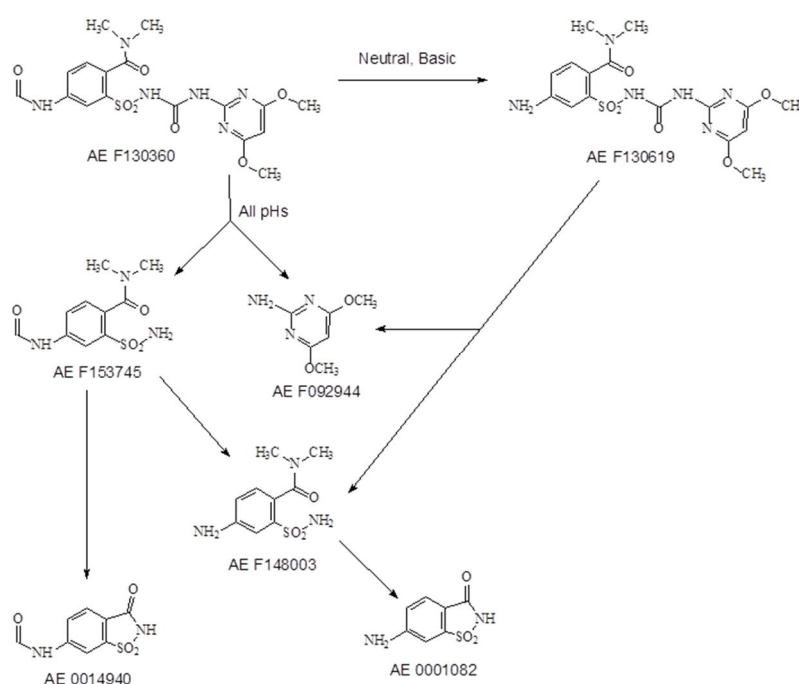
This data requirement has been evaluated within the process of Annex I inclusion (2001) and was considered acceptable by RMS Germany. The study was not re-evaluated by RMS, since the study was performed according to the OECD test guideline No.111: Hydrolysis as a Function of pH. The test guideline has been revised in 2004, but the main principles of the test remained.

The abiotic hydrolysis of foramsulfuron was investigated in a study with:

- sterile aqueous buffer at pH 4, 5, 7 and 9 following application of phenyl-UL-¹⁴C- and pyrimidyl-2-¹⁴C-labeled active substance following incubation at 25°C and 40°C in the dark (Allen & Allen 2000).

The proposed hydrolysis pathway of foramsulfuron in sterile aqueous buffer is summarised in Figure B.2.8.4.1-1.

Figure 2.8.4.1-1: Proposed hydrolysis pathway of foramsulfuron in sterile aqueous buffer



Hydrolysis of foramsulfuron was shown to be dependent on pH and the half-lives of foramsulfuron under sterile aqueous buffer conditions are summarised in Table 2.8.4.1-1. Foramsulfuron was found to form AE F092944 and AE F153745 as major (i.e. >10% AR) hydrolysis products in acidic water system. The compounds AE F092944 and AE F153745 are therefore to be considered in surface water risk assessment.

Table 2.8.4.1-1: Half-lives of foramsulfuron in sterile aqueous buffer at 25°C and 40°C

pH	Half-life (days)	
	25 °C	40 °C
4	3.7	0.41
5	10.1	1.1
7	128	19.4
9	132	36.3

Direct photochemical transformation in water

For detailed information please see Volume 3 CA B.8.4.1.2.1.

The direct photochemical transformation in water was evaluated within the process for Annex I inclusion and were considered acceptable by RMS Germany. The study was not re-evaluated by RMS, since the study was performed according to the US EPA: 161-2 which is in line with the OECD Test No. 316: Phototransformation of Chemicals in Water – Direct Photolysis (2008). The study was performed in buffer solution with pH 7, in which foramsulfuron is hydrolytically stable.

The direct photolysis of foramsulfuron was investigated in a study with:

- sterile aqueous buffer at pH 7 following application of phenyl-UL-¹⁴C-labeled active substance and irradiation with artificial sunlight (xenon light, 290 nm cut off) at 25° (Schmidt & Buerkle 1999)

The evaluation revealed that photolytic degradation of foramsulfuron was negligible to result in photolytic half-lives from 500 days to 538 days when being referenced to natural sunlight and considering a 12 hours day/night interval. Consequently, formation of photo-degradation products was poor as represented by the minor compound 'M1' found at 3.9% AR in maximum in the course of the study.

However, new information generated later indicated that foramsulfuron may undergo indirect photochemical degradation in natural water. The results were thus in some contradiction to the existing data in sterile aqueous buffer. Therefore new data were generated by re-investigation of the behavior of foramsulfuron in sterile aqueous buffer at lower test concentration than submitted previously.

For renewal process, a new study on phototransformation of [¹⁴C]foramsulfuron in aqueous pH 7 buffer was submitted and evaluated by RMS and was considered acceptable. The study was performed in buffer solution with pH 7, in which foramsulfuron is hydrolytically stable.

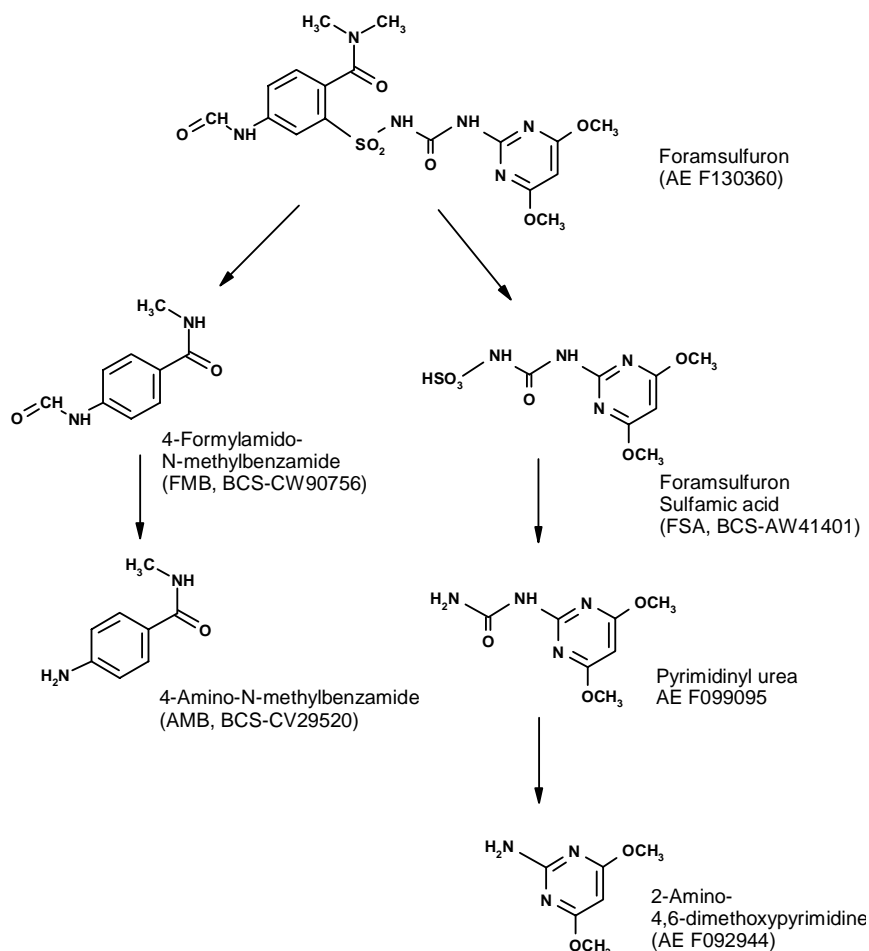
The direct photolysis of foramsulfuron was investigated in a study with:

- sterile aqueous buffer at pH 7 following application of [phenyl-UL-¹⁴C] and [pyrimidine-2-¹⁴C] labelled foramsulfuron and irradiation with artificial sunlight (xenon light, 290 nm cut off) at 25° (Hall 2012)

The kinetic evaluation of foramsulfuron degradation data was performed with KinGui, Version 1.1 by using the three models SFO, FOMC and DFOP for fitting. The photolytic degradation of foramsulfuron in sterile aqueous buffer solution was moderate to result in photolytic half-lives of 11.6 and 14.9 days for phenyl and pyrimidyl labelled active substance, respectively, when being referenced to natural light conditions of Athens, Greece, and considering 12 hours day/night intervals.

Irradiation of phenyl-UL-¹⁴C-labeled foramsulfuron resulted in formation of the major photo-degradation products 4-formamido-N-methylbenzamide and, 4-amino-N-methylbenzamide observed at maximum values of 16.6% and 10.2% of AR in the course of the study (Figure 2.8.2-2). Irradiation of pyrimidine-2-¹⁴C-labeled foramsulfuron resulted in formation of major photo-degradation products sulfamic acid and the pyrimidinyl urea compound AE F099095 observed at maximum values of 14.2% and 35.2% of AR in the course of the study (Figure 2.8.4.1-2). The metabolites are therefore to be considered in surface water risk assessment.

Figure 2.8.4.1-2: Photolysis of foramsulfuron in sterile aqueous buffer solution



Determination of the quantum yield

For renewal process, a new study on determination of the quantum yield and assessment of the environmental half-life of the direct photo-degradation in water was submitted and evaluated by RMS and was considered acceptable.

The UV-VIS adsorption spectra of foramsulfuron was investigated in a study with:

- foramsulfuron in purified water and buffers at pH 7 and pH 9 with irradiation in a merry-go-round device. In addition, the intensity of irradiation was determined by actinometry (Heinemann 2013)

The UV-VIS absorption spectra of foramsulfuron were very similar in pure and the various aqueous buffer solutions. One adsorption maximum was found at 249 nm, thus resulting in no significant overlap of adsorption with the spectrum of visible sunlight, i.e. within the environmentally relevant range of wave length starting at 290 nm to approximately 800 nm. The molar extinction coefficient ϵ of foramsulfuron in pure water was determined to 2257 L/mol x cm at a wave length of 290 nm and 1899 L/mol x cm at 295 nm.

A decline of approximately 12 to 14% was found for foramsulfuron in aqueous solutions in the course of the quantum yield determination experiments. The actinometric determination of light intensity resulted in a mean value of 6.18×10^{-4} for the quantum yield Φ . Based on the value determined for the quantum yield and the molar extinction coefficients determined for wave lengths in the range of 295 to 490 nm, a DT_{50} value of 61 days for summer and a DT_{50} value of 647 days for winter were derived for 50th degree latitude. The results of quantum yield determination and its associated estimation of direct photo-transformation in aqueous solution indicate a limited contribution of this potential route of degradation to the overall elimination of foramsulfuron in the environment.

Indirect phototransformation in water

For detailed information please see Volume 3 CA B.8.4.1.2.2.

For renewal process, two new studies on indirect phototransformation in natural water were submitted. Since indirect photolysis was not a data requirement it was not evaluated within the process for Annex I inclusion. These studies were evaluated by RMS and were considered acceptable. Studies were performed in buffer solutions with pH >7.8, in which foramsulfuron is hydrolytically stable.

The indirect photolysis of foramsulfuron was investigated in:

- sterile natural water at pH 8.3 following application of [phenyl-UL-¹⁴C] labelled foramsulfuron and irradiation (xenon light, 290 nm cut off) at 25°C (Meyer 2009)
- sterile natural water at pH 7.9 following application of [pyrimidine-2-¹⁴C] labelled foramsulfuron and irradiation (xenon light, 290 nm cut off) at 25°C (Meyer 2008)

Following irradiation of [phenyl-UL- ^{14}C] labelled foramsulfuron, AE F130619, 4-formamido-N-methylbenzamide and 4-amino-N-methylbenzamide were formed as major products at maximum values of 10.7% (day 1), 19.7% (day 3) and 12.8% (day 4), respectively (Figure 2.8.2-3). Additionally, foramsulfuron sulfonic acid was found as a minor product at 6.7% AR in maximum (day 4).

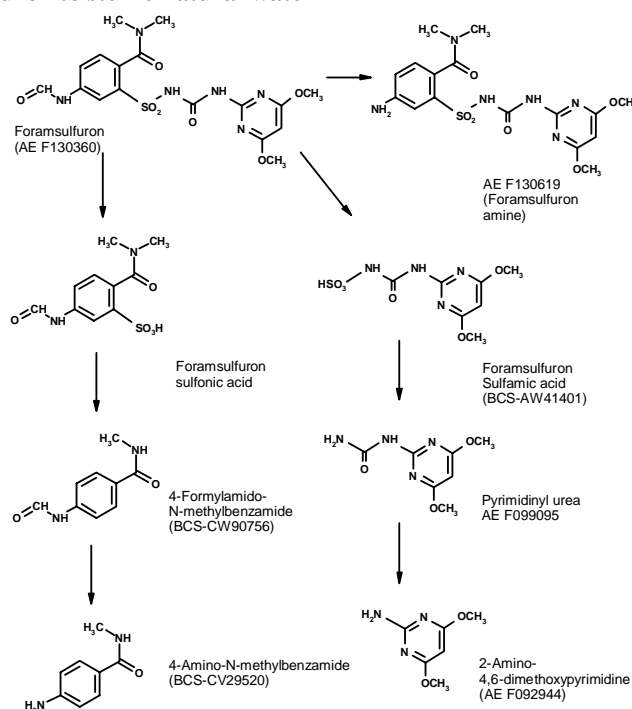
Irradiation of [pyrimidine-2- ^{14}C] foramsulfuron resulted in the formation of the urea-type compound AE F099095, foramsulfuron sulfamic acid and AE F092944 at maximum values of 19.7% (day 5), 17.6% (day 5) and 26.5% (day 5), respectively (Figure 2.8.2-3). Additionally, AE F130619 was found as a minor product at 6.1% AR in maximum (day 1).

The kinetic evaluation of foramsulfuron degradation data was performed with the software KinGui, Version 1.1 by using the SFO model for fitting.

For phenyl-labelled foramsulfuron the experimental half-life was determined to 2.1 days and for pyrimidine-labelled foramsulfuron to 1.9 days for irradiated samples while degradation was slow in dark controls showing a DT₅₀ of 92.4 days and 65.9 days, respectively. The experimental DT₅₀ values have been calculated with no correction for (insignificant) degradation processes in the dark. When transferring the results to outdoor conditions for Athens, Greece considering the (lower) light intensities of natural sunlight, half-lives are 10.7 days for phenyl-labelled and 9.6 days for pyrimidine-labelled foramsulfuron.

According to the Commission regulation No 283/2013 amending the regulation 1107/2009 the indirect photochemical degradation is not a mandatory data requirement. However, the results show that indirect photolysis may contribute to some extent to degradation of foramsulfuron in the aquatic environment, at least in alkaline environment where hydrolysis is not relevant route of degradation. Therefore the major metabolites formed have to be considered in the aquatic risk assessment.

Figure 2.8.4.1-3: Indirect photolytic degradation after application of phenyl- or pyrimidine-labeled foramsulfuron to sterile natural water



2.8.4.2. Biological degradation in water

Ready biodegradability

The data requirement was evaluated within the process for Annex I inclusion. The evaluation revealed that foramsulfuron can be regarded as not readily biodegradable which is supported by the results of biological degradation tests performed on aerobic mineralization in surface water and sediment/water in addition below.

Aerobic mineralisation in surface water

For detailed information please see Volume 3 CA B.8.4.2.2.

Being a new data requirement a new study on aerobic mineralisation of foramsulfuron in surface water were submitted. Since aerobic mineralisation in surface water was not a data requirement it was not evaluated within the process for Annex I inclusion. The study was evaluated by RMS and was considered acceptable. The pH of the tested natural water was 7.5, in which pH the hydrolysis is insignificant. According to the TG the most stable part should be ^{14}C labelled to ensure the determination of the total mineralisation. In this study only [phenyl-UL- ^{14}C] foramsulfuron was used. This can be considered acceptable, since there was no degradation of the active substance in the test. In addition, the water/sediment study shows that phenyl and pyrimidyl labelled foramsulfuron does not mineralize in any significant level. Biological activity of the test water was confirmed by the degradation of reference substance UL- ^{14}C -benzoic acid within 14 days of incubation.

The aerobic mineralisation of foramsulfuron in surface water was investigated in:

- non-sterile natural water of pH 7.5 at 22°C and at two test concentrations following application of phenyl-UL- ^{14}C -labeled-labeled active substance (Fahrbach 2013)

Biotransformation of phenyl-labeled foramsulfuron was negligible to result in values of 96.2% AR at time zero to 93.8% after 58 days for the low dose and 98.3% AR at time zero to 94.3% after 58 days for the high dose. Hence, mineralisation of foramsulfuron in non-sterile natural water was insignificant under the ‘pelagic’ conditions of the test. Formation of minor fractions added up to maximum values of 6.1% after 58 days distributed into two components with none present at more than 4.6% AR in the course of the study. Consequently no major and distinct transformation products were observed requiring further assessment in environmental exposure assessments.

No experimental value could be calculated for the DT_{50} of foramsulfuron in water under conditions of aerobic mineralisation testing.

Route of degradation of foramsulfuron in water sediment system

For detailed information please see Volume 3 CA B.8.4.2.3.

The degradation study of foramsulfuron in two water sediment system was evaluated within the process for Annex I inclusion and were considered acceptable by RMS Germany. The study was not re-evaluated, since it was performed according to the US EPA: 162-4 which is in line with OECD Test

guideline No. 308: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems (2002). Two contrasting sediment-water systems were used to cover the pH dependent hydrolysis.

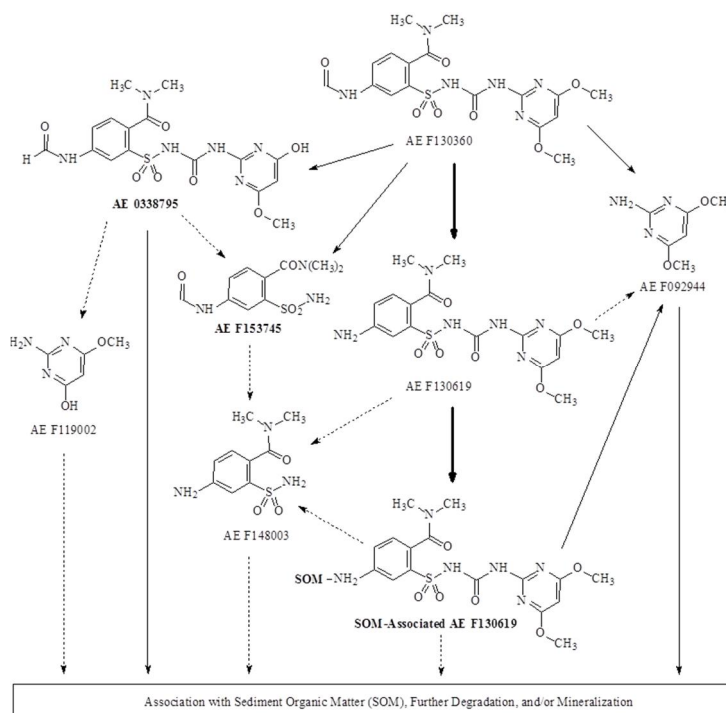
The degradation of foramsulfuron under conditions of water/sediment testing was investigated in:

- 2 contrasting sediments and their associated water at 20°C in the dark for a maximum of 365 days following application of phenyl-UL-¹⁴C- or pyrimidyl-2-¹⁴C-labeled active substance. The two systems were: a silty clay loam from Pikeville (USA) and a sand from Hoechst (Germany) and their respective overlying water at 20°C. The Pikeville water/sediment system was acidic having sediment pH of 5.7 and water pH of 6.2 whereas the Hoechst system was alkaline having sediment pH of 7.8 and water pH of 8.4 (Judge et al 2000).

The evaluation revealed that foramsulfuron completely dissipated in water/sediment systems by a combination of partitioning to the sediment from the water phase and also degradation in water and sediment. Degradation of foramsulfuron proceeded via three pathways in total (Figure 2.8.2-4) with de-methylation at an oxygen atom resulting in AE 0338795 to be the major route. AE 0338795 was subsequently degraded completely in the test systems. Foramsulfuron also degraded via hydrolysis at the formamide moiety to form AE F130619 while hydrolysis at the 'sulfonyl urea bridge' resulted in the formation of AE F153745 and AE F092944. Degradation of foramsulfuron is facilitated by lower pH (hydrolysis) and microbial activity. The degradation was accompanied by significant formation of non-extractable residues (NER; 93.1 %) to undergo slow further degradation within the normal organic carbon material turnover and insignificant formation of CO₂ (max 6.2 %).

The results of degradation tests in water/sediment systems under conditions of the laboratory resulted in the metabolic pathway summarised in Figure 2.8.2-4.

Figure 2.8.4.2-1: Proposed pathway of metabolism of foramsulfuron in water/sediment systems



Foramsulfuron was degraded to major metabolites AE 0338795 (which was subsequently degraded completely) AE F153745 and minor metabolites AE F130619 and AE F092944 (Table 2.8.4.2.-1).

Table 2.8.4.2-1: The maximum amount of metabolites AE F130619, AE 0338795, AE F153745 and AE F092944 formed in two water sediment systems in percentage (%) of applied radioactivity.

	System	Label	AE F130619 (%)	AE 0338795 (%)	AE F153745 (%)	AE F092944 (%)
Total system	Pikeville	Phenyl	1.4	14.0	24.6	7.3
	Pikeville	Pyrimidyl	1.4	13.9		
	Hoechst	Phenyl	5.6	14.5	12.7	1.4
	Hoechst	Pyrimidyl	7.0	23.7		
Water phase	Pikeville	Phenyl	1.1	9.0	24.6	2.2
	Pikeville	Pyrimidyl	0.8	9.4		
	Hoechst	Phenyl	4.5	5.7	12.3	1.4
	Hoechst	Pyrimidyl	5.7	17.0		
Sediment	Pikeville	Phenyl	0.5	5.0	13.6	6.7
	Pikeville	Pyrimidyl	0.6	5.7		
	Hoechst	Phenyl	1.2	6.1	0.5	0.4
	Hoechst	Pyrimidyl	1.4	6.8		

Rate of degradation of foramsulfuron and its metabolites in water sediment system

The kinetics of dissipation from water and sediment and the degradation of foramsulfuron in total system were evaluated from data of tests performed in two water/sediment systems with two positions of radiolabel described above (Schmitt & Mikolasch 2013).

RMS considers that the kinetic evaluation of the phenyl and pyrimidyl labelled foramsulfuron and its metabolites was performed according to the DegKinetics Report (2006). The initial amount of the parent compound was free fitted and the initial amount for metabolites was fixed to a value of zero. All data were weighted equally. Level I dissipation half-lives of foramsulfuron and its metabolites AE F130619, AE F153745, AE F092944 and AE 00338795 for water and sediment were determined as well as the degradation DT₅₀ for the total system. The dissipation from the sediment was calculated on the basis of a conservative approach to result in "apparent" dissipation times by starting at the time point of maximum occurrence followed by the decline, if possible. No evaluations according to Level II were performed since not regarded as mandatory. RMS agrees that the Level 1 values, system DegT_{50/90}; water column DisT_{50/90} and sediment DisT_{50/90} can be used for persistence end point evaluation.

Modelling approach

For kinetic degradation parameters in total systems, the proposed metabolic pathway as given in Figure 2.8.4.2-1 was converted into multi-compartment models illustrated in Figure 2.8.4.2-2 (phenyl-label) and Figure 2.8.4.2-3 (pyrimidine-label). Each compound was represented by one compartment as the total of measured occurrences in water and sediment with no values associated with a sink compartment. Between compartments transformation reactions were assumed to proceed only one-way. The initial amount of the parent compound was free fitted and the initial amount for metabolites was fixed to a value of zero. All data were weighted equally thus corresponding to an absolute error model.

For the evaluation of dissipation in one single compartment (water or sediment or total system) was considered without metabolite formation and degradation as described earlier. If needed, the time axis was shifted to the time t_{\max} of maximum occurrences and residue data were chosen accordingly to result in the corresponding apparent dissipation values.

Figure 2.8.4.2-2: Compartment model for kinetic evaluation of residues from phenyl-labeled foramsulfuron and metabolites in total water-sediment systems (Level I)

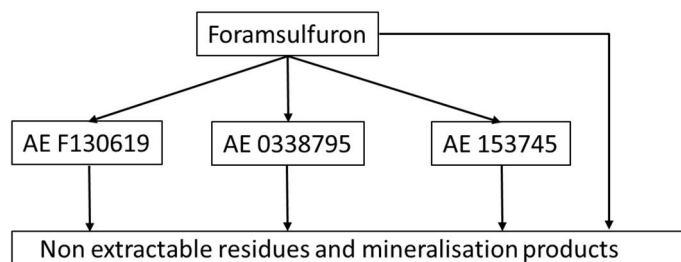
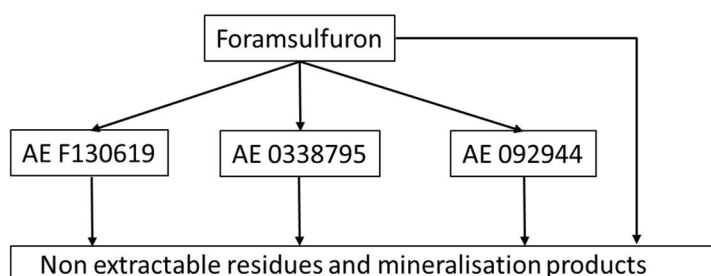


Figure 2.8.4.2-3: Compartment model for kinetic evaluation of residues from pyrimidine-labeled foramsulfuron and metabolites in total water-sediment systems (Level I)



1. Degradation in total systems for foramsulfuron and metabolites AE F130619, AE 0338795, AE F153745 and AE F092944 according to Level I. For the total of four data sets under investigation, it turned out that application of an all-SFO kinetic model to the parent substance and metabolite data resulted in good fits. Apart from very low χ^2 -errors there was also no sign of systematic variations of the residuals. Consequently, no further testing of other kinetic models was considered necessary.

In total systems and for use as modelling endpoint the kinetic evaluation resulted in a geometric mean value for the DegT_{50} of 32.9 days for the parent compound. For metabolites these values are 15.7 days for AE F130619, 65.4 days for AE 0338795, 72.1 days for AE F153745 and 110 days for AE F092944 (Table 2.8.4.2-2).

For evaluation against persistence triggers the worst case DegT_{50} in total system is 39.6 days (Hoechst sand) for parent compound foramsulfuron. For metabolites these values are 45.8 days for AE F130619, 65.4 days for AE 0338795, 72.1 days for AE F153745 and 110 days for AE F092944 (Table 2.8.4.2-2).

2. Dissipation from water for parent compound and metabolites AE F130619, AE 0338795, AE F153745 and AE F092944 according to Level I. The dissipation of foramsulfuron and its metabolites from the water was evaluated starting from the observed maximum value till the end of the study. Where appropriate for the parent compound foramsulfuron, different kinetic models were fitted to the residue data for determination of best fits then being used to derive persistence endpoints. Otherwise SFO kinetics fitted well, except for Hoechst system, for which FOMC kinetics gave better fit for phenyl labelled foramsulfuron with best fit DT_{50} value of 22.4 days and DFOP for pyrimidyl labelled foramsulfuron with best fit DT_{50} value of 21.6 days. For metabolites, a few data points were available for most cases not allowing for the calculation of reliable fits with non-SFO models.

For the dissipation from water and for use as modelling endpoint the corresponding geometric mean value for the $DisT_{50}$ is 25.2 days for the parent compound. For the metabolites these values are 44.0 days for AE F130619, 28.8 days for AE 0338795 and 31.2 days for AE F153745. No $DisT_{50}$ from water could be derived for AE F092944 (Table 2.8.4.2-2).

For evaluation against persistence triggers the worst case $DisT_{50}$ of the parent compound from water 22.0 days (Hoechst system)¹. For the metabolites these values are 115.0 days for AE F130619, 104.0 days for AE 0338795 and 31.2 days for AE F153745. No $DisT_{50}$ from water could be derived for AE F092944 (Table 2.8.4.2-2).

3. Dissipation from sediment for parent compound and metabolites AE F130619, AE 0338795, AE F153745 and AE F092944 according to Level I. The dissipation of foramsulfuron and its metabolites from the sediment were evaluated starting from the observed maximum value till the end of the study. However, the approach resulted in no more than five data points remaining for kinetic evaluation. Consequently, no bi-phasic kinetic models were tested beyond the SFO approach.

For the dissipation from sediment and for use as modelling endpoint the geometric mean value for the $DisT_{50}$ is 45.6 days for the parent compound. For the metabolites these values are 103 days for AE F130619, 49.8 days for AE 0338795 and 147 days for AE F092944. No $DisT_{50}$ from sediment could be derived for AE F153745 (Table 2.8.4.2-2).

For evaluation against persistence triggers the worst case $DisT_{50}$ of the parent compound from sediment is 46.3 days (Hoechst system). For the metabolites these values are 103 days for AE F130619, 89.0 days for AE 0338795 and 147 days for AE F092944. No worst case $DisT_{50}$ from sediment could be derived for AE F153745 (Table 2.8.4.2-2).

¹ This geometric mean value is derived from 22.4 days (FOMC-model, phenyl-label) and 21.6 days (DFOP-model, pyrimidine-label).

Table 2.8.4.2-2: Mean values of half-lives for the dissipation of foramsulfuron from water and sediment and degradation in total systems according to FOCUS Level I for use in environmental modelling (all values SFO DT₅₀ values, except for foramsulfuron Hoechst Sand for which pseudo-SFO DT₅₀ value has been calculated) and worst case DT₅₀ values for each substance and each compartment for evaluation against persistence triggers

Compound	System	DegT ₅₀ , total system (days)	DisT ₅₀ , water (days)	DisT ₅₀ , sediment (days)
Foramsulfuron	Pikeville	27.3	14.8	45.0
	Hoechst Sand	39.6	42.8*/**	46.3
	Mean (geometric)	32.9	25.2	45.6
AE F130619	Pikeville	5.4	16.8	n.d.
	Hoechst Sand	45.8	115.2	103
	Mean (geometric)	15.7	44.0	103
AE 0338795	Pikeville	n.d.	8.0	27.9
	Hoechst Sand	65.4	104.0	89.0
	Mean (geometric)	65.4	28.8	49.8
AE F153745	Pikeville	72.1	n.d.	n.d.
	Hoechst Sand	n.d.	31.2	-
	Mean (geometric)	72.1	31.2	-
AE F092944	Pikeville	110	-	147
	Hoechst Sand	-	-	-
	Mean (geometric)	110	-	147

* For persistence evaluation only, DisT₅₀-value from water following FOMC best fit was of 22.4 days (phenyl-label)

** For persistence evaluation only, DisT₅₀-value from water following DFOP best fit was of DT₅₀ of 21.6 days (pyrimidine-label).

= Geomean DT₅₀ value 22.0 days

Irradiated water/sediment study

This new point is regarded as an optional data requirement in the EU. Foramsulfuron was shown to degrade well under standard conditions of water/sediment testing. In view of the overall limited photolytic degradation observed no additional information is regarded as required to result in a significantly better understanding of the behavior of foramsulfuron in an aquatic environment.

Degradation in the saturated zone

The evaluation revealed that the results of risk assessment in ground water demonstrated no significant risk for a contamination of sub-soils or the saturated zone by the parent compound and its metabolites, when applied according to good agricultural practice. Therefore, the separate investigations on the degradation in the saturated zone are not regarded as necessary.

2.8.5. Assessment in relation to the P-criteria

The criteria for persistence in water and sediment, as stated in Annex II to Regulation (EC) 1107/2009, are: Water: DT₅₀ 40 days (fresh water in PBT), 60 days (POP, marine water in PBT, and all water in vPvB), Sediment: DT₅₀ 120 days (fresh water sediment in PBT), 180 days (POP, marine sediment in PBT, and all sediments in vPvB).

One of the the major metabolites AE F130619 was as toxic as the parent compound to aquatic macrophytes, but since its formation fraction was <10 % in water/sediment study the RMS has focussed this assessment only on the parent compound. No data on fate and behaviour in marine water or sediment was available. This is not considered as a data gap since data from marine compartments are not routinely required.

The water/sediment studies in two different systems did not provide data on rate of degradation in the separate water and sediment compartments. However, the study provided dissipation DT₅₀ values in both compartments. The available data showed that foramsulfuron is mainly present in the water phase. However, the results from aerobic mineralisation, which showed that biotransformation of phenyl-labeled foramsulfuron was negligible, indicates that the degradation of foramsulfuron occurs mainly in sediment. Therefore it would be justified to compare both the sediment dissipation DT₅₀ for foramsulfuron and the whole system DT₅₀ for foramsulfuron with the above criteria for sediment.

The sediment dissipation DT₅₀ value of 45 and 46.3 days and the whole system DT₅₀ values of 27.3 and 39.6 days are below 120 days in fresh water sediment for PBT and 180 days in fresh water sediment for POP/vPvB. In addition, the dissipation DT₅₀ for foramsulfuron in the water phase was below the trigger of 40 days in fresh water for PBT and below the trigger of 60 days in fresh water for POP/vPvB. Hence, the RMS would not identify foramsulfuron as a “P substance”.

2.8.6. Summary of fate and behaviour in air

This data requirement was evaluated within the process for Annex I inclusion and were considered acceptable by RMS Germany. The evaluation revealed that based on rapid degradation in the atmosphere (half-life of 0.07 days in maximum) as calculated by the software AOPWIN, foramsulfuron would not remain stable and thus available for long-range transport due to its susceptibility for reactions with photochemically produced hydroxyl radicals. The value for the vapour pressure of foramsulfuron is 5.8×10^{-12} Pa x m³ x mole⁻¹ at 20°C as reported in Appendix 1 of SANCO/10324/2002-Final from Nov 2002.

Transport via air

This new requirement was evaluated within the process for Annex I inclusion. Due to its low half-life in the atmosphere (0.07 days) combined with a low vapour pressure (4.2×10^{-11} Pa at 20°C) and a low value for the Henry constant (5.8×10^{-12} Pa x m³ x mole⁻¹ at 20°C), foramsulfuron is clearly not subject to transport via air.

In view of the value measured for vapour pressure being below the triggers of 10^{-5} Pa for soil and 10^{-5} Pa for plant, no study on transport of the active substance foramsulfuron via air is necessary.

Local and global effects

This new requirement was evaluated within the process for Annex I inclusion.

Foramsulfuron is applied at low application rates in the field accompanied by fast degradation. Both aspects indicate the presence of only low actual amounts of active substance to be present under outdoor conditions short-term and long-term and thus to be available to set effects at local or global level with respect to its global warming potential (GWP), ozone depleting potential (ODP), photochemical ozone creation potential (POCP), accumulation in the troposphere, acidification potential (AP) or eutrophication potential (EP).

Moreover the potential for local effects of foramsulfuron is considered in risk assessments performed following its use under field conditions in particular by considering factors like spray drift. The combination of exposure assessments with potential effects measured in soil and surface water do thus cover the environmental compartments of interest. In contrast and since there is no aerial application envisaged, air is not a compartment regarded to be major compartment of potential foramsulfuron occurrence following its intended use in the environment.

Following its intended use, its uncritical degradation behavior in air and its low vapour pressure foramsulfuron cannot be transported long range to set effects in the environment at the global level.

2.8.7. Summary of monitoring data concerning fate and behaviour of the active substance, metabolites, degradation and reaction products

Foramsulfuron was not subject of formal monitoring studies in soil or water at EU or national level. Moreover, there are no published monitoring data available indicating findings of foramsulfuron in environmental areas after intended agricultural use. With the safety demonstrated for the active substance as well as for metabolites there is no necessity for monitoring of foramsulfuron residues in the various compartments of the environment.

2.8.8. Definition of the residues in the environment requiring further assessment

The route and rate of degradation of phenyl- or pyrimidine-labeled foramsulfuron has been investigated after application to various test systems in the laboratory with their results delivering endpoints for use in soil, ground water and surface water risk assessments. Following their occurrence above the trigger values set in the relevant tests, metabolites and transformation products are potential residues that have to be addressed.

Residue definition for soil:

Within the process of Annex I inclusion the parent compound foramsulfuron and metabolites AE F092944 and AE F130619 were considered for risk assessment due to their occurrence at >10% of AR in aerobic soil degradation tests. Following new triggers set it is proposed to include AE F153745 in addition. The residue definition for soil is therefore the parent compound foramsulfuron and metabolites AE F092944, AE F130619 and AE F153745 (Table 2.8.8-1).

Residue definition for ground water:

The risk assessment for ground water includes by default all components defined for the risk assessment in soil which is the active substance foramsulfuron and metabolites AE F092944, AE F130619 and AE F153745 (Table 2.8.8-1).

Residue definition for surface water:

The risk assessment for surface water includes by default the active substance foramsulfuron and those components defined for risk assessment in soil and ground water, i.e. metabolites AE F092944, AE F130619 and AE F153745.

During the process of evaluation for Annex I inclusion the metabolite AE 0338795 was additionally included in the surface water risk assessment due to its occurrence at >10% of AR in water/sediment systems. AE 0338795 was observed in water/sediment tests only thus not originating from aerobic soil degradation testing (Table 2.8.8-1).

Current data requirements request also to consider metabolites potentially observed at 'significant level' in other aquatic route studies. These studies include, in particular, sterile abiotic hydrolysis and photolysis (>10% AR) and mineralization in surface water (starting at 5% AR at two successive sampling intervals).

No additional metabolites were observed in sterile buffer hydrolysis or tests on mineralization in surface water. Additional photolysis tests performed in sterile aqueous buffer and natural water resulted in the observation of the four compounds 4-Formamido-N-methylbenzamide (FMB, BCS-CW90756), 4-Amino-N-methylbenzamide (AMB, BCS-CV29520), AE F099095 (foramsulfuron urea) and foramsulfuron sulfamic acid (BCS-AW41401) at >10% AR. It is therefore proposed to consider these compounds in addition within the risk assessment in surface water (Table 2.8.8-1).

Table 2.8.8-1: Definition of the residue for risk assessment

Compartment	Compound / Code
Soil	Foramsulfuron AE F092944 AE F130619 AE F153745
Groundwater	Foramsulfuron AE F092944 AE F130619 AE F153745
Surface water	Foramsulfuron AE F092944 AE F130619 AE F153745 AE 0338795 AE F099095 4-Amino-N-methylbenzamide 4-Formamido-N-methylbenzamide Foramsulfuron sulfamic acid

2.8.9. Summary of exposure calculations and product assessment

PECsoil

For detailed information please see Volume 3 CP B.8.2.

PECsoil values were determined for foramsulfuron and its main soil metabolites AE F130619, AE F153745 and AE F092944 (Schmitt & Mikolasch 2013a). The maximum occurrence of metabolites in soil was 25.7 % for AE F130619, 7.8 % for F153745 and 17.8 % for AE F092944.

Initial, short-term and long-term PECsoil values and the time weighted average values (TWAC_s) were calculated for two use patterns: Maize, application rate 1 x 60 g a.s./ha per season and Maize, application rate 2 x 30 g a.s./ha per season. Also PECplateau values were calculated for the two use patterns. Soil accumulation was investigated for both the 0 – 5 cm and 0 – 20 cm soil layer based on two use patterns.

PECsoil was calculated for single and multiple applications using standard equations from FOCUS (1997) and default soil depth 5 cm and density 1.5 g/cm³. PECsoil calculations are presented in Vol 3CP Annex B.8.2. Worst-case values used for risk assessment are presented in Level 2, sections 2.9.4 and 2.9.5.

PECgroundwater

For detailed information please see Volume 3 CP B.8.3.

The simulations were performed with the FOCUS models FOCUS PEARL version 4.4.4 and FOCUS PELMO version 4.4.3. Application dates for the simulation runs were defined following the crop event dates of the respective crop – maize and scenario as given by FOCUS (2009). PECgw values were calculated for two use patterns: Maize, application rate 1 x 60 g a.s./ha per season and Maize, application rate 2 x 30 g a.s./ha per season. Crop interception was taken into account according to the BBCH growth stage as recommended by FOCUS (2012). Metabolites were simulated together with the parent in all simulations. PECgw values are presented in Vol 3CP Annex B.8.3.

Following input values were used:

Table 2.8.9-1: Substance specific and model related input parameter for PEC_{gw} calculation of foramsulfuron and its metabolites (model parameters not listed are kept as default)

Parameter	Unit	Foramsulfuron	AE F130619	AE F153745	AE F092944
Common					
Molar mass	[g/mol]	452.5	424.4	271.3	155.2
Water solubility	[mg/L]	3293	35.5	5830	5484
Vapour Pressure	[Pa]	4.20E-11	5.80E-13	3.47E-08	3.72E-02
Freundlich Exponent ¹⁾	[-]	0.870	0.930	0.970	0.670
Plant uptake factor	[-]	0.0	0.0	0.0	0.0
Walker Exponent	[-]	0.7	0.7	0.7	0.7
PEARL parameters					
Substance Code	[-]	foram	F619	F745	F944
DT ₅₀ ²⁾	[days]	13.5	2.3	0.9	25.9
Molar activ. energie	[kJ/mol]	65.4	65.4	65.4	65.4
Kom ³⁾	[mL/g]	40.700	36.6	27.8	360.0

Parameter	Unit	Foramsulfuron	AE F130619	AE F153745	AE F092944
Kf	[mL/g]	-	-	-	-
PELMO parameters					
Substance Code	[-]	AS	A1	B1	C1
Rate Constant ²⁾	[1/day]	0.06980	0.30137	0.81547	0.02676
Q10	[-]	2.58	2.58	2.58	2.58
Koc ³⁾	[mL/g]	69.7	63.2	48.0	621.0
Degradation fraction from → to (FOCUS PEARL)		0.92 foram -> F619 0.22 foram -> F745 0.22 foram -> F944			
Degradation rate from → to (FOCUS PELMO)		0.047 Active Substance -> A1 0.011 Active Substance -> B1 0.011 Active Substance -> C1 0.301 A1 -> <BR/CO2 0.815 B1 -> <BR/CO2 0.026 C1 -> <BR/CO2			

1) arithmetic mean of 1/n values from different soils

2) geometric mean of normalised DT₅₀ in aerobic soil under laboratory conditions

3) geometric mean of Koc values from different soils. The Koc values were converted into Kom values with the standard conversion factor of 1.724.

The PEC_{gw} were below 0.001µg/L for foramsulfuron and its soil metabolites AE F130619, AE F153745 and AE F092944 for both applied uses in maize. Results were obtained with both PEARL and PELMO models in 8 scenarios parameterized for maize. Jokioinen scenario is not parameterized for maize (Schmitt & Mikolasch 2013b). Hence, only the Jokioinen scenario was not used in simulations at EU level. Neither the concentration of foramsulfuron nor its metabolites exceeded the trigger 0.1µg/L and hence, there is no need for an assessment of the relevance of metabolites. In addition, no risk mitigation is needed to protect vulnerable groundwater areas.

PEC_{surfacewater}

Predicted environmental concentrations in surface water and sediment (PEC_{sw} and PEC_{sed}) of foramsulfuron and its metabolites AE F130619, AE F092944, AE F153745, AE 0338795, AE F099095, 4-amino-N-methylbenzamide, 4-formamido-N-methylbenzamide and foramsulfuron-sulfamic acid have been calculated for the use in maize in Europe. PEC_{sw} and PEC_{sed} values were calculated for two use patterns: Maize, application rate 1 x 60 g a.s./ha per season and Maize, application rate 2 x 30 g a.s./ha per season (Schmitt & Mikolasch 2013c). Crop interception was taken into account by SWASH based on the application time and the crop stage. The detailed PEC_{sw} values are presented in Vol 3CP Annex B.8.5.

Compound specific input data are summarised below for FOCUS Steps 1-2 (Table 2.8.9-2 and Table 2.8.9-3 and FOCUS Steps 3-4 (Table 2.8.9-4).

Table 2.8.9-2: Substance parameters used for foramsulfuron and its metabolites at Steps 1-2 level

Parameter	Unit	Foramsulfuron	AE F130619	AE F092944	AE F153745	AE 0338795
Molar Mass	g/mol	452.49	424.44	155.16	271.3	438.42
Water Solubility	mg/L	3293	35.5	5484	5830	200000
Koc	mL/g	69.7 ¹⁾	63.2 ¹⁾	621 ¹⁾	48 ¹⁾	17.67 ²⁾
Degradation						
Soil	days	13.5 ³⁾	2.3 ³⁾	25.9 ³⁾	0.9 ³⁾	1000 ⁴⁾
Total System	days	32.9 ⁵⁾	15.7 ⁵⁾	110 ⁵⁾	72.1 ⁵⁾	65.4 ⁵⁾
Water	days	32.9 ⁵⁾	15.7 ⁵⁾	110 ⁵⁾	72.1 ⁵⁾	65.4 ⁵⁾
Sediment	days	32.9 ⁵⁾	15.7 ⁵⁾	110 ⁵⁾	72.1 ⁵⁾	65.4 ⁵⁾
Max Occurrence						
Water / Sediment	%	100	10.7	26.5	24.6	23.7
Soil	%	100	29.1	17.8	7.8	0.001

¹⁾ Geometric mean Koc ²⁾ Estimated by calculation using KOCWIN (US EPA, 2000) ³⁾ Normalised geometric mean value

⁴⁾ Default value (worst case) ⁵⁾ Geometric mean of total system

Table 2.8.9-3: Substance parameters used for the foramsulfuron metabolites at Steps 1-2 level

Parameter	Unit	AE F099095	4-amino-N-methylbenzamide	4-formamido-N-methylbenzamide	Foramsulfuron-sulfamic acid
Molar Mass	g/mol	198.18	150.18	178.19	278.24
Water Solubility	mg/L	1000 ¹⁾	1000 ¹⁾	1000 ¹⁾	1000 ¹⁾
Koc	mL/g	351 ²⁾	0 ¹⁾	0 ¹⁾	0 ¹⁾
Degradation					
Soil	days	1000 ¹⁾	1000 ¹⁾	1000 ¹⁾	1000 ¹⁾
Total System	days	1000 ¹⁾	1000 ¹⁾	1000 ¹⁾	1000 ¹⁾
Water	days	1000 ¹⁾	1000 ¹⁾	1000 ¹⁾	1000 ¹⁾
Sediment	days	1000 ¹⁾	1000 ¹⁾	1000 ¹⁾	1000 ¹⁾
Max Occurrence					
Water / Sediment	%	35.2	12.8	19.7	17.6
Soil	%	0.001	0.001	0.001	0.001

¹⁾ Default value

²⁾ Geometric mean Koc – study was submitted in the dossier for Annex I inclusion of Mesosulfuron; agreed Koc values are listed in SANCO/10298/2003-Final of 25 June 2004.

Table 2.8.9-4: Substance specific and model related input parameter for PEC_{sw} calculation of foramsulfuron and metabolite at Step 3-4 level (model parameters not listed are kept as default)

Parameter	Unit	Foramsulfuron	AE F130619
Company Code	-	AE F130360	AE F130619
SWASH Code	-	Foram2	F619
General Parameters			
Molar Mass	g/mol	452.5	424.4
Water Solubility	mg/L	3293.0	35.5
Vapour Pressure	Pa	4.2E-11	5.8E-13
Plant Uptake Factor	-	0.0	0.0
Wash-Off Factor PRZM	l/cm	0.5	0.5
Wash-Off Factor MACRO	l/mm	0.05	0.05
Sorption			
Koc	mL/g	70 ¹⁾	63 ¹⁾
Freundlich Exponent	-	0.87 ²⁾	0.93 ²⁾
Degradation			
Soil	days	13.5 ³⁾	2.3 ³⁾

Parameter	Unit	Foramsulfuron	AE F130619
Form. Frac. PRZM	molar basis	-	0.920
Form. Frac. MACRO	mass basis	-	0.863
Water	days	32.9 ⁴⁾	15.7 ⁴⁾
Sediment	days	1000 ⁵⁾	1000 ⁵⁾
Walker Exponent	-	0.7	0.7
Effect of Temperature			
Activation Energy	J/mol	65400	65400
Exponent	1/K	0.095	0.095
Q10	-	2.58	2.58

¹⁾ Geometric mean Koc; ²⁾ Arithmetic mean 1/n; ³⁾ Normalised geometric mean value; ⁴⁾ Geometric mean of total system; ⁵⁾ Default value (worst case)

Step 4: At Step 4, the mitigation according to the FOCUS Landscape and Mitigation Factors report (FOCUS 2007) is assessed. For this purpose, calculations using mitigation measures for drift and runoff were defined.

PECair

Foramsulfuron is not subject to transport via air due to its low vapour pressure (4.2×10^{-11} Pa at 20°C) and a low value for the Henry constant (4.52×10^{-12} Pa x m³ x mole⁻¹ at 20°C) combined with a half-life in the atmosphere of 0.07 days calculated by the software AOPWIN.

Other routes of exposure

The exposure via other routes (e.g., by deposition of dust; indirect exposure of surface water from Sewage Treatment Plant; from amenity use) can be excluded.

2.9. EFFECTS ON NON-TARGET SPECIES

2.9.1. Summary of effects on birds and other terrestrial vertebrates

2.9.1.1. Summary of effects on birds

For detailed information please see Volume 3 CA B.9.1.1.

Avian acute, 5-day dietary and reproduction toxicity tests in birds have been conducted with foramsulfuron. Results indicate a low acute toxicity of the active substance to the bobwhite quail and mallard duck (both LD₅₀ values > 2000 mg/kg bw). Dietary toxicity tests were performed with the bobwhite quail (LD₅₀ > 985 mg a.s./kg bw/d) and mallard duck (LD₅₀ > 1792 mg a.s./kg bw/d). Effects of foramsulfuron on the reproductive parameters were studied in the above mentioned two species. The 21 week NOEC in bobwhite quail and mallard duck were found to be > 1000 mg a.s./ kg diet. For the purposes of risk assessment, toxicity endpoint was re-calculated in terms of daily dietary dose (mg/kg bw/day) and NOEL of > 104 mg/kg bw/day for bobwhite quail, as the most sensitive species, was used in the risk assessment. One acute test with the formulation EQUIP OD 45 was available. LD₅₀ is >2000 mg EQUIP OD 45 / kg bw, equivalent to 45 mg a.s./kg bw.

2.9.1.2. Summary of effects on mammals

For detailed information please see Volume 3 CA B.9.1.2.

Acute oral and reproduction toxicity tests in mammals have been conducted with foramsulfuron. Results indicate a low acute toxicity of the active substance to rat ($LD_{50} > 5000$ mg/kg bw). One acute test with the formulation EQUIP OD 45 resulted to a LD_{50} of the EQUIP OD of > 5000 mg/kg bw. In a two-generation reproductive toxicity study on male and female a NOAEC of ≥ 1038 mg/kg bw/day was obtained for males (the most sensitive endpoint). In developmental studies the NOEL for teratogenic effects was 1000 mg a.s./kg bw for rat and 500 mg a.s./kg bw for rabbit.

2.9.2. Summary of effects on aquatic organisms

2.9.2.1. Summary of the effects

For detailed information please see Volume 3 CA B.9.2.

Toxicity studies are available with the active substance foramsulfuron, formulation EQUIP OD 45 (22.5+22.5 g/L), the metabolites AE F153745, AE F092944, AE F130619, AE 0338795, AE F099095, 4-amino-N-methylbenzamide, 4-formamido-N-methylbenzamide, foramsulfuron-sulfamic acid.

Foramsulfuron has low toxicity to fish and aquatic invertebrates. In all acute fish studies no sublethal effects and only random mortality were observed in the highest dose level treatment, resulting in an LC_{50} of > 100 mg a.s./L. Likewise in both chronic fish studies no relevant treatment related effects were observed at the maximum dose level, resulting in a NOEC of 100 or 10.5 mg a.s./L.

Also for Daphnia, no mortality occurred in the acute studies and no chronic effects on survival, growth or reproduction were observed in the reproductive study at the tested dose level of 100 mg a.s./L, resulting in an $EC_{50} > 100$ mg a.s./L and a NOEC of > 100 mg a.s./L.

Potential effects of foramsulfuron on algal growth were investigated with four different algae species, a green alga, a blue-green alga and a freshwater and a marine diatom. The blue-green alga *Anabaena flos-aquae*, was found to be, by a factor of 10, more sensitive than other algae species. The EC_{50} of foramsulfuron for this species is 8.1 mg a.s./L.

As expected for an herbicide, foramsulfuron is significantly more toxic to aquatic macrophytes (E_rC_{50} of 1.01 μ g a.s./L). In addition to the tier 1 test with *Lemna gibba* four further macrophyte studies have been conducted with foramsulfuron technical and the formulation Foramsulfuron WG 50, respectively.

In a 14 d laboratory study *Myriophyllum spicatum* (Banman et al., 2012; KCA 8.2.7 /09) showed lower sensitivity to the active substance compared to *Lemna* with maximum inhibitions of the growth parameters (shoot length, wet weight, dry weight) being less than 20% up to the maximum test concentration (84 μ g a.s./L).

A 6 weeks (42 d) bioassay with *Lemna gibba* (Bruns, 2013; KCA 8.2.7/ 08) was performed to generate an endpoint which can be compared to the macrophyte species tested in the outdoor pond study (see below). Since *Lemna gibba* insufficiently grows under the mesotrophic conditions in outdoor ponds, decreasing concentrations of foramsulfuron, as observed in the pond study, were mimicked in the

laboratory in 20 x APP nutrient medium under sterile conditions. The total test duration of the bioassay was equal to the duration of the pond study. As the most sensitive response variable frond number, a 42 d ErC₅₀ of 1.18 µg a.s./L was obtained.

A 24h- peak exposure study with *Lemna gibba* (Bruns, 2013; KCA 8.2.7/06) was conducted to specifically address peak exposure patterns as predicted e.g. for runoff scenarios. The study should reveal expected differences in the magnitude and duration of effects between a constant exposure as given in a *Lemna* standard test and an exposure for a very limited time span. *Lemna gibba* was exposed to the compound for 24 h after which the plants were transferred to untreated growth medium for further six days. The ErC₅₀ was greater than 56.7 µg a.s./L, the NOEC of growth rates in the period between day 2 and day 7 (post-exposure after the peak) was 2.42 µg a.s./L. These endpoints refer to growth rate of both parameter, frond number and total frond area.

A macrophyte pond study (Kirkwood, 2012; KCA 8.2.7 /07), ten different macrophyte species were exposed to foramsulfuron applied as WG 50 formulation under outdoor conditions. The aim of the study was to deliver an appropriate number of endpoints for an HC5 calculation. The study included two different exposure regimes:

- 1) Constant exposure over 6 weeks with natural degradation of the compound in the ponds; this part was conducted in an ECx design.
- 2) 48 h peak exposure (two peak concentrations 1.6 and 3.9 µg a.s./L, measured) with subsequent replacement of the test solutions with untreated dilution water in the ponds. As with the *Lemna* peak exposure study, this second regime aimed at mimicking short runoff or drift peaks and their effects on macrophytes.

Studies investigating the toxicity to *Lemna gibba* were also performed for all metabolites of the residue definition for risk assessment in surface water. One metabolite, AE F130619, has a similar activity to *Lemna* as the parent compound (ErC₅₀ = 0.000889 mg /L), while all other metabolites turned out to be non-toxic to these and other aquatic organisms.

According to the CLP Regulation (EC) No 1272/2008 the active substance and the formulation EQUIP OD 45 should be classified as **Aquatic Acute 1/ Aquatic Chronic 1, H410 Very toxic to aquatic life with long lasting effects (PP273, P501).**

2.9.2.2. Summary of effects on other aquatic organisms

Also the potential effects of foramsulfuron on *Palaemonetes pugio* and *Crassostrea virginica* were investigated and the 96 hour LC₅₀ of the parent compound to grass shrimp was >100 mg/L and 118 mg/L, respectively.

2.9.2.3. Assessment of bioaccumulation (B)

The criteria for bioaccumulation in aquatic organisms, as stated in Annex II to Reg (EC) 1107/2009, are BCF or BAF > 2000 (PBT) and > 5000 (POP and vBvP). Since foramsulfuron has a Log Pow < 3 (actual value is 0.78 to 1.44 in the pH range of 2 to 7) the potential for bioaccumulation is not likely to occur. None of the metabolites were assessed as having potential for bioaccumulation since Log Pow < 3.

2.9.2.4. Assessment of toxicity (T)

An active substance fulfil the criteria for toxicity in aquatic organisms, as stated in Annex II to Reg (EC) 1107/2009, if the long-term no-observed effect concentration for marine and freshwater organisms is less than 0.01 mg/L. From laboratory studies on the toxicity of foramsulfuron to aquatic organisms it can be concluded that foramsulfuron is very toxic to aquatic macrophytes with a 7 d NOEC as low as 1.01 µg/L for *L. gibba* (derived from study on the active substance). Hence, the T-criterion is fulfilled. In addition, one of the metabolites AE F130619 was also below the trigger value with a NOEC of 0.899 µg/L.

2.9.2.5. Potential for endocrine disruption properties in aquatic organisms

Based on the definition of the WHO/IPCS on endocrine disruption presented in section B.9.1.5 following results concerning relevant adverse effects of foramsulfuron on fish is presented below.

Fish

Population relevant effects of foramsulfuron on fish were studied in an early life-stage test (ELS). No further testing is available to evaluate the endocrine disrupting potential of foramsulfuron to fish. Due to the lack of indications on endocrine disruption from mammalian data, no further data is considered necessary at this stage.

Conclusion:

There were no indications for endocrine activity observed in the available mammalian data. Therefore further special testing for endocrine disrupting behaviour is not warranted.

2.9.3. Summary of effects on arthropods

2.9.3.1. Effect on bees

For detailed information please see Volume 3 CA B.9.3.1.

One study with the active substance and second one with the formulation EQUIP OD 45 were submitted for the process of renewal. Foramsulfuron has a low acute toxicity to honey bees, with LD₅₀ (oral and contact) above the highest tested dose level (oral: LD₅₀ > 110.1 µg a.s./bee, contact: LD₅₀ > 100 µg a.s./bee).

The results of chronic laboratory test show no adverse lethal-, sub-lethal, behavioural or delayed effects when exposing adult honey bees for 10 consecutive days exclusively to sugar solution, containing 120 ppm foramsulfuron (nominal), which corresponded to about the concentration of foramsulfuron in the spray tank of a high-volume use.

A bee brood feeding study according to Oomen *et al.* (1992) was performed to observe the effect of the test substance (Foramsulfuron WG 50 W together with formulated safener cyprosulfamide, as Cyprosulfamide SC 500) to immature honey bee life stages in the hive. The results show statistically significantly increased termination rate of young and old larvae when compared to the control treatment. No adverse effects on the survival of adult bees and pupae, behaviour, colony strength,

condition of the colonies, colony development, brood index and brood compensation index was observed.

In addition to acute laboratory studies with adult honey bees, the Applicant submitted an *in-vitro* larval test conducted with formulation Foramsulfuron WG 50 W, as technical foramsulfuron was not well soluble in water. Results show no adverse effect on larvae mortality at a level of 100 µg a.s./larva, i.e. the (highest) dose tested.

A higher tier semi-field honey bee brood study was conducted by applying the maximum rate (2.68 L) of EQUIP OD 45 (22.5 + 22.5 g/L) under tunnel conditions to the full flowering and highly bee attractive surrogate crop *Phacelia tanacetifolia*. Results show no adverse effects on mortality of worker bees or pupae, foraging activity, behaviour, nectar- and pollen storage as well as on queen survival. Also no effects on colony development, colony strength or bee brood were observed.

2.9.3.2. Effect on non-target arthropods other than bees

For detailed information please see Volume 3 CA B.9.3.2.

Toxicity tests on non-target arthropods were conducted with EQUIP OD 45 on the sensitive standard species *Typhlodromus pyri* and *Aphidius rhopalosiphi*. A new study on the mortality of *Typhlodromus pyri* exposed to EQUIP OD 45 on glass plates showed a $LR_{50} > 60$ g a.s./ha. *Typhlodromus pyri* showed 20% corrected mortality and no effect on reproduction in an extended laboratory study on *Polygonum convolvulus* leaves at the highest test rate (90 g a.s./ha). A new study on the mortality of *Aphidius rhopalosiphi* exposed to EQUIP OD 45 on glass plates showed a $LR_{50} > 60$ g a.s./ha. *Aphidius rhopalosiphi* showed some mortality in a tier 1 glass plate study, but no effects on mortality or reproduction were observed in a higher tier extended lab/aged residue study when exposed to freshly dried residues on maize leaves and residues aged for 3 and 7 days.

In addition, tests on further species are available (*Chrysoperla carnea*, *Aleochara bilineata*, *Poecilus cupreus*, *Pardosa sp.*). These studies showed that EQUIP OD 45 had no or only low effects on mortality, reproduction and feeding rate of these additional species, except for *Aleochara bilineata* for which 46 % mortality was observed already in 45 g a.s./ha. However, the effects of reproduction were low.

2.9.4. Summary of effects on non-target soil meso- and macrofauna

2.9.4.1. Earthworms

For detailed information please see Volume 3 CA B.9.4.1 and B.9.4.2.

Acute toxicity tests on earthworms were conducted with the active substance, the formulation EQUIP OD 45 and metabolite, AE F153745. LC_{50} s ranged from ≥ 453 mg product/kg dws to ≥ 1000 mg/kg dws for the active substance and metabolite AE F153745. Long-term toxicity tests on earthworms were conducted with the active substance and metabolites AE F092944, AE F130619 and AE F153745. In all studies no mortality occurred. NOEC for the active substance was ≥ 2.75 mg/kg dws and 10, 56 and ≥ 100 mg/kg dws for metabolites AE F092944, AE F130619 and AE F153745, respectively.

2.9.4.2. Other soil non-target macro-organisms

For detailed information please see Volume 3 CA B.9.4.3.

Many new toxicity studies on reproduction of *Hypoaspis aculeifer* and *Folsomia candida* were performed for foramsulfuron and its metabolites AE F092944, AE F153745, AE F130619 and for the formulation EQUIP OD 45. These studies showed low long-term toxicity with NOEC values > 100 mg/kg dw.

2.9.5. Summary of effects on soil nitrogen transformation

For detailed information please see Volume 3 CA B.9.5.

Toxicity studies on the effects of foramsulfuron, foramsulfuron and bound residues and formulation EQUIP OD 45 on nitrogen transformation and soil respiration showed no unacceptable effects at the highest tested dose level which ranged from 0.135 mg/kg dws to 0.735 mg/kg dws.

Also soil major metabolites, AE F092944, AE F130619 and AE F153745 showed no unacceptable on nitrogen transformation in soil at the highest tested dose level which ranged from 0.137 mg/kg dws to 0.375 mg/kg dws.

2.9.6. Summary of effects on terrestrial non-target higher plants

For detailed information please see Volume 3 CA B.9.6.

Toxicity tests have been submitted with the representative formulation EQUIP OD 45. For seedlings emergence, a tier 1 and a tier 2 study and for vegetative vigour, only a tier 2 study was performed.

The seedling emergence test is available on seven non-target plants species: Monocots (rye grass, wheat, onion) and Dicots (cabbage, radish, tomato, lettuce). The most sensitive species observed in the study was lettuce with $EC_{50} = 38.8$ g sum of a.i/ha. The vegetative vigour test is available on ten non-target plant species: Monocots (rye grass, maize [corn], wheat, onion) and Dicots (bean, cabbage, radish, tomato, soybean, lettuce). The most sensitive species observed in the study was radish with $EC_{50} = 1.88$ g sum of a.i/ha.

2.9.7. Summary of effects on other terrestrial organisms (flora and fauna)

Studies on effects on other terrestrial organisms are neither available nor required.

2.9.8. Summary of effects on biological methods for sewage treatment

For detailed information please see Volume 3 CA B.9.8.

For foramsulfuron, one study with activated sludge has been conducted. The $EC_{20} > 625.0$ mg/L, $EC_{50} > 625.0$ mg/L and $EC_{80} > 625.0$ mg/L for inhibition of respiratory activity were obtained. It can be assumed that adverse effects on methods of sewage treatment are unlikely when the formulation EQUIP OD is applied according to GAP. No further investigation is then considered necessary.

2.9.9. Summary of product exposure and risk assessment

2.9.9.1. Risk assessment for birds and other terrestrial vertebrates

Risk Assessment for birds

Acute and long-term risk

The risk assessment for birds is carried out according to the latest draft of the 'EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009)'. The acute and long-term risks of EQUIP OD 45 to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with foramsulfuron, and maximum residues occurring on food items following single application (which represents worst case) according to the proposed use pattern.

For detailed information please see Volume 3 CP B.9.2.1.1.

Table 2.9.9.1-1: Screening step - Acute risk (TER_A) to birds from foramsulfuron

Test Substance	Indicator species	LD ₅₀ (mg a.s./kg bw)	DDD (mg a.s./kg bw/day)	TER _A	Trigger value
Foramsulfuron	Small omnivorous bird	> 2000	9.53	>209.86	10

Table 2.9.9.1-2: Screening step – long-term (TER_{LT}) to birds from foramsulfuron

Test substance	Indicator species	NOEL (mg a.s./kg bw/day)	DDD (mg a.s./kg bw/day)	TER _{LT}	Trigger value
Foramsulfuron	Small omnivorous bird	> 104	2.06	> 50.48	5

Acute and long-term TERs values calculated in the screening step for indicator species relevant for the risk following use of EQUIP OD 45 in maize are greater than the respective Annex VI trigger values, indicating that acute and long-term risk to birds are acceptable following the use of EQUIP OD 45 according to the proposed use pattern.

Supervised cage or field trials: TER_A and TER_{LT} being > 10 and 5, respectively, no supervised cage or field trials are necessary.

Risk of secondary poisoning

For detailed information please see Volume 3 CP B.9.2.1.2.

The log K_{ow} of foramsulfuron is low (log Kow value 1.44 at pH 2; 0.78 at pH 7). Thus, no risk of bioaccumulation is expected. In addition, no risk of bioaccumulation of metabolites is expected due to their low Kow values (all well below 3).

Risks from drinking water

For detailed information please see Volume 3 CP B.9.2.1.3.

The resulting ratios of effective application rate to endpoints for foramsulfuron following the use of EQUIP OD 45 fall below the trigger (≤ 50) indicating that further assessment of the acute and long-term risk to birds from drinking water from puddles is not required.

Table 2.9.9.1-3: Ratios of effective application rate to endpoints for foramsulfuron following the use of EQUIP OD 45

Test Substance	K _{oc}	Application rate (g a.s./ha)	Acute endpoint (mg/kg bw)	Ratio of application rate to acute endpoint	Long-term endpoint (mg/kg bw/day)	Ratio of application rate to long-term endpoint	Ratio Trigger
Foramsulfuron	38-151	60	> 2000	< 0.03	> 104	<0.58	≤ 50

Risk assessment for other terrestrial vertebrates

Acute and long-term risk

The risk assessment for other mammals is carried out according to the latest draft of the 'EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009)'. The acute and long-term risks of EQUIP OD 45 to mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with foramsulfuron, and maximum residues occurring on food items following single application (which represents worst case) according to the proposed use pattern.

For detailed information please see Volume 3 CP B.9.2.2.1.

Table 2.9.9.1-4: Screening step - Acute risk (TER_A) to mammals from foramsulfuron and EQUIP OD

Test substance	Indicator species	LD ₅₀ (mg a.s./kg bw)	DDD (mg a.s./kg bw/day)	TER _A	Trigger value
Foramsulfuron	Small herbivorous mammal	> 5000	8.18	> 611.25	10

Table 2.9.9.1-5: Screening step - long-term risk (TER_{LT}) to mammals

Test substance	Indicator species	NOAEL (mg a.s./kg bw/day)	DDD (mg/a.s./kg bw/day)	TER _{LT}	Trigger Value
Foramsulfuron	Small herbivorous mammal	≥ 500	2.30	≥ 217.39	5

Acute and long-term TERs values calculated in the screening step for indicator species relevant for the risk following use of EQUIP OD 45 in maize are greater than the respective Annex VI trigger values, indicating that acute and long-term risk to mammals are acceptable following use of EQUIP OD according to the proposed use pattern.

Risk of secondary poisoning

For detailed information please see Volume 3 CP B.9.2.2.2.

The log K_{ow} of foramsulfuron is low (log Kow value 1.44 at pH 2; 0.78 at pH 7). Thus, no risk of bioaccumulation is expected. In addition, no risk of bioaccumulation of metabolites is expected due to their low Kow values (all well below 3).

Risks from drinking water

For detailed information please see Volume 3 CP B.9.2.2.3.

The resulting ratios of effective application rate to endpoints for foramsulfuron following the use of EQUIP OD 45 fall below the trigger (≤ 50) indicating that further assessment of the acute and long-term risk to mammals from drinking water from puddles is not required.

Table 2.9.9.1-6: Ratios of effective application rate to endpoints for foramsulfuron following the use of EQUIP OD 45

Test substance	K _{oc}	Application rate (g a.s/ha)	Acute endpoint (mg/kg bw)	Ratio of application rate to acute endpoint	Long-term endpoint (mg/kg bw/day)	Ratio of application rate to longterm endpoint	Ratio trigger
Foramsulfuron	38-151	60	> 5000	< 0.012	≥ 500	≤ 0.12	≤ 50

2.9.9.2. Risk assessment for aquatic organisms

The risk assessment has been performed according to “Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC” (Sanco/3268/2001 rev.4 (final) 17 October 2002) and the “Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters” (EFSA Panel on Plant Protection Products and their Residues, 2013, EFSA Journal 2013; 11(7): 3290, 268 pp. has been considered where appropriate.

For detailed information please see Volume 3 CP B.9.4.

The risk assessment of foramsulfuron for aquatic organisms is driven by effects on *Lemna* as most sensitive aquatic species. While acute and chronic risk assessments for fish, *Daphnia* and algae are passed with standard ecotoxicological endpoints and PEC_{sw} at FOCUS Step 2 level, for *Lemna* refinement based on higher tier aquatic studies and FOCUS step 4 calculations is required.

For all metabolites except AE F130619 the assessment also for *Lemna* is passed on FOCUS Step 2 level. For AE F130619 which has a similar effect on *Lemna* as the parent compound, Step 3 calculations and refinement based on higher tier aquatic studies is required.

Acute risk assessment for aquatic organisms**Table 2.9.9.2-1: TER_A calculations based on drift entry for the formulation EQUIP OD 45 and on FOCUS Step 2 values for foramsulfuron and metabolite AE F092944 for fish and invertebrates**

Compound		Endpoint [µg/L]	PEC _{sw,max} [µg/L]	TER _A	Trigger
Maize, 1 x 60 g a.s./ha					
FSN + IDF OD 45 (22.5+22.5)	Fish, acute	LC ₅₀ = 7 800	23.17 ¹⁾	337	100
	Invertebrate, acute	LC ₅₀ = 6 900	23.17 ¹⁾	298	100
Foramsulfuron	Fish, acute	LC ₅₀ > 100 000	4.948	> 20 210	100
	Invertebrate, acute	LC ₅₀ > 100 000	4.948	> 20 210	100
AE F092944	Fish, acute	LC ₅₀ = 254 000	0.189	1 343 915	100
	Invertebrate, acute	LC ₅₀ = 223 000	0.189	1 179 894	100
Maize, 2 x 30 g a.s./ha					
FSN + IDF OD 45 (22.5+22.5)	Fish, acute	LC ₅₀ = 7 800	11.59 ¹⁾	673	100
	Invertebrate, acute	LC ₅₀ = 6 900	11.59 ¹⁾	595	100
Foramsulfuron	Fish, acute	LC ₅₀ > 100 000	4.189	> 23 872	100
	Invertebrate, acute	LC ₅₀ > 100 000	4.189	> 23 872	100
AE F092944	Fish, acute	LC ₅₀ = 254 000	0.172	1 476 744	100
	Invertebrate, acute	LC ₅₀ = 223 000	0.172	1 296 512	100

254 000
223 000

7 800

Bold values require further refinement¹⁾ Based on spray drift values of 2.77 % for the formulationChronic risk assessment for aquatic organisms**Table 2.9.9.2-2: TER_{LT} calculations based on drift entry for the formulation and on FOCUS Step 2 values for foramsulfuron and metabolites for fish, invertebrates, algae and *Lemna***

Compound	Species	Endpoint [µg/L]	PEC _{sw,max} [µg/L]	TER _{LT}	Trigger
Maize, 1 x 60 g a.s./ha					
FSN + IDF OD 45 (22.5+22.5)	Fish, chronic	NOEC = 1 800	23.17 ¹⁾	78	10
	Invertebrate, chronic	NOEC = 400	23.17 ¹⁾	17	10
	Green algae, chronic	ErC ₅₀ > 5 000	23.17 ¹⁾	> 216	10
	Aquatic plants, chronic	ErC ₅₀ = 53.23	23.17 ¹⁾	2.30	10
Foramsulfuron	Fish, chronic	NOEC = 10 500	4.948	2 122	10
	Invertebrate, chronic	NOEC > 100 000	4.948	> 20 210	10
	Green algae, chronic	ErC ₅₀ = 8100	4.948	1637	10
	Aquatic plants, chronic	ErC ₅₀ = 1.01	4.948	0.204	10
AE F092944	Green algae, chronic	ErC ₅₀ > 560 000	0.189	> 2 962 963	10
	Aquatic plants, chronic	EC ₅₀ > 100 000	0.189	> 529 101	10
AE F099095	Green algae, chronic	ErC ₅₀ > 100 000	0.085	> 1 176 471	10
	Aquatic plants, chronic	EC ₅₀ > 100 000	0.085	> 1 176 471	10
AE F153745	Aquatic plants, chronic	EC ₅₀ > 100 000	0.087	> 1 149 425	10
AE 0338795	Aquatic plants, chronic	ErC ₅₀ = 27 200	0.127	214 173	10
AE F130619	Aquatic plants, chronic	EC ₅₀ = 0.889	0.481	1.85	10
4-Amino-N-methylbenzamide	Aquatic plants, chronic	ErC ₅₀ > 10 000	0.023	> 434 783	10

Compound	Species	Endpoint [µg/L]	PEC _{sw} max [µg/L]	TER _{LT}	Trigger
Maize, 1 x 60 g a.s./ha					
4-Formylamido-N-methylbenzamide	Aquatic plants, chronic	ErC ₅₀ > 10 000	0.043	> 232 558	10
Foramsulfuron sulfamic acid	Aquatic plants, chronic	ErC ₅₀ > 10 000	0.060	> 166 667	10
Maize, 2 x 30 g a.s./ha					
FSN + IDF OD 45 (22.5+22.5)	Fish, chronic	NOEC = 1 800	11.59 ¹⁾	155	10
	Invertebrate, chronic	NOEC = 400	11.59 ¹⁾	35	10
	Green algae, chronic	ErC ₅₀ > 5 000	11.59 ¹⁾	> 431	10
	Aquatic plants, chronic	ErC ₅₀ = 53.23	11.59 ¹⁾	4.60	10
Foramsulfuron	Fish, chronic	NOEC = 10 500	4.189	2 507	10
	Invertebrate, chronic	NOEC > 100 000	4.189	> 23 872	10
	Green algae, chronic	ErC ₅₀ = 8100	4.189	1934	10
	Aquatic plants, chronic	ErC ₅₀ = 1.01	4.189	0.24	10
AE F092944	Green algae, chronic	ErC ₅₀ > 560 000	0.172	> 3 255 814	10
	Aquatic plants, chronic	EC ₅₀ > 100 000	0.172	> 581 395	10
AE F099095	Green algae, chronic	ErC ₅₀ > 100 000	0.066	> 1 515 152	10
	Aquatic plants, chronic	EC ₅₀ > 100 000	0.066	> 1 515 152	10
AE F153745	Aquatic plants, chronic	EC ₅₀ > 100 000	0.070	> 1 428 571	10
AE 0338795	Aquatic plants, chronic	ErC ₅₀ = 27 200	0.107	254 206	10
AE F130619	Aquatic plants, chronic	EC ₅₀ = 0.889	0.276	3.22	10
4-Amino-N-methylbenzamide	Aquatic plants, chronic	ErC ₅₀ > 10 000	0.021	> 476 190	10
4-Formylamido-N-methylbenzamide	Aquatic plants, chronic	ErC ₅₀ > 10 000	0.038	> 263 158	10
Foramsulfuron sulfamic acid	Aquatic plants, chronic	ErC ₅₀ > 10 000	0.053	> 188 679	10

Bold values require further refinement

¹⁾ Based on spray drift values of 2.77 % for the formulation

Table 2.9.9.2-3: TER_{LT} calculations based on FOCUS Step 3 for foramsulfuron and metabolite AE F130619 for aquatic plants

Species	Endpoint [µg/L]	PEC _{sw} max [µg/L]	FOCUS scenario	TER _{LT}	Trigger
Foramsulfuron, Maize, 1 x 60 g/ha					
Aquatic plants, chronic	ErC ₅₀ = 1.01	0.314	D3 (ditch)	3.2	10
		0.013	D4 (pond)	78	10
		0.271	D4 (stream)	3.7	10
		0.015	D5 (pond)	67.3	10
		0.251	D5 (stream)	4.0	10
		0.316	D6 (ditch)	3.2	10
		0.025	R1 (pond)	40.4	10
		1.284	R1 (stream)	0.8	10
		0.972	R2 (stream)	1.0	10
		2.225	R3 (stream)	0.5	10
		2.341	R4 (stream)	0.4	10

Species	Endpoint [µg/L]	PEC _{sw} max [µg/L]	FOCUS scenario	TER _{LT}	Trigger
AE F130619, Maize, 1 x 60 g/ha					
Aquatic plants, chronic	ErC ₅₀ = 0.889	0.032	D3 (ditch)	27.8	10
		0.001	D4 (pond)	889	10
		0.001	D4 (stream)	889	10
		0.002	D5 (pond)	445	10
		<0.001	D5 (stream)	>889	10
		0.032	D6 (ditch)	27.8	10
		0.004	R1 (pond)	222.3	10
		0.081	R1 (stream)	11.0	10
		0.106	R2 (stream)	8.4	10
		0.178	R3 (stream)	5.0	10
0.202	R4 (stream)	4.4	10		
Foramsulfuron, Maize, 2 x 30 g/ha					
Aquatic plants, chronic	ErC ₅₀ = 1.01	0.157	D3 (ditch)	6.41	10
		0.010	D4 (pond)	101.0	10
		0.136	D4 (stream)	7.4	10
		0.013	D5 (pond)	77.7	10
		0.126	D5 (stream)	8.0	10
		0.158	D6 (ditch)	6.4	10
		0.062	R1 (pond)	16.3	10
		1.281	R1 (stream)	0.8	10
		0.456	R2 (stream)	2.2	10
		1.084	R3 (stream)	0.9	10
1.315	R4 (stream)	0.8	10		
AE F130619, Maize, 2 x 30 g/ha					
Aquatic plants, chronic	ErC ₅₀ = 0.889	0.016	D3 (ditch)	55.6	10
		<0.001	D4 (pond)	>889	10
		0.001	D4 (stream)	889	10
		0.001	D5 (pond)	889	10
		0.001	D5 (stream)	889	10
		0.016	D6 (ditch)	55.6	10
		0.010	R1 (pond)	88.9	10
		0.099	R1 (stream)	9.0	10
		0.052	R2 (stream)	17.1	10
		0.089	R3 (stream)	10.0	10
0.121	R4 (stream)	7.3	10		

Bold values require further refinement

Aquatic plants: Refined TER_{LT} calculations based on FOCUS Step 3/Step 4 and refined ecotox endpoints

For the refined risk assessment long-term exposure scenarios and peak exposure scenarios were considered separately. Peak scenarios showed a dominant peak (primary peak) that lasted not longer than 24 hours. In some scenarios this primary peak was followed by one or a few smaller peaks called secondary peaks in the following text. The following scenarios were considered as peak-scenarios: D4 stream, D5 stream, D6 ditch, R1 stream, R2 stream, R3 stream and R4 stream

For the long-term scenarios the calculated HC5 was compared to Focus Step 3 max with an assessment factor of 3.

The peak scenarios were considered separately. For the TER calculations the peak ErC₅₀ > 56.7 µg a.s./L from the *Lemna* peak study was taken into account. Regarding the derivation of a regulatory acceptable concentration from a refined exposure laboratory test, the new aquatic guidance document

(EFSA, 2013, p. 110) proposes an assessment factor of 10 in conjunction with the EC₅₀ for plants. This approach is reasonable because:

1. *Lemna* is the most sensitive aquatic macrophyte species,
2. *Lemna* is also most sensitive to peak exposures. The peak NOEC of 3.9 µg a.s./L from the pond study with other aquatic macrophytes is higher than the NOEC of 2.42 µg a.s./L obtained from the *Lemna*-peak study.

A refined risk assessment based on the comparison of the 24 h *Lemna*-peak study with primary peak (PEC_{max}) from peak exposure can be justified for the following reasons:

1. The primary peak lasted not longer than 24 hours.
2. The secondary peaks (if they occurred at all) did not exceed the NOEC of 2.42 µg a.s./L.
3. The temporal distance between primary and secondary peaks was greater or equal than three days (with exception of the R2 stream scenarios, where a slight peak (< 0.1 µg a.s./L) occurred after two days already). Figures 1 and 3 in the *Lemna* peak study (Bruns 2013) reveal that the growth curves even between day 2 and 5 are running parallel to the control at concentrations up to 2.42 µg a.s./L indicating a rapid recovery within a few days. Taking into account that the secondary peaks are far less than 2.42 µg/L and a fast recovery of *Lemna*-growth after a preceding exposure has been observed, it can be concluded that the secondary peaks can be neglected.

Co-RMS agrees with the proposed risk refinement and it is presented in Table 2.9.9.2-4.

The RMS does not agree that an endpoint from a single pulse exposure is suitable to be used for a comparison with a PEC_{sw}. The exposure profiles of many scenarios suggest that at least two to three peaks are available. Although many scenarios suggests only a limited number of exposure peaks, patterns of peaks in the profiles are a result of weather data used in the FOCUS simulations. These may not represent a worst case exposure scenario in a realistic field situation, especially not for hydrophilic substances such as sulfonylureas where aquatic exposure is a result of not just spray drift but also of drainage and run-off. Due to only 16 month weather data in FOCUS models RMS considers that the models are not valid towards actual field at this resolution and therefore it is not scientifically justified to mimic the exposure profiles from FOCUS modelling in higher tier studies.

Hence, as the RMS does not agree to refine risks to aquatic organisms based on the peak pattern of the FOCUS profiles the risk has also been refined using the SSD HC₅ value of 0.652 µg/L and AF of 3 (Table 2.9.9.2-4).

Table 2.9.9.2-4: Refined TER_{LT} calculations based on FOCUS Step 3 and refined ecotox endpoints

Species	Endpoint [µg/L]	PEC _{sw,max} [µg/L]	FOCUS scenario	TER _{LT}	Trigger
Foramsulfuron, Maize, 1 x 60 g/ha					
Aquatic plants, chronic	long-term exposure HC ₅ : 0.652	0.314	D3 (ditch)	2.1	3
		0.013	D4 (pond)	50.2	3
		0.015	D5 (pond)	43.5	3
		0.025	R1 (pond)	26.1	3
	peak exposure peak ErC ₅₀ : > 56.7	0.271	D4 (stream)	> 209.2	10
		0.251	D5 (stream)	> 226	10
		0.316	D6 (ditch)	> 179.4	10
		1.284	R1 (stream)	> 44.2	10
		0.972	R2 (stream)	> 58.3	10
		2.225	R3 (stream)	> 25.5	10
		2.341	R4 (stream)	> 24.2	10

Species	Endpoint [µg/L]	PEC _{sw} ,max [µg/L]	FOCUS scenario	TER _{LT}	Trigger
Foramsulfuron, Maize, 1 x 60 g/ha					
AE F130619, Maize, 1 x 60 g/ha					
Aquatic plants, chronic	peak exposure peak ErC ₅₀ : > 56.7	0.106	R2 (stream)	> 535	20
		0.178	R3 (stream)	> 319	20
		0.202	R4 (stream)	> 281	20
Foramsulfuron, Maize, 2 x 30 g/ha					
Aquatic plants, chronic	long-term exposure HC ₅ : 0.652	0.157	D3 (ditch)	4.2	3
		0.010	D4 (pond)	65.2	3
		0.013	D5 (pond)	50.2	3
		0.062	R1 (pond)	10.5	3
	peak exposure peak ErC ₅₀ : > 56.7	0.136	D4 (stream)	> 417	10
		0.126	D5 (stream)	> 450	10
		0.158	D6 (ditch)	> 359	10
		1.281	R1 (stream)	> 44.3	10
		0.456	R2 (stream)	> 124.3	10
		1.084	R3 (stream)	> 52.3	10
		1.315	R4 (stream)	> 43.1	10
AE F130619, Maize, 2 x 30 g/ha					
Aquatic plants, chronic peak exposure	peak ErC ₅₀ : > 56.7	0.052	R2 (stream)	> 1090	20
		0.089	R3 (stream)	> 637	20
		0.121	R4 (stream)	> 469	20
Foramsulfuron, Maize, 1 x 60 g/ha; 10 m spray drift & runoff buffer					
Aquatic plants, chronic	long-term exposure HC ₅ : 0.652	0.055	D3 (ditch)	11.9	3

Bold TER values require further refinement

Based on the risk assessment accepted by the Co-RMS no mitigation measure is required to pass the aquatic risk assessment in case of the 2-fold application in maize (2 x 30 g a.s./ha), while in case of the single application (1 x 60 g a.s./ha) a 10 m non-spray and vegetated buffer zone is necessary to pass scenario D3.

Since RMS does not agree that an endpoint from a single pulse exposure is suitable to be used for a comparison with a PEC_{sw}, RMS has performed TER_{LT} calculations based on FOCUS Step 4 PEC_{sw} values for foramsulfuron and metabolite AE F130619 together with the SSD HC₅ value of 0.652 µg/L and AF 3 (10 & 20 m spray drift & runoff buffers, respectively; Tables 2.9.9.2-5 and 2.9.9.2-6).

Table 2.9.9.2-5: TER_{LT} calculations based on FOCUS Step 4 for foramsulfuron and metabolite AE F130619 (10 m spray drift & runoff buffer)

Species	Endpoint [µg/L]	PEC _{sw} max [µg/L]	FOCUS scenario	TER _{LT}	Trigger
Foramsulfuron, Maize, 1 x 60 g/ha; 10 m spray drift & runoff buffer					
Aquatic plants, chronic	ErC ₅₀ = 0.652	0.055	D3 (ditch)	11.855	3
		0.008	D4 (pond)	81.500	3
		0.061	D4 (stream)	10.689	3
		0.010	D5 (pond)	65.200	3
		0.057	D5 (stream)	11.439	3

Species	Endpoint [µg/L]	PEC _{sw} max [µg/L]	FOCUS scenario	TER _{LT}	Trigger
Foramsulfuron, Maize, 1 x 60 g/ha; 10 m spray drift & runoff buffer					
		0.058	D6 (ditch)	11.241	3
		0.012	R1 (pond)	54.333	3
		0.547	R1 (stream)	1.192	3
		0.426	R2 (stream)	1.531	3
		1.006	R3 (stream)	0.648	3
		1.065	R4 (stream)	0.612	3
AE F130619, Maize, 1 x 60 g/ha					
Aquatic plants, chronic	ErC ₅₀ = 0.889	<0.001	D3 (ditch)	>889.0	10
		<0.001	D4 (pond)	>889.0	10
		0.001	D4 (stream)	889.0	10
		<0.001	D5 (pond)	>889.0	10
		<0.001	D5 (stream)	>889.0	10
		0.008	D6 (ditch)	111.1	10
		<0.001	R1 (pond)	>889.0	10
		0.035	R1 (stream)	25.4	10
		0.046	R2 (stream)	19.3	10
		0.080	R3 (stream)	11.1	10
0.092	R4 (stream)	9.7	10		
Foramsulfuron, Maize, 2 x 30 g/ha					
Aquatic plants, chronic	ErC ₅₀ = 0.652	0.027	D3 (ditch)	24.01	3
		0.006	D4 (pond)	108.7	3
		0.030	D4 (stream)	21.7	3
		0.009	D5 (pond)	72.4	3
		0.028	D5 (stream)	23.3	3
		0.034	D6 (ditch)	19.2	3
		0.027	R1 (pond)	24.1	3
		0.580	R1 (stream)	1.1	3
		0.200	R2 (stream)	3.3	3
		0.490	R3 (stream)	1.3	3
0.598	R4 (stream)	1.1	3		
AE F130619, Maize, 2 x 30 g/ha					
Aquatic plants, chronic	ErC ₅₀ = 0.889	<0.001	D3 (ditch)	>889.0	10
		<0.001	D4 (pond)	>889.0	10
		0.001	D4 (stream)	889.0	10
		0.001	D5 (pond)	889.0	10
		0.001	D5 (stream)	889.0	10
		0.008	D6 (ditch)	111.1	10
		0.002	R1 (pond)	444.5	10
		0.045	R1 (stream)	19.8	10
		0.023	R2 (stream)	38.7	10
		0.040	R3 (stream)	22.2	10
		0.055	R4 (stream)	16.2	10

Bold values require further refinement

Table 2.9.9.2-6: TER_{LT} calculations based on FOCUS Step 4 for foramsulfuron and metabolite AE F130619 (20 m spray drift & runoff buffer)

Species	Endpoint [µg/L]	PEC _{sw} ,max [µg/L]	FOCUS scenario	TER _{LT}	Trigger
Foramsulfuron, Maize, 1 x 60 g/ha; 20 m spray drift & runoff buffer					
Aquatic plants, chronic	ErC ₅₀ = 0.652	0.279	R1 (stream)	2.3	3
		0.221	R2 (stream)	3.0	3
		0.526	R3 (stream)	1.2	3
		0.558	R4 (stream)	1.2	3
AE F130619, Maize, 1 x 60 g/ha					
Aquatic plants, chronic	ErC ₅₀ = 0.889	0.048	R4 (stream)	18.5	10
Foramsulfuron, Maize, 2 x 30 g/ha					
Aquatic plants, chronic	ErC ₅₀ = 0.652	0.303	R1 (stream)	2.2	3
		0.256	R3 (stream)	2.5	3
		0.313	R4 (stream)	2.1	3

Bold values require further refinement

For foramsulfuron based on the risk assessment accepted by the RMS the risk is unacceptable with 10 m spray drift & runoff buffer for run-off stream scenarios R1, R2, R3 and R4 with application rate of 1 x 60 g a.s./ha and for stream scenarios R1, R3 and R4 with application rate of 2 x 30 g a.s./ha. Using PEC_{sw} values of 20 m spray drift & runoff buffer the risk is still unacceptable R1, R3 and R4 with both application rates of 1 x 60 g a.s./ha and 2 x 30 g a.s./ha.

For the metabolite AE F130619 the risk is acceptable with 20 m spray drift & runoff buffer with application rate of 1 x 60 g a.s./ha while with the multiple application pattern of 2 x 30 g a.s./ha the risk is acceptable with 10 m spray drift & runoff buffer in all scenarios.

2.9.9.3. Risk assessment for non-target arthropods

Risk assessment for bees

For detailed information please see Volume 3 CP B.9.6.1.

Foliar application of pesticides may potentially result in exposure of bees either through direct over-spray (contact exposure) or via residues on plants while bees are foraging for food (contact or oral exposure). For a Tier 1 risk assessment the maximum single field use rate (60 g foramsulfuron/ha) and the LD₅₀ values were used to calculate a hazard quotients. A hazard quotient of less than 50 indicates a low risk to bees in the field (EPPO, 2003).

The hazard quotient for oral and contact exposure of honeybees is given in table below:

Table 2.9.9.3-1: HQ for honeybees

Test substance	Type of test	Toxicity endpoint (µg as/bee)	Exposure (g as/ha)	HQ
foramsulfuron	48h Oral	> 110.1	60	< 0.5
	48h Contact	> 100		< 0.6
foramsulfuron as formulation foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L)	48h Oral	> 5.0	60	< 12
	48h Contact	> 4.66		< 13

Further considerations for the risk assessment for bees

The results of chronic laboratory test show no adverse lethal-, sub-lethal, behavioural or delayed effects were found by exposing adult honey bees for 10 consecutive days exclusively to sugar solution, containing 120 ppm foramsulfuron (nominal), which corresponded to about the concentration of foramsulfuron in the spray tank of a high-volume use.

A bee brood feeding study done by Oomen *et al.* (1992) show statistically significantly increased termination rate of young and old larvae when compared to the control treatment. No adverse effects on the survival of adult bees and pupae, behaviour, colony strength, condition of the colonies, colony development, brood index and brood compensation index was observed.

In an *in-vitro* larval test conducted with Foramsulfuron WG 50, as technical foramsulfuron was not well soluble in water, showed no adverse effect on larvae mortality at a level of 100 µg a.s./larva, i.e. the (highest) dose tested.

A higher tier semi-field honey bee brood study under tunnel conditions to the full flowering and highly bee attractive surrogate crop *Phacelia tanacetifolia* showed no adverse effects on mortality of worker or pupae, foraging activity, behaviour, nectar- and pollen storage as well as on queen survival with. No effects on colony development, colony strength or bee brood were also observed with maximum rate (2.68 L) of EQUIP OD 45 (22.5 + 22.5 g/L).

Overall, it can be concluded that EQUIP OD 45 (22.5+22.5 g/L), when applied at the maximum application rate of 60 g a.s./ha even during the flowering period of potentially bee-attractive weeds inside the cropping area, does not pose an unacceptable risk to honey bees and honey bee colonies

Risk assessment for non-target arthropods other than bees

Risk assessment follows the approach recommended in the ESCORT 2 guidance document (Candolfi *et al.* 2001) as proposed by EC Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC, SANCO/10329, 17 October 2002.

For detailed information please see Volume 3 CP B.9.6.2.

EQUIP OD 45 is intended to be applied once with an application rate of 2.6 L product/ha. Therefore, the multiple application factor (MAF) was set at 1.0. Resulting HQ values are presented in the following tables below. The risk is considered acceptable if the calculated HQ is < 2.

Table 2.9.9.3-2: HQ for terrestrial non-target arthropods for the in-field scenario

Crop	Species	Appl. rate [g a.s./ha]	MAF	LR ₅₀ [g a.s./ha]	HQ	Trigger
Maize	<i>T. pyri</i>	60	1	> 62.2	<1.0	2
	<i>A. rhopalosiphi</i>			5.6	10.8	2

The in-field HQ value for *Typhlodromus pyri* is below the trigger of concern. However, the in-field HQ value for *Aphidius rhopalosiphi* is above the trigger of 2, indicating a need for refinement.

Table 2.9.9.3-3: HQ for terrestrial non-target arthropods for the off-field scenario

Crop	Species	Appl. rate [mL product/ha]	MAF	Drift [%]	VDF	Corr. factor	LR ₅₀ [mL product/ha]	HQ	Trigger
Maize	<i>T. pyri</i>	2600	1	2.77	10	10	> 2670	0.03	2
	<i>A. rhopalosiphi</i>				10	10	241	0.3	2

The calculated off-field HQ values are below the trigger of concern.

In-field tier 2 risk assessment:

The risk is considered acceptable if effects on mortality and reproduction are <50% at the in-field PECmax (application rate x MAF).

Table 2.9.9.3-4: Tier 2 in-field risk assessment (based on study results from extended laboratory studies with the standard species *Typhlodromus pyri* and *Aphidius rhopalosiphi* and laboratory studies with additional species)

Test Species	in-field PECmax [mL product/ha]	LR50/ER50 [mL/ha]	Risk acceptable if:	Refined assessment required?
<i>Aphidius rhopalosiphi</i>	2600	>2670	Effects are < 50%	no
<i>Typhlodromus pyri</i>	2600	>3500	Effects are < 50%	no
<i>Chrysoperla carnea</i>	2600	>4000	Effects are < 50%	no
<i>Aleochara bilineata</i>	2600	>4000	Effects are < 50%	no
<i>Poecilus cupreus</i>	2600	>4660	Effects are < 50%	no
<i>Pardosa</i> sp.	2600	>4000	Effects are < 50%	no

Further tests on additional arthropod species resulted in LR₅₀ and ER₅₀ values above the intended application rate of 2.6 L product/ha.

It can be concluded that the risk to non-target arthropods in the in-field and off-field area from foramsulfuron is acceptable following the use of EQUIP OD 45 according to the proposed use pattern supported in this submission.

2.9.9.4. Risk assessment on non-target soil meso- and macrofauna

Risk assessment for earthworms

The risk assessment has been performed according to Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC (SANCO/10329/2002, 17 October 2002 rev 2 final).

For detailed information please see Volume 3 CP B.9.7.4.1.

Acute risk

Table 2.9.9.4-1: Acute TER values for earthworms

Test material	LC ₅₀ (mg/kg)	PEC _{initial/accu} (mg/kg)	TER _{acute}	Annex VI trigger
as foramsulfuron	> 1000	0.08	> 12500	10
AE F153745	> 1000	0.003	> 333 334	10
formulation (AE F130360 01 1K05 A304)	453	3.5	129	10

All the acute TER values are higher than the Annex VI acute trigger value of 10, indicating that the acute risk to earthworms is acceptable following use foramsulfuron, AE F153745 or formulation EQUIP OD 45 according to the proposed use pattern.

Long-term risk

Table 2.9.9.4-2: Long-term TER values for earthworms

Compound, test design	Endpoint NOEC (mg a.s./kg dws)	PEC _{soil,max/accu} [mg/kg]	TER _{LT}	Trigger
foramsulfuron reproduction	> 2.75	0.063	> 43.7	5
AE F092944 reproduction	10	0.004	2 500	5
AE F153745 reproduction	> 100	0.003	> 33 333	5
AE F130619 reproduction	56	0.016	3 500	5
FSN + IDF OD 45 reproduction	> 370	2.499	> 148	5

Long-term TER values of EQUIP OD 45, foramsulfuron, metabolites AE F092944, AE F153745 and AE F130619 exceed the Annex VI long-term trigger value of 5, indicating that the long-term risk to earthworms is acceptable following use according to the proposed use pattern.

Risk assessment for other soil non-target macro-organisms (other than earthworms)

For detailed information please see Volume 3 CP B.9.7.4.3.

For foramsulfuron and its metabolites AE F092944, AE F153745 and AE F130619 reproductive toxicity studies on *Hypoaspis aculeifer* and *Folsomia candida* were performed.

Table 2.9.9.4-3: TER_{LT} of foramsulfuron and its metabolites AE F092944, AE F153745 and AE F130619 for *Folsomia candida* and *Hypoaspis aculeifer*

Compound	Species	Endpoint (NOEC)	PEC _{soil,max/accu} [mg/kg]	TER	Trigger
FSN + IDF OD 45	<i>Folsomia candida</i>	142 mg product/kg dws	2.499	56.8	5
	<i>Hypoaspis aculeifer</i>	> 370 product /kg dws	2.499	> 148	5
Foramsulfuron	<i>Folsomia candida</i>	178 mg a.s./kg dws	0.063	2 825	5
	<i>Hypoaspis aculeifer</i>	> 1000 mg a.s./kg dws	0.063	> 15 873	5

Compound	Species	Endpoint (NOEC)	PEC _{soil,max/accu} [mg/kg]	TER	Trigger
AE F092944	<i>Folsomia candida</i>	> 100 mg/kg dws	0.004	> 25 000	5
	<i>Hypoaspis aculeifer</i>	> 100 mg/kg dws	0.004	> 25 000	5
AE F153745	<i>Folsomia candida</i>	> 100 mg/kg dws	0.003	> 33 333	5
	<i>Hypoaspis aculeifer</i>	> 100 mg/kg dws	0.003	> 33 333	5
AE F130619	<i>Folsomia candida</i>	> 100 mg/kg dws	0.016	> 6 250	5
	<i>Hypoaspis aculeifer</i>	> 100 mg/kg dws	0.016	> 6 250	5

The TER_{LT} values of product EQUIP OD 45, foramsulfuron and its metabolites AE F092944, AE F153745 and AE F130619 are above the trigger, indicating no unacceptable risk for soil non-target macro-organisms, i.e. collembola and soil mites.

2.9.9.5. Risk assessment for soil nitrogen transformation

For detailed information please see Volume 3 CP B.9.8.1.

For foramsulfuron and its metabolites AE F092944, AE F153745 and AE F130619 studies on the effect on soil nitrogen transformation were performed. In none of the studies unacceptable effects were found at the highest tested dose level which ranged from 0.137 mg/kg dws to 0.735 mg/kg dws. Details of all studies are provided in the table below.

Table 2.9.9.5-1: Toxicity data of foramsulfuron and metabolites to soil non-target micro-organisms

Test item	Test design	Ecotoxicological endpoint		Reference
N-transformation				
EQUIP OD 45	28 d	no unacceptable effects	≥18.59 L prod./ha ≥0.6 mg a.s./kg dws	Van der Kolk, 1999 M-193742-01-1 KCP 10.5/01
Foramsulfuron, tech.	28 d	no unacceptable effects	≥0.3 mg a.s./kg dws	Heusel, 1997 M-142972-01-1 KCA 8.5/01
Foramsulfuron + bound residues	28 d	no unacceptable effects	≥0.735 mg a.s./kg dws	Sowig & Gildemeister, 2000 M-193916-01-1 KCA 8.5/02
AE F153745	28 d	no unacceptable effects	≥0.240 mg/kg dws	Schulz, 2013 M-453508-01-1 KCA 8.5/07
AE F130619	28 d	no unacceptable effects	≥0.375 mg/kg dws	Schulz, 2013 M-453568-01-1 KCA 8.5/06
AE F092944	28 d	no unacceptable effects	≥0.137 mg/kg dws	Schulz, 2013 M-453511-01-1 KCA 8.5/05

dws = dry weight soil

According to current regulatory requirements the risk is considered acceptable if the effect on nitrogen mineralisation at the recommended application rate of a compound/product is ≤ 25% after 100 days. In no study did deviations from the control exceed 25% 28 days after application, indicating that the risk to organic matter breakdown from foramsulfuron and its soil metabolites AE F092944, AE

F153745 and AE F130619 is acceptable following the use of EQUIP OD 45 according to the proposed use pattern supported in this submission.

2.9.9.6. Non-target plants

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area. Spray drift from the treated areas may lead to residues of a product in off-crop areas.

For detailed information please see Volume 3 CP B.9.10.2.

The highest single application rate of EQUIP OD 45 (22.5+22.5 g/L) is 2.7 L product/ha (corresponding to 120 g foramsulfuron + isoxadifen a.i./ha), giving a maximum off-field predicted environmental rate (PER_{off-field}) of 3.324 g sum of a.i./ha.

Table 2.9.9.6-1: Off-crop exposure for non-target terrestrial plants

Crop	Application rate (g as/ha)	Distance (m)	Drift (%)	PER _{off-field} (g a.s./ha)
Maize	120.0 g sum of as/ha	1	2.77	3.324
		5	0.57	0.684
		10	0.29	0.348

Deterministic Risk assessment

According to the Terrestrial Guidance Document², the risk to non-target plants is evaluated by comparing the lowest ER₅₀ observed in the laboratory studies with the drift rates (PER_{off-field}) inclosing a safety factor of 5. In addition, the usage of drift reducing nozzles is considered.

Table 2.9.9.6-2: Deterministic risk assessment for foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) based on effects on seedling emergence

arable field crops, one application, 120.0 g sum of a i./ha; lowest ER ₅₀ = 38.8 g sum of a i./ha						
Distance	Drift	PER	TER			
[m]	(%)	no drift reduction [g sum of a.i./ha]	No drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
1	2.77	3.324	11.67	23.35	46.69	116.73
5	0.57	0.684	56.73	113.45	226.90	567.25
10	0.29	0.348	111.49	222.99	445.98	1114.94

² Anonymous (2002b). Guidance Document on terrestrial ecotoxicology under council directive 91/414/EEC. SANCO/10329/2002. 17 October 2002.

Table 2.9.9.6-3: Deterministic risk assessment for foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) based on effects on vegetative vigour

arable field crops, one application, 120.0 g sum of a.i./ha; lowest ER ₅₀ = 1.880 g sum of a.i./ha						
Distance	Drift	PER	TER			
[m]	(%)	no drift reduction [g sum of a.i./ha]	No drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
1	2.77	3.324	0.57	1.13	2.26	5.66
5	0.57	0.684	2.75	5.50	10.99	27.49
10	0.29	0.348	5.40	10.80	21.61	54.02

All seedling emergence TER values based on ER₅₀ for the most sensitive tested species lettuce (worst case) compared to PER values are greater than the Annex VI trigger value of 5, indicating an acceptable risk to the emergence of non-target plant seedlings following use of EQUIP OD according to the proposed use pattern.

Vegetative vigour TER values are above the Annex VI trigger of 5 are therefore acceptable for most sensitive dicot species (radish) assuming a 10 m buffer distance (without drift reduction). Considering drift reduction in the risk assessment, with the use of 50% drift reducing nozzles the buffer zone can be reduced to 5 m. With the use of 90% drift reducing nozzles no buffer zone is required.

2.10. CLASSIFICATION AND LABELLING

Proposed classification according to Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification ¹⁾	Reason for no classification ²⁾
2.1.	Explosives				
2.2.	Flammable gases				
2.3.	Flammable aerosols				
2.4.	Oxidising gases				
2.5.	Gases under pressure				
2.6.	Flammable liquids				
2.7.	Flammable solids				
2.8.	Self-reactive substances and mixtures				
2.9.	Pyrophoric liquids				
2.10.	Pyrophoric solids				
2.11.	Self-heating substances and mixtures				
2.12.	Substances and mixtures which in contact with water emit flammable gases				
2.13.	Oxidising liquids				
2.14.	Oxidising solids				
2.15.	Organic peroxides				
2.16.	Substance and mixtures corrosive to metals				
3.1.	Acute toxicity - oral				
	Acute toxicity - dermal				
	Acute toxicity - inhalation				
3.2.	Skin corrosion / irritation				
3.3.	Serious eye damage / eye irritation				
3.4.	Respiratory sensitisation				
3.4.	Skin sensitisation				
3.5.	Germ cell mutagenicity				
3.6.	Carcinogenicity				
3.7.	Reproductive toxicity				
3.8.	Specific target organ toxicity –single exposure				
3.9.	Specific target organ toxicity – repeated exposure				
3.10.	Aspiration hazard				

4.1.	Hazardous to the aquatic environment	H400 H410	M-factor 100		
5.1.	Hazardous to the ozone layer				

¹⁾ Including specific concentration limits (SCLs) and M-factors

²⁾ Data lacking, inconclusive, or conclusive but not sufficient for classification

Labelling: Signal word:

Warning

Hazard statements:

H400: Very toxic to aquatic life

H410: Very toxic to aquatic life with long lasting effects

Precautionary statements:



Pictogram:

Proposed notes assigned to an entry:

Notes in accordance with CLP Regulation, Annex VI, Section 1.1.3

Proposed classification according to Dangerous Substances Directive (Directive 67/548/EEC)

Hazardous property	Proposed classification	Proposed SCLs	Current classification ¹⁾	Reason for no classification ²⁾
Explosiveness				
Oxidising properties				
Flammability				
Other physico-chemical properties <i>[Add rows when relevant]</i>				
Thermal stability				
Acute toxicity				
Acute toxicity – irreversible damage after single exposure				
Repeated dose toxicity				
Irritation / Corrosion				
Sensitisation				
Carcinogenicity				
Mutagenicity – Genetic toxicity				
Toxicity to reproduction – fertility				
Toxicity to reproduction – development				
Toxicity to reproduction – breastfed babies. Effects on or via lactation				
Environment	N; R50/53 (“Very toxic to aquatic organisms and May cause long-term adverse effects in the aquatic environment”)		N; R50/53 (“Very toxic to aquatic organisms and May cause long-term adverse effects in the aquatic environment”)	

¹⁾ Including SCLs

²⁾ Data lacking, inconclusive, or conclusive but not sufficient for classification

Labelling:

Indication of danger:

N (“Dangerous for the environment”)

Symbols



Dangerous for the environment

R-phrases:

R50/53 (“Very toxic to aquatic organisms and May cause long-term adverse effects in the aquatic environment”)

S-phrases:

and S60/61 (“This material and its container must be disposed of as hazardous waste”
instructions/safety data sheet”) “Avoid release to the environment. Refer to special

2.11. RELEVANCE OF METABOLITES IN GROUNDWATER**2.11.1. STEP 1: Exclusion of degradation products of no concern****2.11.2. STEP 2: Quantification of potential groundwater contamination****2.11.3. STEP 3: Hazard assessment – identification of relevant metabolites**

2.11.3.1 STEP 3, Stage 1: screening for biological activity

2.11.3.2 STEP 3, Stage 2: screening for genotoxicity

2.11.3.3 STEP 3, Stage 3: screening for toxicity

2.11.4. STEP 4: Exposure assessment – threshold of concern approach**2.11.5. STEP 5: Refined risk assessment****2.11.6. Overall conclusion****2.12. CONSIDERATION OF ISOMERIC COMPOSITION IN THE RISK ASSESSMENT**

The Applicant has provided following argumentations: As no guidance document is currently available that details how questions concerning stereoisomers might be dealt with, it is the opinion of the applicant that it is not appropriate to address this issue until such guidance is available. Therefore the risk assessment should be conducted in accordance with the current published guidelines. For information it should be noted that foramsulfuron does not have any stereoisomers.

2.12.1. Identity and physical chemical properties**2.12.2. Methods of analysis****2.12.3. Mammalian toxicity****2.12.4. Operator, Worker, Bystander and Resident exposure**

2.12.5. Residues and Consumer risk assessment**2.12.6. Environmental fate****2.12.7. Ecotoxicology****2.13. RESIDUE DEFINITIONS****2.13.1. Definition of residues for exposure/risk assessment**

Food of plant origin: Foramsulfuron

Food of animal origin: Foramsulfuron

Soil: Foramsulfuron and its metabolites AE F092944, AE F130619 and AE F153745

Groundwater: Foramsulfuron and its metabolites AE F092944, AE F130619 and AE F153745

Surface water: Foramsulfuron, AE F092944, AE F130619, AE F153745, AE 0338795, AE F099095, 4-Amino-N-methylbenzamide, 4-Formamido-N-methylbenzamide, Foramsulfuron sulfamic acid

Sediment: Foramsulfuron, AE F153745

Air: Foramsulfuron

2.13.2. Definition of residues for monitoring

Food of plant origin: Foramsulfuron

Food of animal origin: Foramsulfuron

Soil: Foramsulfuron

Groundwater: Foramsulfuron

Surface water: Foramsulfuron

Sediment: Foramsulfuron

Air: Foramsulfuron

Level 3

FORAMSULFURON

3. PROPOSED DECISION WITH RESPECT TO THE APPLICATION

3.1. BACKGROUND TO THE PROPOSED DECISION

3.1.1. Proposal on acceptability against the decision making criteria – Article 4 and annex II of regulation (EC) No 1107/2009

3.1.1.1. Article 4			
		Yes	No
i)	It is considered that Article 4 of Regulation (EC) No 1107/2009 is complied with. Specifically the RMS considers that authorisation in at least one Member State is expected to be possible for at least one plant protection product containing the active substance for at least one of the representative uses.	Y	
			It is considered that Article 4 of Regulation(EC) No 1107/2009 is complied with Foramsulfuron for the representative uses (please refer to Section 1.5.1 Level 1 for details of representative uses).
3.1.1.2. Submission of further information			
		Yes	No
i)	It is considered that a complete dossier has been submitted	Y	
			With regards to the submission made, a complete dossier is considered to have been submitted, which enables a regulatory decision of Foramsulfuron to be made. Minor data gaps were identified . Please see the point 3.1.4.
ii)	It is considered that in the absence of a full dossier the active substance may be approved even though certain information is still to be submitted because: (a) the data requirements have been amended or refined after the submission of the dossier; or (b) the information is considered to be confirmatory in nature, as required to increase confidence in the decision.		
			Not applicable
3.1.1.3. Restrictions on approval			
		Yes	No
	It is considered that in line with Article 6 of Regulation (EC) No 1107/2009 approval should be subject to conditions and restrictions.	Y	
			(a) <i>the minimum degree of purity of the active substance</i> ; : 973 g/kg; The purity of the active substance has increased from 940 g/kg (original EU specification) to 973 g/kg based on the new material accountability study.

3.1.1.4. Criteria for the approval of an active substance			
Dossier			
		Yes	No
	It is considered the dossier contains the information needed to establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL) and Acute Reference Dose (ARfD).	Y	
	<p>It is considered that the dossier contains the information necessary to carry out a risk assessment and for enforcement purposes (relevant for substances for which one or more representative uses includes use on feed or food crops or leads indirectly to residues in food or feed). In particular it is considered that the dossier:</p> <p>(a) permits any residue of concern to be defined;</p> <p>(b) reliably predicts the residues in food and feed, including succeeding crops</p> <p>(c) reliably predicts, where relevant, the corresponding residue level reflecting the effects of processing and/or mixing;</p> <p>(d) permits a maximum residue level to be defined and to be determined by appropriate methods in general use for the commodity and, where appropriate, for products of animal origin where the commodity or parts of it is fed to animals;</p> <p>(e) permits, where relevant, concentration or dilution factors due to processing and/or mixing to be defined.</p>	Y	<p>Primary crop metabolism of the a.s. was investigated only in maize (cereal group) definitions are thus not universal.</p> <p>Studies on rotational crops showed comparable metabolism to primary crops and that significant residues in rotational crops are not expected.</p> <p>The data submitted support residue definition comprising parent foramsulfuron only for both enforcement and risk assessment for cereals.</p> <p>Based on new submitted analytical method, it is concluded that the previous data are valid and can be used to propose MRLs.</p> <p>As the chronic exposure does not exceed 10 % of the ADI, the effect of industrial and/or household processing was not studied.</p> <p>MRLs for all plant and animal derived commodities can be set at LOQ.</p> <p>Chronic risks assessed by EFSA PRIMo represented less than 0.1 % of the ADI (0.5 mg/kg bw /d). No acute risks were identified.</p> <p>The present evaluation covers the intended use on maize.</p> <p>No risks to consumers were identified.</p>
	It is considered that the dossier submitted is sufficient to permit, where relevant, an estimate of the fate and distribution of the active substance in the environment, and its impact on non-target species.	Y	
Efficacy			
		Yes	No
	It is considered that it has been established for one or more representative uses that the plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use is sufficiently effective.	Y	

Relevance of metabolites			
		Yes	No
	It is considered that the documentation submitted is sufficient to permit the establishment of the toxicological, ecotoxicological or environmental relevance of metabolites.	Y	
			A toxicological assessment of metabolites was not necessary. The dossier did permit establishment of the ecotoxicological and environmental relevance of metabolites.
Composition			
		Yes	No
	It is considered that the specification defines the minimum degree of purity, the identity and maximum content of impurities and, where relevant, of isomers/diastereo-isomers and additives, and the content of impurities of toxicological, ecotoxicological or environmental concern within acceptable limits.	Y	
			Proposed specification of foramsulfuron is acceptable, the analytical methods provided are acceptable. Proposed representative formulation EQUIP OD is acceptable.
	It is considered that the specification is in compliance with the relevant Food and Agriculture Organisation specification, where such specification exists.	-	
			FAO specification does not exist.
	It is considered for reasons of protection of human or animal health or the environment, stricter specifications than that provided for by the FAO specification should be adopted	-	
			Not applicable.
Methods of analysis			
		Yes	No
	It is considered that the methods of analysis of the active substance, safener or synergist as manufactured and of determination of impurities of toxicological, ecotoxicological or environmental concern or which are present in quantities greater than 1 g/kg in the active substance, safener or synergist as manufactured, have been validated and shown to be sufficiently specific, correctly calibrated, accurate and precise.	Y	
			The provided analytical methods for the determination of the active substance and/or impurities in technical material and in the plant protection product are acceptable.
	It is considered that the methods of residue analysis for the active substance and relevant metabolites in plant, animal and environmental matrices and drinking water, as appropriate, shall have been validated and shown to be sufficiently sensitive with respect to the levels of concern.	Y	
			The provided analytical methods for residue analysis in plants and plant products, foodstuffs and feeding stuffs, soil, water and air are acceptable.
	It is confirmed that the evaluation has been carried out in accordance with the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) of Regulation 1107/2009.	Y	
			The provided validation of analytical methods is in accordance with the uniform principles, it is acceptable.

Impact on human health				
Impact on human health – ADI, AOEL, ARfD				
		Yes	No	
	It is confirmed that (where relevant) an ADI, AOEL and ARfD can be established with an appropriate safety margin of at least 100 taking into account the type and severity of effects and the vulnerability of specific groups of the population.	Y		<p>An ADI of 0.5 mg/kg bw/day has been established based on a NOAEL of 50 mg/kg bw/day determined in a rabbit developmental toxicity study and a 100-fold safety factor. (See Level 2, Section 2.6.11.)</p> <p>An ARfD is not allocated because not necessary. On the basis of its toxicological profile, foramsulfuron is considered unlikely to present an acute hazard. (See Level 2, Section 2.6.12.)</p> <p>An AOEL of 0.1 mg/kg bw/day is derived from a NOAEL of 50 mg/kg bw/day in a rabbit developmental toxicity study by applying a standard safety factor of 100. The AOEL is corrected for 20 % oral absorption. (See Level 2, Section 2.6.13.)</p>
Impact on human health – proposed genotoxicity classification				
		Yes	No	
	It is considered that, on the basis of assessment of higher tier genotoxicity testing carried out in accordance with the data requirements and other available data and information, including a review of the scientific literature, reviewed by the Authority, the substance SHOULD BE classified or proposed for classification , in accordance with the provisions of Regulation (EC) No 1272/2008, as mutagen category 1A or 1B .		N	The potential genotoxicity of foramsulfuron was studied in three <i>in vitro</i> tests and two <i>in vivo</i> tests. Bacterial and mammalian gene mutation tests gave a negative result. <i>In vitro</i> chromosome aberration test with human lymphocytes was positive. <i>In vivo</i> mouse micronucleus test and <i>in vivo</i> UDS test were negative. Weight of evidence suggests that foramsulfuron is of no genotoxic concern. (See Level 2, Section 2.6.4.)
Impact on human health – proposed carcinogenicity classification				
		Yes	No	
i)	It is considered that, on the basis of assessment of the carcinogenicity testing carried out in accordance with the data requirements for the active substances, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the Authority, the substance SHOULD BE classified or proposed for classification , in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B .		N	There was no evidence of carcinogenicity in the long-term rat and mouse studies. (See Level 2, Section 2.6.5.)
ii)	Linked to above classification proposal. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in	n/a	n/a	Not applicable. Foramsulfuron is not classified for carcinogenicity.

	closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			
Impact on human health – proposed reproductive toxicity classification				
		Yes	No	
i)	It is considered that, on the basis of assessment of the reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, the substance SHOULD BE classified or proposed for classification , in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B.		N	There were no effects on fertility or development in rat or rabbit studies. (See Level 2, Section 2.6.6.)
ii)	Linked to above classification proposal. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.	n/a	n/a	Not applicable. Foramsulfuron is not classified for reproductive or developmental toxicity.
Impact on human health – proposed endocrine disrupting properties classification				
		Yes	No	
i)	It is considered that the substance SHOULD BE classified or proposed for classification in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogenic category 2 and toxic for reproduction category 2 and on that basis shall be considered to have endocrine disrupting properties		N	There was no evidence of carcinogenicity, effects on fertility or development or endocrine disrupting properties. (See Level 2, Section 2.6.8.)
ii)	It is considered that the substance SHOULD BE classified or proposed for classification in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 2 and in addition the RMS considers the substance has toxic effects on the endocrine organs and on that basis shall be considered to have endocrine disrupting properties		N	There was no evidence of carcinogenicity, effects on fertility or development or endocrine disrupting properties. (See Level 2, Section 2.6.8.)

iii)	Linked to either i) or ii) immediately above. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.	n/a	n/a	Not applicable. Foramsulfuron does not have endocrine disrupting properties.
Fate and behaviour in the environment				
Persistent organic pollutant (POP)				
		Yes	No	
	It is considered that the active substance FULFILS the criteria of a persistent organic pollutant (POP) as laid out in Regulation 1107/2009 Annex II Section 3.7.1.		N	The criteria for bioaccumulation or long-range transport were not fulfilled. The half-life in soil did not exceed the criterion for persistence in soil. The dissipation half life in water or sediment or the degradation half-life in total system did not exceed the criterion for persistence. The RMS concludes that foramsulfuron does not fulfil the criteria of a POP. See discussion under separate sub-headings in Vol 1, Level 2.8.2, 2.8.5 and 2.9.2.3.
Persistent, bioaccumulative and toxic substance (PBT)				
		Yes	No	
	It is considered that the active substance FULFILS the criteria of a persistent, bioaccumulative and toxic (PBT) substance as laid out in Regulation 1107/2009 Annex II Section 3.7.2.		N	Only the toxicity criterion (T) is fulfilled. The criteria for bioaccumulation are not fulfilled. The half-life in soil did not exceed the criterion for persistence in soil. The dissipation half life in water or sediment or the degradation half-life in total system did not exceed the criterion for persistence. The RMS concludes that foramsulfuron does not fulfil the criteria of a PBT. See discussion under separate sub-headings in Vol 1, Level 2, sections 2.8.2, 2.8.5, 2.9.2.3 and 2.9.2.4.
Very persistent and very bioaccumulative substance (vPvB).				
		Yes	No	
	It is considered that the active substance FULFILS the criteria of a		N	The criteria for bioaccumulation is not fulfilled. The half-life in soil did not exceed the criterion for persistence in soil.

	very persistent and very bioaccumulative substance (vPvB) as laid out in Regulation 1107/2009 Annex II Section 3.7.3.			<p>The dissipation half life in water or sediment or the degradation half-life in total system did not exceed the criterion for persistence.</p> <p>The RMS concludes that foramsulfuron does not fulfil the criteria of a vPvB.</p> <p>See discussion under separate sub-headings in Vol 1, Level 2.8.2, 2.8.5 and 2.9.2.3.</p>
Ecotoxicology				
		Yes	No	
	<p>It is considered that the risk assessment demonstrates risks to be acceptable in accordance with the criteria laid down in the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) under realistic proposed conditions of use of a plant protection product containing the active substance, safener or synergist. The RMS is content that the assessment takes into account the severity of effects, the uncertainty of the data, and the number of organism groups which the active substance, safener or synergist is expected to affect adversely by the intended use.</p>	Y		<p>The representative formulation EQUIP OD contains a safener isoxadifen-ethyl (22.5 g/L foramsulfuron and 22.5 g/L of the safener isoxadifen-ethyl).</p> <p>No acute or reproductive risks were identified for birds and mammals.</p> <p>No risks were identified for fish, aquatic invertebrates and algae.</p> <p>Co-RMS considers that for the active substance, risks were identified to aquatic macrophytes in FOCUS scenario D3 at step 3 level in 1 x 60 g a.s./ha. The RMS does not agree that an endpoint from a single pulse exposure is suitable to be used for a comparison with a PEC_{SW}. Based on other higher tier studies risks were not acceptable with a 20 m non-spray and run-off buffer to aquatic macrophytes in FOCUS scenario R1, R3 and R4 with both application rates of 1 x 60 g a.s./ha and 2 x 30 g a.s./ha.</p> <p>No risks were identified for bees and other non-target arthropods.</p> <p>No acute or reproductive risks were identified for earthworms and other macro soil dwelling organisms.</p> <p>No risks were identified for soil micro-organisms.</p> <p>Risks to non-target plants were concluded to be low providing appropriate mitigation measures are applied.</p> <p>See discussion under separate sub-headings in Vol 1, Level 2: B.2.9.1 to B.2.9.9.</p>
	It is considered that, on the basis of the assessment of Community or internationally agreed test guidelines, the substance HAS endocrine disrupting properties that may cause adverse effects on non-target		N	See discussion under Vol 1, Level 2, sections 2.9.2.5.

	organisms.			
	Linked to the consideration of the endocrine properties immediately above. It is considered that the exposure of non-target organisms to the active substance in a plant protection product under realistic proposed conditions of use is negligible.	-		Not applicable
	It is considered that it is established following an appropriate risk assessment on the basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist: — will result in a negligible exposure of honeybees, or — has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour.	Y		Foramsulfuron has no unacceptable acute or chronic effects on colony survival or development of honey bees under the proposed conditions of use of plant protection product. See discussion under sub-heading in Vol 1, Level 2: B.2.9.3.
Residue definition				
		Yes	No	
	It is considered that, where relevant, a residue definition can be established for the purposes of risk assessment and for enforcement purposes.	Y		Foramsulfuron
Fate and behaviour concerning groundwater				
		Yes	No	
	It is considered that it has been established for one or more representative uses, that consequently after application of the plant protection product consistent with realistic conditions on use, the predicted concentration of the active substance or of metabolites, degradation or reaction products in groundwater complies with the respective criteria of the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) of Regulation 1107/2009.	Y		The PEC _{gw} were below 0.001µg/L for foramsulfuron and its soil metabolites AE F130619, AE F153745 and AE F092944 for both applied uses in maize. Results were obtained with both PEARL and PELMO models in 8 scenarios parameterized for maize. Jokioinen scenario is not parameterized for maize. See discussion under sub-heading in Vol 1, Level 2: B.2.8.7.

3.1.2. Proposal – Candidate for substitution

Candidate for substitution

		Yes	No	
	It is considered that the active substance shall be approved as a candidate for substitution		N	The RMS concludes that foramsulfuron does not fulfil any of the criteria for identification of candidates for substitution.

3.1.3. Proposal – Low risk active substance

Low-risk active substances			
		Yes	No
	<p>It is considered that the active substance shall be considered of low risk.</p> <p>In particular it is considered that the substance should NOT be classified or proposed for classification in accordance with Regulation (EC) No 1272/2008 as at least one of the following:</p> <ul style="list-style-type: none"> — carcinogenic, — mutagenic, — toxic to reproduction, — sensitising chemicals, — very toxic or toxic, — explosive, — corrosive. <p>In addition it is considered that the substance is NOT:</p> <ul style="list-style-type: none"> — persistent (half-life in soil more than 60 days), — has a bioconcentration factor higher than 100, — is deemed to be an endocrine disrupter, or — has neurotoxic or immunotoxic effects. 		N

3.1.4. List of studies to be generated, still ongoing or available but not peer reviewed

Data gap	Relevance in relation to representative use(s)	Study status		
		No confirmation that study available or on-going.	Study on-going and anticipated date of completion	Study available but not peer-reviewed
3.1.4.1. Identity of the active substance or formulation				
3.1.4.2. Physical and chemical properties of the active substance and physical, chemical and technical properties of the formulation				
2-year storage stability study (shelf life test)	relevant for all uses		the study is on-going and should be available by the end of 2015	
3.1.4.3. Data on uses and efficacy				
3.1.4.4. Data on handling, storage, transport, packaging and labelling				

3.1.4.5. Methods of analysis				
Methods for risk assessment: ILV of the analytical method for determination of residues of foramsulfuron and metabolite AE F153745 in maize.	Yes	Yes		
Method for the degradation products in the formulation: The test has been performed in a GLP test facility but the test itself has not been performed according to GLP. However, as the validation is done in compliance with SANCO/3030/99 rev. 4, the missing GLP is considered as a minor data gap.	relevant for all uses	Yes		
3.1.4.6. Toxicology and metabolism				
3.1.4.7. Residue data				
3.1.4.8. Environmental fate and behaviour				
None				
3.1.4.9. Ecotoxicology				

3.1.5. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles, as laid out in Commission Regulation (EU) No 546/2011, and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

Area of the risk assessment that could not be finalised on the basis of the available data	Relevance in relation to representative use(s)
	<i>[specify if measure relates to a specific representative use/use scenario/product or to all uses/products]</i>

3.1.6. Critical areas of concern

An issue is listed as a critical area of concern:

(a) where the substance does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II of Regulation (EC) No 1107/2009 and the applicant has not provided detailed evidence that the active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, taking into account risk mitigation measures to ensure that exposure of humans and the environment is minimised, or

(b) where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles, as laid out in Commission Regulation (EU) 546/2011, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

Critical area of concern identified	Relevance in relation to representative use(s)
	<i>[specify if concern relates to all or specific representative use/use scenario/product or to all uses/products]</i>

3.1.7. Overview table of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in 3.3.1, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)

All columns are grey as the material tested in the toxicological studies has not been demonstrated to be representative of the technical specification.

Representative use		Maize 60 g a.s./ha	Maize 2 x 30 g a.s./ha
Operator risk	Risk identified		
	Assessment not finalised		
Worker risk	Risk identified		
	Assessment not finalised		
Bystander risk	Risk identified		
	Assessment not finalised		
Consumer risk	Risk identified		
	Assessment not finalised		
Risk to wild non target terrestrial vertebrates	Risk identified		
	Assessment not finalised		
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified		
	Assessment not finalised		
Risk to aquatic organisms	Risk identified	X	X
	Assessment not finalised		
Groundwater exposure active substance	Legal parametric value breached		
	Assessment not finalised		
Groundwater exposure metabolites	Legal parametric value breached		
	Parametric value of 10µg/L ^(a) breached		
	Assessment not finalised		
Comments/Remarks			

The superscript numbers in this table relate to the numbered points indicated within chapter 3.1.5 and 3.1.6. Where there is no superscript number, see level 2 for more explanation.

(a): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

3.1.8. Area(s) where expert consultation is considered necessary

It is recommended to organise a consultation of experts on the following parts of the assessment report:

Area(s) where expert consultation is considered necessary	Justification
Aquatic organisms	Different conclusion between RMS and Co-RMS to macrophyte risk assessment.

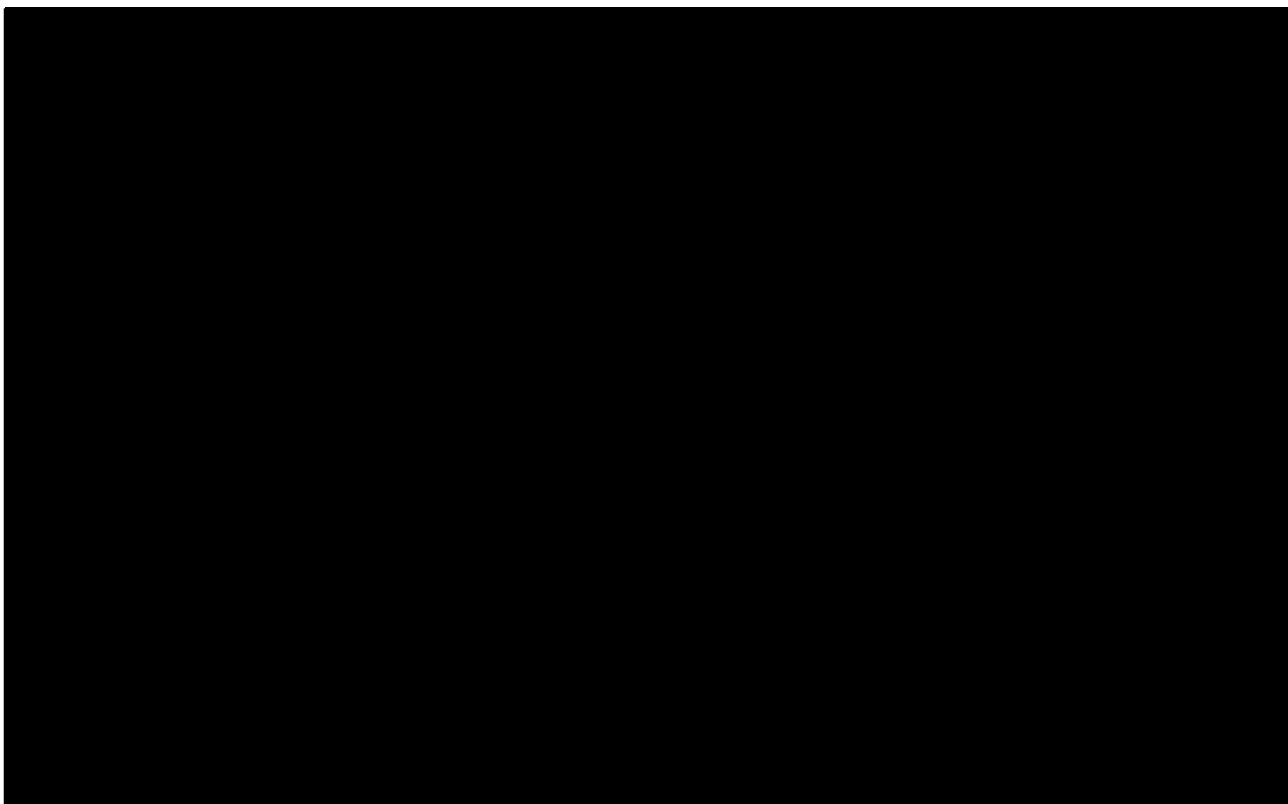
3.1.9. Critical issues on which the Co RMS did not agree with the assessment by the RMS

Points on which the co-rapporteur Member State did not agree with the assessment by the rapporteur member state. Only the points relevant for the decision making process should be listed.

Issue on which Co-RMS disagrees with RMS	Opinion of Co-RMS	Opinion of RMS

3.2. PROPOSED DECISION

It is proposed that:



3.3. RATIONAL FOR THE CONDITIONS AND RESTRICTIONS TO BE ASSOCIATED WITH THE APPROVAL OR AUTHORISATION(S), AS APPROPRIATE

3.3.1. Particular conditions proposed to be taken into account to manage the risks identified

Proposed condition/risk mitigation measure	Relevance in relation to representative use(s)

3.4. APPENDICES

GUIDANCE DOCUMENTS USED IN THIS ASSESSEMENT

Volume 3 – B1: Identity

None

Volume 3 - B2: Physicochemical properties

None

Volume 3 - B5: Analytical methods

Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414 (SANCO/3029/99 rev. 4)

Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414 (SANCO/3030/99 rev. 4)

Guidance document on pesticide residue analytical methods (SANCO/825/00 rev. 8.1)

Volume 3 - B6: Toxicology and metabolism of the active substance

EFSA (2011). Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (OJ L 309, 24.11.2009, p. 1-50). EFSA Journal 2011;9(2):2092. [49 pp.]. doi:10.2903/j.efsa.2011.2092

EFSA Panel on Plant Protection Products and their Residues (PPR); Guidance on Dermal Absorption. EFSA Journal 2012;10(4):2665. [30 pp.] doi:10.2903/j.efsa.2012.2665

Guidance on the Application of the CLP Criteria, Version 2.0 (April 2012)

Guidance document for applicants on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to Regulation (EU) 283/2013 and Regulation (EU) No 284/2013 (SANCO/10181/2013– rev. 2, May 2013)

Volume 3 - B7: Residues

EC (European Commission), 2011. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs; 7525/VI/95-rev.9

EFSA (2011). Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (OJ L 309, 24.11.2009, p. 1-50). EFSA Journal 2011;9(2):2092. [49 pp.]. doi:10.2903/j.efsa.2011.2092

Guidance document for applicants on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to Regulation (EU) 283/2013 and Regulation (EU) No 284/2013 (SANCO/10181/2013– rev. 2, May 2013)

OECD (Organisation for Economic Co-operation and Development), 2011; OECD MRL Calculator: User Guide. In: Series on Pesticides No 56. ENV/JM/MONO(2011)2, 01 March 2011.

H. Bleiholder E. Weber, M. Hess, H. Wicke, T. van den Boom, P. D. Lancashire, L. Buhr, H. Hack, R. Klose, R. Stauss, and R. Stauss Uwe Meier (editor). BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

Volume 3 - B8: Environmental Fate and Behaviour

FOCUS (2006) Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration. Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp

FOCUS (2009). Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU. Report of the FOCUS Ground Water Work Group, EC Document Reference SANCO/13144/2010 version 1, 604 pp.

FOCUS (2003) FOCUS surface water scenarios in the EU evaluation process under 91/414/EEC. Report prepared by the FOCUS Working Group on Surface Water Scenarios. SANCO/4802/2001-rev.2 final (May 2003).

FOCUS (2007). Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations. Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 169 pp.

EFSA (2011). Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (OJ L 309, 24.11.2009, p. 1-50). EFSA Journal 2011;9(2):2092. [49 pp.]. doi:10.2903/j.efsa.2011.2092.

Volume 3 - B9: Ecotoxicology

Risk Assessment for Birds and Mammals, EFSA Journal 2009;7(12):1438

Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC, SANCO/3268/2001 rev. 4 (final), 17 October 2002.

Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290.

EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus spp.* and solitary bees), EFSA Journal 2013;11(7):3295

Candolfi et al., 2000, Guidance Document on Regulatory Testing and Risk Assessment Procedures for Plant Protection Products with Non-Target Arthropods, ESCORT 2 SETAC Workshop

Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/141/EEC, SANCO/10329/2002, 17 October 2002 rev. 2 final

EFSA (2011). Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (OJ L 309, 24.11.2009, p. 1-50). EFSA Journal 2011;9(2):2092. [49 pp.]. doi:10.2903/j.efsa.2011.2092

Guidance document for applicants on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to Regulation (EU) 283/2013 and Regulation (EU) No 284/2013 (SANCO/10181/2013– rev. 2, May 2013).

Volume 4 Annex C:

Guidance document on the assessment of the equivalence of technical materials of substances regulated under regulation (EC) No 1107/2009 (SANCO/10597/2003 –rev. 10)

Guidance document on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) No 1107/2009 of the EU Parliament and Council on placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. (SANCO/12638/2011 20 November 2012 rev. 2)

3.5. REFERENCE LIST

No references specifically cited in Volume 1