CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance azimsulfuron[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Commission Regulation (EC) No 737/2007[3] (hereinafter referred to as 'the Regulation') lays down the procedure for the renewal of the inclusion of a first group of active substances in Annex I to Council Directive 91/414/EEC and establishes the list of those substances. Azimsulfuron is one of the first group of active substances listed in the Regulation.

In accordance with Article 6 of the Regulation, the notifier DuPont de Nemours (Deutschland) GmbH submitted a dossier on azimsulfuron to Sweden and Slovenia, being the designated rapporteur Member State (RMS) and co-rapporteur Member State (co-RMS) respectively. In accordance with Article 10 of the Regulation, Sweden prepared an Assessment Report in consultation with Slovenia, which was submitted to the EFSA and the Commission of the European Communities (hereafter referred to as 'the Commission'). The Assessment Report was received by the EFSA on 1 June 2009.

In accordance with Article 11 of the Regulation, the EFSA distributed the Assessment Report to Member States and the notifier for comments on 10 June 2009. The EFSA collated and forwarded all comments received to the Commission on 13 July 2009.

In accordance with Article 12, following consideration of the Assessment Report and the comments received, the Commission requested the EFSA to arrange an expert consultation on the Assessment Report as appropriate and deliver its conclusions on azimsulfuron.

The conclusions presented in this report were reached on the basis of the evaluation of the representative uses of azimsulfuron as a herbicide on rice, as proposed by the notifier(s). Full details of the representative uses can be found in Appendix A to this report.

No areas of concern were identified in the physical and chemical properties section.

No areas of concern were identified in the mammalian toxicology section.

No additional data were provided for the residue section in the framework of the resubmission. No areas of concern were identified in the residue section. The residue definition for monitoring and risk assessment was defined as parent azimsulfuron only and an MRL of 0.02* mg/kg was proposed for rice grain. No chronic concern was identified, the various consumer intake calculations showing TMDIs lower than 1% of the ADI.

---

1 On request from the European Commission, Question No EFSA-Q-2009-00808, issued on 12 March 2010.

2 Correspondence: praper@efsa.europa.eu

3 OJ L169, 29.06.2007, p.10

* MRL is proposed at the LOQ.

Suggested citation: European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance azimsulfuron. EFSA Journal 2010; 8(3):1554. [61 pp.]. doi:10.2903/j.efsa.2010.1554. Available online: www.efsa.europa.eu

The data available on fate and behaviour in the environment are sufficient to carry out the required environmental exposure assessments in line with the agreed EU MED-Rice (2003) guidance, with the exception that a complete route of degradation of azimsulfuron under irradiated conditions in the aquatic environment could not be finalised. It can be concluded that a refined surface water exposure assessment is necessary to demonstrate a safe use for aquatic organisms. In situations represented by the MED-Rice sandy scenario (one of two agreed scenarios) it cannot be excluded with the available data that azimsulfuron may be present in vulnerable groundwater at concentrations greater than 0.1 µg/L (tier 1 PEC_{gw} indicated concentrations up to 0.1158 µg/L).

A high risk was identified in-field for aquatic organisms. An in-field no spray buffer zone of 20m is required to address the risk for non-target plants. The risk was assessed as low to other non-target organisms.

KEY WORDS

azimsulfuron, peer review, risk assessment, pesticide, herbicide

TABLE OF CONTENTS

BACKGROUND

Commission Regulation (EC) No 737/2007[4] (hereinafter referred to as 'the Regulation') lays down the procedure for the renewal of the inclusion of a first group of active substances in Annex I to Council Directive 91/414/EEC and establishes the list of those substances. Azimsulfuron is one of the first group of active substances listed in the Regulation.

In accordance with Article 6 of the Regulation, the notifier DuPont de Nemours (Deutschland) GmbH submitted a dossier on azimsulfuron to Sweden and Slovenia, being the designated rapporteur Member State (RMS) and co-rapporteur Member State (co-RMS) respectively. In accordance with Article 10 of the Regulation, Sweden prepared an Assessment Report in consultation with Slovenia, which was submitted to the EFSA and the Commission of the European Communities (hereafter referred to as 'the Commission'). The Assessment Report was received by the EFSA on 1 June 2009.

In accordance with Article 11 of the Regulation, the EFSA distributed the Assessment Report to Member States and the notifier for comments on 10 June 2009. A 30-day period was provided for commenting. In addition, the EFSA conducted a public consultation on the Assessment Report. The EFSA collated and forwarded all comments received to the Commission on 13 July 2009. At the same time, the collated comments were forwarded to the RMS for compilation in the format of a Reporting Table. The notifier was invited to respond to the comments in column 3 of the Reporting Table. The RMS also provided a response to the comments in column 3.

In accordance with Article 12, following consideration of the Assessment Report and the comments received, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 15 September 2009, the Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on azimsulfuron. The need for expert consultation was considered in a telephone conference between the EFSA, the RMS, the co-RMS and the Commission on 3 September 2009. On the basis of the comments received, the notifier's response to the comments, and the RMS' subsequent evaluation thereof, it was concluded that the EFSA should organise a consultation with Member State experts in the areas of physical-chemical properties and environmental fate and behaviour.

The outcome of the telephone conference, together with EFSA's further consideration of the comments, is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in consultation with Member State experts, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert discussions where these took place, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in December 2009.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a herbicide on rice, as proposed by the notifier. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the peer review report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report comprises the following documents:

[4] OJ L169, 29.06.2007, p.10

- the comments received,
- the Reporting Table (revision 1-1; 7 September 2009),
- the Evaluation Table (4 December 2009),
- the report(s) of the scientific consultation with Member State experts (where relevant).

Given the importance of the Assessment Report including its addendum (compiled version of 4 December 2009 containing all individually submitted addenda) and the peer review report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Azimsulfuron is the ISO common name for 1-(4,6-dimethoxypyrimidin-2-yl)-3-[1-methyl-4-(2-methyl-2H-tetrazol-5-yl)-pyrazol-5-ylsulfonyl]-urea (IUPAC).

The representative formulated product for the evaluation was 'Azimsulfuron 50 WG' a wettable granule (WG) containing 500 g/kg azimsulfuron.

The representative use evaluated is on rice. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

1. Identity, physical/chemical/technical properties and methods of analysis

The technical specification and given in table C.1.2.3.5-1 of the Draft Re-Assessment Report Vol. C rev. 1 September 2009 was agreed (Sweden, 2009b). The specified minimum purity is in line with the FAO specification. Phenol was considered as a relevant impurity but, based on its hazards and the level proposed in the technical specification (2 g/kg), it does not give rise to significant toxicological concern. Only one data gap remains for the formulation for an attrition test after storage.

LC-MS/MS methods are available to analyse azimsulfuron in plants, soil, water and air. Methods are not required for products of animal origin or body fluids and tissues.

2. Mammalian toxicity

Azimsulfuron has a low acute toxicity (oral, dermal or by inhalation), is not irritating to the skin or the eyes, and is not a skin sensitizer. In repeat dose studies, the main target organs were the pancreas, the liver and the white/red blood cells. The relevant short-term NOAEL was 17.9 mg/kg bw/day based on the 1-year dog study. Azimsulfuron is not genotoxic; and was not demonstrated to have carcinogenic properties of relevance for humans. The relevant long term NOAEL was 34.3 mg/kg bw/day based on the 2-year rat study. Effects in the testes were observed in the 2-year and multigeneration rat studies at high doses, without clear identification of the mode of action; but a sufficient margin of safety was present when deriving the reference values, and no adverse effects on the fertility parameters were noted. The parental NOAEL was 9.6 mg/kg bw/day based on increased pancreas weight, the offspring NOAEL was 85.2 mg/kg bw/day, and the NOAEL for the fertility parameters was 601 mg/kg bw/day. No teratogenic effects were observed in rats or rabbits, with higher maternal and developmental NOAEL values than in other repeated dose studies. On the basis of the available mechanistic studies, it could not be concluded that the effect on the pancreas was not relevant to humans.

The Acceptable Daily Intake (**ADI**) is 0.10 mg/kg bw/day based on the rat multigeneration study, and the Acceptable Operator Exposure Level (**AOEL**) is 0.10 mg/kg bw/day based on the rat multigeneration study supported by the short term dog studies. Based on the toxicological profile of azimsulfuron, no Acute Reference Dose (**ARfD**) was derived. The default dermal absorption value of 100% is applied for the risk assessment. With the German model (Sweden, 2009a), the estimated operator exposure is below the AOEL without the use of personal protective equipment. The bystander exposure to spray drift and the worker exposure during re-entry for crop inspection are both below the AOEL.

3. Residues

No additional data were provided for the residue section in the framework of the submission for Annex I inclusion.

The metabolic fate of azimsulfuron has been investigated in rice using ^{14}C-labelled compound either on the pyrazole or pyrimidine moiety. Different experiments and several treatment patterns representative of the agricultural practices were investigated (application to paddy water and to the soil culture), the application rate being 21 g/ha (0.8N). In addition, to determine the absorption and translocation in rice seedling, experiments were conducted on hydroponic cultures. Azimsulfuron is rapidly and almost completely metabolised in rice. The parent compound was only observed in immature interim plant samples but was not detected in grain and roots at harvest (<0.001 mg/kg) and accounted for less than 1% TRR in foliage. The metabolic pathway proceeds though demethylation on the pyrazole ring leading to the hydroxy analogue IN-JJ999 and by hydrolysis of the sulfonylurea bridge, yielding the pyrimidine amine (IN-J290) and pyrazole sulphonamide (IN-A8342) metabolites and their glucoside conjugates. The metabolites identified in rice were also present in the rat metabolism. Considering the absolute low level at which these metabolites were present (<0.003 mg/kg), none were considered to be an adequate marker for the residues and it was proposed to define the residue definition for monitoring and risk assessment by default as azimsulfuron.

A sufficient number of residue trials conducted in Spain and Italy over two different growing seasons are available and are fully supported by storage stability data where azimsulfuron was shown to be stable in rice matrices at *ca.* -20°C over 14 months. Having regard to the DT_{90} in soil below 100 days, a rotational crop study was not provided. Animal metabolism, livestock feeding and processing studies were not provided and not required, the residues in rice being below the LOQ. Using different consumer intake models, the maximum TMDI was less than 1% of the ADI. The acute exposure has not been estimated since no ARfD was proposed for azimsulfuron.

4. Environmental fate and behaviour

Laboratory studies on route and rate of aerobic degradation are available for two Japanese soils under flooded and non-flooded conditions, and two Italian soils under flooded conditions. The rate of degradation in non-flooded soil was also tested in four European soils. Major degradation products (> 10% of the applied radioactivity (AR)) were IN-JJ999 and IN-A8342, and minor non-transient metabolites (> 5% AR at least at two sequential measurements) of [pyrazole-4-^{14}C]-azimsulfuron was IN-KQ962. Additionally, [pyrimidine-2-^{14}C]-azimsulfuron formed in non-flooded soil the major metabolite IN-J290. The degradation pattern under anaerobic conditions was similar to that described for aerobic conditions, except for the formation of one additional minor non-transient metabolite (IN-H9235) in the pyrimidine labelled samples. Since anaerobic conditions are generally considered being less relevant for rice cultivations in the EU, further assessment of this metabolite was not considered necessary. The study on photolysis in soil indicates that azimsulfuron is stable towards photolytic degradation in this compartment. In flooded soil azimsulfuron and metabolites IN-A8342 and IN-JJ999 exhibited moderate persistence, whilst in unflooded soil azimsulfuron was characterised as exhibiting moderate to high persistence, metabolite IN-JJ999 low to high persistence and metabolite IN-J290 low to moderate persistence. No reliable degradation parameters could be calculated for metabolite IN-KQ962 and therefore a worst case DT_{50} value of 1000 days was used in the risk assessment. In the reliable rice field dissipation studies (two Italian sites: pH in water 6.3 and 6.6; clay 7.3 % and 13.2 %) no significant residues of azimsulfuron were found in the soil samples. Under field conditions the dissipation rate of azimsulfuron was estimated to be 2 – 3 days. Azimsulfuron exhibits high mobility in soil, metabolites IN-A8342 and IN-KQ962 high to very high mobility, IN-JJ999 very high mobility and IN-J290 medium to high mobility. From the available data no quantitative pH relationship could be derived for adsorption of azimsulfuron to soil, although a pH dependency is expected based on the physical-chemical properties of the active substance. The predicted ground water concentrations (PEC_{gw}) were generated to simulate applications of azimsulfuron to flooded or saturated rice paddies in the EU. PEC_{gw} values were determined using methods, scenarios and the simple screening calculation (Tier 1) specified by EU MED-Rice (European Commission, 2003). Results indicated that the average concentration of azimsulfuron in groundwater after one year (0.1158 µg/L) slightly exceeded the limit of 0.1 µg/L in the MED-Rice scenario representing conditions vulnerable to leaching and groundwater contamination (scenario 2, sandy). None of the metabolites exceeded the concentration limit. The experts of PRAPeR 72 meeting considered not valid the refined MED-Rice simulation for azimsulfuron conducted using an indirect aqueous photolysis DT_{50} for azimsulfuron in the flooded soil water layer and the refined MED-Rice simulation for azimsulfuron conducted using the DT_{50} from the field dissipation data (see details in the Report of PRAPeR Expert Meeting 72, open point 4.18). After the experts meeting, in the comments on the draft EFSA conclusions, the RMS indicated they re-calculated Tier I MED-RICE PEC_{gw} based on the available laboratory data for azimsulfuron. The new PEC_{gw} values have not been peer reviewed, however the EFSA considered the use of the geometric mean DT_{50} from the available flooded soil studies as appropriate but disagrees with the conclusion on the pH dependency of soil adsorption (PRAPeR 72 concluded that with the available data no quantitative pH relations can be derived).

The available data indicated that indirect photolysis may contribute significantly to the degradation of azimsulfuron in shallow aquatic environments; however the identification of the degradation products in the submitted photolysis study was not completed and a data gap was identified by the peer review. In water/sediment systems azimsulfuron exhibited high persistence in the whole system forming the major metabolite IN-A8342 (13% AR in the water phase and 16% AR in the sediment). The metabolites IN-JJ999 and IN-J290 reached maximum levels of 10.8% AR and 9% AR, respectively, at the end of the study in the whole system. Azimsulfuron partitioned from the water to the sediment. No reliable degradation parameters were obtained for azimsulfuron and therefore the whole system DT_{50} in the degrading compartment, and a worst case default of 1000 days in the other compartment were used in modelling. For metabolites where no reliable declination rate could be established in the water-sediment study, a conservative worst-case assumption of DT_{50} value of 1000 days was used in the risk assessment. Step 1 PEC values for paddy water (PEC_{pw}), surface water (PEC_{sw}) and sediment (PEC_{sed}) for azimsulfuron and metabolites IN-A8342, IN-JJ999, IN-J290 and IN-KQ962 using the procedures described in EU MED-Rice guidance were available. The reliable PEC values resulting from these calculations can be found in Appendix A. Based on ecotoxicity data, refinement of the surface water exposure assessment was necessary for azimsulfuron and submitted by the notifier using data on indirect photolysis degradation rate or field dissipation rate or refined modelling based on the linked model system RICEWQ-RIVWQ. The Member State experts did not accept these higher tier calculations, in particular the presentation of the modelling results for use in the aquatic risk assessments (90^{th} percentile 7-day seasonal time weighted average PEC values) was considered inappropriate as it does not afford sufficient protection for aquatic life (see details in the Report of PRAPeR Expert Meeting 72, open point 4.23).

5. Ecotoxicology

The environmental risk assessment of azimsulfuron was conducted according with the current guidance documents (see reference list). Toxicity studies indicate a low toxicity of azimsulfuron to birds and mammals and the risk from the representative use in rice was assessed as low.

Based on the available data, azimsulfuron and its formulation were considered to be very toxic to aquatic organisms. The metabolites IN-A8342, IN-JJ999 and IN-KQ962 were found to be of lower toxicity than the parent substance. The azimsulfuron toxicity to *Lemna gibba* drives the risk assessment (EyC_{50}= 0.00062 mg a.s./L; see details in the Evaluation Table, open point 5.1). A high risk was identified in-field for azimsulfuron to *L. gibba* and algae (only one scenario did not meet the trigger value) when the MED-RICE PEC_{sw} step 2 was used. The fate and behaviour experts did not accept the higher tier 7-day time weighted average PEC_{sw} calculations with the RICEWQ model (see details in the Evaluation Table, open point 4.23 and 4.24) that the RMS used to refined the high in-field risk. Further information is required to address the in-field and off-field risk of azimsulfuron to aquatic organisms. The risk for the relevant metabolites IN-A8342, IN-JJ999 and IN-KQ962 was assessed as low based on the first tier risk assessment.

Hazard quotient (HQ) calculations based on the acute oral and contact toxicity of azimsulfuron indicated a low risk to bees. Laboratory studies on non-target arthropods were provided on the two standard species *Typhlodromus pyri* and *Aphidius rhopalosiphi*. Additional Tier I studies were provided with *Chrysoperla carnea* and *Poecillus cupreus*, although not required. Based on the assessment of all the studies the in-field and off-field risk for the non-target arthropods was assessed as low.

The acute toxicity to earthworms was assessed for azimsulfuron and for one of the relevant metabolites, IN-KQ962. However, there were no acute toxicity data for the other three metabolites IN-A8342, IN-JJ999 and IN-J290. The long-term toxicity to earthworms was assessed also for azimsulfuron. The acute and long-term risk to earthworm from the representative use of azimsulfuron was assessed as low. The risk for the metabolites was assessed as low.

Additionally, the risk to the soil processes from the representative use of azimsulfuron was assessed as low. No significant adverse effects on sewage treatment were expected.

Studies were evaluated on the effect of the plant protection product on a number of monocotyledon and dicotyledon non-target plants species. An in-field no-spray buffer zone of 20m, or other comparable risk mitigation measure, is required to mitigate the risk for non-target plants exposed post-emergence.

6. Overview of the risk assessment of compounds listed in residue definitions for the environmental compartments

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Azimsulfuron	Moderate persistence First order $DT_{50whole\ system}$ 13-51 days (20-25°C, aerobic flooded soil) Moderate to high persistence Single first order DT_{50} 17-133 days (20°C and pF2 soil moisture, aerobic unflooded soil)	The risk of azimsulfuron to earthworms was assessed as low.
IN-A8342	Moderate persistence Single first order $DT_{50whole\ system}$ 27-55 days (20-25°C, aerobic flooded soil) No reliable degradation parameters for unflooded soil available, data not required (worst case DT_{50} 1000 days used in the assessment)	The risk of IN-A8342 to earthworms was assessed as low.
IN-JJ999	Moderate persistence First order $DT_{50whole\ system}$ 19-46 days (20-25°C, aerobic flooded soil) Low to high persistence First order DT_{50} 6.5-142 days (20°C/75 MWHC, 25°C/45 MWHC and 25°C/59 MWHC, aerobic unflooded soil)	The risk of IN-JJ999 to earthworms was assessed as low.
IN-KQ962	No reliable degradation parameters for flooded and unflooded soils available, data not required (worst case DT_{50} 1000 days used in the assessment)	The risk of IN-KQ962 to earthworms was assessed as low.
IN-J290 (major metabolite in unflooded soil only)	Low to moderate persistence First order DT_{50} 3-19 days (20°C and 50% MWHC soil moisture, aerobic unflooded soil)	The risk of IN-J290 to earthworms was assessed as low.

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one MED-Rice scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
Azimsulfuron	High mobility K_{Foc} 54-78 mL/g	Yes, up to 0.1158 µg/L in the Sandy scenario (Scenario 2)	Yes	Yes	Azimsulfuron is very toxic to aquatic organisms.
IN-A8342	Very high to high mobility K_{doc} 48-142 mL/g	No	No	Ames test negative Oral LD_{50} = 2850 mg/kg bw	IN-A8342 is toxic to aquatic organisms. The risk for aquatic organisms was assessed as low.
IN-JJ999	Very high mobility K_{doc} 28-40 mL/g	No	-	Ames test negative Oral LD_{50} >5000 mg/kg bw	IN-JJ999 is very toxic to aquatic organisms. The risk for aquatic organisms was assessed as low.
IN-KQ962	Very high to high mobility K_{doc} 28-57 mL/g	No	No	Minor rat metabolite	IN-KQ962 is harmful to aquatic organisms. The risk for aquatic organisms was assessed as low.
IN-J290	High to medium mobility K_{Foc} 58-452 mL/g	No	No	Ames test negative Oral LD_{50} = 920 mg/kg bw	The risk for aquatic organisms was assessed as low.

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Azimsulfuron	Azimsulfuron is very toxic to aquatic organisms.
IN-A8342	IN-A8342 is toxic to aquatic organisms. The risk for aquatic organisms was assessed as low.
IN-JJ999	IN-JJ999 is very toxic to aquatic organisms. The risk for aquatic organisms was assessed as low.
IN-KQ962	IN-KQ962 is harmful to aquatic organisms. The risk for aquatic organisms was assessed as low.
Unidentified radioactivity fraction > 10% AR in the aqueous photolysis study	

6.4. Air

Compound (name and/or code)	Toxicology
Azimsulfuron	Low acute toxicity by inhalation (LC_{50} > 5.94 mg/L)

LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED

- Attrition test on the formulation after two years storage (relevant for all representative uses evaluated; submission date unknown; see section 1).
- The available data on aqueous photolysis does not allow for identification/characterization of degradation products (see section 4).
- Further information is required to address the risk for aquatic organisms, this might include further refinement of the exposure assessment (relevant for all representative uses evaluated; submission date unknown; see sections 4 and 5).

PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED

- A 20m non-spray buffer zone is required to mitigate the risk to non-target plants (see section 5).

ISSUES THAT COULD NOT BE FINALISED

- The identification of the degradation products in the aqueous photolysis study could not be finalised.
- The risk for aquatic organisms could not be finalised.

CRITICAL AREAS OF CONCERN

- In situations represented by the MED-Rice sandy scenario (one of two agreed scenarios) it cannot be excluded with the available data that azimsulfuron may be present in vulnerable groundwater at concentrations greater than 0.1 µg/L.
- A high in-field risk was identified for aquatic organisms.

REFERENCES

Sweden, 2009a. Assessment Report on the active substance azimsulfuron prepared by the rapporteur Member State Sweden in consultation with Slovenia in the framework of Commission Regulation (EC) No 737/2007, May 2009.

Sweden, 2009b. Final Addendum to Assessment Report on azimsulfuron, compiled by EFSA, December 2009.

EFSA (European Food Safety Authority), 2010. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance azimsulfuron.

Thomas, R.G. 1990. Volatilization from soil. In: Lyman, W.J., W.F. Reehl, D.H. Rosenblatt (Eds.) Handbook of Chemical Property Estimation Methods, chapter 16, 1-50.

Guidance documents[5]:

European Commission, 2002a. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002 rev.2 final, 17 October 2002.

European Commission, 2002b. Guidance Document on Aquatic Ecotoxicology Under Council Directive 91/414/EEC. SANCO/3268/2001 rev 4 (final), 17 October 2002.

European Commission, 2002c. Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC. SANCO/4145/2000.

European Commission, 2003. EU MED-Rice - Guidance document for environmental risk assessments of active substances used on rice in the EU for Annex I inclusion. SANCO/1090/2000, rev. 1 June 2003.

OECD (Organisation for Economic Co-operation and Development), 2006. Guidance Document on Overview of Residue Chemistry Studies. ENV/JM/MONO(2006)32, 10 October 2006.

Sanco/1090/2000-rev.1 June 2003. Guidance document for environmental risk assessments of active substances used on rice in the EU for annex 1 inclusion. Document prepared by Working Group on MED-Rice.

SETAC (Society of Environmental Toxicology and Chemistry), 2001. Guidance Document on Regulatory Testing and Risk Assessment procedures for Plant Protection Products with Non-Target Arthropods. ESCORT 2.

[5] For further guidance documents see http://ec.europa.eu/food/plant/protection/resources/publications_en.htm#council (EC) or http://www.oecd.org/document/59/0,3343,en_2649_34383_1916347_1_1_1_1,00.html (OECD)

APPENDICES

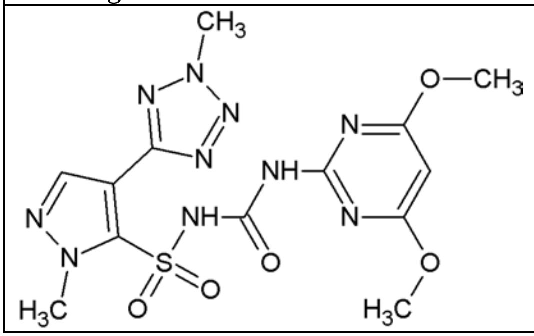
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

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

Active substance (ISO Common Name) ‡	Azimsulfuron
Function (e.g. fungicide)	herbicide

Rapporteur Member State	Sweden
Co-rapporteur Member State	Slovenia

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	1-(4,6-dimethoxypyrimidin-2-yl)-3-[1-methyl-4-(2-methyl-2H-tetrazol-5-yl)-pyrazol-5-ylsulfonyl]-urea
Chemical name (CA) ‡	N-[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]-1-methyl-4-(2-methyl-2H-tetrazol-5-yl)-1H-pyrazole-5-sulfonamide
CIPAC No ‡	584
CAS No ‡	120162-55-2
EC No (EINECS or ELINCS) ‡	Not assigned
FAO Specification (including year of publication) ‡	FAO specification 584/TC published February 2005 Minimum purity: 980g/kg
Minimum purity of the active substance as manufactured ‡	980 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Phenol 2 g/kg
Molecular formula ‡	$C_{13}H_{16}N_{10}O_5S$
Molecular mass ‡	424.40 g/mol
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	170°C (99.62% purity)
Boiling point (state purity) ‡	Not applicable due to decompisiton before boiling
Temperature of decomposition (state purity)	Decomposition starts at approximately 180°C (99.6% purity)
Appearance (state purity) ‡	Physcal stateand colour Technical and purified material are white powdered solids (98.9% and 99.62% purity) Odour Sharpodour - similar to phenol (99.62% purity) Same as above but less sharp (98.91% purity)
Vapour pressure (state temperature, state purity) ‡	4×10^{-9} Pa at 25°C Extrapolated from measurements in the range 86-125°C (99.62% purity)
Henry's law constant ‡	pH H 5 8×10^{-9} 7 5×10^{-10} 9 9×10^{-11}
Solubility in water (state temperature, state purity and pH) ‡	At 20°C using buffered solutions (99.64% purity): at pH 5, 72.3 mg/l at pH 7, 1050 mg/l at pH 9, 6536 mg/l
Solubility in organic solvents ‡ (state temperature, state purity)	At 25°C (99.62% purity): solvent g/l acetone 26.4 acetonitrile 13.9 ethyl acetate 13.0 hexane <0.2 methanol 2.1 methylene chloride 65.9 toluene 1.8
Surface tension ‡ (state concentration and temperature, state purity)	In buffered solution at pH 7 and 23.7 ± 0.2°C (99.7% purity): 68.1×10^{-3} N/m at ~0.9 g/l (corresponds approximately to 90% of the saturation concentration at the pH).
Partition co-efficient ‡ (state temperature, pH and purity)	Log P_{ow} at ~25°C (99.62% purity): 0.6 at pH 5 -1.4 at pH 7 -2.1 at pH 9
Dissociation constant (state purity) ‡	pK_a=3.6 (99.62% purity) Dissociation of N-H next to sulfone group.

UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	In buffered solutions (99.7% purity): Maxima (nm): ε (L x mol^{-1} x cm^{-1}) 242 23014 242 23988 242 24099 ε < 10 at wavelength >290 nm for pH 2, 7 and 10.
Flammability ‡ (state purity)	Not highly flammable (98.91% purity)
Explosive properties ‡ (state purity)	Not explosive (99.6% purity)
Oxidising properties ‡ (state purity)	Not oxidizing (theoretical consideration)

Summary of representative uses evaluated *

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/max (k)	interval between application (min)	kg as/hL min-max (l)	water L/ha min-max	kg as/ha min-max (l)		
Rice	Italy Spain France Greece Portugal Romania	Azim-sulfuron 50WG	F	Broadleaved weeds Cyperaceae Grasses	WG	500 g/kg azim-sulfuron	Flooded Rice Tractor mounted sprayer, Broadcast, ground directed spraying	Post-emergence Application from 18 to 50 days after sowing (BBCH 12 Two leaves to BBCH 29 Maximum tillers)	1	N/A	0.003-0.013	200-600	0.020-0.025	Not applicable	Application on Flooded land (5-10 cm depth of water) – Do not remove the water for a minimum of 5-7 days after the application.
Rice	Italy Spain France Greece Portugal Romania	Azim-sulfuron 50WG	F	Broadleaved weeds Cyperaceae Grasses	WG	500 g/kg azim-sulfuron	Saturated Rice Tractor mounted sprayer, Broadcast, ground directed spraying	Post-emergence Application from 18 to 50 days after sowing (BBCH 12 Two leaves to BBCH 29 Maximum tillers)	1	N/A	0.003-0.013	200-600	0.020-0.025	Not applicable	Application on Saturated land Remove water 1-3 days before product application, leaving 0-1 cm depth of water – Make the application of the product and do not re-introduce the water for as long time period as the crop will allow, but at least not before 2-5 days after the application.

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
(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 suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(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 at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use

(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989 (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	(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

Methods of Analysis

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

Technical as (analytical technique)	HPLC-UV
Impurities in technical as (analytical technique)	HPLC-UV
Plant protection product (analytical technique)	HPLC-UV

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		azimsulfuron
Food of animal origin		azimsulfuron
Soil		azimsulfuron
Water	surface	azimsulfuron
	drinking/ground	azimsulfuron
Air		azimsulfuron

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Soybean Seed, LC-MS/MS, 0.01 mg/kg Lettuce, LC-MS/MS, 0.01 mg/kg Orange, LC-MS/MS, 0.01 mg/kg Wheat grain, LC-MS/MS, 0.01 mg/kg
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required
Soil (analytical technique and LOQ)	LC-MS/MS, 0.05 µg/kg
Water (analytical technique and LOQ)	LC-MS/MS, 0.05 µg/L
Air (analytical technique and LOQ)	LC-MS/MS, 3 $\mu g/m^3$
Body fluids and tissues (analytical technique and LOQ)	Not required

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

	RMS/peer review proposal
Active substance	None

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Rapidly and extensively absorbed after oral administration (>90% within 48h)
Distribution ‡	Highest levels in liver, plasma and kidney. Less than 0.2% of the radioactive dose was retained in erythrocyte (M-label).
Potential for accumulation ‡	No potential for accumulation
Rate and extent of excretion ‡	74-81% was eliminated into the urine and 16-25% to faeces. 11% (females) and 17% (males) were detected in bile excreta in 48 hours.
Metabolism in animals ‡	Approximately 60-73% of the dose was eliminated unchanged into the urine and faeces. Test substance was metabolised by the following routes: *O*-demethylation to IN-JJ999, main metabolite accounting for ca. 40-50% of the total metabolites in excreta; pyrimidine ring hydroxylation and cleavage ; hydrolysis of the sulfonylurea bridge; *N*-demethylation of the methylpyrazole or methyl tetrazole. 13 metabolites were identified in urine, faeces, bile and tissues.
Toxicologically relevant compounds ‡ (animals and plants)	Azimsulfuron
Toxicologically relevant compounds ‡ (environment)	Azimsulfuron

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 5,000 mg/kg bw	
Mouse LD_{50} oral ‡	7,161mg/kg bw	
Rat LD_{50} dermal ‡	> 2,000 mg/kg bw	
Rat LC_{50} inhalation ‡	> 5.94 mg/L (4h, whole-body exposure)	
Skin irritation ‡	Non-irritant	
Eye irritation ‡	Non-irritant	
Skin sensitisation ‡	Not a skin senzitizer (Maximisation test)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Pancreas, liver and body weight (rat, mouse, dog), red and white blood cells and associated organs (rat, dog)	
Relevant oral NOAEL ‡	17.9 mg/kg bw/d (1-yr dog) 75.3 mg/kg bw/d (90-d rat) 131.7 mg/kg bw/d (90-d mouse)	
Relevant dermal NOAEL ‡	No data – not required	
Relevant inhalation NOAEL ‡	No data – not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

	No genotoxic potential *in vitro* or *in vivo*	

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

Target/critical effect ‡	Pancreas, bw, testes (atrophy, tumours at 1-yr at the high dose of 282 mg/kg bw/d) (rat) Amyloidosis (mouse)	
Relevant NOAEL ‡	34.3 mg/kg bw/d (rat) 69.9 mg/kg bw/d (mouse)	
Carcinogenicity ‡	No carcinogenic potential relevant for humans	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect ‡	Parental: pancreas (increased weight and acinar cell hypertrophy); Reproductive: reduced epididymal sperm count in F1 males; no adverse effect on fertility parameters; Offspring: lower body weight	
Relevant parental NOAEL ‡	9.6 mg/kg bw/d (125 ppm)	
Relevant reproductive NOAEL ‡	601 mg/kg bw/d (8000 ppm)	
Relevant offspring NOAEL ‡	85.2 mg/kg bw/d (1000 ppm)	

Developmental toxicity

Developmental target / critical effect ‡	Maternal: reduced food consumption and bwg (rat, rabbit); pancreas hypertrophy (rat); increased mortality (rabbit). Foetal: reduced bw, skeletal variations. No teratogenic effect.	
Relevant maternal NOAEL ‡	150 mg/kgbw/d, rabbit 200 mg/kg bw/d, rat	
Relevant developmental NOAEL ‡	500 mg/kgbw/d, rabbit 200 mg/kg bw/d, rat	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data – not required	
Repeated neurotoxicity ‡	No data – not required	
Delayed neurotoxicity ‡	No data – not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Mechanistic studies with azimsulfuron for pancreatic and testicular effects, feeding study in rats (28-56 days): NOAEL = 17.8 mg/kgbw/day (300 ppm) Based on decreased plasma estradiol levels, increased pancreas weights, increased acinar cell labeling index, and pancreatic hypertrophy in the 10,000 ppm group. Subchronic mechanistic feeding study in dogs: Supports the hypothesis that azimsulfuron acts as a hapten to induce an immune reaction against the circulating blood cells. Additionally, the metabolic study in rats (B.6.1.1) showed that a small amount of radiolabeled azimsulfuron was retained in erythrocytes. No definitive mechanism of action for the testicular effects observed in the rat multigeneration study was established based on existing azimsulfuron data and a literature review.
Studies performed on metabolites or impurities ‡	IN-JJ999 Ames test: not mutagenic Acute oral toxicity study: rat LD_{50} > 5,000 mg/kg bw IN-J290 Ames test: not mutagenic Acute oral toxicity study: rat LD_{50} = 920 mg/kg bw IN-A8342 Ames test: not mutagenic Acute oral toxicity study: rat LD_{50} = 2850 mg/kg bw

Medical data ‡ (Annex IIA, point 5.9)

	No reported accidental poisonings with azimsulfuron. No known specific adverse human health effects. In case of poisoning, the patient should be treated symptomatically.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor

ADI ‡	0.10 mg/kg bw/d	Rat multigen. study	100
AOEL ‡	0.10 mg/kg bw/d	Rat multigen. study, supported by 90-d and 1-yr dog	100
ARfD ‡	Not established. No toxicological alerts from acute toxicity studies.		

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation: Azimsulfuron 50WG (Gulliver)	100% (default value) for formulation and spray

Exposure scenarios (Annex IIIA, point 7.2)

Operator	German model:	29% AOEL
	German model (PPE):	15% AOEL
	UK POEM:	207% AOEL
	UK POEM (gloves):	89% AOEL
Workers	EUROPOEM II (2002)	<1% AOEL
Bystanders	BBA (2000)	<1 % AOEL

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

	RMS/peer review proposal
Substance (azimsulfuron)	None

Residues

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

Plant groups covered	Cereals (Rice)
Rotational crops	Not required: .No residues (<0.01 mg as/kg) of azimsulfuron remain in the treated soil at the time of harvest or at the next seeding time as shown by the field residue trials.
Metabolism in rotational crops similar to metabolism in primary crops?	Not applicable.
Processed commodities	No data supplied or required.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not applicable.
Plant residue definition for monitoring	Azimsulfuron
Plant residue definition for risk assessment	Azimsulfuron
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	No significant residues (<0.1 ppm) in livestock feeds; therefore metabolism in livestock not required.
Time needed to reach a plateau concentration in milk and eggs	Not relevant
Animal residue definition for monitoring	Not required
Animal residue definition for risk assessment	Not required
Conversion factor (monitoring to risk assessment)	-
Metabolism in rat and ruminant similar (yes/no)	No information available nor required
Fat soluble residue: (yes/no)	No

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

………………………………………………… …..	No data supplied or required. Since there are no residues (<0.01 ppm) of azimsulfuron in soil at the time of seeding succeeding crop, no residues are expected in succeeding crops.

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

………………………………………………… …..	Stable in brown rice, rice straw and paddy soil stored frozen at temperature of -20°C for up to 430 days.

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 level)	No	No	No
Potential for accumulation (yes/no):	No	No	No

Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Not required	Not required	Not required
	Feeding studies Residue levels in matrices : Mean (max) mg/kg		
Muscle	No	No	No
Liver	No	No	No
Kidney	No	No	No
Fat	No	No	No
Milk	No		
Eggs		No	

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 Southern Region, field or glasshouse	Trials results relevant to the representative uses (a)	Recommendation/comments	**MRL** estimated from trials according to the representative use mg/kg	**HR** mg/kg (c)	**STMR** mg/kg (b)
Rice	Southern (Spain and Italy)	Grain: 4x <0.01, 4x <0.02 mg/kg	2 trials were performed in the same location in 1995 (Villafranco, Spain)	0.02*	0.02	0.02
		Straw: 4x <0.02, 4x <0.05 mg/kg		-	0.05	0.05

(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

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

ADI	0.1 mg/kg bw/day
TMDI (% ADI) according to WHO European diets	<0.02%
TMDI (% ADI) according to EFSA PRIMo Model	<0.02%
IEDI (WHO European Diet) (% ADI)	0.004%
NEDI (specify diet) (% ADI)	0.10% (UK Model, 7-10 years old children)
Factors included in IEDI and NEDI	MRL
ARfD	Not allocated.
IESTI (% ARfD)	-
NESTI (% ARfD) according to national (to be specified) large portion consumption data	-
Factors included in IESTI and NESTI	-

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	
Not applicable, residue levels are <0.1 mg/kg	-	-	-	-

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

Rice grain	0.02* mg/kg

* LOQ

Fate and Behaviour in the Environment

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

Mineralization after 100 days ‡	Flooded soil: 0%, [^{14}C-pyrazole] –label (n = 2) 2% after 84 days [^{14}C-pyrimidine] label (n = 2) 0.2-0.6%, [^{14}C-pyrazole] label (n = 2) 0.9-1.8% after 120 days [^{14}C-pyrimidine] label (n = 2) Upland soil (unflooded): 0%, [^{14}C-pyrazole] –label (n = 2) 2-13% after 84 d [^{14}C-pyrimidine] label (n = 2)
Non-extractable residues after 100 days ‡	Flooded soil: 42-45% after 84 d [^{14}C- pyrazole] label (n =2) 48-51% after 84 d [^{14}C- pyrimidine] label (n =2) 55-56% after 120d [^{14}C- pyrazole] label (n =2) 64-66% after 120d [^{14}C- pyrimidine] label (n =2) Upland soil (unflooded): 34 - 35 % after 84 d [^{14}C- pyrazole] label (n =2) 40 -47 % after 84 d [^{14}C- pyrimidine] label (n = 2)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	Flooded soil: IN-A8342: max 6% (at end of study, 84 d) (n = 2) IN-J290: max 3% (at days 3-28) (n = 2) IN-JJ999: max 7% (at 28 d) (n = 2) IN-KQ962: max 7% (at end of study, 84 d) (n = 2) IN-A8342: max 14% (at end of study, 120 d) (n = 2) IN-JJ999: max 13% (at 38 d) (n = 2) IN-KQ962: max 7.5% (at end of study, 120 d) (n = 2) Upland soil (unflooded): IN-A8342: max 28%, (at end of study, 84 d) (n = 2) IN-J290: max 24% (at end of study, 84 d) (n = 2) IN-JJ999: max 2% (max at days 3-14) (n = 2) IN-KQ962: max 13% (at end of study, 84 d) (n = 2) [^{14}C-pyrazole] and [^{14}C-pyrimidine] labels

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

Anaerobic degradation ‡

Mineralization after 100 days	Not determined. Total radioactive recovery was 92 and 98% at the end of incubation (162 days) for pyrimidine label and pyrazole label, respectively.

Non-extractable residues after 100 days	49 and 46% at the end of incubation (162 days) for pyrimidine-label and pyrazole-label, respectively (n = 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	IN-JJ999: max 9% at 162 d (end of study) pyrazole- and pyrimidine labels IN-A8342: max 15% at 162 d (n =1) pyrazole label IN-J290: max 5% at 162 d (n = 1) pyrimidine label IN-H9235: max 7% at 162 d (n=1) pyrimidine label
Soil photolysis ‡ Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Stable.

Rate of degradation in flooded soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)
Laboratory studies ‡

Azimsulfuron	Aerobic conditions – flooded soil									
Soil type	pH water phase	pH soil	t. °C	DT_{50}-DT_{90} whole sys.	St. (χ^2)	DT_{50}-DT_{90} water	St. (χ^2)	DT_{50}-DT_{90} sed	St. (χ^2)	Method of calculation (*=best fit)
Iwate light clay	n.r.	5.9	25	17.7-58.7 12.9-80.2	9 4	3.5-11.6 2.8-21.4	16 9	21.0-69.6 17.4-96.1	7 4	SFO DFOP* FOMC*
Ushiku light clay	n.r.	5.6	25	20.5-68.2 19.0-77.3	3 2	- 3.0-12.9	- 12	27.0-89.7	6	SFO FOMC*
Borgovercelli sandy loam	7.5-8.2	6.9-7.2	20	35.8-119	7	26.1-86.7	9	45.5-151	9	SFO**
Salussola clay loam	7.7-8.1	6.8-7.1	20	51-169	5	32.9-109	7	48.9-162	4	SFO**
Geometric mean/median				Not used		Not used		Not used		

**only SFO optimisation presented by the notifier

Rate of degradation in unflooded soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)
Laboratory studies ‡

Azimsulfuron	Aerobic conditions – unflooded soil						
Soil type	% Org. C	pH	t °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (χ^2)	Method of calculation (*=best fit)
Iwate light clay	1.59	5.9	25/45MWHC	39.8-132 30.9-158	63.9	9 3	SFO DFOP*
Ushiku light clay	2.07	5.6	25/59MWHC	31.9-106 17.7-529	51.2	11 4	SFO DFOP*
Tama silty loam	1.05	6.1	20/75MHC	20.1-66.6 13.7-181	32.3	14 5	SFO FOMC*
Novara sandy loam	1.45	5.8	20/20 moisture	17.3-57.5	17.3	5	SFO*

Vercelli silt loam	1.91	6.9	20/23 moisture	28.4-94.3 21.9-144	28.4	8 3	SFO FOMC*
Cullera clay	1.74	8.1	20/30 moisture	123-409 109-509	123	7 4	SFO DFOP*
Cullera silt clay	1.63	8.1	20/28 moisture	133-441	133	7	SFO*
Geometric/arithmetric mean from SFO					51/64		

Rate of degradation in flooded soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)
Laboratory studies ‡

IN-A8342	Aerobic conditions – flooded soil							
Soil type	% Org. C	pH	t. °C	DT_{50}/ DT_{90} (d) whole system	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (χ^2)	Method of calculation (*=best fit)
Ushiku light clay	2.07	5.6	25	27.3/90.8	-	43.9	24	SFO*
Borgovercelli sandy loam	7.5-8.0	6.9-7.5	20	43.8/145	-	43.8	10	SFO**
Salussola clay loam	7.7-8.3	6.8-7.2	20	55.0/183	-	55.0	9	SFO**
Geometric mean/median						Not used		

**only SFO optimisation presented by the notifier

Rate of degradation in unflooded soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)
Laboratory studies ‡

IN-A8342	Aerobic conditions – unflooded soil
No reliable degradation parameters could be calculated, and therefore the default value of 1000 days will be used for modelling purposes.	

Rate of degradation in flooded soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)
Laboratory studies ‡

IN-JJ999	Aerobic conditions – flooded soil							
Soil type	% Org. C	pH	t. °C	DT_{50}/ DT_{90} (d) whole system	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (χ^2)	Method of calculation (*=best fit)
Iwate light clay	1.59	5.9	25	31/103	-	-	16	DFOP*
Ushiku light clay	2.07	5.6	25	18.8/62.6 22.6/75.2	-	30.2	10 13	SFO* DFOP
Borgovercelli sandy loam	7.5-8.0	6.9-7.5	20	39.1/130	-	39.1	13	SFO**
Salussola clay loam	7.7-8.3	6.8-7.2	20	46.1/153	-	46.1	7	SFO**
Geometric mean/median						Not used		

**only SFO optimisation presented by the notifier

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

Laboratory studies ‡

IN-JJ999	Aerobic conditions – unflooded soil							
Soil type	% Org. C	pH	t. °C / %MWHC	DT_{50}/DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d)20 °C pF2/10kPa	St. (χ^2)	Method of calculation
Iwate light clay	1.59	5.9	25/45MWHC	9.9/33	-	-	20	DFOP*
Ushiku light clay	2.07	5.6	25/59MWHC	6.5/21.7	-	-	24	DFOP*
Tama silty loam	1.05	6.1	20/75MHC	142/472	-		11	SFO*
Geometric mean/median						Not used		

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

Laboratory studies ‡

IN-KQ962	Aerobic conditions – flooded soil
No reliable degradation parameters could be calculated, and therefore the default value of 1000 days will be used for modelling purposes.	

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

Laboratory studies ‡

IN-KQ962	Aerobic conditions – unflooded soil
No reliable degradation parameters could be calculated, and therefore the default value of 1000 days will be used for modelling purposes.	

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

Laboratory studies ‡

IN-J290	Aerobic conditions – unflooded soil							
Soil type	% Org. C	pH	t. °C / %MWHC	DT_{50}/DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d)20 °C pF2/10kPa	St. (χ^2)	Method of calculation (*=best fit)
Speyer 2.2 sandy loam	2.5	6.7	20/50% of MWHC	3.1/10.2 2.8-12.5	-	3.1	7 5	SFO FOMC*
Pavia loamy sand	0.3	5.5	20/50% of MWHC	18.0/59.9 10.6/157.5	-	- 47.4	19 7	SFO FOMC*
Nambsheim sandy loam	0.8	8.0	20/50% of MWHC	18.7/62.1 11.2/117	-	18.7	15 5	SFO FOMC*
Vercelli silt loam	1.0	6.1	20/50% of MWHC	12.6/41.8 6.9/127	-	38.3	23 5	SFO FOMC*
Geometric mean/median						18.0/28.5		

Field studies ‡

Parent	Aerobic conditions, rice paddies								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	% Org C	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (χ^2)	DT_{50} (d) Norm.	Method of calculation
S. Angello Lomellina sandy loam	Italy	0.72	6.3	9/15 w/s	2.1	6.9	15	-	SFO

Field studies ‡

Parent	Aerobic conditions, rice paddies								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	% Org C	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (χ^2)	DT_{50} (d) Norm.	Method of calculation
Marano sul Po loam	Italy	1.06	6.6	10/15 w/s	3.2	10.6	6	-	SFO
Geometric mean/median									

pH dependence ‡ (yes / no) (if yes type of dependence)	Yes, slower degradation at higher pH
Soil accumulation and plateau concentration ‡	Not available, not needed.

Laboratory studies ‡

Parent	Anaerobic conditions						
Soil type	% Org C	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (χ^2)	Method of calculation (*=best fit)
Tama silty loam	1.05	6.1	20/75 % of MHC	63.1/210 30.6/1475	101	14 7	SFO FOMC*
Geometric mean/median					101		

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent Azimsulfuron (Boucher, 1995)‡							
Soil Type	OC %	Soil pH	K_d (mL/g)	K_{oc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Cullera-001 clay	1.7	8.1	1.60	94	1.31	77	0.98
Cullera-002 silty clay	1.6	8.1	1.43	89	1.24	78	0.93
Vercelli silt loam	1.9	6.9	1.22	64	1.25	66	0.88
Novara sandy loam	1.4	5.8	0.67	48	0.75	54	0.95
Geometric mean			**1.17**	**71**	**1.11**	**68**	**0.93**
Arithmetic mean			**1.23**	**74**	**1.14**	**69**	**0.94**
pH dependence, Yes or No			No (no quantitative pH relationship can be derived from the available data, although pH dependence for soil adsorption is expected)				

Metabolite IN-JJ999 (Spare, 1995) ‡							
Soil Type	OC %	Soil pH	K_d (mL/g)	K_{oc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Cullera-001 clay	1.7	8.1	0.59	34	n.d.	n.d.	n.d.
Cullera-002 silty clay	1.6	8.1	0.64	40	n.d.	n.d.	n.d.
Vercelli silt loam	1.9	6.9	0.54	28	n.d.	n.d.	n.d.
Novara sandy loam	1.4	5.8	0.42	29	n.d.	n.d.	n.d.
Geometric mean			**0.54**	**32**			
Arithmetic mean			**0.55**	**33**			
pH dependence (yes or no)			No				

Metabolite IN-KQ962 (Spare, 1995) ‡							
Soil Type	OC %	Soil pH	K_d (mL/g)	K_{oc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Cullera-001 clay	1.7	8.1	0.89	51	n.d.	n.d.	n.d.
Cullera-002 silty clay	1.6	8.1	0.92	57	n.d.	n.d.	n.d.
Vercelli silt loam	1.9	6.9	0.70	37	n.d.	n.d.	n.d.
Novara sandy loam	1.4	5.8	0.41	28	n.d.	n.d.	n.d.
Geometric mean			**0.70**	**42**			
Arithmetic mean			**0.73**	**43**			
pH dependence (yes or no)			No				

Metabolite IN-A8342 (Spare, 1995) ‡							
Soil Type	OC %	Soil pH	K_d (mL/g)	K_{oc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Cullera-001 clay	1.7	8.1	2.48	142	n.d.	n.d.	n.d.
Cullera-002 silty clay	1.6	8.1	1.95	120	n.d.	n.d.	n.d.
Vercelli silt loam	1.9	6.9	1.73	90	n.d.	n.d.	n.d.
Novara sandy loam	1.4	5.8	0.69	48	n.d.	n.d.	n.d.
Geometric mean			**1.55**	**93**			
Arithmetic mean			**1.71**	**100**			
pH dependence (yes or no)			No				

Metabolite IN-J290 (Spare, 1995; Aikens, 2001) ‡							
Soil Type	OC %	Soil pH	K_d (mL/g)	K_{oc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Cullera-001 clay	1.7	8.1	1.94	111*	n.d.	n.d.	n.d.
Cullera-002 silty clay	1.6	8.1	1.83	113*	n.d.	n.d.	n.d.
Vercelli silt loam	1.9	6.9	1.82	95*	n.d.	n.d.	n.d.
Novara sandy loam	1.4	5.8	1.32	91*	n.d.	n.d.	n.d.
Speyer 2.2	2.1	6.4	1.37	65	1.22	58	0.85
Pavia	0.5	5.2	2.75	549	2.26	452	0.81
Nambsheim	0.7	7.8	0.90	128	0.86	123	0.79
Vercelli	1.2	5.8	2.92	244	2.35	196	0.82
Geometric mean			**1.77**	**137**	**1.54**	**158**	**0.82**
Arithmetic mean			**1.99**	**175**	**1.67**	**207**	**0.82**
pH dependence (yes or no)			No				

**In this case, the K_d values were derived from a test at a nominal test concentration of 5.0 mg/L and is therefore not directly comparable with the K_{Foc} values that are generally preferred. For the rest of the soils, the Koc values were derived from 1 mg/L test concentration. These values were lower than the corresponding 5.0 mg/L values and therefore represent a worst case. This was a way to make use of all available data in the calculated geometric mean of the Koc values for modelling purposes. NOTE that based on comments received during the peer review of azimsulfuron, the recommended values for modelling purposes are the arithmetic mean Kfoc.*

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

Column leaching ‡	No data submitted, not required.
Aged residues leaching ‡	Sufficient information was obtained from the previous studies with metabolites to obviate the need for aged residue column leaching. No further data considered necessary.

Lysimeter/ field leaching studies ‡	No data submitted, not required.

PEC (paddy soil) (Annex IIIA, point 9.1.3)

Parent	MED-RICE Step 1: DT_{50} (d): 51 days (longest total system from paddy soils)
Method of calculation	MED-RICE (2003) Kinetics: FOCUS (2001)
Application data	Crop: Rice Depth of soil layer: 0.05 m Soil bulk density: 1.5 kg/dm^3 % plant interception: 25 Application rate(s): 25 g a.s./ha K_{FOC}: 68 mL/g
Scenario 1	Clayey soil pH 8 1.8% OC 1 mm/d leakage (infiltration rate) 0.01 leakage rate constant (1/d)
Scenario 2	Sandy soil pH 6 0.9% OC 10 mm/d leakage (infiltration rate) 0.1 leakage rate constant (1/d)

Inputs used in MED-RICE Step 1 PECsoil calculations for azimsulfuron metabolites

Metabolite	Molecular weight (g/mol)	Maximum formed [a] (%)	Foliar interception[b] (%)	Equivalent application rate[c] (g/ha)	K_{FOC}[d] (mL/g)	DT_{50}[e] (days)
FLOODED AND SATURATED						
IN-A8342	243	16.58 (extrapolated)	Not applicable	1.78	93	55
IN-JJ999	410	13 (observed)	Not applicable	2.36	32	46.1
IN-KQ962	328	8.7 (extrapolated)	Not applicable	1.26	42	1000
SATURATED ONLY						
IN-J290	155	29 (extrapolated)	Not applicable	1.99	137	18

[a] The maximum percent observed in flooded soil or unflooded soil degradation studies, respectively. In cases where the highest values were observed at the last sampling day, an extrapolated theoretical maximum was used (for explanation, see Corrigendum to the DRAR, September 2009).

[b] Applied as post-emergent at 3-leaf to tillering (BBCH-code 13 to 20) to flooded paddies. FOCUS SW: 0.25 crop cover for BBCH-code 10 to 19 for cereals and corn. Foliar interception for metabolites is accounted for in the equivalent application rate.

[c] Equivalent application rate = (azimsulfuron rate - foliar interception) × (metabolite molecular weight/parent molecular weight) x fraction of metabolite formed. Assumes instantaneous conversion from azimsulfuron to the metabolite.

[d] The geometric mean K_{Foc} values were selected. *NOTE that based on comments received during the peer review of azimsulfuron, the recommended values for modelling purposes are the arithmetic mean Kfoc.*

[e] The longest total system degradation DT_{50} values from flooded or unflooded soil degradation studies were used, except for IN-J290 in saturated soil where the geomean value was used since four soils were tested.

Summary of maximum Step 1 PEC_{soil} (µg/kg) values for azimsulfuron determined using the methods given in MED-RICE (2003) for saturated soil.

		Maximum PEC value for saturated soil
		CLAY and SAND
Calculation method	Compound	PEC_{soil} (µg/kg dry soil)
MED-RICE Step 1 for saturated soil, 5 cm depth, soil bulk density 1.5 L/kg	Azimsulfuron	25.0
	IN-A8342	2.38
	IN-J290	2.65
	IN-JJ999	3.14
	IN-KQ962	1.68

Summary of Step 1 PEC_{soil} (µg/kg) values for azimsulfuron determined using the methods given in MED-RICE (2003) for flooded soil.

	Clay		Sand	
Time after application (days)	Actual PEC_{soil} (µg/kg)	Time weighted PEC_{soil} (µg/kg)	Actual PEC_{soil} (µg/kg)	Time weighted PEC_{soil} (µg/kg)
0	12.0	-	7.86	-
1	11.8	11.9	7.76	7.81
2	11.6	11.8	7.65	7.76
4	11.3	11.6	7.45	7.66
7	10.9	11.4	7.15	7.50
14	9.89	10.9	6.50	7.16
21	8.98	10.4	5.91	6.84
28	8.18	10.0	5.38	6.54
42	6.76	9.10	4.44	5.99
50	6.06	8.67	3.99	5.71
100	3.07	6.53	2.02	4.30

Summary of Step 1 PEC_{soil} (µg/kg) values for IN-A8342 determined using the methods given in MED-RICE (2003) for flooded soil.

	Clay		Sand	
Time after application (days)	Actual PEC_{soil} (µg/kg)	Time weighted PEC_{soil} (µg/kg)	Actual PEC_{soil} (µg/kg)	Time weighted PEC_{soil} (µg/kg)
0	0.99	-	0.69	-
1	0.98	0.98	0.68	0.68
2	0.97	0.98	0.67	0.68
4	0.94	0.97	0.65	0.67
7	0.91	0.95	0.63	0.66
14	0.83	0.91	0.58	0.63
21	0.76	0.87	0.53	0.60
28	0.70	0.83	0.48	0.58
42	0.58	0.77	0.40	0.53
50	0.53	0.74	0.37	0.51
100	0.28	0.56	0.19	0.39

Summary of Step 1 PEC_{soil} (µg/kg) values for IN-JJ999 determined using the methods given in MED-RICE (2003) for flooded soil.

Time after application (days)	Clay		Sand	
	Actual PEC_{soil} (µg/kg)	Time weighted PEC_{soil} (µg/kg)	Actual PEC_{soil} (µg/kg)	Time weighted PEC_{soil} (µg/kg)
0	0.71	-	0.42	-
1	0.70	0.71	0.41	0.42
2	0.69	0.70	0.41	0.41
4	0.67	0.69	0.39	0.41
7	0.64	0.68	0.38	0.40
14	0.58	0.64	0.34	0.38
21	0.52	0.61	0.31	0.36
28	0.47	0.58	0.28	0.34
42	0.38	0.53	0.22	0.31
50	0.34	0.50	0.20	0.29
100	0.16	0.37	0.09	0.22

Summary of Step 1 PEC_{soil} (µg/kg) values for IN-KQ962 determined using the methods given in MED-RICE (2003) for flooded soil.

Time after application (days)	Clay		Sand	
	Actual PEC_{soil} (µg/kg)	Time weighted PEC_{soil} (µg/kg)	Actual PEC_{soil} (µg/kg)	Time weighted PEC_{soil} (µg/kg)
0	0.46	-	0.28	-
1	0.46	0.46	0.28	0.28
2	0.46	0.46	0.28	0.28
4	0.45	0.46	0.28	0.28
7	0.45	0.45	0.28	0.28
14	0.45	0.45	0.28	0.28
21	0.45	0.45	0.27	0.28
28	0.45	0.45	0.27	0.28
42	0.44	0.45	0.27	0.27
50	0.44	0.45	0.27	0.27
100	0.43	0.44	0.26	0.27

Summary of Step 1 PEC_{pw} (µg/L) values for azimsulfuron determined using the methods given in MED-RICE (2003) for flooded soil.

Time after application (days)	Clay		Sand	
	Actual PEC_{pw} (µg/L)	Time weighted PEC_{pw} (µg/L)	Actual PEC_{pw} (µg/L)	Time weighted PEC_{pw} (µg/L)
0	9.78	-	12.85	-
1	9.64	9.71	12.68	12.76
2	9.51	9.64	12.51	12.68
4	9.26	9.51	12.17	12.51
7	8.89	9.33	11.68	12.26
14	8.08	8.90	10.62	11.70
21	7.35	8.50	9.66	11.18
28	6.68	8.13	8.78	10.69
42	5.52	7.45	7.26	9.79

50	4.95	7.09	6.51	9.33
100	2.51	5.35	3.30	7.03

Summary of Step 1 PEC_{pw} (µg/L) values for IN-A8342 determined using the methods given in MED-RICE (2003) for flooded soil.

Time after application (days)	Clay		Sand	
	Actual PEC_{pw} (µg/L)	Time weighted PEC_{pw} (µg/L)	Actual PEC_{pw} (µg/L)	Time weighted PEC_{pw} (µg/L)
0	0.59	-	0.82	-
1	0.58	0.59	0.81	0.82
2	0.58	0.58	0.80	0.81
4	0.56	0.58	0.78	0.80
7	0.54	0.57	0.75	0.79
14	0.50	0.54	0.69	0.75
21	0.45	0.52	0.63	0.72
28	0.42	0.50	0.58	0.69
42	0.35	0.46	0.48	0.64
50	0.32	0.44	0.44	0.61
100	0.17	0.34	0.23	0.47

Summary of Step 1 PEC_{pw} (µg/L) values for IN-JJ999 determined using the methods given in MED-RICE (2003) for flooded soil.

Time after application (days)	Clay		Sand	
	Actual PEC_{pw} (µg/L)	Time weighted PEC_{pw} (µg/L)	Actual PEC_{pw} (µg/L)	Time weighted PEC_{pw} (µg/L)
0	1.24	-	1.46	-
1	1.22	1.23	1.43	1.44
2	1.20	1.22	1.41	1.43
4	1.16	1.20	1.37	1.41
7	1.11	1.17	1.31	1.38
14	1.00	1.11	1.18	1.31
21	0.90	1.06	1.06	1.25
28	0.81	1.01	0.96	1.19
42	0.66	0.92	0.77	1.08
50	0.58	0.87	0.69	1.02
100	0.27	0.64	0.32	0.75

Summary of Step 1 PEC_{pw} (µg/L) values for IN-KQ962 determined using the methods given in MED-RICE (2003) for flooded soil.

Time after application (days)	Clay		Sand	
	Actual PEC_{pw} (µg/L)	Time weighted PEC_{pw} (µg/L)	Actual PEC_{pw} (µg/L)	Time weighted PEC_{pw} (µg/L)
0	0.60	-	0.74	-
1	0.60	0.60	0.74	0.74
2	0.60	0.60	0.74	0.74
4	0.60	0.60	0.73	0.74
7	0.60	0.60	0.73	0.73
14	0.60	0.60	0.73	0.73
21	0.59	0.60	0.73	0.73

28	0.59	0.60	0.72	0.73
42	0.59	0.59	0.72	0.73
50	0.58	0.59	0.71	0.72
100	0.56	0.58	0.69	0.71

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 5: 89 days at 26°C (1st order, $r^2 \geq 0.95$) IN-J290: 21% AR (30 d, end of study) IN-A8342: 21% AR (30 d end of study)
	pH 7: 124 days at 26°C (1st order, $r^2 \geq 0.95$) IN-J290: 15% AR (27-30 d, end of study) IN-A8342: 15% AR (30 d)
	pH 9: 132 days at 26°C (1st order, $r^2 \geq 0.95$) IN-J290: 15% AR (27-30 d, end of study) IN-A8342: 16% AR (30 d , end of study)
Photolytic degradation of active substance and metabolites above 10 % ‡	Direct photolysis: pH 5. DT_{50}: 103 days pH 7. DT_{50}: 164 days pH 9. DT_{50}: 225 days Same metabolites (IN-J290 and IN-A8342) formed in dark control samples in similar amounts, hence not considered as photolysis products. Natural light, 40°N; DT_{50} 496 days, calculated from quantum efficiency for degradation of azimsulfuron in water. Natural river water (pH=7) Sterile DT_{50}: 15.4 days (χ^2 1.7%) based on continuous light (30.8 days at 12 hours light per day). No correction was made for possible hydrolysis since little degradation took place in the dark controls. No clear identification of metabolites in the study report. Indirect photolysis Hydroxyl radical degradation (H_2O_2 added to buffer). Predicted DT_{50} in natural water: 2-23 d
Quantum yield of direct phototransformation in water at Σ > 290 nm	Quantum efficiency = 9×10^{-4}
Readily biodegradable ‡ (yes/no)	No

Degradation in water / sediment

Azimsulfuron	Distribution: max in water 88% after 0 d. Max in sediment 44% after 60 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (χ^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation (*=best fit)
Aversley Wood, UK	6.7	5.0	20	111-369	3	*	4	Inadequate decline	-	SFO*
Houghton Meadow, UK	7.0	7.4	20	142-473	3	*	6	Inadequate decline	-	SFO*
Geometric mean/median				127-421						

* Degradation rates not reliable

IN-A8342	Distribution: max not reached in water (13% after 100 d) or in sediment (16% after 100 d)
No reliable degradation parameters could be calculated, and therefore the default value of 1000 days in water and sediment will be used for modelling purposes.	

IN-JJ999	Distribution: max not reached in water (6.5% after 100 d) or in sediment (4.3% after 100 d)
No reliable degradation parameters could be calculated, and therefore the default value of 1000 days in water and sediment will be used for modelling purposes.	

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after 100 d (end of the study).	Non-extractable residues in sed. max x % after 100 d	Non-extractable residues in sed. max x % after 100 d (end of the study)
Aversley Wood, UK	6.7	5.0	<1.5	19.3	19.3
Houghton Meadow, UK	7.0	7.4	<1.5	27.4	27.4

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

Parent: Azimsulfuron Parameters used in MED-RICE Step 1	2003 Version of Med-Rice Molecular weight (g/mol): 424 **Scenario 1 (clayey soil):** OC soil (%): 1.8 Water depth in field (m): 0.1 Infiltration rate (mm/d): 1 Leakage rate constant (1/d): 0.01 DT_{50} soil (d): 51 days (lab) DT_{50} water/sediment system (d): 142.4 days DT_{50} water (d): 142.4 days DT_{50} sediment (d): 142.4 days Crop interception (%): 25 F_{sorbed} (soil): 0.479 F_{sorbed} (sediment): 0.075 Kd (soil): 1.22 Kd (sediment): 1.09 **Scenario 2 (sandy soil):**

	OC soil (%):0.9 Water depth in field (m): 0.1 Infiltration rate (mm/d): 10 Leakage rate constant (1/d): 0.1 DT_{50} soil (d): 51 days (lab) DT_{50} water/sediment system (d): 142.4 days DT_{50} water (d): 142.4 days DT_{50} sediment (d): 142.4 days Crop interception (%): 25 F_{sorbed} (soil): 0.315 F_{sorbed} (sediment): 0.075 Kd (soil): 0.621 Kd (sediment): 1.09
Application rate	Crop: Rice Crop interception: 25% Number of applications: 1 Interval (d): Not applicable Application rate(s): 25 g a.s./ha Application window: Post-emergent at 3-leaf to tillering to flooded paddies

Inputs used in MED-RICE Step 1 PECsurface water and sediment calculations for azimsulfuron metabolites

Metabolite	Molecular weight (g/mol)	Maximum formed [a] (%)	Foliar interception[b] (%)	Equivalent application rate[c] (g/ha)	K_{FOC}[d] (mL/g)	DT_{50}[e] (days) in flooded soil	DT_{50}[f] (days) in water-sediment
FLOODED							
IN-A8342	243	41 (extrapolated)	Not applicable	4.41	93	55.0	1000
IN-JJ999	410	16 (extrapolated)	Not applicable	2.90	32	46.1	1000
IN-KQ962	328	8.7 (extrapolated)	Not applicable	1.26	42	1000	1000

[a] The maximum percent observed in flooded soil degradation studies or water-sediment studies, whichever were highest. In cases where the highest values were observed at the last sampling day, an extrapolated theoretical maximum was used (for explanation, see Corrigendum to the DRAR, September 2009). In this case, the maximum values for all metabolites were derived from flooded soil studies.

[b] Applied as post-emergent at 3-leaf to tillering (BBCH-code 13 to 20) to flooded paddies. FOCUS SW: 0.25 crop cover for BBCH-code 10 to 19 for cereals and corn. Foliar interception for metabolites is accounted for in the equivalent application rate.

[c] Equivalent application rate = (azimsulfuron rate - foliar interception) × (metabolite molecular weight/parent molecular weight) x fraction of metabolite formed. Assumes instantaneous conversion from azimsulfuron to the metabolite.

[d] The geometric mean K_{Foc} values were selected. *NOTE that based on comments received during the peer review of azimsulfuron, the recommended values for modelling purposes are the arithmetic mean Kfoc.*

[e] The longest total system degradation DT_{50} values from flooded or unflooded soil degradation studies were used.

[f] The longest total system degradation DT_{50} values from water-sediment degradation studies were used.

Summary of Step 1 PEC_{sw} (µg/L) and PEC_{sed} (µg/kg) values for azimsulfuron determined using the methods given in MED-RICE (2003) for flooded soil scenarios.

MED-RICE Step 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
CLAY	0	0.89	-	0.99	-
	1	0.88	0.88	0.98	0.98
	2	0.88	0.88	0.98	0.98
	4	0.87	0.88	0.97	0.98
	7	0.86	0.87	0.95	0.97
	14	0.83	0.86	0.92	0.95
	21	0.80	0.84	0.89	0.94
	28	0.77	0.83	0.86	0.92
	42	0.72	0.80	0.80	0.89
	50	0.70	0.79	0.77	0.88
	100	0.54	0.70	0.61	0.78
SAND	0	1.15	-	1.28	-
	1	1.14	1.15	1.27	1.27
	2	1.14	1.14	1.26	1.27
	4	1.13	1.14	1.25	1.26
	7	1.11	1.13	1.23	1.25
	14	1.07	1.11	1.19	1.23
	21	1.04	1.09	1.15	1.21
	28	1.00	1.07	1.11	1.19
	42	0.94	1.04	1.04	1.15
	50	0.90	1.02	1.00	1.13
	100	0.70	0.91	0.78	1.01

Summary of Step 1 PEC_{sw} (µg/L) and PEC_{sed} (µg/kg) values for IN-A8342 determined using the methods given in MED-RICE (2003) for flooded soil scenarios.

MED-RICE Step 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
CLAY	0	0.14	-	0.20	-
	1	0.14	0.14	0.20	0.20
	2	0.13	0.14	0.20	0.20
	4	0.13	0.13	0.20	0.20
	7	0.13	0.13	0.20	0.20
	14	0.13	0.13	0.20	0.20
	21	0.13	0.13	0.20	0.20
	28	0.13	0.13	0.20	0.20
	42	0.13	0.13	0.19	0.20
	50	0.13	0.13	0.19	0.20
	100	0.13	0.13	0.19	0.19
SAND	0	0.18	-	0.27	-
	1	0.18	0.18	0.27	0.27
	2	0.18	0.18	0.27	0.27
	4	0.18	0.18	0.27	0.27
	7	0.18	0.18	0.27	0.27

Summary of Step 1 PEC_{sw} (µg/L) and PEC_{sed} (µg/kg) values for IN-A8342 determined using the methods given in MED-RICE (2003) for flooded soil scenarios.

MED-RICE Step 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	14	0.18	0.18	0.27	0.27
	21	0.18	0.18	0.27	0.27
	28	0.18	0.18	0.27	0.27
	42	0.18	0.18	0.26	0.27
	50	0.18	0.18	0.26	0.27
	100	0.17	0.18	0.25	0.26

Summary of Step 1 PEC_{sw} (µg/L) and PEC_{sed} (µg/kg) values for IN-JJ999 determined using the methods given in MED-RICE (2003) for flooded soil scenarios.

MED-RICE Step 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
CLAY	0	0.14	-	0.073	-
	1	0.13	0.14	0.073	0.073
	2	0.13	0.13	0.073	0.073
	4	0.13	0.13	0.073	0.073
	7	0.13	0.13	0.073	0.073
	14	0.13	0.13	0.073	0.073
	21	0.13	0.13	0.072	0.073
	28	0.13	0.13	0.072	0.073
	42	0.13	0.13	0.071	0.072
	50	0.13	0.13	0.071	0.072
	100	0.13	0.13	0.068	0.071
SAND	0	0.16	-	0.086	-
	1	0.16	0.16	0.086	0.086
	2	0.16	0.16	0.086	0.086
	4	0.16	0.16	0.086	0.086
	7	0.16	0.16	0.085	0.086
	14	0.16	0.16	0.085	0.085
	21	0.16	0.16	0.085	0.085
	28	0.15	0.16	0.084	0.085
	42	0.15	0.16	0.083	0.085
	50	0.15	0.16	0.083	0.084
	100	0.15	0.15	0.080	0.083

Summary of Step 1 PEC_{sw} (µg/L) and PEC_{sed} (µg/kg) values for IN-KQ962 determined using the methods given in MED-RICE (2003) for flooded soil scenarios.

MED-RICE Step 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
CLAY	0	0.058	-	0.041	-
	1	0.058	0.058	0.041	0.041
	2	0.058	0.058	0.041	0.041
	4	0.057	0.058	0.041	0.041
	7	0.057	0.058	0.040	0.041
	14	0.057	0.057	0.040	0.040
	21	0.057	0.057	0.040	0.040

Summary of Step 1 PEC_{sw} (µg/L) and PEC_{sed} (µg/kg) values for IN-KQ962 determined using the methods given in MED-RICE (2003) for flooded soil scenarios.

MED-RICE Step 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	28	0.057	0.057	0.040	0.040
	42	0.056	0.057	0.040	0.040
	50	0.056	0.057	0.039	0.040
	100	0.054	0.056	0.038	0.039
SAND	0	0.070	-	0.049	-
	1	0.070	0.070	0.049	0.049
	2	0.070	0.070	0.049	0.049
	4	0.070	0.070	0.049	0.049
	7	0.069	0.070	0.049	0.049
	14	0.069	0.069	0.049	0.049
	21	0.069	0.069	0.048	0.049
	28	0.068	0.069	0.048	0.049
	42	0.068	0.069	0.048	0.048
	50	0.067	0.069	0.047	0.048
	100	0.065	0.067	0.046	0.048

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

Method of calculation and type of study (e.g. modelling, field leaching, lysimeter)	MED-RICE (2003) Step 1: DT_{50} (d): 51 days (longest total system from paddy soils) and 142.4 days (longest total system from water/sediment studies)
Application rate	25 g as/ha

Summary of the modified scenario input data for the MED-RICE simulations of $PEC_{groundwater}$ for azimsulfuron.

INPUT: Scenario data I	**Scenario 1**	**Scenario 2**
Soil texture	clayey	sandy
OC soil (%)	1.8	0.9
pH	8	6
depth $_{water}$ (m) (water level in field)	0.1	0.1
Water velocity:		
field (L/sec/ha)**	**1.8**	**2.8**
outflow (L/sec/ha)	0.5	0.5
Leakage (mm/d) (infiltration rate)	1	10
Leakage rate constant (1/d)*	**0.01**	**0.1**
t $_{close}$ (d) (time of closure of field)	5	5
t $_{flood}$ (d) (time of flooding)	120	120
depth $_{canal}$ (m) (deepness of outflow)	1	1

INPUT: Scenario data II		
area (m^2) (area of rice field)	10000	10000
Volume of water in field (L)	1000000	1000000
depth $_{soil}$ (m)	0.05	0.05
BD soil (kg/dm^3) (soil bulk density)	1.5	1.5
Outflow rate constant (1/d)	0.0432	0.0432
Dilution factor	10	10
depth $_{sediment}$ (m) (active sediment depth)	0.05	0.05
OC (%) of sediment	1.6	1.6
BD $_{sediment}$ (kg/dm^3) (sediment bulk densitiy)	1.5	1.5

**These constants were added by the notifier and resulted in modified values for field water velocity.*
***modified due to the addition of the leakage rate constants made by the notifier.*

Inputs used in MED-RICE Step 1 PECgw calculations for azimsulfuron metabolites

Metabolite	**Molecular weight (g/mol)**	**Maximum formed [a] (%)**	**Foliar interception[b] (%)**	**Equivalent application rate[c] (g/ha)**	**K_{FOC}[d] (mL/g)**	**DT_{50}[e] (days)**
FLOODED						
IN-A8342	243	16.58 (extrapolated)	Not applicable	1.78	93	55.0
IN-JJ999	410	13 (observed)	Not applicable	2.36	32	46.1
IN-KQ962	328	8.7 (extrapolated)	Not applicable	1.26	42	1000
UNFLOODED						
IN-J290	155	29 (extrapolated)	Not applicable	1.99	137	18

[a] The maximum percent observed in flooded/unflooded soil degradation studies, respectively. In cases where the highest values were observed at the last sampling day, an extrapolated theoretical maximum was used (for explanation, see Corrigendum to the DRAR, September 2009).

[b] Applied as post-emergent at 3-leaf to tillering (BBCH-code 13 to 20) to flooded paddies. FOCUS SW: 0.25 crop cover for BBCH-code 10 to 19 for cereals and corn. Foliar interception for metabolites is accounted for in the equivalent application rate.

[c] Equivalent application rate = (azimsulfuron rate - foliar interception) × (metabolite molecular weight/parent molecular weight) x fraction of metabolite formed. Assumes instantaneous conversion from azimsulfuron to the metabolite.

[d] The geometric mean K_{Foc} values were selected. *NOTE that based on comments received during the peer review of azimsulfuron, the recommended values for modelling purposes are the arithmetric mean Kfoc.*

[e] The longest total system degradation DT_{50} values from flooded soil degradation studies were used for IN-A8342, IN-JJ999 and IN-KQ962, while for IN-J290 the geomean from unflooded soil studies were used since four soils were tested.

PEC(gw) – MED-RICE (2003) Step 1 results (annual average concentration at 1m)

Compound	**Annual average PEC_{gw} (µg/L)**	
	CLAY	**SAND**
Azimsulfuron	0.0000	**0.1158**
IN-A8342	0.0000	0.0066

IN-JJ999	0.0000	0.0161
IN-J0290	0.0000 (saturated soil only)	0.0003 (saturated soil only)
IN-KQ962	0.0225	0.0159

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

Direct photolysis in air ‡	Latitude: 30° Season: Summer DT_{50}: 487 d
Quantum yield of direct phototransformation	Active substance: Quantum efficiency = 9×10^{-4}
Photochemical oxidative degradation in air ‡	DT_{50} of 0.632 hours derived by the Atmospheric Oxidation Program v 1.83 of Syracuse Research Corp.
Volatilisation ‡	From plant surfaces: 2.7% after 24 hours From soil: 12.9% after 24 hours
Metabolites	None.

PEC (air)

Method of calculation	Volatilisation estimation method using "Dow method" (Thomas, 1990) <<0.01% of the azimsulfuron from a 25 g a.s./ha application would be volatilized from the surface of treated soil into the air, even considering the lowest water solubility value reported of 72.3 mg/L at pH 5.
$PEC_{(a)}$ Maximum concentration	Assuming a uniformly mixed stagnate layer of air to a height of 1 m over a treated field, the PEC_{air} in this layer would be negligible following application (6.0×10^{-4} µg/m^3).

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	**Soil:** azimsulfuron, IN-A8342 (flooded and saturated), IN-JJ999 (flooded and saturated), IN-KQ962 (flooded and saturated), IN-J290 (saturated only) **Surface Water:** azimsulfuron, IN-A8342, IN-JJ999, IN-KQ962 (provisional as a data gap was identified for identification of degradation products in the aqueous photolysis study) **Sediment:** azimsulfuron, IN-A8342, IN-JJ999 **Ground water:** azimsulfuron, IN-A8342, IN-JJ999, IN-KQ962, IN-J290 **Air:** azimsulfuron

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

Soil (indicate location and type of study)	None available
Surface water (indicate location and type of study)	None available
Ground water (indicate location and type of study)	None available
Air (indicate location and type of study)	None available

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

Active substance	Candidate for R53

Effects on non-target Species

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 ‡				
Quail (*C. virginianus*)	Azimsulfuron	Acute	LD_{50} > 2250	-
Mallard (*A. platyrhynchos*)	Azimsulfuron	Acute	LD_{50} > 2250	-
Quail (*C. virginianus*)	Preparation (DF)[a]	Acute	LD_{50} > 2250	-
Mallard (*A. platyrhynchos*)	Azimsulfuron	Short-term	LD_{50} > 2039	LC_{50} > 5620
Quail (*C. virginianus*)	Azimsulfuron	Short-term	LD_{50} > 3147	LC_{50} > 5620
Quail (*C. virginianus*)	Preparation (DF) [a]	Short-term	LD_{50} > 1543	LC_{50} > 5620
Mallard (*A. platyrhynchos*)	Preparation (DF) [a]	Short-term	LD_{50} > 2338	LC_{50} > 5620
Mallard (*A. platyrhynchos*)	Azimsulfuron	Long-term	NOEL 172	NOEC 1250
Mammals ‡				
Rat	Azimsulfuron	Acute	LD_{50} > 5000	-
Rat	Azimsulfuron	Long-term	$NOAEL_{repro}$ 76.6	$NOAEC_{repro}$ 1000
Additional higher tier studies ‡ Not available, not requested.				

a 50DF formulation, identical to 50WG

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)
Application of Azimsulfuron 50WG to rice (flooded and/or saturated land) at 50 g product/ha (0.025 kg a.s./ha).

Indicator species/Category	Time scale	ETE, mg/kg bw	TER	Annex VI Trigger
Tier 1 – uptake via diet (Birds)				
Small insectivore	Acute	1.352	>1664	10
Large herbivore	Acute	1.562	>1440	10
Small insectivore	Short-term	0.754	>2704	10
Large herbivore	Short-term	0.836	>2439	10
Small insectivore	Long-term	0.754	228	5
Large herbivore	Long-term	0.443	388	5
Tier 1 – uptake via drinking water (Birds)				
Small (10 g) bird, surface water (Step 1), flooded	Acute	0.310×10^{-3}	$>7.2 \times 10^{6}$	10
Small (10 g) bird, puddles, saturated land	Acute	6.75	>330	10
Small (10 g) bird, paddy water, flooded land	Acute	3.47×10^{-3}	$>6.48 \times 10^{5}$	10
Small (10 g) bird, paddy water, flooded land	Long-term	3.47×10^{-3}	49600	5
Tier 1 – uptake via diet (Mammals)				

Indicator species/Category	Time scale	ETE, mg/kg bw	TER	Annex VI Trigger
Small herbivore	Acute	4.934	>1013	10
Small herbivore	Long-term	1.400	54.7	5
Tier 1 – uptake via drinking water (Mammals)				
Small (25 g) mammal, surface water (Step 1), flooded	Acute	0.165×10^{-3}	$>30 \times 10^{6}$	10
Small (25 g) mammal, puddles, saturated land	Acute	3.6	>1400	10
Small (25 g) mammal, paddy water, flooded land	Acute	1.84×10^{-3}	$>2.7 \times 10^{6}$	10
Small (25 g) mammal, paddy water, flooded land	Long-term	1.84×10^{-3}	41600	5

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				
Rainbow (*O. mykiss*)	Azimsulfuron	96 hr (static)	Mortality, LC_{50}	154 (mm)
Rainbow (*O. mykiss*)	Preparation (DF)[a]	96 hr (static)	Mortality, LC_{50}	492 (nom)[b]
Fish	IN-A8342	96 hr	Mortality, LC_{50}	392[c]
Fish	IN-JJ999	96 hr	Mortality, LC_{50}	441[c]
Fish	IN-KQ962	96 hr	Mortality, LC_{50}	613[c]
Rainbow (*O. mykiss*)	Azimsulfuron	90 d (flow-through)	NOEC based on first and last day of hatch	6.3 (mm)
Aquatic invertebrate				
Daphnia magna	Azimsulfuron	48 h (semi-static)	Mortality, EC_{50}	378 (mm)
Daphnia magna	Preparation (DF)[a]	48 h (static)	Mortality, EC_{50}	>1000 (nom)[b]
Daphnia magna	IN-A8342	48 h	Mortality, EC_{50}	115 [c]
Daphnia magna	IN-JJ999	48 h	Mortality, EC_{50}	147 [c]
Daphnia magna	IN-KQ962	48 h	Mortality, EC_{50}	172 [c]
Daphnia magna	Azimsulfuron	21 d (semi-static)	Reproduction, NOEC	5.4 (mm)
Sediment dwelling organisms				
No data, not requested				
Algae				
P. subcapitata	Azimsulfuron	72 h (static)	Yield: E_yC_{50} Growth rate: E_rC_{50}	0.0111 (ini m)[d] 0.0523 (ini m)[d]
S. costatum	Azimsulfuron	72 h (static)	Yield: E_yC_{50} Growth rate: E_rC_{50}	> 0.022 (ini m)[d] > 0.022 (ini m)[d]
P. subcapitata	Preparation (DF)[a]	72 h (static)	Yield: E_yC_{50} Growth rate: E_rC_{50}	0.0175 (ini m)[d] 0.188 (ini m)[d]
P. subcapitata	IN-A8342	72 h (static)	Yield: E_yC_{50} Growth rate: E_rC_{50}	> 1.0 (nom)[b] > 1.0 (nom)[b]
Algae	IN-JJ999	96 h	EC_{50}	0.046 [c]
Algae	IN-KQ962	96 h	EC_{50}	0.037 [c]
Higher plant				
Lemna gibba	Azimsulfuron	7d (semi-static)	Yield: E_yC_{50} Growth rate: E_rC_{50}	0.00062 (mm) 0.00145 (mm)
Lemna gibba	IN-A8342	7/14 d (static)	Yield: E_yC_{50} Growth rate: E_rC_{50}	> 1.0 (nom) [b] > 1.0 (nom) [b]
Lemna gibba	IN-J0290	7/14 d (static)	Yield: E_yC_{50} Growth rate: E_rC_{50}	>100 (nom)[b] >100 (nom) [b]

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg/L)
Lemna gibba	IN-KQ962	7 d (semi-static)	Yield: E_yC_{50} Growth rate: E_rC_{50}	>119 (mm) >119 (mm)
Lemna gibba	IN-JJ999	7 d (semi-static)	Yield: E_yC_{50} Growth rate: E_rC_{50}	0.087 (mm) 0.15 (mm)
Microcosm or mesocosm tests Not submitted, not requested				

a 50DF formulation, identical to 50WG

b Nominal concentration, verified by measurement of active ingredient/metabolite.

c ECOSAR estimate.

d Based on initial (day 0) measurement of test concentration.

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

MED-RICE Step 1 – Tier 1 Risk assessment for Azimsulfuron and its' metabolites
Application of Azimsulfuron 50WG to rice - flooded land - at 50 g product/ha (0.025 kg a.s./ha).
Sand soil scenario (worst-case).

Test substance	Organism	Toxicity end point (mg/L)	PEC_i (mg/L)		TER	Annex VI Trigger
Azimsulfuron	Fish acute	96-h LC_{50} 154	0.00115		134000	100
Azimsulfuron	Fish prolonged	90-d NOEC 6.3	0.00115		5500	10
Azimsulfuron	Daphnia acute	48-h EC_{50} 378	0.00115		329000	100
Azimsulfuron	Daphnia prolonged	21-d NOEC 5.4	0.00115		4700	10
Azimsulfuron	Algae	72-h E_yC_{50} 0.0088	0.00115		**7.7**	10
Azimsulfuron	Algae	72-h E_rC_{50} 0.0523	0.00115		45	10
Azimsulfuron	Higher plant, *Lemna*	7-d E_yC_{50} 0.00062	0.00115		**0.54**	10
Azimsulfuron	Higher plant, *Lemna*	7-d E_rC_{50} 0.00145	0.00115		**1.3**	10
IN-A8342	Fish acute	96-h LC_{50} 392	0.00018		2200000	100
IN-A8342	Daphnia acute	48-h LC_{50} 115	0.00018		640000	100
IN-A8342	Algae	72-h $E_{y/r}C_{50}$ >1.0	0.00018		>5500	10
IN-A8342	Higher plant, *Lemna*	7-d $E_{y/r}C_{50}$ >1.0	0.00018		>5500	10
IN-JJ999	Fish acute	96-h LC_{50} 441	0.00016		2700000	100
IN-JJ999	Daphnia acute	48-h LC_{50} 147	0.00016		919000	100
IN-JJ999	Algae	96-h EC_{50} 0.046	0.00016		288	10
IN-JJ999	Higher plant, *Lemna*	7-d E_yC_{50} 0.087	0.00016		544	10
IN-JJ999	Higher plant, *Lemna*	7-d E_rC_{50} 0.15	0.00016		938	10
IN-KQ962	Fish acute	96-h LC_{50} 613	0.000070		8700000	100
IN-KQ962	Daphnia acute	48-h LC_{50} 172	0.000070		2457000	100
IN-KQ962	Algae	96-h EC_{50} 0.037	0.000070		529	10
IN-KQ962	Higher plant, *Lemna*	7-d $E_{y/r/b}C_{50}$ >119	0.000070		>1700000	10

Bioconcentration		
	Azimsulfuron	Metabolites
$logP_{O/W}$	0.6 (pH 5) -1.4 (pH 7) -2.1 (pH 9)	Not available, but on the basis of Koc values metabolites are likely tob e polar in nature.
Bioconcentration factor (BCF) ‡	not available, not requested	-
Annex VI Trigger for the bioconcentration factor	100	-
Clearance time (days) (CT_{50})	not applicable	-
(CT_{90})	not applicable	-

Bioconcentration		
Level and nature of residues (%) in organisms after the 14 day depuration phase	not applicable	-

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)
Azimsulfuron ‡	data only supportive	> 25[b]
Preparation (DF)[a]	> 350 (>187 µg a.s./bee)	> 400 (>214 µg a.s./bee)
Field or semi-field tests Not available, not required		

a 50DF formulation, identical to 50WG
b Uncertain data due to lack of toxic standard.

Hazard quotients for honey bees (Annex IIIA, point 10.4)
Application of Azimsulfuron 50WG to rice (flooded or saturated land) at 50 g product/ha (0.025 kg a.s./ha).

Test substance	Route	Hazard quotient	Annex VI Trigger
Azimsulfuron	contact	not calculated	50
Azimsulfuron	oral	not calculated	50
Preparation (DF)[a]	contact	< 0.14	50
Preparation (DF)[a]	oral	< 0.12	50

a 50DF formulation, identical to 50WG

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)
Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} g product/ha)
Typhlodromus pyri ‡	Preparation (DF)[a]	Mortality	> 54.3
Aphidius rhopalosiphi ‡	Preparation (DF)[a]	Mortality	> 58.8

a 50DF formulation, identical to 50WG

Hazard quotients for other arthropod species (Annex IIIA, point 10.4)
Application of Azimsulfuron 50WG to rice (flooded or saturated land) at 50 g product/ha (0.025 kg a.s./ha).

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field	Trigger
Preparation (DF)[a]	*Typhlodromus pyri*	> 54.3	< 0.92	< 0.03	2
Preparation (DF)[a]	*Aphidius rhopalosiphi*	> 58.8	< 0.85	< 0.02	2

Further laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	End point	% effect	Trigger value
Typhlodromus pyri	proto-nymph	Preparation (DF)[a], glass, 7 days	54.3	mortality	1.1[b]	50%
Typhlodromus pyri	adult	Preparation (DF)[a], glass, 7 days	54.3	reproduction	12.9	50 %
Aphidius rhopalosiphi	juve-niles	Preparation (DF)[a], glass, 48 hours	58.8	mortality	-21.4[b,c]	50%
Poecilus cupreus	adult	Preparation (DF)[a], sand, 14 days	64	mortality and feeding rate	0 -8.2[c]	50 %
Chrysoperla carnea	larvae adult	Preparation (DF)[a], glass, 2-3 days old larvae exposed during larval stage and pupation; egg laying and hatching observed over 36 days	56	mortality reproduction	-4.8[c] -0.83[c]	50%

a 50DF formulation, identical to 50WG
bResult used for risk assessment.
c Negative value represent decreased mortality/ increased feeding rate as compared to control.

Field or semi-field tests
Not available, 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	Azimsulfuron	Acute 14 days	LC_{50} > 1000 mg/kg
Eisenia andrei	Preparation (DF)[a]	Acute 14 days	LC_{50} > 1000 mg/kg
Eisenia fetida	IN-KQ962	Acute 14 days	LC_{50} > 1000 mg/kg
Eisenia fetida	Azimsulfuron	Chronic 56 d	$NOEC_{repro}$ 12.5 mg/kg
Other soil macro-organisms			
Not available, not required			
Soil micro-organisms			
Nitrogen mineralisation	Preparation (DF)[a]	28 days	Effect on ammonium decrease at 0.16 mg prod/kg (120 g prod/ha): 0.13 d: 0%; 14 d: +38.4%; 21 d: -17%; 28 d: 0% Effect on nitrate formation at 0.16 mg prod/kg (120 g prod/ha): 0.13 d: +4%; 14 d: +5%; 21 d: +0.2%; 28 d: +3%
Nitrogen mineralisation	IN-KQ962	28 days	Effect on nitrate formation at 0.37 mg/kg soil: 0 d: +2.8%*; 7 d: +3.2%; 14 d: -4.8%; 28 d: -2.2% Effect on cumulative rate of nitrate formation at 0.37 mg/kg soil: 0-7: +2.9%; 0-14 d: +240%; 0-28 d: -11.4%
Carbon mineralisation	Preparation (DF)[a]	28 days	Effect on cumulative CO_2 release at 0.16 mg prod/kg (120 g prod/ha): 0.13 d: -11%; 2 d: +0.6%; 7 d: -0.2%; 14 d: +0.2%; 21 d: +0.9%; 28 d: +1.3%
Carbon mineralisation	IN-KQ962	28 days	Effect on glucose-induced CO_2-release at 0.37 mg/kg soil: 0 d: +4.5%; 7 d: +3.2%; 14 d: +14.3%*; 28 d: +12.6%*
Studies on metabolites IN-A8342, IN-JJ999 and IN-J290 on soil micro organisms are not available. A risk would be identified only in case these would be 25-34 X more toxic than the parent compound.			
Field studies Not available, not required			

a 50DF formulation, identical to 50WG

Toxicity/exposure ratios for soil organisms

Application of Azimsulfuron 50WG to rice (flooded or saturated land) at 50 g product/ha (0.025 kg a.s./ha).

Test organism	Test substance	Time scale	Soil PEC mg/kg	TER	Trigger
Earthworms					
Flooded – clay soil	Azimsulfuron	Acute	0.01197	>84000	10
Flooded – sand soil	Azimsulfuron	Acute	0.00786	>127000	10
Saturated – clay/sand	Azimsulfuron	Acute	0.025	>40000	10
Flooded – clay soil	IN-KQ962	Acute	0.00046	>2200000	10
Flooded – sand soil	IN-KQ962	Acute	0.00028	>3600000	10
Saturated – clay/sand	IN-KQ962	Acute	0.00168	>595000	10
Flooded/saturated Flooded/saturated Saturated	IN-A8342 IN-JJ999 IN-J290	Acute Acute Acute	Only in case these metabolites would be > 10^4 times more toxic than the a.s. a TERof 10 would be calculated		
Flooded – clay soil	Azimsulfuron	Chronic	0.01197	1044	5
Flooded – sand soil	Azimsulfuron	Chronic	0.00786	1590	5
Saturated – clay/sand	Azimsulfuron	Chronic	0.025	500	5
Other soil macro-organisms					
Not available, not requested					

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data

Not required for herbicides as ER_{50} tests should be provided

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g prod/ha) vegetative vigour	ER_{50} (g prod/ha) emergence	Exposure (g prod/ha)[b]	TER	Trigger
Onion (*Allium cepa*)[c]	Preparation (DF)[a]	-	2.64	1 m: 1.383 5 m: 0.285	**1.91** 9.26	5
Sugar beet (*Beta vulgaris*)[d]	Preparation (DF)[a]	0.450	-	1 m: 1.383 5 m: 0.285 10 m: 0.145 15 m: 0.10 20 m: 0.075 5 m and 75% drift reduction nozzles 10 m and 50% drift reduction	**0.325** **1.58** **3.10** **4.5** 6.0 6.32	5

Most sensitive species	Test substance	ER_{50} (g prod/ha) vegetative vigour	ER_{50} (g prod/ha) emergence	Exposure (g prod/ha)[b]	TER	Trigger
				nozzles	6.21	

a 50DF formulation, identical to 50WG

b Drift rates according to Rautmann et al (2001):

1 m-2.77%; 5 m–0.57%; 10 m–0.29%; 15 m–0.20%; 20 m–0.15%.

c Onion (monocot) was most sensitive species out of 4 monocotyledonous and 6 dicotyledonous species included in seedling emergence test.

d Sugar beet (dicot) was most sensitive out of 4 monocotyledonous and 6 dicotyledonous species included in vegetative vigour test.

Additional studies (e.g. semi-field or field studies)

Not available, not requested

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	Endpoint
Activated sludge	3 hour EC_{50} for inhibition of respiration > 100 mg azimsulfuron/L

Ecotoxicologically relevant compounds

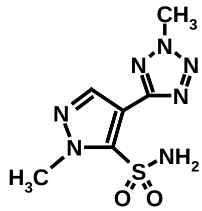
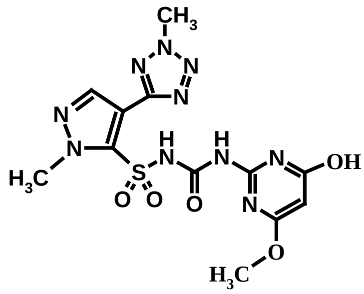
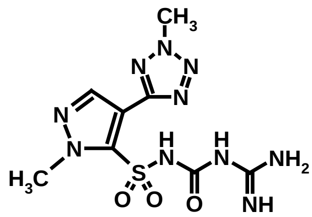
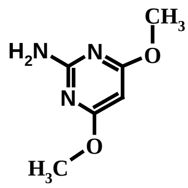
Compartment	
soil	Azimsulfuron
water	Azimsulfuron
sediment	Azimsulfuron

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	N, R50/53

	RMS/peer review proposal
Preparation	N, R50/53

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
IN-A8342	1-methyl-4-2(2-methyl-2*H*-tetrazol-5-yl)-1*H*-pyrazole-5-sulfonamide	
IN-JJ999	*N*-[[(4-hydroxy-6-methoxypyrimidin-2-yl)amino]carbonyl]-1-methyl-4-(2-methyl-2*H*-tetrazol-5-yl)-1*H*-pyrazole-5-sulfonamide	
IN-KQ962	*N*-[[(Aminoiminomethyl)amino]carbonyl]-1-methyl-4-(2-methyl-2*H*-tetrazole-5-yl)-1*H*-pyrazole-5-sulfonamide	
IN-J290	1-Amino-4,6-dimethoxypyrimidine	

ABBREVIATIONS

1/n	slope of Freundlich isotherm
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstract Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticide Analytical Council Limited
CL	confidence limits
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)

GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
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)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OM	organic matter content
Pa	Pascal

PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{pw}	predicted environmental concentration in paddy water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation
wk	week
yr	year