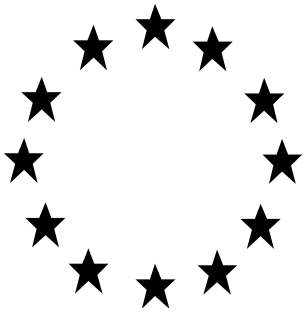
Regulation (EC) No. 1107/2009 of the European Council and Parliament



Asulam sodium

Volume 1

Report and Proposed Decision of the United Kingdom made to the European Commission under Regulation (EC) No. 1107/2009 for first approval of an active substance

Draft: April 2016

Version history

When	What
2016-04-18	Initial DAR

LEVEL 1: STATEMENT OF THE SUBJECT MATTER AND PURPOSE FOR WHICH THE DRAFT ASSESSMENT REPORT WAS PREPARED 5

1.1 Purpose for which the draft assessment report was prepared 6
1.2 Summary and assessment of information relating to the collective provision of the dossier 6
1.3 Identity of the active substance 6
1.4 Identity of the plant protection product 10
1.5 Uses of the plant protection product 11

LEVEL 2: REASONED STATEMENT OF THE OVERALL CONCLUSIONS DRAWN BY THE RAPPORTEUR MEMBER STATE 19

2.1.1 Identity 20
2.1.2 Physical and chemical properties 20
2.1.3 Details of uses, summary of efficacy and further information 20
2.1.4 Classification and labelling 20
2.2 Methods of analysis ..... **Error! Bookmark not defined.**
2.3 Impact on human and animal health 22
2.4 Residues 31
2.5 Fate and behaviour in the environment 32
2.6 Effects on non-target species 46

LEVEL 3: CONCLUSIONS AND PROPOSED DECISION WITH RESPECT TO THE CRITERIA AND REQUIREMENTS OF REGULATION (EC) NO. 1107/2009 58

3 PROPOSED DECISION WITH RESPECT TO THE APPLICATION 59
3.1 Background to the proposed decision 59
3.1.1 Proposal on acceptability against the decision-making criteria – Article 4 and Annex II of Regulation (EC) No. 1107/2009 59
3.1.2 Proposal – Candidate for substitution 69
3.1.3 Proposal – Low risk active substance 71
3.1.4 List of studies to be generated, still ongoing or available but not peer reviewed 73
3.1.5 Issues that could not be finalised 75
3.1.6 Critical areas of concern 76
3.1.7 Overview table of the concerns identified for each representative use considered 77
3.1.8 Area(s) where expert consultation is considered necessary 78
3.2 PROPOSED DECISION 79
3.3 RATIONALE FOR THE CONDITIONS AND RESTRICTIONS TO BE ASSOCIATED WITH THE APPROVAL OR AUTHORISATION(S), AS APPROPRIATE 80
3.3.1 Particular conditions proposed to be taken into account to manage the risks identified 80

APPENDIX I: STANDARD TERMS AND ABBREVIATIONS 81

APPENDIX II: SPECIFIC TERMS AND ABBREVIATIONS 92

APPENDIX III: LIST OF METABOLITES IN THE ENVIRONMENT, PLANTS AND ANIMALS 95

APPENDIX IV: GUIDANCE DOCUMENTS USED IN THIS ASSESSMENT 99

APPENDIX V: SPECIFIC REFERENCES USED IN THIS ASSESSMENT 101

APPENDIX VI: LIST OF END POINTS 103

LEVEL 1

Asulam sodium

LEVEL 1: STATEMENT OF THE SUBJECT MATTER AND PURPOSE FOR WHICH THE DRAFT ASSESSMENT REPORT WAS PREPARED

1.1 Purpose for which the draft assessment report was prepared

Asulam was previously reviewed in 2010 by the UK regulatory authority, (existing active substance review programme - List 3B). The recommendations were considered at peer review and an EFSA conclusion was published on the active substance (EFSA Journal 2010; 8(12):1822). Non-approval of asulam was given under Commission Implementing Regulation (EU) 1045/2011.

The applicant UPL Europe Limited has now submitted a dossier for asulam sodium for consideration as a new active substance under Regulation 1107/2009 with the intention of addressing the reasons for non-approval.

This draft assessment report on asulam sodium has been prepared for submission to the European Commission to enable a decision to be made on the approval of asulam sodium as a new active substance under Regulation (EC) No. 1107/2009. The UK Chemicals Regulation Directorate, HSE, is the Rapporteur Member State for asulam sodium.

The RMS has assessed the new submission in accordance with Regulation (EC) 544/2011 as the dossier was submitted prior to 1st January 2014 and presented the data accordingly.

The UK have prepared and submitted a CLH report to ECHA in December 2015, with proposals for the harmonisation of the classification and labelling of asulam sodium.

1.2 Summary and assessment of information relating to the collective provision of the dossier

Not relevant as UPL Europe Limited is the sole notifier for asulam sodium.

1.3 Identity of the active substance

1.3.1 Name and address of applicant(s) for approval of the active substance (Annex IIA 1.1)

Name:	UPL Europe Limited
Address:	The Centre, 1st Floor Birchwood Park Warrington Cheshire WA3 6YN United Kingdom
Contact:	[redacted] [redacted]

Telephone No.: [redacted]

Telefax No.: [redacted]

1.3.2 Common name and synonyms (IIA 1.3)

Common name:	Asulam-sodium (ISO 1750 (published))
	Unless otherwise stated, the data in this dossier relate to the variant asulam-sodium
Synonyms:	no synonym

1.3.3 Chemical name (IIA 1.4)

Chemical name as in Annex I to Directive 67/548/EEC:	Not included
IUPAC:	sodium methyl (EZ)-sulfanilylcarbonimidate
CA	methyl N-[(4-aminophenyl)sulfonyl]carbamate sodium salt (1:1)

1.3.4 Manufacturer's development code number (IIA 1.5)

The original applicant for the active substance asulam sodium was Bayer CropScience. Since 2004, United Phosphorus Limited has acquired the active substance asulam sodium from Bayer CropScience and is now the only applicant supporting the EU approval of asulam sodium. This dossier uses data generated by the original applicant and the codes previously used are shown below.

Active substance – asulam sodium

Codes previously used: AE F102789*, M&B 9057*, M&B-9057*, MB009057, RPA413636, Hoe 102789, AE C518360

Asulam

Codes previously used: M&B 9057*, MB009057*, M&B-9057*, RPA096215, RPA590048, Hoe 074383, AE B106159, XN-36111

*previously asulam and asulam sodium were not differentiated by different codes, and the same code may have been used for both.

Formulations containing the active substance

Trade name:	Asulox
Development code number: (Applicant, UPL)	HBM01
Former development codes of Bayer CropScience:	EXP04668A AE F074383 00 SL33 A1

Asulox (HBM01) is completely equivalent to the product EXP04668A (AE F074383 00 SL33 A1) and data from any testing on EXP04668A fully supports the Applicant product in this submission.

1.3.5 CAS, EEC and CIPAC numbers (IIA 1.6)

Asulam

CAS:	33337-71-1
EINECS/ELINCS:	222-077-1
CIPAC:	240

Asulam sodium

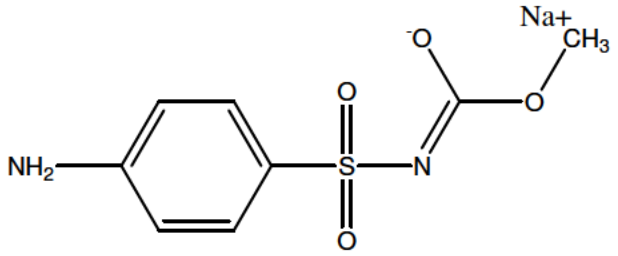
CAS:	2302-17-2
EINECS/ELINCS:	218-953-8
CIPAC:	240.011

1.3.6 Molecular and structural formulae, molecular mass (IIA 1.7)

Asulam sodium

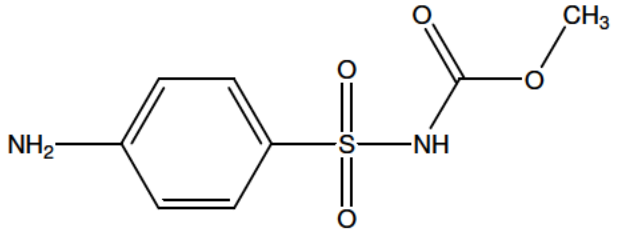
Molecular formula: $C_8H_9N_2O_4S$ Na
Molecular mass: 252.2

Structural formula:



Asulam

Molecular formula: $C_8H_{10}N_2O_4S$
Molecular mass: 230.2 asulam
Structural formula:



1.3.7 Manufacturer(s) of the active substance (IIA 1.2)

Confidential information - refer to Annex C (Volume 4), Section C.1.1.

1.3.8 Method(s) of manufacture (IIA 1.8)

Confidential information - refer to Annex C (Volume 4). C.1.1.

Method of manufacture (pathways, by-products and impurities) for each plant, whether or not relevant to a pilot plant

Confidential information - refer to Annex C (Volume 4), Section C.1.1.

Description of starting materials

Confidential information - refer to Annex C (Volume 4), Section C.1.1.

1.3.9 Specification of purity of the active substance (IIA 1.9)

Active substance (asulam sodium) has a proposed minimum specification of 876 g/kg, expressed on a dry weight basis after elimination of water. In terms of asulam this is equivalent to 800 g/kg. Specification is matching the FAO specification [Asulam sodium technical, FAO Specification 240/TC/S/F (1997)].

For further information, refer to Annex C (Volume 4).

Minimum and/or nominal content (g/kg) of pure active substance (excluding inactive isomers), whether or not relevant to a pilot plant

Refer to the file of confidential information

Minimum content (g/kg) of pure active substance (excluding inactive isomers), whether or not relevant to a pilot plant

Refer to the file of confidential information

Nominal content (g/kg) of pure active substance (excluding inactive isomers), whether or not relevant to a pilot plant

Refer to the file of confidential information

Certified limits of the active substances

Not an EU data requirement.

Control Product Specification Form or Confidential Statement of Formula

Not an EU data requirement.

1.3.10 Identity of isomers, impurities and additives (IIA 1.10)

Confidential information refer to Annex C (Volume 4), Section C.1.2.

Inactive isomers

Confidential information refer to Annex C (Volume 4), Section C.1.2.

Impurities and additives

Confidential information refer to Annex C (Volume 4), Section C.1.2.

1.3.11 Analytical profile of batches (IIA 1.11)

Confidential information refer to Annex C (Volume 4), Section C.1.2.

Results of analyses of batches produced in laboratory or pilot scale production systems and used in toxicological testing

Confidential information refer to Annex C (Volume 4), Section C.1.2.

1.4 Identity of the plant protection product

1.4.1 Current, former and proposed trade names and development code numbers (IIIA 1.3)

Trade name: Asulox

Development code number: (Applicant, UPL)	HBM01
Former development codes of Bayer CropScience:	EXP04668A AE F074383 00 SL33 A1

Asulox (HBM01) is completely equivalent to the product EXP04668A (AE F074383 00 SL33 A1) and data from any testing on EXP04668A fully supports the Applicant product in this submission.

1.4.2 Manufacturer(s) of the plant protection product (IIIA 1.2)

Confidential information refer to Annex C (Volume 4).

1.4.3 Type of the preparation and code (IIIA 1.5)

Physical state:	Liquid
Nature:	Soluble Concentrate (code: SL)
Code:	HBM01

1.4.4 Function (IIA 3.1, IIIA 1.6)

Herbicide

1.4.5 Composition of the preparation (IIIA 1.4)

Content of: Technical active substance(s); Pure active substance(s); Formulants

Technical active substance(s)

Content of technical active substance:	500 g/L
Limits (± 5% of the declared content):	475.0 to 525.0 g/L

Pure active substance(s)

Content of pure active substance:	438 g/L*
Limits (± 5% of the declared content):	416.1 to 459.9 g/L
Content of pure active substance (asulam equivalent):	400 g/L**

* at a typical purity of the technical active substance of
897.6% (w/w, FAO specification)
** considering molecular weight ratio asulam / asulam sodium = 0.913

Formulants

Confidential information refer to Annex C (Volume 4).

1.5 Uses of the plant protection product

1.5.1 Field of use (IIA 3.3, IIIA 3.1)

Asulam sodium is a herbicide intended for use in spinach and ornamental flower bulbs.

1.5.2 Effects on harmful organisms (IIA 3.2; IIIA 3.2)

Nature of the effects on harmful organisms e.g. contact action

Asulam sodium is a systemic herbicide, mainly absorbed by the leaves. It exerts its main effect by inhibiting the process of cell division in the meristematic organs of the plant and the greatest visual effects of the treatment therefore occur in new growth. The herbicidal symptoms in susceptible species are a slow chlorosis and stunting in newly developing leaves. Weeds are normally killed several days to several weeks after the treatment with asulam sodium. Tissue which is mature at the time of asulam sodium treatment undergoes a slow senescence.

Whether or not translocated in plants and if translocated whether such translocation is apoplastic, symplastic or both

Asulam sodium is a systemic herbicide which may be taken up by leaves or roots from which it is translocated to the growing points of the plant. Uptake through the shoots is more effective than through the roots.

Growing points are usually killed rapidly but mature leaves which are present at spraying senesce slowly.

Climatic conditions affect the rate of penetration of asulam sodium and thereby control its subsequent efficacy. Optimum conditions for penetration include high relative humidity and high temperature. Application during, or immediately after a drought period, is not recommended.

Correct weed growth stage at application is important to ensure optimum level of performance. Against perennial weeds, translocation to underground meristematic organs is essential for effective control. It is necessary to wait until the aerial parts are sufficiently developed to enable sufficient absorption and to carry out treatment before the leaves start to lose their uptake capabilities.

Asulam sodium is also effective on some annual broad-leaf weeds and grasses, pre-emergence, owing to its slight residual properties. This allows it also to be used for selective weed control in some vegetables.

1.5.3 Summary of intended uses (IIA 3.4; IIIA 3.3, 3.4, 3.5, 3.6, 3.7, 3.9)

Asulam sodium is intended for use in spinach and ornamental flower bulbs.

Asulam sodium is an herbicide, which is effective against annual and perennial weeds, both monocotyledons and dicotyledons, and on some perennial pteridophytes. It is particularly effective against certain perennial grasses and broad-leaved weeds being readily translocated to the root systems of susceptible species.

1.5.3.1 Details of intended uses (IIIA 3.3, IIA 3.4)

Details of existing and intended uses (crops, groups of crops, plants or plant products treated or protected)

Details of the intended uses are presented in Table ref: 1.5.1.

Asulam sodium is well tolerated by the following crops:

Spinach

Asulam sodium may be used on spinach, treating immediately after sowing and before the onset of germination and also post emergence (BBCH 12-14) at a dose rate up to 2400 g a.s./ha. It controls annual grasses and broad leaved weeds.

Tulip, hyacinth, lily

Asulam sodium may also be used on tulip, hyacinth and lily with application post emergence, when weeds have a height of 4 to 6 cm at an application rate of 1600 to 2400 g a.s/ha. It controls composite weeds, including camomile, groundsel and vetch weeds.

Details of harmful organisms against which protection is afforded

Asulam sodium is active against a wide range of annual and perennial grass weeds species as well as several broad leafed weeds such as some members of the Polygonacae, Compositae, *Matricaria spp, Senecio jacobea, Galinsoga parviflora, Chenopodium spp, Polygonum spp,* and *Solanum nigrum*.

Asulam sodium is very active against most of the Rumex species: *Rumex obtusifolius, Rumex crispus, Rumex obtusifolius x crispus hybrids* and *Rumex alpinus*. But sorrels (*Rumex acetosa* and *Rumex acetosella*) are not controlled.

Crop	Crop code	Organism	Organism code
Spinach	SPQOL	Broadleaved and grass weeds	Annual broad-leaved plants: BBBAN Annual grasses: GGGAN
Tulip	TULSS	Composite weeds (camomile, groundsel) and vetch weeds.	Compositae: FFFCO Chamomile: ANTNO, ANTAR, MATCH Groundsel: BACHA Vetch: VICSA
Hyacinth	HYAOR		
Lily	LILSS		

Effects achieved e.g. sprout suppression

The spectrum of efficacy includes some members of the Polygonacae, Compositae, and Cruciferae.

Asulam sodium is very active against most of Rumex species: *Rumex obtusifolius, Rumex crispus, Rumex obtusifolius x crispus hybrids* and *Rumex alpinus*. It controls annual grasses and *Matricaria spp, Senecio jacobea, Galinsoga parviflora, Chenopodium spp, Polygonum spp, Solanum nigrum.* It controls especially *Brassica spp*, *Matricaria spp, Senecio vulgaris, Poa annua and Polygonum spp.*

Table 1.5.1 Details of intended uses

Crop and/or situation (a)	Member State	Product Name	F G 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 a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	Kg a.s./hl min max (g/hl)	Water l/ha min max	Kg a.s./ha min max (*) (g/ha)		
Spinach	Belgium, Nether-lands	Asulox	F	Pre-emergence broadleaved and grass weeds. Post-emergence broadleaved and grass weeds.	SL	400 g/L asulam = 438 g/L asulam sodium	Ground boom sprayers	Until 3 days after sowing at the latest. The seed may not be pre-emerged. (spring-summer) **or** Post-emergence BBCH 12-14 (spring-summer)	1	-	-	200-600	2.4 asulam = 2.628 asulam sodium	28	For consumption and for seed cultivation.
Tulip, hyacinth and lily (bulb production)	Netherlands	Asulox	F	Composite weeds (camomile, groundsel) and vetch weeds.	SL	400 g/L asulam = 438 g/L asulam sodium	Ground boom sprayers	Post-emergence when the weeds have a height of 4 to 6 cm (spring-summer)	1	-	-	200-600	1.6- 2.4 asulam = 1.752 - 2.628 aslam sodium	n.a	Apply on a hardened and dry crop. During spraying and until a few hours later the weather has to be dry and growing

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage range from first to 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
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

1.5.3.2 Application rate (IIIA 3.4)

Rate of application per unit treated (ha, m^2, m^3, tonne), in terms of g or kg of preparation and active substance

Spinach	6 L product/ha (2.4 kg a.s./ha)
Tulip, Hyacinth, Lily	4 - 6 L product/ha (1.6 - 2.4 kg a.s./ha)

For the intended use in spinach the recommended application rate is 6 kg of Asulox® (equivalent to 2.4 kg of asulam and 2.628 kg of asulam sodium).

1.5.3.3 Concentration of active substance in material used (IIIA 3.5)

Concentration of active substance in material used (e.g. diluted spray, baits, treated seed) in g/L, g/kg, mg/kg or g/tonne

Spinach	400 - 1200 g a.s./L
Tulip, Hyacinth, Lily	270 - 1200 g a.s./L

Asulox® is a SL formulation containing 400g/L of asulam and 438 g/L of asulam sodium. It has other brand names such as Asilax, Asulox 40, Asulox N, Sempalox and Asulam 400.

1.5.3.4 Method of application (IIIA 3.6)

Description of the method of application, type of equipment used and type and volume of diluent per unit of area or volume

Method of application:	High volume spray
Type of equipment used:	Ground boom sprayer
Volume of diluent per unit of area or volume Spinach: Tulip, hyacinth, lily:	 200 - 600 L/ha 200 - 600 L/ha

Asulox® is applied using conventional terrestrial boom sprayer equipment.

Asulox® should be applied in a volume of 200 – 600 L/ha of water. A spray pressure of at least 2 bar is advised. Good even spray coverage is essential for optimum efficacy.

1.5.3.5 Number and timing of applications and duration of protection (IIIA 3.7)

***Ma*ximum number of applications and their timing**

One application of Asulox® at the recommended rate should be made per crop.

For each application, growth stages of the crop or plants to be protected

Spinach (pre emergence): Until 3 days after sowing.

Spinach (post emergence): BBCH 12 -14.

Tulip, hyacinth, lily: Post emergence when weeds have height of 4 - 6 cm.

For each application, development stages of the harmful organism concerned

Inhibition process of cell division in the meristematic organs of the plant and the greatest visual effects of the treatment therefore occur in new growth .

Duration of protection afforded by each application

Protection last approximately 2-3 weeks.

Duration of protection afforded by the maximum number of applications

Protection last approximately 2-3 weeks.

1.5.3.6 Necessary waiting period or other precautions to avoid phytotoxic effects on succeeding crops (IIIA 3.8)

There is no recommended waiting period other than the normal crop duration. Asulox® is well tolerated by succeeding crops.

Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops

Post-emergence application of asulam sodium to spinach at rates up to 2400 g a.s./ha is not likely to induce significant residues in following crops. As shown by the confined crop rotation study the uptake and transfer of asulam sodium from soil into the root and aerial part of plants is extremely low. Therefore, it is not necessary to define a waiting period between post-emergence application of asulam sodium to spinach and sowing or planting the succeeding crop.

Limitations on choice of succeeding crops

There are no limitations on choice of succeeding crops after application of asulam.

Description of damage to rotational crops

No information available.

1.5.3.7 Proposed instructions for use (IIIA 3.9)

A copy of a draft label is not available.

1.5.4 Information on authorisations in EU Member States (IIIA 12.1)

There are currently no authorised products in the EU.

LEVEL 2

Asulam sodium

LEVEL 2: REASONED STATEMENT OF THE OVERALL CONCLUSIONS DRAWN BY THE RAPPORTEUR MEMBER STATE

2.1.1 Identity

Asulam sodium is the proposed common name for sodium methyl (EZ)-sulfanilylcarbonimidate. The technical material is manufactured with a minimum purity of 876 g/kg. Batch analysis data have been provided on full scale production.

2.1.2 Physical and chemical properties

Asulam sodium is a white solid with a moderately high melting point (228-232°C) and a very low volatility (5 x 10^{-7} Pa at 45°C). It is readily soluble in water (962 g/L at 20°C) and is soluble (117 g/L at 25°C) in methanol. The octanol/water partition coefficient (Log P_{OW} = 0.15 at 25°C) does not indicate the potential to bio-accumulate or to be fat soluble. The pure active substance is hydrolytically stable at pH 5, 7 and 9 after 30 days at 25°C, has a photolytic half life of less than 1 day at pH 7 in sterile aqueous buffered solution and does not require classification with regards to flammability, explosive and oxidising properties.

Asulam sodium is formulated as a soluble concentrate 'Asulox', containing 438 g/L asulam sodium. Data submitted indicated that the formulation was chemically and physically stable for 2 years at ambient temperatures and does not require classification with regards to flammability, explosive and oxidising properties. With regards to relevant impurities, none of them had altered significantly.

2.1.3 Details of uses, summary of efficacy and further information

Asulox is a herbicide containing 400 g/L asulam (=438 g/L asulam sodium). Asulox is claimed for the control of broadleaved and grass weeds in spinach and for the control of composite and vetch weeds in the bulb production of tulip.

Asulox is applied by spraying pre- or post-emergence of the crop at dose rates between 4 and 6 L product/ha (1.6 and 2.4 kg as/ha).

The effectiveness of the active substance asulam against weeds was tested in a total of 22 efficacy trials conducted in the Netherlands and the United Kingdom from 1987 to 2011. Trials were conducted in the field in spinach (14 trials), tulip (3 trials), lily (4 trials) and hyacinth (1 trial). All trials were carried out by officially recognized organisations.

The active substance asulam was effective in the control of weeds after pre-emergence application in spinach and post-emergence application in flower bulbs.

Assessments on adverse effects on treated crops were made in the efficacy trials and in 17 specific crop safety trials. Crop safety trials were conducted in tulip (12) and lily (5). Trials were conducted in the Netherlands from 1990 to 2006 by officially recognized organisations.

With the exception of some phytotoxic symptoms observed in lily varieties Connecticut King and Star Gazer when applied late in the season, overall generally no phytotoxicity or negative effects on crop condition were observed after single

application of asulam at the proposed dose rate of 2.4 kg as/ha. It should be noted that currently only use on spinach and tulips is proposed.

Overall asulam is considered to have proven its effectiveness in the control of weeds and, when used as proposed, it has no unacceptable effects on crop safety.

2.1.4 Classification and labelling

2.1.4.1 Active substance classification and labelling requirements

Classification of the active substance on the basis of toxicological properties

Classification: Skin sensitisation Category 1B

Hazard symbol: GHS07

Indication of danger: Warning

Risk phrases: H317- may cause skin sensitisation

Safety phrases: P261- Avoid breathing dust/fume/gas/mist/vapours/spray
P272- Contaminated work clothing should not be allowed out of the workplace
P280- wear protective gloves/clothing/eye protection/face protection
P302+P352- If on skin: wash with plenty of soap and water
P333+P313- If skin irritation or rash occurs: get medical advice/attention
P363-Wash contaminated clothing before reuse

CLP Classification of the active substance for environmental effects

Classification: 'Acute category 1' and 'Chronic category 1'.

Hazard symbol: GHS09

Signal word: Warning

Hazard statement: H400 & H410: 'Very toxicity to aquatic life with long lasting effects'

Precautionary statements: P391: 'Collect spillage'
P501: 'Dispose of contents container to …' [wording to be completed in accordance with local/ regional/ national/ international regulation].

2.1.4.2 Preparation classification and labelling requirements proposed by the rapporteur

Classification of the preparation on the basis of toxicological properties

Classification: Skin sensitisation Category 1B

Hazard symbol: GHS07

Indication of danger: Warning

Risk phrases: H317- may cause skin sensitisation

Safety phrases: P261- Avoid breathing dust/fume/gas/mist/vapours/spray
P272- Contaminated work clothing should not be allowed out of the workplace
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P302+P352- If on skin: wash with plenty of soap and water
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CLP Classification of the preparation for environmental effects

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Hazard symbol:	GHS09
Signal word:	Warning
Hazard statement:	H400 & H410: 'Very toxicity to aquatic life with long lasting effects'
Precautionary statements:	P391: 'Collect spillage' P501: 'Dispose of contents container to …' [wording to be completed in accordance with local/ regional/ national/ international regulation].

2.2 Methods of analysis

2.2.1 Analytical methods for analysis of the active substance as manufactured

Asulam and [redacted] were determined in the technical active substance by HPLC-UV, using a C_{18} column. The limit of determination of [redacted] was [redacted] Acceptable validation data were submitted.

Methanol was determined in the technical active substance by GC-FID, using a CP capillary column. The limit of determination was [redacted]. Acceptable validation data were submitted.

2.2.2 Analytical methods for formulation analysis

Asulam and [redacted] were determined in plant protection product by HPLC-UV, using a C_{18} column. The limit of determination of [redacted] was [redacted] Acceptable validation data were submitted.
Methanol was determined in the technical active substance and plant protection product by GC-FID, using a CP capillary column. The limit of determination was [redacted]. Acceptable validation data were submitted.

2.2.3 Analytical methods for residue analysis

Plants
Asulam (and its metabolite malonyl-asulam) residues in plants and plant products (Spinach, Orange, Barley Grain and Sunflower Seed) were determined by extraction with acetonitrile/water and the resulting extracts evaporated to an aqueous remainder and analysed by LC/MS/MS (monitoring for in the case of parent asulam the precursor ion m/z 231 and the product ion m/z 156 and for its metabolite malonyl-asulam the precursor ion m/z 317 and the product ion m/z 242), using a C_{18} column. The limit of determination was 0.1 mg/kg (asulam plus its metabolite malonyl-asulam expressed as asulam). Acceptable validation data were submitted and the method was validated by an independent laboratory.

Animal products
Asulam (and its metabolites containing the sulphanilamide moiety) residues in animal products (milk, muscle, fat, kidney and egg) were determined by extracted with acetonitrile/acidified water (for milk methanol/acetonitrile/acidified water) and the resulting extracts acetylated using sodium acetate/acetic anhydride, converting asulam (and its metabolites acetylasulam and sulphanilamide) to its metabolite acetylasulam, which was in turn converted to acetylsulfanilamide. The resulting extracts were analysed by HPLC-MS/MS (monitoring for the precursor ion m/z 215 and the product ion m/z 198), using a Luna 5C column. The limit of determination was 0.01 mg/kg. Acceptable validation data were submitted.
No independent laboratory validation data were submitted, however no positive EU MRLs have been proposed, due to animal transfer studies indicating that positive residues would not result in animal products.

Soil
Asulam (and its metabolite sulphanilamide) residues in water were determined by directly injected into a LC/MS/MS (monitoring for the precursor ion 231 and the product ion m/z 156 [and 92 for confirmation] for asulam and for its metabolite sulphanilamide the precursor ion m/z 173 and the product ion m/z 156 [and 92 for confirmation]), using a C18 column. The limit of determination was 0.05 µg/l for asulam and sulphanilamide in surface and drinking water. Acceptable validation data were submitted.

Water
Asulam (and its metabolite sulphanilamide) residues in water were determined by directly injected into a LC/MS/MS (monitoring for the precursor ion 231 and the product ion m/z 156 [and 92 for confirmation] for asulam and for its metabolite sulphanilamide the precursor ion m/z 173 and the product ion m/z 156 [and 92 for confirmation]), using a C18 column. The limit of determination was 0.05 µg/l for asulam and sulphanilamide in surface and drinking water. Acceptable validation data were submitted.

Air
Asulam residues in air were determined by drawing air through a XAD adsorption tube and extracting the tube with methanol. The resulting extracts were analysed by HPLC/MS/MS, using a C_{18} column. The limit of determination was 10 µg/m^3. Acceptable validation data were submitted.

Human and animal tissues and fluids
In support of therapeutic and diagnostic regimes, no methods of analysis were submitted or required as asulam is not classified as toxic.

2.3 Impact on human and animal health

Toxicokinetics

Asulam sodium was found to be rapidly and extensively absorbed from the gastro-intestinal tract; the extent of oral absorption is estimated to be at least 80%. Asulam sodium was rapidly and widely distributed, with no evidence for bio-accumulation but some binding to blood cells. Excretion was rapid (largely within 24 hours) and mainly (82.0-92.3%) in the urine following oral administration. Urinary excretion was slightly higher (and faecal excretion slightly lower) at the top dose level, indicating a saturation of metabolism or biliary excretion. Faecal excretion in intravenously-dosed animals (3.3-4.6% of the administered radioactivity) is consistent with limited biliary excretion of a conjugated metabolite. Asulam sodium was excreted largely unchanged in studies in the rat, with parent compound accounting for up to ~80% of the administered radioactivity. The major urinary and faecal metabolite was identified as acetyl-asulam, with sulphanilamide and acetyl-sulphanilamide also identified as minor urinary metabolites. A higher proportion of the administered radioactivity was excreted unchanged at the high dose level, suggesting the saturation of metabolism.

Toxicity

Asulam sodium is a carbamate herbicide. Its mode of action in plants is inhibition of 7,8-dihydropteroate synthase; there is no equivalent mammalian target. Although chemically a carbamate, no evidence of cholinesterase inhibition was seen in the 8-week mouse study ([redacted], 1989c), 21-day dermal study in rabbits and 6-month dog study ([redacted], 1980).

Acute toxicity

Asulam sodium is of low toxicity in the rat by the oral, dermal and inhalation routes and is also of low acute dermal toxicity in the rabbit; signs of toxicity in these studies were non-specific and transient. Slight skin and moderate eye irritation was seen in studies in the rabbit. Clear evidence of sensitisation was seen in a Guinea pig Maximisation test and classification as a skin sensitiser (Category 1B, H317) under Regulation (EC) 1272/2008 is proposed.

There were no additional effects reported in any single dose study that are indicative of target organ toxicity, narcosis or respiratory irritation, therefore asulam sodium is not classified as category 1,2 or 3 STOT-SE under Regulation (EC) 1272/2008.

Short-term toxicity

Asulam/ asulam sodium was found to be of relatively low toxicity by the dermal route in rabbits and by the oral route in the rat, mouse and dog. The erythrocyte and thyroid were identified as targets of toxicity in the 90-day rat study; results show mild macrocytic anaemia (and histopathology consistent with increased erythrocyte turnover) and thyroid follicular hypertrophy at the top dose level of 20,000 ppm (>1000 mg/kg bw/day) . Treatment-related findings in the mouse were limited to minor bodyweight effects at high dose levels (>5000 mg/kg bw/day). In the dog, histopathology also identified the thyroid as a target of toxicity in both studies at 300 mg/kg bw and above. Significantly reduced white blood cell counts and significantly elevated plasma glucose concentration seen in treated groups in the 6-month dog study were not apparent in the 1-year study.

The thyroid effects were a consistent finding across the test species but this was deemed not to be of relevance to human risk assessment due to species differences in sensitivity to thyroid hormone perturbation (see section 6.3.6).

With regard to classification, STOT RE is assigned on the basis of a substance demonstrating evidence of significant or severe toxicity, generally at or below the oral guidance value of 100 mg/kg/d (for a classification in category 2) obtained in a 90-day rat study. The equivalent guidance values for a one-year and a two-year study are ≤ 25 mg/kg/d and ≤ 12.5 mg/kg/d, respectively. The dermal guidance value for a classification in category 2 is ≤ 200 mg/kg/d obtained in a 90-day rat or rabbit study. In all of the available studies, the lowest dose tested was in excess of the guidance value for classification for STOT RE (adjusted as necessary for study duration).

Genotoxicity

The genotoxicity of asulam sodium was investigated in a number of studies *in vitro* and *in vivo*. No evidence of mutagenicity was seen in two recent Ames tests, which supersede two previously evaluated bacterial reverse mutation assays as

these were not conducted to modern regulatory standards. Two mouse lymphoma assays have been reported; the study previously evaluated had a significantly increased mutation frequency at the highest (cytotoxic) concentration in the presence of metabolic activation, whilst the 2009 study does not show any increase in mutations at any dose with or without S9. An equivocal result (increased proportion of cells with chromosomal aberrations at the highest (cytotoxic) concentration in the absence of metabolic activation) was seen in a study of clastogenicity *in vitro*. No evidence of unscheduled DNA synthesis was seen in a study *in vitro*, however there are concerns over the design and performance of this study. In an *in vivo* mouse micronucleus study, the proportion of micronucleated PCEs was elevated (and exceeded the historical control range) but at an intermediate concentration only and statistical significance compared to the control was not attained. On this basis the study is considered to be negative.

Overall, the more recent studies show that asulam sodium was not mutagenic to bacteria or mammalian cells. A positive result was seen in an *in vitro* study for clastogenicity, but this was not expressed *in vivo*. Overall, the weight of evidence is that current production batches of asulam sodium are not mutagenic *in vivo*.

Under CLP, substances can be classified as a Cat 1A, 1B or 2 mutagen. For Category 1 A and B, the substance should be known to induce heritable changes or regarded as if they induce heritable changes in germ cells of humans or produce positive results *in vivo* somatic cell tests in combination with evidence that the substance has the potential to cause mutations in germ cells. There are no human data or clear positive results *in vivo* to suggest that asulam sodium causes heritable mutations and therefore is not a Cat 1A or Cat 1B mutagen.

To attain category 2 under CLP, the substance needs to show positive results in mammals and /or in some cases *in vitro* experiments. Whilst, two studies were equivocal according to the conducting laboratory's criteria, none of the studies provided strong or reliable evidence that asulam sodium was positive for mutagenicity. Overall, asulam sodium does not meet the criteria for classification for mutagenicity.

Chronic toxicity and carcinogenicity

Haematological effects indicative of mild anaemia and histopathology consistent with the increased breakdown of red blood cells were seen in chronic studies in the rat and mouse (at doses of ≥ 180 and ≥700 mg/kg bw/day respectively) and ; minor effects on bodyweight were also seen at high dose levels (>243 mg/kg bw/day). Consistent with effects in the 90-day rat study and in the dog, increased thyroid weights and hyperplastic change was noted in the 2 year rat study at 183 mg/kg bw/day and above . The adrenal was also identified as a target organ in the male rat, with increased incidences of medullary hyperplasia at high dose levels.

Evidence of carcinogenicity was seen in the male rat, with an increased incidence (20% versus 6% in controls) of phaeochromocytoma at the top dose level of 953 mg/kg bw/day. Whilst the incidence of this neoplasm exceeded the laboratory's

historical control data, there is information in the publically available literature on the incidence of this tumour type in Sprague Dawley rats which shows phaeochromocytomas can spontaneously occur at an incidence of up to 33%. Furthermore, this tumour is referenced in the CLP guidance as having a high spontaneous incidence rate in Sprague Dawley rats. The tumour was also not dose responsive, limited to a single sex and species, with no evidence of a multi-site response to asulam sodium and no direct evidence from the toxicology package of studies to support chemical induction of phaeochromocytomas in accordance with published literature ([redacted], 2008).

Previously, no evidence of carcinogenicity was concluded for the mouse following administration of asulam sodium. Hepatocellular adenomas and carcinomas were reported in both sexes which were outside the historical control data for the conducting laboratory. In females, the hepatocellular carcinomas were elevated and outside the HCD but no dose response was observed, there was no accompanying liver toxicity i.e. histopathological changes or variation in liver weight and the lack of tumours in higher dose groups cannot be explained by toxicity to the test compound. Equally, the increase in hepatocellular adenoma was within the collated historical control data incidence, no dose response was observed and no accompanying liver histopathology was reported. In males, the incidence of hepatocellular adenomas and carcinomas was highest at the lowest tested dose and both were outside the historical control data. The incidence of these tumour types was not dose responsive, there was no accompanying liver toxicity i.e. histopathological changes or variation in liver weight and the lack of tumours in higher dose groups cannot be explained by toxicity to the test compound.

Overall, the adenoma and carcinomas are not sufficient for classification purposes particularly in the absence of a dose response and no toxicity to asulam sodium at higher dose levels to account for the lack of tumour incidence but these conclusions are based on a compromised study (high mortality, non-GLP, pre-guideline).

Under Regulation (EC) 1272/2008, classification in category 1A for carcinogenicity is not justified as there is no evidence of asulam sodium having caused cancer in humans. To attain category 1B there should be sufficient evidence for carcinogenicity in experimental animals. In the case of asulam sodium, the animal data are only limited rather than sufficient. Ordinarily, limited evidence in experimental animals would be sufficient for asulam sodium to be classified in Category 2 for carcinogenicity, but taking into account available data, published literature and the criteria under Regulation (EC) 1272/2008, the tumours reported in rats and mice are insufficient for classification of asulam sodium.

Reproductive and developmental toxicity

Evidence of a reproductive effect was seen in the multi-generation study as litter size was significantly reduced at dose levels of ≥5000 ppm in the F1 generation. The underlying reasons for this effect was unclear as there was no difference in the number of foetuses dead at birth across the treated groups compared with the controls. Furthermore, this effect was not dose responsive as a 5-fold increase in asulam resulted in only a further 0.3 reduction in litter loss and the effect was not reproduced in the F2 generation, particularly at the highest dose tested. There were no effects on reproductive organ weights or macroscopic findings in these organs in parental animals or offspring. Repeat dose studies in the rat, mouse and dog did not record any alterations in reproductive organs and support the results of the fertility study.

In a developmental study in rats, there was no evidence of toxicity at any dose level in the dams. Effects in the foetuses were reported only at the top dose and comprised of slight increases in the incidences of short/ absent 13th rib, and decreased ossification of caudal vertebrae (without a clear dose-response relationship) but neither of these findings were statistically significantly increased compared with the control group. Decreased ossification of the cranium and fused cervical arches were each only reported in one pup and so do not provide evidence of a specific effect on development. The decreased ossification of caudal vertebrae did not demonstrate a clear dose-response relationship; furthermore, reduced ossification is generally considered to be a developmental delay and not sufficient to support classification. The combined incidence of short/ absent 13th rib in rats was outside the historical control data and appeared to be treatment-related. The UK CA consulted the raw data and separated out the incidence of short and absent 13th rib. The short rib is seen in concurrent control animals, only at the highest dose (above limit dose) and in accordance with the ECETOC monograph 31 (2002), this effect is a variation of low-moderate concern only. Although the absence of ribs is viewed as a malformation of high concern in the ECETOC monograph 31 (2002), the incidence of the absent 13th rib was only reported at the highest dose (above guideline limit dose) and the incidence of absence or short 13th rib was similar to concurrent controls. In isolation, the incidence of short/absent 13th rib does not provide sufficient evidence of a specific effect on development.

Toxicity was observed in rabbits at 750 mg/kg bw/d where bodyweight gain during the treatment phase was reduced and feed consumption declined during days 5-17. There was no evidence of toxicity in dams at 300 mg/kg bw/d or lower. The only developmental findings were single cases of malformations in 2 foetuses in two different litters at each of the doses 300 and 750 mg/kg bw/d: cyclopia, distortion of skull bones, agenesis of lung lobe or kidney and hydrocephalus. The single cases of malformations are considered to be incidental findings, as there was no dose-response relationship observed, the malformations were restricted to 2 foetuses across two litters at each dose level (300 and 750 mg/kg bw/d) and the type of malformations were not consistent across the affected foetuses. There was no indication of the effects seen in the rabbits being reproduced in the rat. There was

no evidence from the rabbit study that asulam had a specific developmental toxic effect however, the absolute power of this study is compromised by high mortality and low number of litters per group.

From the available data, the only possible indication of an adverse effect on reproductive toxicity was a reduction in litter size in the F1 generation of the rat two-generation study. It is noted that the reduction in litter size was slight, did not increase over a wide dose range (from 278 to 1531 mg/kg/d) and was not reproduced in the F2 generation. Furthermore, the two available developmental toxicity studies indicate that asulam does not adversely affect post-implantation loss or other parameters of developmental toxicity and hence the reduction in litter size is not predicted to be a consequence of adversity during the developmental phase.

Overall, it is concluded that this isolated finding of reduced litter size does not provide sufficient evidence of a specific effect on reproduction to support classification; however, this conclusion is based on compromised fertility and developmental studies.

Neurotoxicity

Whilst asulam sodium contains a carbamate group, which are known to be associated with neurotoxicity, plasma, erythrocyte or brain cholinesterase activities were measured in the eight-week mouse study, 6-month dog study and the 21-day repeat dose dermal toxicity study in the rabbit. No significant inhibition was observed across the species or sexes in any of these studies.

Immunotoxicity

No specific studies of immunotoxicity are available for asulam sodium. No effects indicative of neurotoxicity were observed in any of the available studies.

Toxicity of metabolites

The major metabolites in plants and the environment were not considered a toxicological concern in the 2010 review with the exception of sulphanilamide. Subsequently a data gap on consumer risk to this metabolite was identified and additional information has been evaluated in this submission.

Sulphanilamide is not considered to be acutely toxic by the oral route but effects including increased water consumption, reduced body weight gain and haematopoiesis were observed in 7 and 28 day studies at doses of 300 mg/kg bw/day and above. Sulphanilamide is not genotoxic *in vitro*.

Evaluation of the available literature is problematic due to the age of publications, studies not conforming to regulatory standards and the tainting of the literature due to the Sulphanilamide ‘elixir’ tragedy. Overall, there were no additional robust publications on Sulphanilamide to further elucidate the toxicity of this metabolite

and therefore the vertebrate studies provided with this submission were relied upon.

Toxicity of the preparation

The preparation was tested in acute toxicity, irritation and sensitisation studies. Asulox is not acutely toxic by the oral, dermal or inhalation routes, it is not a skin or eye irritant but it is a skin sensitiser (classification see section 2.14.2).

Asulox was also tested for dermal absorption and the proposed values are 0.5% for the concentrate and 3% for the in-use dilution.

2.3.1 Effects having relevance to human and animal health arising from exposure to the active substance or to impurities contained in the active substance or to their transformation products

The active substance has been adequately tested from a toxicology perspective (see section 2.3), none of the impurities in the technical material are considered to be toxicologically relevant, nor is the biotransformation of Asulam-sodium.

None of the metabolites identified in plants and the environment were a concern in the previous review with the exception of Sulphanilamide. Studies have been evaluated and Sulphanilamide is not acutely toxic, has minor effects in longer term studies and is not genotoxic *in vitro*. An exposure assessment for consumers to Sulphanilamide on spinach has been completed and the outcome is reported in Volume 3 Section B7 Residues.

2.3.2 Proposal for an acceptable daily intake (ADI)

An ADI of 0.36 mg/kg bw/d can be derived for asulam sodium, based on the NOAEL of 36 mg/kg bw/d (1000 ppm) in male rats in the chronic rat study and applying a standard assessment factor of 100. A standard assessment factor is considered appropriate in the absence of teratogenicity; carcinogenicity was only seen at the highest dose level in the male rat (equivalent to 953 mg/kg bw/d), giving an acceptable margin of safety.

This ADI was agreed at the EU level (EFSA Journal 2010; 8(12): 1822).

An ARfD of 0.05 mg/kg bw is proposed for sulphanilamide. This is based on the NOAEL of 30 mg/kg bw/d in the 28 day oral toxicity study and an additional factor of 6 to convert from a 28 day study to a lifetime exposure.

2.3.3 Proposal for an acute reference dose (ARfD)

Asulam sodium is of relatively low acute toxicity, however clinical signs (vomiting and salivation) were seen following gavage dosing in the dog for 6 or 12 months. An ARfD of 1 mg/kg bw/d can therefore be derived, based on the NOAEL of 100 mg/kg bw/d in the 12-month dog study. Although a lower NOAEL (60 mg/kg bw/d) was determined for the 6-month dog study, the LOAEL in both studies was

the same (300 mg/kg bw/d). The use of the NOAEL from the longer term study is therefore appropriate.

This ARfD was acceptable at the EU level in the previous submission (EFSA Journal 2010; 8(12): 1822).

An ARfD of 0.3 mg/kg bw is proposed for sulphanilamide. This is based on the NOAEL of 30 mg/kg bw/d in the 28 day oral toxicity study.

2.3.4 Proposal for an acceptable operator exposure level (AOEL)

A short-term systemic AOEL of 0.46 mg/kg bw/day can be determined, based on the NOAEL of 46 mg/kg bw/day from the rat reproduction study based on reduced litter size. A safety factor of 100 is appropriate. No correction for oral absorption is necessary as asulam sodium is extensively absorbed from the gastro-intestinal tract (>80% excreted in urine).

This was agreed in the previous EFSA conclusions (EFSA Journal 2010; 8(12): 1822).

2.3.5 Proposal for a maximum allowable concentration (MAC) in drinking water / drinking water limit (DWL)

An MAC of 1.08 mg/l can be determined based on an average bodyweight of 60 kg, water consumption of 2 litres/day and allowing drinking water to contribute 10% of the ADI. However the maximum level of all pesticides in drinking water is limited to 0.1 µg/l under EC legislation.

2.3.6 Impact on human and animal health arising from exposure to the active substance or to impurities contained in it

Operator exposure estimates using the German Model predict that the supported use of 'Asulox' on spinach and ornamentals through tractor-mounted/trailed field crop sprayers will result in an acceptable level of exposure to asulam for an operator without PPE (systemic exposure equivalent to 11% of the proposed AOEL). Corresponding UK POEM estimates also predict an acceptable level of exposure for an operator without PPE (systemic exposure equivalent to 68% of the systemic AOEL).

Worker exposure estimates using EUROPOEM II predict acceptable levels of exposure to asulam for unprotected workers harvesting spinach (systemic exposure equivalent to 16% of the AOEL) or ornamentals (systemic exposure equivalent to 31% of the AOEL) treated with 'Asulox'.

Bystander and resident exposure estimates using the UK and German approaches predict that the supported uses of 'Asulox' will result in acceptable levels of exposure to asulam for bystanders and residents (systemic exposure equivalent to 2% or less of the AOEL).

2.4 Residues

2.4.1 Definition of the residues relevant to MRL's

Plant metabolism

The metabolism of asulam was investigated in spinach and rye grass, by applying phenyl ring labelled [14C] asulam as a foliar application, at rate of 2.4 kg as/ha (N) to spinach (both pre and post emergence) and 2 x 1.12 kg as/ha rye grass. At harvest the total [14C] residues (expressed as parent equivalent) in spinach were 184 mg/kg and in rye grass 32 mg/kg (day 7), in the glasshouse studies and in the field spinach studies 0.062 mg/kg (day 41) in the pre-emergence study and 1.4 mg/kg (day 21) in the post emergence study.

On characterisation of the extractable radioactivity one major component was identified in the spinach and rye at harvest as parent asulam (plus its conjugate malonyl asulam).

For the glasshouse studies, parent asulam (plus its conjugate malonyl asulam) accounted for 86% of the total radioactivity in the spinach and 11% of the total radioactivity in the rye grass. Several other metabolites were identified (tentatively in the case of rye grass) plus several unknowns, which individually did not represent more than 5% (unknowns less than 1%) of the total radioactivity in the spinach at harvest for the foliar treatments. The remaining unextractable radioactivity accounted for less than 7% of the total radioactivity in the crops.

For the pre-emergence field study, parent asulam (plus its conjugate malonyl-asulam) accounted for 45% of the total radioactivity in the spinach at harvest. One other component was identified as desamino asulam, which was present at a level of less than 14% (<0.01 mg/kg) of the total radioactivity in the spinach. One unknown was also present representing 7.3% (<0.01 mg/kg) of the total radioactivity in the spinach. The remaining unextractable radioactivity accounted for less than 28% (0.02 mg/kg) of the total radioactivity in the spinach. On further extraction of the unextractable material, using acid hydrolysis, a further 6.8% (0.004 mg/kg) was extracted.

For the post emergence field study, parent asulam (plus its conjugate malonyl-asulam) accounted for 77% of the total radioactivity in the spinach at harvest. One other component was identified as asulam glucoside, which was present at a level of less than 1.7% (0.02 mg/kg) of the total radioactivity in the spinach. Several unknown were also present representing individually representing up to 6.8% (<0.1 mg/kg) of the total radioactivity in the spinach. The remaining unextractable radioactivity accounted for less than 8.4% (0.12 mg/kg) of the total radioactivity in the spinach. On further extraction of the unextractable material, using acid/base hydrolysis, a further 5.3% (0.08 mg/kg) was extracted , the remaining unextractable radioactivity was probably associated with fragmentation of the compound and the natural incorporation of these fragments into the plant tissue.

For the proposed lead use on spinach, appropriate plant metabolism data are available to support this use and potential uses on other leafy crops, however the main uses of asulam are on grassland and fruit crops. In the case of grassland, a plant metabolism study on rye grass is available, however the study was carried out

in 1974, the characterisation work is tentative at best and there may be an issue with the stability of asulam during freezer storage of the samples (unclear how long the samples were stored frozen – issue with spinach see Section B.7.7). In the case of fruit crops (e.g. strawberries) no plant metabolism data were available. Therefore, it is recommended that if approval is to be sought on grassland and fruit crops, at least two further metabolism studies are required on grass and a fruit crop (e.g. strawberries), applying phenyl ring labelled [^{14}C] asulam at the required GAP, storing the samples for the minimum period possible.

Based on the plant metabolism data submitted for spinach, residues in leafy crops should be defined as the sum of parent asulam plus its metabolite asulam-malonyl expressed as asulam.

Rotational crop metabolism

The metabolism and distribution of asulam sodium in rotational crops was investigated in wheat, spinach and radish. The crops were grown in soil treated (bare ground application) with phenyl and ring labelled [^{14}C] asulam at a rate of 3.74 kg as/ha (1.6N). At harvest total [^{14}C] residues (expressed as parent equivalent) were less than 0.07 mg/kg, with the exception of wheat straw which gave residues of 0.47 mg/kg in the 28 day study falling to 0.39 mg/kg in the 365 day studies and radish root 0.18 mg/kg in the 28 day study falling to 0.03 mg/kg in the 365 day study.

On characterisation of the extractable radioactivity several component were identified in the crops at harvest in the 29 day study as parent asulam and its metabolites acetyl asulam, sulphanilamide, 4-acetyl benzene sulphonamide and sulfanilic acid. Individually the components did not account for more than 10% (0.04 mg/kg) of the radioactivity in the crops at harvest, with the majority of the extractable radioactivity remaining uncharacterised. It was surmised that the remaining uncharacterised radioactivity was associated with the fragmentation (soil and plant) of the compound and the natural incorporation of these fragments into the plant tissue. In addition, the total [^{14}C] residues in the crops at harvest was low (less than 0.2 mg/kg), with the exception of wheat straw (0.6 mg/kg) which is not directly consumed by humans. The remaining unextractable radioactivity accounted for less than 12% (0.02 mg/kg) of the total radioactivity in the crops.

For the proposed lead use on spinach, the rotational crop metabolism data is sufficient to cover the use on spinach. However asulam sodium may also be used on grassland, at an increased rate of 4.4 kg as/ha. Therefore, consideration should be given to the generation of a new rotation crop metabolism study, applying phenyl ring labelled [^{14}C] asulam at the required GAP, storing the samples for the minimum period possible and the characterisation of a greater amount of the extractable radioactivity.

The majority of plant metabolites identified in the plant metabolism study were also identified in the rat metabolism studies, however the glucoside conjugate (malonyl included in the residues definition) of asulam and the asulam dimers were not, but were not considered to be of toxicological concern (see Section B.6.8). In the case of 4-acetyl benzene sulphonamide and sulfanilic acid, residue levels in

crops consumed by humans were less than 0.02 mg/kg (less than 0.05 mg/kg in fodder crops).

Animal metabolism

The metabolism and distribution of asulam sodium in animals was investigated in lactating goats and chickens, using phenyl ring labelled [^{14}C] asulam. For lactating goats dosed at rates of 20 mg/kg in feed, overall recovery of radioactivity was 89-102%, the bulk of the radioactivity was excreted (89-102%), with less than 0.1% in the milk and less than 0.1% in the tissues.

On characterisation of the extractable radioactivity one major component was identified in the milk as parent asulam which accounted for 85% of the total radioactivity in the milk. The remaining unextractable radioactivity, accounted for 15% (<0.01 mg/kg) of the total radioactivity in the milk.

On characterisation of the extractable radioactivity one major component was identified in the kidney as parent asulam, which accounted for 95% of the total radioactivity in the kidney. The remaining unextractable radioactivity, accounted for 5% (<0.01 mg/kg) of the total radioactivity in the kidney. For liver, one major component was identified in the liver as acetyl sulphanilamide, which accounted for 64% of the total radioactivity in the liver. One unknown was isolated, which accounted for 26% (0.02 mg/kg) of the total radioactivity in the liver. The remaining unextractable radioactivity accounted for less than 10% (<0.01 mg/kg) of the total radioactivity in the liver.

For chickens dosed at a rate of 23 mg/kg in feed overall recovery of radioactivity was 86%, the bulk of which was excreted (86%), with less than 0.1% in the eggs and less than 0.1% in the tissues.

On characterisation of the extractable radioactivity two major components were identified in the eggs as parent asulam and its metabolite acetyl sulfanilamide, which accounted for more than 90% of the total radioactivity in the egg yolk and white. The remaining unextractable radioactivity, accounted for less than 0.01 mg/kg in the egg yolk and white.

On characterisation of the extractable radioactivity two major components were identified in the tissues as parent asulam and its metabolite acetyl sulphanilamide, which accounted for more than 80% of the radioactivity in the tissues. One unknown was isolated, which did not exceed 0.04 mg/kg in the tissues. The remaining unextractable radioactivity accounted for less than 0.04 mg/kg in the tissues.

The animal metabolite (edible animal products) identified in the animal metabolism study was also identified in the rat metabolism study.

Based on the metabolism data submitted for domestic animals, residues in products of ruminant origin should be defined as the sum of parent asulam plus its metabolite acetyl sulphanilamide expressed as asulam.

Residues trials

Spinach (NMS Post emergence use) - Twelve trials support the proposed critical GAP with residues in Spinach up to 23 mg/kg (appropriate EUMRL = 30 mg/kg; STMR = 0.36 mg/kg).

Spinach (NMS Pre-emergence use) - Eight trials support the proposed critical GAP with residues in Spinach up to 0.07 mg/kg (appropriate EUMRL = 30 mg/kg; STMR = <0.02 mg/kg).

Spinach (SMS Post emergence use) - Only two trail are available giving residues in Spinach up to 0.88 mg/kg, however no approval is being sought in SMS.

Residues of metabolites in trial samples

Residue trial samples from 2013 were also analysed for the following metabolites, as outlined in the EFSA conclusion.

Acetyl asulam

Residues in all the 2013 trials were below the limit of determination (0.01 mg/kg) at harvest (in immature crops were up to 0.07 mg/kg).

Asulam glucosides

Residues in the 2013 post emergence trials were up to 0.68 mg/kg (residues of asulam and malonyl asulam in the sample were 0.17 mg/kg) at harvest, with 4 out of the 5 trials containing residues above 0.01 mg/kg (1 out of the 3 pre-emergence 2013 trials gave a residues of 0.13 mg/kg at harvest). Immature crops gave residues of up to 104 mg/kg on day 3, decreasing to up to 5.4 mg/kg by day 21. Consideration should be given to the inclusion of asulam glucosides into the residues definition (monitoring method has been validated for this metabolite). However, the levels seen at harvest were well below the maximum level of asulam and its metabolite malonyl asulam seen at harvest (12 mg/kg) and would only increase the STMR slightly to 0.61 mg/kg. Only 5 of the 12 residue trials were analysed for asulam glucoside, however possibly in the 2003/4 trials were high levels of malonyl asulam were detected at harvest, the method employed was not capable of separating malonyl asulam from asulam glucosides and both give similar mass fragments of 242 (malonyl asulam) and 239 (asulam glucosides).

Acetyl sulphanilamide

Residues in all the 2013 trials were below the limit of determination (0.01 mg/kg) at harvest (in immature crops were up to 0.02 mg/kg).

Desamino asulam

Residues in all the 2013 trials were below the limit of determination (0.01 mg/kg) at harvest (in immature crops were up to 0.15 mg/kg).

Formyl asulam

Residues in all the 2013 trials were below the limit of determination (0.01 mg/kg) at harvest (in immature crops were up to 0.24 mg/kg).

Malonyl sulphanilamide

Residues in all the 2013 trials were below the limit of determination (0.05 mg/kg) at harvest.

Sulphanailanide
Residues in all the 2013 trials were below the limit of determination (0.01 mg/kg) at harvest (in immature crops were up to 8.1 mg/kg on day 0 declining quickly to up to 0.1 mg/kg by day 3, 0.03 mg/kg on day 7 and less than 0.01 mg/kg by day 21).

Asulam Dimers (Applicants case for non-submission of residues trials data)
A spinach study not conducted to the GAP suggested that low-level unidentified components of the residue could be asulam 'dimers' of some sort or another. EFSA concluded that in crops grown according to GAP these 'dimers' might reach significant levels and so should be taken into account in residue trials. A new study conducted outdoors in support of the post-emergence spinach GAP showed conclusively that such compounds did not reach significant levels in the residue and that there was no evidence for their existence. Therefore there was no justification for any additional metabolites to be included in the target analytes. The list of analytes for the new residue studies conducted in 2013 [see section CA 6.3] was very comprehensive including parent, asulam glucosides and malonyl asulam, as seen to be significant in the pre- and post-emergence spinach studies but also desamino asulam (seen at low levels in the pre-emergence application study), acetyl asulam and formyl asulam as well as acetyl sulfanilamide, malonyl sulfanilamide (which could theoretically be formed from acetyl asulam and malonyl asulam) and sulfanilamide (to demonstrate that it was not a significant plant metabolite). All credible potential residue components were covered by the validated analytical method. It can be concluded that there is no justification to also analyse for asulam related dimer compounds.

Freezer stability – Plants and animal products
Residues of asulam are stable for up to 3 months in spinach and its metabolite asulam-malonyl for at least 11 months, when stored at -18°C.

Effects of industrial processing and/or household processing
Processing studies were carried out on spinach and showed that residues of asulam plus its metabolite asulam-malonyl in the canned/cooked/frozen samples had decreased (by a factor of 0.5, 0.6 and 0.7 respectively). With regards to Sulfanilamide and Malonyl sulphanilamide, residues in mature spinach and processed spinach were below the limit of determination. Studies on the nature of the residue indicate that asulam and its metabolite asulam-malonyl degrade abiotically under conditions representative of industrial or domestic food processing, most notable at pH 5 and 6 forming the metabolite sulphanilamide [23-62%] (or the malonyl derivative [7-27%]).

Animal transfer
No data were submitted or required, due to approval only being required on spinach which is not normally fed to cattle or poultry.

Rotational crops
No data (US study was submitted but was deemed not to be relevant) were submitted or required, due to total [^{14}C] residues in rotational crops at harvest being less than 0.2 mg/kg in the rotational crop metabolism study, with the

exception of wheat straw which gave residues of up to 0.6 mg/kg. However, it is unlikely that residues of asulam in the soil would contribute significantly to the residue in following cereal crops from the application of asulam to spinach for the following reasons:

a) The study being carried out at 1.6N
b) radiolabelled asulam being applied to bare soil instead of a crop.
c) the low levels of parent asulam and its metabolites found in rotational crops at harvest (<0.05 mg/kg)
d) the DT_{50} and DT_{90} for asulam being 3.2 and 11 days respectively and for sulphanilamide 28 and 94 days respectively.
e) total [^{14}C] residues at harvest in crops consumed by humans being less than 0.2 mg/kg.
f) the low probability of crop failure

Risk assessment

Individual TMDIs and IESTIs, NEDIs and NESTIs from the consumption of spinach for adults, infants, toddlers, children, vegetarians and the elderly are all below the ADI and ARfD of 0.36 and 1 mg/kg bw/day respectively. With regards to sulphanilamide (and malonyl sulphanilamide), residues in processed spinach were below the limit of determination (0.01 and 0.05 mg/kg respectively), with the exception of spinach treated at a later grow stage (GS 43 – proposed treatment GS14), which gave residues of up to 0.021 and 0.083 mg/kg respectively, even at these levels the resulting individual TMDIs and IESTIs, NEDIs and NESTIs would be well below (less than 1%) the ADI and ARfD of sulphanilamide of 0.05 and 0.3 mg/kg bw/day respectively.

2.4.2 Residues relevant to consumer safety

Based on the metabolism data submitted for spinach, residues should be defined as follows:

Leafy crops (MRL and monitoring): Asulam plus its metabolite asulam-malonyl expressed as asulam.
Leafy crops (Risk Assessment): Asulam plus its metabolite asulam-malonyl expressed as asulam.

Based on the metabolism data submitted for goats and hens, residues should be defined as follows:

Animal products (MRL and monitoring): Asulam plus its metabolite acetyl sulphanilamide expressed as asulam.
Animal products (Risk Assessment): Asulam plus its metabolite acetyl sulphanilamide expressed as asulam.

2.4.3 Residues relevant to worker safety

Worker exposure estimates using EUROPOEM II predict acceptable levels of exposure to asulam for unprotected workers harvesting spinach (systemic exposure

equivalent to 16% of the AOEL) or ornamentals (systemic exposure equivalent to 31% of the AOEL) treated with 'Asulox'.

2.4.4 Proposed EU MRL's and compliance with existing MRL's

Sufficient data have been submitted to propose an MRL for spinach:

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Spinach	0.5	30	HR (asulam plus malonyl asulam) = 23 mg/kg Rber = 3 mg/kg Rmax = 22 mg/kg OECD = 30 mg/kg Codex = - mg/kg

Based on the acute intakes, the proposed EU MRL for spinach would not lead to an exceedance of the ARfD.

2.4.5 Proposed EU import tolerances and compliance with existing MRL's

No requests have been made for EU import tolerances for asulam.

2.4.6 Basis for differences, if any, in conclusions reached having regard to established or proposed CAC MRL's

No CAC MRLs are available for asulam.

2.5 Fate and behaviour in the environment

2.5.1 Definition of the residues relevant to the environment

In soil the extractable residues of asulam comprise principally the parent plus sulphanilamide (>10%). Under anaerobic conditions, only asulam was the major component (>10%).

In surface water and sediment, asulam was the major component in the residue (>10%), sulphanilamide being a minor metabolite.

In groundwater asulam and sulphanilamide were considered with the metabolites regarded as non-relevant as predicted 80th percentile annual average concentrations were <0.001 in all relevant FOCUS scenarios.

2.5.2 Fate and behaviour in soil

2.5.2.1 Route and rate of degradation

The environmental fate of asulam sodium was investigated in a number of laboratory studies using ring labelled material. Results of the laboratory aerobic route and rate of degradation carried out at 10 or 20°C are available for twelve different soils.

The major metabolite was identified as sulphanilamide which peaked at 14% AR after 14 days at 20°C in clay loam soil. An unidentified metabolite showed levels of up to ca. 20% AR but was found in a supplementary study to be an artefact caused by the scintillant. Bound residues were found associated with all three soil fractions (fulvic, humic and humin) the least radioactivity being associated with the fulvic acids (19 to 32%) and the most associated with the humic acids (22 to 53%) and humin (29 to 67%). The total unextracted residues accounted for 46 to 66% AR. Mineralisation to CO_2 ranged from 4 to 6% AR by 59 days and accounted for between 6 to 8% AR after 120 days (study end) in soils incubated at 20°C.

One study tentatively assigned a further metabolite as methyl benzenesulfonyl carbamate (MBSC) however the study was not considered reliable for a number of reasons including non-GLP, non-guideline, time zero samples not determined, no mass balance. Characterisation of radioactivity was by TLC alone without further confirmation and not considered reliable. Overall it was considered that the study was not reliable.

The major degradation path of asulam is hydrolysis to sulphanilamide. The major route of dissipation is the formation of unextractable bound residues, either of asulam itself but more likely of sulphanilamide. A number of minor metabolites are formed and some of these may be further degraded to carbon dioxide along with a small portion of sulphanilamide. These mechanisms are accelerated by light, without the formation of unique photoproducts, but are slowed by anaerobic conditions.

Laboratory single first order DT_{50} values for asulam normalised to 20°C and moisture at field capacity (pF2) ranged from 2.1 to 11.1 days (geometric mean 4.6 days, results from a four studies on 12 soils). Corresponding DT_{90} values were in the range of 7.1 to 37.2 days.

For metabolite sulphanilamide, laboratory DT_{50} values were available from six soils. Acceptable fits were achieved with either FOMC or DFOP kinetics, the normalised degradation rates (20°C/pF2) ranged from 3.1 to 76.3 days (geometric mean 13.4 days). Using FOMC or DFOP kinetics giving the best fit, the DT_{90} values were in the range 10.3 to 148.7 days

The anaerobic route of degradation has been investigated in two studies (2 soils). In the first study, asulam degraded more slowly than under aerobic conditions. DT_{50} values of 91 days in the water phase and 356 days for the total system were calculated using double first order in parallel kinetics (DFOP). DT_{90} values were

not calculated. Metabolite sulphanilamide formed at peak levels of 0.8% AR in soil after 120 d but was not detected in the water. Additionally a major unidentified metabolite labelled "unknown 1" reached a maximum of 9% AR after 7 days and the largest unknown reached a maximum of 2.8% after 30 days. Bound residues reached a maximum of 7.9% AR after 120 days. In the second study, the rate of decline was only calculated by the applicant for the aerobic phase, asulam did not degrade in the anaerobic phase but actually displayed an increase. It is considered that in the anaerobic phase, asulam was re-dissolving from the bound residues in the soil. Sulphanilamide was the only metabolite reaching a maximum of 15.3% AR in the anaerobic phase.

Photodegradation in soil was investigated in two studies using artificial illumination.
In both studies the degradation of asulam was accelerated the presence of light compared to the dark controls without producing any unique photodegradates. Asulam was shown to have a short half-life (3.71 and 5.6 days for the irradiated samples and 6.69 and 18.4 days for the dark controls). The DT_{50} corrected for photolysis only was 8.3 days. The principal identified metabolite was sulphanilamide, which accounted for up to 4% in the irradiated samples and 11% AR in the dark controls. A number of minor metabolites including acetyl asulam were quantified but none of the metabolites accounted for >5% AR at the end of the study. Overall the Rapporteur considers that photolysis is unlikely to be a significant route of dissipation in the field compared with biotic degradation in the absence of light.

It is concluded that the studies whose results are summarised above were of appropriate design with appropriately positioned radiolabels. They were considered by the Rapporteur to provide sufficient information of an appropriate quality to elucidate and propose the route of degradation of asulam in soil under aerobic and anaerobic conditions and in the presence of light.

For calculating soil, surface water and groundwater PEC values, the pertinent residues in soil are therefore considered by the Rapporteur to be asulam and metabolite sulphanilamide.

2.5.2.2 PECsoil calculations

PECsoil used in the risk assessment representing the use pattern following single application on spinach and flower bulbs (1 x 2400 g a.s./ha per year) was 3.2 mg/kg for parent asulam (this value was derived from worst case laboratory data).

For the major soil metabolite sulphanilamide, based on the initial PECsoil value for asulam, factored for molecular weight differences (asulam 230.2, sulphanilamide 172.2) and maximum formation in laboratory soil studies (17.2%) the PECsoil value would be 0.41 mg/kg.

2.5.2.3 Adsorption and desorption

Batch adsorption was conducted in two studies with asulam sodium on 8 soils, a sand and a sediment (pH 4.6 – 7.5; organic matter content 0.2 – 10.5%). In both studies a soil solution ratio of 1:1 (determined in the preliminary test) were chosen due to the high water solubility of asulam. In the first study an equilibrium time of 24 hours was chosen during which asulam was found to be stable. By contrast, in the second study, an equilibrium time of 48 hours was selected. In one soil, degradation products were detected in the supernatant by HPLC, therefore the amount of radioactivity was corrected by the applicant The K_{foc} values ranged from 15.4 to 149.7 mL/g (mean 25.4 mL/g) and 1/n values were in a range of 0.68 to 0.87 (mean 0.75). With the exception of the sand (with very low carbon content) variation between K_{foc} values was less than between K_f values, indicating that organic carbon of soil content is an important factor in determining adsorption. Adsorption was not noted to correlate with any other soil parameter. For the purposes of calculating mean values for input to computer models, the values for the sand and the sediment were excluded by the Notifier giving a mean K_{foc} of 25.4 mL/g and 1/n value of 0.75.

A batch equilibrium aged desorption study was conducted with asulam sodium on four UK soils (pH 5.8 – 7.0; organic matter 1.2 – 6.2%) over seven days. The $K_{f\ des}$ and $K_{foc\ des}$ values increased at each desorption cycle particularly at seven days indicating that different adsorption mechanisms may be at work, some of which resulted in very strong adsorption of some of the asulam applied to the soil. The effect of the aging period indicated that the potential for mobility of asulam may be significantly reduced with time.

Batch adsorption studies were also conducted with metabolite sulphanilamide on 8 soils. K_{foc} values showed that adsorption of sulphanilamide correlated with soil organic carbon content but no relationship was observed with soil pH. The K_{foc} values ranged from 124 to 179 ml/g (mean 145 mL/g) and 1/n values were in the range 0.673 to 0.748 (mean 0.711). Desorption results indicated that adsorption may not be completely reversible.

A batch adsorption study was conducted on metabolite methyl-benzene-sulfonyl-carbamate (MBSC) on four soils. Due to the low adsorption, the study was conducted at a single concentration only and no adsorption isotherms were determined. The Koc values ranged between 1.53 and 3.88 mL/g (mean 2.8 mL/g). Due to the low adsorption of methyl-benzene-sulfonyl-carbamate on soil, desorption was not considered reliable.

It is considered by the Rapporteur that the batch sorption results are appropriate to allow assessment of leaching potential to groundwater by standard FOCUS modelling approaches.

A column leaching study was conducted with asulam sodium on four UK soils (pH 7.10 – 7.26; organic matter 0.84 – 3.56%). The percentage of AR found in the leachates ranged from 90 to 98%. The radioactivity remaining on the soil was distributed throughout the columns mainly in the form of bound residue. There was

insufficient radioactivity in solvent extracts of the soil to perform chromatographic analysis. Analysis of the leachates from all four soils showed only the presence of asulam indicating a high mobility in these soil types.

An aged column leaching study was conducted with asulam sodium on four UK soils discussed above. The amount of AR in the leachate was less than for the unaged leaching study ranging from 49 to 77%. The majority of the radioactivity remaining on the columns was in the top 6 cm layer of the soil mainly in the form of bound residue. Analysis of the leachates from all four soils showed asulam as the main component. Solvent extracts of the soil layers containing sufficient radioactivity also showed the presence of asulam and a minor component suggested to be sulphanilamide. The results suggested medium to high mobility for previously aged asulam in these soil types.

2.5.3 Fate and behaviour in water

Asulam was stable to hydrolysis at all pH values (pH 5, 7, and 9) over 31 days. There was insufficient degradation to calculate degradation half lives.

An aqueous photolysis study was performed with asulam sodium in sterile buffer solutions at pH 4 and pH9 at 25°C. DT_{50} values for asulam were calculated assuming single first order kinetics to be 0.44 days (pH 4) and 0.87 days (pH9) following artificial illumination (equivalent to 0.78 and 1.56 days of 52°N summer sunlight respectively) (see Table B.8.45). Estimated photolytic half life of asulam in natural surface waters, calculated from the quantum yield, ranged from 7 to 119 hours at pH 4 and 8 to 135 hours at pH 9 in central European latitudes (52°N). Photolytic half life of asulam was also calculated from the quantum yield using the GC Solar program of Zepp and Cline to generate data at 40°, 50° and 60°N by season, at the surface and at depths of 30 and 100cm in the water body. A number of photodegradates were produced at both pH's. The major photodegradate at pH 4 was sulphanilic acid which reached a maximum of 55.5% AR after 20 hours. The major photodegradates at pH 9 identified as N-(4-aminophenyl)formamide and (4(4-methoxycarbonylaminophenyl)aminophenyl)carbamic acid reached maxima of 24.2 and 11.9% respectively. DT_{50} values were calculated for the metabolites using ModelManager, however the confidence limits were very wide and were considered by the Rapporteur to be unacceptable.

A further aqueous photolysis study was performed with asulam sodium in sterile natural water at 25°C to meet Japanese registration requirements. The DT_{50} was calculated using first order kinetics to be 0.84 days (equivalent to 4.21 days spring sunlight at 35°N in Japan, which is comparable to Athens, Southern Europe). It is noted from dark water sediment studies below that the partitioning of asulam from the water phase to sediment was relatively slow (DT_{50} 58 to 68 days) compared to the photolytic half-life suggesting that asulam would be available in the surface water for photolysis to occur. Many minor photodegradates were formed, all <10% AR. DT_{50}'s were not calculated for these metabolites. In natural surface water, none of the major (i.e. >10%) metabolites identified in the photolysis study performed in sterile buffer solutions summarised above were formed in significant amounts. The Notifier has proposed that the results from the natural water study

are more relevant than from the sterile buffer study for the purposes of the exposure assessment, since the effects of indirect phototransformation are considered alongside those of direct phototransformation in the natural water study.

Although the Rapporteur notes that the two aqueous photolysis studies were performed in separate studies under contrasting illumination schemes (i.e. equivalent to either Northern Europe or Southern Europe in each study) and in waters of different pH, overall the Rapporteur considered that the Notifier's case regarding the influence that indirect phototransformation may have on the formation of metabolites was plausible. However the Rapporteur also considered that in the absence of further information on the influence of direct and indirect phototransformation under comparable experimental conditions (i.e. identical illumination, pH, incubation conditions etc.) it was not possible to conclude that aqueous photolysis metabolites would not be formed in major amounts in the upper layers of some natural surface waters. In the absence of specific aquatic toxicity data on the major photolysis metabolites formed in the sterile buffer study (i.e. sulphanilic acid, N-(4-aminophenyl)formamide and (4(4-methoxycarbonylaminophenyl) aminophenyl) carbamic acid) no calculation of PECsw values has been performed. Further information is required to assess the environmental relevance of these photolysis metabolites.

A further aqueous photolysis study was also performed with asulam in sterile buffer at pH 4 and pH 9 at 25°C. The DT_{50} values calculated using SFO kinetics were comparable with the original study above, 0.28 days (pH 4) and 0.86 days (pH 9) following artificial illumination equivalent to 0.54 days (pH4) and 1.64 days (pH9) in natural sunlight at 52°N. The calculated quantum yield was 0.168 at pH 4 and 0.0612 at pH 9 from which the half-life of asulam in the top few millimetres ranged from 0.183 days in Summer at latitude 40° N to 5 days in Winter at latitude 60° N and that of asulam at pH 9 to ranged from 0.25 days in Summer at latitude 40° N to 5.1 days in Winter at latitude 60° N. A number of photodegradates were observed in the irradiated samples. Seven of these exceeded 4% of applied radioactivity. The second most abundant photodegradate reached a maximum of 15.4% and was identified as N (4-aminophenyl)formamide. Sulphanilic acid, a known metabolite of asulam, was confirmed to be present at levels up to 18.9% of applied radioactivity. There was no evidence for further degradation of the observed photodegradates. No significant degradation of asulam was observed in the non-irradiated system.

A supplementary study was performed to clarify quantification of four metabolites found at between 5% and 10% of applied radioactivity in the above study. At pH 4, the only major metabolite (>10% AR) was identified as sulphanilic acid in the previous study and reached a maximum 61.3%. No other photodegradates reached 4%. In particular the degradate of interest, rrt = 0.95, which reached between 5% and 10% in the previous study, was shown to be very minor and so no further identification of this component was attempted. At pH 9, two major photodegradates (i.e. >10% of applied radioactivity) reached maxima of 18.4% (sulphanilic acid) and 10.6% (N-(4-aminophenyl)formamide). A third photodegradate, at rrt = 0.50, reached 6.2% (benzenesulphonic acid). Three degradates of interest, which reached between 5% and 10% in the previous study

which in this study reached 6.1%, 4.1% and 7.2% respectively. These three regions of radioactivity were investigated further and calculated to be respectively 2.2%, 1.4% and 3.0% AR. Thus no unidentified component in the pH 9 samples reached 4% and all considered of minor significance by the applicant and no further attempt at identification was made.

The ready biodegradability of asulam was investigated in two studies. Asulam showed 31% and 51% biodegradation over 28 days, based on biochemical oxygen demand asulam was considered not readily biodegradable.

The fate and behaviour of asulam was investigated in 2 studies totalling 4 aerobic laboratory (dark, 20°C) natural water/sediment systems. Asulam was a major component in all surface water and sediment samples analysed. Partitioning of radioactivity between the surface water and sediment was observed in both studies. The quantity of asulam in the surface water declined from initial levels of 87% to 96% initially to 18% and 13% after 153 days in the first study and 36 to 8.7% after 120 days in the second study. In the first study, small quantities of (up to 2.8%) of sulphanilamide and an unknown compound (up to 0.74%) were detected in the surface water of both systems. Acetyl asulam was detected in one system (up to 1%) after 30 days. In the sediment there was a corresponding increase in the percentage of applied radioactivity as asulam from 8% and 7% at the start which increased to a maximum of 22 and 18% after 30 days and then declined to 8% and 4% after 153 days. Small quantities (of up to 1.7, 0.2, 1.7 and 0.4%) of acetyl asulam, sulphanilic acid, sulphanilamide and acetyl sulphanilamide respectively were detected in the sediment of both systems. A number of unknown compounds were detected in total amounts up to 6.8% AR but no individual unknown was greater than 2.5%. Summation of the separate phases to consider the total system showed a steady decline in the amount of asulam present down to 26 and 17% after 153 days. In the degradation pathway proposed by the Notifier, asulam, or its degradates are bound or incorporated into the sediment (up to 58%) or degraded to carbon dioxide (3.0% and 13.9%) or to one of four degradates (acetyl asulam, sulphanilic acid, sulphanilamide and acetyl sulphanilamide), all less than 3.8%.

In the second study, the RMS notes that a number of metabolites were detected. Met A, B and C are minor metabolites (max 1.4%). Met D is tentatively assigned as sulphanilamide reaching a maximum of 9.7% AR (day 28) in the total system. Met E reached a maximum of 9.6% AR and is unidentified. Although this metabolite remains below 10% AR, which was in accordance with the guidance at the time of the study, under modern guidance Met E exceeds 5% on 2 or more consecutive timepoints and should have been identified and given further consideration. Met F is tentatively identified as methylbenzenesulphonylcarbamate (MBSC) reached a maximum of 10.3% AR at day 2 in the total system. The applicant considers this an outlier as it 'does not fit the observed asulam degradation pattern'. The RMS does not agree with this and considers that further evidence should be provided to support this statement or, since the metabolite exceeds 10% AR it should be considered as a major metabolite and should have been investigated further and included in the surface water exposure modelling. FOCUS sw exposure modelling was therefore provided by the applicant (Steps 1 – 3). Since MBSC is a major water metabolite, the RMS requested further data from

which has been provided by the applicant which includes MBSC soil metabolism and sorption studies and surface water exposure modelling.

Water phase dissipation DT_{50} rates for asulam ranged from 26.4 to 97.6 days using a single first order model. Whole system degradation DT_{50} values were 61.9 to 78.8 days (geometric mean 70.3 days).

2.5.3.1 Predicted environmental concentrations in surface water, sediment and groundwater (PEC_{sw} and PEC_{gw}) (IIIA 9.2.1, 9.2.3)

Groundwater - asulam

The 80th percentile annual average concentrations in leachate leaving the top 1 m soil layer for asulam and sulphanilamide were predicted to be less than 0.001 µg/l in the seven FOCUS scenarios modelled.

Surface water - asulam

The major routes of entry to surface water are likely to be via spray drift and runoff/drainage and concentrations were estimated using FOCUS Steps 1, 2 and 3. The maximum instantaneous PEC_{SW} value for asulam at Step 1 and 2 were 795.87 µg/l and 190.15 µg/l (spring applications to leafy vegetables in Southern Europe modelled at Step 2 as a worst case).

For sulphanilamide the maximum initial PEC_{SW} values at Step 1 and Step 2 were 86.35 and 28.96 µg/l respectively.

At Step 3 the maximum PECsw value was 62.969 µg/l (R4 Stream). At Step 3 the Rapporteur noted that for the majority of scenarios the pattern of surface water exposure was the result of peak concentrations occurring on the day of application (indicating a significant contribution from spray drift) with the exception of R2 stream (peak on 16 March), R3 stream (peak on 3 March and 9 June) and R4 stream (peak on 12 March and 7 June) due to run-off.

The three major asulam photodegradates at Step 3 were sulphanilic acid 26.287 µg/L (R4 stream), AP formamide 9.011 µg/L (R4 stream) and MCAPAP carbamic acid 9.806 µg/L (R4 stream).

2.5.3.2 Monitoring data

Four monitoring studies were performed to investigate the leaching of asulam into groundwater or surface water following application of asulam in the field. A Danish study demonstrated the potential for asulam to leach into groundwater in areas of high vulnerability with shallow sandy soil. Two studies were performed in America. A groundwater monitoring study was investigated with application of asulam sodium to sugar cane and turf. Asulam was found in surface water soon after application and was observed in groundwater but dissipated quickly. A drinking water monitoring study showed residues of asulam at greater than the 0.1 µg/L limit for drinking water although the studies were performed in areas of high

application and limits of quantification were 1 µg/L. A UK study was conducted in which asulam was applied by aerial spray from a helicopter to bracken close to streams and reservoirs. Monitoring of levels of asulam and sulphanilamide demonstrated the importance of adequate no spray zones to avoid spray drift. Levels of asulam in surface water were initially high but decreased rapidly although the concentrations detected at the two reservoir outlets exceeded the EC Drinking water directive limit of 0.1µg/L after 13 days. In the above studies, application rates of asulam were higher (up to 3 times) than the GAP for use on spinach and although may be of interest for additional uses at Member State level are of limited significance to the representative use on spinach.

2.5.4 Fate and behaviour in air

Asulam has an estimated vapour pressure of <5 x 10^{-7} Pa at 45°C and an estimated Henry's Law constant of <1.31 x 10^{-10} Pa m^3/mol at 20°C. Therefore asulam would be considered only very slightly volatile, and there is little potential for volatilisation from soil, plant or water surfaces. Based on a theoretical calculation of the potential for photo-oxidation of asulam in the atmosphere a first order half-life of 0.372 d was estimated. Based on the short half-life and the low vapour pressure of asulam it is concluded that asulam would be unlikely to be subject to long range transport. Consequently air is not a likely route of environmental contamination.

2.6 Effects on non-target species

2.6.1 Effects on birds

Summary of avian toxicity studies

Avian toxicity endpoints concluded from studies conducted using asulam or asulam sodium are summarised in Table 2.6.1. Avian toxicity studies with the formulation were not performed and are not required, since for this simple soluble concentrate spray applied product, the formulation is not considered to pose any additional risk – which can be assessed based on studies conducted with the active substance.

Table 2.6.1 Overview on acute, short-term and reproductive toxicity of asulam sodium /asulam to birds ##

Test species	Time scale/ study type	Ecotoxicological endpoint	Test guideline	References
Bobwhite quail	Acute	**LD_{50}** > 2000 mg asulam sodium/kg = **> 1825.6 mg asulam kg bw**	EPA 71-1	[redacted] (2000)
Mallard duck	Short-term dietary	LC_{50} > 100000 mg asulam /kg diet = > 22732 mg a.s./kg bw	No guidelines in place	[redacted] (1970a)
Pheasant	Short-term dietary	LC_{50} mg asulam/kg diet >75000*	No guidelines in place	[redacted] (1970a)
Japanese quail	Subchronic, reproduction toxicity study	NOEC = < 500 mg asulam/kg diet = < 65 mg a.s./kg bw /day **NOAEC** = 500 mg asulam /kg diet = **65 mg a.s./kg bw /day#**	OECD draft 1999	[redacted] (2001a)
	Subchronic, reproduction toxicity study ##	NOEC = 100 mg a.s./kg diet = 19.0 mg a.s./kg bw/day # NOAEC = 500 mg a.s./kg diet = 93.8 mg a.s./kg bw/day #	OECD draft 2000	[redacted] (2003)

* Not possible to convert into mg asulam/kg bw

Endpoint supported by RMS's evaluation of submitted review papers ([redacted] 2004 & [redacted] 1991)
Including further assessment of effects on egg shell quality
Endpoints in **bold** used in the regulatory risk assessment.

Summary of results of avian risk assessment

The risk to birds from the proposed crop uses of 'Asulox' (containing 400g asulam /L) has been evaluated based on current EFSA (2009) risk assessment guidance. This differs from that used in the previous Ecotoxicology Volume 3 DAR (2006) - which was based on earlier SANCO/4145/2000 (2002) methodology.

The conducted risk assessment (Section B.9.1.5) indicates that the proposed crop uses of asulam in spinach and flower bulb crops pose a low and acceptable risk to birds from exposure via their diet or from drinking water. There is a lack of potential for bioaccumulation in fish and earthworms (log Pow < 3.0) and therefore a low risk of secondary poisoning to fish-eating and earthworm-eating birds. Given the current absence of defined criteria for identifying avian endocrine disruptors under 1107/2009, a regulatory assessment of asulam's endocrine disrupting properties cannot be made at this time.

2.6.2 Effects on terrestrial vertebrates other than birds

Summary of relevant mammalian toxicity studies:

Data on the mammalian toxicity of asulam are summarised in Section B.6 'Mammalian Toxicology' of the Volume 3 Assessment Report. No additional ecotoxicologically relevant data have been provided in this submission over that considered previously for the earlier Annex I evaluation of asulam.

A summary of mammalian toxicity endpoints relevant to the 'other terrestrial vertebrate' wildlife risk assessment is presented below in Table 2.6.2, with the previously agreed toxicity endpoints for use in the ecotoxicology risk assessment highlighted in bold.

Table 2.6.2 Summary of mammalian toxicity endpoints relevant to the 'other terrestrial vertebrate' risk assessment.

Type of exposure	Test substance	Toxicity*	References Doc. No.
Acute oral toxicity on rat	'Asulox'	LD_{50} >2000 mg product /kg bw #	[redacted] (2001n) [redacted]
Acute oral toxicity on rat	Asulam sodium	**LD_{50}** > 5000 mg asulam sodium /kg bw ≡ **>4564 mg asulam/kg bw**	[redacted] (1987) [redacted]
	Asulam sodium	As above.	[redacted] (1988) [redacted]
2-generation study on rat	Asulam sodium	NOAEL = **46 mg asulam/kg bw/day**	[redacted] (1981) [redacted]

No mortality or clinical signs of toxicity observed in the study
* Values in bold = previously agreed regulatory endpoints (EFSA conclusion report) - used in the previous and current 'Other terrestrial vertebrate' risk assessment.

Risk to 'other terrestrial vertebrates' (wild mammals)

The risk to wild mammals from the proposed crop uses of Asulox (containing 400g asulam/L) has been evaluated based on current EFSA (2009) risk assessment guidance. This differs from that used in the previous Ecotoxicology Volume 3 DAR (2006) - which was based on earlier SANCO/4145/2000 (2002) methodology.

Given that the formulation 'Asulam 400g/L SL' is a simple solution of asulam in water, it does not pose any additional risk over that from the active substance. Therefore, the risk from the formulation will be covered by the asulam risk assessment.

The risk assessment (Section B.9.3.2) indicates that the proposed crop uses of asulam in spinach and flower bulb crops pose a low and acceptable risk to wild mammals from consumption via their diet or from drinking water, with the exception of the risk to small herbivorous mammals from late post-crop emergence use in flower bulbs (BBCH ≥ 40) – for which an acceptable long-term risk has not been (numerically) demonstrated (refined long-term TER = 4.5). However the risk assessment conducted for small herbivorous mammals is conservative in assuming that all of the diet of small herbivorous mammals will be obtained from within treated crops (i.e. PT = 1) and also in assuming for voles (the EFSA indicator species) a dietary spray deposition value of 0.6 – which is likely to be an over-estimate when it is taking into account that voles usually feed in habitats that provide good ground cover. Therefore, the RMS considers that when these factors are taking into account ,the small herbivorous mammal long-term TER is likely to be greater than the trigger value of 5 – indicating an acceptable risk to small herbivorous mammals.

There is a lack of potential for bioaccumulation in fish and earthworms (log Pow < 3.0) and therefore a low risk of secondary poisoning to fish-eating and earthworm-eating birds. Mammalian toxicity data indicate a lack of endocrine effects and on this basis there is considered to be a low risk of such effects in exposed wild mammals.

2.6.3 Effects on aquatic species

Toxicity to aquatic life:

Aquatic life toxicity studies have been conducted with asulam or its salt 'asulam sodium' and for algae and aquatic plants also with its major metabolite sulphanilamide. As discussed under Section B.9.0 (Background information) of the Volume 3, asulam and asulam sodium can be regarded as biologically equivalent when molecular weight differences are taken into account. To enable a comparison in the risk assessment with maximum surface water exposure values (PECsw) given in terms of concentrations of asulam, study endpoints derived from use of asulam sodium have been converted into asulam equivalents using a conversion factor of 0.9128 - based on the molecular weight differences of asulam (230.2) and asulam sodium (252.2).

Given that the representative formulation 'Asulox' (also referred to as 'Asulam 400 g/L SL') contains only additional water, acute toxicity formulation studies have not

been conducted for all aquatic groups – it being possible instead to calculate its toxicity based on toxicity values derived from studies conducted with the technical active substance.

Details of the results of the reported aquatic life toxicity studies are summarised in Table 2.6.3

Table 2.6.3 Summary of aquatic life toxicity data for asulam and its major metabolite sulphanilamide

Type of study	Species (test duration)	Test material	EC/LC_{50} #	NOEC #	Reference
Fish					
Acute toxicity	*Oncorhynchus mykiss* (Rainbow trout) (96-hour acute)	Asulam sodium #	>159.8 mg asulam/L (m.m.)	159.8 mg asulam/L (m.m.)	[redacted] (1988a)
	Lepomis macrochirus (Bluegill sunfish) (96-hour acute)	Asulam sodium #	**>91.3 mg asulam/L** (m.m.)	91.3 mg asulam/L (m.m.)	[redacted] (2000)
Chronic toxicity	Oncorhynchus mykiss (Rainbow trout) (28-day chronic)	Asulam	>119.1 mg asulam/L (m.m.)	**119.1 mg asulam/L** (m.m.)	[redacted] (1997a)
Aquatic invertebrates (including sediment dwellers)					
Acute toxicity	*Daphnia magna* (48-hour acute)	Asulam sodium	**57.87 mg asulam/L** (m.m.)	23.28 mg asulam/L (m.m.)	Manning (1988b)
Chronic toxicity	*Daphnia magna* (21-day chronic)	Asulam	57.1 mg asulam/L (m.m.)	**6.4 mg asulam/L** (m.m.)	McElligott (1997b)
	Daphnia magna (20-day chronic)	'Asulam 80 SG'	21.48 mg asulam/L (nominal) ##	8.96 mg asulam/L (nominal) ##	Herrmann *et al.* (1992a)
	Chironomus riparius (28-day spiked water study in a sediment/water test system)	Asulam sodium	>91.3 mg asulam/L (nominal- assuming all applied active in water phase) ##	**91.3 mg asulam/L** (nominal- assuming all applied active in water phase) ##	Heintze (2002)
Algae					
Standard laboratory (OECD/ EPA) algal growth inhibition studies	*Pseudokirchneriella subcapitata* (120-hour growth)	Asulam sodium	E_bC_{50} (72h) = 0.06 mg asulam /L (m.m.) E_rC_{50} (72 h) 1.73 mg asulam/L (m.m.)	0.018 mg asulam/L (120h, m.m.)	Hoberg (1992a)/Dorgerloh (2004a)
	Anabaena flos-aquae (120-hour growth)	Asulam sodium	E_bC_{50} (72h) = 0.15 mg asulam /L (m.m.) **E_rC_{50} (72 h) >0.66 mg asulam/L** (m.m.)	0.17 mg asulam/L (120h, m.m.)	Hoberg (1992b)/Dorgerloh (2004b)

Type of study	Species (test duration)	Test material	EC/LC$_{50}$ #	NOEC #	Reference
	Navicula pelliculosa (120-hour growth)	Asulam sodium	E_bC_{50} (72h) = 3.1 mg asulam /L (m.m.) E_bC_{50} (120h) = 2.1 mg asulam /L (m.m.) E_rC_{50} not calculated.	0.14 mg asulam/L (120h, m.m.)	Hoberg (1992c)
	Skeletonema costatum (120-hour growth)	Asulam sodium	E_bC_{50} (96h) = 0.146 mg asulam /L (m.m.) E_rC_{50} (72 h) >1.64 mg asulam/L (m.m.)	0.02 mg asulam/L (120h, m.m.)	Hoberg (1992d)/Dorgerloh (2004c)
	Pseudokirchneriella subcapitata (120-hour growth)	Sulphanil-amide	E_bC_{50} (72 h) 7.6 **E_rC_{50} (72 h) >21.15 (m.m.)**	2.78 mg metabolite /L (120h, m.m.)	Gosch & Sowig (2003)
Higher aquatic plants					
Standard laboratory (OECD/ EPA) *Lemna* growth inhibition studies	*Lemna gibba* (14-day growth)	Asulam sodium	E_bC_{50} **(14 day)** = 0.3 mg asulam sodium /L = **0.27 mg asulam/L** [1] **(initial measured)** E_rC_{50} = 0.16 mg asulam sodium /L = 0.146 mg asulam /L [2] (mean measured) [Mean analysed concns: 99% of nominal at test start & 15% at test end]	0.11 mg asulam/L (14 days, initial measured) 0.051 mg asulam sodium /L (14 days, mean measured)	Hoberg (1992e)
	Lemna gibba (7-day growth)	'Asulam 400g/L SL' (≡ Asulox)	E_bC_{50} (7 day) = 0.32 mg product /L = 0.106 mg asulam /L (nominal) E_rC_{50} (7 day) = 2.56 mg product /L = 0.845 mg asulam /L (nominal) [Mean analysed concns: 97% of nominal at test start & 90% at test end]	0.1 mg product /L = 0.033 mg asulam /L (based on nominal test concns. supported by chemical analysis)	Vinken & Wydra (2007)
	Lemna paucicostata (7-day growth)	Asulam	E_rC50 (14 day) 93.8 mg asulam /L (unsupported nominal conc.[##]) Note: Study not GLP compliant.	-	Michel *et al.* (2004)
	Lemna minor (7-day growth)	Sulphanil-amide	**E_rC_{50} 5.82** E_yC_{50} 2.30 (Based on nominal test concentrations - supported by results of chemical analysis)	0.67 mg/L	Juckeland (2011)

Type of study	Species (test duration)	Test material	EC/LC$_{50}$ #	NOEC #	Reference
Non-standard replicated (x 2-3) study in which two or three excised 10cm long apical shoots of each test species were grown in 1.5 litre vessels (containing test solution without sediment)	Five aquatic macrophytes including: *Myriophyllum spicatum*, *Elodea nuttallii*, *Elodea canadensis*, *Ranunculus circinatus* and *Potamogeton crispus* (21 day study duration, effects assessed on shoot length and biomass).	'Asulox' (400g asulam /litre)	Most sensitive test species *Myriophyllum spicatum* E_bC_{50} (21 day) = 0.0107 mg /L (Based on nominal test concentrations - supported by results of chemical analysis) ###	Not reported	Arts & Belgers (2013)
Lab growth inhibition study conducted to *Myriophyllum* draft OECD test guideline (dated July 2014), using rooted plants in a water sediment test system.	*Myriophyllum spicatum* (14 day growth)	'Asulam 400 g/L SL' (≡ Asulox)	14-day (wet weight) biomass E_yC_{50} = 0.39 mg asulam /L 14-day (wet weight) specific growth rate E_rC_{50}> 2.56 mg asulam /L (Based on nominal test concentrations - supported by results of chemical analysis)	0.01 mg asulam /L (or 0.011 mg asulam sodium /L)	Seeland-Fremer & Wydra (2014)

Effects endpoints assessed at end of study unless indicated otherwise and expressed for active substance studies in term of amounts of asulam, using where required a conversion factor from amounts of asulam sodium to asulam of 0.9128.

These studies are considered to be of limited reliability due to no chemical analysis included to confirm test concentrations at the test start and /or over the duration of the study.

Study non-GLP compliant and 95% confidence intervals for the most sensitive total dry weight E_bC_{50} of 10.7 µg/L are large i.e. 2-74 µg/L - indicating uncertainty in the accuracy of this determined endpoint. Given these deficiencies, the results of this study are not considered sufficiently reliable for regulatory use.

[1] Asulam frond number (biomass) toxicity endpoint (E_bC_{50}) derived based on initial measured test concentrations used in aquatic risk assessment.

[2] Asulam sodium specific growth rate toxicity endpoints (E_rC_{50} and NOErC) derived based on mean measured test concentrations used in the CLP active substance hazard classification.

CLP environmental hazard classification and aquatic life risk assessment:

Asulox is of low to moderate toxicity to fish and aquatic invertebrates (including sediment dwellers) but of high toxicity to algae and higher aquatic plants. The log Pow values of asulam and its metabolites are below the bioaccumulation trigger value of log 3.0 (asulam log Pow = 0.15), indicating a lack of potential for bioaccumulation in fish and other aquatic organisms.

Based on asulam's high toxicity to algae and higher aquatic plants and lack of rapid degradability, both asulam and its formulated product 'Asulox' should be classified under the 'CLP Regulation' as 'acute category 1' and 'chronic category 1' (with H410 hazard statement 'Very toxic to aquatic life with long lasting effects'). For further labelling details see Section B.9.5.2.

The risk assessment (Section B.9.5.4 of Volume 3 Assessment Report) indicates, for the proposed uses in spinach and flower bulb crops that risk mitigation measures are required to protect aquatic life. The conducted FOCUS Step 4 risk assessment is considered sufficient to indicates an acceptable risk to aquatic life with the inclusion of a 5 metre 'no spray' spray drift buffer zone plus a vegetative field strip of sufficient width to reduce run-off by 80%. However, individual Member States may choose to use other risk mitigation measures.

2.6.4 Effects on bees

The risk assessment has been conducted in line with current terrestrial ecotoxicology guidance detailed under SANCO/10329/2002 (October 2002), based on Directive 91/414's ecotoxicology data requirements – carried over as an interim measure to Regulation 1107/2009 applicable to submissions received prior to 1st January 2015. There is no additional risk from the formulated product 'Asulam 400g/L SL' over that of the active substance asulam, as it is a simple dilution in water, therefore the risk assessment for the active substance will cover that for the formulation.

The conducted Literature review has identified the presence of asulam (and its metabolite sulphamilamide) in honey sampled from hives in Switzerland (ref. Kaufmann A & Kaenzig A (2004) – with the foraging of bees in treated crops being implicated as the potential source of exposure. This is considered further below.

'Hazard quotient' acute risk assessment for bees:

Table 2.6.4 Hazard quotients for honeybees based on laboratory toxicity studies

Application rate (g asulam/ha)	Exposure route	LD_{50} (µg/bee)	Hazard quotient	Uniform Principles trigger
2400	Oral	> 123.7	< 19.4	50
	Contact	> 100	< 24	50

A comparison of the application rate with the acute oral and contact toxicity of asulam results in hazard quotients which are less than the Uniform Principles trigger value of 50. Therefore, based on this hazard quotient risk assessment, the proposed crop uses pose a low risk to bees, with no risk mitigation measures being required.

Risk to bees from possible residues in hive honey:

Details in the literature review paper by Kaufmann and Kaenzig (2004) indicates maximum residues present in hive honey of 200 µg asulam /Kg and 227 µg sulphanilamide /Kg – it is thought likely that these residues originated from bees foraging in treated grassland meadows. This crop use differs from the proposed uses in spinach and flower bulb crops. There are also possible differences in the rate of application - no information being available to the RMS regarding the application rate of asulam used in Swiss meadows prior to the sampling of hive honey for residue analysis. Therefore, there is uncertainty regarding the applicability of the asulam and sulphanilamide honey residues data to the proposed crop uses, which needs to be taken account of in any risk assessment.

In the absence of an EU agreed risk assessment methodology to assess the risk from active substance residues in honey, no specific risk assessment for this route of exposure has been included in this current evaluation.

2.6.5 Effects on other arthropod species

In line with ESCORT 2 guidance and the current 'Guidance Document on Terrestrial Ecotoxicology' (SANCO/10329/2002), details have been supplied for glass plate residue toxicity tests conducted with the indicator species *A. rhopalosiphi* and *T. pyri*. The results of these studies have been used to conduct an in-field and off-field 'Tier 1' ESCORT2 risk assessment. Given that for both crop uses (i.e. spinach and flower bulbs) only one application is applied per crop, there is no need to include a multiple application factor when estimating exposure in these calculations.

ESCORT 2: 'Tier 1' risk assessment Hazard Quotient (HQ) calculations:

The following equations were used to calculate indicator species hazard quotients from in-field and off-field exposure:

In-field HQ = Application rate ÷ LR_{50}

Off-field HQ = Application rate x (drift factor ÷ VDF) x CF ÷ LR_{50}

- Vegetation distribution factor (VDF) = 10 (assumed standard value to adapt the overestimated exposure given by the 90th percentile drift values to a more realistic deposit estimation for off-field habitats).
- Correction factor (CF) = 10 ('Tier 1' uncertainty factor for the extrapolation from indicator species to all off-field non-target arthropods).
- The drift value is set at 2.77% for 1 application in field crops at 1m distance.

In-field and off-field hazard quotients for *A. rhopalosiphi* and *T. pyri*, calculated as above, are given in Table 2.6.5.

Table 2.6.5 Hazard quotients (HQ) for in-field and off-field exposure scenarios from the proposed crop uses of 'Asulam 400g/L SL'

Species	Application rate: litres 'Asulam 400g/L SL' /ha	LR_{50}: litres 'Asulam 400g/L SL' /ha	In-field HQ	Off-field HQ
A. rhopalosiphi	6.0	3.088	1.94	0.05
T. pyri	6.0	7.566	0.79	0.02

As the hazard quotients are less than the trigger value of 2 this indicates under the ESCORT 2 risk assessment methodology an acceptable risk to non-target terrestrial arthropods present in 'in-field' and 'off-field' habitats from the recommended application rate of Asulox (6.0 L/ha). This is further supported by a lack of adverse effects from exposure to asulam reported in laboratory toxicity studies with other crops relevant to foliar and soil dwelling predators, although based on the results of extended laboratory studies with *T. pyri* there may possibly be some initial adverse effects on fecundity. However, given the short foliar half-life of asulam, any adverse fecundity effects are likely to be short lived.

It is concluded that the proposed use of 'Asulam 400g/L SL' in spinach and flower bulb crops poses an acceptable risk to non-target arthropods.

2.6.6 Effects on earthworms

Assessment of exposure and risk was conducted according to the principles as laid down in the current terrestrial ecotoxicology guidance document SANCO/10329/2002 rev 2 final, dated 17 October 2002. Based on acute and long-term earthworm toxicity endpoints determined in laboratory studies with asulam and its major soil metabolite sulphanilamide, acute and long-term TERs for earthworms are presented in Table 2.6.6.

Table 2.6.6 Risk to earthworms from exposure to asulam and sulphanilamide

Compound	Toxicity endpoint mg/kg soil	PEC mg/kg soil#	TER	Trigger
Asulam	Acute: 14 d LC_{50} = 1004	3.2	313.7	10
	Long-term: 8 week NOEC = 180.7	3.2	56.5	5
Sulphanilamide	Acute: 14 d LC_{50} >1000	0.41	> 2439	10
	Long-term: 8 week NOEC = 3.75	0.41	9.1	5

See Section B.8.3 and Table B.8.108 for full details of these values

Conclusions:

The acute and long-term TERs for asulam and sulphanilamide are within the Uniform Principles trigger values, indicating a low and acceptable risk to earthworms from these substances.

2.6.7 Effects on other soil non-target macro-organisms

Details have been provided for an asulam chronic toxicity study conducted with the soil mite *Hypoaspis aculeifer* which was considered in the previous Annex I evaluation for asulam (with no issues identified) and for a new study on sulphanilamide's chronic toxicity to the collembola *Folsomia candida*. Both are considered to be scientifically valid studies, suitable for use in a regulatory risk assessment. Both studies include an assessment of adverse reproductive effects on soil macro-organisms and as such address the possible potential for some initial adverse effects on fecundity reported in some of the crop dwelling non-target arthropod toxicity studies (Section B.9.5.1 of Volume 3 Assessment Report).

Soil macro-organism long-term toxicity exposure values (TERs) are presented in Table 2.6.7 for asulam and its metabolite sulphanilamide, based on a comparison of the soil macro-organism long-term endpoint (NOEC /NOAEC) with the maximum derived soil PEC.

Table 2.6.7 Soil macro-organism risk assessment

Test material	Organism	Endpoint	mg/kg soil	Maximum PEC mg/kg soil#	TER	Trigger value
'Asulam 400 g/L SL'	*Hypoaspis*	NOEC	4370	3.20	1366	5
Sulphanilamide (major soil metabolite)	*Folsomia*	NOAEC	50	0.41	122	5

Estimated by RMS in Section B.8.3 of Volume 3 Assessment Report.

The long-term TERs for asulam and its major soil metabolite sulphanilamide are all in excess of the trigger value of 5, indicating a low and acceptable long-term risk to soil macro-organisms from exposure to asulam and sulphanilamide following the proposed use of 'Asulam 400 g/L SL' ('Asulox') in spinach and flower bulb crops.

2.6.8 Effects on soil micro-organisms

Effects on soil microbial carbon and nitrogen transformation are reported from two studies: use in one study (Luscombe 1981a) at 16 mg asulam /kg dw soil resulting (when assessed on day 28) in no effects on nitrate formation and reductions in carbon dioxide production of less than 25%; and use in the other study (Kölzer 2002) at 9.6 mg asulam /kg dw soil resulting when assessed on day 28) in a reduction in nitrate formation of 9% and an increase in carbon dioxide production of 3.6%. Additionally, in a third study (Luscombe 1981b) exposure at a test dose of 8.93 mg asulam /kg dw soil caused no adverse effects on nitrogen fixation in the root nodules of alfalfa plants – providing some further supporting evidence (although not strictly required). Therefore, it is concluded that the study results indicate effects on nitrogen and carbon transformation of well within the Uniform Principles trigger value of '>25% after 100 days' from soil exposure levels of between 3-5 times the maximum soil PECs from the proposed use in spinach and flower bulb crops. Therefore, a low and acceptable risk from asulam exposure to soil micro-organisms can be concluded.

With respect to effects of the major soil metabolite sulphanilamide, the RMS in Section B.8.3 of the Volume 3 AR estimates a maximum soil PEC of 0.41 mg metabolite /kg dw soil from the proposed use in spinach and flower bulb crops. Given the reported lack of adverse effects of sulphanilamide on soil nitrate formulation at exposure concentrates of up to 3.3 mg metabolite /kg dw soil (Schulz L 2011) – equivalent to 8 times the maximum soil PEC – it is concluded that the risk of adverse effects on soil nitrogen transformation processes is low. Although, no specific studies on the effects on soil respiration /carbon transformation have been provided, paragraph 4 of the OECD 216 'nitrogen transformation test' guideline states '*The test method also allows estimation of the effects of substances on carbon transformation by the soil microflora. Nitrate formation takes place subsequent to the degradation of carbon-nitrogen bonds. Therefore, if equal rates of nitrate production are found in treated and control soils, it is highly probable that the major carbon degradation pathways are intact and functional*. Therefore, a lack of reported significant adverse effects on nitrogen transformation also indicates a lack of adverse effects on carbon transformation. This is further supported by the non-requirement for such a carbon transformation study under Regulation 1107/2009.

A low and acceptable risk to soil micro-organisms for both asulam and sulphanilamide exposure from the proposed crop uses can therefore be concluded.

2.6.9 Effects on other non-target organisms (flora and fauna) believed to be at risk

Effects on non-target fauna and aquatic plants have been addressed in other sections of this report. Therefore, this section refers only to non-target terrestrial plants.

Asulox is to be applied as a single application in spinach and flower bulb crops at a maximum dose of 240g asulam /ha. Spray drift is considered to be the principle exposure route for non-target terrestrial plants located in the vicinity of the treated area and has been estimated using Rautmann et al (2001) 90th percentile spray drift data.

Based on use of the maximum application rate for asulam and the lowest (most sensitive) derived seedling emergence (pre-emergence) and vegetative vigour (post-emergence) EC_{50} values, a standard SANCO/10329 'Tier 2' deterministic risk assessment has been conducted in the following table.

Table 2.6.8 Non-target plant deterministic risk assessment - using the most sensitive seedling emergence and vegetative vigour toxicity EC_{50} values.

Distance m	Drift rate %	PEC g asulam/ha	Seedling emergence (pre-emergence) TER values (based on an EC_{50} of 228 g asulam/ha)	Vegetative vigour (post emergence) TER values (based on an EC_{50} of 11 g asulam/ha)
0	100	2400	**0.095**	**0.0046**
1	2.77	66.48	**3.43**	**0.17**
5	0.57	13.68	16.67	**0.80**
10	0.29	6.96	32.76	**1.58**
20	0.15	3.60	63.33	**3.06**
30	0.10	2.40	95.00	**4.58**
40	0.07	1.68	135.71	6.55

Note: figures in bold indicate areas of concern

Overall to identify an acceptable risk, based on the use of the most sensitive reported EC_{50} values and the need for a TER of greater than 5, with respect to pre-emergence seedling emergence effects, a 5 metre buffer zone would be required and with respect to post-emergence (vegetative vigour) effects, a 40 metre buffer zone would be required.

Need for further 'higher' tier risk assessment

When considered previously by EFSA /Member States (EFSA Conclusion Report 2010), the largest permissible no-spray buffer zone was considered to be 30 metres. Given that the above deterministic risk assessment indicated the need for a buffer zone of 40 metres, this was not considered acceptable. Consequently, a data gap was set to address the risk to non-target plants – with this being specified as a 'critical area of concern'. The Notifier has addressed this data gap by conducting a probabilistic risk assessment, which takes into account the likely distribution of sensitive non-target plants - as outlined in Section 7.3 of SANCO/10329 (October 2002) terrestrial ecotoxicology guidance – details for which are presented in Section B.9.9.2 of the Volume 3 Assessment report.

Based on the probabilistic risk assessment (which is considered valid by the RMS) a vegetative vigour median HC_5 value of 13.82 g asulam /ha is concluded as the most sensitive relevant regulatory endpoint. Without spray drift risk mitigation, spray drift exposure is estimated to be 66.48 g asulam /ha – which is greater than the vegetative vigour HC5 of 13.82 g asulam /ha indicating a potential risk. However, when a 5 metre 'no-spray buffer zone is included, spray drift exposure is reduced to 13.68 g asulam /ha – which is less than the HC5 value – indicating an acceptable risk.

RMS's conclusions regarding risk to non-target plants

Risk mitigation measures are required to be included in order to provide an acceptable risk to non-target plants. However, as demonstrated by a higher tier probabilistic risk assessment, provided a 5 metre spray drift buffer zone is included (or other appropriate risk mitigation measures), the proposed use of asulam in spinach and flower bulb crops will pose an acceptable risk to non-target plants.

2.6.10 Effects on biological methods of sewage treatment

Normal outside agricultural/horticultural use is not considered likely to result in significant exposure of sewage treatment works from the proposed crop uses of asulam. Additionally, the results of two studies conducted to determine effects of asulam on wastewater treatment processes /microbial respiration indicate a lack of adverse effects. A low and acceptable risk from the proposed crop uses is therefore concluded.

2.6.11 Overall Ecotoxicology Risk Assessment Conclusions

The proposed uses of asulam sodium (formulated as 'Asulox') in spinach and flower bulb crops pose an acceptable risk to birds, other terrestrial vertebrates, terrestrial crop dwelling 'other non-target arthropods', earthworms, soil macro-organisms, soil micro-organisms, and biological sewage treatment processes.

Details included in a single published paper indicate the possible potential for contamination of hive honey as a result of bees foraging in treated grassland meadows (see Sections B.9.4.3 and B.9.11.1 for further details). However, the evidence for this is limited and this grassland use differs from that proposed. Also the conducted standard bee acute oral and dermal 'hazard quotient' risk assessment indicates a low risk to bees from the proposed crop uses. EFSA /Member States to consider whether any further evaluation is required.

The log Pow values of asulam and its metabolites are well below the bioaccumulation trigger value of log 3.0, indicating a lack of potential for bioaccumulation in fish and other aquatic organisms.

The aquatic life risk assessment indicates that the proposed uses in spinach and flower bulb crops require the inclusion of risk mitigation measures (e.g. 5 metre no-spray buffer zone plus vegetative strip to reduce run-off by 80%) in order to provide an acceptable risk to aquatic life.

Also, for the proposed crop uses, there is a high risk to non-target plants situated adjacent to the target crop, with risk mitigation measures required to provide an acceptable risk (e.g. a 5 metre no-spray buffer zone).

LEVEL 3

Asulam sodium

LEVEL 3: CONCLUSIONS AND PROPOSED DECISION WITH RESPECT TO THE CRITERIA AND REQUIREMENTS OF REGULATION (EC) NO. 1107/2009

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.	X		It is considered that Article 4 of Regulation (EC) No 1107/2009 is complied with for asulam sodium for use as a herbicide on spinach and ornamental flower bulbs (refer to Level 1, Table 1.5.1. for further details of the representative uses considered).
3.1.1.2 Submission of further information				
		Yes	No	
i)	It is considered that a complete dossier has been submitted	X		A complete dossier has been submitted to allow the conduct of a comprehensive risk assessment.
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.			
3.1.1.3 Restrictions on approval				
		Yes	No	
	It is considered that in line with Article 6 of Regulation		X	No specific restriction is proposed as a result of this

	(EC) No 1107/2009 approval should be subject to conditions and restrictions.			evaluation, other than purity should be specified as a minimum purity of 876 g/kg asulam sodium (dry weight basis). This is unchanged from the purity specified in the previous approval and is supported by the most recent batch analysis.
3.1.1.5 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).	X		See comments below 'Impact on human health – ADI, AOEL, ARfD'
	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: (a) permits any residue of concern to be defined; (b) reliably predicts the residues in food and feed, including succeeding crops (c) reliably predicts, where relevant, the corresponding residue level reflecting the effects of processing and/or mixing; (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; (e) permits, where relevant, concentration or dilution	X		See 2.4 above for further details. The data submitted are sufficient to establish the nature and magnitude of residues in crops and in foodstuffs of animal origin that are likely to result from the proposed use of asulam sodium on spinach. Estimates of human dietary intakes of residues indicate that the risk to consumers is well within acceptable limits. Estimates of human dietary intakes of residues indicate that the risk to consumers is well within acceptable limits < 10% of the ADI and < 70% of the ARfD.

	factors due to processing and/or mixing to be defined.			
	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.	X		This is considered to apply to the representative uses examined.
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.	X		Sufficient information was submitted to demonstrate control of several weeds in both spinach and tulips at the proposed rates and no unacceptable effects were observed on plant parts or plant products. A detailed examination will be necessary of all the data at product authorisation.
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.	X		This applies to all representative uses considered as part of this evaluation. The soil metabolite sulphanilamide is considered to be low risk at the levels found and not ecotoxicologically or toxicologically relevant.
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.	X		Sufficient information has been presented to support the declared technical specification of asulam sodium with respect to the identity and content of impurities in the specification.
	It is considered that the specification is in compliance with the relevant Food and Agriculture Organisation specification, where such specification exists.	X		FAO specification for asulam sodium technical is available.
	It is considered for reasons of protection of human or animal health or the environment, stricter specifications	X		Asulam (240/TC/M/3, CIPAC H, p. 26) The asulam content shall be declared (not less than 800 g/kg,

	than that provided for by the FAO specification should be adopted			equivalent to 876 g/kg asulam-sodium) and, when determined, the content obtained shall not differ from that declared by more than ± 25 g/kg.
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.	X		The information submitted with regards to methods of analysis is sufficient to support approval. Refer also to Level 2, Section 2.2.
	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.	X		The information submitted with regards to methods of analysis is sufficient to support approval. Refer also to Level 2, Section 2.2
	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.	X		Refer to Level 2, Section 2.2 for further details.
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.	X		The reference values were decided upon in the previous consideration of Asulam sodium and remain applicable. ADI= 0.36mg/kg bw/d (NOAEL rat chronic study plus SF 100) ARfD= 1mg/kg bw/d (NOAEL 12 month dog study plus SF 100) AOEL= 0.46mg/kg bw/d (NOAEL rat multi-generation study

				plus SF 100) See sections 2.3.2-2.3.4 for further details.
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.**		X	No new data was provided with this submission and the conclusion from the assessment in 2010 is re-proposed (see section 2.3). Asulam sodium is not an in vivo mutagen and classification as mutagen category 1A or 1B is not required.
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.**		X	There was no clear evidence of treatment related carcinogenicity in an adequate programme of well conducted studies in rats and mice. See section 2.3.
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	N/A		Not applicable. Asulam sodium is not classed as a carcinogen.

	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.**		X	Reproductive and developmental toxicity of Asulam sodium was investigated in a multigeneration study in the rat and developmental studies in the rat and rabbit. There was a reduction in litter size reported in the rat multigeneration study (see section 2.3). As this was the only reproductive finding, it is considered insufficient for classification as toxic for reproduction category 1A or 1B.
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		Not applicable. Asulam sodium is not classified for reproductive 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**		X	No treatment related tumours were reported after exposure to Asulam sodium in rats or mice. The active substance does not qualify for classification as carcinogenic category 2. Furthermore, the only reproductive effect is a reduction in litter size which in isolation is not sufficient to warrant classification as toxic for reproduction category 2. The 1st interim criterion

	endocrine disrupting properties			for endocrine disruption is not fulfilled. See section 2.3.
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**		X	The only reproductive effect is a reduction in litter size which in isolation is not sufficient to warrant classification as toxic for reproduction category 2. There were no significant toxic effects reported on endocrine organs in this evaluation (see section 2.3). Therefore, the 2nd interim criterion for endocrine disruption is also not fulfilled.
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		Not applicable. Asulam sodium is not classed as an endocrine disruptor.
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.		X	Asulam sodium does not fulfil the POP criteria laid out in Regulation 1107/2009. The DT_{50} in water, soil and sediment is significantly less than the criteria for persistence. The bioconcentration factor is 0.1 to 1.4.The logKow (25°C) is 0.15, 0.11 and 0.77 at pH 4, 7 and 9 respectively. There is no evidence of potential for long-range transport.

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.		X	Asulam sodium does not fulfil the PBT criteria laid out in Regulation 1107/2009. The DT_{50} in water, soil and sediment is significantly less than the criteria for persistence. Additionally, the log Pow value of asulam (and also of its metabolites) is below the bioaccumulation trigger value of log 3.0 (asulam log Pow = 0.15), indicating a lack of potential for bioaccumulation in fish and other aquatic organisms.
Very persistent and very bioaccumulative substance (vPvB).				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a a very persistent and very bioaccumulative substance (vPvB) as laid out in Regulation 1107/2009 Annex II Section 3.7.3.		X	Asulam sodium does not fulfil the the vPvB criteria laid out in Regulation 1107/2009. The DT_{50} in water, soil and sediment is significantly less than the criteria for persistence and the bioconcentration factor is 0.1 to 1.4.
Ecotoxicology				
		Yes	No	
	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, provided appropriate risk mitigation measures are included.	X		The proposed uses of asulam sodium (formulated as 'Asulox') in spinach and flower bulb crops poses an acceptable risk to birds, other terrestrial vertebrates, terrestrial crop dwelling 'other non-target arthropods', earthworms, soil macro-organisms, soil micro-organisms, and biological sewage treatment processes. Details included in a single published paper indicate the possible potential for contamination of hive honey as a result of bees foraging in treated grassland meadows (see Sections B.9.4.3 and B.9.11.1 for further details). However, the evidence for this is limited and this grassland use differs from that proposed. Also the conducted standard bee acute oral and dermal 'hazard quotient' risk assessment indicates a low risk to bees from the proposed crop uses. The log Pow values of asulam and its metabolites are well

				below the bioaccumulation trigger value of log 3.0, indicating a lack of potential for bioaccumulation in fish and other aquatic organisms. The aquatic life risk assessment indicates that the proposed uses in spinach and flower bulb crops require the inclusion of risk mitigation measures (e.g. 5 metre no-spray buffer zone plus vegetative strip to reduce run-off by 80%) in order to provide an acceptable risk to aquatic life. Also, for the proposed crop uses, there is a high risk to non-target plants situated adjacent to the target crop, with risk mitigation measures required to provide an acceptable risk (e.g. a 5 metre no-spray buffer zone).
	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 organisms.		X	Based on lack of endocrine disrupting effects concluded in Section B.6.10 of the Mammalian Toxicology evaluation, adverse endocrine related effects on any exposed wild mammals are not considered likely. There are currently no defined criteria for identifying avian endocrine disruptors under 1107/2009 and because of this a full regulatory assessment of asulam's endocrine disrupting properties cannot be made at this time. No evidence in relation to the potential for endocrine related effects in fish have been provided and no specific risk assessment for this is included.
	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.		X	There is the potential for exposure to non-target organisms (including vertebrates e.g. birds, wild mammals and fish). However, there is no evidence to indicate that endocrine effects are likely.
	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			Details included in a single published paper indicate the possible potential for contamination of hive honey as a result of bees foraging in treated grassland meadows (see Sections B.9.4.3 and B.9.11.1 for further details). However, the

	containing this active substance: — 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.			evidence for this is limited and this grassland use differs from that proposed. Also the conducted standard bee acute oral and dermal 'hazard quotient' risk assessment indicates a low risk to bees from the proposed crop uses. EFSA/Member States to consider whether the currently included bee risk assessment is sufficient.
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.	X		It is considered sufficient data have been submitted to establish the residue definition for both risk assessment and enforcement purposes.
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		Groundwater modelling with PEARL v4.4.4 and PELMO v.4.4.3. The PECgw for the representative uses on spinach and flower bulbs for both asulam and major soil metabolite, sulphanilamide, are <0.001 µg/L for all scenarios.

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		X	It is considered as a result of the evaluation of asulam sodium **does not meet** the criteria necessary to identify it as a candidate as follows: The ADI, ARfD or AOEL is not significantly lower than those of the majority of the approved active substances within groups of substances/use categories, — it does not meets the criteria to be considered as a PBT substance — there are no reasons for concern linked to the nature of the critical effects (such as developmental neurotoxic or immunotoxic effects) which, in combination with the use/exposure patterns, amount to situations of use that could still cause concern, for example, high potential of risk to groundwater; even with very restrictive risk management measures (such as extensive personal protective equipment or very large buffer zones), — it does not contain a significant proportion of non-active isomers, — it is not classified or proposed for classification, in accordance with the provisions of Regulation (EC) No

				1272/2008, as carcinogen category 1A or 1B, if the substance has not been excluded in accordance with the criteria laid down in point 3.6.3, — it is not to 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 if the substance has not been excluded in accordance with the criteria laid down in point 3.6.4, - it is not considered to have endocrine disrupting properties that may cause adverse effects in humans.

3.1.3 Proposal – Low risk active substance

Low-risk active substances				
		Yes	No	
	It is considered that the active substance **shall be considered of low risk.** 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: — carcinogenic, — mutagenic, — toxic to reproduction, — sensitising chemicals, — very toxic or toxic, — explosive, — corrosive. In addition it is considered that **the substance is NOT**: — persistent (half-life in soil more than 60 days), — has a bioconcentration factor higher than 100,		X	May not be regarded as of low risk because of environmental classification of H400 and H410 - 'Very toxic to aquatic life with long lasting effects'.

	— is deemed to be an endocrine disrupter, or — has neurotoxic or immunotoxic effects.			

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				
-				
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				
-				
3.1.4.6 Toxicology and metabolism				
-				
3.1.4.7 Residue data				

-				
3.1.4.8 Environmental fate and behaviour				
-				
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)
-	-

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)
-	-

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.)

[NOTE: all columns should be greyed if the material tested in the toxicological studies has not been demonstrated to be representative of the technical specification.]

Representative use		Spinach (X^1)	Ornamental flower bulbs (X^1)
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		
	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
Ecotoxicology risk assessment for bees: Details included in a single published paper indicate the possible potential for contamination of hive honey as a result of bees foraging in treated grassland meadows (see Sections B.9.4.3 and B.9.11.1 of Volume 3 for further details). However, the evidence for this is limited and grassland use differs from that proposed. Also, the conducted standard bee acute oral and dermal 'hazard quotient' risk assessment indicates a low risk to bees from the proposed crop uses. EFSA /Member States to consider whether any further evaluation is required.	Bees may forage in previously treated spinach and flower bulb fields and therefore consideration of the possibility of this route of exposure is relevant to these 'representative uses'.

3.2 PROPOSED DECISION

[redacted]

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

[redacted]

Appendix I

APPENDIX I: STANDARD TERMS AND ABBREVIATIONS

Technical Terms

A	ampere
Ach	acetylcholine
Ache	acetylcholinesterase
ADI	Acceptable Daily Intake
ADP	adenosine diphosphate
AE	acid equivalent
AFID	alkali flame-ionization detector or detection
A/G	albumin/globulin ratio
ai	active ingredient
ALD50	approximate median lethal dose 50%
ALT	alanine aminotransferase (SGPT)
AOEL	Acceptable Operator Exposure Level
AMD	automatic multiple development
ANOVA	analysis of variance
AP	alkaline phosphatase
approx	approximate
ARC	anticipated residue contribution
ARfD	acute reference dose
as	active substance
AST	aspartate aminotransferase (SGOT)
ASV	air saturation value
ATP	adenosine triphosphate
BCF	bioconcentration factor
bfa	body fluid
BOD	biological oxygen demand
bp	boiling point
BSAF	biota-sediment accumulation factor
BSE	bovine spongiform encephalopathie
BSP	bromosulfophthalein
Bt	bacillus thuringiensis
Bti	bacillus thuringiensis israelensis
Btk	bacillus thuringiensis kurstaki
Btt	bacillus thuringiensis tenebrionis
BUN	blood urea nitrogen
bw	body weight
c	centi-(x 10^{-2}
°C	degree celsius (centigrade)
CA	controlled atmosphere
CAD	computer aided design
CADDY	computer aided dossier and data supply (an electronic dossier interchange and archiving format)
cd	candela
CDA	controlled drop(let) application
cDNA	complementary DNA
CEC	cation exchange capacity
cf	confer, compare to

CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CL	confidence limits
cm	centimetre
CNS	central nervous system
COD	chemical oxygen demand
CPK	creatinine phosphatase
cv	coefficient of variation
Cv	ceiling value
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DES	diethylstilboestrol
DFR	dislodgeable foliar residue
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic Acid
dna	designated national authority
DO	dissolved oxygen
DOC	dissolved organic carbon
dpi	days pot inoculation
DRES	dietary risk evaluation system
DT	disappearance time
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
DWQG	drinking water quality guidelines
ε	decadic molar extinction coefficient
EC_{50}	effective concentration
ECD	electron capture detector
ECU	European currency unit
ED_{50}	median effective dose
EDI	estimated daily intake
ELISA	enzyme lined immunosorbent assay
e-mail	electronic mail
EMDI	estimated maximum daily intake
EPMA	electron probe micro analysis
ERC	environmentally relevant concentration
ERL	extraneous residue limit
F	field
F_o	parental generation
F_1	filial generation, first
F_2	filial generation, second
FIA	fluorescence immuno assay
FID	flame ionization detector
FOB	functional observation battery
fp	freezing point
FPD	flame photometric detector

FPLC	fast protein liquid chromatography
g	gram
G	glasshouse
GAP	Good Agricultural Practice
GC	gas chromatography
GC-EC	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionization detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GEP	good experimental practice
GFP	good field practice
GGT	gamma glutamyl transferase
GI	gastro-intestinal
GIT	gastro-intestinal tract
GL	guideline level
GLC	gas liquid chromatography
GLP	good laboratory practice
GM	geometric mean
GMO	genetically modified organism
GMM	genetically modified micro-organism
GPC	gel-permeation chromatography
GPPP	good plant protection practice
GPS	global positioning system
GSH	glutathion
GV	granulosevirus
h	hour(s)
H	Henry's Law constant (calculated as a unitless value) (see also K)
ha	hectare
Hb	haemoglobin
HCG	human chorionic gonadotropin
Hct	haematocrit
HDT	highest dose tested
hL	hectolitre
HEED	high energy electron diffraction
HID	helium ionization detector
HPAEC	high performance anion exchange chromatography
HPLC	high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography - mass spectrometry
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography
HRGC	high resolution gas chromatography
H_s	Shannon-Weaver index
Ht	haematocrit
I	indoor
I_{50}	inhibitory dose, 50%
IC_{50}	median immobilisation concentration
ICM	integrated crop management

ID	ionization detector
IEDI	international estimated daily intake
IGR	insect growth regulator
im	intramuscular
inh	inhalation
ip	intraperitoneal
IPM	integrated pest management
IR	infrared
ISBN	international standard book number
ISSN	international standard serial number
iv	intravenous
IVF	*in vitro* fertilization
k	kilo
K	Kelvin or Henry's Law constant (in atmospheres per cubic meter per mole) (see also H)[13]
K_{ads}	adsorption constant
K_{des}	apparent desorption coefficient
K_{oc}	organic carbon adsorption coefficient
K_{om}	organic matter adsorption coefficient
kg	kilogram
L	litre
LAN	local area network
LASER	light amplification by stimulated
LBC	loosely bound capacity
LC	liquid chromatography
LC-MS	liquid chromatography - mass spectrometry
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dose letalis media
LCA	life cycle analysis
LC_{Lo}	lethal concentration low
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LD_{Lo}	lethal dose low
LDH	lactate dehydrogenase
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level
LOD	limit of determination
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
LOQ	limit of quantification (determination)
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counter
LSD	least squared denominator multiple range test
LSS	liquid scintillation spectrometry
LT	lethal threshold
m	metre
M	molar

µm	micrometer (micron)
MC	moisture content
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
MDL	method detection limit
MFO	mixed function oxidase
µg	microgram
mg	milligram
MHC	moisture holding capacity
min	minute(s)
mL	millilitre
MLT	median lethal time
MLD	minimum lethal dose
mm	millimetre
mol	Mol
MOS	margin of safety
mp	melting point
MRE	maximum residue expected
mM	Milimoles
MRL	maximum residue level
mRNA	messenger ribonucleic acid
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
n	normal (defining isomeric configuration)
NAEL	no adverse effect level
nd	not detected
NEDI	national estimated daily intake
NEL	no effect level
NERL	no effect residue level
ng	nanogram
nm	nonometer
NMR	nuclear magnetic resonance
no	number
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOED	no observed effect dose
NOEL	no observed effect level
NOIS	notice of intent to suspend
NPD	nitrogen-phosphorus detector or detection
NPV	nuclear polyhedrosis virus
NR	not reported
NTE	neurotoxic target esterase
OC	organic carbon content
OCR	optical character recognition

ODP	ozone-depleting potential
ODS	ozone-depleting substances
OM	organic matter
op	organophosphorous pesticide
Pa	pascal
PAD	pulsed amperometric detection
2-PAM	2-pralidoxime
pc	paper chromatography
PC	personal computer
PCV	haematocrit (packed corpuscular volume)
PEC	Predicted Environmental Concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PED	plasma-emissions-detector
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIC	prior informed consent
pic	phage inhibitory capacity
PIXE	proton induced X-ray emission
pKa	negative logarithm (to the base 10) of the dissociation constant)
PNEC	predicted no effect concentration
po	by mouth
P_{ow}	partition coefficient between n-octanol and water
POP	persistent organic pollutants
ppb	parts per billion
PPE	personal protective equipment
ppm	parts per million
ppp	plant protection product
ppq	parts per quadrillion (10^{-24})
ppt	parts per trillion ($10^{-12)}$
PSP	phenolsulfophthalein
PrT	prothrombin time
PRL	practical residue limit
PT	prothrombin time
PTDI	provisional tolerable daily intake
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r	correlation coefficient
r^2	coefficient of determination
RBC	red blood cell
REI	restricted entry interval
Rf	retardation factor
RfD	reference dose
RH	relative humidity

RL_{50}	median residual lifetime
RNA	ribonucleic acid
RP	reversed phase
rpm	rotations per minute
rRNA	ribosomal ribonucleic acid
RRT	relative retention time
RSD	relative standard deviation
s	second
SAC	strong adsorption capacity
SAP	serum alkaline phosphatase
SAR	structure/activity relationship
SBLC	shallow bed liquid chromatography
sc	subcutaneous
sce	sister chromatid exchange
SD	standard deviation
se	standard error
SEM	standard error of the mean
SEP	standard evaluation procedure
SF	safety factor
SFC	supercritical fluid chromatography
SFE	supercritical fluid extraction
SIMS	secondary ion mass spectroscopy
SOP	standard operating procedures
sp	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
spp	subspecies
sq	square
SSD	sulphur specific detector
SSMS	spark source mass spectrometry
STEL	short term exposure limit
STMR	supervised trials median residue
t	tonne (metric ton)
$t_{½}$	half-life (define method of estimation)
T_3	tri-iodothyroxine
T_4	thyroxine
TADI	temporary acceptable daily intake
TBC	tightly bound capacity
TCD	thermal conductivity detector
TC_{Lo}	toxic concentration, low
TID	thermionic detector, alkali flame detector
TD_{Lo}	toxic dose low
TDR	time domain reflectrometry
TER	Toxicity Exposure Ratio
TER_1	toxicity exposure ration for initial exposure
TER_{ST}	toxicity exposure ration following repeated exposure
TER_{LT}	toxicity exposure ration following chronic exposure

tert	tertiary (in a chemical name)
TEP	typical end-use product
TGGE	temperature gradient gel electrophoresis
TIFF	tag image file format
TLC	thin layer chromatography
Tlm	median tolerance limit
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TMRC	theoretical maximum residue contribution
TMRL	temporary maximum residue limit
TOC	total organic carbon
Tremcard	Transport emergency card
tRNA	transfer ribonucleic acid
TSH	Thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor (safety factor)
ULV	ultra low volume
UV	ultraviolet
v/v	volume ratio (volume per volume)
WBC	white blood cell
wk	week
wt	weight
w/v	weight per volume
w/w	weight per weight
XRFA	X-ray fluorescence analysis
yr	year
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to

Organisations and Publications

ACPA	American Crop Protection Association
ASTM	American Society for Testing and Materials
BA	Biological Abstracts (Philadelphia)
BART	Beneficial Arthropod Registration Testing Group
CA	Chemical Abstracts
CAB	Centre for Agriculture and Biosciences International
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCFAC	Codex Committee on Food Additives and Contaminants
CCGP	Codex Committee on General Principles
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Food
CE	Council of Europe

CIPAC	Collaborative International Pesticides Analytical Council Limited
COREPER	Comite des Representants Permanents
EC	European Commission
ECB	European Chemical Bureau
ECCA	European Crop Care Association
ECDIN	Environmental Chemicals Data and Information Network of the European Communities
ECDIS	European Environmental Chemicals Data and Information System
ECE	Economic Commission for Europe
ECETOC	European Chemical Industry Ecology and Toxicology Centre
ECHA	European Chemicals Agency
ECLO	Emergency Centre for Locust Operations
ECMWF	European Centre for Medium Range Weather Forecasting
ECPA	European Crop Protection Association
EDEXIM	European Database on Export and Import of Dangerous Chemicals
EHC (number)	Environmental Health Criteria (number)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMIC	Environmental Mutagens Information Centre
EPA	Environmental Protection Agency
EPO	European Patent Office
EPPO	European and Mediterranean Plant Protection Organisation
ESCORT	European Standard Characteristics of Beneficials Regulatory Testing
EU	European Union
EUPHIDS	European Pesticide Hazard Information and Decision Support System
EUROPOEM	European Predictive Operator Exposure Model
FAO	Food and Agriculture Organisation of the UN
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FRAC	Fungicide Resistance Action Committee
GATT	General Agreement on Tariffs and Trade
GAW	Global Atmosphere Watch
GIFAP	Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques
GCOS	Global Climate Observing System
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GEDD	Global Environmental Data Directory
GEMS	Global Environmental Monitoring System
GIEWS	Global Information and Early Warning System for Food and Agriculture
GRIN	Germplasm Resources Information Network
HRAC	Herbicide Resistance Action Committee
IARC	International Agency for Research on Cancer
IATS	International Academy of Toxicological Science
IBT	Industrial Bio-Test Laboratories
ICBB	International Commission of Bee Botany
ICBP	International Council for Bird Preservation
ICES	International Council for the Exploration of the Seas

ICPBR	International Commission for Plant-Bee Relationships
ILO	International Labour Organisation
IMO	International Maritime Organisation
IOBC	International Organisation for Biological Control of Noxious Animals and Plants
IPCS	International Programme on Chemical Safety
IRAC	Insecticide Resistance Action Committee
IRC	International Rice Commission
ISCO	International Soil Conservation Organisation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JECFA	FAO/WHO Joint Expert Committee on Food Additives
JFCMP	Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme
JMP	Joint Meeting on Pesticides (WHO/FAO)
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
NATO	North Atlantic Treaty Organisation
NAFTA	North American Free Trade Agreement
NCI	National Cancer Institute (USA)
NCTR	National Centre for Toxicological Research (USA)
NGO	non-governmental organisation
NTP	National Toxicology Programme (USA)
OECD	Organisation for Economic Co-operation and Development
OLIS	On-line Information Service of OECD
PAN	Pesticide Action Network
RNN	Re-registration Notification Network
RTECS	Registry of Toxic Effects of Chemical Substances (USA)
SCPH	Standing Committee on Plant Health
SETAC	Society of Environmental Toxicology and Chemistry
SI	Systeme International d'Unites
SITC	Standard International Trade Classification
TOXLINE	Toxicology Information On-line
UN	United Nations
UNEP	United Nations Environment Programme
WCDP	World Climate Data Programme
WCP	World Climate Programme
WCRP	World Climate Research Programme
WFP	World Food Programme
WHO	World Health Organisation
WTO	World Trade Organisation
WWF	World Wildlife Fund

Appendix II

APPENDIX II: SPECIFIC TERMS AND ABBREVIATIONS

Technical Terms

ADME	adsorption, distribution, metabolism and excretion
ADR	European agreement concerning the international carriage of dangerous goods by road
AR	applied radioactivity
AUC	area under curve
CHO	Chinese hamster ovary
EC	emulsifiable concentrate
EVOH	ethyl vinyl alcohol
HDPE	high density polyethylene
HPT	hypothalamus-pituitary-testicular
K_{ads}	adsorption constant
K_F	freudlich coefficient
K_{OH}	hydroxyl radical rate constant
K_{OW}	octanol water partition coefficient
LH	Luteinizing Hormone
LOQ	limit of quantification
MATC	Maximum Acceptable Toxic Concentration
MMAD	mass median aerodynamic diameter
Mbq	Mega becquerels
MS	Member State
MWHC	maximum water holding capacity
NMS	Northern Member State
OM	Organic Matter
P_0 / P_1	parental generation, first (author dependent)
PCN	potato cyst nematode
PDE	potential dermal exposure
PEC_a	predicted environmental exposure in air
PEC_{gw}	predicted environmental exposure in ground water
PEC_s	predicted environmental exposure in soil
PEC_{sw}	predicted environmental exposure in surface water
PELMO	Pesticide Leaching Model
PHED	Pesticide Handlers Exposure Database
pKa	dissociation constant
POEM	Predictive Operator Exposure Model
PPE	personal protective equipment
r^2	correlation coefficient
RPE	respiratory protective equipment
RSD	relative standard deviation
s	second
SC	suspension concentrate
SMS	Southern Member State
TER	toxicity exposure ratio
TLC	thin layer chromatography
WP	wettable powder

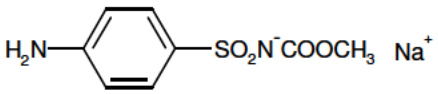
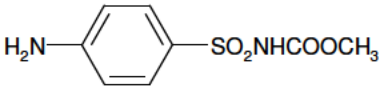
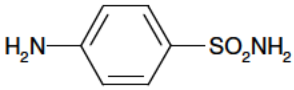
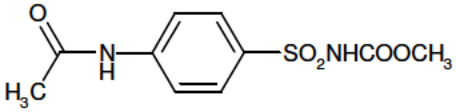
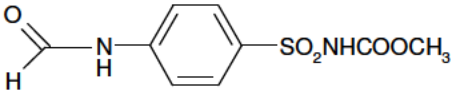
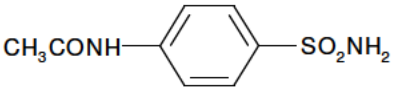
Organisations and Publications

BBA	Federal Biological Research Centre for Agriculture and Forestry (Germany)
EPA	Environmental Protection Agency (USA)
Defra	Department for the Environment Food and Rural Affairs (UK)
CRD	Chemicals Regulation Directorate (UK)

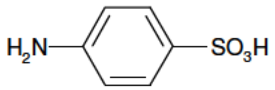
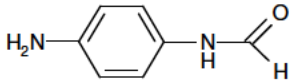
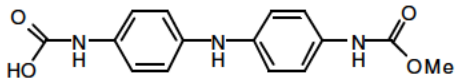
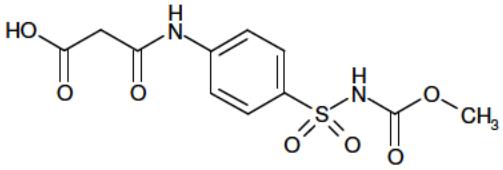
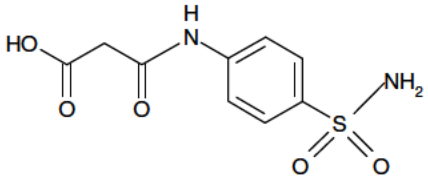
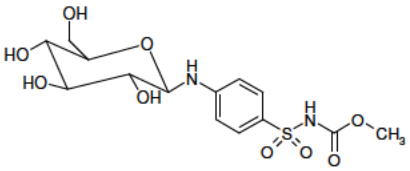
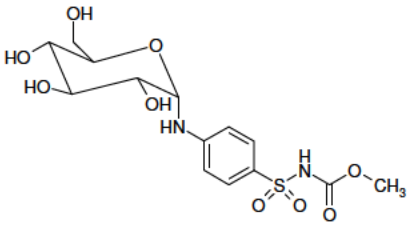
Appendix III

APPENDIX III: LIST OF METABOLITES IN THE ENVIRONMENT, PLANTS AND ANIMALS

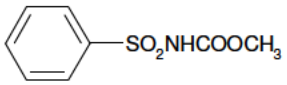
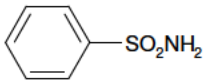
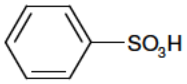
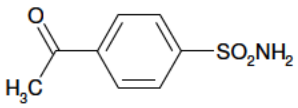
Substances and metabolites; structures, codes and synonyms

Structure, chemical name and CAS Number (where available)	Other names/codes used	Occurrence	Importance
 Sodium methyl [(4-aminophenyl)sulphonyl]carbamate CAS RN 2302-17-2	Asulam-sodium Sodium asulam (Asulox) AE F102789 RPA413636 Hoe 102789 AE C518360	Active substance	Active substance Found in all categories
 Methyl sulphanilylcarbamate CAS RN 3337-71-1	Asulam AE F074383 M&B 9057, MB009057, RPA096215, RPA590048, Hoe 074383 AE B106159	Free acid of active substance	Free acid of active substance
 4-Aminobenzenesulphonamide CAS RN 63-74-1	Sulphanilamide / sulfanilamide AE C473799 MB000631 MB000863 RP014501 RPA023385 RPA718068	Animal Soil Processing	Minor Major Potential degradate
 Methyl [(4-acetamidophenyl)sulphonyl]carbamate CAS RN 18431-25-9	Acetyl asulam AE F073557 MB 9495 MB009495 Hoe 073553 AE C440740	Animal Plant Soil	Major in rat Minor Very minor
 Methyl{[(4-formylamino)phenyl] sulfonyl}carbamate	Formyl asulam	Plant	Minor
 N-(4-Sulphamoylphenyl)acetamide CAS RN 121-61-69 CAS RN 5661-14-3	Acetyl sulphanilamide AE F073547 MB24805 MB024805 Hoe 073547 AE C418106 AE C426035 AE C500816	Animal Soil	Major in poultry and ruminants, minor in rat Very minor

List of metabolites in the environment plants and animals

Structure, chemical name and CAS Number (where available)	Other names/codes used	Occurrence	Importance
 Aminobenzenesulphonic acid CAS RN 121-57-3	Sulphanilic acid AE B0041074-	Soil Water + light	Very minor Major in laboratory study, minor in environment
 N-(4-Aminophenyl)formamide	AP Formamide	Water + light	Major in laboratory study, minor in environment
 (4-(4-methoxycarbonylaminophenyl)aminophenyl) carbamic acid	MCAPAP carbamic acid	Water + light	Major in laboratory study, minor in environment
 4-(N-methoxycarbonylsulphamoyl)phenylcarbamoyl acetic acid	Malonyl-asulam AE 1388213	Plant	Major
 4-Sulphamoylphenylcarbamoylacetic Acid	Malonyl-sulphanilamide	Processing	Potential degradate
  Asulam glucosides	Asulam-glc	Plant	Major

List of metabolites in the environment plants and animals

Structure, chemical name and CAS Number (where available)	Other names/codes used	Occurrence	Importance
 Methyl phenylsulphonylcarbamate (methylbenzenesulphonylcarbamate) CAS RN 32324-23-5	MBSC Desamino asulam MB022232	Plant Soil	Very minor Very minor
 Benzenesulphonamide CAS RN 98-10-2	-	Soil	Very minor
 Benzenesulphonic acid CAS RN 98-11-3	-	Soil	Minor in early leaching study.
 4-Acetylbenzenesulphonamide CAS RN 1565-17-9	-	Plant	Very minor. (not found in spinach)

Appendix IV

APPENDIX IV: GUIDANCE DOCUMENTS USED IN THIS ASSESSMENT

GUIDANCE DOCUMENTS USED IN THIS ASSESSMENT

Ecotoxicology guidance documents:

SANCO/3268/2001 (October 2002): 'Guidance document on Aquatic Ecotoxicology'.
SANCO/10329/2002 (October 2002): 'Guidance document on Terrestrial Ecotoxicology'.
EFSA (2009): 'Risk Assessment for Birds and Mammals'.
SETAC (2000) 'Guidance document on Regulatory testing and risk assessment procedures for plant protection products with non-target arthropods' ('ESCORT 2').

Appendix V

APPENDIX V: SPECIFIC REFERENCES USED IN THIS ASSESSMENT

REFERENCE LIST

Conclusion on the peer review of the pesticide risk assessment of the active substance asulam, EFSA Journal 2010; 8(12): 1822

Appendix VI

APPENDIX VII: LIST OF END POINTS

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Asulam sodium (ISO 1750 published)
Function (*e.g.* fungicide)	Herbicide

Rapporteur Member State	United Kingdom
Co-rapporteur Member State	-

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	sodium methyl (EZ)-sulfanilylcarbonimidate
Chemical name (CA) ‡	methyl N-[(4-aminophenyl)sulfonyl]carbamate sodium salt (1:1)
CIPAC No ‡	240.011
CAS No ‡	2302-17-2
EC No (EINECS or ELINCS) ‡	218-953-8
FAO Specification (including year of publication) ‡	Asulam sodium technical, 240/TC/S/F (1997)
Minimum purity of the active substance as manufactured ‡	876 g/kg (asulam sodium) 800 g/kg (asulam)
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	g/kg
Molecular formula ‡	$C_8H_9N_2O_4S$ Na
Molecular mass ‡	252.2 g/mol

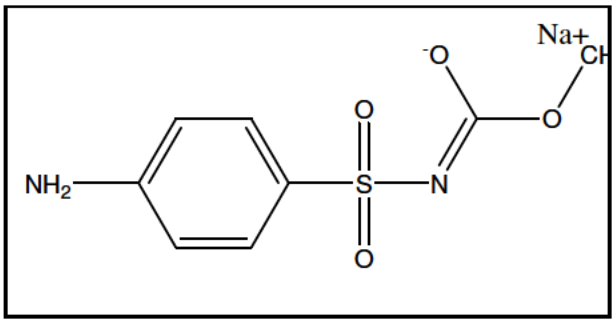
‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Structural formula ‡



Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	230°C °C (99.1%)
Boiling point (state purity) ‡	Not measured, decomposes above 230°C
Temperature of decomposition (state purity)	>230°C (99.1%)
Appearance (state purity) ‡	White solid (99.1%)
Vapour pressure (state temperature, state purity) ‡	5 x 10^{-7} Pa at 45°C (99.1%)
Henry's law constant ‡	<1.31 x 10^{-10} Pa m^3 mol^{-1}
Solubility in water (state temperature, state purity and pH) ‡	962g/l at pH 8 and 20°C (99.1%) 5.5 g/L at pH 4 and 20°C (99.1%) 1048 g/L at pH 9 and 20°C (99.1%)
Solubility in organic solvents ‡ (state temperature, state purity)	n-heptane 0.00007 g/l at 25°C(99.1%) xylene 0.098 g/l at 25°C(99.1%) dichloromethane 0.033 g/l at 25°C (99.1%) methanol 117 g/l at 25°C (99.1%) n-octanol 0.03 g/l at 25°C (99.1%) acetone 1.1 g/l at 25°C (99.1%) ethyl acetate 0.5 g/l at 25°C (99.1%) acetonitrile 2.3 g/l at 25°C (99.1%)
Surface tension ‡ (state concentration and temperature, state purity)	71.5 mN/m at 20°C mN/m (90 % saturated solution)(89.6%) – 1 g/l

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Partition co-efficient ‡ (state temperature, pH and purity)	Log P_{ow} = 0.15 at pH7 and 25°C (99.1%) Log P_{ow} = 0.11 at pH 4 and 25°C (99.1%) Log P_{ow} = 0.77 at pH 9 and 25°C (99.1%)
Dissociation constant (state purity) ‡	pKa1 = 1.29 at 20°C (99.1%) pKa2 = 4.68 at 20°C (99.1%)
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	UV absorb 203 nm (ε = 22177 l mol^{-1} cm^{-1}) (99.1%) UV absorb 293 nm (ε = 2750 l mol^{-1} cm^{-1}) (99.1%)
Flammability ‡ (state purity)	Not highly flammable
Explosive properties ‡ (state purity)	Non-explosive
Oxidising properties ‡ (state purity)	Non-oxidising

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Summary of intended uses

Crop and/or situation (a)	Member State	Product Name	F G 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 a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	Kg a.s./hl min max (g/hl)	Water l/ha min max	Kg a.s./ha min max (*) (g/ha)		
Spinach	Belgium, Nether-lands	Asulox	F	Pre-emergence broadleaved and grass weeds. Post-emergence broadleaved and grass weeds.	SL	400 g/L asulam = 438 g/L asulam sodium	Ground boom sprayers	Until 3 days after sowing at the latest. The seed may not be pre-emerged. (spring-summer) **or** Post-emergence BBCH 12-14 (spring-summer)	1	-	-	200-600	2.4 asulam = 2.628 asulam sodium	28	For consumption and for seed cultivation.
Tulip, hyacinth and lily (bulb production)	Netherlands	Asulox	F	Composite weeds (camomile, groundsel) and vetch weeds.	SL	400 g/L asulam = 438 g/L asulam sodium	Ground boom sprayers	Post-emergence when the weeds have a height of 4 to 6 cm (spring-summer)	1	-	-	200-600	1.6- 2.4 asulam = 1.752 - 2.628 aslam sodium	n.a	Apply on a hardened and dry crop. During spraying and until a few hours later the weather has to be dry and growing

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List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage range from first to 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
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

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List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Methods of Analysis

Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (analytical technique)	Asulam in technical material was determined by HPLC-UV (270 nm), using a C18 column [identification was based on MS and retention times of certified standards].
Impurities in technical as (analytical technique)	Organic impurities were determined by HPLC-UV or by GC-FID, a CP capillary column [identification was based on MS spectra and retention times of certified standards] (limit of determination [redacted])
Plant protection product (analytical technique)	Asulam in the plant protection product was determined by HPLC-UV (270 nm), using a C18 column. [redacted] in the plant protection product was determined by HPLC-UV (270 nm), using a C18 column (limit of determination [redacted]). Methanol in the plant protection product was determined by GC-FID, using a CP-PoraBOND column (limit of determination 3g/l).

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Asulam plus its metabolite malonyl-asulam expressed as asulam.
Food of animal origin		Asulam plus its metabolite acetyl sulphanilamide expressed as asulam.
Soil		Asulam (and its metabolite sulfanilamide)
Water	surface	Asulam (and its metabolite sulfanilamide)
	drinking/ground	Asulam (and its metabolite sulfanilamide)
Air		Asulam

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Methods of Analysis

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Asulam (and its metabolite malonyl-asulam) residues in plants and plant products (Spinach, Orange, Barley Grain and Sunflower Seed) were determined by extraction with acetonitrile/water and the resulting extracts evaporated to an aqueous remainder and analysed by LC/MS/MS (monitoring for in the case of parent asulam the precursor ion m/z 231 and the product ion m/z 156 and for its metabolite malonyl-asulam the precursor ion m/z 317 and the product ion m/z 242), using a C_{18} column. The limit of determination was 0.1 mg/kg (asulam plus its metabolite malonyl-asulam expressed as asulam).
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Asulam (and its metabolites containing the sulphanilamide moiety) residues in animal products (milk, muscle, fat, kidney and egg) were determined by extracted with acetonitrile/acidified water (for milk methanol/acetonitrile/acidified water) and the resulting extracts acetylated using sodium acetate/acetic anhydride, converting asulam (and its metabilites acetylasulam and sulphanilamide) to its metabolite acetylasulam, which was in turn converted to acetylsulfanilamide. The resulting extracts were analysed by HPLC-MS/MS (monitoring for the precursor ion m/z 215 and the product ion m/z 198), using a Luna 5C column. The limit of determination was 0.01 mg/kg.
Soil (analytical technique and LOQ)	Asulam (and its metabolite sulphanilamide) residues in water were determined by directly injected into a LC/MS/MS (monitoring for the precursor ion 231 and the product ion m/z 156 [and 92 for confirmation] for asulam and for its metabolite sulphanilamide the precursor ion m/z 173 and the product ion m/z 156 [and 92 for confirmation]), using a C18 column. The limit of determination was 0.05 µg/l for asulam and sulphanilamide in surface and drinking water.

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List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Methods of Analysis

Water (analytical technique and LOQ)	Asulam (and its metabolite sulphanilamide) residues in water were determined by directly injected into a LC/MS/MS (monitoring for the precursor ion 231 and the product ion m/z 156 [and 92 for confirmation] for asulam and for its metabolite sulphanilamide the precursor ion m/z 173 and the product ion m/z 156 [and 92 for confirmation]), using a C18 column. The limit of determination was 0.05 µg/l for asulam and sulphanilamide in surface and drinking water.
Air (analytical technique and LOQ)	Asulam residues in air were determined by drawing air through a XAD adsorption tube and extracting the tube with methanol. The resulting extracts were analysed by HPLC/MS/MS, using a C_{18} column. The limit of determination was 10 µg/m^3.
Body fluids and tissues (analytical technique and LOQ)	No methods of analysis were submitted or required as asulam is not classified as toxic.

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

	RMS/peer review proposal
Active substance	-

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Mammalian toxicology

Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption ‡	Rapid and extensive ≥80%
Distribution ‡	Rapid and widely distributed particularly to carcass, muscle, skin/fur and uterus
Potential for accumulation ‡	No evidence of bioaccumulation but limited evidence of preferential binding to blood cells
Rate and extent of excretion ‡	Rapid >80% in urine after 24 hours, limited biliary excretion (3-5%)
Metabolism in animals ‡	Mainly parent (69- 80%), major metabolite acetyl-asulam (2-16%)
Toxicologically relevant compounds ‡ (animals and plants)	Asulam and Sulphanilamide
Toxicologically relevant compounds ‡ (environment)	Asulam

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 5000 mg/kg bw	
Rat LD_{50} dermal ‡	> 2000mg/kg bw	
Rat LC_{50} inhalation ‡	> 5.46mg/l	
Skin irritation ‡	Slight irritant	
Eye irritation ‡	Moderate irritant	
Skin sensitisation ‡	Sensitiser (Guinea pig maximisation test)	H317

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Rat: increased clotting time and reduced binding proteins in the blood, thyroid and kidney histopathology effects Dog:salivation and vomiting (both sexes), increased thyroid weight (males) and thyroid histopathology changes (both sexes)	
Relevant oral NOAEL ‡	Rat: 129mg/kg bw/d Dog: 100mg/kg bw/d	
Relevant dermal NOAEL ‡	> 1000mg/kg bw/d (rabbit 21 day study)	

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Mammalian toxicology

Relevant inhalation NOAEL ‡	No studies submitted	

Genotoxicity ‡ (Annex IIA, point 5.4)

	Not genotoxic based on weight of evidence	

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	Rat: reduced body weight gain (F), proliferation of the adrenal medulla (M), haematological effects (M&F) Mouse: Haematological effects e.g. reduced haematocrit and increased mean cell volume.	
Relevant NOAEL ‡	Rat: 36mg/kg bw/d	
Carcinogenicity ‡	No evidence of treatment-related tumours	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Reproduction: reduced litter size Parental: reduced body weight, increased thyroid weight (M) and decreased liver weight (F) Offspring: no effects reported	
Relevant parental NOAEL ‡	224mg/kg bw/d	
Relevant reproductive NOAEL ‡	46mg/kg bw/d	
Relevant offspring NOAEL ‡	1136mg/kg bw/d (highest dose tested)	

Developmental toxicity

Developmental target / critical effect ‡	Maternal (rabbit): Reduced body weight and body weight gain Developmental (rat): minor skeletal effects	
Relevant maternal NOAEL ‡	300mg/kg bw/d (rabbit)	
Relevant developmental NOAEL ‡	1000mg/kg bw/d (rat)	

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List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Mammalian toxicology

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	None-submitted- no effects noted in other studies in any species	
Repeated neurotoxicity ‡	None-submitted- no effects noted in other studies in any species	
Delayed neurotoxicity ‡	None submitted- no effects noted in other studies in any species	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	None
Studies performed on metabolites or impurities ‡	[redacted] Acute oral toxicity- LD50> 2000mg/kg bw/d (female rats) 28d oral (gavage) study (rat)- increased water intake, haematopoietic effects in liver, spleen and bone marrow. NOAEL= 30mg/kg bw/d Bacterial reverse mutation assay- negative L5178Y $TK^{+/-}$ mouse lymphoma assay- negative Chromosome aberration test with human lymphocytes- negative

Medical data ‡ (Annex IIA, point 5.9)

Medical surveillance data has no adverse findings recorded or known cases of ill-health.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.36mg/kg bw	Chronic 2y rat study	100
AOEL ‡	0.46mg/kg bw/d	Rat multi-generation study	100
ARfD ‡	1mg/kg bw/d	12-month dog study	100

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List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Mammalian toxicology

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (e.g. name 50 % EC)	Asulox 400g/L SC 0.5% concentrate 3% in-use dilution

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Operator exposure estimates using the German Model predict that the supported use of 'Asulox' on spinach and ornamentals through tractor-mounted/trailed field crop sprayers will result in a level of systemic exposure to asulam equivalent to 11% of the AOEL for an operator without PPE. Corresponding UK POEM estimates predict a level of systemic exposure for an operator without PPE equivalent to 68% of the AOEL.
Workers	Worker exposure estimates using the EUROPOEM worker re-entry model predict levels of systemic exposure equivalent to 16% of the AOEL for workers harvesting spinach and 31% of the AOEL for workers harvesting ornamentals without the use of PPE.

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List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Mammalian toxicology

Bystanders	Using the UK approach the following levels of bystander/resident exposure to asulam are predicted from the proposed uses of 'Asulox'. • Vapour exposure (worst case): systemic exposure equivalent to 2% of the AOEL • Drift exposure: systemic exposure equivalent to 0.4% of the AOEL • Children's exposure to fallout on lawns: systemic exposure equivalent to 0.14% of the AOEL. Using the German approach the following levels of bystander/resident exposure are predicted to result from the proposed uses of 'Asulox'. • Adult bystander: systemic exposure equivalent to 0.08% of the AOEL. • Child bystander: systemic exposure equivalent to 0.06% of the AOEL. • Adult resident: systemic exposure equivalent to 0.07% of the AOEL. • Child resident: systemic exposure equivalent to 0.14% of the AOEL.

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

	RMS/peer review proposal
Substance classified (name)	Skin sensitisation Category 1- H317

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Residues

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Spinach
Rotational crops	Spinach, wheat and radish
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Spinach
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes
Plant residue definition for monitoring	Asulam plus its metabolite asulam-malonyl expressed as asulam
Plant residue definition for risk assessment	Asulam plus its metabolite asulam-malonyl expressed as asulam
Conversion factor (monitoring to risk assessment)	None

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Lactating goats and hens
Time needed to reach a plateau concentration in milk and eggs	Milk = 2 days Eggs = 7 days
Animal residue definition for monitoring	Asulam plus its metabolite acetyl sulphanilamide expressed as asulam
Animal residue definition for risk assessment	Asulam plus its metabolite acetyl sulphanilamide expressed as asulam
Conversion factor (monitoring to risk assessment)	None
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Residues

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

Rotational crop metabolism study indicates that a cold rotational crop study is not required.

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 Introduction)

Freezer storage stability study indicated that residues of asulam in spinach are stable for up to 3 months and its metabolite asulam-malonyl for at least 11 months.

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	No	No	No
Potential for accumulation (yes/no):			
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)			
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle	-	-	-
Liver	-	-	-
Kidney	-	-	--
Fat	-	-	-
Milk	-		
Eggs		-	

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List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Residues

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Spinach	N	<0.02, 0.14, 0.19, 0.22, 0.24, 0.29, 0.43, 0.54, 1.1, 1.6, 9.7, 23	-	30	23	0.36

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use
(c) Highest residue

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List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Residues

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Residues

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.36 (mg/kg bw/day)
TMDI (% ADI) – EFSA Model	Less than 10%
Total NEDI (% ADI) – UK Model	Less than 1%
ARfD	1 (mg/kg bw/day)
IESTI (% ARfD) – EFSA Model	Less than 70%
NESTI (% ARfD) – UK Model	Less than 70%

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Asulam/Malonyl asulam Canned spinach Cooked spinach Frozen spinach	9	 0.5 0.5 0.7		

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List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Residues

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Spinach	30 mg/kg
.....	
.....	
.....	

When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days ‡	6.1-7.5 % after 120 d, [^{14}C-Ph]-label (n[1]= 4) 31.5-6.17 % after 119 d, [^{14}C-Ph]-label (n= 4)
Non-extractable residues after 100 days ‡	63.9-76 % after 120 d, [^{14}C-Ph]-label (n= 4) 69.08-82.49 % after 119 d, [^{14}C-Ph]-label (n= 4)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	Sulphanilamide, Peak *13.9 %* at *14* d (n= 3) [^{14}C-PH] label

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡

Mineralization after 100 days	0.4 % after 120 d, [^{14}C-Ph]-label (n= 1) 0.7 % after 118 d, [^{14}C-Ph]-label (n= 1)
Non-extractable residues after 100 days	7.9 % after 120 d, [^{14}C-Ph]-label (n= 1) 48.5 % after 14 d, [^{14}C-Ph]-label (n= 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	None

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Parent DT_{50}: 3.71d irradiated; 6.69d dark controls Sulphanilamide: Irradiated: 3.6% after 10 d, 1.7% after 24 d, Dark controls: 10.7% after 10 d, 4.2% after 24d presumed to be photo-degrading in soil

[1] n corresponds to the number of soils.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type	X[1]	pH (KCl)	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	Chi^2 error	Method of calculation
Loam		6.7	20°C / 45 %	3.8 / 12.7	3.8	8.0	SFO
Sandy loam		5.1	20°C / 45 %	3.4 / 11.5	3.4	12.3	SFO
Silt loam		6.1	20°C / 45 %	2.1 / 7.1	2.1	13.0	SFO
Clay loam		7.3	20°C / 45 %	4.0 / 13.4	4.0	11.0	SFO
Sandy loam		4.9	20°C / 45 %	2.4 / 8.0	2.4	14.7	SFO
Silt loam		6.1	20°C / 45 %	4.8 / -	3.3	11.7	DFOP DT_{90}/3.32
Clay loam		7.3	20°C / 45 %	2.6 / 8.6	2.6	11.9	SFO
Loamy sand		5.2	20°C / 63	11.2 / 37.2	9.3	7.5	SFO
Clay loam		6.1	20°C / 90	7.1 / 23.6	7.0	7.7	SFO
Clay loam		7.3	20°C / 93	10.8 / 36	10.4	7.8	SFO
Loamy sand		3.9	20°C / 28	11.1 / 36.8	11.1	9.6	SFO
Sandy loam		5.01	20°C / 40	0.6 / 19.6	4.9	7.6	FOMC DT_{90}/3.322
Geometric mean/median					4.6*		
					4.7**		

* Overall geometric mean; ** geomean of sandy loam and silt loam calculated first

Sulphanilamide	Aerobic conditions							
Soil type	X[1]	pH (KCl)	t. °C / % MWHC	DT_{50} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	Chi^2 error	Method of calculation
Sandy loam		3.9	20°C / 42 %	76.5 [a]	-	76.3	6.1	DFOP
Clay Loam		7.0	20°C / 50 %	30.4 [b]	-	22.4	5.8	FOMC
Clay Loam		7.9	20°C / 50 %	16.4 [b]	-	21.9	7.3	FOMC

[1] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

Loamy sand		5.2	20°C / 63 %	7.3 [a]	-	6.0	3.9	DFOP
Clay loam		5.8	20°C / 90 %	3.1 [b]	-	3.1	4.0	FOMC
Loamy sand		3.9	20°C / 28 %	8.4 [a]	-	8.4	4.4	DFOP
Geometric mean/median			-	-	-	13.4	-	-

[a] ln(2)/DFOP slow phase rate constant [b] FOMC DT_{90}/3.322 [c] DFOP DT_{90}/3.322

Field studies ‡ No data, not required

pH dependence ‡ (yes / no) (if yes type of dependence)	None
Soil accumulation and plateau concentration ‡	Not studied. Not required

Laboratory studies ‡

Parent	Anaerobic conditions						
Soil type	X[2]	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam		6.7	20°C	356 / 1343	356	0.942	DFOP
Loamy sand		5.69	20°C	stable		n/a	Not calculated
Geometric mean/median							

Met 1	Anaerobic conditions							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ ~~DT_{90}~~ (d)	f. f. k_{dp}/ k_f	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation

[2] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

Loamy sand		5.69	20℃	195	-	195	7	SFO
Geometric mean/median								

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Asulam ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
PT102 Sandy loam	2.5	7.1			0.3879	15.5	0.728
PT103 Sandy Loam	1.3	5.5			0.3044	23.4	0.822
SK961089 Clay loam	5.4	7.5			0.832	15.4	0.712
LA98-983 Sand*	0.1	6			0.1497	149.7	0.817
LA99-3 Sandy silt loam	2.5	6.8			0.6379	25.5	0.733
Emperor Lake (sediment)*	6.1	6			2.59	42.5	0.684
Soil I, Silt loam	2.12	5.74			0.513	24.2	0.660
Soil II, Loam	4.93	4.6			3.28	66.5	0.870
Soil III, Loamy sand	1.4	6.05			0.218	15.6	0.700
Soil IV, Silty clay	3.93	7.36			0.677	17.2	0.770
Arithmetic mean/median						25.4	0.75
pH dependence, Yes or No			No				

* sand and sediment excluded from the mean calculation

Sulphanilamide ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Clay Loam (01/01)	2	7.9			3.59	179	0.716
Low pH Sandy Loam (01/03)	1	5.0			1.45	145	0.748
Sandy Loam (01/07)	2	7.8			2.48	124	0.705
Calcareous Silty Clay Loam (01/09)	3.1	8.2			4.07	131	0.673
LUFA Speyer 2.2, Loamy sand	1.9	5.8			2.55	134	0.712
Further Field, Clay loam	1.6	6.7			4.44	278	0.708
Flint Hall, Clay loam	2.5	8.2			2.39	96	0.723
Warsop A1, Loamy sand	0.9	5.1			2.2	244	0.681
Arithmetic mean/median					2.90	166	0.708

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

pH dependence (yes or no)			No				
Methyl-benzene-sulfonyl-carbamate (MBSC) ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Speyer 2.1, Sand	0.59	6.0	0.015	2.93	-	-	-
Speyer 2.2, Loamy sand	2.32	5.6	0.090	3.88	-	-	-
Marknesse, Silt loam	2.5	7.2	0.025	1.53	-	-	-
Arithmetic mean				2.8	-	-	1.0*
pH dependence (yes or no)			No				

FOCUS default used in modelling

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡	Elution (mm): 576 mL on 4 soils Time period (d): Rate which did not exceed infiltration capacity of each soil (time not specified in report)
	Leachate: 90.5 to 97.9% total residues/radioactivity in leachate indicated to be asulam only 0.115 to 0.89 % total residues/radioactivity retained in top 6 cm Koc (When it has not been possible to determine it by batch sorption experiments).
Aged residues leaching ‡	Aged for (d): 7 to 31 d Time period (d): Rate which did not exceed infiltration capacity of each soil Elution: 576 mL
	Analysis of soil residues post ageing (soil residues pre-leaching): *25.26 to 40.89* % active substance >40 % total residues/radioactivity retained in top 6 cm
	Leachate: 49.5 to 76.8% total residues/radioactivity in leachate present as asulam 14.1 to 40.7 % total residues/radioactivity retained in top 6 cm

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

Lysimeter/ field leaching studies ‡	None submitted and none required

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

PEC (soil) (Annex IIIA, point 9.1.3)

Parent: Asulam Method of calculation	DT_{50} (d): 11.2 days Kinetics: SFO Field or Lab: representative worst case from lab studies.
Application data	Crop: spinach/flowering bulbs Depth of soil layer: 5 cm. Soil bulk density: 1.5g/cm^3 % plant interception: Pre-emergence therefore no crop interception Number of applications: 1 Interval (d): *n/a* Application rate(s): 2400 g as/ha

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	3.200		x	
Short term 24h	3.008	3.103	x	x
2d	2.827	3.010	x	x
4d	2.498	2.835	x	x
Long term 7d	2.075	2.597	x	x
28d	0.566	1.520	x	x
50d	0.145	0.987	x	x
100d	0.007	0.516	x	x
Plateau concentration	Not calculated			

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

Metabolite: Sulphanilamide Method of calculation	Molecular weight relative to the parent: 172.2/230.2 DT_{50} (d): not used, initial value only calculated Kinetics: SFO Field or Lab: representative worst case from lab studies.
Application data	Application rate assumed: 308.8 g as/ha (assumed Met I is formed at a maximum of 17.2 % of the applied dose)

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.41		x	
Short term	x	x	x	x
2d	x	x	x	x
4d	x	x	x	x
Long term	x	x	x	x
28d	x	x	x	x
50d	x	x	x	x
100d	x	x	x	x
Plateau concentration	Not calculated Not required			

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 5: Insufficient degradation to calculate degradation half-lives
	pH 7: Insufficient degradation to calculate degradation half-lives
	pH 9: Insufficient degradation to calculate degradation half-lives
Photolytic degradation of active substance and metabolites above 10 % ‡	Buffers pH 9 and pH4 Artificial light equivalent to UK summer sunlight 52°N; Asulam DT_{50}; pH 9: 1.56 days, pH4: 0.78 days pH 9: AP formamide, 24.2%; MCAPAP carbamate, 11.9% pH 4: sulphanilic acid, 55.5% Natural water at 25°C Artificial light equivalent to Japan spring sunlight 35°N comparable with Athens S.Eu. DT_{50} 4.21 d No metabolites >10%
Quantum yield of direct phototransformation in water at Σ > 290 nm	0.157 mol · Einstein $^{-1}$ at pH 9, 0.114 mol · Einstein $^{-1}$ at pH 4 Average half-life in surface waters of Central Europe in June calculated to be 0.5 d at pH 9 and 0.29 d at pH 4.
Readily biodegradable ‡ (yes/no)	Substance considered not readily biodegradable.

Degradation in water / sediment

Parent	Distribution (eg max in water *x* after *n* d. Max. sed x % after *n* d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50} whole sys.	(χ^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
Mill stream pond	8.29	7.8	20	78.8	3.6					SFO
Emperor lake	6.01	5.8	20	65.6	4.8					SFO
Oostvaardersplassen	8.0	-	20	76.2	8.8					SFO

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

Schoonrewoerds ewiel	7.7	-	20	61.9	7.4					HS slow phase rate constant
Geometric mean/median				70.3						

Metabolite 1	Distribution (eg max in water *x* after *n* d. Max. sed x % after *n* d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
Geometric mean/median										

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

PEC (surface water) and PEC sediment (Annex IIIA, point 9.2.3)

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: 2.1 Molecular weight (g/mol): 230 Water solubility (mg/L): 962000 K_{OC} (L/kg): 25.4 DT_{50} soil (d): 4.6 days (Lab or field. In accordance with FOCUS SFO) DT_{50} water/sediment system (d): 70.3 (representative worst case from sediment water studies) DT_{50} water (d): 70.3 DT_{50} sediment (d): 1000 Crop interception (%): 0%
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: FOCUS SWASH 3.1 FOCUS MACRO 4.4.2 FOCUS PRZM SW 3.1.1 FOCUS TOXSWA 3.3.1 Vapour pressure: 5×10^{-7} Pa Kom/Koc: 14.7/25.4 1/n: 0.75 (Freundlich exponent general or for soil ,susp. solids or sediment respectively)
Application rate	Crop: vegetables leafy/vegetables bulb Crop interception: calculated by model Number of applications: 1 Interval (d): n/a Application rate(s): 2400 g as/ha Application window: 30 days

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	795.87		199.98	
	24 h				
	2 d				
	4 d				
	7 d				
	14 d				
	21 d				
	28 d				
	42 d				

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	105.54		26.47	
	24 h				
	2 d				
	4 d				
	7 d				
	14 d				
	21 d				
	28 d				
	42 d				
Southern EU	0 h	190.15		47.77	
	24 h				
	2 d				
	4 d				
	7 d				
	14 d				
	21 d				
	28 d				

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	42 d				

FOCUS STEP 3

Maximum PEC_{SW} and PEC_{Sed} of asulam at Step 3 following application to spinach

Scenario	1st or 2nd Crop	Application dates	$PEC_{SW, Max}$ (µg L^{-1})	$PEC_{Sed, Max}$ (µg kg^{-1})	Dominant entry route
D3 Vredepeel Ditch	1st	10-Apr	15.204	2.367	Drift
D3 Vredepeel Ditch	2nd	25-Jul	15.253	2.890	Drift
D4 Skousbo Pond	1st	16-May	0.527	0.887	Drift
D4 Skousbo Stream	1st	16-May	12.102	0.465	Drift
D6 Thiva Ditch	1st	04-Aug	15.350	6.784	Drift
R1 Weiherbach Pond	1st	26-Apr	0.525	0.891	Drift
R1 Weiherbach Stream	1st	26-Apr	10.032	1.324	Drift
R1 Weiherbach Pond	2nd	28-Jul	0.525	0.801	Drift
R1 Weiherbach Stream	2nd	28-Jul	9.950	0.669	Drift
R2 Porto Stream	1st	16-Mar	21.850	2.795	Run-off
R2 Porto Stream	2nd	05-Aug	13.492	0.690	Drift
R3 Bologna Stream	1st	03-Mar	36.279	4.421	Run-off
R3 Bologna Stream	2nd	09-Jun	16.007	3.406	Run-off
R4 Roujan Stream	1st	12-Mar	62.969	9.451	Run-off
R4 Roujan Stream	2nd	07-Jun	42.370	6.883	Run-off

Maximum PEC_{SW} and PEC_{Sed} of asulam at Step 3 following application to flower-bulbs

Scenario	1st or 2nd Crop	Application dates	$PEC_{sw, max}$ (µg L^{-1})	$PEC_{sed, ma}$ (µg kg^{-1})	Dominant entry route
D3 Vredepeel Ditch	1st	10-Apr	15.199	2.371	Drift
D4 Skousbo Pond	1st	18-Apr	0.527	1.045	Drift
D4 Skousbo Stream	1st	18-Apr-	11.827	0.383	Drift
D6 Thiva Ditch	1st	03-May	15.176	2.281	Drift
D6 Thiva Ditch	2nd	06-Oct	15.350	7.016	Drift
R1 Weiherbach Pond	1st	26-Apr	0.570	1.003	Run-off
R1 Weiherbach Stream	1st	26-Apr	24.052	3.061	Run-off
R2 Porto Stream	1st	06-Mar	21.145	2.716	Run-off
R3 Bologna Stream	1st	19-Feb	36.379	4.410	Run-off
R4 Roujan Stream	1st	27-Feb	61.081	9.243	Run-off

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

Maximum PEC_{SW} and TWAC values of asulam at Step 3 following application to spinach

Scenario	1st or 2nd Crop	$PEC_{SW\ Max}$ (µg/L)	TWACs (µg/L)			
			2-day	7-day	21-day	28-day
D3 Vredepeel Ditch	1st	15.204	7.290	2.135	0.713	0.535
D3 Vredepeel Ditch	2nd	15.253	10.024	3.213	1.074	0.806
D4 Skousbo Pond	1st	0.527	0.516	0.500	0.461	0.445
D4 Skousbo Stream	1st	12.102	0.423	0.130	0.072	0.067
D6 Thiva Ditch	1st	15.350	14.702	12.521	5.713	4.336
R1 Weiherbach Pond	1st	0.525	0.514	0.496	0.465	0.452
R1 Weiherbach Stream	1st	10.032	1.865	0.533	0.271	0.213
R1 Weiherbach Pond	2nd	0.525	0.511	0.489	0.440	0.419
R1 Weiherbach Stream	2nd	9.950	0.788	0.225	0.075	0.056
R2 Porto Stream	1st	21.850	4.615	1.319	0.490	0.368
R2 Porto Stream	2nd	13.492	0.754	0.216	0.072	0.054
R3 Bologna Stream	1st	36.279	9.177	2.627	1.134	0.850
R3 Bologna Stream	2nd	16.007	7.548	2.162	0.949	0.712
R4 Roujan Stream	1st	62.969	22.518	6.437	2.232	1.674
R4 Roujan Stream	2nd	42.370	14.971	4.589	1.612	1.209

Maximum PEC_{SW} and TWAC values of asulam at Step 3 following application to flower-bulbs

Scenario	1st or 2nd Crop	$PEC_{SW\ Max}$ (µg/L)	TWACs (µg/L)			
			2-day	7-day	21-day	28-day
D3 Vredepeel Ditch	1st	15.199	7.311	2.141	0.715	0.537
D4 Skousbo Pond	1st	0.527	0.517	0.502	0.467	0.450
D4 Skousbo Stream	1st	11.827	0.345	0.276	0.137	0.117
D6 Thiva Ditch	1st	15.176	2.605	0.930	0.485	0.423
D6 Thiva Ditch	2nd	15.350	14.810	12.814	5.577	4.392
R1 Weiherbach Pond	1st	0.570	0.563	0.545	0.509	0.503
R1 Weiherbach Stream	1st	24.052	5.108	1.460	0.596	0.451
R2 Porto Stream	1st	21.145	4.465	1.276	0.475	0.357
R3 Bologna Stream	1st	36.379	9.143	2.617	1.129	0.847
R4 Roujan Stream	1st	61.081	21.978	6.283	2.206	1.664

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

FOCUS STEP 4

Maximum PEC_{SW} and PEC_{Sed} of asulam at Step 4 – no drift buffer and 80% run-off mitigation – following application to spinach

Scenario	1st or 2nd Crop	Application dates	$PEC_{SW, Max}$ (µg/L)	$PEC_{Sed, Max}$ (µg/kg)	Dominant entry route
D3 Vredepeel Ditch	1st	10-Apr	15.204	2.367	Drift
D3 Vredepeel Ditch	2nd	25-Jul	15.253	2.890	Drift
D4 Skousbo Pond	1st	16-May	0.527	0.887	Drift
D4 Skousbo Stream	1st	16-May	12.102	0.465	Drift
D6 Thiva Ditch	1st	04-Aug	15.350	6.784	Drift
R1 Weiherbach Pond	1st	26-Apr	0.525	0.850	Drift
R1 Weiherbach Stream	1st	26-Apr	10.032	0.762	Drift
R1 Weiherbach Pond	2nd	28-Jul	0.525	0.805	Drift
R1 Weiherbach Stream	2nd	28-Jul	9.950	0.669	Drift
R2 Porto Stream	1st	16-Mar	13.157	0.794	Run-off
R2 Porto Stream	2nd	05-Aug	13.492	0.690	Drift
R3 Bologna Stream	1st	03-Mar	14.187	1.464	Run-off
R3 Bologna Stream	2nd	09-Jun	14.144	1.371	Run-off
R4 Roujan Stream	1st	12-Mar	14.946	2.631	Run-off
R4 Roujan Stream	2nd	07-Jun	10.142	1.952	Run-off

Maximum PEC_{SW} and PEC_{Sed} of asulam at Step 4 – no drift buffer and 80% run-off mitigation – following application to flower-bulbs

Scenario	1st or 2nd Crop	Application dates	$PEC_{SW, Max}$ (µg L^{-1})	$PEC_{Sed, Ma}$ (µg kg^{-1})	Dominant entry route
D3 Vredepeel Ditch	1st	10-Apr	15.199	2.371	Drift
D4 Skousbo Pond	1st	18-Apr	0.527	1.045	Drift
D4 Skousbo Stream	1st	18-Apr-	11.827	0.383	Drift
D6 Thiva Ditch	1st	03-May	15.176	2.281	Drift
D6 Thiva Ditch	2nd	06-Oct	15.350	7.016	Drift
R1 Weiherbach Pond	1st	26-Apr	0.525	0.870	Run-off
R1 Weiherbach Stream	1st	26-Apr	10.025	0.847	Run-off
R2 Porto Stream	1st	06-Mar	13.151	0.773	Run-off
R3 Bologna Stream	1st	19-Feb	14.185	1.459	Run-off
R4 Roujan Stream	1st	27-Feb	14.514	2.607	Run-off

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

Maximum PEC_{SW} and TWAC values of asulam at Step 4 - no drift buffer and 80% run-off mitigation - following application to spinach

Scenario	1st or 2nd Crop	$PEC_{SW\ Max}$ (µg/L)	TWACs (µg/L)			
			2-day	7-day	21-day	28-day
D3 Vredepeel Ditch	1st	15.204	7.290	2.135	0.713	0.535
D3 Vredepeel Ditch	2nd	15.253	10.024	3.213	1.074	0.806
D4 Skousbo Pond	1st	0.527	0.516	0.500	0.461	0.445
D4 Skousbo Stream	1st	12.102	0.423	0.130	0.072	0.067
D6 Thiva Ditch	1st	15.350	14.702	12.521	5.713	4.336
R1 Weiherbach Pond	1st	0.525	0.514	0.496	0.456	0.438
R1 Weiherbach Stream	1st	10.032	0.981	0.280	0.129	0.099
R1 Weiherbach Pond	2nd	0.525	0.511	0.489	0.440	0.419
R1 Weiherbach Stream	2nd	9.950	0.788	0.225	0.075	0.056
R2 Porto Stream	1st	13.157	1.063	0.304	0.151	0.114
R2 Porto Stream	2nd	13.492	0.754	0.216	0.072	0.054
R3 Bologna Stream	1st	14.187	2.702	0.773	0.461	0.346
R3 Bologna Stream	2nd	14.144	2.389	0.863	0.404	0.303
R4 Roujan Stream	1st	14.946	5.347	1.529	0.578	0.434
R4 Roujan Stream	2nd	10.142	3.618	1.270	0.450	0.337

Maximum PEC_{SW} and TWAC values of asulam at Step 4 - no drift buffer and 80% run-off mitigation - following application to flower-bulbs

Scenario	1st or 2nd Crop	$PEC_{SW\ Max}$ (µg/L)	TWACs (µg/L)			
			2-day	7-day	21-day	28-day
D3 Vredepeel Ditch	1st	15.199	7.311	2.141	0.715	0.537
D4 Skousbo Pond	1st	0.527	0.517	0.502	0.467	0.450
D4 Skousbo Stream	1st	11.827	0.345	0.276	0.137	0.117
D6 Thiva Ditch	1st	15.176	2.605	0.930	0.485	0.423
D6 Thiva Ditch	2nd	15.350	14.810	12.814	5.577	4.392
R1 Weiherbach Pond	1st	0.525	0.514	0.496	0.464	0.448
R1 Weiherbach Stream	1st	10.025	1.088	0.311	0.199	0.150
R2 Porto Stream	1st	13.151	1.029	0.294	0.148	0.111
R3 Bologna Stream	1st	14.185	2.686	0.769	0.459	0.345
R4 Roujan Stream	1st	14.514	5.228	1.495	0.603	0.455

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

Maximum PEC_{SW} and PEC_{Sed} of asulam at Step 4 – 5 m buffer and 80% run-off mitigation – following application to spinach

Scenario	1st or 2nd Crop	Application dates	$PEC_{SW, Max}$ (µg/L)	$PEC_{Sed, Max}$ (µg/kg)	Dominant entry route
D3 Vredepeel Ditch	1st	10-Apr	4.121	0.739	Drift
D3 Vredepeel Ditch	2nd	25-Jul	4.134	0.903	Drift
D4 Skousbo Pond	1st	16-May	0.457	0.789	Drift
D4 Skousbo Stream	1st	16-May	4.422	0.190	Drift
D6 Thiva Ditch	1st	04-Aug	5.625	2.674	Drainage
R1 Weiherbach Pond	1st	26-Apr	0.454	0.749	Drift
R1 Weiherbach Stream	1st	26-Apr	3.664	0.333	Drift
R1 Weiherbach Pond	2nd	28-Jul	0.454	0.708	Drift
R1 Weiherbach Stream	2nd	28-Jul	3.635	0.267	Drift
R2 Porto Stream	1st	16-Mar	5.057	0.757	Run-off
R2 Porto Stream	2nd	05-Aug	4.928	0.272	Drift
R3 Bologna Stream	1st	03-Mar	8.446	1.234	Run-off
R3 Bologna Stream	2nd	09-Jun	5.166	0.977	Drift
R4 Roujan Stream	1st	12-Mar	14.946	2.587	Run-off
R4 Roujan Stream	2nd	07-Jun	10.142	1.885	Run-off

Maximum PEC_{SW} and PEC_{Sed} of asulam at Step 4 – 5 m buffer and 80% run-off mitigation – following application to flower-bulbs

Scenario	1st or 2nd Crop	Application dates	$PEC_{SW, Max}$ (µg L^{-1})	$PEC_{Sed, Ma}$ (µg kg^{-1})	Dominant entry route
D3 Vredepeel Ditch	1st	10-Apr	4.119	0.740	Drift
D4 Skousbo Pond	1st	18-Apr	0.457	0.946	Drift
D4 Skousbo Stream	1st	18-Apr-	4.322	0.296	Drift
D6 Thiva Ditch	1st	03-May	4.279	1.374	Drift
D6 Thiva Ditch	2nd	06-Oct	4.160	2.328	Drift
R1 Weiherbach Pond	1st	26-Apr	0.454	0.770	Drift
R1 Weiherbach Stream	1st	26-Apr	5.176	0.784	Run-off
R2 Porto Stream	1st	06-Mar	4.896	0.736	Run-off
R3 Bologna Stream	1st	19-Feb	8.485	1.235	Run-off
R4 Roujan Stream	1st	27-Feb	14.514	2.539	Run-off

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

Metabolites: Methylbenzenesulphonylcarbamate (MBSC) Parameters used in FOCUSsw step 1 and 2	Molecular weight: 215 Water solubility (mg/L): 100,000 (20°C) Soil or water metabolite: water Koc/Kom (L/kg): 2.8/1.6 (if necessary, soil metabolites) DT_{50} soil (d): 14.9 days (If necessary, Lab or field. In accordance with FOCUS SFO) DT_{50} water/sediment system (d): (representative worst case from sediment water studies) DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 Crop interception (%): 0 Maximum occurrence observed (% molar basis with respect to the parent) Water: 10.3% Sediment:10.3%
Parameters used in FOCUSsw step 3 (if performed)	Vapour pressure: 0 Koc/Kom (L/kg): 2.8/1.6 1/n: 1.0 (Freundlich exponent general or for soil ,susp. solids or sediment respectively) Metabolite kinetically generated in simulation (yes/no): no Formation fraction in soil (k_{dp}/k_f): (If formation degradation of metabolite is kinetically simulated by PRZM) n/a
Application rate	Crop: spinach/flower bulbs Number of applications: 1 Interval (d): n/a Application rate(s): 2400 g as/ha Depth of water body: 30 cm Application window: 30 days
Main routes of entry	Drift/Runoff

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Leafy vegetables	0h	46.8		1.31	
	24h				
	2d				
	4d				
	7d				
	14d				
	21d				
	28d				
	42d				

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	8.71		0.24	
	24 h				
	2 d				
	4 d				
	7 d				
	14 d				
	21 d				
	28 d				
	42 d				
Southern EU	0 h				
	24 h				
	2 d				
	4 d				
	7 d				
	14 d				
	21 d				

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	28 d				
	42 d				

FOCUS STEP 3

Maximum PEC_{sw} and PEC_{sed} of MBSC from application of asulam to spinach at Step 3

Scenario	1st or 2nd Crop	Application dates	$PEC_{SW, Max}$ (µg L^{-1})	$PEC_{Sed, Max}$ (µg kg^{-1})	Dominant entry route
D3 Vredepeel Ditch	1st	10-Apr	1.473	0.100	Drift
D3 Vredepeel Ditch	2nd	25-Jul	1.623	0.233	Drift
D4 Skousbo Pond	1st	16-May	0.214	0.125	Drainage
D4 Skousbo Stream	1st	16-May	0.242	0.083	Drainage
D6 Thiva Ditch	1st	04-Aug	1.620	0.309	Drainage
R1 Weiherbach Pond	1st	26-Apr	0.051	0.021	Drift
R1 Weiherbach Stream	1st	26-Apr	0.150	0.008	Run-off
R1 Weiherbach Pond	2nd	28-Jul	0.051	0.021	Drift
R1 Weiherbach Stream	2nd	28-Jul	0.000	0.000	Run-off
R2 Porto Stream	1st	16-Mar	0.493	0.028	Run-off
R2 Porto Stream	2nd	05-Aug	0.013	0.001	Run-off
R3 Bologna Stream	1st	03-Mar	0.517	0.027	Run-off
R3 Bologna Stream	2nd	09-Jun	1.657	0.138	Run-off
R4 Roujan Stream	1st	12-Mar	1.505	0.111	Run-off
R4 Roujan Stream	2nd	07-Jun	3.714	0.278	Run-off

Maximum PEC_{sw} and PEC_{sed} of MBSC from application of asulam to flower-bulbs at Step 3

Scenario	1st or 2nd Crop	Application dates	$PEC_{SW, Max}$ (µg L^{-1})	$PEC_{Sed, Ma}$ (µg kg^{-1})	Dominant entry route
D3 Vredepeel Ditch	1st	10-Apr	1.476	0.101	Drift
D4 Skousbo Pond	1st	18-Apr	0.455	0.276	Drainage
D4 Skousbo Stream	1st	18-Apr-	1.178	0.233	Drainage
D6 Thiva Ditch	1st	03-May	1.479	0.086	Drift
D6 Thiva Ditch	2nd	06-Oct	1.478	0.293	Drift
R1 Weiherbach Pond	1st	26-Apr	0.051	0.022	Drift
R1 Weiherbach Stream	1st	26-Apr	0.746	0.041	Run-off
R2 Porto Stream	1st	06-Mar	0.462	0.026	Run-off
R3 Bologna Stream	1st	19-Feb	0.525	0.028	Run-off
R4 Roujan Stream	1st	27-Feb	1.518	0.112	Run-off

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

PECsw photodegradates

Three major photodegradates formed in the direct photolysis study were:

	Sulphanilic acid	AP formamide	MCAPAP carbamic acid
Molecular mass	173	136	301
% formation	55.5	24.2	11.9

Step 3 and Step 4 PECsw values were calculated based on the concentration of asulam and the relative molecular mass and percent formation.

Step 3

PEC_{SW} values of asulam photodegradates at Step 3 following application to spinach

Scenario	1st or 2nd Crop	PECsw (µg/L)			
		Asulam	Sulphanilic acid	AP formamide	MCAPAP carbamic acid
D3 Vredepeel Ditch	1st	15.204	6.347	2.176	2.368
D3 Vredepeel Ditch	2nd	15.253	6.367	2.183	2.375
D4 Skousbo Pond	1st	0.527	0.220	0.075	0.082
D4 Skousbo Stream	1st	12.102	5.052	1.732	1.885
D6 Thiva Ditch	1st	15.350	6.408	2.197	2.391
R1 Weiherbach Pond	1st	0.525	0.219	0.075	0.082
R1 Weiherbach Stream	1st	10.032	4.188	1.436	1.562
R1 Weiherbach Pond	2nd	0.525	0.219	0.075	0.082
R1 Weiherbach Stream	2nd	9.950	4.154	1.424	1.550
R2 Porto Stream	1st	21.850	9.121	3.127	3.403
R2 Porto Stream	2nd	13.492	5.632	1.931	2.101
R3 Bologna Stream	1st	36.279	15.145	5.191	5.650
R3 Bologna Stream	2nd	16.007	6.682	2.291	2.493
R4 Roujan Stream	1st	62.969	26.287	9.011	9.806
R4 Roujan Stream	2nd	42.370	17.688	6.063	6.598

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

PEC_{SW} values of asulam photodegradates at Step 3 following application to flower-bulbs

Scenario	1st or 2nd Crop	PECsw (µg/L)			
		Asulam	Sulphanilic acid	AP formamide	MCAPAP carbamic acid
D3 Vredepeel Ditch	1st	15.199	6.345	2.175	2.367
D4 Skousbo Pond	1st	0.527	0.220	0.075	0.082
D4 Skousbo Stream	1st	11.827	4.937	1.692	1.842
D6 Thiva Ditch	1st	15.176	6.335	2.172	2.363
D6 Thiva Ditch	2nd	15.350	6.408	2.197	2.391
R1 Weiherbach Pond	1st	0.570	0.238	0.082	0.089
R1 Weiherbach Stream	1st	24.052	10.041	3.442	3.746
R2 Porto Stream	1st	21.145	8.827	3.026	3.293
R3 Bologna Stream	1st	36.379	15.187	5.206	5.665
R4 Roujan Stream	1st	61.081	25.499	8.740	9.512

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

Step 4

PEC_{SW} values of asulam photodegradates at Step 4 – 5 m buffer and 80% run-off mitigation - following application to spinach

Scenario	1st or 2nd Crop	PECsw (µg/L)			
		Asulam	Sulphanilic acid	AP formamide	MCAPAP carbamic acid
D3 Vredepeel Ditch	1st	4.121	1.720	0.590	0.642
D3 Vredepeel Ditch	2nd	4.134	1.726	0.592	0.644
D4 Skousbo Pond	1st	0.457	0.191	0.065	0.071
D4 Skousbo Stream	1st	4.422	1.846	0.633	0.689
D6 Thiva Ditch	1st	5.625	2.348	0.805	0.876
R1 Weiherbach Pond	1st	0.454	0.190	0.065	0.071
R1 Weiherbach Stream	1st	3.664	1.530	0.524	0.571
R1 Weiherbach Pond	2nd	0.454	0.190	0.065	0.071
R1 Weiherbach Stream	2nd	3.635	1.517	0.520	0.566
R2 Porto Stream	1st	5.057	2.111	0.724	0.788
R2 Porto Stream	2nd	4.928	2.057	0.705	0.767
R3 Bologna Stream	1st	8.446	3.526	1.209	1.315
R3 Bologna Stream	2nd	5.166	2.157	0.739	0.805
R4 Roujan Stream	1st	14.946	6.239	2.139	2.328
R4 Roujan Stream	2nd	10.142	4.234	1.451	1.579

PEC_{SW} values of asulam photodegradates at Step 4 – 5 m buffer and 80% run-off mitigation - following application to flower-bulbs

Scenario	1st or 2nd Crop	PECsw (µg/L)			
		Asulam	Sulphanilic acid	AP formamide	MCAPAP carbamic acid
D3 Vredepeel Ditch	1st	4.119	1.720	0.589	0.641
D4 Skousbo Pond	1st	0.457	0.191	0.065	0.071
D4 Skousbo Stream	1st	4.322	1.804	0.618	0.673
D6 Thiva Ditch	1st	4.279	1.786	0.612	0.666
D6 Thiva Ditch	2nd	4.160	1.737	0.595	0.648
R1 Weiherbach Pond	1st	0.454	0.190	0.065	0.071
R1 Weiherbach Stream	1st	5.176	2.161	0.741	0.806
R2 Porto Stream	1st	4.896	2.044	0.701	0.762
R3 Bologna Stream	1st	8.485	3.542	1.214	1.321
R4 Roujan Stream	1st	14.514	6.059	2.077	2.260

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: (with version control no.(s)) FOCUS PEARL v.4.4.4 and FOCUS PELMO v. 4.4.3 Scenarios (list of names): Châteaudun, Hamburg, Jokioinen, Kremsmünster, Porto, Sevilla, Thiva Crop: Cabbage (surrogate for spinach), flower bulbs Geometric mean or median parent DT_{50lab} 4.6 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58). K_{OC}: parent, arithmetic mean 25.4, $^{1}/_{n}$= 0.75. Metabolites: Geometric mean sulphanilamide DT_{50lab} 13.4 d (normalisation to 10kPa or pF2, 20°C with Q10 of 2.58). Kfoc: sulphanilamide, arithmetic mean 166, 1/n= 0.71. For field and lysimeter studies: N/A Location: UK, N. Yorkshire Study type (e.g.lysimeter, field): lysimeter Soil properties: pH = , OC= , MWHC = Dates of application : Crop : /Interception estimated: Number of applications: x years, x applications year Duration. Average annual rainfall (mm): x mm Average annual leachate volume (mm): x mm
Application rate	Application rate: 2400 g/ha. No. of applications: 1 Time of application (month or season): Spring/summer

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
PELMO & PEARL/Spinach			Sulphanilamide		
	Chateaudun	<0.001	<0.001		
	Hamburg	<0.001	<0.001		
	Jokioinen	<0.001	<0.001		
	Kremsmunster	<0.001	<0.001		
	Porto	<0.001	<0.001		
	Sevilla	<0.001	<0.001		
	Thiva	<0.001	<0.001		

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
PELMO & PEARL/Flower bulbs			Sulphanilamide		
	Chateaudun	<0.001	<0.001		
	Hamburg	<0.001	<0.001		
	Jokioinen	<0.001	<0.001		
	Kremsmunster	<0.001	<0.001		
	Porto	<0.001	<0.001		
	Sevilla	<0.001	<0.001		
	Thiva	<0.001	<0.001		

PEC$_{(gw)}$ From lysimeter / field studies: not applicable

Parent	1st year	2nd year	3rd year
Annual average (µg/L)			

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List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

Metabolite X	1st year	2nd year	3rd year
Annual average (µg/L)			

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	0.157 mol · Einstein $^{-1}$ at pH 9, 0.114 mol · Einstein $^{-1}$ at pH 4 Average half-life in surface waters of Central Europe in June calculated to be 0.5 d at pH 9 and 0.29 d at pH 4.
Photochemical oxidative degradation in air ‡	DT_{50} of 0.372 days derived by the Atkinson model (AOPWIN v1.88). OH (12 h) concentration assumed = 1.5×10^{-6}
Volatilisation ‡	from plant surfaces (BBA guideline): Not studied - no data requested
	from soil surfaces (BBA guideline): Not studied - no data requested
Metabolites	None

PEC (air)

Method of calculation	Expert judgement, based on vapour pressure, dimensionless Henry's Law Constant and information on volatilisation from plants and soil.

$PEC_{(a)}$

Maximum concentration	negligible

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: Asulam, Sulphanilamide Surface Water: Asulam, Sulphanilamide, MBSC, sulphanilic acid, AP formamide, MCAPAP carbamate Sediment: Asulam, Sulphanilamide Ground water: Asulam, Sulphanilamide Air: Asulam

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Fate and behaviour in the environment

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	No data provided - none requested
Surface water (indicate location and type of study)	Florida and Lousiana, USA, to assess human exposure to asulam and sulphanilamide in high use areas. Louisiana site: traces of asulam and sulphanilamide <1µg/L in surface water. Florida site: residues <1µg/L May & June only. North Yorkshire, UK, 1993. in steams and receiving rivers in an area where asulam was applied annually to treat bracken in moorland. streams: peaks of 28.4 to 618 µg/L asulam and 0.77 to13.9 µg/l sulphanilamide on day of application
Ground water (indicate location and type of study)	Feddet Plantation, Denmark, monitoring of a shallow aquifer underlying forested land from 1990-1991 (active substance and metabolite sulphanilamide). Asulam: Maximum in borehole 0.21 µg/L Sulphanilamide: Maximum in borehole 0.13 µg/l
Air (indicate location and type of study)	No data available

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

Not readily biodegradable; candidate for R53

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Ecotoxicology

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
Bobwhite quail (*Colinus virginianus*)	Asulam sodium	Acute	LD_{50} > 1825.6 mg asulam /kg bw	Not applicable
Mallard duck *(Anas platyrhynchos)*	'Asulox'	Short-term	LD_{50} > 22732 mg asulam /kg bw /day	LC_{50} >100000 mg asulam /kg feed
Pheasant *(Phasianus colchicus)*	'Asulox'	Short-term	Not calculable#	LC50 >75000 mg asulam /kg feed
Japanese quail (*Coturnix coturnix japonica*)	Asulam sodium	Long-term	NOEL < 65 mg asulam /kg bw /day **NOAEL = 65 mg asulam /kg bw /day**	NOEC < 500 mg asulam /kg feed NOAEC = 500 mg asulam /kg feed
Japanese quail (*Coturnix coturnix japonica*)	Asulam sodium	Long-term	NOEL 19 mg asulam /kg bw /day NOAEL = 93.8 mg asulam /kg bw /day	NOEC 100 mg asulam /kg feed NOAEC = 500 mg asulam /kg feed
Mammals ‡				
Rat	Asulam sodium	Acute	LD_{50} > 4564 mg asulam/kg bw	Not applicable
Rat	'Asulox'	Acute	LD_{50} > 2000 mg product /kg bw	Not applicable
Rat	Asulam sodium	Long-term	NOEL = 46 mg asulam/kg bw	1000 mg asulam /kg feed
Additional higher tier studies ‡				
Details have been provided for a field study monitoring the foraging behaviour of birds and mammals in maize and sugar beet fields in Austria (ref. Wolf C 2005). Radio-tracking data reported in this study for skylarks foraging in seedling sugar beet fields indicate for 'potential consumers' (i.e. individuals whose home ranges included newly emerged beet crops) a 90th percentile PT value of 0.6 (i.e. 0.6 of total diet obtained in seedling beet fields) and a mean PT value of 0.18, based on observations on a limited number of tracked birds (n = 9). These data need to be considered with other available data (e.g. UK published data relating to a larger data set) and have not been specifically used in the current risk assessment.				

Unable to convert to 'dose' due to unreliable food consumption data as a result of food wastage by birds, plus indications of reduced food consumption at 75000 mg /kg diet.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Ecotoxicology

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3):

Crop use: early post crop emergence in spinach, as one application of 2.4 kg asulam /ha.

'Indicator species' (screening step) or 'generic focal species' (Tier 1 and refined RA)	Time scale	DDD	TER	Uniform Principles Trigger
Screening step (Birds): Use in spinach and flower bulb crops				
Small granivorous bird (pre-crop emergence use in spinach)	Acute	59.3	> 31	10
Small omnivorous bird (post-crop emergence use in spinach and flower bulbs)	Acute	381	**> 4.8**	10
Small granivorous bird (pre-crop emergence use in spinach)	Long-term	14.5	**4.5**	5
Small omnivorous bird (post-crop emergence use in spinach and flower bulbs)	Long-term	82.4	**0.8**	5
Tier 1 (Birds): Use in spinach ('Leafy vegetables')				
Small granivorous bird (post-emergence use)	Acute	65.8	> 27.7	10
Small omnivorous bird (post-emergence use)	Acute	57.6	> 31.7	10
Medium herbivorous bird (post-emergence use)	Acute	217.0	**> 8.4**	10
Small insectivorous bird (post-emergence use)	Acute	64.3	> 28.4	10
Small granivorous bird (pre-emergence use)	Long-term	14.5	**4.5**	5
Small omnivorous bird (pre-emergence use)	Long-term	10.43	6.3	5
Small insectivorous bird (pre-emergence use)	Long-term	7.5	8.7	5
Small granivorous bird (post-emergence use)	Long-term	16.02	**4.1**	5
Small omnivorous bird (post-emergence use)	Long-term	13.86	**4.7**	5
Medium herbivorous bird (post-emergence use)	Long-term	47.06	**1.4**	5
Small insectivorous bird (post-emergence use)	Long-term	14.37	**4.5**	5
Tier 1 (Birds): Use in flower bulbs ('Bulbs and onion like crops')				
Small granivorous bird (post-emergence use)	Acute	59.28	>30.8	
Small omnivorous bird (post-emergence use)	Acute	57.6	>31.7	
Small insectivorous bird (post-emergence use)	Acute	64.3	>28.4	5
Small granivorous bird (post-emergence use)	Long-term	14.5	**4.5**	
Small omnivorous bird (post-emergence use)	Long-term	13.86	**4.7**	
Small insectivorous bird (post-emergence use)	Long-term	14.37	**4.5**	
Small granivorous bird (post-emergence use)	Acute	59.28	>30.8	

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Ecotoxicology

'Indicator species' (screening step) or 'generic focal species' (Tier 1 and refined RA)	Time scale	DDD	TER	Uniform Principles Trigger
Refined avian risk assessment: Use in spinach ('Leafy vegetables'):				
Refined acute risk assessment for 'medium herbivorous bird' (post-crop emergence): Based on use of a refined acute LD_{50} – with inclusion of 'extrapolation factor' (from Table 1 of Section 2.1.2 of EFSA 2009 guidance) = 1825.6 x 1.888 = 3446.7 mg asulam /kg bw /day.	Acute	217.0	15.9	10
Refined long-term risk assessment for small granivorous bird (pre and post crop emergence) - using the Linnet as 'focal species':	Long-term	8.45	7.7	5
Refined long-term risk assessment for 'small omnivorous bird' (post-emergence use) – based on use of foliar residue data indicating a DT_{50} of 1.44 days (in place of the 'Tier 1' default DT_{50} = 10 days).	Long-term	12.26	5.3	5
Refined long-term risk assessment for 'small insectivorous bird' (post-emergence use) using the yellow wagtail as focal species. Note: Taking into account the conservatism of several areas of the exposure assessment (particularly in relation to use of a PT of 1.0) the DDD is considered by the RMS to be an over-estimate - such that the actual TER is likely to be in excess of the trigger value of 5, indicating an acceptable risk.	Long-term	15.8	**4.1**	5
Refined avian risk assessment: Use in flower bulb crops ('Bulbs and onion like crops'):				
Refined long-term risk assessment for small granivorous bird (post crop emergence) - using the Linnet as 'focal species':	Long-term	8.45	7.7	5
Refined long-term risk assessment for 'small omnivorous bird' (post-emergence use) – based on use of foliar residue data indicating a DT_{50} of 1.44 days (in place of the 'Tier 1' default DT_{50} = 10 days).	Long-term	12.26	5.3	5
Refined long-term risk assessment for 'small insectivorous bird' (post-emergence use) using the yellow wagtail as focal species. Note: Taking into account the conservatism of several areas of the exposure assessment (particularly in relation to use of a PT of 1.0) the DDD is considered by the RMS to be an over-estimate - such that the actual TER is likely to be in excess of the trigger value of 5, indicating an acceptable risk.	Long-term	15.8	**4.1**	5

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Ecotoxicology

'Indicator species' (screening step) or 'generic focal species' (Tier 1 and refined RA)	Time scale	DDD	TER	Uniform Principles Trigger
Screening step (Wild mammals): Use in spinach and flower bulb crops				
Small granivorous mammal (pre-crop emergence use in spinach)	Acute	34.6	> 131.9	10
Small herbivorous mammal (post-crop emergence use in flower bulbs)	Acute	284.2	> 16.1	10
Small herbivorous mammal (post-crop emergence use in spinach)	Acute	327.4	> 13.9	10
Small granivorous mammal (pre-crop emergence use in spinach)	Long-term	8.4	5.5	5
Small herbivorous mammal (post-crop emergence use in flower bulbs)	Long-term	61.4	**0.7**	5
Small herbivorous mammal (post-crop emergence use in spinach)	Long-term	92.0	**0.5**	5
Tier 1 (Wild mammals): Use in spinach ('Leafy vegetables')				
Small insectivorous mammal (post-emergence use)	Long-term	5.3	8.7	5
Large herbivorous mammal (post-emergence use)	Long-term	18.2	**2.5**	5
Small omnivorous mammal (post-emergence use)	Long-term	9.9	**4.6**	5
Tier 1 (Wild mammals): Use in flower bulbs ('Bulbs and onion like crops')				
Small insectivorous mammal (post-emergence use)	Long-term	5.3	8.7	5
Small herbivorous mammal (post-emergence use)	Long-term	55.2	**0.8**	5
Small omnivorous mammal (post-emergence use)	Long-term	6.0	7.7	5
Refined wild mammal risk assessment: Use in spinach ('Leafy vegetables'):				
Refined long-term risk assessment for 'large herbivorous mammal' (post-crop emergence) – based on use of foliar residue data indicating a DT_{50} of 1.44 days (in place of the 'Tier 1' default DT_{50} = 10 days).	Long-term	3.39	13.6	5
Refined long-term risk assessment for 'small omnivorous mammal' (post-crop emergence) – based on use (for consumed weeds) of refined foliar residue DT_{50} of 1.44 days (in place of the 'Tier 1' default DT_{50} = 10 days).	Long-term	8.01	5.7	5

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Ecotoxicology

'Indicator species' (screening step) or 'generic focal species' (Tier 1 and refined RA)	Time scale	DDD	TER	Uniform Principles Trigger
Refined wild mammal risk assessment: Use in flower bulb crops ('Bulbs and onion like crops'):				
Refined long-term risk assessment for 'small herbivorous mammal' (post-crop emergence) – based on use of foliar residue data indicating a DT_{50} of 1.44 days (in place of the 'Tier 1' default DT_{50} = 10 days). Note: The exposure assessment is considered conservative in assuming a PT=1 and also in assuming a dietary spray interception level of 60% given that voles as the representative 'small herbivore' species will only feed in habitats providing good cover. Therefore in practice the TER is likely to be >5.0 – indicating an acceptable risk.	Long-term	10.3	**4.5**	5
Risk to fish-eating and earthworm-eating birds and mammals from potential secondary poisoning via bio-accumulation in fish and earthworms.				
Given a Pow for asulam sodium and its major environmental metabolites of less than the bioaccumulation trigger value of log 3.0 (asulam log Pow = 0.15), there is a lack of potential for bioaccumulation and therefore there is a low risk to fish-eating and earthworm-eating birds and wild mammals				
Risk to birds and wild mammals from exposure via contaminated drinking water				
For the proposed crop uses only a 'puddle water scenario' needs to be considered. As per EFSA (2009) guidance, no specific calculations of exposure and TER are necessary when the ratio of the effective application rate (in g/ha) to the acute and long-term relevant endpoints (in mg/kg bw/d) does not exceed 50 for 'less sorptive substances' with a Koc of <500 L/kg (which is the case for asulam – Koc = 25.4, ref. Section B.8.6 of current Volume 3 DAR). Therefore, an initial risk assessment has been conducted on this basis: Avian drinking water risk assessment Acute risk ratio = <0.13 Long-term risk ratio = 3.69 Therefore, there is a low risk to birds from consumption of contaminated drinking water. Wild mammal drinking water risk assessment Acute risk ratio <0.05 Long-term risk ratio = 5.2 Therefore, there is a low risk to wild mammals from consumption of contaminated drinking water.				

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Ecotoxicology

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale (Test type)	End point	Toxicity # (mg/L)
Laboratory tests ‡				
Fish				
Lepomis macrochirus	Asulam sodium	96 hr (semi-static)	LC_{50}	**> 91.3 mg asulam/L** (nom.)
Oncorhynchus mykiss	Asulam sodium	96 hr (static)	LC_{50}	>159.8 mg asulam/L (m.m.)
Oncorhynchus mykiss	Asulam	28 d (flow-through)	NOEC	**119.1 mg asulam/L** (m.m.)
Aquatic invertebrates				
Daphnia magna	Asulam sodium	48 h (flow-through)	EC_{50} (Immobilisation)	57.87 mg asulam/L (m.m.)
Daphnia magna	'Asulam 80 SG'	20 d (semi-static)	NOEC	8.96 mg asulam/L (nom.) ##
Daphnia magna	Asulam	21 d (semi-static)	NOEC	6.4 mg asulam/L
Sediment dwelling organisms				
Chironomus riparius	Asulam	28 d (static)	NOEC	91.3 mg asulam/L (nominal. – assuming all applied active in water phase) ##
Algae				
Pseudokirchneriella subcapitata	Asulam sodium	120 hr (static)	E_bC_{50} (72h) E_rC_{50} (72 h)	0.06 mg asulam /L (m.m.) 1.73 mg asulam /L (m.m.)
Anabaena flosaquae	Asulam sodium	120 h (static)	E_bC_{50} (72h) **E_rC_{50} (72 h)**	0.15 mg asulam /L (m.m.) >0.66 mg asulam /L (m.m.)
Navicula pelliculosa	Asulam sodium	120 hr (static)	E_bC_{50} (72h) E_bC_{50} (120h) **E_rC_{50}**	3.1 mg asulam /L (m.m.) 2.1 mg asulam /L (m.m.) Not calculated
Skeletonema costatum	Asulam sodium	120 hr (static)	E_bC_{50} (96h) E_rC_{50} (72 h)	0.146 mg asulam /L (m.m.) >1.64 mg asulam /L (m.m.)

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity # (mg/L)
Pseudokirchneriella subcapitata	Sulphanil-amide (metabolite)	120 hr (static)	E_bC_{50} (72h) E_rC_{50} (72 h)	7.6 mg met. /L (m.m.) >21.15 mg met. /L (m.m.)
Higher plant				
Lemna gibba	Asulam sodium	14 d (static)	Frond number E_bC_{50} E_rC_{50}	0.27 mg asulam /L (initial measured) 0.16 mg asulam /L (mean measured) Note: measured conc. 99% at test start and 15% at test end.
Lemna paucicostata	Asulam	7 d (static) Non-GLP compliant.	E_rC_{50}	93.8 mg asulam /L (nom.) ##
Lemna minor	Sulphanil-amide (metabolite)	7 d (static)	E_yC_{50} E_rC_{50}	2.30 mg met. /L (nom.) 5.82 mg met. /L (nom.)
Myriophyllum spicatum, *Elodea nuttallii*, *Elodea canadensis*, *Ranunculus circinatus* and *Potamogeton crispus.*	'Asulox'	21 day non-standard multi-species higher aquatic plant growth inhibition study. Non-GLP compliant. ###	E_bC_{50}	0.0107 mg /L (nom.) for most sensitive tested species (*Myriophyllum spicatum).*
Myriophyllum spicatum.	'Asulam 400g/L SL' (= 'Asulox')	14 day *Myrio-phyllum spicatum* (OECD 2014) growth inhibition study ###	E_yC_{50} E_rC_{50}	0.39 mg asulam /L (nom.) >2.56 mg asulam /L (nom.)
Microcosm or mesocosm tests				
Not required or submitted.				

Based on mean measured (m.m.), initial measured, or nominal (nom.). Chemical analysis of test concentrations included unless indicated otherwise by ##.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Ecotoxicology

These study endpoints are considered to be of limited reliability due to a lack of any chemical analysis to confirm nominal test concentrations.
Study non-GLP compliant and 95% confidence intervals for the most sensitive total dry weight E_bC_{50} of 10.7 µg/L are large i.e. 2-74 µg/L - indicating uncertainty in the accuracy of this determined endpoint. Given these deficiencies, the results of this study are not considered sufficiently reliable for regulatory use.

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

One application of 2.4 kg asulam/ha to spinach (pre or post-emergence) and flower bulb crops (post-emergence)

FOCUS Step 1 TERs for asulam:

Test organism	Test type and duration	Toxicity endpoint (mg asulam/L)	Initial (maximum) PEC_{sw} (mg asulam/L)	TER	TER trigger
Fish (*Lepomis macrochirus*)	Acute, 96 h static test	LC_{50} > 91.3	0.796 #	>114.7	100
Fish (*Oncorhyn-chus mykiss*)	Chronic, 28 h flow through juvenile growth test	NOEC = 119.1		149.6	10
Daphnia magna	Acute, 48 h flow through test	EC_{50} = 57.87		**72.7**	100
	Chronic 21 day semi-static test	NOEC = 6.4		**8.0**	10
Chironomus riparius	Chronic 28 day spiked water test	NOEC = 91.3		111.1	10
Algae (*Anabaena flosaquae)*	Acute, 120 hour static test	72h E_rC_{50} > 0.66		**> 0.8**	10
Lemna gibba	Acute, 14 day static test	E_bC_{50} = 0.27 *		**0.3**	10

Figures in bold indicate a breaching of the Uniform Principles trigger value.
* Based on effects on frond number
Note: Focus Step 1 initial (maximum) PECsw values for proposed crop uses have been used in TER calculations except for sediment dwellers (Chironomid) where a FOCUS Step 1 'total load' PECsw of 822 µg asulam/L has been used.

FOCUS Step 1 TERs for major metabolite sulphanilamide:

Test organism	Test type and duration	Toxicity endpoint (mg/L)	PEC_{sw} # (mg/L)	TER	TER trigger
Pseudokirchneriella subcapitata (algae)	Acute, 120 h static test	72 h E_rC_{50} > 21.15	0.08635	244.9	10
Lemna minor (higher aquatic plant)	Acute, 7 day static test	7 day E_rC_{50} = 5.82		67.4	10

Note: Figures in bold indicate a breaching of the Annex VI trigger
Initial (maximum) Step 1 PECsw.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Ecotoxicology

FOCUS Step 2 for asulam:
One application of 2.4 kg asulam/ha to spinach (pre or post-emergence) and flower bulb crops (post-emergence)

Scenario	Test organism	Test type & duration	Toxicity endpoint (mg asulam/L)	Maximum PEC_{sw} (mg asulam/L)#	TER	TER trigger
Spinach - Southern Europe (March – May)	*Daphnia magna*	Acute, 48 h flow through test	EC_{50} 57.87	0.19015	304.3	100
		Chronic 21 day semi-static test	NOEC 6.4		33.7	10
	Algae (*Anabaena flosaquae)*	Acute, 72h static test	E_rC_{50}> 0.66		**> 3.5**	10
	Lemna gibba	Acute, 14 day static test	EC_{50} 0.27		**1.4**	10
Spinach - Northern Europe (March to May)	*Daphnia magna*	Acute, 48 h flow through test	EC_{50} 57.87	0.10554	548.3	100
		Chronic 21 day semi-static test	NOEC 6.4		60.6	10
	Algae (*Anabaena flosaquae*)	Acute, 72h static test	E_rC_{50} > 0.66		**> 6.3**	10
	Lemna gibba	Acute, 14 day static test	EC_{50} 0.27		**2.6**	10
Flower bulbs - Southern Europe (March – May)	*Daphnia magna*	Acute, 48 h flow through test	EC_{50} 57.87	0.17321	334.1	100
		Chronic 21 day semi-static test	NOEC 6.4		36.9	10
	Algae (*Anabaena flosaquae)*	Acute, 72h static test	E_rC_{50} > 0.66		**> 3.8**	10
	Lemna gibba	Acute, 14 day static test	EC_{50} 0.27		**1.6**	10
Flower bulbs - Northern Europe (March to May)	*Daphnia magna*	Acute, 48 h flow through test	EC_{50} 57.87	0.09698	596.7	100
		Chronic 21 day semi-static test	NOEC 6.4		66.0	10
	Algae (*Anabaena flosaquae*)	Acute, 72h static test	E_rC_{50} > 0.66		**> 6.8**	10
	Lemna gibba	Acute, 14 day static test	EC_{50} 0.27		**2.8**	10

Note: Figures in bold indicate a breaching of the Uniform Principles trigger value.
PECsw values taken from Table B.8.148 of Section B.8.6 of Volume 3.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Ecotoxicology

Refined aquatic risk assessment using higher tier FOCUS modelling.
One application of 2.4 kg asulam/ha to spinach (pre or post-emergence) and flower bulb crops (post-emergence)

Step 3 TERs for asulam:

Organism: *Anabaena flosaquae* (algae)
Time scale: Acute

Scenario type	Exposure from spray drift plus drain flow #				Exposure from spray drift plus run-off #				
	D3	D4	D4	D6	R1	R1	R2	R3	R4
Water body	ditch	pond	stream	ditch	pond	stream	stream	stream	stream
Use in spinach crops:									
PEC_{sw} * [µg a.s./L]	15.253	0.527	12.102	15.350	0.525	10.032	21.850	36.279	62.969
72 h E_rC_{50} [µg a.s./L]	> 660								
TER	> 43.3	> 1252.4	> 54.5	> 43.0	>1257.1	> 65.8	> 30.2	> 18.2	> 10.5
Use in flower bulb crops:									
PEC_{sw} * [µg a.s./L]	15.199	0.527	11.827	15.350	0.570	24.052	21.145	36.379	61.081
72 h E_rC_{50} [µg a.s./L]	> 660								
TER	> 43.4	> 1252.4	> 55.8	> 43.0	>1157.9	> 27.4	> 31.2	> 18.1	> 10.8

* In scenarios where it is possible to grow a second crop, the maximum PECsw value for the crop which gives the higher exposure value is included.
# Maximum (peak) PECsw values taken from Table B.8.150 and B.8.151 of Section B.8.6 of Vol. 3.

Organism: *Lemna gibba* (higher aquatic plants)
Time scale: Acute

Scenario type	Exposure from spray drift plus drain flow #				Exposure from spray drift plus run-off #				
	D3	D4	D4	D6	R1	R1	R2	R3	R4
Water body	ditch	pond	stream	ditch	pond	stream	stream	stream	stream
Use in spinach crops:									
PEC_{sw} * [µg a.s./L]	15.253	0.527	12.102	15.350	0.525	10.032	21.850	36.279	62.969
72 h E_rC_{50} [µg a.s./L]	270								
TER	17.7	512.3	22.3	17.6	514.3	26.9	12.4	**7.4**	**4.3**
Use in flower bulb crops:									
PEC_{sw} * [µg a.s./L]	15.199	0.527	11.827	15.350	0.570	24.052	21.145	36.379	61.081
72 h E_rC_{50} [µg a.s./L]	270								
TER	17.8	512.3	22.8	17.6	473.7	11.2	12.8	**7.4**	**4.4**

* In scenarios where it is possible to grow a second crop, the maximum PECsw value for the crop which gives the higher exposure value is included.
# Maximum (peak) PECsw values taken from Table B.8.150 and B.8.151 of Section B.8.6 of Vol. 3.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Ecotoxicology

Step 3 TERs for sulphanilic acid (aquatic photodegradate):

Scenario type	Exposure from spray drift plus drain flow #				Exposure from spray drift plus run-off #				
	D3	D4	D4	D6	R1	R1	R2	R3	R4
Water body	ditch	pond	stream	ditch	pond	stream	stream	stream	stream
Assumed algal 72 h E_rC_{50} [µg a.s./L] ##	66	66	66	66	66	66	66	66	66
Assumed *Lemna* 7 day E_rC_{50} [µg a.s./L]##	27	27	27	27	27	27	27	27	27
Use in spinach crops:									
PEC_{sw} * [µg a.s./L]	6.367	0.22	5.052	6.408	0.219	4.188	9.121	15.145	26.287
Algal TER:	10.4	300.0	13.1	10.3	301.4	15.8	**7.2**	**4.4**	**2.5**
Lemna TER:	**4.2**	122.7	**5.3**	**4.2**	123.3	**6.4**	**3.0**	**1.8**	**1.0**
Use in flower bulb crops:									
PEC_{sw} * [µg a.s./L]	6.345	0.22	4.937	6.408	0.238	10.041	8.827	15.187	25.499
Algal TER:	10.4	300.0	13.4	10.3	277.3	**6.6**	**7.5**	**4.3**	**2.6**
Lemna TER:	**4.3**	122.7	**5.5**	**4.2**	113.4	**2.7**	**3.1**	**1.8**	**1.1**

* In scenarios where it is possible to grow a second crop, the maximum PECsw value for the crop which gives the higher exposure value is included.

Maximum (peak) PECsw values taken from Table B.8.162 (spinach) and B.8.163 (flower bulbs) of Section B.6

Based on extrapolation of asulam toxicity endpoints assuming a 10 fold higher toxicity of the sulphanilic acid metabolite.

Step 3 TERs forAP formamide:

Scenario type	Exposure from spray drift plus drain flow #				Exposure from spray drift plus run-off #				
	D3	D4	D4	D6	R1	R1	R2	R3	R4
Water body	ditch	pond	stream	ditch	pond	stream	stream	stream	stream
Assumed algal 72 h E_rC_{50} [µg a.s./L]##	66	66	66	66	66	66	66	66	66
Assumed *Lemna* 7 day E_rC_{50} [µg a.s./L]##	27	27	27	27	27	27	27	27	27
Use in spinach crops:									
PEC_{sw} * [µg a.s./L]	2.183	0.075	1.732	2.197	0.075	1.436	3.127	5.191	9.011
Algal TER:	30.2	880.0	38.1	30.0	880.0	46.0	21.1	12.7	**7.3**
Lemna TER:	12.4	360.0	15.6	12.3	360.0	18.8	**8.6**	**5.2**	**3.0**
Use in flower bulb crops:									
PEC_{sw} * [µg a.s./L]	2.175	0.075	1.692	2.197	0.082	3.442	3.026	5.206	8.74
Algal TER:	30.3	880.0	39.0	30.0	804.9	19.2	21.8	12.7	**7.6**
Lemna TER:	12.4	360.0	16.0	12.3	329.3	**7.8**	**8.9**	**5.2**	**3.1**

* In scenarios where it is possible to grow a second crop, the maximum PECsw value for the crop which gives the higher exposure value is included.

Maximum (peak) PECsw values taken from Table B.8.162 (spinach) and B.8.163 (flower bulbs) of Section B.6

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Ecotoxicology

Based on extrapolation of asulam toxicity endpoints assuming a 10 fold higher toxicity of the AP formamide metabolite.

Step 3 TERs for MCAPAP carbamic acid (aquatic photodegradate):

Scenario type	Exposure from spray drift plus drain flow #				Exposure from spray drift plus run-off #				
	D3	D4	D4	D6	R1	R1	R2	R3	R4
Water body	ditch	pond	stream	ditch	pond	stream	stream	stream	stream
Assumed algal 72 h E_rC_{50} [µg a.s./L]##	66	66	66	66	66	66	66	66	66
Assumed *Lemna* 7 day E_rC_{50} [µg a.s./L]##	27	27	27	27	27	27	27	27	27
Use in spinach crops:									
PEC_{sw} * [µg a.s./L]	2.375	0.082	1.885	2.391	0.082	1.562	3.403	5.65	9.806
Algal TER:	27.8	804.9	35.0	27.6	804.9	42.3	19.4	11.7	**6.7**
Lemna TER:	11.4	329.3	14.3	11.3	329.3	17.3	**7.9**	**4.8**	**2.8**
Use in flower bulb crops:									
PEC_{sw} * [µg a.s./L]	2.367	0.082	1.842	2.391	0.089	3.746	3.293	5.665	9.512
Algal TER:	27.9	804.9	35.8	27.6	741.6	17.6	20.0	11.7	**6.9**
Lemna TER:	11.4	329.3	14.7	11.3	303.4	**7.2**	**8.2**	**4.8**	**2.8**

* In scenarios where it is possible to grow a second crop, the maximum PECsw value for the crop which gives the higher exposure value is included.

Maximum (peak) PECsw values taken from Table B.8.162 (spinach) and B.8.163 (flower bulbs) of Section B.6.

Based on extrapolation of asulam toxicity endpoints assuming a 10 fold higher toxicity of the MCAPAP carbamic acid metabolite.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Ecotoxicology

Step 4 TERs for asulam with 80% run-off mitigation (i.e. surrounding vegetative strip):

One application of 2.4 kg asulam/ha to spinach (pre or post-emergence) and flower bulb crops (post-emergence)

Scenario type	Exposure from spray drift plus drain flow #				Exposure from spray drift plus run-off #				
	D3	D4	D4	D6	R1	R1	R2	R3	R4
Water body	ditch	pond	stream	ditch	pond	stream	stream	stream	stream
Use in spinach crops:									
PEC_{sw} * [µg a.s./L]	15.253	0.527	12.102	15.350	0.525	10.032	13.492	14.187	14.946
72 h E_rC_{50} [µg a.s./L]	270								
TER	17.7	512.3	22.3	17.6	514.3	26.9	20.0	19.0	18.1
Use in flower bulb crops:									
PEC_{sw} * [µg a.s./L]	15.199	0.527	11.827	15.350	0.525	10.025	13.151	14.185	14.514
72 h E_rC_{50} [µg a.s./L]	270								
TER	17.8	512.3	22.8	17.6	514.3	26.9	20.5	19.0	18.6

* In scenarios where it is possible to grow a second crop, the maximum PECsw value for the crop which gives the higher exposure value is included.

Maximum (peak) FOCUS Step 4 PECsw values estimated in Section 8.6 (Tables B.8.154 and B.8.155 for spinach and flower bulb crops respectively).

Step 4 TERs for sulphanilic acid (aquatic photodegradate) with 5 metre spray drift buffer zone and 80% run-off mitigation:

Scenario type	Exposure from spray drift plus drain flow #				Exposure from spray drift plus run-off #				
	D3	D4	D4	D6	R1	R1	R2	R3	R4
Water body	ditch	pond	stream	ditch	pond	stream	stream	stream	stream
Assumed algal 72 h E_rC_{50} [µg a.s./L]##	66	66	66	66	66	66	66	66	66
Assumed *Lemna* 7 day E_rC_{50} [µg a.s./L]##	27	27	27	27	27	27	27	27	27
Use in spinach crops:									
PEC_{sw} * [µg a.s./L]	1.726	0.191	1.846	2.348	0.19	1.53	2.111	3.526	6.239
Algal TER:	38.2	345.5	35.8	28.1	347.4	43.1	31.3	18.7	10.6
Lemna TER:	15.6	141.4	14.6	11.5	142.1	17.6	12.8	**7.7**	**4.3**
Use in flower bulb crops:									
PEC_{sw} * [µg a.s./L]	1.72	0.191	1.804	1.786	0.19	2.161	2.044	3.542	6.059
Algal TER:	38.4	345.5	36.6	37.0	347.4	30.5	32.3	18.6	10.9
Lemna TER:	15.7	141.4	15.0	15.1	142.1	12.5	13.2	**7.6**	**4.5**

* In scenarios where it is possible to grow a second crop, the maximum PECsw value for the crop which gives the higher exposure value is included.

Maximum (peak) PECsw values taken from Table B8.164 and Table B.8.165 of Section B.8.6 of Volume 3.

Based on extrapolation of asulam toxicity endpoints assuming a 10 fold higher toxicity of the sulphanilic acid metabolite.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Ecotoxicology

Step 4 TERs for AP formamide (aquatic photodegradate) with 5 metre spray drift buffer zone and 80% run-off mitigation:

Scenario type	Exposure from spray drift plus drain flow #				Exposure from spray drift plus run-off #				
	D3	D4	D4	D6	R1	R1	R2	R3	R4
Water body	ditch	pond	stream	ditch	pond	stream	stream	stream	stream
Assumed algal 72 h E_rC_{50} [µg a.s./L] ##	66	66	66	66	66	66	66	66	66
Assumed *Lemna* 7 day E_rC_{50} [µg a.s./L] ##	27	27	27	27	27	27	27	27	27
Use in spinach crops:									
PEC_{sw} * [µg a.s./L]	0.592	0.065	0.633	0.805	0.065	0.524	0.724	1.209	2.139
Algal TER:	111.5	1015.4	104.3	82.0	1015.4	126.0	91.2	54.6	30.9
Lemna TER:	45.6	415.4	42.7	33.5	415.4	51.5	37.3	22.3	12.6
Use in flower bulb crops:									
PEC_{sw} * [µg a.s./L]	0.589	0.065	0.618	0.612	0.065	0.741	0.701	1.214	2.077
Algal TER:	112.1	1015.4	106.8	107.8	1015.4	89.1	94.2	54.4	31.8
Lemna TER:	45.8	415.4	43.7	44.1	415.4	36.4	38.5	22.2	13.0

* In scenarios where it is possible to grow a second crop, the maximum PECsw value for the crop which gives the higher exposure value is included.
# Maximum (peak) PECsw values taken from Table B8.164 and Table B.8.165 of Section B.8.6.
Based on extrapolation of asulam toxicity endpoints assuming a 10 fold higher toxicity of the AP formamide metabolite.

Step 4 TERs for 'MCAPAP carbamic acid' (aquatic photodegradate) with 5 metre spray drift buffer zone and 80% run-off mitigation:

Scenario type	Exposure from spray drift plus drain flow #				Exposure from spray drift plus run-off #				
	D3	D4	D4	D6	R1	R1	R2	R3	R4
Water body	ditch	pond	stream	ditch	pond	stream	stream	stream	stream
Assumed algal 72 h E_rC_{50} [µg a.s./L] ##	66	66	66	66	66	66	66	66	66
Assumed *Lemna* 7 day E_rC_{50} [µg a.s./L] ##	27	27	27	27	27	27	27	27	27
Use in spinach crops:									
PEC_{sw} * [µg a.s./L]	0.644	0.071	0.689	0.876	0.071	0.571	0.788	1.315	2.328
Algal TER:	102.5	929.6	95.8	75.3	929.6	115.6	83.8	50.2	28.4
Lemna TER:	41.9	380.3	39.2	30.8	380.3	47.3	34.3	20.5	11.6
Use in flower bulb crops:									
PEC_{sw} * [µg a.s./L]	0.641	0.071	0.673	0.666	0.071	0.806	0.762	1.321	2.26
Algal TER:	103.0	929.6	98.1	99.1	929.6	81.9	86.6	50.0	29.2
Lemna TER:	42.1	380.3	40.1	40.5	380.3	33.5	35.4	20.4	11.9

* In scenarios where it is possible to grow a second crop, the maximum PECsw value for the crop which gives the higher exposure value is included.
# Maximum (peak) PECsw values taken from Table B8.164 and Table B.8.165 of Section B.8.6.
Based on extrapolation of asulam toxicity endpoints assuming a 10 fold higher toxicity of the MCAPAP carbamic acid metabolite.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Ecotoxicology

Bioconcentration	
	Active substance
Log P_{OW}	0.15
Bioconcentration factor (BCF) ‡:	No standard study (i.e. to OECD 305) conducted.
Uniform Principles trigger for bioconcentration factor:	100
Clearance time (days) (CT_{50})	-
Clearance time (days) (CT_{90})	-

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
Asulam ‡	> 123.7 µg asulam/bee	> 100 µg asulam/bee
Preparation	-	-
Field or semi-field tests		
Not required		

Hazard quotients for honey bees (Annex IIIA, point 10.4)

One application of 2.4 kg asulam/ha to spinach

Test substance	Route	Hazard quotient	Annex VI Trigger
Asulam	Contact	< 24	50
Asulam	Oral	< 19.4	50

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Most sensitive reported laboratory glassplate dose response tests with standard 'Tier 1' ESCORT2 test species

Species	Test Substance	End point	Effect
Typhlodromus pyri ‡	Asulox	Mortality LR_{50}	LR_{50} = 7.566 L Asulox/ha
Aphidius rhopalosiphi ‡	Asulox	Mortality LR_{50}	LR_{50} = 3.088 L Asulox/ha

One application of 6 litres 'Asulox' /ha (2.4 kg asulam /ha) to spinach (pre or post-emergence) and flower bulb crops (post-emergence)

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Ecotoxicology

Test substance	Species	Effect (LR_{50})	HQ in-field	HQ off-field *	Trigger
Asulox	*Typhlodromus pyri*	7.566 L product /ha	0.79	0.02	2
Asulox	*Aphidius rhopalosiphi*	3.088 L product /ha	1.94	0.05	2

* Spray drift assumed to be 2.77% of in-field dose (at 1m distance, from 1 application in crop)

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Effect measured	Dose (L Asulox /ha)	Percentage reduction*	Trigger value
Aphidius rhopalo-siphi	Adults	Exposure to fresh dry Asulox residues on barley seedlings	Mortality	0.44 11	0% 0%	50 %
			Parasitism	0.44 11	27% 21%	
Typhlo-dromus pyri	Proto-nymphs	Exposure to fresh dry Asulox residues on bean leaves	Mortality	0.44 11	16% 38%	50 %
			Fecundity	0.44 11	51% 75%	
Aleochara bilineata	Adults	Exposure to fresh dry Asulox residues on glass plates	Emergence	0.276 1.10 27.6	9% 11% 11%	50%
Chryso-perla carnea	Larvae	Exposure to fresh dry Asulox residues on glass plates	Mortality	0.051 0.204 5.10	4.8% 4.8% 0%	50%
			Fertility	0.051 0.204 5.10	0% 0% 1%	
Pardosa	Immature adults	Exposure to fresh Asulox residues on moist sand substrate	Mortality	9.18	0%	50%
			Food consumption	9.18	0%	
Hypoaspis aculeifer	Proto-nymphs	Exposure to fresh Asulox residues on moist sand substrate	Mortality	400	0%	50%
			Repro-duction	400	0%	

* Control corrected values

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Ecotoxicology

Field or semi-field tests
Not required

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point*
Earthworms			
Eisenia fetida	Asulam ‡	Acute 14 days	LC_{50} =1004 mg asulam /kg dw soil
Eisenia fetida	Asulam ‡	Chronic 8 weeks	NOEC = 180.7 mg asulam /kg dw soil
Eisenia fetida	Sulphanilamide (major soil metabolite)	Acute	LC_{50} > 1000 mg sulphanilamide /kg dw soil
Eisenia fetida	Sulphanilamide (major soil metabolite)	Chronic 8 weeks	NOEC = 3.75 mg sulphanilamide /kg dw soil
Other soil macro-organisms			
Hypoaspis aculeifer (soil mite)	Asulam ‡	Acute	LR_{50} > 4370 mg a.s. /kg dw soil
Folsomia candida (collembola)	Sulphanilamide (major soil metabolite)	Chronic 28 day s	NOAEC = 50 mg sulphanilamide /kg dw soil.
Soil micro-organisms			
Nitrogen mineralisation	Asulam ‡	56 days	< 25% effect by day 56 at up to 16 mg asulam/kg dw soil.
Carbon mineralisation	Asulam ‡	56 days	< 25% effects by day 28 at up to 160 mg asulam/kg dw soil
Nitrogen mineralisation	Sulphanilamide (major soil metabolite)	28 days	< 25% effects by day 28 at up to 3.3 mg metabolite /kg dw soil
Field studies			
Not required			

* EPPO correction factor not required as log Pow < 2.0, for both asulam and sulphanilamide.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Ecotoxicology

Toxicity/exposure ratios for soil macro-organisms

One application of 2.4 kg asulam /ha to spinach (pre or post-emergence) and flower bulb crops (post-emergence)

Test organism	Test substance	Time scale	Soil PEC_i	TER	Trigger
Earthworms					
Eisenia fetida	Asulam ‡	Acute	3.2 mg asulam. /kg dw soil	313.7	10
Eisenia fetida	Asulam ‡	Chronic (8 weeks)	3.2 mg asulam /kg dw soil	56.5	5
Eisenia fetida	Sulphanilamide (major soil metabolite)	Acute	0.41 mg met. /kg dw soil	> 2439	10
Eisenia fetida	Sulphanilamide (major soil metabolite)	Chronic (8 weeks)	0.41 mg met. /kg dw soil	9.1	5
Other soil macro-organisms					
Hypoaspis aculeifer (soil mite)	Asulam ‡	Acute	3.2 mg a.s. /kg soil	> 1366	5
Folsomia candida	Sulphanilamide (major soil metabolite)	Chronic (4 weeks)	0.41	122	5

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data

Not required

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Ecotoxicology

Laboratory dose response tests

Most sensitive species	Test sub-stance	Vegetative vigour EC_{50} (g/ha) (post-emer. effects)	Emergence ER_{50} (g/ha) (pre-emergence effects)	Distance (m)	Drift rate (%)	Exposure (g/ha)	TER	Trigger
Lettuce	a.s.	-	228g asulam /ha	0	100	2400	0.095	-
				1	2.77	66.48	**3.43**	5
				5	0.57	13.68	16.67	5
Cucumber	a.s.	11g asulam/ha	-	0	100	2400	0.0046	-
				1	2.77	66.48	**0.17**	5
				5	0.57	13.68	**0.80**	5
				10	0.29	6.96	**1.58**	5
				20	0.15	3.60	**3.06**	5
				30	0.10	2.40	**4.58**	5
				40	0.07	1.68	6.55	5

Higher-tier risk assessment:
Based on most sensitive reported vegetative vigour (post-emergence) ER50 of 11g /ha a no-spray buffer zone of 40 metres would be required to provide a low risk to non-target plants (in off-crop areas). However, based on a probabistic risk assessment which takes into account the distribution of sensitivity – a vegetative vigour HC5 value of 13.82g asulam /ha has been estimated. Based on current SANCO/10329 (2002) risk assessment guidance, the risk is acceptable provided exposure does not exceed this value – indicating that a 5 metre no-spray buffer zone (or other equivalent exposure mitigation measures) will be sufficient to provide an acceptable risk to non-target plants.

Additional studies (e.g. semi-field or field studies)

Not required

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	End point
Activated sludge	3 hour EC_{50} > 1000 mg asulam /L. 3 hour NOEC = 1000 mg asulam /L.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points (based on EPCO Manual E4 - rev. 4 (September 2005))

Rapporteur Member State	Month and year	Active Substance (Name)
United Kingdom	March 2016	Asulam sodium

Ecotoxicology

Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	Compound
Soil	Asulam #
Surface water	Asulam, sulphanilamide *
Sediment	None **
Ground water	None present (from proposed use in spinach and flower bulb crops)

Sulphanilamide may be present as a major metabolite in soil but is likely to pose a lower risk to soil organisms than asulam; on this basis it is not classed as ecotoxicologically relevant.
* The photodegradates sulphanilic acid, AP formamide, MCAPAP carbamate may also occur in surface water, however given their presence at lower concentrations than the a.s. and their likely lower toxicity to aquatic life, they are not considered 'ecotoxicologically relevant'.
** Although both asulam and sulphanilamide may occur in sediment, given their likely low toxicity to sediment dwelling invertebrates, residues are not considered ecotoxicologically relevant.

Air: None

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/peer review proposal
Active substance	It is recommended that under the CLP Regulation asulam sodium is classified as 'Acute Category 1' and 'Chronic category 1', with the following labelling requirements: 'GHS09 Pictogram' and associated signal word 'Warning' Hazard statement: H410 'Very toxicity to aquatic life with long lasting effects' (which also covers need for 'acute category 1' related 'H400' hazard statement) Precautionary statements: 'P391' and 'P501' are required.

	RMS/peer review proposal
Preparation	It is recommended that under the CLP Regulation the preparation 'Asulox' is classified as 'Acute Category 1' and 'Chronic category 1', with the following labelling requirements: 'GHS09 Pictogram' and associated signal word 'Warning' Hazard statement: H410 'Very toxicity to aquatic life with long lasting effects' (which also covers need for 'acute category 1' related 'H400' hazard statement) Precautionary statements: 'P391' and 'P501' are required.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
Bobwhite quail (*Colinus virginianus*)	Asulam sodium	Acute	LD_{50} > 1825.6 mg asulam /kg bw	Not applicable
Mallard duck *(Anas platyrhynchos)*	'Asulox'	Short-term	LD_{50} > 22732 mg asulam /kg bw /day	LC50 >100000 mg asulam /kg feed
Pheasant *(Phasianus colchicus)*	'Asulox'	Short-term	Not calculable#	LC50 >75000 mg asulam /kg feed
Japanese quail (*Coturnix coturnix japonica*)	Asulam sodium	Long-term	NOEL < 65 mg asulam /kg bw /day **NOAEL = 65 mg asulam /kg bw /day**	NOEC < 500 mg asulam /kg feed NOAEC = 500 mg asulam /kg feed
Japanese quail (*Coturnix coturnix japonica*)	Asulam sodium	Long-term	NOEL 19 mg asulam /kg bw /day NOAEL = 93.8 mg asulam /kg bw /day	NOEC 100 mg asulam /kg feed NOAEC = 500 mg asulam /kg feed
Mammals ‡				
Rat	Asulam sodium	Acute	LD_{50} > 4564 mg asulam/kg bw	Not applicable
Rat	'Asulox'	Acute	LD_{50} > 2000 mg product /kg bw	Not applicable
Rat	Asulam sodium	Long-term	NOEL = 46 mg asulam/kg bw	1000 mg asulam /kg feed
Additional higher tier studies ‡				
Details have been provided for a field study monitoring the foraging behaviour of birds and mammals in maize and sugar beet fields in Austria (ref. Wolf C 2005). Radio-tracking data reported in this study for skylarks foraging in seedling sugar beet fields indicate for 'potential consumers' (i.e. individuals whose home ranges included newly emerged beet crops) a 90th percentile PT value of 0.6 (i.e. 0.6 of total diet obtained in seedling beet fields) and a mean PT value of 0.18, based on observations on a limited number of tracked birds (n = 9). These data need to be considered with other available data (e.g. UK published data relating to a larger data set) and have not been specifically used in the current risk assessment.				

Unable to convert to 'dose' due to unreliable food consumption data as a result of food wastage by birds, plus indications of reduced food consumption at 75000 mg /kg diet.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3):

Crop use: early post crop emergence in spinach, as one application of 2.4 kg asulam /ha.

'Indicator species' (screening step) or 'generic focal species' (Tier 1 and refined RA)	Time scale	DDD	TER	Uniform Principles Trigger
Screening step (Birds): Use in spinach and flower bulb crops				
Small granivorous bird (pre-crop emergence use in spinach)	Acute	59.3	> 31	10
Small omnivorous bird (post-crop emergence use in spinach and flower bulbs)	Acute	381	**> 4.8**	10
Small granivorous bird (pre-crop emergence use in spinach)	Long-term	14.5	**4.5**	5
Small omnivorous bird (post-crop emergence use in spinach and flower bulbs)	Long-term	82.4	**0.8**	5
Tier 1 (Birds): Use in spinach ('Leafy vegetables')				
Small granivorous bird (post-emergence use)	Acute	65.8	> 27.7	10
Small omnivorous bird (post-emergence use)	Acute	57.6	> 31.7	10
Medium herbivorous bird (post-emergence use)	Acute	217.0	**> 8.4**	10
Small insectivorous bird (post-emergence use)	Acute	64.3	> 28.4	10
Small granivorous bird (pre-emergence use)	Long-term	14.5	**4.5**	5
Small omnivorous bird (pre-emergence use)	Long-term	10.43	6.3	5
Small insectivorous bird (pre-emergence use)	Long-term	7.5	8.7	5
Small granivorous bird (post-emergence use)	Long-term	16.02	**4.1**	5
Small omnivorous bird (post-emergence use)	Long-term	13.86	**4.7**	5
Medium herbivorous bird (post-emergence use)	Long-term	47.06	**1.4**	5
Small insectivorous bird (post-emergence use)	Long-term	14.37	**4.5**	5
Tier 1 (Birds): Use in flower bulbs ('Bulbs and onion like crops')				
Small granivorous bird (post-emergence use)	Acute	59.28	>30.8	
Small omnivorous bird (post-emergence use)	Acute	57.6	>31.7	
Small insectivorous bird (post-emergence use)	Acute	64.3	>28.4	5
Small granivorous bird (post-emergence use)	Long-term	14.5	**4.5**	
Small omnivorous bird (post-emergence use)	Long-term	13.86	**4.7**	
Small insectivorous bird (post-emergence use)	Long-term	14.37	**4.5**	
Small granivorous bird (post-emergence use)	Acute	59.28	>30.8	
Refined avian risk assessment: Use in spinach ('Leafy vegetables'):				

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

'Indicator species' (screening step) or 'generic focal species' (Tier 1 and refined RA)	Time scale	DDD	TER	Uniform Principles Trigger
Refined acute risk assessment for 'medium herbivorous bird' (post-crop emergence): Based on use of a refined acute LD50 – with inclusion of 'extrapolation factor' (from Table 1 of Section 2.1.2 of EFSA 2009 guidance) = 1825.6 x 1.888 = 3446.7 mg asulam /kg bw /day.	Acute	217.0	15.9	10
Refined long-term risk assessment for small granivorous bird (pre and post crop emergence) - using the Linnet as 'focal species':	Long-term	8.45	7.7	5
Refined long-term risk assessment for 'small omnivorous bird' (post-emergence use) – based on use of foliar residue data indicating a DT_{50} of 1.44 days (in place of the 'Tier 1' default DT_{50} = 10 days).	Long-term	12.26	5.3	5
Refined long-term risk assessment for 'small insectivorous bird' (post-emergence use) using the yellow wagtail as focal species. Note: Taking into account the conservatism of several areas of the exposure assessment (particularly in relation to use of a PT of 1.0) the DDD is considered by the RMS to be an over-estimate - such that the actual TER is likely to be in excess of the trigger value of 5, indicating an acceptable risk.	Long-term	15.8	**4.1**	5
<u>Refined avian risk assessment: Use in flower bulb crops ('Bulbs and onion like crops'):</u>				
Refined long-term risk assessment for small granivorous bird (post crop emergence) - using the Linnet as 'focal species':	Long-term	8.45	7.7	5
Refined long-term risk assessment for 'small omnivorous bird' (post-emergence use) – based on use of foliar residue data indicating a DT_{50} of 1.44 days (in place of the 'Tier 1' default DT_{50} = 10 days).	Long-term	12.26	5.3	5
Refined long-term risk assessment for 'small insectivorous bird' (post-emergence use) using the yellow wagtail as focal species. Note: Taking into account the conservatism of several areas of the exposure assessment (particularly in relation to use of a PT of 1.0) the DDD is considered by the RMS to be an over-estimate - such that the actual TER is likely to be in excess of the trigger value of 5, indicating an acceptable risk.	Long-term	15.8	**4.1**	5
<u>Screening step (Wild mammals): Use in spinach and flower bulb crops</u>				
Small granivorous mammal (pre-crop emergence use in spinach)	Acute	34.6	> 131.9	10
Small herbivorous mammal (post-crop emergence use in flower bulbs)	Acute	284.2	> 16.1	10

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

'Indicator species' (screening step) or 'generic focal species' (Tier 1 and refined RA)	Time scale	DDD	TER	Uniform Principles Trigger
Small herbivorous mammal (post-crop emergence use in spinach)	Acute	327.4	> 13.9	10
Small granivorous mammal (pre-crop emergence use in spinach)	Long-term	8.4	5.5	5
Small herbivorous mammal (post-crop emergence use in flower bulbs)	Long-term	61.4	**0.7**	5
Small herbivorous mammal (post-crop emergence use in spinach)	Long-term	92.0	**0.5**	5
Tier 1 (Wild mammals): Use in spinach ('Leafy vegetables')				
Small insectivorous mammal (post-emergence use)	Long-term	5.3	8.7	5
Large herbivorous mammal (post-emergence use)	Long-term	18.2	**2.5**	5
Small omnivorous mammal (post-emergence use)	Long-term	9.9	**4.6**	5
Tier 1 (Wild mammals): Use in flower bulbs ('Bulbs and onion like crops')				
Small insectivorous mammal (post-emergence use)	Long-term	5.3	8.7	5
Small herbivorous mammal (post-emergence use)	Long-term	55.2	**0.8**	5
Small omnivorous mammal (post-emergence use)	Long-term	6.0	7.7	5
Refined wild mammal risk assessment: Use in spinach ('Leafy vegetables'):				
Refined long-term risk assessment for 'large herbivorous mammal' (post-crop emergence) – based on use of foliar residue data indicating a DT_{50} of 1.44 days (in place of the 'Tier 1' default DT_{50} = 10 days).	Long-term	3.39	13.6	5
Refined long-term risk assessment for 'small omnivorous mammal' (post-crop emergence) – based on use (for consumed weeds) of refined foliar residue DT_{50} of 1.44 days (in place of the 'Tier 1' default DT_{50} = 10 days).	Long-term	8.01	5.7	5
Refined wild mammal risk assessment: Use in flower bulb crops ('Bulbs and onion like crops'):				
Refined long-term risk assessment for 'small herbivorous mammal' (post-crop emergence) – based on use of foliar residue data indicating a DT_{50} of 1.44 days (in place of the 'Tier 1' default DT_{50} = 10 days). Note: The exposure assessment is considered conservative in assuming a PT=1 and also in assuming a dietary spray interception level of 60% given that voles as the representative 'small herbivore' species will only feed in habitats providing good cover. Therefore in practice the TER is likely to be >5.0 – indicating an acceptable risk.	Long-term	10.3	**4.5**	5

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

'Indicator species' (screening step) or 'generic focal species' (Tier 1 and refined RA)	Time scale	DDD	TER	Uniform Principles Trigger
Risk to fish-eating and earthworm-eating birds and mammals from potential secondary poisoning via bio-accumulation in fish and earthworms.				
Given a Pow for asulam sodium and its major environmental metabolites of less than the bioaccumulation trigger value of log 3.0 (asulam log Pow = 0.15), there is a lack of potential for bioaccumulation and therefore there is a low risk to fish-eating and earthworm-eating birds and wild mammals				
Risk to birds and wild mammals from exposure via contaminated drinking water				
For the proposed crop uses only a 'puddle water scenario' needs to be considered. As per EFSA (2009) guidance, no specific calculations of exposure and TER are necessary when the ratio of the effective application rate (in g/ha) to the acute and long-term relevant endpoints (in mg/kg bw/d) does not exceed 50 for 'less sorptive substances' with a Koc of <500 L/kg (which is the case for asulam – Koc = 25.4, ref. Section B.8.6 of current Volume 3 DAR). Therefore, an initial risk assessment has been conducted on this basis first, with a further refined risk assessment conducted if required: Avian drinking water risk assessment Acute risk ratio = < 1.3 Long-term risk ratio = 36.9 Therefore for the proposed crop uses both the acute and long-term ratios are within the required risk ratio trigger value of 50 - indicating a low risk to birds from consumption of contaminated drinking water. Wild mammal drinking water risk assessment Acute risk ratio < 0.53 Long-term risk ratio = 52 The acute risk ratio is within the trigger value of 50 but the long-term risk ratio is in breach of this value - indicating a low acute risk to wild mammals from comtaminated drinking water but the need for a further refined EFSA (2009) risk assessment to assess the potential risk from long-term effects. Using the EFSA (2009) Excel spreadsheet and based on a maximum dose of 2400g asulam /ha, a concentration in spray from the proposed crop uses of 12 grams /L (maximum dose divided by minimum spray volume of 200 L /ha), an asulam Koc value = 25.4 L/Kg and a long-term NOAEL of 46 mg asulam /kg bw /day, the long-term drinking water TER = 46.4. This long-term TER is in excess of the required long-term TER trigger value of 5 - indicating a low long-term risk to wild mammals. Therefore, for the proposed crop uses there is a low risk to wild mammals from consumption of contaminated drinking water.				

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale (Test type)	End point	Toxicity # (mg/L)
Laboratory tests ‡				
Fish				
Lepomis macrochirus	Asulam sodium	96 hr (semi-static)	LC_{50}	**> 91.3 mg asulam/L** (nom.)
Oncorhynchus mykiss	Asulam sodium	96 hr (static)	LC_{50}	>159.8 mg asulam/L (m.m.)
Oncorhynchus mykiss	Asulam	28 d (flow-through)	NOEC	**119.1 mg asulam/L** (m.m.)
Aquatic invertebrates				
Daphnia magna	Asulam sodium	48 h (flow-through)	EC_{50} (Immobilisation)	57.87 mg asulam/L (m.m.)
Daphnia magna	'Asulam 80 SG'	20 d (semi-static)	NOEC	8.96 mg asulam/L (nom.) ##
Daphnia magna	Asulam	21 d (semi-static)	NOEC	6.4 mg asulam/L
Sediment dwelling organisms				
Chironomus riparius	Asulam	28 d (static)	NOEC	91.3 mg asulam/L (nominal. – assuming all applied active in water phase) ##
Algae				
Pseudokirchneriella subcapitata	Asulam sodium	120 hr (static)	E_bC_{50} (72h) E_rC_{50} (72 h)	0.06 mg asulam /L (m.m.) 1.73 mg asulam /L (m.m.)
Anabaena flosaquae	Asulam sodium	120 h (static)	E_bC_{50} (72h) **E_rC_{50} (72 h)**	0.15 mg asulam /L (m.m.) >0.66 mg asulam /L (m.m.)
Navicula pelliculosa	Asulam sodium	120 hr (static)	E_bC_{50} (72h) E_bC_{50} (120h) **E_rC_{50}**	3.1 mg asulam /L (m.m.) 2.1 mg asulam /L (m.m.) Not calculated
Skeletonema costatum	Asulam sodium	120 hr (static)	E_bC_{50} (96h) E_rC_{50} (72 h)	0.146 mg asulam /L (m.m.) >1.64 mg asulam /L (m.m.)
Pseudokirchneriella subcapitata	Sulphanil-amide (metabolite)	120 hr (static)	E_bC_{50} (72h) E_rC_{50} (72 h)	7.6 mg met. /L (m.m.) >21.15 mg met. /L (m.m.)

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Group	Test substance	Time-scale (Test type)	End point	Toxicity # (mg/L)
Higher plant				
Lemna gibba	Asulam sodium	14 d (static)	Frond number E_bC_{50} E_rC_{50}	0.27 mg asulam /L (initial measured) 0.16 mg asulam /L (mean measured) Note: measured conc. 99% at test start and 15% at test end.
Lemna gibba	'Asulam 400g/L SL' (≡ Asulox)	7 day (static)	Frond number E_bC_{50} Frond number E_rC_{50}	0.106 mg asulam /L (nominal) 0.845 mg asulam /L (nominal)
Lemna paucicostata	Asulam	7 d (static) Non-GLP compliant.	E_rC_{50}	93.8 mg asulam /L (nom.) ##
Lemna minor	Sulphanil-amide (metabolite)	7 d (static)	E_yC_{50} E_rC_{50}	2.30 mg met. /L (nom.) 5.82 mg met. /L (nom.)
Myriophyllum spicatum, *Elodea nuttallii*, *Elodea canadensis*, *Ranunculus circinatus* and *Potamogeton crispus.*	'Asulox'	21 day non-standard multi-species higher aquatic plant growth inhibition study. Non-GLP compliant. ###	E_bC_{50}	0.0107 mg /L (nom.) for most sensitive tested species (*Myriophyllum spicatum).*
Myriophyllum spicatum.	'Asulam 400g/L SL' (= 'Asulox')	14 day *Myrio-phyllum spicatum* (OECD 2014) growth inhibition study ###	E_yC_{50} E_rC_{50}	0.39 mg asulam /L (nom.) >2.56 mg asulam /L (nom.)
<u>Microcosm or mesocosm tests</u>				
Not required or submitted.				

Based on mean measured (m.m.), initial measured, or nominal (nom.). Chemical analysis of test concentrations included unless indicated otherwise by ##.
These study endpoints are considered to be of limited reliability due to a lack of any chemical analysis to confirm nominal test concentrations.
Study non-GLP compliant and 95% confidence intervals for the most sensitive total dry weight E_bC_{50} of 10.7 µg/L are large i.e. 2-74 µg/L - indicating uncertainty in the accuracy of this determined endpoint. Given these deficiencies, the results of this study are not considered sufficiently reliable for regulatory use.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

One application of 2.4 kg asulam/ha to spinach (pre or post-emergence) and flower bulb crops (post-emergence)

FOCUS Step 1 TERs for asulam:

Test organism	Test type and duration	Toxicity endpoint (mg asulam/L)	Initial (maximum) PEC_{sw} (mg asulam/L)	TER	TER trigger
Fish (*Lepomis macrochirus*)	Acute, 96 h static test	LC_{50} > 91.3	0.796 #	>114.7	100
Fish (*Oncorhyn-chus mykiss*)	Chronic, 28 h flow through juvenile growth test	NOEC = 119.1		149.6	10
Daphnia magna	Acute, 48 h flow through test	EC_{50} = 57.87		**72.7**	100
	Chronic 21 day semi-static test	NOEC = 6.4		**8.0**	10
Chironomus riparius	Chronic 28 day spiked water test	NOEC = 91.3		111.1	10
Algae (*Anabaena flosaquae)*	Acute, 120 hour static test	72h E_rC_{50} > 0.66		**> 0.8**	10
Lemna gibba	Acute, 14 day static test	E_bC_{50} = 0.27 *		**0.3**	10

Figures in bold indicate a breaching of the Uniform Principles trigger value.

* Based on effects on frond number

Note: Focus Step 1 initial (maximum) PECsw values for proposed crop uses have been used in TER calculations except for sediment dwellers (Chironomid) where a FOCUS Step 1 'total load' PECsw of 822 µg asulam/L has been used.

FOCUS Step 1 TERs for major metabolite sulphanilamide:

Test organism	Test type and duration	Toxicity endpoint (mg/L)	PEC_{sw} # (mg/L)	TER	TER trigger
Pseudokirchneriella subcapitata (algae)	Acute, 120 h static test	72 h E_rC_{50} > 21.15	0.08635	244.9	10
Lemna minor (higher aquatic plant)	Acute, 7 day static test	7 day E_rC_{50} = 5.82		67.4	10

Note: Figures in bold indicate a breaching of the Annex VI trigger

Initial (maximum) Step 1 PECsw.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

FOCUS Step 2 for asulam:
One application of 2.4 kg asulam/ha to spinach (pre or post-emergence) and flower bulb crops (post-emergence)

Scenario	Test organism	Test type & duration	Toxicity endpoint (mg asulam/L)	Maximum PEC_{sw} (mg asulam/L)#	TER	TER trigger
Spinach - Southern Europe (March – May)	*Daphnia magna*	Acute, 48 h flow through test	EC_{50} 57.87	0.19015	304.3	100
		Chronic 21 day semi-static test	NOEC 6.4		33.7	10
	Algae (*Anabaena flosaquae)*	Acute, 72h static test	E_rC_{50} > 0.66		**> 3.5**	10
	Lemna gibba	Acute, 14 day static test	EC_{50} 0.27		**1.4**	10
Spinach - Northern Europe (March to May)	*Daphnia magna*	Acute, 48 h flow through test	EC_{50} 57.87	0.10554	548.3	100
		Chronic 21 day semi-static test	NOEC 6.4		60.6	10
	Algae (*Anabaena flosaquae*)	Acute, 72h static test	E_rC_{50} > 0.66		**> 6.3**	10
	Lemna gibba	Acute, 14 day static test	EC_{50} 0.27		**2.6**	10
Flower bulbs - Southern Europe (March – May)	*Daphnia magna*	Acute, 48 h flow through test	EC_{50} 57.87	0.17321	334.1	100
		Chronic 21 day semi-static test	NOEC 6.4		36.9	10
	Algae (*Anabaena flosaquae)*	Acute, 72h static test	E_rC_{50} > 0.66		**> 3.8**	10
	Lemna gibba	Acute, 14 day static test	EC_{50} 0.27		**1.6**	10
Flower bulbs - Northern Europe (March to May)	*Daphnia magna*	Acute, 48 h flow through test	EC_{50} 57.87	0.09698	596.7	100
		Chronic 21 day semi-static test	NOEC 6.4		66.0	10
	Algae (*Anabaena flosaquae*)	Acute, 72h static test	E_rC_{50} > 0.66		**> 6.8**	10
	Lemna gibba	Acute, 14 day static test	EC_{50} 0.27		**2.8**	10

Note: Figures in bold indicate a breaching of the Uniform Principles trigger value.
PECsw values taken from Table B.8.148 of Section B.8.6 of Volume 3.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Refined aquatic risk assessment using higher tier FOCUS modelling.
One application of 2.4 kg asulam/ha to spinach (pre or post-emergence) and flower bulb crops (post-emergence)

Step 3 TERs for asulam:
Organism: *Anabaena flosaquae* (algae)
Time scale: Acute

Scenario type	**Exposure from spray drift plus drain flow #**				**Exposure from spray drift plus run-off #**				
	D3	**D4**	**D4**	**D6**	**R1**	**R1**	**R2**	**R3**	**R4**
Water body	**ditch**	**pond**	**stream**	**ditch**	**pond**	**stream**	**stream**	**stream**	**stream**
Use in spinach crops:									
PEC_{sw} * [µg a.s./L]	15.253	0.527	12.102	15.350	0.525	10.032	21.850	36.279	62.969
72 h E_rC_{50} [µg a.s./L]	> 660								
TER	> 43.3	> 1252.4	> 54.5	> 43.0	>1257.1	> 65.8	> 30.2	> 18.2	> 10.5
Use in flower bulb crops:									
PEC_{sw} * [µg a.s./L]	15.199	0.527	11.827	15.350	0.570	24.052	21.145	36.379	61.081
72 h E_rC_{50} [µg a.s./L]	> 660								
TER	> 43.4	> 1252.4	> 55.8	> 43.0	>1157.9	> 27.4	> 31.2	> 18.1	> 10.8

* In scenarios where it is possible to grow a second crop, the maximum PECsw value for the crop which gives the higher exposure value is included.
# Maximum (peak) PECsw values taken from Table B.8.150 and B.8.151 of Section B.8.6 of Vol. 3.

Organism: *Lemna gibba* (higher aquatic plants)
Time scale: Acute

Scenario type	**Exposure from spray drift plus drain flow #**				**Exposure from spray drift plus run-off #**				
	D3	**D4**	**D4**	**D6**	**R1**	**R1**	**R2**	**R3**	**R4**
Water body	**ditch**	**pond**	**stream**	**ditch**	**pond**	**stream**	**stream**	**stream**	**stream**
Use in spinach crops:									
PEC_{sw} * [µg a.s./L]	15.253	0.527	12.102	15.350	0.525	10.032	21.850	36.279	62.969
72 h E_rC_{50} [µg a.s./L]	270								
TER	17.7	512.3	22.3	17.6	514.3	26.9	12.4	**7.4**	**4.3**
Use in flower bulb crops:									
PEC_{sw} * [µg a.s./L]	15.199	0.527	11.827	15.350	0.570	24.052	21.145	36.379	61.081
72 h E_rC_{50} [µg a.s./L]	270								
TER	17.8	512.3	22.8	17.6	473.7	11.2	12.8	**7.4**	**4.4**

* In scenarios where it is possible to grow a second crop, the maximum PECsw value for the crop which gives the higher exposure value is included.
# Maximum (peak) PECsw values taken from Table B.8.150 and B.8.151 of Section B.8.6 of Vol. 3.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Step 3 TERs for sulphanilic acid (aquatic photodegradate):

Scenario type	Exposure from spray drift plus drain flow #				Exposure from spray drift plus run-off #				
	D3	D4	D4	D6	R1	R1	R2	R3	R4
Water body	ditch	pond	stream	ditch	pond	stream	stream	stream	stream
Assumed algal 72 h E_rC_{50} [µg a.s./L] ##	66	66	66	66	66	66	66	66	66
Assumed *Lemna* 7 day E_rC_{50} [µg a.s./L]##	27	27	27	27	27	27	27	27	27
Use in spinach crops:									
PEC_{sw} * [µg a.s./L]	6.367	0.22	5.052	6.408	0.219	4.188	9.121	15.145	26.287
Algal TER:	10.4	300.0	13.1	10.3	301.4	15.8	**7.2**	**4.4**	**2.5**
Lemna TER:	**4.2**	122.7	**5.3**	**4.2**	123.3	**6.4**	**3.0**	**1.8**	**1.0**
Use in flower bulb crops:									
PEC_{sw} * [µg a.s./L]	6.345	0.22	4.937	6.408	0.238	10.041	8.827	15.187	25.499
Algal TER:	10.4	300.0	13.4	10.3	277.3	**6.6**	**7.5**	**4.3**	**2.6**
Lemna TER:	**4.3**	122.7	**5.5**	**4.2**	113.4	**2.7**	**3.1**	**1.8**	**1.1**

* In scenarios where it is possible to grow a second crop, the maximum PECsw value for the crop which gives the higher exposure value is included.
# Maximum (peak) PECsw values taken from Table B.8.162 (spinach) and B.8.163 (flower bulbs) of Section B.6
Based on extrapolation of asulam toxicity endpoints assuming a 10 fold higher toxicity of the sulphanilic acid metabolite.

Step 3 TERs forAP formamide:

Scenario type	Exposure from spray drift plus drain flow #				Exposure from spray drift plus run-off #				
	D3	D4	D4	D6	R1	R1	R2	R3	R4
Water body	ditch	pond	stream	ditch	pond	stream	stream	stream	stream
Assumed algal 72 h E_rC_{50} [µg a.s./L]##	66	66	66	66	66	66	66	66	66
Assumed *Lemna* 7 day E_rC_{50} [µg a.s./L]##	27	27	27	27	27	27	27	27	27
Use in spinach crops:									
PEC_{sw} * [µg a.s./L]	2.183	0.075	1.732	2.197	0.075	1.436	3.127	5.191	9.011
Algal TER:	30.2	880.0	38.1	30.0	880.0	46.0	21.1	12.7	**7.3**
Lemna TER:	12.4	360.0	15.6	12.3	360.0	18.8	**8.6**	**5.2**	**3.0**
Use in flower bulb crops:									
PEC_{sw} * [µg a.s./L]	2.175	0.075	1.692	2.197	0.082	3.442	3.026	5.206	8.74
Algal TER:	30.3	880.0	39.0	30.0	804.9	19.2	21.8	12.7	**7.6**
Lemna TER:	12.4	360.0	16.0	12.3	329.3	**7.8**	**8.9**	**5.2**	**3.1**

* In scenarios where it is possible to grow a second crop, the maximum PECsw value for the crop which gives the higher exposure value is included.
# Maximum (peak) PECsw values taken from Table B.8.162 (spinach) and B.8.163 (flower bulbs) of Section B.6
Based on extrapolation of asulam toxicity endpoints assuming a 10 fold higher toxicity of the AP formamide metabolite.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Step 3 TERs for MCAPAP carbamic acid (aquatic photodegradate):

Scenario type	Exposure from spray drift plus drain flow #				Exposure from spray drift plus run-off #				
	D3	D4	D4	D6	R1	R1	R2	R3	R4
Water body	ditch	pond	stream	ditch	pond	stream	stream	stream	stream
Assumed algal 72 h E_rC_{50} [µg a.s./L]##	66	66	66	66	66	66	66	66	66
Assumed *Lemna* 7 day E_rC_{50} [µg a.s./L]##	27	27	27	27	27	27	27	27	27
Use in spinach crops:									
PEC_{sw} * [µg a.s./L]	2.375	0.082	1.885	2.391	0.082	1.562	3.403	5.65	9.806
Algal TER:	27.8	804.9	35.0	27.6	804.9	42.3	19.4	11.7	**6.7**
Lemna TER:	11.4	329.3	14.3	11.3	329.3	17.3	**7.9**	**4.8**	**2.8**
Use in flower bulb crops:									
PEC_{sw} * [µg a.s./L]	2.367	0.082	1.842	2.391	0.089	3.746	3.293	5.665	9.512
Algal TER:	27.9	804.9	35.8	27.6	741.6	17.6	20.0	11.7	**6.9**
Lemna TER:	11.4	329.3	14.7	11.3	303.4	**7.2**	**8.2**	**4.8**	**2.8**

* In scenarios where it is possible to grow a second crop, the maximum PECsw value for the crop which gives the higher exposure value is included.
# Maximum (peak) PECsw values taken from Table B.8.162 (spinach) and B.8.163 (flower bulbs) of Section B.6.
Based on extrapolation of asulam toxicity endpoints assuming a 10 fold higher toxicity of the MCAPAP carbamic acid metabolite.

Step 4 TERs for asulam with 80% run-off mitigation (i.e. surrounding vegetative strip):

One application of 2.4 kg asulam/ha to spinach (pre or post-emergence) and flower bulb crops (post-emergence)

Scenario type	Exposure from spray drift plus drain flow #				Exposure from spray drift plus run-off #				
	D3	D4	D4	D6	R1	R1	R2	R3	R4
Water body	ditch	pond	stream	ditch	pond	stream	stream	stream	stream
Use in spinach crops:									
PEC_{sw} * [µg a.s./L]	15.253	0.527	12.102	15.350	0.525	10.032	13.492	14.187	14.946
72 h E_rC_{50} [µg a.s./L]	270								
TER	17.7	512.3	22.3	17.6	514.3	26.9	20.0	19.0	18.1
Use in flower bulb crops:									
PEC_{sw} * [µg a.s./L]	15.199	0.527	11.827	15.350	0.525	10.025	13.151	14.185	14.514
72 h E_rC_{50} [µg a.s./L]	270								
TER	17.8	512.3	22.8	17.6	514.3	26.9	20.5	19.0	18.6

* In scenarios where it is possible to grow a second crop, the maximum PECsw value for the crop which gives the higher exposure value is included.
# Maximum (peak) FOCUS Step 4 PECsw values estimated in Section 8.6 (Tables B.8.154 and B.8.155 for spinach and flower bulb crops respectively).

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Step 4 TERs for sulphanilic acid (aquatic photodegradate) with 5 metre spray drift buffer zone and 80% run-off mitigation:

Scenario type	Exposure from spray drift plus drain flow #				Exposure from spray drift plus run-off #				
	D3	D4	D4	D6	R1	R1	R2	R3	R4
Water body	ditch	pond	stream	ditch	pond	stream	stream	stream	stream
Assumed algal 72 h E_rC_{50} [µg a.s./L]##	66	66	66	66	66	66	66	66	66
Assumed *Lemna* 7 day E_rC_{50} [µg a.s./L]##	27	27	27	27	27	27	27	27	27
Use in spinach crops:									
PEC_{sw} * [µg a.s./L]	1.726	0.191	1.846	2.348	0.19	1.53	2.111	3.526	6.239
Algal TER:	38.2	345.5	35.8	28.1	347.4	43.1	31.3	18.7	10.6
Lemna TER:	15.6	141.4	14.6	11.5	142.1	17.6	12.8	**7.7**	**4.3**
Use in flower bulb crops:									
PEC_{sw} * [µg a.s./L]	1.72	0.191	1.804	1.786	0.19	2.161	2.044	3.542	6.059
Algal TER:	38.4	345.5	36.6	37.0	347.4	30.5	32.3	18.6	10.9
Lemna TER:	15.7	141.4	15.0	15.1	142.1	12.5	13.2	**7.6**	**4.5**

* In scenarios where it is possible to grow a second crop, the maximum PECsw value for the crop which gives the higher exposure value is included.
# Maximum (peak) PECsw values taken from Table B8.164 and Table B.8.165 of Section B.8.6 of Volume 3.
Based on extrapolation of asulam toxicity endpoints assuming a 10 fold higher toxicity of the sulphanilic acid metabolite.

Step 4 TERs for AP formamide (aquatic photodegradate) with 5 metre spray drift buffer zone and 80% run-off mitigation:

Scenario type	Exposure from spray drift plus drain flow #				Exposure from spray drift plus run-off #				
	D3	D4	D4	D6	R1	R1	R2	R3	R4
Water body	ditch	pond	stream	ditch	pond	stream	stream	stream	stream
Assumed algal 72 h E_rC_{50} [µg a.s./L] ##	66	66	66	66	66	66	66	66	66
Assumed *Lemna* 7 day E_rC_{50} [µg a.s./L] ##	27	27	27	27	27	27	27	27	27
Use in spinach crops:									
PEC_{sw} * [µg a.s./L]	0.592	0.065	0.633	0.805	0.065	0.524	0.724	1.209	2.139
Algal TER:	111.5	1015.4	104.3	82.0	1015.4	126.0	91.2	54.6	30.9
Lemna TER:	45.6	415.4	42.7	33.5	415.4	51.5	37.3	22.3	12.6
Use in flower bulb crops:									
PEC_{sw} * [µg a.s./L]	0.589	0.065	0.618	0.612	0.065	0.741	0.701	1.214	2.077
Algal TER:	112.1	1015.4	106.8	107.8	1015.4	89.1	94.2	54.4	31.8
Lemna TER:	45.8	415.4	43.7	44.1	415.4	36.4	38.5	22.2	13.0

* In scenarios where it is possible to grow a second crop, the maximum PECsw value for the crop which gives the higher exposure value is included.
# Maximum (peak) PECsw values taken from Table B8.164 and Table B.8.165 of Section B.8.6.
Based on extrapolation of asulam toxicity endpoints assuming a 10 fold higher toxicity of the AP formamide metabolite.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Step 4 TERs for 'MCAPAP carbamic acid' (aquatic photodegradate) with 5 metre spray drift buffer zone and 80% run-off mitigation:

Scenario type	Exposure from spray drift plus drain flow #				Exposure from spray drift plus run-off #				
	D3	D4	D4	D6	R1	R1	R2	R3	R4
Water body	ditch	pond	stream	ditch	pond	stream	stream	stream	stream
Assumed algal 72 h E_rC_{50} [µg a.s./L] ##	66	66	66	66	66	66	66	66	66
Assumed *Lemna* 7 day E_rC_{50} [µg a.s./L] ##	27	27	27	27	27	27	27	27	27
Use in spinach crops:									
PEC_{sw} * [µg a.s./L]	0.644	0.071	0.689	0.876	0.071	0.571	0.788	1.315	2.328
Algal TER:	102.5	929.6	95.8	75.3	929.6	115.6	83.8	50.2	28.4
Lemna TER:	41.9	380.3	39.2	30.8	380.3	47.3	34.3	20.5	11.6
Use in flower bulb crops:									
PEC_{sw} * [µg a.s./L]	0.641	0.071	0.673	0.666	0.071	0.806	0.762	1.321	2.26
Algal TER:	103.0	929.6	98.1	99.1	929.6	81.9	86.6	50.0	29.2
Lemna TER:	42.1	380.3	40.1	40.5	380.3	33.5	35.4	20.4	11.9

* In scenarios where it is possible to grow a second crop, the maximum PECsw value for the crop which gives the higher exposure value is included.
# Maximum (peak) PECsw values taken from Table B8.164 and Table B.8.165 of Section B.8.6.
Based on extrapolation of asulam toxicity endpoints assuming a 10 fold higher toxicity of the MCAPAP carbamic acid metabolite.

Bioconcentration	
	Active substance
Log P_{OW}	0.15
Bioconcentration factor (BCF) ‡:	No standard study (i.e. to OECD 305) conducted.
Uniform Principles trigger for bioconcentration factor:	100
Clearance time (days) (CT_{50})	-
Clearance time (days) (CT_{90})	-

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
Asulam ‡	> 123.7 µg asulam/bee	> 100 µg asulam/bee
Preparation	-	-
Field or semi-field tests		
Not required		

Hazard quotients for honey bees (Annex IIIA, point 10.4)

One application of 2.4 kg asulam/ha to spinach

Test substance	Route	Hazard quotient	Annex VI Trigger
Asulam	Contact	< 24	50
Asulam	Oral	< 19.4	50

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Most sensitive reported laboratory glassplate dose response tests with standard 'Tier 1' ESCORT2 test species

Species	Test Substance	End point	Effect
Typhlodromus pyri ‡	Asulox	Mortality LR_{50}	LR_{50} = 7.566 L Asulox/ha
Aphidius rhopalosiphi ‡	Asulox	Mortality LR_{50}	LR_{50} = 3.088 L Asulox/ha

One application of 6 litres 'Asulox' /ha (2.4 kg asulam /ha) to spinach (pre or post-emergence) and flower bulb crops (post-emergence)

Test substance	Species	Effect (LR_{50})	HQ in-field	HQ off-field *	Trigger
Asulox	*Typhlodromus pyri*	7.566 L product /ha	0.79	0.02	2
Asulox	*Aphidius rhopalosiphi*	3.088 L product /ha	1.94	0.05	2

* Spray drift assumed to be 2.77% of in-field dose (at 1m distance, from 1 application in crop)

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Effect measured	Dose (L Asulox /ha)	Percentage reduction*	Trigger value
Aphidius rhopalo-siphi	Adults	Exposure to fresh dry Asulox residues on barley seedlings	Mortality	0.44 11	0% 0%	50 %
			Parasitism	0.44 11	27% 21%	
Typhlo-dromus pyri	Proto-nymphs	Exposure to fresh dry Asulox residues on bean leaves	Mortality	0.44 11	16% 38%	50 %
			Fecundity	0.44 11	51% 75%	
Aleochara bilineata	Adults	Exposure to fresh dry Asulox residues on glass plates	Emergence	0.276 1.10 27.6	9% 11% 11%	50%
Chryso-perla carnea	Larvae	Exposure to fresh dry Asulox residues on glass plates	Mortality	0.051 0.204 5.10	4.8% 4.8% 0%	50%
			Fertility	0.051 0.204 5.10	0% 0% 1%	
Pardosa	Immature adults	Exposure to fresh Asulox residues on moist sand substrate	Mortality	9.18	0%	50%
			Food consumption	9.18	0%	
Hypoaspis aculeifer	Proto-nymphs	Exposure to fresh Asulox residues on moist sand substrate	Mortality	400	0%	50%
			Repro-duction	400	0%	

* Control corrected values

Field or semi-field tests
Not required

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point*
Earthworms			
Eisenia fetida	Asulam ‡	Acute 14 days	LC_{50} =1004 mg asulam /kg dw soil
Eisenia fetida	Asulam ‡	Chronic 8 weeks	NOEC = 180.7 mg asulam /kg dw soil
Eisenia fetida	Sulphanilamide (major soil metabolite)	Acute	LC_{50} > 1000 mg sulphanilamide /kg dw soil
Eisenia fetida	Sulphanilamide (major soil metabolite)	Chronic 8 weeks	NOEC = 3.75 mg sulphanilamide /kg dw soil
Other soil macro-organisms			
Hypoaspis aculeifer (soil mite)	Asulam ‡	Acute	LR_{50} > 4370 mg a.s. /kg dw soil
Folsomia candida (collembola)	Sulphanilamide (major soil metabolite)	Chronic 28 day s	NOAEC = 50 mg sulphanilamide /kg dw soil.
Soil micro-organisms			
Nitrogen mineralisation	Asulam ‡	56 days	< 25% effect by day 56 at up to 16 mg asulam/kg dw soil.
Carbon mineralisation	Asulam ‡	56 days	< 25% effects by day 28 at up to 160 mg asulam/kg dw soil
Nitrogen mineralisation	Sulphanilamide (major soil metabolite)	28 days	< 25% effects by day 28 at up to 3.3 mg metabolite /kg dw soil
Field studies			
Not required			

* EPPO correction factor not required as log Pow < 2.0, for both asulam and sulphanilamide.

Toxicity/exposure ratios for soil macro-organisms

One application of 2.4 kg asulam /ha to spinach (pre or post-emergence) and flower bulb crops (post-emergence)

Test organism	Test substance	Time scale	Soil PEC_i	TER	Trigger
Earthworms					
Eisenia fetida	Asulam ‡	Acute	3.2 mg asulam. /kg dw soil	313.7	10
Eisenia fetida	Asulam ‡	Chronic (8 weeks)	3.2 mg asulam /kg dw soil	56.5	5
Eisenia fetida	Sulphanilamide (major soil metabolite)	Acute	0.41 mg met. /kg dw soil	> 2439	10
Eisenia fetida	Sulphanilamide (major soil metabolite)	Chronic (8 weeks)	0.41 mg met. /kg dw soil	9.1	5

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Test organism	Test substance	Time scale	Soil PEC_i	TER	Trigger
Other soil macro-organisms					
Hypoaspis aculeifer (soil mite)	Asulam ‡	Acute	3.2 mg asulam /kg soil	> 1366	5
Folsomia candida	Sulphanilamide (major soil metabolite)	Chronic (4 weeks)	0.41	122	5

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data

Not required

Laboratory dose response tests

Most sensitive species	Test sub-stance	Vegetative vigour EC_{50} (g/ha) (post-emer. effects)	Emergence ER_{50} (g/ha) (pre-emergence effects)	Distance (m)	Drift rate (%)	Exposure (g/ha)	TER	Trigger
Lettuce	a.s.	-	228g asulam /ha	0	100	2400	0.095	-
				1	2.77	66.48	**3.43**	5
				5	0.57	13.68	16.67	5
Cucumber	a.s.	11g asulam/ha	-	0	100	2400	0.0046	-
				1	2.77	66.48	**0.17**	5
				5	0.57	13.68	**0.80**	5
				10	0.29	6.96	**1.58**	5
				20	0.15	3.60	**3.06**	5
				30	0.10	2.40	**4.58**	5
				40	0.07	1.68	6.55	5

Higher-tier risk assessment:
Based on most sensitive reported vegetative vigour (post-emergence) ER_{50} of 11g /ha a no-spray buffer zone of 40 metres would be required to provide a low risk to non-target plants (in off-crop areas). However, based on a probabistic risk assessment which takes into account the distribution of sensitivity – a vegetative vigour HC5 value of 13.82g asulam /ha has been estimated. Based on current SANCO/10329 (2002) risk assessment guidance, the risk is acceptable provided exposure does not exceed this value – indicating that a 5 metre no-spray buffer zone (or other equivalent exposure mitigation measures) will be sufficient to provide an acceptable risk to non-target plants.

Additional studies (e.g. semi-field or field studies)

Not required

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	End point
Activated sludge	3 hour EC_{50} > 1000 mg asulam /L. 3 hour NOEC = 1000 mg asulam /L.

Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	Compound
Soil	Asulam #
Surface water	Asulam, sulphanilamide *
Sediment	None **
Ground water	None present (from proposed use in spinach and flower bulb crops)

Sulphanilamide may be present as a major metabolite in soil but is likely to pose a lower risk to soil organisms than asulam; on this basis it is not classed as ecotoxicologically relevant.
* The photodegradates sulphanilic acid, AP formamide, MCAPAP carbamate may also occur in surface water, however given their presence at lower concentrations than the a.s. and their likely lower toxicity to aquatic life, they are not considered 'ecotoxicologically relevant'.
** Although both asulam and sulphanilamide may occur in sediment, given their likely low toxicity to sediment dwelling invertebrates, residues are not considered ecotoxicologically relevant.

Air: None

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/peer review proposal
Active substance	It is recommended that under the CLP Regulation asulam sodium is classified as 'Acute Category 1' and 'Chronic category 1', with the following labelling requirements: 'GHS09 Pictogram' and associated signal word 'Warning' Hazard statement: H410 'Very toxicity to aquatic life with long lasting effects' (which also covers need for 'acute category 1' related 'H400' hazard statement) Precautionary statements: 'P391' and 'P501' are required.

	RMS/peer review proposal
Preparation	It is recommended that under the CLP Regulation the preparation 'Asulox' is classified as 'Acute Category 1' and 'Chronic category 1', with the following labelling requirements: 'GHS09 Pictogram' and associated signal word 'Warning' Hazard statement: H410 'Very toxicity to aquatic life with long lasting effects' (which also covers need for 'acute category 1' related 'H400' hazard statement) Precautionary statements: 'P391' and 'P501' are required.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles