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 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. 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 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 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 to DuPont, 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.

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 data gap was identified for a search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites.

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 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. In addition, there were some issues not finalised regarding genotoxicity and endocrine-disrupting potential.

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.

With respect to fate and behaviour into the environment, a data gap is identified to address the groundwater leaching potential using a second FOCUS GW model (e.g PELMO) for all representative uses. The applicants did not provide appropriate information to address the effect of water treatments 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 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 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 to DuPont, 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.

During the course of the peer-review, the RMS revised the Good Agricultural Practice (GAP) tables for DuPont and TFR to ensure consistency in presenting the representative uses provided by the RMS in the original RAR and in D1 documents provided by the applicants.

[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, p. 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, p. 1–50.

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. 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), 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);
- 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 RAR, including its revisions (Slovenia, 2018), 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 European Union (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 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 five 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 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 a 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 a 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. An appropriate HPLC–MS/MS method exists for monitoring of rimsulfuron residue in air with a LOQ of 3.0 μg/m^3.

The 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.

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[3]: 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 active substance 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

[3] 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.

in whole blood, skin, kidneys, lungs and liver. Toxicokinetics parameters (such as C_{max}, T_{max}, $T_{½}$, 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 observed 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 a micronucleus assay. In addition, the test for clastogenicity in mammalian cells 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 and this issue could not be finalised. 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.

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

Regarding endocrine-disrupting (ED) 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 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 ED potential of rimsulfuron and both aromatase inhibition and steroidogenesis assays are required. Therefore, this issue could not be finalised and is listed in chapter 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 four *in vitro* genotoxicity studies. Since the *in vitro* gene mutation assay in bacteria, the chromosomal aberration test in human lymphocytes and the mouse lymphomas assay presented some weaknesses, it was not possible to conclude on genotoxic potential of IN-E9260 and a data gap was identified for an *in vitro* micronucleus test. No conclusion of the relevance could be provided and, considering that no NOAEL could be set in the 4-week study, no reference values were derived. A 10-day subchronic toxicity study and three genotoxicity assays were performed with IN-70941 at the approximate lethal dose and this metabolite was not considered genotoxic. In the absence of repeat-dose studies performed with IN-90941, no reference values could be derived. A battery of *in vitro* genotoxicity studies was provided with IN-70942 and this metabolite was not considered genotoxic. Finally, in the absence of repeat-dose studies, no reference values could 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).

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 (TRRs) 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% 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 sugarbeet, 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 requested (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 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. Unmetabolised 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 requested.

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.

A risk assessment for the ground water metabolite IN-E9260 which occurs at concentration above 0.75 μg/L is also pending toxicological information. Hence, also the estimate of exposure to this metabolite from occurrence in drinking water cannot be finalised (see Section 4).

4. Environmental fate and behaviour

Rimsulfuron was discussed at the Pesticides Peer Review Teleconference 155 in 16 November 2017.

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 (FR, 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 and IN-E9260 were up to 2,130, 1,400 and 843 days. These data indicate that in the field, the metabolites IN-70941, IN-70942 and IN-E9620 have the potential to accumulate in soil. Normalised field half-life values for the metabolites were only calculated for two of the available sites. These two values were used together with laboratory data for exposure modelling.

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 sulfunylurea herbicides, is expected to be high to low mobile in soil. Adsorption to soil was considered to be independent of soil pH and/or other soils 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 lees 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 (9–100 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 (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 (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 while run-off mitigation is included in the step 4 calculations available, the FOCUS (2007) report acknowledges that for substances with K_{Foc} < 2,000 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 (2009) scenarios and the model PEARL 4.4.4 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 one scenario in acidic conditions (for one of the uses in maize and tomato and two uses in potato) and by metabolite IN-70942 in the majority of the scenarios for all uses (in maize potato and tomato) in acidic conditions and in some of the scenarios in alkaline soil. In relation to metabolite IN-E9260, the parametric drinking water limit of 0.1 μg/L was exceeded for all scenarios an uses simulated (in many instances at levels > 0.75 μg/L. Nevertheless, the groundwater exposure assessment cannot be considered finalised because simulations need to be performed with at least two different FOCUS GW models to account for the uncertainty associated to the different modelling approaches. Therefore, a data gap is identified to address the groundwater leaching potential using a second FOCUS GW model (e.g. PELMO) for all representative uses.

The applicants did not provide appropriate information to address the effect of water treatments 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,b), 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 EC_{10}/EC_{20} 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 PEC_{sw}. 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 (1 out of 6 FOCUS scenarios) and tomatoes (1 out of 4 FOCUS scenarios) by using Step 3&4 PEC_{sw} 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 PEC_{sw} 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 macroorganisms 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-disruptive 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} = 3.2–26 days)	Low risk
IN-70941	Moderate to very high (DT_{50} = 34.3–552.5 days)	Low risk
IN-70942	Medium to very high (DT_{50} = 87.9–383.2 days)	Low risk
IN-E9260	High to very high (DT_{50} = 246.7–2162.2 days)	Low risk
IN-J0290[(a)]	Low to high (DT_{50} = 2.5–174.6 days)	Low risk

DT_{50}: period required for 50% dissipation; DT_{90}: period required for 90% dissipation.
(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, up to 1/8 scenario under acidic conditions	No	No Unlikely to be genotoxic; low acute oral toxicity (rat)
IN-70942	Medium to high	FOCUS GW: yes, up to 7/8, 7/9 scenario under acidic soil conditions, up to 3/7 scenarios under alkaline soil conditions	No	No Unlikely to be genotoxic
IN-E9260	High to very high	FOCUS GW: yes, all simulated scenarios for the representative uses considered. Some scenarios > 0.75 µg/L	No	Yes Positive gene mutation assay in mammalian cells *in vitro* was not sufficiently addressed to conclude on the genotoxic potential *in vivo*; low acute oral and dermal toxicity; oral 4-week study in rat LOAEL 50 mg/kg bw per day
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} 737–2,000 mg/kg bw

FOCUS: Forum for the Co-ordination of Pesticide Fate Models and their Use; GW: ground water; LOAEL: lowest observable adverse effect level; bw: body weight.
(a): FOCUS scenarios or a 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

LC_{50}: lethal concentration, median.

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; submission date proposed by the applicant: unknown, relevant for Section 2, 4 and 5).
- Spectra for identification of the relevant impurities (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1).
- Content of relevant impurities in the plant protection products, before and after storage (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1).
- A method for determination of the relevant impurities in the representative formulations. (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; 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; submission date proposed by the applicant: unknown; see Section 1).
- Toxicokinetic parameters such as C_{max}, T_{max}, $T_{½}$, AUC (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2).
- *In vitro* tests for skin sensitisation (relevant for all representative uses evaluated; submission date proposed by the applicant: January 2018; see Section 2).
- Aromatase inhibition and steroidogenesis assays to assess the ED potential (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2).
- *In vivo* study to demonstrate the exposure of bone marrow in micronucleus assay (relevant for all representative uses evaluated; submission date proposed by the applicant: February 2018; see Section 2).
- Genotoxicity study on clastogenicity in mammalian cells (relevant for all representative uses evaluated; submission date proposed by the applicant: January 2018; see Section 2).
- *In vitro* micronucleus test for the metabolite IN-E9260 (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2).
- 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; submission date proposed by the applicant: unknown; see Section 3).
- Critical GAP-compliant residue trials for tomato for both applicants (relevant for the representative use on tomato; submission date proposed by the applicant: unknown; 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; submission date proposed by the applicant: unknown; see Section 3)
- A data gap is identified to address the groundwater leaching potential using a second FOCUS GW model (e.g. PELMO) (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 4).
- Applicants to provide appropriate information to address the effect of water treatments 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; submission date proposed by the applicant: no date proposed; see Section 4).

- Extended summaries of the studies included in the RAR were not always available (relevant for all the representative uses; submission date proposed by the applicant: no date proposed; see Section 5).
- The EC_{10}/EC_{20} values for the relevant studies according to the Regulation (EU) No 283/2013 were not always provided (relevant for all the representative uses; submission date proposed by the applicant: no date proposed; 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; submission date proposed by the applicant: no date proposed; see Section 5).
- A study with a second species of algae was not available (relevant for all the representative uses; submission date proposed by the applicant: no date proposed; see Section 5).
- Further data on the toxicity of the metabolite IN-JF999 on sediment-dwelling organisms (relevant for all the representative uses; submission date proposed by the applicant: no date proposed; 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; submission date proposed by the applicant: no date proposed; 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; submission date proposed by the applicant: no date proposed; 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; submission date proposed by the applicant: no date proposed; 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; submission date proposed by the applicant: no date proposed; 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 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[4] 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.

[4] 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, p. 127–175.

1) Genotoxicity cannot be considered finalised since bone marrow exposure was not demonstrated and chromosomal aberration was not adequately assessed for rimsulfuron; in addition, gene mutation in mammalian cells was not sufficiently addressed for the metabolite IN-E9260 (see Section 2).
2) ED 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).
3) Exposure to ground water cannot be considered finalised since simulations need to be calculated with a second FOCUS GW model (e.g. PELMO) to account for the uncertainty associated to the different modelling approaches (see Section 4).
4) The applicants did not provide appropriate information to address the effect of water treatments 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).

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 the 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.

5) For toxicologically relevant metabolite IN-E9260 the parametric drinking water limit of 0.1 μg/L was exceeded for all scenarios an uses simulated (see Sections 2, 4).

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[3]	X[3]	X[3]
Risk to wild non-target terrestrial vertebrates	Risk identified			
	Assessment not finalised			

Representative Use		Maize	Potato	Tomato
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		X (1 out of 6 FOCUS scenarios)	X (1 out of 4 FOCUS scenarios)
	Assessment not finalised			
Groundwater exposure to active substance	Legal parametric value breached			
	Assessment not finalised	X[3]	X[3]	X[3]
Groundwater exposure to metabolites	Legal parametric value breached[(a)]	X	X	X
	Parametric value of 10 μg/L[(b)] breached			
	Assessment not finalised	X[3]	X[3]	X[3]

The superscript numbers relate to the numbered points indicated in Sections 9.1 and 9.2. Where there is no superscript number, see Sections 2–6 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

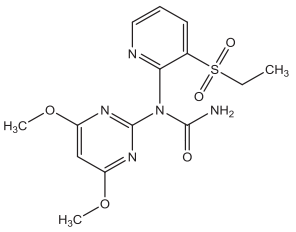
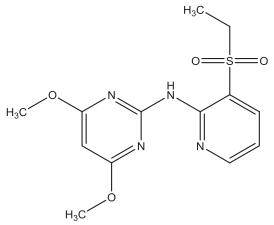
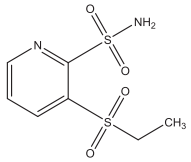
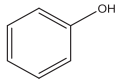
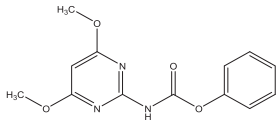
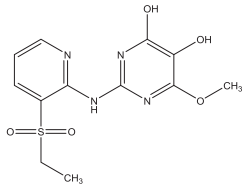
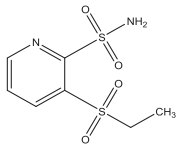
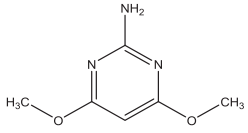
a.s.	active substance
AAOEL	acute acceptable operator exposure level
ADI	acceptable daily intake
ALARA	as low as reasonably achievable
AOEL	acceptable operator exposure level
AR	applied radioactivity
ARfD	acute reference dose
AUC	area under the blood concentration/time curve
bw	body weight
CLP	classification, labelling and packaging
C_{max}	concentration achieved at peak blood level

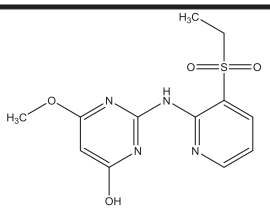
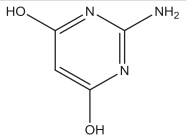
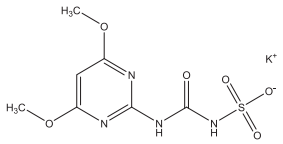
DAR	draft assessment report
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
EC_{10}	effective concentration, 10%
EC_{20}	effective concentration, 20%
ECHA	European Chemicals Agency
ED	endocrine-disrupting
EEC	European Economic Community
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
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
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_{Foc}	Freundlich organic carbon adsorption coefficient
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOQ	limit of quantification
MRL	maximum residue level
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in groundwater
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PHI	preharvest interval
PIE	potential inhalation exposure
POEM	(UK) Predictive Operator Exposure Model
PPE	personal protective equipment
QuEChERS	quick, easy, cheap, effective and safe method
RAR	Renewal Assessment Report
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SMILES	simplified molecular-input line-entry system
STOT-RE	specific target organ toxicity – repeated exposure
$T_{1/2}$	half-life (define method of estimation)
T_{max}	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.2018.5258

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-E9260	3-(ethylsulfonyl)pyridine-2-sulfonamide O=S(C1=NC=CC=C1S(=O)(CC)=O)(N)=O ZVAJJLYQUHJURI-UHFFFAOYSA-N	
IN-J0290IN-J290	4,6-dimethoxypyrimidin-2-amine NC1=NC(OC)=CC(OC)=N1 LVFRCHIUUKWBLR-UHFFFAOYSA-N	

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[b]
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	
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	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system.
(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.