CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance halosulfuron (evaluated variant halosulfuron-methyl)[1]

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ABSTRACT

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State Italy, for the pesticide active substance halosulfuron (evaluated variant halosulfuron-methyl) are reported. The context of the peer review was that required by Commission Regulation (EU) No 188/2011. The conclusions were reached on the basis of the evaluation of the representative use of halosulfuron-methyl as a herbicide on rice. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and literature in the dossier peer reviewed, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

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KEY WORDS

halosulfuron, halosulfuron-methyl, peer review, risk assessment, pesticide, herbicide

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SUMMARY

Halosulfuron is a new active substance for which in accordance with Article 6(2) of Council Directive 91/414/EEC Italy (hereinafter referred to as the 'RMS') received an application from Nissan Chemical Europe SARL for approval. Complying with Article 6(3) of Directive 91/414/EEC, the completeness of the dossier was checked by the RMS. The European Commission recognised in principle the completeness of the dossier by Commission Decision 2006/586/EC.

The RMS provided its initial evaluation of the dossier on halosulfuron-methyl in the Draft Assessment Report (DAR), which was received by the EFSA on 30 March 2008. The peer review was initiated on 5 October 2011 by dispatching the DAR for consultation of the Member States and the applicant Nissan Chemical Europe SARL.

Following consideration of the comments received on the DAR, it was concluded that EFSA should conduct an expert consultation in the areas of mammalian toxicology and ecotoxicology and EFSA should adopt a conclusion on whether halosulfuron can be expected to meet the conditions provided for in Article 5 of Directive 91/414/EEC, in accordance with Article 8 of Commission Regulation (EU) No 188/2011.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative use of halosulfuron-methyl as a herbicide on rice, as proposed by the applicant. Full details of the representative use can be found in Appendix A to this report.

No data gaps or areas of concern were identified in the section on identity, physical/chemical/technical properties and methods of analysis.

Data gaps were identified in the mammalian toxicology section to address the relevance of the impurities present in the technical specification and to clarify the potential genotoxic properties of the metabolite chlorosulfonamide acid in the context of consumer exposure of residues in food and groundwater relevance, the second of these leading to non finalised issues. A critical area of concern was identified since equivalence of the tested material with the technical specification was not demonstrated for the toxicity studies.

In the residue section the residue definition for risk assessment is only set provisionally, since the genotoxic potential of the major plant metabolite chlorosulfonamide acid is insufficiently addressed. Although residues in rice grains are very low, finalisation of the consumer risk assessment is pending a conclusion regarding the genotoxic potential of chlorosulfonamide acid.

The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at the EU level for the representative use, with the notable exception that information to estimate the potential for groundwater exposure by the metabolites 'halosulfuron rearrangement' and chlorosulfonamide acid is not available. Consequently, the groundwater exposure assessments for these metabolites are not finalised.

Three data gaps were identified in the ecotoxicology section. Critical areas of concern were identified in the ecotoxicology sections regarding the high risk for non-target terrestrial plants and since equivalence of the tested material with the technical specification was not demonstrated for the ecotoxicity studies.

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BACKGROUND

In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009,[3] Council Directive 91/414/EEC[4] continues to apply with respect to the procedure and conditions for approval for active substances for which a decision recognising in principle the completeness of the dossier was adopted in accordance with Article 6(3) of that Directive before 14 June 2011.

Commission Regulation (EU) No 188/2011[5] (hereinafter referred to as 'the Regulation') lays down the detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market on 26 July 1993. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and the applicant for comments on the initial evaluation in the Draft Assessment Report (DAR) provided by the rapporteur Member State (RMS), and the organisation of an expert consultation, where appropriate.

In accordance with Article 8 of the Regulation, EFSA is required to adopt a conclusion on whether the active substance is expected to meet the conditions provided for in Article 5 of Directive 91/414/EEC within 4 months from the end of the period provided for the submission of written comments, subject to an extension of 2 months where an expert consultation is necessary, and a further extension of up to 8 months where additional information is required to be submitted by the applicant(s) in accordance with Article 8(3).

In accordance with Article 6(2) of Council Directive 91/414/EEC Italy (hereinafter referred to as the 'RMS') received an application from Nissan Chemical Europe SARL for approval of the active substance halosulfuron-methyl. Complying with Article 6(3) of Directive 91/414/EEC, the completeness of the dossier was checked by the RMS. The European Commission recognised in principle the completeness of the dossier by Commission Decision 2006/586/EC.[6]

The RMS provided its initial evaluation of the dossier on halosulfuron-methyl in the DAR, which was received by the EFSA on 30 March 2008 (Italy, 2007). The peer review was initiated on 5 October 2011 by dispatching the DAR to Member States and the applicant Nissan Chemical Europe SARL for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 8(3) of the Regulation were considered in a telephone conference between the EFSA, the RMS, and the European Commission on 28 March 2012. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof it was concluded that additional information should be requested from applicant and that the EFSA should organise an expert consultation in the areas of mammalian toxicology and ecotoxicology.

[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ No L 309, 24.11.2009, p. 1-50.
[4] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1-32, as last amended.
[5] Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ No L 53, 26.2.2011, p. 51-55.
[6] Commission Decision 2006/586/EC of 25 August 2006 recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of chromafenozide, halosulfuron, tembotrione, valiphenal and Zucchini yellow mosaic virus — weak strain in Annex I to Council Directive 91/414/EEC. OJ No L 236, 31.8.2006, p. 31-33.

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 an expert consultation, and the additional information to be submitted by the applicant, 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 consultation where this 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 November 2012.

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 use as a herbicide on rice, as proposed by the applicant. 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 (EFSA, 2012) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the DAR,
- the Reporting Table (29 March 2012),
- the Evaluation Table (23 November 2012),
- the reports of the scientific consultation with Member State experts (where relevant),
- the comments received on the assessment of the additional information (where relevant),
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of October 2012 containing all individually submitted addenda (Italy, 2012)) 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

Halosulfuron is the ISO common name for 3-chloro-5-(4,6-dimethoxypyrimidin-2-ylcarbamoylsulfamoyl)-1-methylpyrazole-4-carboxylic acid (IUPAC). The evaluated data belong to the variant halosulfuron-methyl, unless otherwise specified.

The representative formulated product for the evaluation was 'Halosulfuron-methyl 75WG', a water dispersible granules (WG) containing 750 g/kg pure halosulfuron-methyl.

The representative use evaluated comprises field spraying against annual and perennial broad-leaf and sedge weeds 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 following guidance documents were followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000) and SANCO/825/00 rev. 7 (European Commission, 2004a).

The minimum purity of halosulfuron-methyl as manufactured is 980 g/kg. The relevance of the impurities present in the technical specification is still open (See Section 2.). At the moment no FAO specification exists.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of halosulfuron-methyl or the representative formulation. The main data regarding the identity of halosulfuron-methyl and its physical and chemical properties are given in Appendix A.

Residue analytical method (LC-MS/MS) for analysis of halosulfuron-methyl in dry commodities (relevant for the representative use) is available. Since the residue definition for monitoring purposes in food of plant origin has not been finalised, a validated method for analysis of additional analytes might be required. Methods of analysis for products of animal origin are not necessary as no residue definition is required regarding the representative use. The available analytical methods (LC-MS/MS) for halosulfuron-methyl in soil, water and air are sufficiently validated. Validation of LC-MS method for determination of halosulfuron-methyl (HSM) and metabolites 'halosulfuron-methyl rearrangement' (HSMR), 'halosulfuron rearrangement' (HSR), chlorosulfonamide (CSE) and chlorosulfonamide acid (CSA) in paddy water is also provided with LOQ of 5 µg/L for each of the individual compounds. The residue definition for monitoring purposes in surface, drinking and groundwater is open, therefore a more sensitive analytical method for some of the metabolites might be necessary. A method of analysis for body fluids and tissues is not required as the active substance is not classified as toxic or very toxic.

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: SANCO/221/2000 rev. 10 - final (European Commission, 2003b), SANCO/222/2000 rev. 7 (European Commission, 2004b) and SANCO/10597/2003 – rev. 8.1 (European Commission, 2009).

Halosulfuron-methyl was discussed at the Pesticides Peer Review Meeting 95 in September 2012.

As the information on the impurity profile of the batches used in the toxicological studies is not available (most studies were performed during the early 1990s), it is unknown whether these batches support the technical specification. The toxicological relevance of the impurities present in the technical specification has not been adequately addressed and a data gap was identified. These facts

resulted in a critical area of concern as equivalence was not demonstrated for the technical material specification proposed and the material used in the toxicity studies.

Low acute toxicity has been observed when halosulfuron-methyl was administered by oral, dermal and inhalation routes. No skin or eye irritation was observed and no potential for skin sensitisation was reported in a Magnusson and Kligman test.

The most prominent effect observed upon repeated dose testing with halosulfuron-methyl upon short-term and long-term exposure was reduction of body weight gain in dogs, rats and mice. In dogs, which were the most sensitive species, changes in clinical chemistry, haematological parameters and liver weight were also observed. The relevant short-term NOAEL was 10 mg/kg bw per day from the 90-day and 1-year studies in dogs and the long-term NOAEL was 43.8 mg/kg bw per day from the 2-year rat study. No carcinogenic potential was observed in either rats or mice. Halosulfuron-methyl did not present a genotoxic potential either in *in vitro* or *in vivo* studies.

Reproductive and developmental studies showed a higher sensitivity of the offspring to halosulfuron-methyl exposure than the adult animals. The offspring's NOAEL in the multigeneration reproduction toxicity study was 6.3 mg/kg bw per day based on reduced pup body weight gain, while the parental NOAEL was 50.4 mg/kg bw per day regarding the same endpoint. In this study no effect on fertility or reproduction was observed up to the highest dose level of 223.2 mg/kg bw per day. In the developmental toxicity study in rabbits, the maternal and developmental NOAELs were 50 mg/kg bw per day based on early resorptions, decreased number of foetuses and reduced maternal body weight gain. In the rat, foetal toxicity was observed in the absence of maternal toxicity: the developmental NOAEL was 75 mg/kg bw per day based on a higher incidence of visceral and skeletal variations and the maternal NOAEL was 250 mg/kg bw per day due to reduced body weight, body weight gain and food consumption. These effects suggest that classification regarding developmental toxicity would be required for halosulfuron-methyl as 'Reprotox cat. 2, H361fd, suspected of damaging the unborn child'.[7]

No evidence of neurotoxicity was seen in acute and short-term neurotoxicity studies, except for transient increases in uncoordinated righting reflex at 2000 mg/kg bw in the acute neurotoxicity study.

Toxicological studies were provided on two metabolites. The metabolite chlorosulfonamide acid (CSA) was found in plants and in groundwater at levels potentially exceeding 0.1 µg/L according to environmental fate and behaviour calculations (see section 4). The metabolite presented low acute oral toxicity; the 90-day oral NOAEL in rat was 75.8 mg/kg bw per day based on reduced body weight gain. Maternal and developmental NOAELs were the limit dose of 1000 mg/kg bw per day, showing that the metabolite does not share the developmental toxicity profile of the parent, halosulfuron-methyl. Negative results were found in an Ames test and an *in vivo* micronucleus test, however, an equivocal result in an *in vitro* gene mutation test has to be clarified to conclude on the overall genotoxic potential of the metabolite; this was identified as a data gap.

The metabolite 'halosulfuron-methyl rearrangement' (HSMR) presented low acute oral toxicity and negative results in an Ames test. According to environmental fate and behaviour models, it would not appear in groundwater above the threshold of 0.1 µg/L.

No toxicological data were provided on the metabolite 'halosulfuron rearrangement' (HSR) that may appear in groundwater at levels exceeding 0.1 µg/L according to environmental fate and behaviour calculations. No assessment of the toxicological relevance of the metabolite was provided, however the metabolite is considered relevant according to the guidance document on groundwater metabolites

[7] It should be noted that proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals. Classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

(European Commission, 2003b) based on the developmental effects observed in the developmental toxicity study in rats performed with the parent, halosulfuron-methyl.

The acceptable daily intake (ADI) of halosulfuron-methyl is 0.063 mg/kg bw per day, based on the offspring's NOAEL of 6.3 mg/kg bw per day from the multigeneration study in rat, applying the standard uncertainty factor (UF) of 100. The acceptable operator exposure level (AOEL) is 0.063 mg/kg bw per day, based on the same NOAEL of 6.3 mg/kg bw per day from the multigeneration study in rat, 100 UF applied, no correction regarding oral absorption being required. The acute reference dose (ARfD) is 0.5 mg/kg bw, based on the NOAEL of 50 mg/kg bw/day from the maternal effects observed in the developmental toxicity study in rabbits, 100 UF applied.

As no study has been provided to determine the dermal absorption of the representative formulation, the default value of 100 % was retained to perform the operator, worker and bystander exposure risk assessment. The estimated operator exposure level is below the AOEL when no personal protective equipment (PPE) is worn according to the German model, or when the use of gloves during mixing, loading and application are considered according to the UK POEM model. Worker and bystander exposure are estimated to be lower than the AOEL, also when workers do not wear PPE.

3. Residues

The assessment in the residue section is based on the guidance documents listed in the document 1607/VI/97 rev.2 (European Commission, 1999), and the JMPR recommendations on livestock burden calculations stated in the 2004 and 2007 JMPR reports (JMPR, 2004, 2007).

The plant metabolism was studied in maize and sugar cane upon pre- and post-emergence application, and in rice after application of halosulfuron-methyl to the paddy water.

Upon foliar application, halosulfuron-methyl was the major residue in the leafy parts of maize and sugar cane plants (47 – 95 % TRR). Halosulfuron-methyl was present in lower proportions in sugar cane stalks (11 % TRR) and virtually not present in maize kernels (2 % TRR), relating to extremely low levels (<0.001 to 0.002 mg/kg at approximately 15 N rate, based on the intended rate in rice). The only significant metabolite in crop parts for human consumption was chlorosulfonamide acid (20 – 35 % TRR; 0.003 to 0.012 mg/kg).

When applied pre-emergence or to the paddy water, unchanged halosulfuron-methyl was either not detected or was recovered in extremely low amounts in all crop parts of maize, sugar cane and rice, indicating extensive metabolism of halosulfuron-methyl, probably initiated already by a breakdown of the molecule in the soil or water. Chlorosulfonamide acid was the major residue identified in all commodities and accounted for up to 56 % TRR in the maize crop, up to 41 % TRR in sugar cane, and up to 42% TRR in rice. Assuming the intended application rate in rice as the common rate applied to cereals, residues greater than 0.01 mg/kg of chlorosulfonamide acid would have to be expected in all maize commodities and in rice foliage.

Chlorosulfonamide acid was not detected in the rat metabolism studies. The toxicity of this metabolite was evaluated, however a final conclusion could not be drawn on the genotoxic potential due to equivocal results in genotoxicity tests, and further data are required to clarify the toxicological profile chlorosulfonamide acid.

Therefore the residue definition for risk assessment for the cereal crop group should provisionally be set as halosulfuron-methyl and chlorosulfonamide acid.

For the monitoring of residues in cereal food commodities, the metabolite chlorosulfonamide acid would be a better marker for residues than halosulfuron-methyl. If chlorosulfonamide acid were demonstrated as being of no toxicological concern, the monitoring residue definition could possibly also be proposed by default as either halosulfuron-methyl, or as halosulfuron (including its esters and

salts) expressed as halosulfuron. However, currently a proposal for a meaningful monitoring residue definition cannot be made.

To support the representative use on rice, a sufficient number of valid residue trials are available. Residues of halosulfuron-methyl in rice grain and straw were consistently below the LOQ of 0.01 mg/kg. Residues of the major metabolite chlorosulfonamide acid were not determined in the available residue trials, however, based on the findings in the rice metabolism study, residues of chlorosulfonamide acid greater than 0.01 mg/kg are not expected in rice grains. Data on food processing and in livestock were not triggered due to the very low residues in rice, and were also not available in the regulatory dossier. Hence, a residue definition for livestock was not considered by the peer review.

Rice is not frequently rotated with other crops and rotational crop studies with halosulfuron-methyl were not triggered based on the $DT90_{field}$ of halosulfuron-methyl and its soil metabolites.

If a consumer dietary risk assessment is conducted with the EFSA PRIMo, assuming halosulfuron-methyl residues at LOQ level of 0.01 mg/kg in rice grains, the consumer dietary exposure is below 0.1% of the ADI and the ARfD set for halosulfuron-methyl. The risk assessment does not consider residues of chlorosulfonamide acid, since its toxicological relevance in particular with regard to the genotoxic potential has to be clarified, and toxicological reference values are currently not available. Therefore, the consumer risk assessment is not finalised for the major plant metabolite chlorosulfonamide acid.

It is noted that there is the possibility for additional consumer exposure to chlorosulfonamide acid from groundwater used as drinking water. However, the groundwater assessment is currently not finalised.

4. Environmental fate and behaviour

In soil laboratory incubations under aerobic flooded conditions in the dark, halosulfuron-methyl exhibited low to moderate persistence, forming the major (>10 % applied radioactivity (AR)) metabolites 'halosulfuron-methyl rearrangement' (HSMR, max. 48 % AR), 'halosulfuron rearrangement' (HSR, max. 24 % AR), chlorosulfonamide (CSE, max. 20 % AR) and chlorosulfonamide acid (CSA, max. 24 % AR) which exhibited low to high persistence, uncertain persistence, medium to high persistence and uncertain persistence, respectively. The minor metabolite aminopyrimidine (AP) was also formed at levels (max. 9.5 % AR) triggering a groundwater exposure assessment. It exhibited moderate to high persistence. Mineralisation of the pyrimidine and pyrazole ring ^{14}C radiolabels to carbon dioxide accounted for 0.3 – 12 % AR after 120 days. The formation of unextractable residues (not extracted by ethyl acetate) for these radiolabels accounted for 23 – 45 % AR after 120 days. 'Halosulfuron rearrangement' (HSR) was still increasing at the end of the incubation in the soil incubation where it was formed in significant amounts. A data gap was therefore identified for two reliable soil DT_{50} to be generated for 'halosulfuron rearrangement' (HSR) under aerobic flooded conditions. This information is required to reduce the uncertainty in the groundwater exposure estimates. Following the same reasoning, a comparable data gap was also identified for chlorosulfonamide acid (CSA). Halosulfuron-methyl exhibited very high to medium mobility in soil. 'Halosulfuron-methyl rearrangement' (HSMR) and chlorosulfonamide (CSE) exhibited high to medium soil mobility, chlorosulfonamide acid (CSA) exhibited very high soil mobility and aminopyrimidine (AP) would be immobile/exhibit medium soil mobility. 'Halosulfuron rearrangement' (HSR) would be expected to exhibit very high soil mobility at environmentally relevant pH on the basis of non-retention on a reverse phase HPLC column in an OECD 121 adsorption screening experiment. A data gap is identified for adsorption measurements for 'halosulfuron rearrangement' (HSR) using soil. There is no indication that the mobility of these compounds is dependent on soil pH in the normal pH range of rice paddy soils. In satisfactory field paddy dissipation studies carried out at two sites (Italy and Spain) where paddies were flooded after application but there was no subsequent flow through the experimental paddies, halosulfuron-methyl

exhibited low persistence. 'Halosulfuron-methyl rearrangement' (HSMR) exhibited low to moderate persistence. 'Halosulfuron rearrangement' (HSR), chlorosulfonamide (CSE), and chlorosulfonamide acid (CSA) were analysed for, but not detected (LOD 0.25µg/kg soil and 2µg/L paddy water).

In laboratory incubations in dark aerobic natural sediment water systems, halosulfuron-methyl exhibited low persistence, forming the major metabolites 'halosulfuron-methyl rearrangement' (HSMR, max 42 % AR in both water and sediment, exhibiting moderate persistence) and 'halosulfuron rearrangement' (HSR, 40% AR in water with the concentration still increasing at study end, 100 days). The unextractable sediment fraction (not extracted by acetonitrile followed by acidified acetontrile) was a major sink for the pyrimidine and pyrazole ring ^{14}C radiolabel, accounting for 19 – 60 % AR at study end (100 days). Mineralisation of these radiolabels accounted for only 0.2 – 5.7 % AR at the end of the study.

Transparent presentations of how some DT_{50}s in soil and surface water were not presented in the Addendum (Italy, 2012). This is indicated in section 7. For further background information regarding this, see the evaluation table in the peer review report (EFSA, 2012).

The necessary surface water and sediment exposure assessment calculations (predicted environmental concentrations (PEC)) were carried out for halosulfuron-methyl, 'halosulfuron-methyl rearrangement' (HSMR) and 'halosulfuron rearrangement' (HSR), using an Excel spreadsheet implementing the MED-RICE (European Commission, 2003a) guidance on calculating these PEC in rice cultivation.

The necessary groundwater exposure assessments were appropriately carried out using an Excel spreadsheet implementing the MED-RICE guidance for the active substance halosulfuron-methyl and metabolites 'halosulfuron-methyl rearrangement' (HSMR), 'halosulfuron rearrangement' (HSR), chlorosulfonamide (CSE), chlorosulfonamide acid (CSA) and aminopyrimidine (AP). The potential for groundwater exposure from the representative use by halosulfuron-methyl, 'halosulfuron-methyl rearrangement' (HSMR), chlorosulfonamide (CSE) and aminopyrimidine (AP) above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by the two MED-RICE scenarios. For the metabolites 'halosulfuron rearrangement' (HSR) and chlorosulfonamide acid (CSA) the groundwater exposure assessment cannot be finalised with the usual level of uncertainty, before the data gaps for flooded aerobic soil DT_{50} values and for 'halosulfuron rearrangement' (HSR) soil adsorption data, are made available. However, using a best case soil DT_{50} for 'halosulfuron rearrangement' (HSR), it is clear that the potential for groundwater exposure from the representative use by 'halosulfuron rearrangement' (HSR) above the parametric drinking water limit of 0.1 µg/L is high in the MED-RICE sandy scenario. With a better (more representative) soil DT_{50} estimate for 'halosulfuron rearrangement' (HSR, i.e. including data from more than just the available soil incubation where a decline was observed), 0.1 µg/L might also be estimated to be exceeded in the MED-RICE clay scenario. For chlorosulfonamide acid (CSA) using the conservative assumption that the soil DT50 is 1000 days, then there is an indication of groundwater exposure by chlorosulfonamide acid (CSA) above the parametric drinking water limit of 0.1 µg/L in the MED-RICE clay scenario. Note that section 2 concluded that, based on the available information, 'halosulfuron rearrangement' (HSR) needs to be considered a relevant groundwater metabolite.

The PEC in soil, surface water, sediment, and groundwater covering the representative use assessed and calculated following the MED-RICE guidance can be found in Appendix A of this conclusion.

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a, 2002b, 2002c, 2003a), SETAC (2001) and EFSA (2009).

Equivalence of the tested material with the technical specification was not demonstrated for the toxicity studies in the ecotoxicology section.

Acute, short-term and long-term toxicity studies on birds were available. The acute, short-term and long-term risk for herbivorous and insectivorous birds via dietary exposure was indicated as low at the first tier, for the representative use. A few acute and long-term toxicity studies on mammals were available in the section for mammalian toxicology. Concerns were raised during the peer-review regarding the long-term endpoint for mammals. The experts at the Pesticides Peer Review teleconference 77 in September 2012 agreed that a NOAEL of 6.3 mg a.s./kg bw day based on decreased pup bodyweight gain should be used. The acute risk for mammals via dietary exposure was assessed as low at tier 1. While, a low long-term risk was indicated for insectivorous mammals, a high potential long-term risk for herbivorous mammals was assessed on the basis of the earlier guidance (European Commission, 2002c). Nevertheless, it was noted that the long-term risk for herbivorous mammals was assessed as low at Tier 1 in accordance with the updated guidance (EFSA, 2009) in the Addendum of October 2012 (Italy, 2012). Overall the risk of halosulfuron-methyl for birds and mammals was assessed as low for the representative use on rice. The risk for birds and mammals from the consumption of contaminated drinking water was assessed as low.

Regarding aquatic organisms, toxicity studies on fish, daphnids, sediment-dwellers, algae and aquatic plants were available. In addition to the usual study with *Lemna gibba*, higher tier studies on aquatic plants with sediment present in the aquaria were submitted. The studies indicated that *Lemna gibba* is the most sensitive species investigated, so effects on *Lemna gibba* drive the risk assessment. In addition to the standard guideline *Lemna gibba* effects studies, two *Lemna gibba* studies were provided (active substance and formulated product), where the exposure pattern in the study was modified (this was achieved by including sediment in the test system to which the halosulfuron-methyl partitioned). The pattern of decline of halosulfuron-methyl concentrations in the water column was measured in these tests. The Member States experts on ecotoxicology at the Pesticides Peer Review teleconference 77 discussed the risk assessment for aquatic plants. The majority of the experts did not agree that a refined *Lemna gibba* toxicity endpoint from these two modified exposure studies were suitable for use in risk assessment as they considered it had not been demonstrated that the exposure profile in the study is comparable to that which they envisaged would occur in the field (water bodies adjacent to rice paddies). The experts proposed to use the biomass endpoint from the standard laboratory study with *Lemna gibba*. They considered that the only utility of the *Lemna gibba* study in the presence of sediment was that it enabled it to be confirmed that *Lemna gibba* was the most sensitive species compared to the other macrophytes tested (these tests were also conducted in the presence of sediment).

EFSA agrees that *Lemna gibba* was the most sensitive aquatic macrophyte species on the basis of the available higher tier studies. However EFSA does not agree with the majority view of the experts that it had not been demonstrated that the modified exposure profiles in the two *Lemna gibba* studies would be comparable to that in the field. The exposure profile that was measured in the test was similar to the one that the MED-RICE PEC calculations indicate are predicted in the field. In fact the rate of concentration decline in the studies was slower than that predicted to occur in natural water bodies adjacent to the treated paddy in the two MED-RICE scenarios. Using the endpoints from these two *Lemna gibba* modified exposure studies the risk from the active substance for aquatic macrophytes was indicated as low for the representative use assessed by the TERs calculated.

As aquatic plants were the most sensitive species for halosulfuron-methyl the peer review concluded that toxicity studies on aquatic plants are needed to conclude on the risk for the metabolites. Some studies with metabolites were provided and evaluated in the Addendum (Italy, 2012). EFSA and the RMS consider that since these studies did not include the most sensitive species *Lemna gibba* they do not address the issue. A data gap was identified

The in-field and off-field risk for the two standard test species was assessed as low by the in- and off-field hazard quotients on the basis of the available studies on the two standard arthropods other than bees. Based on the available data, the risk for honey bees was indicated as low by the acute and contact hazard quotients.

The risk assessment of halosulfuron-methyl for earthworms was indicated as low by the TER calculation on the basis of studies with the active substance. The risk for the soil metabolite 'halosulfuron-methyl rearrangement' for earthworms was addressed as low, when using the halosulfuron-methyl end-point divided by 10.

Some studies on vegetative vigour and emergence on non-target terrestrial plants were available. The risk from exposure to the active substance for non-target terrestrial plants was assessed as high even using a no-spray buffer zone up to 30 m. A probabilistic risk assessment was carried out to refine the risk assessment (a HC5 of 0.1 was obtained). However, the refined risk assessments presented, based on the HC5 and a 30 m no-spray buffer zone were not sufficient to address the risk. Therefore a data gap was identified for the applicant to further refine the risk assessment to terrestrial plants.

Based on the available data the risk for soil micro organisms and for biological methods of sewage treatment plants was assessed as low.

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

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
halosulfuron-methyl	Low to moderate persistence. Single first-order DT_{50} 17 – 33 days (20 ºC aerobic flooded soil). Southern European field dissipation studies single first-order DT_{50} 4.3 days.	The risk for earthworms was assessed as low.
'halosulfuron-methyl rearrangement'	Low to high persistence. Single first-order DT_{50} 102 – 142 days (20 ºC aerobic flooded soil). Southern European field dissipation studies single first-order DT_{50} <3 – 28 days.	The risk for 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 use (at least one MED-RICE scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
halosulfuron-methyl	Very high to medium mobility. K_{doc} 31 – 199 mL/g	No	Yes	Yes	Yes

'halosulfuron-methyl rearrangement'	High to medium mobility. K_{Foc} 75 – 167 mL/g	No	No	Yes Mouse oral LD_{50} > 5000 mg/kg bw. Ames test negative. Based on the toxicological properties of the parent suggesting that it would require classification as Repr. Tox cat 2, H361fd .[8]	Satisfactory information not available, but assessment not triggered.
'halosulfuron rearrangement'	Data gap, expected to exhibit very high mobility, K_{doc} 0 mL/g used in the available assessments.	0.1389 µg/L in MED-RICE sandy scenario. 0.0474 µg/L in MED-RICE clay scenario. Data gap for DT_{50} in a further two soils to provide less uncertain, but expected to be higher groundwater exposure estimates.	No	Yes No data provided. Based on the toxicological properties of the parent suggesting that it would require classification as Repr. Tox cat 2, H361fd.	Satisfactory information not available. Data gap.
chlororosulfonamide	high to medium mobility. K_{doc} 65 – 343 mL/g	No	No	No data provided, data not needed.	Satisfactory information not available, but assessment not triggered.

[8] It should be noted that proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals. Classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

chlororosulfonamide acid	Very high mobility. K_{doc} 0-9.95 mL/g	0.1716 µg/L in MED-RICE clay scenario. 0.0779 µg/L in MED-RICE sandy scenario. Data gap for DT_{50} in a further two soils to provide less uncertain groundwater exposure estimates.	No	Not concluded. Rat oral LD50 > 5000 mg/kg bw. 90-day, rat NOAEL: 75.8 mg/kg bw per day. Rat developmental study: maternal and developmental NOAEL: 1000 mg/kg bw per day (the highest dose tested) – giving evidence that the metabolite doesn't share the developmental toxicity properties of the parent, halosulfuron-methyl. Ames and *in vivo* micronucleus tests: negative. *In vitro* gene mutation test: **equivocal.** The genotoxic potential of the metabolite needs to be clarified (data gap).	Satisfactory information not available. Data gap.
aminopyrimidine	Immobile to medium mobility. K_{doc} 260-8280 mL/g	No	No	No data provided, data not needed.	Satisfactory information not available, but assessment not triggered.

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
halosulfuron-methyl (water and sediment)	Low risk was identified for aquatic organisms.
'halosulfuron-methyl rearrangement' (water and sediment)	Satisfactory information not available. Data gap for organisms exposed in the water column.
halosulfuron 'rearrangement' (water only)	Satisfactory information not available. Data gap.

6.4. Air

Compound (name and/or code)	Toxicology
halosulfuron-methyl	Rat LC_{50} inhalation > 6.0 mg/L air/4h (whole body), no classification required.

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

This is a complete list of the data gaps identified during the peer review process, including those areas where a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 7 of Directive 91/414/EEC concerning information on potentially harmful effects).

- The relevance of the impurities present in the technical specification needs to be addressed (relevant for the representative use evaluated; submission date proposed by the applicant: unknown; see section 2).

- Data to clarify the potential genotoxic properties of chlorosulfonamide acid in the context of consumer exposure from residues in food and groundwater relevance (relevant for the representative use evaluated; submission date proposed by the applicant: unknown; see sections 2, 3 and 4).

- A transparent presentation of the fitting of DT_{50} endpoints from the laboratory incubations on the two aerobic flooded soil systems for halosulfuron-methyl and the metabolites: 'halosulfuron-methyl rearrangement', 'halosulfuron rearrangement', halosulfuron, chlorosulfonamide, chlorosulfonamide acid and aminopyrimidine was not provided by the applicant. The data needed for this assessment are in the dossier but visual fits as required by FOCUS (2006) kinetics guidance have not been provided (relevant for the representative use evaluated, submission date proposed by the applicant: unknown; see section 4).

- A transparent presentation of the fitting of DT_{50} endpoints from the laboratory incubations on the single anaerobic flooded soil system for halosulfuron-methyl and the metabolites: 'halosulfuron-methyl rearrangement', halosulfuron, chlorosulfonamide and aminopyrimidine, was not provided by the applicant. The data needed for this assessment are in the dossier but visual fits as required by FOCUS (2006) kinetics guidance have not been provided (relevant for the representative use evaluated, submission date proposed by the applicant: unknown; see section 4).

- A transparent presentation of the fitting of DT_{50} endpoints from the laboratory incubations on the two aerobic sediment water systems for halosulfuron-methyl and the metabolite: 'halosulfuron-methyl rearrangement', was not provided by the applicant. The data needed for this assessment are in the dossier but visual fits as required by FOCUS (2006) kinetics guidance have not been provided (relevant for the representative use evaluated, submission date proposed by the applicant: unknown; see section 4).

- Two reliable DT_{50} in aerobic flooded soil for the metabolites 'halosulfuron rearrangement' and chlorosulfonamide acid are needed, to complete more reliable, less uncertain, groundwater exposure estimates (relevant for the representative use evaluated, submission date proposed by the applicant: unknown; see section 4).

- Satisfactory soil adsorption measurements for the metabolite 'halosulfuron rearrangement' are not available (relevant for the representative use evaluated, submission date proposed by the applicant: unknown; see section 4).

- The applicant to submit the analytical profile of the toxicity studies used in the ecotoxicology section (relevant for the representative use evaluated; submission date proposed by the applicant: unknown; see section 5).

- Data to address the risk to aquatic macrophytes from exposure to the surface water metabolites 'halosulfuron-methyl rearrangement' and 'halosulfuron rearrangement' and to cover the situation when groundwater may become surface water in relation to potential exposure to

chlorosulfonamide acid (relevant for the representative use evaluated; submission date proposed by the applicant: unknown; see section 5).

- Data to further refine the risk assessment for the terrestrial plants, as the available assessment indicates a high risk (relevant for the representative use evaluated; submission date proposed by the applicant: unknown; see section 5).

8. Particular conditions proposed to be taken into account to manage the risk(s) identified

None.

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to the representative use).

1. The consumer risk assessment does not consider residues of chlorosulfonamide acid. The toxicological relevance, in particular the genotoxic potential, of the major plant metabolite chlorosulfonamide acid needs to be clarified by further data.

2. The metabolite 'halosulfuron rearrangement' (HSR) is concluded as a relevant groundwater metabolite using the available toxicological information. The available groundwater exposure assessments (calculations) indicate that with the available relatively best-case assessment, 'halosulfuron rearrangement' (HSR) exceeds the parametric drinking water limit of 0.1 µg/L in annual average groundwater recharge at the MED-RICE sandy scenario. However further DT_{50} and K_{oc} data are needed before the assessment of the potential for 0.1µg/L to be exceeded at the MED-RICE clay scenario can be finalised, with the usual level of uncertainty.

3. For chlorosulfonamide acid (CSA), the available worst case groundwater exposure assessment indicates exceedence of the parametric drinking water limit of 0.1µg/L at the MED-RICE clay scenario. Provision of reliable soil DT_{50} data would allow this exposure assessment to be finalised with the more usual level of uncertainty. If exceedence of 0.1µg/L were to be confirmed, further toxicological data (i.e. clarification on its genotoxic properties) would be required before it could be concluded whether chlorosulfonamide acid (CSA) is a relevant groundwater metabolite.

4. Risk to aquatic plants when exposed to the metabolites 'halosulfuron-methyl rearrangement' (HSMR), 'halosulfuron rearrangement' (HSR) predicted to be present in surface water and possibly chlorosulfonamide acid (CSA) in situations where groundwater becomes surface water.

9.2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a

plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

5. A high risk was indicated for non-target terrestrial plants with the available data and assessment that already include proposals for exposure mitigation.

6. Equivalence of the tested material with the technical specification was not demonstrated for the toxicity studies in the mammalian toxicology and ecotoxicology sections.

9.3. Overview of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in section 8, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)

In addition to the issues identified in the table, all columns are grey as equivalence was not demonstrated for the technical material specification proposed and the material used in the testing that was used to derive the toxicological and ecotoxicological reference values.

Representative use		**Rice**
Operator risk	Risk identified	
	Assessment not finalised	
Worker risk	Risk identified	
	Assessment not finalised	
Bystander risk	Risk identified	
	Assessment not finalised	
Consumer risk	Risk identified	
	Assessment not finalised	X[1]
Risk to wild non target terrestrial vertebrates	Risk identified	
	Assessment not finalised	
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	X[5]
	Assessment not finalised	
Risk to aquatic organisms	Risk identified	
	Assessment not finalised	X[4]
Groundwater exposure active substance	Legal parametric value breached	
	Assessment not finalised	
Groundwater exposure metabolites	Legal parametric value breached	1/2 MED-RICE scenarios[2]
	Parametric value of 10µg/L[(a)] breached	
	Assessment not finalised	X[2,3]
Comments/Remarks		

The superscript numbers in this table relate to the numbered points indicated in sections 9.1 and 9.2. Where there is no superscript number see sections 2 to 6 for further information.
(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003b

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APPENDICES

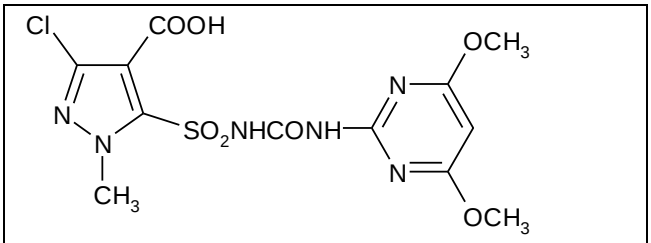
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

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

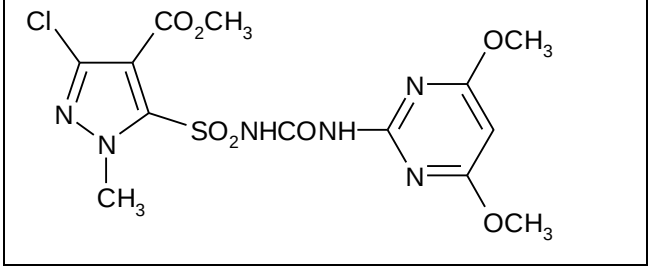
Active substance (ISO Common Name)	Halosulfuron Unless stated otherwise, the following data relate to the variant halosulfuron-methyl (modified ISO 1750)
Function (*e.g.* fungicide)	Herbicide
RapporteurMemberState	ITALY
Co-rapporteurMemberState	none

Identity (Annex IIA, point 1)

Chemical name (IUPAC)	Halosulfuron 3-chloro-5-(4,6-dimethoxypyrimidin-2-ylcarbamoylsulfamoyl)-1-methylpyrazole-4-carboxylic acid Halosulfuron-methyl methyl 3-chloro-5-(4,6-dimethoxypyrimidin-2-ylcarbamoylsulfamoyl)-1-methylpyrazole-4-carboxylate
Chemical name (CA)	Halosulfuron 3-chloro-5-[[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]-1-methyl-1*H*-pyrazole-4-carboxylic acid Halosulfuron-methyl methyl 3-chloro-5-[[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]-1-methyl-1*H*-pyrazole-4-carboxylate
CIPAC No	Halosulfuron: 785 Halosulfuron-methyl: 785.201
CAS No	Halosulfuron: 135397-30-7 Halosulfuron-methyl: 100784-20-1
EC No (EINECS or ELINCS)	Not allocated
FAO Specification (including year of publication)	Not allocated
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	Open
Molecular formula	Halosulfuron: $C_{12}H_{13}ClN_6O_7S$ Halosulfuron-methyl: $C_{13}H_{15}ClN_6O_7S$
Molecular mass	Halosulfuron: 420.79 g/mol Halosulfuron-methyl: 434.82 g/mol
Structural formula	Halosulfuron:



Halosulfuron-methyl:



Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity)	175.5 - 177.2°C (99.1%)
Boiling point (state purity)	Not applicable.
Temperature of decomposition (state purity)	Peak temperature due to endothermic effect (melting): 181.6°C in air, 180.3°C in nitrogen. (99.9%)
Appearance (state purity)	Pure material: fine white powder containing some crystalline particles at 20ºC (99.9%)
	Technical material: powdered solid at 25°C (99.1%)
Vapour pressure (state temperature, state purity)	$<1.33 \times 10^{-5}$ Pa at 25 ± 1°C (99.9%)
Henry's law constant	3.5×10^{-6} Pa m^3 mol^{-1}
Solubility in water (state temperature, state purity and pH)	0.0102 g/L at 20°C (pH=6.5) (99.9%)
	(Purity = 99.1%) 0.015 g/L at 20 ± 0.5°C (n=9) (pH = 5) 1.65 g/L at 20 ± 0.5°C (n=9) (pH=7) 7.47 g/l at 20 ± 0.5°C (24 hours) (pH=9) 3.83 g/l at 20 ± 0.5°C (48 hours) (pH=9) 2.63 g/l at 20 ± 0.5°C (72 hours) (pH=9) Halosulfuron-methyl is not stable in water at pH 9
Solubility in organic solvents (state temperature, state purity)	Methanol at 20°C 1.616 g/L (99.1%) Hexane at 20°C 1.278×10^{-2} g/L (99.1%) Toluene at 20°C 3.640 g/L (99.9%) Dichloromethane at 20°C 52.76 g/L (99.9%) Acetone at 20°C 21.96 g/L (99.9%) Ethyl acetate at 20°C 15.26 g/L (99.9%) Acetonitrile at 20°C 9.968 g/L (99.9%)
Surface tension (state concentration and temperature, statepurity)	70.5 mN/m at 20°C (90 % saturated solution) (99.6%)
Partition co-efficient (state temperature, pH and purity)	(Purity: 99.9 %) Halosulfuron methyl log $P_{O/W}$ = 1.67 at 22.8 °C pH = 5 log $P_{O/W}$ = -0.0186 at 22.8 °C pH = 7 log $P_{O/W}$ = -0.542 at 22.5 °C pH = 9 Halosulfuron-methyl is not stable in water at pH 9
	(Purity: 100.0%) metabolite 'Halosulfuron methyl rearrangement' log $P_{O/W}$ = 2.313 by HPLC
Dissociation constant (state purity)	pKa_1 = 3.44 at 22.4°C (99.9%)
UV/VIS absorption (max.) incl. ε (state purity, pH)	(Purity: 99.9%) neutral solution: λ_{max} (nm)= 245.0; ε ($L.mol^{-1}.cm^{-1}$) = 20347 λ_{max} (nm)= 203.0; ε ($L.mol^{-1}.cm^{-1}$) = 34896 Acidic solution: λ_{max} (nm)= 244.0; ε ($L.mol^{-1}.cm^{-1}$) = 19570 λ_{max} (nm)= 203.0; ε ($L.mol^{-1}.cm^{-1}$) = 39329 Basic solution: λ_{max} (nm)= 260.0; ε ($L.mol^{-1}.cm^{-1}$) = 11492 λ_{max} (nm)= 233.0; ε ($L.mol^{-1}.cm^{-1}$) = 15312 λ_{max} (nm)= 215.5; ε ($L.mol^{-1}.cm^{-1}$) = 14869
Flammability (state purity)	Not highly flammable. (99.2%) Could not be ignited with a flame
Explosive properties (state purity)	No explosive properties (99.2%)
Oxidising properties (state purity)	No oxidising properties (99.6%)

Summary of intended uses

Crop and/or situation (a)	Member State or Country	Product Name	F, G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s. (i)	Method kind (f-h)	Growth stage & season (j)	Number min- max (k)	Interval between applications (min)	kg a.s./hl min- max	Water (l/ha) min- max	kg a.s./ha min- max		
Rice	IT ES FR GR PT	NC-319 75WG Halosulfuron-methyl 75WG	F	*Bolboschoenus maritimus* *Schoenoplectus mucronatus* *Cyperus* spp. *Alisma* spp. Annual broad-leaf weeds Perennial weeds	WG	750 g/kg	Boom sprayer	BBCH 12 - 24	1	-	0.0075 - 0.01875	200 - 400	0.030 - 0.0375	77-119*	*Application timing based on growth stage. PHI given as an indication of expected PHI based on residue trials.

(a) For crops, the CODEX and EU (or other) classifications should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(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
(i) g/kg or g/l
(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 application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) PHI – minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

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		Open
Food of animal origin		Not applicable
Soil		Halosulfuron-methyl
Water	surface	At least halosulfuron-methyl, open for metabolites
	drinking/ground	At least halosulfuron-methyl, open for metabolites
Air		Halosulfuron-methyl

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Analyte: Halosulfuron-methyl LC-MS/MS; LOQ = 0.01 mg/kg (rice grain and straw)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not applicable
Soil (analytical technique and LOQ)	Analyte: Halosulfuron-methyl LC-MS/MS; LOQ = 0.0005 mg/kg (paddy soil)
Water (analytical technique and LOQ)	Analyte: Halosulfuron-methyl LC-MS/MS; LOQ = 0.1 µg/L (ground, surface, drinking water)
Air (analytical technique and LOQ)	LC-MS/MS; LOQ = 0.002 mg/m^3
Body fluids and tissues (analytical technique and LOQ)	Not applicable because halosulfuron-methyl is not classified as toxic

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

Halosulfuron-methyl	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 absorbed (highest concentrations at 0.5 hour post-dosing) and high bioavailability (> 80 % of dose, based on urinary and biliary excretion and residues in the carcass). No evidence for absorption saturation.
Distribution ‡	Widely distributed to different organs
Potential for accumulation ‡	Very low potential for accumulation (< 1 % of residues 168 hours after dosing, independently on treatment regimen)
Rate and extent of excretion ‡	Rapid and extensive (> 70 % within 12 hours in urine and within 48 hours in faeces). Between 79-102 % excreted within 7 days. Urinary excretion: 33-55 % of the dose; faecal excretion: 35-55 % of the dose within 7 days. Biliary excretion:29-40 % within 48h
Metabolism in animals ‡	Extensively metabolised : no parent compound detected in urine and low amount (0.6-1 %) in faeces. Major pathways: demethylation and hydroxylation of pyrimidine moiety with a minor pathway (< 3 %) of cleavage between pyrimidine and pyrazole moieties. Major metabolites: Demethyl halosulfuron-methyl (urine: 13-35 %; faeces: 7-8 %) and 5-hydroxy demethyl halosulfuron-methyl (urine: 9-14 %; faeces: 15-25 %)
Toxicologically relevant compounds ‡ (animals and plants)	Halosulfuron-methyl
Toxicologically relevant compounds ‡ (environment)	Halosulfuron-methyl

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	Rat: 7758 mg/kg bw Mouse: 9295 mg/kg bw	
Rat LD_{50} dermal ‡	> 2000 mg/kg bw	
Rat LC_{50} inhalation ‡	> 6.0 mg/L air/4h (whole body)	
Skin irritation ‡	Non-irritant	
Eye irritation ‡	Non-irritant	
Skin sensitisation ‡	Non-sensitiser (Magnusson and Kligman test)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Reduced body weight gain, liver effects and haematological changes (dog and rat) Increased haemosiderin pigmentation in the renal tubular epithelium (rat)

Relevant oral NOAEL ‡	90-day & 1-year, dog: 10 mg/kg bw per day 90-day, rat: 116 mg/kg bw per day	
Relevant dermal NOAEL ‡	21-day, rat: 100 mg/kg bw per day	
Relevant inhalation NOAEL ‡	No data - not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

No genotoxic potential	

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

Target/critical effect ‡	Reduced body weight gain (rats and mice) Increased microconcretions/mineralisation in testis and epididymal tubules (mice)	
Relevant NOAEL ‡	43.8 mg/kg bw per day; 2-year, rat 410.0 mg/kg bw per day; 18-month, mouse	
Carcinogenicity ‡	No carcinogenic potential	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parental: reduced body weight/body weight gain Reproduction: no adverse effect observed Offspring: Reduced pup body weight gain in F1, F2a and F2b generations	
Relevant parental NOAEL ‡	50.4 mg/kg bw per day	
Relevant reproductive NOAEL ‡	223.2 mg/kg bw per day (the highest dose tested)	
Relevant offspring NOAEL ‡	6.3 mg/kg bw per day	

Developmental toxicity

Developmental target / critical effect ‡	Rat: Maternal: decreased body weight/body weight gain and reduced food consumption Developmental: increased number of foetuses and litters with visceral and skeletal variations Rabbit: Maternal: reduced maternal body weight gain Developmental: increased in mean early resorptions and decreased number of foetuses	Repro tox cat 2, H361fd
Relevant maternal NOAEL ‡	Rat: 250 mg/kg bw per day Rabbit: 50 mg/kg bw per day	
Relevant developmental NOAEL ‡	Rat: 75 mg/kg bw per day Rabbit: 50 mg/kg bw per day	

Neurotoxicity(Annex IIA, point 5.7)

Acute neurotoxicity ‡	NOAEL: 600 mg/kg bw based on transient increases in uncoordinated righting reflex at 7 hours post-dosing and reduced male body weight gain at 2000 mg/kg bw	
Repeated neurotoxicity ‡	NOAEL for neurotoxicity: 315.9 mg/kg bw per day (the highest dose tested) NOAEL for systemic toxicity: 62.8 mg/kg bw per day, based on reduced bw gain and liver effects	
Delayed neurotoxicity ‡	No data - not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data	
Studies performed on metabolites or impurities ‡ Metabolite CSA	Rat acute oral toxicity: 90-day, rat: Rat developmental toxicity: *In vitro* bacterial mutation test: negative *In vitro* mammalian cell gene mutation test: equivocal *In vivo* micronucleus test: negative Further genotoxicity data required	LD_{50}: > 5000 mg/kg bw NOAEL:75.8 mg/kg bw per day, based on reduced bw gain maternal and developmental NOAEL: 1000 mg/kg bw per day (the highest dose tested)
Metabolite HSMR	Mouse acute oral toxicity: *In vitro* bacterial mutation test: negative	LD_{50}: > 5000 mg/kg bw

Medical data ‡ (Annex IIA, point 5.9)

No adverse health effects have been reported in manufacturing personnel, or workers in manufacturing plants

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.063 mg/kg bw per day	Rat reproductive study - offspring toxicity	100
AOEL ‡	0.063 mg/kg bw per day	Rat reproductive study - offspring toxicity	100*
ARfD ‡	0.5 mg/kg bw	Rabbit developmental study - maternal toxicity	100

* no correction regarding oral absorption needed

Dermal absorption (Annex IIIA, point 7.3)

Halosulfuron-methyl 75WG (750 g/kg WG formulation)	No data. 100 % absorption assumed.

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Tractor-mounted application of Halosulfuron-methyl 75WG on rice (application rate 0.0375 kg halosulfuron-methyl/ha) UK POEM % of AOEL Without PPE 502 % With PPE (gloves during M/L & application) 47.1 % German model Without PPE 69 %
Workers	Without PPE: 8.5 % of AOEL
Bystanders	1.2 % of the AOEL

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

	RMS/peer review proposal
Halosulfuron-methyl	Reproductive toxicant category 2, **H361fd** 'Suspected of damaging the unborn child'[9]
	Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation): Currently not available

[9] It should be noted that proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals. Classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

Residues

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

Plant groups covered	Rice, corn, sugar cane (paddy water treatment or pre-emergence soil treatment, respectively, and post-emergence foliar application)
Rotational crops	No data, not required
Metabolism in rotational crops similar to metabolism in primary crops?	Not necessary
Processed commodities	Not necessary
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not necessary
Plant residue definition for monitoring	unable to conclude
Plant residue definition for risk assessment	1) halosulfuron-methyl and 2) chlorosulfonamide acid (provisional, pending further data on genotoxic potential of chlorosulfonamide acid)
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 data, not triggered by representative use
Time needed to reach a plateau concentration in milk and eggs	No data
Animal residue definition for monitoring	Not necessary
Animal residue definition for risk assessment	Not necessary
Conversion factor (monitoring to risk assessment)	Not necessary
Metabolism in rat and ruminant similar (yes/no)	No
Fat soluble residue: (yes/no)	No

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

No data.

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

Residues are stable for six months in rice grain, rice straw, paddy soil and paddy water at approximately -18°C

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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	No	No	No
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of	No	No	No

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
residues ≥ 0.01 mg/kg in edible tissues (yes/no)			

	Residue levels in matrices: Mean (max) mg/kg		
Muscle	none	none	none
Liver	none	none	none
Kidney	none	none	none
Fat	none	none	none
Milk	none		
Eggs		none	

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

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Rice	Southern Europe	Grain – 12 x <0.01 mg/kg Straw – 12 x <0.01 mg/kg		0.01 mg/kg	0.01 mg/kg	0.01 mg/kg

(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)

The consumer risk assessment is not finalised since the toxicological profile, and in particular the genotoxic potential, of the major plant chlorosufonamide acid is currently inconclusive.

ADI	0.063 mg/kg bw per day
TMDI (% ADI) according to WHO European diet	<0.1%ADI
TMDI (% ADI) according to national (to be specified) diets	EFSA Model: <0.1%ADI for all diets
IEDI (WHO European Diet) (% ADI)	see TMDI
NEDI (specify diet) (% ADI)	see TMDI
Factors included in IEDI and NEDI	none
ARfD	0.5 mg/kg bw
IESTI (% ARfD)	<0.1% (IESTI 1 and IESTI 2)
NESTI (% ARfD) according to national (to be specified) large portion consumption data	<0.1%
Factors included in IESTI and NESTI	Not necessary

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 necessary	No data	No data	No data	No data

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

Rice (provisional, based on residues determined as halosulfuron-methyl)	0.01 mg/kg

Fate and Behaviour in the Environment

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

Mineralisation after 120 days	Maximum 0.3% AR and 12.2% AR, clay loam and loamy sand paddy soil respectively Radiolabels used: [^{14}C-pyrimidine] and [^{14}C-pyrazole]
Non-extractable residues after 120 days	Clay loam: 23 - 24% AR Loamy sand: 24 - 45% AR Radiolabels used: [^{14}C-pyrimidine] and [^{14}C-pyrazole]
Relevant metabolites - name and/or code, % of applied (range and maximum)	Major metabolites (≥10%AR) were: Clay loam (total system) halosulfuron-methyl rearrangement (HSMR): 1.5% - 48.3% AR (maximum at 59 days) halosulfuron rearrangement (HSR): 0.6% - 24.0% AR (maximum at 120 days) chlorosulfonamide (CSE) 5.4 - 12.9% AR at (maximum at 30 days) chlorosulfonamide acid (CSA) 0.9% - 10.7% AR at (maximum at 120 days) Loamy sand (total system) halosulfuron-methyl rearrangement: 1.2 - 8.5 % AR (maximum at 30 days) halosulfuron rearrangement: 0.1% - 4.4% AR (maximum at 59 days) chlorosulfonamide 1.7% - 20.3% AR (maximum at 59 days) chlorosulfonamide acid 2.1% - 23.7% AR (maximum at 120 days) Radiolabels used: [^{14}C-pyrimidine] and [^{14}C-pyrazole] Metabolites (≥5%AR at 2 times) was: Clay loam (total system) aminopyrimidine (AP): 0.7% - 8.9% AR (maximum at 59 days) Loamy sand (total system) aminopyrimidine: 3.1% - 9.5% AR (maximum at 59 days)

Route of degradation in soil (anaerobic & photolysis) (Annex IIA, point 7.1.11.2)

Anaerobic degradation	Degradation products exceeding 10% AR in the anaerobic total system (aqueous and soil) were halosulfuron-methyl rearrangement (maximum 24.8% AR after 90 days), halosulfuron rearrangement (maximum 20.5% AR after 120 days), chlorosulfonamide (maximum 22.7% AR after 61 days), chlorosulfonamide acid (maximum 19.6% AR after 120 days), Pd3 (unstable aminopyrimidine derivative, maximum 12.2% AR after 120 days). Radiolabels used: [^{14}C-pyrimidine] and [^{14}C-pyrazole]
Soil photolysis	Halosulfuron-methyl was photolytically stable following 30 days exposure to natural sunlight

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

halosulfuron-methyl			Aerobic conditions (flooded soil study)					
Soil type	X	pH	t.°C/% MWHC	DT_{50} /DT_{90} (d) Paddy soil	DT_{50} /DT_{90} (d) Paddy water	DT_{50} /DT_{90} (d) Total system	St. (r^2)	Method of calculation
Spain (Clay loam)		7.7	20	1.7/5.6	13.0/43.2	17.2/57.3	> 98	First order kinetics
Italy (Loamy sand)		6.2	20	3.7/12.1	27.0/89.7	33.3/111	> 0.97	First order kinetics
Geometric mean						23.9		

HSMR			Aerobic conditions (flooded soil study), decline from maximum observed					
Soil type	X	pH	t.°C/% MWHC	DT_{50} /DT_{90} (d) Paddy soil	DT_{50} /DT_{90} (d) Paddy water	DT_{50} /DT_{90} (d) Total system	St. (r^2)	Method of calculation
Spain (Clay loam)		7.7	20			142/470	0.84-0.89	First order kinetics
Italy (Loamy sand)		6.2	20			102/339	0.93-1	First order kinetics
Geometric mean						120		

HSR			Aerobic conditions (flooded soil study), decline from maximum observed					
Soil type	X	pH	t.°C/% MWHC	DT_{50} /DT_{90} (d) Paddy soil	DT_{50} /DT_{90} (d) Paddy water	DT_{50} /DT_{90} (d) Total system	St. (r^2)	Method of calculation
Spain (Clay loam)		7.7	20			No decline, still increasing, data gap		-
Italy (Loamy sand)		6.2	20			79*/262	0.78-1	First order kinetics
Geometric mean/median								

*formation levels in this system were low max 3-4.4%, therefore this DT50 is uncertain.

CSE			Aerobic conditions (flooded soil study), decline from maximum observed					
Soil type	X	pH	t.°C/% MWHC	DT_{50} /DT_{90} (d) Paddy soil	DT_{50} /DT_{90} (d) Paddy water	DT_{50} /DT_{90} (d) Total system	St. (r^2)	Method of calculation
Spain (Clay loam)		7.7	20			75/249	0.82	First order kinetics
Italy (Loamy sand)		6.2	20			156/518	0.75	First order kinetics
Geometric mean						108		

CSA		Aerobic conditions (flooded soil study), Data Gap

AP			Aerobic conditions (flooded soil study), decline from maximum observed					
Soil type	X	pH	t.°C/% MWHC	DT_{50} /DT_{90} (d) Paddy soil	DT_{50} /DT_{90} (d) Paddy water	DT_{50} /DT_{90} (d) Total system	St. (r^2)	Method of calculation
Spain		7.7	20			124/412	0.97	First order

(Clay loam)								kinetics
Italy (Loamy sand)		6.2	20			47/156	0.98	First order kinetics
Geometric mean						76		

HS			Aerobic conditions (flooded soil study), decline from maximum observed					
Soil type	X	pH	t.°C/% MWHC	DT_{50} /DT_{90} (d) Paddy soil	DT_{50} /DT_{90} (d) Paddy water	DT_{50} /DT_{90} (d) Total system	St. (r^2)	Method of calculation
Spain (Clay loam)		7.7	20			38/126	1	First order kinetics
Italy (Loamy sand)		6.2	20			47/156	0.86-1	First order kinetics
Geometric mean						44		

halosulfuron-methyl	Anaerobic conditions						
Soil type	X	pH	t.°C/% MWHC	DT_{50} /DT_{90} (d) soil phase	DT_{50} /DT_{90} (d) Total system	St. (r^2)	Method of calculation
Loamy sand		6.2	20	18.9/62.7	37.4/125	>0.91	First order kinetics

HSMR	Anaerobic conditions						
Soil type	X	pH	t.°C/% MWHC		DT_{50} /DT_{90} (d) total system	St. (r^2)	Method of calculation
Loamy sand		6.2	20		410/1362	0.34	First order kinetics

CSE	Anaerobic conditions, decline from maximum observed						
Soil type	X	pH	t.°C/% MWHC		DT_{50} /DT_{90} (d) total system	St. (r^2)	Method of calculation
Loamy sand		6.2	20		212/704	0.43	First order kinetics

HS	Anaerobic conditions, decline from maximum observed						
Soil type	X	pH	t.°C/% MWHC		DT_{50} /DT_{90} (d) total system	St. (r^2)	Method of calculation
Loamy sand		6.2	20		191/634	0.17	First order kinetics

AP	Anaerobic conditions, decline from maximum observed						
Soil type	X	pH	t.°C/% MWHC		DT_{50} /DT_{90} (d) total system	St. (r^2)	Method of calculation
Loamy sand		6.2	20		55/183	0.66	First order kinetics

Field studies

halosulfuron-methyl	Aerobic conditions						
Soil type	X	pH	t.°C/% MWHC	DT_{50} /DT_{90} (d) Paddy soil	DT_{50} /DT_{90} (d) Paddy water	St. (r^2)	Method of calculation
Spain (Non-		7.8		4.3/14	1.0/3.5	> 0.99	First order

cropped paddy)							kinetics
Italy (Non-cropped paddy)		6.9		4.3/14	0.5/1.6	> 0.99 $\chi 2$=25.5	First order kinetics
Geometric mean				4.3			

HSMR	Aerobic conditions						
Soil type	X	pH	t.°C/% MWHC	DT_{50} /DT_{90} (d) Paddy soil	DT_{50} /DT_{90} (d) Paddy water	St. (r^2)	Method of calculation
Spain (Non-cropped paddy)		7.8		28/92	-	0.83	First order kinetics
Italy (Non-cropped paddy)		6.9		<3/<9	-	0.91	First order kinetics
Geometric mean				<9.2			

HSR, CSE, and CSA were analysed for but not detected (LOD =0.25µg/kg soil and =2µg/L paddy water)

Soil adsorption/desorption (Annex IIA, point 7.1.2)

halosulfuron-methyl							
Soil Type	OC %	Soil pH	Kd (mL/g)	Kdoc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Silt loam	1.78	6.9	1.66	93.54	1.48	-	0.76
Sandy loam	0.58	8.0	0.66	113.69	0.68	-	1.08
Loamy sand	1.15	6.8	0.36	31.10	0.32	-	0.61
Silty clay loam	2.0	5.8	3.98	199.22	3.56	-	0.85
Arithmetic mean				109.39			
pH dependence, Yes or No			No				

CSE							
Soil Type	OC %	Soil pH	Kd (mL/g)	Kdoc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Silt loam	1.78	6.9	3.24	182.08	2.98	-	0.87
Sandy loam	0.58	8.0	0.85	146.09	0.80	-	0.85
Loamy sand	1.15	6.8	0.75	65.04	0.70	-	0.82
Silty clay loam	2.0	5.8	6.85	342.70	5.93	-	0.86
Arithmetic mean				183.98			
pH dependence, Yes or No			No				

CSA							
Soil Type	OC %	Soil pH	Kd (mL/g)	Kdoc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Silt loam	1.78	6.9	0.03	1.49	0.02	-	0.28
Sandy loam	0.58	8.0	0	0	0	-	-
Loamy sand	1.15	6.8	0.11	9.95	0.18	-	2.81
Silty clay loam	2.0	5.8	0.16	7.96	0.22	-	2.20
Arithmetic mean				4.85			
pH dependence, Yes or No			No				

AP							
Soil Type	OC %	Soil pH	Kd (mL/g)	Kdoc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Silt loam	1.78	6.9	18.56	1042.43	11.54	-	0.72
Sandy loam	0.58	8.0	2.32	399.55	1.92	-	0.68
Loamy sand	1.15	6.8	2.99	259.98	2.59	-	0.79
Silty clay loam	2.0	5.8	165.60	8279.97	32.23	-	0.56
Arithmetic mean				2495.48			
pH dependence, Yes or No			No				

HSMR							
Soil Type	OC %	Soil pH	Kd (mL/g)	Kdoc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Clay loam	1.0	7.7	-	-	0.98	98.0	0.87
Loamy sand	0.7	6.2	-	-	1.17	167.0	0.87
Sandy loam	3.2	5.6	-	-	2.40	75.0	0.93
Arithmetic mean						113	
pH dependence, Yes or No			No				

HSR Data gap.

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

Column leaching	Not applicable, reliable adsorption/desorption coefficients for the active substance have been obtained.
Aged residues leaching	Not applicable, reliable adsorption/desorption coefficients

	for the appropriate metabolites except HSR have been obtained.
Lysimeter / field leaching studies	-

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

Method of calculation	1. Spreadsheet described in SANCO/1090/2000 (rev. 1, June 2003), Tier 1 exposure assessment Halosulfuron-methyl Koc 110mL/g, DT50 flooded soil 23.9 days (applied to water and soil phase). HSMR halosulfuron-methyl Koc 113mL/g, DT50 flooded soil 120 days (applied to water and soil phase).
Application rate	Crop: rice % plant interception: 25% Single application Halosulfuron-methyl: 37.5 g/ha (both scenarios) Halosulfuron-methyl rearrangement: 13.7 g/ha

$PEC_{(s)}$		
Maximum PEC_s (µg/kg) for halosulfuron-methyl		
Scenario	**Tier 1 ('MED-RICE')**	
1 (clayey)	22.41	
2 (sandy)	15.98	
Maximum PEC_s (µg/kg) for halosulfuron-methyl rearrangement		
Scenario	**Tier 1 ('MED-RICE')**	
1 (clayey)	8.2753	
2 (sandy)	5.9281	

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

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	Halosulfuron-methyl: pH 5: DT_{50} 26.9 days at 25 °C* pH 7: DT_{50} 14.4 days at 25 °C* pH 9: DT_{50} 18.6 hours at 25 °C* * Mean values derived from reported data Aminopyrimidine and chlorosulfonamide: DT_{50} not calculable as levels did not decline during the study. Radiolabels used: [^{14}C-pyrimidine] and [^{14}C-pyrazole]
Photolytic degradation of active substance and relevant metabolites	Under natural sun light at approximately 25 °C for 30 days latitude 37.5200N and longitude 84.2004W, there was no photolytic degradation of halosulfuron-methyl. Radiolabels used: [^{14}C-pyrimidine] and [^{14}C-pyrazole]
Readily biodegradable (yes/no)	No

Degradation in water/sediment

halosulfuron-methyl	Water: Day 0 92.2 - 95.9% AR Day 100 <0.1%- 2.1% AR Sediment: Day 1 6.2- 16.1% A Day 100 0.2 - 1.2% AR									
Water/sediment system	pH water phase	pH sed	t.° C	DT_{50}/DT_{90} whole sys	St. (r^2)	DT_{50}/DT_{90} water	St. (r^2)	DT_{50}/DT_{90} sed	St. (r^2)	Method of calculation
Clay loam		8.1	20	6.3/20.9		4.6/15.3		-		First order kinetics

Sandy loam		6.7	20	10.4/34.4		8.1/26.8		-		First order kinetics
Geomean DT_{50}				8.1		6.1				

HS	Decline from maximum observed, 7-15% whole system on days 7-30. Max 8.3% in water and 5.4% in sediment.									
Water/sediment system	pH water phase	pH sed	t.° C	DT_{50}/DT_{90} whole sys	St. (r^2)	DT_{50}/DT_{90} water	St. (r^2)	DT_{50}/DT_{90} sed	St. (r^2)	Method of calculation
Clay loam		8.1	20	32.6/108	0.79 - 0.94	-		-		First order kinetics
Sandy loam		6.7	20	101.7/338	0.74 to0. 79	-		-		First order kinetics
Geomean DT_{50}				58						

HSMR	Decline from maximum observed, 35-42% whole system on day 14									
Water/sediment system	pH water phase	pH sed	t.° C	DT_{50}/DT_{90} whole sys	St. (r^2)	DT_{50}/DT_{90} water	St. (r^2)	DT_{50}/DT_{90} sed	St. (r^2)	Method of calculation
Clay loam		8.1	20	23.2/77	0.89 - 0.99	-		-		First order kinetics
Sandy loam		6.7	20	38.9/129	0.95 - 0.99	-		-		First order kinetics
Geomean DT_{50}				30						

HSR	No Decline from maximum observed of 39.6 % whole system at study end 100 day in the sandy loam system. Did not reach levels that triggered assessment in the clay loam system (max 2.6-4.4%AR)									
Water/sediment system	pH water phase	pH sed	t.° C	DT_{50}/DT_{90} whole sys	St. (r^2)	DT_{50}/DT_{90} water	St. (r^2)	DT_{50}/DT_{90} sed	St. (r^2)	Method of calculation
Clay loam		8.1	20	-		-		-		First order kinetics
Sandy loam		6.7	20	No decline still increasing		Nodecline still increasing		-		First order kinetics

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

Method of calculation	**Halosulfuron-methyl,** Koc 110mL/g, DT50 flooded soil 4.3 days, paddy water 0.7071 days, surface water, 8.1 days, sediment of surface water 8.1 days 1. Spreadsheet described in SANCO/1090/2000 (rev. 1, June 2003), Tier 1 exposure assessment **Halosulfuron-methyl rearrangement:** Koc 113mL/g, DT50 flooded soil 9.2 days, paddy water 120 days, surface water, 30 days, sediment of surface water 30 days **Halosulfuron rearrangement** Koc 0mL/g, DT50 flooded soil 79 days, paddy water 79 days, surface water, 300 days, sediment of surface water 300 days (defaults from aquatic guidance document for metabolites when there is no decline observed).
Application rate	Crop: rice % plant interception: 25% Single application Halosulfuron-methyl: 37.5 g/ha Halosulfuron-methyl rearrangement: 11.9 g/ha (42% formation in water sediment studies) Halosulfuron rearrangement: 10.7 g/ha (39.6% formation in water sediment studies
Main routes of entry	**Halosulfuron-methyl,** Spray drift and outflow from paddies **Halosulfuron-methyl rearrangement and halosufuron rearrangement:** Primarily spray drift

PEC_{sw}

Maximum PEC_{sw} (µg/litre) for halosulfuron-methyl				
Scenario	**Tier 1 ('MED-RICE')** 1 (clayey)		**Tier 1 ('MED-RICE')** (sandy)	
Time		TWA		TWA
0	0.0620	-	0.0653	-
1	0.0569	0.0595	0.0599	0.0626
2	0.0523	0.0570	0.0550	0.0600
4	0.0441	0.0525	0.0464	0.0553
7	0.0341	0.0467	0.0359	0.0491
14	0.0187	0.0362	0.0197	0.0381
21	0.0103	0.0288	0.0108	0.0303
28	0.0056	0.0235	0.0059	0.0248
42	0.0017	0.0168	0.0018	0.0177
50	0.0009	0.0143	0.0009	0.0150
100	0.0000	0.0072	0.0000	0.0076

Maximum PEC_{sw} (µg/litre) for halosulfuron-methyl rearrangement	
Scenario	**PEC_{sw} (µg/litre)**
1 (clayey)	0.3356
2 (sandy)	0.4707
Maximum PEC_{sw} (µg/litre) for halosulfuron rearrangement	
Scenario	**PEC_{sw} (µg/litre)**
1 (clayey)	0.7249
2 (sandy)	0.7249

PEC (sediment) (Annex IIIA, point 9.2.3)

Application rate	Crop: rice % plant interception: 25%

Single application Halosulfuron-methyl: 37.5 g/ha Halosulfuron-methyl rearrangement: 11.9 g/ha Halosulfuron rearrangement: 10.7 g/ha Chlorosulfonamide: 4.4 g/ha Chlorosulfonamide acid: 4.9 g/ha

$PEC_{(sed)}$		
Maximum PEC_{sed} (µg/kg) for halosulfuron-methyl		
Scenario	**Tier 1 ('MED-RICE')**	
1 (clayey)	0.1184	
2 (sandy)	0.1239	
Maximum PEC_{sed} (µg/kg) for halosulfuron-methyl rearrangement		
Scenario	PEC_{sed} (µg/kg)	
1 (clayey)	0.5934	
2 (sandy)	0.8299	
Maximum PEC_{sed} (µg/kg) for halosulfuron rearrangement		
Scenario	**PEC_{sed} (µg/kg)**	
1 (clayey)	essentially zero exposure dues to low Koc	
2 (sandy)	essentially zero exposure dues to low Koc	

PEC (ground water) (Annex IIIA, point 9.2.1)
Method of calculation and type of study (e.g. modelling, monitoring, lysimeter)

Method of calculation	Spreadsheet described in SANCO/1090/2000 (rev. 1, June 2003, version with leakage rate constant implemented), Tier 1 exposure assessment Halosulfuron-methyl Koc 110mL/g, DT50 flooded soil 23.9 days. HSMR halosulfuron-methyl Koc 113mL/g, DT50 flooded soil 120 days. HSR Koc 0mL/g, DT50 flooded soil 79 days. CSE Koc 184mL/g, DT50 flooded soil 108 days. CSA Koc 4.85mL/g, DT50 flooded soil 1000days. AP Koc 2496mL/g, DT50 flooded soil 76 days (flooded soil DT50 for all compounds applied to water and soil phase in the calculations).
Application rate	Crop: rice % plant interception: 25% Single application Halosulfuron-methyl: 37.5 g/ha Halosulfuron-methyl rearrangement: 13.7 g/ha Halosulfuron rearrangement: 10.7 g/ha Chlorosulfonamide: 4.4 g/ha Chlorosulfonamide acid: 4.9 g/ha Aminopyrimidine: 1.3 g/ha

$PEC_{(gw)}$
PEC_{gw} (µg/L) for halosulfuron-methyl

Scenario 1 (clay soil)	**Scenario 2 (sandy soil)**	
<0.0001	0.0266	
PEC_{gw} (µg/L) for aminopyrimidine		
Scenario 1 (clay soil)	**Scenario 2 (sandy soil)**	
<0.0001	<0.0001	

PEC_{gw} (µg/L) for halosulfuron-methyl rearrangement		
Scenario 1 (clay soil)	**Scenario 2 (sandy soil)**	
<0.0001	0.0766	
PEC_{gw} (µg/L) for halosulfuron rearrangement		
Scenario 1 (clay soil)	**Scenario 2 (sandy soil)**	
0.0474	0.1389	
PEC_{gw} (µg/L) for chlorosulfonamide		
Scenario 1 (clay soil)	**Scenario 2 (sandy soil)**	
<0.0001	0.0142	
PECgw (µg/L) for chlorosulfonamide acid		
Scenario 1 (clay soil)	**Scenario 2 (sandy soil)**	
0.1716	0.0779	
PEC values are annual time-weighted average concentrations.		

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

Direct photolysis in air	Not applicable. Halosulfuron methyl has a moderately low vapour pressure (<1.33 x 10^{-5} Pa at 25 ± 1°C). This indicates little potential for volatilisation from either soil or plant surfaces. Consequently, this is not a likely route of environmental contamination.
Quantum yield of direct phototransformation	The existing data demonstrates that there is no appreciable difference between the irradiated and dark control results therefore the measurement of quantum yield would not be practical.
Photochemical oxidative degradation in air	Calculated hydroxyl rate constant: 203 x 10^{-12} cm^3/$molecules^{-sec}$. Degradation half-life: 38 minutes assuming an hydroxyl radical concentration of 1.5 x 10^6 cm^3.
Volatilisation	The low vapour pressure of halosulfuron-methyl (<1.33 x 10^{-5} Pa at 25 ± 1°C), indicates little potential for volatilisation from plant surfaces or soil.

PEC (air)

Method of calculation	Not applicable

PEC_a

Maximum concentration	The low vapour pressure of halosulfuron-methyl (<1.33 x 10^{-5} Pa at 25 ± 1°C), indicates little potential for volatilisation of halosulfuron-methyl and thus it would not be expected to be found in any significant concentration in the air. The potential persistence of the compound in air has been estimated according to the models developed by Atkins.

Definition of the residue

Environmental residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure	Paddy soil: halosulfuron-methyl, halosulfuron-methyl rearrangement. Groundwater: halosulfuron-methyl, halosulfuron-methyl rearrangement, halosulfuron rearrangement, chlorosulfonamide, chlorosulfonamide acid, aminopyrimidine Surface water :halosulfuron-methyl, halosulfuron-methyl rearrangement, halosulfuron rearrangement. Sediment: halosulfuron-methyl, halosulfuron-methyl rearrangement Air: halosulfuron-methyl

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

No data monitoring data available as products containing the active substance were not yet commercialised within the EU

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 per day)	End point (mg/kg feed)
Birds				
Bobwhite quail	a.s.	Acute	LD_{50} > 2250 mg/kg bw	
	Halosulfuron-methyl 75WG	Acute	No data available – not required	
	Chlorosulfonamide acid	Acute	No data available – not required	
Bobwhite quail	a.s.	Short-term (5d)	LD_{50} > 2810 mg/kg bw	LC_{50} > 5620 mg/kg
Mallard duck	a.s.	Short-term (5d)	LD_{50} > 1936 mg/kg bw	LC_{50} > 5620 mg/kg
Mallard duck	a.s.	Long-term (22 weeks)	119 males 131 females mg/kg per day	NOEL 1000 mg/kg
Mammals				
Rat	a.s.	Acute	LD_{50} 7758 mg/kg bw (oral)	
	a.s.	Long term	NOAEL 6.3 mg/kg bw per day	
	Halosulfuron-methyl 75WG		No data submitted	
	Halosulfuron-methyl rearrangement	Acute	LD_{50} >5000 mg/kg bw (oral)	
	Chlorosulfonamide acid	Acute	LD_{50} >5000 mg/kg bw (oral)	
Additional higher tier studies				
No data available – not required				

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

Rice, 37.5 g/ha/year, BBCH 12-24 (from 2 leaves unfolded to 4 tillers detectable), Southern Europe

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
Bobwhite quail/early crop stage	Acute	2343	>960	10

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Bobwhite quail, Mallard duck/early crop stage	Short-term	1254	>1544	10
Mallard duck/early crop stage	Long-term	1131	>105	5
Higher tier refinement (Birds)				
	Acute	Not relevant		10
	Short-term	Not relevant		10
	Long-term	Not relevant		5
Tier 1– uptake via contaminated water (Birds)				
	Acute	10.114 mg a.s./kg bw/day	>222	10
Tier 1 – secondary poisoning (Birds)				
Earthworm-eating bird	Not expected (log Pow <3)			
Fish-eating bird				
Tier 1– uptake via diet (Mammals) –				
Rat/early crop stage	Acute	7.4	1048	10
Rat/early crop stage	Long-term	2.1 0.44	3.0 [1)] 14.3 [2)]	5
Higher tier refinement (Mammals)				
	Acute	Not relevant		10
	Long-term	Not relevant		5
Tier 1– uptake via drinking water (Mammals)				
	Acute	5.88 mg a.s./kg bw/day	1319	10
Tier 1 – secondary poisoning (Mammals)				
Earthworm-eating mammals	Not expected (log Pow <3)			
Fish-eating mammals				

1) According to SANCO/4145/2000 (European Commission, 2002c)
2) According to EFSA Guidance Document on Risk Assessment for Birds & Mammals (EFSA Journal 2009).

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				

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg/L)
Fish				
Rainbow trout	a.s.	96 hr (flow-through)	Mortality, LC_{50}	>131 mg/l_{mm}
Bluegill	a.s.	96 hr (flow-through)	Mortality, LC_{50}	>118 mg/l_{mm}
Oncorhynchus mykiss	Halosulfuron-methyl rearrangement	96 hr (semi-static)	Mortality, LC_{50}	>15.3 mg/l_{mm}
Oncorhynchus mykiss	Halosulfuron-methyl 75WG	96 hr (semi-static)	Mortality, LC_{50}	>97.3 mg a.s./l_{mm}
Oncorhynchus mykiss	a.s.	87-day (flow-through, early life stage)	Survival and growth, NOEC	34 mg/l_{mm}
Aquatic invertebrate				
Daphnia magna	a.s.	48 h (flow-through)	Immobility, EC_{50}	>107 mg/l_{mm}
Daphnia magna	Halosulfuron-methyl rearrangement	48 h (static)	Immobility, EC_{50}	>19.2 mg/l_{mm}
Daphnia magna	Halosulfuron-methyl 75WG	48 h (static)	Immobility, EC_{50}	121 mg a.s./l_{mm}
Mysidopsis bahia	a.s.	96 h (flow-through)	Mortality, LC_{50}	109 mg/l_{mm}
Lymnaea peregra	a.s.	96 h (semi-static)	Mortality, LC_{50}	>89.9 mg/l_{mm}
Daphnia magna	a.s.	21d (flow-through)	Survival and reproduction, LOEC	6.9 mg/l_{mm}
Daphnia magna	a.s.	21d (flow-through)	Survival and reproduction, NOEC	7.2 mg/l_{mm}
Sediment dwelling organisms				
Chironomus riparius	a.s.	28 d (static)	Emergence and development, EC_{50}	>10 mg/l_{mm}
Chironomus riparius	a.s.	28 d (static)	Emergence and development, NOEC	5 mg/l_{mm} (4.94 mg/Kg_{mm})
Algae				
Pseudokirchneriella subcapitata	a.s.	72 h (static)	Biomass: E_yC_{50} Growth rate: E_rC_{50} Biomass: E_bC_{50}	0.00194 mg/l_{nom} 0.00507 mg/l_{nom} 0.00203 mg/l_{nom}
Navicula pelliculosa	a.s.	120 h (static)	Biomass: EC_{50}	>0.35 mg/l_{nom}

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg/L)
Skeletonema costatum	a.s.	120 h (static)	Biomass: EC_{50}	>0.4 mg/l_{nom}
Pseudokirchneriella subcapitata	Halosulfuron	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	84.7 mg/l_{mm} >98 mg/l_{mm}
Pseudokirchneriella subcapitata	Halosulfuron-methyl rearrangement	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	17.5 mg/l_{mm} >20.3 mg/l_{mm}
Pseudokirchneriella subcapitata	Aminopyrimidine	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	269 mg/l_{nom} 521 mg/l_{nom}
Pseudokirchneriella subcapitata	Halosulfuron-methyl 75WG	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.00295 mga.s./l_{mm} 0.0189 mga.s./l_{mm}
Higher plant				
Lemna gibba	a.s.	7 d (semi-static)	Fronds, E_bC_{50}	0.000217 mg/l_{mm}
Lemna gibba modified exposure (+ sediment)	a.s.	7 day (static)	Biomass: E_bC_{50}	0.000942 mg/l
Lemna gibba	Halosulfuron-methyl 75WG	7 d (semi-static)	Fronds, E_bC_{50}	0.000863 mg a.s./l_{mm}
Lemna gibba modified exposure (+ sediment)	Halosulfuron-methyl 75WG	7 day (static)	Biomass: EbC50	0.000845 mg/l
Elodea canadensis in the presence of sandy loam soil	Halosulfuron-methyl 75WG	15 d (static)	Biomass, NOEC	0.00816 mg a.s./l_{nom}
Myriophyllum proserpinacoides in the presence of sandy loam soil	Halosulfuron-methyl 75WG	14 d (static)	Biomass, NOEC	0.01 mg a.s./l_{nom}
Ceratophyllum demersum in the presence of sandy loam soil	Halosulfuron-methyl 75WG	15 day (static)	NOEC	0.0032 mg/l
Saggitaria saggitifolia in the presence of sandy loam soil	Halosulfuron-methyl 75WG	21 day (static)	NOEC	0.00156 mg/l
Aquatic weeds				
Echinochloa oryzicola *Schoenoplectus juncoides* *Monochoria vaginalis* *Eleocharis kuroguwai*	a.s., halosulfuron, O-demethyl halosulfuron-methyl, halosulfuron-methyl rearrangement, halosulfuron-rearrangement, aminopyrimidine, chlorosulfonamide, chlorosulfonamide acid	17 day following pre or post emergence treatment	Herbicidal activity	≥63 reduction in toxicity vs halosulfuron-methyl

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg/L)
Field test – A field study was submitted (Gray, J., 2005) evaluating the impact of Halosulfuron-methyl 75 WG on algae under field use conditions. Two trial sites were used, one located in Spain and one located in Italy, consisting of a single control and a single treated plot (each plot was a minimum of 50 m2 in area). Halosulfuron-methyl 75 WG was applied at a nominal rate of 50 g/ha of (equivalent to 37.5 g a.s./ha) at the BBCH growth stage 24 (four tillers detectable). The depth of water at the time of application was 0 cm in Spain and 4 cm in Italy. Paddies were re-flooded following application. Over the 63d of the trial, Halosulfuron-methyl 75WG was shown to have no significant effects on natural populations of algae in comparison to controls. Neither species diversity or total cell numbers appeared to be affected. In Spain Residues were < LOQ (0.03 µg/l)) and < LOD (0.0125 µg/l) at 5 and 10 days post-flooding; in Italy, residues were 0.08 µg/l and equivalent to the LOQ (0.03 µg/l) at 5 and 10 days post-flooding , respectively. The results of this test were not directly used in the risk assessment presented in the DAR, which was limited to the off-field risk. The RMS has some doubts about the relevance of the results of the field test conducted in the paddy for the off-field conditions, in view of the marked reduction in species and total cell numbers recorded in the control of the in-field population, and the contrasting results for chlorophyll a.				
Microcosm or mesocosm tests				
No data available – not required				

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

FOCUS Step1 – not applicable

MED-Rice Step 1c

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC (µg/L)	TER	Annex VI trigger
a.s.	Fish	>118	Acute	0.0653	>1807044	100
a.s.	Fish	34	Chronic	0.0653	520674	10
a.s.	Aquatic invertebrates	109	Acute	0.0653	1669219	100
a.s.	Aquatic invertebrates	5	Chronic	0.0653	76570	10
a.s.	Algae	0.00194	Chronic (72 hr)	0.0653	30	10
a.s.	Higher plants	0.000217	Chronic	0.0653	**3.3**	10
a.s.	Sediment-dwelling organisms	4940 µg /Kg_{mm}	Chronic	0.1239µg/kg	39871	10
metabolite HSMR	Algae	17.5	Chronic	0.4707	37179	10
metabolite HSMR	Sediment-dwelling organisms	494 µg /Kg assumption 10xparent toxicity	Chronic	0.8299µg/kg	595	10
Product	Relevant organisms (Higher plants)	0.000863	Chronic	0.0653	13.2	10
a.s.	Higher plants Lemna modified exposure	0.000942	Chronic	0.0653	14.4	10
Product	Higher plants Lemna modified exposure	0.000845	Chronic	0.0653	12.9	10

Data Gap to address the risk to aquatic macrophytes (Lemna) from exposure to the surface water metabolites 'halosulfuron-methyl rearrangement' and 'halosulfuron rearrangement' and to cover the situation when groundwater may become surface water in relation to potential exposure to chlorosulfonamide acid.

Bioconcentration				
	Active substance	Metabolite1	Metabolite2	Metabolite3
$logP_{O/W}$	-0.0186			
Bioconcentration factor (BCF)[1]	No data available - not required			
Annex VI Trigger for the bioconcentration factor				
Clearance time (days) (CT_{50})				
(CT_{90})				
Level and nature of residues (%) in organisms after the 14 day depuration phase				

[1] only required if log $P_{O/W}$ >3.

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)
a.s.	>100 µg/bee	>100 µg/bee
Halosulfuron-methyl 75WG	>100 µg a.s./bee	>100 µg a.s./bee
Field or semi-field tests		
No data available – not required		

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

Crop and application rate

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	0.375	50
a.s.	oral	0.375	50
Halosulfuron-methyl 75WG	Contact	0.375	50
Halosulfuron-methyl 75WG	oral	0.375	50

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/ha)
Typhlodromus pyri	Halosulfuron-methyl 75WG	Mortality	>300 g a.s./ha
Aphidius rhopalosiphi	Halosulfuron-methyl 75WG	Mortality	>300 g a.s./ha

Crop and application rate

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
Halosulfuron-methyl 75WG	*Typhlodromus pyri*	>300 g a.s./ha	< 0.125	< 0.0035 (1m)	2
Halosulfuron-methyl 75WG	*Aphidius rhopalosiphi*	>300 g a.s./ha	< 0.125	< 0.0035 (1m)	2

[1] indicate distance assumed to calculate the drift rate

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	End point	% effect	Trigger value
				No data available – not required		50 %
Field or semi-field tests						
No data 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 foetida	a.s.	Acute 14 days	LC_{50} >1000 mg a.s./kg d.w.soil
Other soil macro-organisms			
Soil mite	a.s.		No data available – not required
	Halosulfuron-methyl 75WG		No data available – not required
	Metabolite 1		Not relevant
Collembola			
	a.s.	Chronic	No data available
	Halosulfuron-methyl 75WG		No data available – not required

Test organism	Test substance	Time scale	End point
	Metabolite 1		
Soil micro-organisms			
Nitrogen mineralisation	a.s.	Long term 28d	No effect at day 28 at 200000 mg a.s/ha
	Metabolite 1		Not relevant
Carbon mineralisation	a.s.	Long term 28d	No effect at day 28 at 200000 mg a.s/ha
	Metabolite 1		Not relevant
Field studies			
No data available – not required			

Toxicity/exposure ratios for soil organisms

Crop and application rate

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
Eisenia foetida	a.s.	Acute	0.0224 mg a.s./kg	>44642	10
Eisenia foetida	halosulfuron methyl rearrangement	Acute	0.0083 mg a.s./kg	>12048 assuming 10x a.s. toxicity	10
Other soil macro-organisms					
Soil mite	a.s.				
Collembola	a.s.				

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

Preliminary screening data

No data available – not required

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g/ha) vegetative vigour	ER_{50} (g/ha) emergence	Exposure $(g/ha)^2$	TER	Trigger
Radish	a.s.	0.21565 (plant dry weight)		1.04 (2.77% drift, ESCORT 2 and SANCO/10329/2002 rev 2 final, worst case)	0.21	5
				0.0375 (0.1% drift ESCORT 2, for 30m buffer zone)	5.7	5
Lettuce	a.s.		0.12 (plant dry weight)	1.04 (2.77% drift, ESCORT 2 and SANCO/10329/2002 rev 2 final, worst case)	0.11	5
				0.0375 (0.1% drift ESCORT 2, for 30m buffer zone)	3.2	5

Probabilistic approach

HC5 (g a.s./ha) dry weight	Exposure (g a.s./ha)	TER	Trigger
0.1	1.04 (2.77% drift, ESCORT 2 and SANCO/10329/2002 rev 2 final, worst case)	0.096	5 (considered not sufficiently protective by the RMS)
	0.10875 (0.29% drift ESCORT 2 and SANCO/10329/2002 rev 2 final, for 10 m buffer zone)	0.9	
	0.075 (0.20% drift ESCORT 2, for 15 m buffer zone)	1.3	
	0.056 (0.15% drift ESCORT 2, for 20 m buffer zone)	1.8	
	0.0375 (0.10% drift ESCORT 2, for 30 m buffer zone)	2.7	

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

No data available.

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

Test type/organism	End point
Activated sludge	No respiration inhibition at 100 mg/l

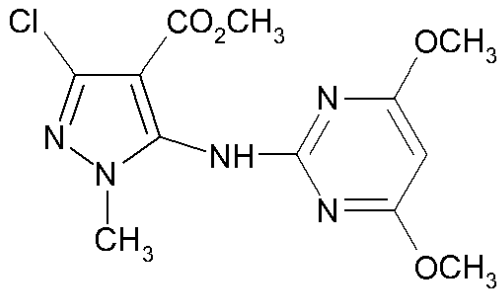
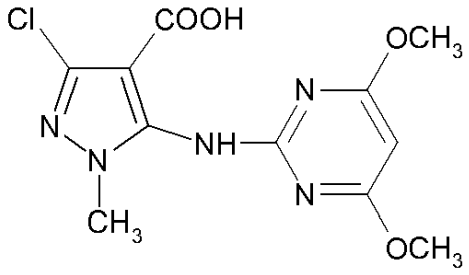
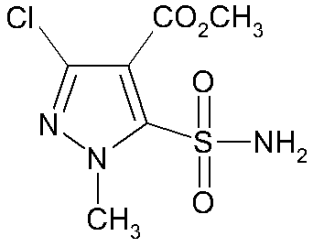
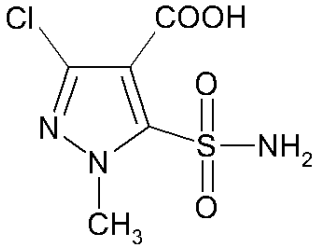
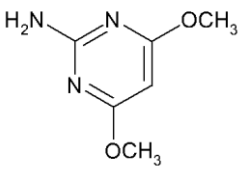
Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

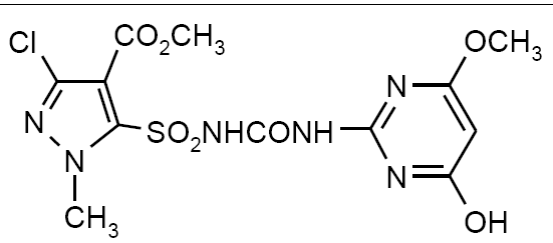
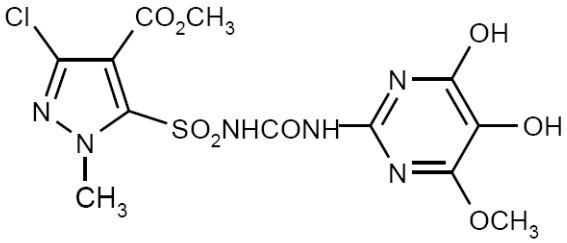
Compartment	
soil	Parent (Halosulfuron-methyl).
water	Parent (Halosulfuron-methyl) Data gaps needs to be addressed before a conclusion can be reached for halosulfuron rearrangement and halosulfuron-methyl rearrangement.
sediment	Parent (Halusulfuron-methyl)
groundwater	Parent (Halusulfuron-methyl). Data gaps needs to be addressed before a conclusion can be reached for halosulfuron rearrangement and halosulfuron-methyl rearrangement.

EFSA the classification and labelling
Halosulfuron methyl: Directive 67/548/EEC R50

New Regulation 1272/2008: H400

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name**	Structural formula
halosulfuron-methyl rearrangement **HSMR**	methyl 3-chloro-5-[(4,6-dimethoxy-2-pyrimidinyl)amino]-1-methyl-1*H*-pyrazole-4-carboxylate	
halosulfuron rearrangement **HSR**	3-chloro-5-[(4,6-dimethoxy-2-pyrimidinyl)amino]-1-methyl-1*H*-pyrazole-4-carboxylic acid	
chlorosulfonamide **CSE**	methyl 3-chloro-1-methyl-5-sulfamoyl-1*H*-pyrazole-4-carboxylate	
chlorosulfonamide acid **CSA**	3-chloro-1-methyl-5-sulfamoyl-1*H*-pyrazole-4-carboxylic acid	
aminopyrimidine **AP**	4,6-dimethoxy-2-pyrimidinamine	

demethyl-halosulfuron-methyl	methyl 3-chloro-5-{[(4-methoxy-6-oxo-1,6-dihydro-2-pyrimidinyl)carbamoyl]sulfamoyl}-1-methyl-1*H*-pyrazole-4-carboxylate	
5-hydroxy demethyl halosulfuron-methyl	methyl 3-chloro-5-{[(5-hydroxy-4-methoxy-6-oxo-1,6-dihydro-2-pyrimidinyl)carbamoyl]sulfamoyl}-1-methyl-1*H*-pyrazole-4-carboxylate	

* The metabolite name in bold is the name used in the conclusion.
** ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008)

ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
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 Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
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
F1	filial generation, first
F2a	filial generation, second, first mating
F2b	filial generation, second, second mating
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
M/L	mixing and loading
mm	millimetre
mN	milli-newton
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
OECD	Organisation for Economic Co-operation and Development
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_{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
POEM	Predictive Operator Exposure Model
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
REACH	Registration, Evaluation, Authorisation of CHemicals
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
UF	uncertainty factor
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