CONCLUSION ON PESTICIDES PEER REVIEW

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Peer review of the pesticide risk assessment of the active substance rimsulfuron

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Abstract

The conclusions of the EFSA following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State, Slovenia, and co-rapporteur Member State, Finland, for the pesticide active substance rimsulfuron are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012. The conclusions were reached on the basis of the evaluation of the representative uses of rimsulfuron as an herbicide on maize, potato and tomato and updated following the request to update the risk assessment of rimsulfuron in view of the renewal process under Commission Implementing Regulation (EU) No 844/2012. The reliable end points, appropriate for use in regulatory risk assessment, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are reported where identified.

Keywords: rimsulfuron, peer review, risk assessment, pesticide, herbicide

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Summary

Commission Implementing Regulation (EU) No 844/2012 (hereinafter referred to as 'the Regulation') lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012.

Rimsulfuron is one of the active substances listed in Regulation (EU) No 686/2012. In accordance with Article 1 of the Regulation, the rapporteur Member State (RMS), Slovenia, and co-rapporteur Member State (co-RMS), Finland, received an application from the Helm AG and Sapec Agro S.A. forming a Task Force and from DuPont (which became Corteva Agriscience), for the renewal of approval of the active substance rimsulfuron. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicants, the co-RMS (Finland), the European Commission and the European Food Safety Authority (EFSA) about the admissibility.

The RMS provided its initial evaluation of the dossier on rimsulfuron in the renewal assessment report (RAR), which was received by EFSA on 31 January 2017. In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicants, the Task Force consisting of Helm AG and Sapec Agro S.A. and DuPont (which became Corteva Agriscience), for comments on 9 March 2017. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 10 May 2017.

Following consideration of the comments received on the RAR, it was concluded that additional information should be requested from the applicants, and that EFSA should conduct an expert consultation in the areas of mammalian toxicology, environmental fate and behaviour and ecotoxicology.

In accordance with Article 13(1) of the Regulation, EFSA should adopt a conclusion on whether rimsulfuron can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council.

EFSA published its conclusion on the peer review of the pesticide risk assessment of rimsulfuron on 29 May 2018. On 10 May 2021, the European Commission sent a mandate to EFSA requesting an update to the risk assessment of rimsulfuron in view of the renewal process under Regulation (EU) No 844/2012. Following further correspondence with one of the applicants (Corteva Agriscience), the rapporteur Member State and EFSA, the points to be reviewed as part of the updated assessment were revised in an amended mandate sent to EFSA on 23 September 2021. The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of rimsulfuron as a herbicide on maize, potato and tomato, as proposed by the applicants. Full details of the representative uses can be found in Appendix A of this report.

The use of rimsulfuron according to the representative uses proposed at the European Union (EU) level results in a sufficient herbicidal efficacy against the target weeds.

A general data gap was identified for a search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites. No critical areas of concern were identified.

In the section identity, physical/chemical properties, analytical methods data gaps were identified for spectra of the relevant impurities; for the content of the relevant impurities in the plant protection products before and after storage; for methods for the determination of the relevant impurities in the representative formulations; for methods for monitoring of rimsulfuron residue in plant commodities with high acid and high oil content, animal products, soil, air and body fluids and tissues for Task Force.

In the mammalian toxicology area, data gaps were identified for toxicokinetic data, *in vitro* tests for skin sensitisation, aromatase inhibition and steroidogenesis assays to assess the endocrine-disrupting potential, *in vivo* study to demonstrate the exposure of bone marrow in micronucleus assay, clastogenicity study in mammalian cells and *in vitro* micronucleus test for the metabolite IN-E9260. Considering that IN-E9260 is a major rat metabolite, reference values of the parent apply also to IN-E9260. In addition, there were some issues not finalised regarding genotoxicity, endocrine-disrupting potential. Setting of reference values for metabolite IN-70941 was not possible. This led to the groundwater relevance assessment of IN-70941 being not finalised.

Data gaps in the residue section are related to information on the nature and/or magnitude of residues in rotational crops, critical good agricultural practice (GAP) compliant field trials in tomato and

information on residues in pollen and residues in bee products for human consumption. This led to the groundwater relevance assessment of IN-E9260 being not finalised whilst the consumer intake of water and food residues for this metabolite could not be estimated whilst residue levels in rotational crops were a data gap.

The information on fate and behaviour into the environment was sufficient to carry out the necessary EU level exposure assessments for the representative uses. The applicants did not provide appropriate information to address the effect of water treatment processes on the nature of the residues that might be present in surface water and groundwater, when surface water or groundwater is abstracted for drinking water. This has led to the identification of a data gap and results in the consumer risk assessment not being finalised.

In the area of ecotoxicology, several data gaps were identified for birds and mammals, aquatic organisms, bees and non-target arthropods.

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Background

Commission Implementing Regulation (EU) No 844/2012[1] (hereinafter referred to as 'the Regulation') lays down the provisions for the procedure of the renewal of the approval of active substances, submitted under Article 14 of Regulation (EC) No 1107/2009[2]. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States, the applicant(s) and the public on the initial evaluation provided by the rapporteur Member State (RMS) and/or co-rapporteur Member State (co-RMS) in the renewal assessment report (RAR), and the organisation of an expert consultation where appropriate.

In accordance with Article 13 of the Regulation, unless formally informed by the European Commission that a conclusion is not necessary, EFSA is required to adopt a conclusion on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 within 5 months from the end of the period provided for the submission of written comments, subject to an extension of an additional 3 months where additional information is required to be submitted by the applicant(s) in accordance with Article 13(3).

In accordance with Article 1 of the Regulation, the RMS, Slovenia, and co-RMS, Finland, received an application from Helm AG and Sapec Agro S.A. forming a Task Force and from DuPont (which became Corteva Agriscience), for the renewal of approval of the active substance rimsulfuron. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicants, the co-RMS (Finland), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on rimsulfuron in the RAR, which was received by EFSA on 31 January 2017 (Slovenia, 2017).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicants, the Task Force consisting of Helm AG and Sapec Agro S.A. and DuPont (which became Corteva Agriscience), for consultation and comments on 9 March 2017. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 10 May 2017. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of a reporting table. The applicants were invited to respond to the comments in column 3 of the reporting table. The comments and the applicants' 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 applicants in accordance with Article 13(3) of the Regulation were considered in a telephone conference between EFSA, the RMS on 22 June 2017. On the basis of the comments received, the applicants' response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicants, and that EFSA should conduct an expert consultation in the areas of mammalian toxicology, environmental fate and behaviour and ecotoxicology.

The outcome of the expert consultation, 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, were compiled by EFSA in the format of an evaluation table.

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the evaluation table, together with the outcome of the expert consultation and the written consultation on the assessment of additional information, where these took place, were reported in the final column of the evaluation table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in February–March 2018.

EFSA published its conclusion on the peer review of the pesticide risk assessment of rimsulfuron on 29 May 2018 (EFSA, 2018). On 10 May 2021, the European Commission sent a mandate to EFSA requesting an update to the risk assessment of rimsulfuron in view of the renewal process under

[1] Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 252, 19.9.2012, pp. 26–32.

[2] Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, pp. 1–50.

Regulation (EU) No 844/2012. Following further correspondence with one of the applicants, the rapporteur Member State and EFSA, the points to be reviewed as part of the updated assessment were revised in an amended mandate sent to EFSA on 23 September 2021.

Originally, a critical area of concern had been identified by EFSA in relation to the contamination of groundwater by metabolite IN-E9260, for which the genotoxicity assessment could not be concluded based on the available data. Decision-making concerning the renewal of approval of rimsulfuron could not be finalised due to the need for the groundwater exposure assessment to be completed and a further consideration of the genotoxicity assessment for metabolite IN-E9260.

In its dossier, the applicant submitted a groundwater exposure assessment, based on modelling using two FOCUS models (PELMO and PEARL), which was evaluated by the rapporteur Member State (RMS) and presented in the draft renewal assessment report (RAR). During the peer review process, changes were made to the assessment of the degradation of rimsulfuron and its metabolites in soil. Consequently, the groundwater modelling was recalculated by the rapporteur Member State only using FOCUS PEARL but not FOCUS PELMO; thus, the EFSA Conclusion originally indicated that exposure calculations according to FOCUS PELMO were missing.

In addition, the DegT50 values for the metabolites for use in the groundwater modelling had been derived from laboratory data, although field data were available (four field dissipation studies conducted following the EFSA (2014) guidance). Therefore, a further review of the field data was considered appropriate.

The applicant also provided data to address the potential genotoxicity of the metabolite IN-E9260, taking into account advice provided by the RMS before submission of the dossier. No further information was requested from the applicant by EFSA on this metabolite during the peer review at the stage foreseen for such requests; however, during the expert consultation at the Pesticides Peer Review Teleconference 154 in November 2017 where the available data on IN-E9260 were discussed, it was concluded that based on the available information, the genotoxicity assessment could not be concluded (uncertainties were highlighted regarding available genotoxicity tests) and that an *in vitro* micronucleus test is missing. Consequently, IN-E9260 was concluded to be a toxicologically relevant groundwater metabolite according to the applicable guidance (European Commission, 2003).

Taking into account the above, EFSA was asked to arrange a further peer review, including consultation of relevant experts, where appropriate, on the following points:

1. Consideration of the groundwater exposure assessment:
   - Reassessment of the field data submitted in the dossiers including the kinetics. Depending on the outcome of such assessment, the DegT50 values for the metabolites may need to be revised based on all of the available data (i.e. field studies submitted by Corteva and the agreed endpoints from the two field studies submitted by the Rimsulfuron Task Force).
   - Updated modelling using both the FOCUS PEARL and PELMO models to complete the groundwater exposure assessment for rimsulfuron and its metabolites (already assessed as triggering a groundwater exposure assessment).[3] Calculations should be performed for the crops and use patterns as already assessed in the published EFSA conclusion on rimsulfuron (2018). In addition, calculations based on biennial and triennial use of rimsulfuron according to PEARL and PELMO models should be provided (in order to provide all relevant information for risk managers for decision-making).

EFSA should base its further considerations on the additional groundwater exposure assessments as described above, that will be carried out by the RMS. The RMS prepared an amended RAR and updated list of endpoints to present this additional field data assessment and exposure modelling (Slovenia, 2022).

2. Further consideration of the genotoxic potential of metabolite IN-E9260 and the setting of reference values, taking into account all data available in the dossier and the comments and considerations in the earlier peer review process.
   As part of the assessment, the following points should be considered:
   - Pertinence of the positive results at 24 h observed in the gene mutation assay according to OECD guideline 476 in the light of other information available on the genotoxic potential of the metabolite IN-E9260;

[3] In the event that the DegT50 values are not amended, only the calculations for FOCUS PELMO need to be updated.

- consideration of the biological relevance of the results considering that the metabolite IN-E9260 is insoluble;
- available data for the metabolite IN-E9260 and for the parent rimsulfuron in a weight of evidence approach;
- setting of reference values for IN-E9260 taking into account data available for rimsulfuron and its metabolites, where appropriate, and in the event that reference values can be established, a consumer risk assessment from exposure to IN-E9260 in drinking water and through food, as required by the guidance on relevance of groundwater metabolites, should be carried out.

In accordance with Article 13(5) of Regulation (EC) No 844/2012, data or studies not available before the deadline set in accordance with Article 13(3) of that Regulation cannot be taken into account; however, comments submitted by the applicant on the EFSA Conclusion may be considered.

EFSA was requested to update the conclusion on rimsulfuron to reflect the outcome of points 1 and 2 above within a period of 8 months from the date of delivery of the updated assessment by the RMS, by 30 June 2022 at the latest.

Depending on the outcome of points 1 and 2, EFSA may be requested by separate mandate to complete the assessment of ED properties as required by points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, in accordance with the guidance document to identify endocrine-disrupting substances, and in accordance with Commission Implementing Regulation (EU) 844/2012 (as amended by 2018/1659), if required for decision-making concerning the renewal of approval of rimsulfuron.

During the course of the peer review, the RMS revised the good agricultural practice (GAP) tables for DuPont and Task Force to ensure consistency in presenting the representative uses provided by the RMS in the original RAR and in D1 documents provided by the applicants.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the representative formulation, evaluated on the basis of the representative uses of rimsulfuron as a herbicide on maize, potato and tomato as proposed by the applicants and updated following the request to update the risk assessment of rimsulfuron in view of the renewal process under Commission Implementing Regulation (EU) No 844/2012. A list of the relevant end points for the active substance and the formulation is provided in Appendix A.

In addition, a key supporting document to this conclusion is the peer review report (EFSA, 2018, 2022), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report comprises the following documents, in which all views expressed during the course of the peer review, including minority views, where applicable, can be found:

- the comments received on the RAR;
- the reporting table (23 June 2017);
- the evaluation table (21 March 2018, updated in 2022);
- 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 revised RAR containing the RMS evaluations in the context of the mandate to review the risk assessment of rimsulfuron.
- the comments received on the draft EFSA conclusion and the updated EFSA conclusion.

Given the importance of the RAR, including its revisions (Slovenia, 2018, 2022), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated that it has regulatory access to the information on which this conclusion report is based.

The active substance and the formulated product

Rimsulfuron is the ISO common name for 1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-ethylsulfonyl-2-pyridylsulfonyl)urea (IUPAC).

The representative formulated products for the evaluation were 'Rimsulfuron 25WG'(DuPont) and 'Rimsulfuron 25WG'(Task Force Helm AG and Sapec Agro S.A.), water-dispersible granules (WG) containing 250 g/kg rimsulfuron.

The representative uses evaluated were hydraulic foliar spray application with or without a surfactant for the control of annual and perennial grass weeds and annual broad-leaved weeds in maize (grain field and silage), potato and tomato. Full details of the GAPs can be found in the list of end points in Appendix A.

Data were submitted to conclude that the uses of rimsulfuron according to the representative uses proposed at EU level result in a sufficient herbicidal efficacy against the target weeds, following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014a).

A data gap has been identified for a search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites, dealing with side effects on health, the environment and non-target species and published within the 10 years before the date of submission of the dossier, to be conducted and reported in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011).

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/3029/99-rev. 4 (European Commission, 2000a), SANCO/3030/99-rev. 4 (European Commission, 2000b) and SANCO/825/00-rev. 8.1 (European Commission, 2010).

The proposed specifications for rimsulfuron are based on batch data from industrial plants. The proposed minimum purity of the technical material is 980 g/kg (DuPont), 975 g/kg (Helm) and 970 g/kg (Sapec). Phenol, acetonitrile and phenyl *N*-(4,6-dimethoxypyrimidin-2-yl)carbamate are considered relevant impurities with maximum contents of 1 g/kg, 3 g/kg and 1 g/kg, respectively (see Section 2). It should be noted that the levels of phenol in the 5 representative batches of DuPont were above 1 g/kg. In the current reference specification, no relevant impurities are specified as a consequence it is proposed an updated of the reference specification. The manufactured technical material meets the requirements of the existing FAO specification (716/TC, February 2006) in terms of minimum purity; relevant impurities are not specified in the FAO specification.

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 rimsulfuron or the representative formulations; however data gaps were identified for spectra of the relevant impurities and for the content of the relevant impurities in the plant protection products before and after storage. The main data regarding the identity of rimsulfuron and its physical and chemical properties are given in Appendix A.

Adequate methods are available for the generation of pre-approval data required for the risk assessment. Methods of analysis are available for the determination of the active substance in the technical material and in the representative formulations. However, a data gap was identified for validated analytical methods for the determination of the relevant impurities in the plant protection products.

Rimsulfuron residue can be monitored in food and feed of plant origin by high performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) with a limit of quantification (LOQ) of 0.01 mg/kg in all commodity groups. Rimsulfuron residue in dry and high water content commodities can be determined also by the quick, easy, cheap, effective and safe method (QuEChERS) using HPLC–MS/MS with an LOQ of 0.01 mg/kg. An analytical method for food of animal origin is not required due to the fact that no residue definition is proposed.

Rimsulfuron residue in soil can be monitored by HPLC–MS/MS with an LOQ 0.05 μg/kg. Rimsulfuron residue in water can be monitored by QuEChERS HPLC–MS/MS or single HPLC–MS/MS with LOQs 0.05 μg/L and 0.1 μg/L, respectively. Appropriate HPLC–MS/MS method exists for monitoring of rimsulfuron residue in air with an LOQ of 3.0 $\mu g/m^3$.

HPLC-MS/MS method can be used for monitoring of rimsulfuron in body fluids (urine and plasma) with LOQ of 0.01 mg/kg. Rimsulfuron residue in body tissues can be determined by HPLC-MS/MS with LOQ of 0.01 mg/kg.

It should be noted that data gaps for methods for monitoring of rimsulfuron residue in: plant commodities with high acid and high oil content, soil, air and body fluids and tissues for Task Force were identified.

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: SANCO/221/2000-rev. 10-final (European Commission, 2003), SANCO/10597/2003-rev. 10.1 (European Commission, 2012), Guidance on dermal absorption (EFSA PPR Panel, 2012) and Guidance on the application of the CLP Criteria (ECHA, 2015).

Rimsulfuron was discussed at the Pesticides Peer Review Teleconference 154 in November 2017 and Pesticides Peer Review Teleconference TC 70 in January 2022.

The technical specifications of the Sapec and Helm sources are supported by the toxicological assessment, but not the source by DuPont (current and new), in particular the current specification. Three impurities, phenol, acetonitrile and phenyl *N*-(4,6-dimethoxypyrimidin-2-yl)carbamate, were found to be relevant due to their respective harmonised classification - Annex VI of Regulation (EC) No 1272/2008[4]: Acute Tox 3 (toxic) if swallowed, in contact with skin and if inhaled, skin corrosive 1B, mutagen cat 2 and STOT RE 2 for phenol; Acute Tox 4 (harmful) if swallowed, in contact with skin and if inhaled for acetonitrile; and skin sensitiser for phenyl *N*-(4,6-dimethoxypyrimidin-2-yl)carbamate. Accordingly, the level of phenol in the technical specification should remain ALARA (as low as reasonably achievable), or at least below 1 g/kg. The level of 5 g/kg reported in the technical specification from the DuPont source (either the current or the newly proposed ones) would lead to a change in the classification of the active substance produced by DuPont (ECHA, 2015). Regarding acetonitrile, its specified level does not raise a concern in either the current or the newly proposed technical specification (3 g/kg). For the impurity phenyl *N*-(4,6-dimethoxypyrimidin-2-yl)carbamate, the current specified level (3 g/kg) may require a change in the classification of the a.s. from the DuPont source regarding skin sensitisation, however no concern would be raised according to the newly proposed technical specification at the level of 1 g/kg. Analytical methods used in key toxicity studies have been considered appropriate to validate the toxicological assessment.

Rimsulfuron is extensively absorbed after oral administration and rapidly eliminated mostly with urine and faeces in 72 h. Rimsulfuron is largely excreted as parent material and it is mainly distributed in whole blood, skin, kidneys, lungs and liver. Toxicokinetics parameters (such as Cmax, Tmax, T½, AUC) were not determined according to up-to-date data requirements and this was identified as a data gap. Low acute toxicity was observed when rimsulfuron was administered by the oral, inhalation and dermal routes. However, a data gap was set for the *in vitro* tests for skin sensitisation since the concentration used for induction and challenge in the skin sensitisation study was too low and was already criticised during the previous assessment (EFSA, 2005). Rimsulfuron was considered unlikely to be phototoxic and therefore photomutagenicity testing is not required; no skin and eye irritation were attributed to the active substance.

The main target organs of rimsulfuron in repeated dose studies are kidney, liver and testes. The relevant short-term no adverse effect level (NOAEL) is 1.6 mg/kg body weight (bw) per day from the 1-year study in dogs, based on increased alkaline phosphatase (ALP) in females, increased absolute liver and kidney weight in males, atrophy of seminiferous tubules and spermatid giant cells. The relevant long-term NOAEL is 12 mg/kg bw per day from the 2-year study in rats, based on reduced body weight, body weight gain, decreased food efficiency and increase in relative testes weight and 351 mg/kg bw per day from the 18-month study in mouse, based on reduction in body weight and body weight gain, on increased incidence of cataracts and benign liver tumours, organ weight changes and testicular effects. Overall rimsulfuron did not present genotoxic potential *in vitro* and *in vivo*. However, bone marrow exposure was not demonstrated and therefore a data gap was set for an *in vivo* study to demonstrate the exposure of bone marrow in micronucleus assay. In addition, the test for clastogenicity in mammalian cells, although negative, deviated from guidelines and it was doubtful if the potential to induce chromosomal aberrations was adequately assessed; a data gap was therefore set for the genotoxicity study on clastogenicity in mammalian cells. No evidence of carcinogenicity was observed in rats. The increased incidence in liver adenoma was considered treatment related in mice; however, classification Carc. Cat.2 was not proposed. Reproduction and fertility were not affected by rimsulfuron administration. Increased incidence of partially ossified skull bones was observed, but classification for teratogenic effects was not required.

[4] 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, 1–1,355.

There was no evidence of neurotoxic effects or immunotoxicity induced by rimsulfuron treatment in studies provided.

Regarding endocrine disrupting properties rimsulfuron is not classified or proposed to be classified as carcinogenic or toxic for reproduction category 2, on this basis, the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine disrupting (ED) properties are not met. From a scientific perspective, it was noted that effects on testes were observed in different species, but a consistent picture was missing; in addition, lack of investigations of spermatogenic and oestrous cycles and developmental landmarks were pointed out. Therefore, a data gap was identified since it was not possible to conclude on endocrine disrupting potential of rimsulfuron and both aromatase inhibition and steroidogenesis assays are required. Therefore, this issue could not be finalised and is listed in Section 9.

Three rimsulfuron metabolites, IN-E9260, IN-70941 and IN-70942 were tested in several toxicological studies. Metabolite IN-E9260 was tested for acute oral and dermal toxicity, skin and eye irritation potential, skin sensitisation, 4-week repeated toxicity and a package of genotoxicity studies. The *in vitro* gene mutation assay in bacteria, the chromosomal aberration test in human lymphocytes and the mouse lymphomas assay presented some weaknesses; although aneugenicity was considered not covered in the absence of an *in vitro* MN assay, the endpoints gene mutation and structural chromosome aberration appeared to be covered by the negative *in vivo* Comet assay. Since IN-E9260 can be considered a major rat metabolite,[5] when accounting for the fact that total radioactivity excreted in urine was >10% of the absorbed dose, the same conclusions as the parent should apply as regards genotoxicity and general toxicity (i.e. reference values of the parent rimsulfuron are also applicable to IN-E9260). Considering the data gap for proof of bone marrow exposure in the *in vivo* MN test with the parent and the lack of aneugenicity assessment with the metabolite, EFSA considers appropriate to set a data gap for an *in vitro* MN test for the metabolite. The RMS disagreed. A 10-days subchronic toxicity study and three genotoxicity assays were performed with IN-70941 at the approximate lethal dose and this metabolite was considered unlikely to be genotoxic. In the absence of repeat-dose studies performed with IN-70941 no reference values could be derived (data gap and assessment not finalised considering that predicted groundwater concentrations trigger a consumer risk assessment, see Sections 4 and 6). A battery of *in vitro* genotoxicity studies was provided with IN-70942 and this metabolite was considered unlikely to be genotoxic. Finally, in the absence of repeat-dose studies, reference values could not be derived for IN-70942.

The acceptable daily intake (ADI) of rimsulfuron is 0.1 mg/kg bw per day with no change in the ADI value compared to SANCO/10528/2005-rev.2 (European Commission, 2006), based on decreased body weight and body weight gain, decreased food efficiency and increased in relative testes weight in the rat 2-year study by applying an uncertainty factor (UF) of 100. The acceptable operator exposure level (AOEL) is 0.06 mg/kg bw per day with a slight change in the AOEL value compared to previous assessment (European Commission, 2006), based on body weight gain, clinical chemistry and organ weight changes in the 1-year dog study supported by the 90-day dog study and by applying an UF of 100 with correction factor for oral absorption of 0.62. The acute acceptable operator exposure level (AAOEL), which was not set in the review report assessment (European Commission, 2006) following the previous evaluation, is 1 mg/kg bw based on decreased food consumption and on mortality observed in the developmental study in the rabbit and by applying an UF of 100 (with correction factor for oral absorption of 0.62). The acute reference dose (ARfD), which was not set in the review report assessment (European Commission, 2006) following the previous evaluation, is 1.7 mg/kg bw based on decreased food consumption, and mortality observed in the developmental study in the rabbit and applying an UF of 100.

Estimated operator exposure did not exceed the AOEL/AAOEL even when the use of personal protective equipment (PPE) was not considered according to the UK POEM, the German model or the EFSA calculator. Estimated worker, bystanders and residents' exposure did remain below the AOEL even when specific PPE was not considered for workers. Bystander and resident's exposure did remain below the AOEL, representing up to *ca*. 8% of the AOEL in the case of residents children (all pathways).

[5] Please refer to the Pesticide Peer Review Teleconference TC 70 (discussion point 2.1) (EFSA 2022).

3. Residues

The assessment in the residue section is based on the OECD guidance document on overview of residue chemistry studies (OECD, 2009), the OECD publication on maximum residue level (MRL) calculations (OECD, 2011), the European Commission guideline document on MRL setting (European Commission, 2017) and the Joint Meeting on Pesticide Residues (JMPR) recommendations on livestock burden calculations (JMPR, 2004, 2007).

The metabolism in primary crops was investigated upon foliar spray application on fruits (tomato), cereals (maize) and tuber (potato) using [pyridine-2-^{14}C]rimsulfuron and [pyrimidine-2-^{14}C]rimsulfuron. Although applied at exaggerated application rates of 2.6 N for tomato and maize and 3.1 N for potato, the total radioactive residues in the grain (both mature and immature), silage and fodder, potato and tomato were < 0.02 mg/kg. Metabolism was therefore studied in foliage of potato and tomato and in maize (whole plant) where detectable radioactivity occurred. In all three matrices, the parent compound is the major residue (22% total radioactive residue (TRR) in maize foliage at preharvest interval (PHI) 15, 22.1% TRR in potato foliage at PHI 14 and 78% TRR in tomato foliage at PHI 0). In potato foliage, the metabolites IN-70941, IN-70942, IN-J0290 and IN-E9260 were observed in the pyrimidine- and pyridine-labelled studies at levels of 4.4–14.6%TRR at PHI 14 after second treatment. In tomato foliage, the metabolites IN-70941 and IN-JF999 were detected at levels below and slightly above 10% TRR, respectively, and their respective glucose conjugates CM2 and CM4, in concentrations up to 42% TRR and 25%, respectively. In immature maize plant, the metabolites IN-70941 occurred at levels above 10% TRR and the metabolite IN-70942 and IN-E9260 below 10% TRR, whereas IN-J0290 was no longer detected at PHI 15. The metabolism studies were in general performed according to critical GAP parameters. Exceptions were the application times in the maize and potato studies which were slightly earlier as in the critical GAPs from both applicants. However, these deviations are not expected to change the overall metabolic pattern; hence, the metabolism studies are considered reliable to set a residue definition.

Metabolism was investigated in lettuce, wheat, sorghum, sugar beets, soybean and sunflower in a non-good laboratory practice (GLP) and non-guideline compliant rotational crop study applying 52 g a.s./ha (2N rate for tomato) [pyridine-2-^{14}C]rimsulfuron and [pyrimidine-2-^{14}C]rimsulfuron. Radioactivity above 0.05 mg eq/kg was detected in wheat and soybean straw (up to 0.46 mg eq/kg) and immature sugar beet, soybean and wheat plants (up to 0.12 mg eq/kg). Identification was limited to IN-70941 and is not sufficient to elucidate the metabolism in plants given also the low concentration of the relevant soil metabolites IN-70941, IN-70942, IN-E9260 and IN-J0290 in the aged soil. A new study addressing the metabolism and/or nature in rotational crops is therefore needed (data gap).

The residue definition for primary crops both for risk assessment and monitoring is set as rimsulfuron.

A sufficient number of valid field trials with maize and potato supported by storage stability data were provided by both applicants indicating residues below the LOQ of 0.01 mg/kg in edible and feed commodities. Critical GAP compliant residue trials for tomato with analysis of the rimsulfuron residues in a short time interval where acceptable storage stability is demonstrated were provided by neither of the applicants. Storage stability data for tomatoes indicate a decline of rimsulfuron from day 3 onwards and do not cover therefore the field trial data (data gap for both applicants for tomato).

Although a livestock dietary burden calculation using the limit of quantification (LOQ) values from the field trials as input values resulted in the request for animal metabolism studies, in practice, residues in animal tissues from the proposed use of primary crops are not expected as shown from the metabolism studies in plants. However, data on nature and/or magnitude of residues in rotational crops are outstanding and could result in the need for animal studies. Metabolism studies in lactating goat and poultry with [pyridine-2-^{14}C]rimsulfuron and [pyrimidine-2-^{14}C]rimsulfuron were presented. The two studies are not OECD guideline compliant as the duration of the feeding is too short, information on storage periods of the samples is not reported and LOQs in various goat matrices were high (0.05–0.14 mg/kg) not allowing for identification/characterisation. A plateau could neither be established for milk nor for egg. Un-metabolised rimsulfuron (0.03 mg eq/kg) and IN-70941 (0.01 mg eq/kg) were found in poultry liver. Further metabolism was only investigated in excreta. No compounds were identified in liver and kidney of goat despite the high relatively high total radioactivity of 0.140 mg eq/kg and 0.128 mg eq/kg, respectively.

A residue definition for animals is not needed for the current proposed uses, not derived. However, pending the outcome of the investigation of the metabolism in rotational crops residue definition for animals and animal feeding studies might be needed.

Information on residue levels in pollen and in bee products for human consumption was not submitted (data gap).

An indicative consumer risk assessment was conducted with the residue levels from potato and maize only. The chronic exposure (theoretical maximum daily intake (TMDI)) was around 0.1% of the ADI of rimsulfuron (NL, child) and acute exposure was at maximum 0.1% ARfD of rimsulfuron for the same population from consume of potato. This assessment does not take into account information on nature and/or magnitude levels from rotational crops and the residue levels in tomato.

The parametric drinking water limit of 0.1 μg/L was exceeded for metabolite IN- E9260 in some scenarios (see Section 4). IN-E9260 was observed in primary crop metabolism studies in the leafy crop parts while residues in the crop parts relevant for human diet (potato tubers, tomato fruit, maize grain) were very low and not identified. Since IN-E9260 is also a soil metabolite and a crop rotation study is still pending a final conclusion on whether dietary exposure to IN-E9260 is possible, can only be made once the outstanding crop rotation study becomes available. Hence, also the estimate of exposure to this metabolite from occurrence in food and drinking water could not be finalised.

4. Environmental fate and behaviour

Rimsulfuron was discussed at the Pesticides Peer Review Teleconference 155 on 16 November 2017 and at the Pesticides Peer Review Teleconference 71 in January 2022.

The rates of dissipation and degradation in the environmental matrices investigated were estimated using FOCUS (2006) kinetics guidance. Aerobic degradation laboratory studies in nine soils with ^{14}C-rimsulfuron are available. In these experiments, rimsulfuron exhibited low to moderate persistence, forming the major (>10% applied radioactivity (AR)) metabolites IN-70941(max. 53.7% AR), IN-70942 (max. 65.4% AR) and IN-E9260 (max. 18.9% AR) which exhibited moderate to very high, medium to very high and high to very high persistence, respectively. In the case of metabolite IN-70941, a degradation in soil pH dependence (with longer persistence at soil pH < 6) was identified and taken into account for the exposure assessment. Also metabolite IN-J0290, common to other sulfonylureas, has been considered for the risk assessment (observed in degradation in soil under anaerobic conditions and in photolysis experiments). Consolidated data on metabolite IN-J0290 indicated that this metabolite exhibited low to high persistence in soil. Mineralisation of the active substance to CO_2 was limited (0.79% AR pyridine label experiments and 3.63% AR pyrimidine label experiments after 90 days). The formation of unextractable residues accounted for 21.3% AR (pyridine label) and 22.1% AR (pyrimidine label) both at 90 days. In anaerobic soil incubations, rimsulfuron exhibited low to moderate persistence. In the available irradiated laboratory experiments, photolysis does not significantly increase the rate of the degradation in soil.

In the field studies conducted in Europe (F, IT, DE [2 sites], DK, ES, BG), where rimsulfuron was the applied test substance, single first-order DT_{90} values for metabolites IN-70941, IN-70942, IN-E9260 and IN-J0290 were up to 2,130 days, 1,400 days, 848 days and 245 dsys, respectively. These data indicate that in the field, the metabolites IN-70941, IN-70942 and IN-E9620 have the potential to accumulate in soil. Reliable normalised field DegT50 values in line with EFSA (2014) guidance were available from these sites for the active substance and four of these sites (F, IT, DE, BG) for the metabolites. In line with EFSA (2014) guidance, geomean field DegT50 values were used as FOCUS modelling input for rimsulfuron, IN-70942 and IN-E9260. For IN-70941 and IN-J0290, field endpoints were put together with laboratory data for this exposure modelling (geomean value of the whole data set for IN-J0290 and geomean values based on pH grouping for IN-70941).

Rimsulfuron is expected to exhibit high to very high mobility in soil. The Metabolite IN-70941 is expected to exhibit high to very high mobility, the metabolite IN-70942 is expected to exhibit medium to high soil mobility and the metabolite IN-E9260 is expected to exhibit high to very high mobility in soil. The Metabolite IN-J0290, common to other sulfonylurea herbicides, is expected to have high to low mobility in soil. Adsorption to soil was considered to be independent of soil pH and/or other soil properties for all compounds considered.

Column leaching studies showed a high leaching potential of rimsulfuron with 47–93% AR in the leachate (mainly rimsulfuron and metabolites IN-70941 and IN-70942). Aged residue column leaching studies showed a reduction of the leaching of rimsulfuron and the metabolites with amounts between 23 and 36% AR. Lysimeter studies were not conducted.

Rimsulfuron hydrolyses relatively rapidly in water. Contraction of the sulfonylurea bridge leads to the formation of the major (> 10% AR) hydrolysis products IN-70941 and IN-70942. Cleavage of the sulfonylurea bridge to form IN-E9260 and IN-J0290 was a less important process during hydrolysis. IN-70941 hydrolysed readily in water. Metabolites IN-70942 and IN-E9260 were stable to hydrolysis. Photolysis does not contribute significantly to de degradation of rimsulfuron in water. The results of an OECD 301B ready biodegradability test indicated rimsulfuron should be classified as 'not readily biodegradable' (OECD, 1992).

In laboratory incubations in dark aerobic natural sediment water systems, rimsulfuron exhibited low or very low persistence, forming the metabolites IN-70941 (max. ca. 85.7% AR in the whole system, exhibiting moderate persistence), IN-70942 (max. ca. 79.1% AR in the whole system, exhibiting high persistence), IN-E9260 (max. ca. 5.1% AR in the whole system, exhibiting medium persistence), IN-JF999 (max. ca. 24.6% AR in the whole system, exhibiting moderate and medium persistence), IN-J0290 (max. ca. 2% AR in the whole system, exhibiting high persistence). The unextractable sediment fraction accounted for 9.5–42.3% AR at study end (99–100 days). Mineralisation was insignificant in both systems.

Surface water and sediment exposure assessments (predicted environmental concentrations (PEC) calculations) were carried out for the metabolites IN-70941, IN-70942, IN-E9260 and IN-J0290, IN-JF999 and IN-S9H84 using the FOCUS (FOCUS, 2001) step 1 and step 2 (only for IN-70942) approach (version 2.1 of the Steps 1–2 in FOCUS calculator). For the active substance rimsulfuron, step 3 (FOCUS, 2001) and step 4 calculations are available. The step 4 calculations followed the FOCUS (FOCUS, 2007) guidance, with no-spray drift buffer zones of up to 10 m (maize, tomatoes) or 20 m (potatoes) being implemented for the drainage scenarios, and combined no-spray buffer zones with vegetative buffer strips of up to 10 m (maize, tomatoes) or 20 m (potatoes) being implemented for the run-off scenarios. However, risk managers and others may wish to note that whilst run-off mitigation is included in the step 4 calculations available, the FOCUS (FOCUS, 2007) report acknowledges that for substances with KFoc < 2000 mL/g (i.e. rimsulfuron), the general applicability and effectiveness of run-off mitigation measures had been less clearly demonstrated in the available scientific literature, than for more strongly adsorbed compounds.

The groundwater exposure assessments were carried out using FOCUS scenarios European Commission (2014b) guidance and the models PEARL 4.4.4 and PELMO 5.5.3 for the active substance rimsulfuron and metabolites IN-70941, IN-70942, IN-E9260 and IN-J0290. In these simulations, the potential for groundwater exposure from the representative uses by rimsulfuron and metabolite IN-J0290 above the parametric drinking water limit of 0.1 μg/L was concluded to be low in geoclimatic situations that are represented by all relevant FOCUS groundwater scenarios for uses in maize, potato and tomato. For the metabolites IN-70941 and IN-70942, separated simulations to consider situations in acidic or alkaline soils were performed, to take into account the pH dependence on the degradation of metabolite IN-70941 in soil. In these simulations, the parametric drinking water limit of 0.1 μg/L was exceeded by metabolite IN-70941 in all the scenarios for all uses (in maize, potato and tomato) in acidic conditions and the majority of the scenarios under alkaline conditions for all uses. The situation for metabolite IN-70942 was that 1/8 scenarios for the use in maize, 2/9 scenarios for the use on potato and 2/5 scenarios for the use on tomato in acidic conditions and none of the scenarios in alkaline soil were above the parametric limit. In relation to metabolite IN-E9260, the parametric drinking water limit of 0.1 μg/L was exceeded for the use in maize at just the Hamburg scenario, use in potato at the Chateaudun, Jokioinen and Hamburg scenarios and use on tomato at just the Chateaudun scenario. For these three crops, this was only the case when simulations included applications being made every year.

The applicants did not provide appropriate information to address the effect of water treatment processes on the nature of the residues that might be present in surface water and groundwater, when surface water or groundwater are abstracted for drinking water. This has led to the identification of a data gap (see Section 7) and results in the consumer risk assessment not being finalised (see Section 9).

The available PEC in soil, surface water, sediment and groundwater covering the representative uses assessed can be found in Appendix A of this conclusion.

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a, 2002b), SETAC (2001), EFSA (2009), EFSA PPR Panel (2013) and EFSA (2013).

The technical specifications of the Sapec and the Helm sources are supported by the ecotoxicological assessment, but not the source by DuPont (current and new), in particular the current specification. It should be noted that the levels of phenol in the five representative batches of DuPont were above 1 g/kg.

The long-term endpoints for mammals, the available studies on aquatic plants and the probabilistic risk assessment for non-target terrestrial plants were discussed at the Pesticides Peer Review Teleconference 156.

For many studies included in the original draft assessment report, only short summaries were available not allowing for a proper re-evaluation (data gap). The EC10/EC20 values for the relevant studies according to the Regulation (EU) No 283/2013 were not provided; therefore, a data gap was identified.

Based on the available data, a low risk to birds and mammals was identified for all the assessed relevant routes of exposure and for all the representative uses. The risk to birds and mammals form plant metabolites was not performed (data gap).

Studies were available on all the standard aquatic organisms with the active substance, the formulations (except for aquatic plants and the formulation of DuPont) and the majority of the pertinent metabolites. For the active substance, a valid study with a second algal species was, however, not available (data gap). In the absence of data, a screening assessment was conducted, considering the metabolite being ten times more toxic than the parent.

A low risk was identified for fish, aquatic invertebrates and algae by using FOCUS Step 1 PECsw. For aquatic plants, a low risk was identified for the representative uses on maize by implementing risk mitigation measures comparable to a 10-m no-spray buffer zone and a 10-m vegetative buffer strip. A high risk was identified for the representative uses on potatoes (one of six FOCUS scenarios) and tomatoes (one of four FOCUS scenarios) by using Step 3&4 PECsw with the implementation of risk mitigation measures up to a 20-m no-spray buffer zone and a 20-m vegetative buffer strip (data gap). Low risk was also concluded for all the pertinent metabolites by using PECsw Step 1&2. No data were available on sediment-dwelling organisms for the metabolite IN-JF999 (data gap).

The risk assessment for bees was partially conducted according to EFSA (2013). A low risk was concluded for honeybees for all the assessed routes of exposure. For larvae, only a single-dose study was available. However, considering that a low risk was identified at the screening step, further data are not deemed necessary. The acute risk was also low for bumblebees. No risk assessment was provided for the potential metabolites occurring in pollen and nectar (data gap), for exposure via surface water, guttation water and puddle water (data gap) and no data were available on cumulative effects. No data were available on other species of wild bees.

Tier I and II data were available on standard and additional species of non-target arthropods. Based on the available data, low risk is concluded for all the representative uses of Rimsulfuron 25 WG (DuPont). Based on the effects on reproduction observed (> 50%) in one of the standard species, high risk is identified for all the representative uses of Rimsulfuron 25 WG (TaskForce) for non-target arthropods (data gap).

A low risk was concluded for earthworms, soil macro-organisms other than earthworms and soil microorganism both for rimsulfuron and the pertinent metabolites.

A low risk for non-target terrestrial plant was identified by implementing risk mitigation measures up to 5 m buffer strip and 90% drift reduction for all the representative uses.

Low risk was concluded for biological methods of sewage treatment.

With regard to the potential of endocrine disrupting properties of rimsulfuron, pending on the outcome of the data gap identified in Section 2, further data might be needed for non-target organisms, in particular for fish.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (Tables 1–4)

Table 1: Soil

Compound (name and/or code)	Persistence	Ecotoxicology
rimsulfuron	low to moderate (DT_{50} = 3.2 d – 26 d)	Low risk
IN-70941	moderate to very high (DT_{50} = 34.3 d – 552.5 d)	Low risk
IN-70942	medium to very high (DT_{50} = 87.9 d – 383.2 d)	Low risk
IN-E9260	high to very high (DT_{50} = 246.7–2162.2 d	Low risk
IN-J0290[(a)]	low to high (DT_{50} = 2.5 d – 174.6 d)	Low risk

(a): (observed under anaerobic conditions and irradiated experiments).

Table 2: Groundwater

Compound (name and/or code)	Mobility in soil	> 0.1 µg/L at 1 m depth for the representative uses[(a)]	Pesticidal activity	Toxicological relevance
rimsulfuron	high to very high	FOCUS GW: no	Yes	Yes
IN-70941	high to very high	FOCUS GW: yes, all 9 scenarios under acidic conditions with concentrations up to 5.49 µg/L, up to 7/9 scenarios under alkaline soil conditions with concentrations up to 0.316 µg/L	No	Open Unlikely to be genotoxic; low acute oral toxicity (rat) Groundwater concentrations trigger the need to carry out a consumer risk assessment, the available data were insufficient to derive reference values, so this assessment could not be completed.
IN-70942	medium to high	FOCUS GW: yes, up to 2/5, 2/9 scenario under acidic soil conditions with concentrations up to up to 0.145 µg/L, No under alkaline soil conditions	No	No Unlikely to be genotoxic
IN-E9260	high to very high	FOCUS GW: yes Maize 1/8 scenarios annual applications 0.146 µg/L Potato 3/9 scenarios annual applications up to 0.127 µg/L Tomato 1/5 scenarios annual applications 0.111 µg/L	No	Open Based on the weight of evidence, unlikely to be genotoxic. Reference values of rimsulfuron apply. However, the consumer intakes from combined water and food residues could not be estimated whilst the information on the potential for residues of IN-E9260 in following crops was insufficient.

Compound (name and/or code)	Mobility in soil	> 0.1 µg/L at 1 m depth for the representative uses[a]	Pesticidal activity	Toxicological relevance
IN-J0290	high to low	FOCUS GW: No	No	Open No data presented in this dossier, insufficient data available from other sulfonylureas active substances: negative Ames test and rat acute oral LD_{50} 737–2000 mg/kg bw

(a): FOCUS scenarios or relevant lysimeter.

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Rimsulfuron (surface water and sediment)	High risk to aquatic organisms (1 out of 6 FOCUS scenarios for potato and 1 out of 4 FOCUS scenario for the use in tomato). Low risk to aquatic organisms for the use in maize
IN-70941 (surface water and sediment)	Low risk to aquatic organisms
IN-70942 (surface water and sediment)	Low risk to aquatic organisms
IN-E9260 (surface water)	Low risk to aquatic organisms
IN-S9H84 (surface water)	Low risk to aquatic organisms
IN-JF999 (sediment)	Data gap
IN-J0290 (surface water)	Low risk to aquatic organisms

Table 4: Air

Compound (name and/or code)	Toxicology
Rimsulfuron	Rat inhalation LC_{50} > 5.4 mg/L (4-h exposure, nose only), no classification required

7. Data gaps

This is a list of data gaps identified during the peer review process, including those areas in which 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 56 of Regulation (EC) No 1107/2009 concerning information on potentially harmful effects).

7.1. Data gaps identified for the representative uses evaluated

- A search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites, dealing with side effects on health, the environment and non-target species and published within the 10 years before the date of submission of the dossier, to be conducted and reported in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011; relevant for all representative uses evaluated; relevant for Sections 2, 4 and 5).
- Spectra for identification of the relevant impurities (relevant for all representative uses evaluated; see Section 1).
- Content of relevant impurities in the plant protection products, before and after storage (relevant for all representative uses evaluated; see Section 1).
- A method for determination of the relevant impurities in the representative formulations. (relevant for all representative uses evaluated; see Section 1).
- Methods for monitoring of rimsulfuron residue in: plant commodities with high acid and high oil content, soil, air and body fluids and tissues (relevant for all representative uses evaluated for Task Force formulation; see Section 1).
- Toxicokinetic parameters such as Cmax, Tmax, T½, AUC (relevant for all representative uses evaluated; see Section 2).
- *In vitro* tests for skin sensitisation (relevant for all representative uses evaluated; see Section 2).
- Aromatase inhibition and steroidogenesis assays to assess the endocrine-disrupting potential (relevant for all representative uses evaluated; see Section 2).
- *In vivo* study to demonstrate the exposure of bone marrow in micronucleus assay (relevant for all representative uses evaluated; see Section 2).
- Genotoxicity study on clastogenicity in mammalian cells (relevant for all representative uses evaluated; see Section 2).
- *In vitro* micronucleus test for the metabolite IN-E9260 (relevant for all representative uses evaluated; see Section 2).
- Mammalian toxicity data to set reference values for groundwater metabolite IN-70941 (relevant for all representative uses evaluated; see Sections 2, 4 and 6)
- Data on the nature and/or magnitude of residues of rimsulfuron and its four relevant soil metabolites in rotational crops (relevant for all representative uses; see Section 3).
- Critical GAP compliant residue trials for tomato for both applicants (relevant for the representative use on tomato; see Section 3)
- Determination of the residues in pollen and bee products from human consumption resulting from residues taken up by honeybees from crops at blossom (relevant for all representative uses; see Section 3)
- Applicants to provide appropriate information to address the effect of water treatment processes on the nature of the residues that might be present in surface water and groundwater, when surface water or groundwater are abstracted for drinking water (relevant for all representative uses evaluated; see Section 4).
- Extended summaries of the studies included in the RAR were not always available (relevant for all the representative uses; see Section 5).
- The EC10/EC20 values for the relevant studies according to the Regulation (EU) No 283/2013 were not always provided (relevant for all the representative uses; see Section 5).
- The risk to birds and mammals through exposure to metabolites occurring in plants was not performed (relevant for all the representative uses; see Section 5).
- A study with a second species of algae was not available (relevant for all the representative uses; see Section 5).

- Further data on the toxicity of the metabolite IN-JF999 on sediment-dwelling organisms (relevant for all the representative uses; see Section 5).
- Further data to refine the risk to aquatic plants in situation represented by the FOCUS scenarios D6 (relevant for the all the representative uses on potato; see Section 5).
- Further data to refine the risk to aquatic plants in situation represented by the FOCUS scenarios D6 (relevant for the representative use on tomato at 15 + 12.5 or 12.5 + 7.5 + 7.5 g a.s./ha and 15 g a.s./ha; see Section 5).
- The risk assessment for bees was not assessed when considering the exposure to contaminated water (surface water, guttation and puddle water) and exposure to metabolites occurring in pollen and nectar (relevant for all the representative uses; see Section 5).
- Further data to refine the risk to non-target arthropods (relevant for the representative uses of Rimsulfuron 25 WG + HAG 530 01 S, TaskForce; see Section 5).

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

- Risk mitigation measures up to 10 m no-spray buffer zone and 10 m vegetative buffer strip are needed to address the risk for aquatic organisms for all the representative uses on maize and tomato (see Section 5).
- Risk mitigation measures up to 20 m no-spray buffer zone and vegetative buffer strip are needed for addressing the risk for aquatic organisms for the representative uses on potato (see Section 5).
- Risk mitigation measures up to 5-m buffer strip and 90% drift reduction are needed to address the risk to non-target terrestrial plants for all the representative uses.

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as 'could not be finalised' if 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 in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011[6] and if the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

An issue is also listed as 'could not be finalised' if the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

1) Endocrine-disrupting potential cannot be considered finalised since effects on testes were observed in different species, but a consistent picture was missing; in addition, the lack of investigations of spermatogenic and oestrus cycles and developmental landmarks were pointed out (see Section 2).
2) Concentrations predicted in groundwater for metabolite IN-70941 are at levels that trigger the need for a consumer risk assessment. The available mammalian toxicity data are insufficient to set reference values. Residues of IN-E9260 in following crops are not known, so combined consumer intakes from water and food are not available. Consequently, the groundwater metabolite relevance assessments for IN-70941 and IN-E9260 could not be completed (see Sections 2, 4 and 6).
3) The applicants did not provide appropriate information to address the effect of water treatment processes on the nature of the residues that might be present in surface water and groundwater, when surface water or groundwater are abstracted for drinking water. This resulted in the consumer risk assessment being not finalised (see Section 4).

[6] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, pp. 127–175.

9.2. Critical areas of concern

An issue is listed as a critical area of concern if there is enough information available to perform an assessment for the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and if this assessment does not permit the conclusion 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 if the assessment at a higher tier level could not be finalised due to lack of information, and if the assessment performed at the lower tier level does not permit the conclusion 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 if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

Critical areas of concern were not identified.

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 Table 5.)

Table 5: Overview of concerns

Representative use		Maize	Potato	Tomato
Operator risk	Risk identified			
	Assessment not finalised			
Worker risk	Risk identified			
	Assessment not finalised			
Resident/bystander risk	Risk identified			
	Assessment not finalised			
Consumer risk	Risk identified			
	Assessment not finalised	X[2,3]	X[2,3]	X[2,3]
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 (For all the uses of Rimsulfuron 25 WG, TaskForce)	X For all the uses of Rimsulfuron 25 WG, TaskForce)	X For all the uses of Rimsulfuron 25 WG, TaskForce)
	Assessment not finalised			
Risk to aquatic organisms	Risk identified		1 of 6 FOCUS scenarios	1 of 4 FOCUS scenarios
	Assessment not finalised			
Groundwater exposure to active substance	Legal parametric value breached			
	Assessment not finalised			

Representative use		Maize	Potato	Tomato
Groundwater exposure to metabolites	Legal parametric value breached[(a)]			
	Parametric value of 10 μg/L[(b)] breached			
	Assessment not finalised	X[2]	X[2]	X[2]

The superscript numbers relate to the numbered points indicated in Sections 9.1 and 9.2. Where there is no superscript number, see Section 5 for further information.

(a): When the consideration for classification made in the context of this evaluation under Regulation (EC) No 1107/2009 is confirmed under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008.

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

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Abbreviations

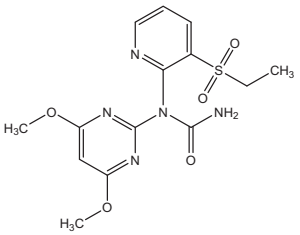
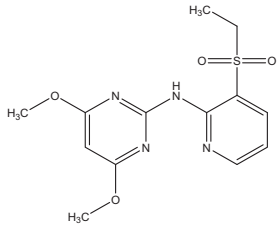
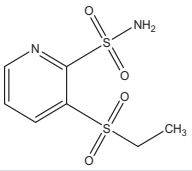
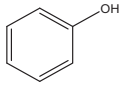
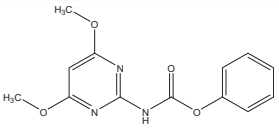
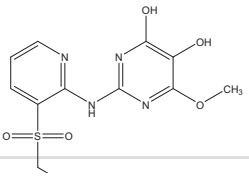
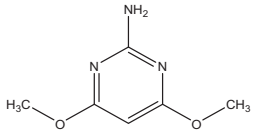
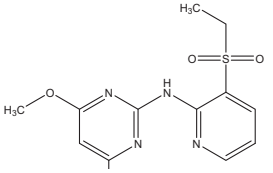
1/*n*	slope of Freundlich isotherm
3 T3	standard fibroblast cell line (3-day transfer, inoculum $3x10^5$ cells)
λ	Wavelength
ε	decadic molar extinction coefficient
a.s.	active substance
AAOEL	acute acceptable operator exposure level
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
ALT	alanine aminotransferase (SGPT)
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose

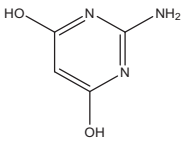
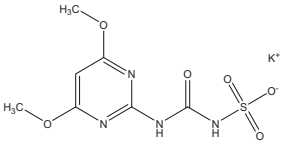
AST	aspartate aminotransferase (SGOT)
AUC	area under the blood concentration/time curve
AV	avoidance factor
bw	body weight
Cmax	concentration achieved at peak blood level
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
ECHA	European Chemicals Agency
F_2	filial generation, second
FAO	Food and Agriculture Organization of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
HPLC	high-pressure liquid chromatography or high-performance liquid chromatography
HPLC-MS	high-pressure liquid chromatography–mass spectrometry
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
iv	Intravenous
JMPR	Joint Meeting of 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
K_{Foc}	Freundlich organic carbon adsorption coefficient
LC	liquid chromatography
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LOQ	limit of quantification
mm	millimetre (also used for mean measured concentrations)
mN	milli-newton
MRL	maximum residue level
MS	mass spectrometry
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
Pa	Pascal
PEC_{sw}	predicted environmental concentration in surface water
PHI	preharvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
POEM	(UK) Predictive Operator Exposure Model
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
r^2	coefficient of determination
RAR	Renewal Assessment Report
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SMILES	simplified molecular-input line-entry system
$t_{1/2}$	half-life (define method of estimation)
Tmax	time until peak blood levels achieved
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UF	uncertainty factor
WG	water-dispersible granule
WHO	World Health Organization

Appendix A – List of end points for the active substance and the representative formulation

Appendix A can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2022.7447

Appendix B – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[b]
IN-70941	1-(4,6-dimethoxypyrimidin-2-yl)-1-(3-(ethylsulfonyl) pyridin-2-yl)urea O=C(N)N(C1=NC(OC)=CC(OC)=N1)C2=NC=CC=C2S (=O)(CC)=O YKUAHBLGZCTWPS-UHFFFAOYSA-N	
IN-70942	*N*-(3-(ethylsulfonyl)pyridin-2-yl)-4,6-dimethoxypyrimidin-2-amine COC1=CC(OC)=NC(NC2=NC=CC=C2S(=O)(CC)=O) =N1 AFOZBVKCZXHDER-UHFFFAOYSA-N	
IN-E9260	3-(ethylsulfonyl)pyridine-2-sulfonamide O=S(C1=NC=CC=C1S(=O)(CC)=O)(N)=O ZVAJJLYQUHJURI-UHFFFAOYSA-N	
phenol	Phenol OC1=CC=CC=C1 ISWSIDIOOBJBQZ-UHFFFAOYSA-N	
acetonitrile	Acetonitrile CC#N WEVYAHXRMPXWCK-UHFFFAOYSA-N	
phenyl N-(4,6-dimethoxypyrimidin-2-yl)carbamate	phenyl (4,6-dimethoxypyrimidin-2-yl)carbamate O=C(OC1=CC=CC=C1)NC2=NC(OC)=CC(OC)=N2 MESPVSMSORHLAX-UHFFFAOYSA-N	
P4	2-((3-(ethylsulfonyl)pyridin-2-yl)amino)-6-methoxypyrimidine-4,5-diol OC1=C(O)C(OC)=NC(NC2=NC=CC=C2S(=O)(CC) =O)=N1 CRFWKSHZEJPSOJ-UHFFFAOYSA-N	
IN-J0290 IN-J290	4,6-dimethoxypyrimidin-2-amine NC1=NC(OC)=CC(OC)=N1 LVFRCHIUUKWBLR-UHFFFAOYSA-N	
IN-JF999	2-((3-(ethylsulfonyl)pyridin-2-yl)amino)-6-methoxypyrimidin-4-ol OC1=CC(OC)=NC(NC2=NC=CC=C2S(=O)(CC)=O) =N1 ALBJPZLTGKBZLV-UHFFFAOYSA-N	

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[b]
IN-H1043	2-aminopyrimidine-4,6-diol OC1=CC(O)=NC(N)=N1 AUFJTVGCSJNQIF-UHFFFAOYSA-N	
IN-S9H84	potassium ((4,6-dimethoxypyrimidin-2-yl)carbamoyl)sulfamate O=S([O-])(NC(NC1=NC(OC)=CC(OC)=N1)=O)=O.[K+] SFYYMXORDCOKRR-UHFFFAOYSA-M	

(a): The compound name in bold is the name used in the conclusion.
(b): Names, SMILE codes and InChI Keys are generated by ChemBioDraw ver. 13.0.2.3021.