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CONCLUSION ON PESTICIDES PEER REVIEW

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Peer review of the pesticide risk assessment of the active substance bensulfuron-methyl

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Abstract

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State Italy and co-rapporteur Member State Spain for the pesticide active substance bensulfuron-methyl are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The conclusions were reached on the basis of the evaluation of the representative uses of bensulfuron-methyl as an herbicide on rice and spring cereals (spring wheat, spring barley, oat, rye, triticale). 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

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

CONTENTS

SUMMARY

Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659, 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 as amended by Commission Implementing Regulation (EU) No 2016/183. Bensulfuron-methyl[1] is one of the active substances listed in that Regulation.

In accordance with Article 1 of Regulation (EU) No 844/2012, the rapporteur Member State (RMS), Italy and co-rapporteur Member State (co-RMS), Spain, received an application from UPL Europe Ltd for the renewal of approval of the active substance bensulfuron-methyl.

An initial evaluation of the dossier on bensulfuron-methyl was provided by the RMS in the renewal assessment report (RAR) and subsequently, a peer review of the pesticide risk assessment on the RMS evaluation was conducted by EFSA in accordance with Article 13 of Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The following conclusions are derived.

The uses of bensulfuron-methyl according to the representative uses as an herbicide on rice and spring cereals (encompassing spring wheat, spring barley, oat, rye, triticale), as proposed at EU level result in a sufficient herbicidal efficacy against broadleaved weeds in crops of rice, spring wheat, spring barley, oat, rye and triticale crops and to control *Cyperaceae* (sedges) in crops of rice.

The assessment of the data package revealed no issues that could not be finalised or that needed to be included as critical areas of concern with respect to identity, physical–chemical and technical properties of the active substance and the formulation for representative uses, and analytical methods.

The assessment of the data package revealed no issues that could not be finalised or that needed to be included as critical area of concern with respect to mammalian toxicology.

In the area of residues, the consumer risk assessment for groundwater metabolites could not be finalised due to a missing refined groundwater exposure assessment for metabolite IN-N5297 and missing toxicological information for metabolites IN-R9419 and IN-N5297. The consumer risk assessment is not finalised with regard to the unknown nature of residues that might be present in drinking water, consequent to water treatment following abstraction of surface water that might contain the active substance and its metabolites.

The data available on environmental fate and behaviour were sufficient to carry out the required environmental exposure assessments at EU level for the representative uses on spring cereals only. The exposure estimates for bensulfuron-methyl for the representative uses in rice fields are missing for all environmental compartments. In addition, surface water/sediment exposure for potential metabolites only found in aquatic compartments and groundwater exposure and relevance assessment of soil metabolites could not be finalised for both representative uses. Based on the available estimates for representative uses in spring cereals, there is the potential for groundwater exposure by bensulfuron-methyl and metabolites bensulfuron (identified as IN-R9419), IN-N5297 and IN-DAT97 above the parametric drinking water limit of 0.1 µg/L in geoclimatic situations represented by 6/6, 5/6, 5/6 and 6/6 FOCUS scenarios, respectively. Since groundwater exposure for bensulfuron-methyl for uses on rice could not be finalised, the current risk assessment does not permit the conclusion to be drawn, that at least one of the representative uses will not result in the legal parametric drinking water limit being exceeded. It cannot be excluded that the legal parametric drinking water is being exceeded also for the representative use in rice using current scientific and technical knowledge. This led to the identification of a critical area of concern.

In the area of ecotoxicology, due to the absence of reliable exposure estimates for bensulfuron-methyl in surface water, sediment and soil, the risk assessment for aquatic and soil organisms could not be finalised for the uses in rice. A high risk to aquatic plants was concluded in two out five scenarios for the uses on cereals. Risk mitigation measures are required to conclude low risk for non-target terrestrial plants.

Based on the available evidence, it can be concluded that bensulfuron-methyl is not an endocrine disruptor, according to point 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.

[1]In the aforementioned regulation the active substance bensulfuron-methyl is commonly referred to as 'bensulfuron' since this active substance was previously assessed under the name bensulfuron but all the data submitted were actually related to bensulfuron-methyl.

BACKGROUND

Commission Implementing Regulation (EU) No 844/2012,[2] as amended by Commission Implementing Regulation (EU) No 2018/1659,[3] (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.[4] 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). Furthermore, in accordance with Article 13(3a), where the information available in the dossier is not sufficient to conclude the assessment on whether the approval criteria for endocrine disruption are met, additional information can be requested to be submitted in a period of minimum 3 months, not exceeding 30 months, depending on the type of information requested.

In accordance with Article 1 of the Regulation, the RMS Italy and co-RMS Spain received an application from UPL Europe Ltd for the renewal of approval of the active substance bensulfuron-methyl. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Spain), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on bensulfuron-methyl in the RAR, which was received by EFSA on 18 July 2022 (Italy, 2022).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, UPL Europe Ltd, for consultation and comments on 27 September 2022. 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 19 December 2022. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of reporting table. In addition, the applicant was invited to respond to the comments received. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 13(3) of the Regulation were considered in a teleconference between EFSA and the RMS on 13 March 2023. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicant, and that EFSA should conduct an expert consultation in the areas of mammalian toxicology, residues, environmental fate and behaviour, and ecotoxicology.

The outcome of the teleconference, 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 July 2024.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the formulation for representative uses, evaluated on the basis of the representative uses of bensulfuron-methyl as an herbicide on rice and spring cereals (encompassing spring wheat, spring barley, oat, rye and triticale), as proposed by the applicant. In accordance with Article 12(2) of Regulation (EC) No 1107/2009, risk mitigation options identified in the RAR and considered during the peer review, if any, are presented in the conclusion.

A list of the relevant end points for the active substance and the formulation is provided in Appendix B. In addition, the considerations as regards the cut-off criteria for bensulfuron-methyl, according to Annex II of Regulation (EC) No 1107/2009, are summarised in Appendix B.

A key supporting document to this conclusion is the peer review report (EFSA, 2024), 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:

[2]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.

[3]Commission Implementing Regulation (EU) No 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605.

[4]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.

- the comments received on the RAR;
- the reporting table (13 March 2023);
- the evaluation table (25 June 2024);
- 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 (Italy, 2024), 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 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 FORMULATION FOR REPRESENTATIVE USES

Bensulfuron-methyl is the parent-ISO name for methyl 2-({[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}methyl) benzoate (IUPAC name). It is a methyl ester of bensulfuron, which is the ISO common name of 2-({[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}methyl)benzoic acid (IUPAC name). This substance was previously assessed under the name bensulfuron but all the data submitted were actually related to bensulfuron-methyl (EFSA, 2008b).

The formulation for representative uses for the evaluation was 'Londax 60 DF, (HCG01)', a wettable granule formulation containing 600 g/kg of pure bensulfuron-methyl.

The information on the active substance and the formulation for representative uses, including the co-formulants in this formulation, was considered in the overall assessment during the peer review. None of the co-formulants is an unacceptable co-formulant listed in Annex III of Regulation (EC) No 1107/2009,[5] however one co-formulant is currently approved as active substance, one co-formulant is not approved as active substance, and two co-formulants are currently approved as basic active substances under Regulation (EC) 1107/2009.[6] Details on the composition of the formulation cannot be reported in conclusions because of the provisions in Article 63(2)(d) of Regulation (EC) No 1107/2009, however this information was fully available and evaluated during the peer review. A proposal for classification of the formulation according to Regulation (EC) 1272/2008 was provided by the applicant and assessed by the RMS (please see Volumes 3 CP of the RAR).

The representative uses evaluated comprise applications with tractor-mounted sprayer to control broadleaved weeds in crops of rice, spring wheat, spring barley, oat, rye and triticale crops and to control *Cyperaceae* (sedges) in crops of rice. Full details of the GAP can be found in the list of end points in Appendix B.

Data were submitted to conclude that the representative uses of bensulfuron-methyl proposed at EU level result in a sufficient herbicidal effect following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014b).

CONCLUSIONS OF THE EVALUATION

General aspects

With regard to the mammalian toxicity information available for the formulation for representative uses 'Londax 60 BF, (HCG01)', studies were performed for acute toxicity endpoints. With regard to the co-formulants contained in 'Londax 60 BF, (HCG01)', sufficient toxicological data were available for all components but two (one present in significant amount in the final formulation). For these two co-formulants, insufficient information about their specifications/composition was available and the experts considered that the available toxicological information did not sufficiently address the repeated dose toxicity potential of 'Londax 60BF, (HCG01)' over long-term, therefore this might be considered for further assessment (see Section 10). In addition, for a third co-formulant,[7] (present in significant amount in the final formulation), the experts considered that the available toxicological information show concerns in relation to possible adverse effects over long term and carcinogenicity from exposure via inhalation.[8] It is noted that collected information (not covering all endpoints), including the existing approved uses other than plant protection products, under EU regulated frameworks, did not highlight any additional concern.

[5]Commission Regulation (EU) 2021/383 of 3 March 2021 amending Annex III to Regulation (EC) No 1107/2009 of the European Parliament and Council listing co-formulants which are not accepted for inclusion in plant protection products. OJ L 74, 4.3.2021, p. 7–26.

[6]Please see Regulation (EC) No 1107/2009 for acceptability criteria for co-formulants and Section 2.13.6 of the Technical report on the outcome of the pesticides peer review meeting on general recurring issues in physical and chemical properties and analytical methods. EFSA Supporting Publication, EN-1623. https://doi/org/10.2903/sp.efsa.2019.EN-1623

[7]Under discussion in the ECHA Committee for Risk Assessment (RAC) with classification proposal amongst others as Carc. 2, H351, see: https://echa.europa.eu/documents/10162/2166371/rac_70_provisional_draft_agenda_en.pdf/c2fbb2e4-37bc-4f21-aaa3-7db893aebf1b?t=1721308269245.

[8]Please refer to experts' consultation 2.14 in the Report of Pesticides Peer Review Experts' Meeting TC 125 (EFSA, 2024).

The available ecotoxicity data with the formulation for representative uses was discussed at the experts' meeting.[9] No concerns were identified.

1 | IDENTITY, PHYSICAL/CHEMICAL/TECHNICAL PROPERTIES AND METHODS OF ANALYSIS

The following guidance documents were applied in the production of this conclusion: European Commission (2000a, 2000b, 2010, 2012).

The proposed specification for bensulfuron-methyl was based on batch data from industrial production. The proposed minimum purity is 975 g/kg, however based on the data submitted in support of the renewal of approval process a higher minimum purity could be proposed. An individual source technical specification was derived based on the batch data submitted for the renewal. The RMS compared this individual source specification to the current EU reference specification according to the criteria given in the guidance document SANCO/10597/2003 rev. 10.1 (European Commission, 2012) and concluded that it is equivalent, hence proposed to maintain the current EU reference specification. EFSA notes that two new significant impurities were found in the technical grade active ingredient and the toxicological relevance for one of them is open (see Sections 2 and 10). As a consequence, an update of the proposed reference specification and additional data consisting of spectral data, content of the impurity before and after storage of the formulation and method for its analysis in the formulation might be required. The batches used in the (eco)toxicological assessment support the current EU reference specification (See Sections 2 and 5). The proposed minimum purity of 975 g/kg meets the requirements of the FAO specification 502/TC (2002), that covers bensulfuron-methyl technical material of E. I. du Pont de Nemours and Company.

The main data regarding the identity of bensulfuron-methyl and their physical and chemical properties are given in Appendix B. A **data gap** was set for octanol water partition coefficient data for the metabolites IN-DAT97 and IN-YY142 (see Section 10).

Adequate methods are available for the generation of data required for the risk assessment. Methods of analysis are available for the determination of the active substance in the technical material and the formulation for representative uses.

The QuEChERS multi-residue method using liquid chromatography with tandem mass spectrometry (LC–MS/MS) can be used for the determination of bensulfuron-methyl residues in all plant commodity groups with a limit of quantification (LOQ) of 0.01 mg/kg. Peer-review concluded that metabolite O-desmethyl bensulfuron-methyl (IN-F7880) should be set as a residue definition for monitoring in food and feed of animal origin (see Section 3), thus a **data gap** was set for a respective analytical method (see Section 10).

Bensulfuron-methyl in soil can be monitored by LC–MS/MS with LOQ of 0.08 µg/kg. An appropriate LC–MS/MS method is available for monitoring residues of bensulfuron-methyl in groundwater, drinking water and surface water with LOQs of 0.05 µg/L. Residues of bensulfuron-methyl in air can be monitored by LC–MS/MS with a LOQ of 3 µg/m^3.

Residues of bensulfuron-methyl in body fluids (blood) can be monitored by LC–MS/MS with LOQ of 0.01 mg/L, while residues of bensulfuron-methyl in body tissues can be monitored by the LC–MS/MS method developed for the determination of bensulfuron-methyl residues in food and feed of animal origin (milk, fat, liver, muscle and eggs) with a LOQ of 0.01 mg/kg.

2 | MAMMALIAN TOXICITY

The toxicological profile of the active substance bensulfuron-methyl and its metabolites was discussed at the Pesticides Peer Review Experts' Teleconference 124–125 in January 2024. The assessment is based on the following guidance documents: European Commission (2003, 2012), EFSA (2014c), EFSA PPR Panel (2012, 2017), and ECHA (2017).

No toxicologically relevant impurity has been identified in the proposed specification that is corresponding to the current EU reference specification. However, two new significant impurities were found in the technical grade active ingredient (see Section 1) and the toxicological relevance of one of these impurities[10] still needs to be determined (**data gap**, see Section 10). Should data to conclude on the relevance of this impurity become available, an update of the proposed reference specification may be required.

As regards the representativeness of the batches used in toxicological studies, information on the impurity profiles is lacking for some of them, thus preventing to conclude whether the test material used in toxicity studies is fully representative of the reference specification. Nevertheless, since the test material in these batches had a lower degree of purity than the reference specification, this can be assumed as a 'worst-case' scenario. Additionally, the outcome of the toxicity studies with these batches having undefined impurity profile did not trigger further experimental investigations to address the impact of impurities on the study results. Therefore, it is concluded that the reference specification is adequately represented by the batches used in the toxicological studies.

[9]Please refer to experts' consultation 0.1 in the Report of Pesticides Peer Review Experts' Meeting TC 129 (EFSA, 2024).

[10]Refer to confidential evaluation table 0.4 (EFSA, 2024).

The **systemic bioavailability** of bensulfuron-methyl is estimated to be around 60% based on the sum of the radioactivity retrieved in urine, cage wash, tissues and G.I. tract values. **Excretion** occurs predominantly via the urine and bile/faecal route and is completed within 48–72 h post oral administration. In the rat, bensulfuron-methyl is **distributed** throughout the body, with minimal potential for **bioaccumulation**. The main **metabolic** pathway is O-demethylation and hydroxylation of the pyrimidine ring, as well as sulphonamide bridge cleavage. Based on comparative in vitro metabolism study, bensulfuron methyl has a similar metabolic pathway in humans and rats. Metabolism in dogs is also similar, with the exception of one metabolite, bensulfuron (IN-R9419), not detected in dogs.

The **residue definition** for body fluids and tissues is bensulfuron-methyl.

Bensulfuron-methyl has low **acute** toxicity by oral, dermal and inhalation exposure. It has no irritating properties, but it is a skin sensitiser (harmonised classification: Skin Sens. 1; H 317). Bensulfuron-methyl was not **phototoxic** in the OECD 3T3 NRU-PT test, which however might not be suitable to test UVB absorbers such as bensulfuron-methyl (**data gap**, see Section 10).

Based on the results of **short-term** oral toxicity studies in rats, mice and dogs, the effects of bensulfuron-methyl are characterised primarily by changes in haematology parameters in rats, with a no observed adverse effect level (NOAEL) of 93 mg/kg bw per day in a 90-day study, and changes in serum liver enzyme activity, and liver enlargement in mice and dogs with respective NOAELs of 38.9 mg/kg bw per day in a 90-day mouse study and of 19.9 mg/kg bw per day in a 1-year dog study.

Based on the available **genotoxicity** data package, bensulfuron-methyl in unlikely to be genotoxic.[11]

Testing for photomutagenicity is not required for bensulfuron-methyl.

After **long-term exposure**, target organ for toxicity was liver in both rats and mice. The lowest relevant NOAEL of 30 mg/kg bw per day was identified in the 2-year study in rats, based on reduced body weight and body weight gain and, haematological changes (reduced haemoglobin concentration) and liver toxicity (increased incidence of centrilobular hepatocellular hypertrophy and focal fatty changes).

The substance showed no treatment-related tumours in rats and mice and it was concluded unlikely to be carcinogenic for humans.[12]

With regard to **reproductive toxicity** studies, fertility and overall reproductive performance were not affected. In the multigeneration rat study, the parental NOAEL is 19.5 mg/kg bw per day, based on slightly reduced body weight in F1 adult males. The offspring NOAEL is 22.3 mg/kg bw per day, based on reduced body weight of F1 pups. Finally, in the absence of effect, the reproductive NOAEL is 1404.5 mg/kg bw per day (the highest tested dose).

In the rat teratogenicity study, the maternal NOAEL is the highest tested dose of 2000 mg/kg bw per day. The developmental NOAEL is 50 mg/kg bw per day, based on increased incidences of foetuses with skeletal variations per litter, i.e. partially or unossified hyoid and extra rib ossification centre in the absence of maternal toxicity. In the rabbit teratogenicity study, the maternal NOAEL is 300 mg/kg bw per day based on decreased body weights and food consumption, and on the occurrence of spontaneous deaths. The developmental NOAEL is also 300 mg/kg bw per day, based on increased total resorptions and reduced foetal weights (> 10%) at the next higher dose.

The substance was concluded unlikely to be a developmental toxicant in humans.[13]

With respect to **neurotoxicity** and **immunotoxicity**, bensulfuron methyl did not show any potential for neurotoxic or immunotoxic effects in the available standard regulatory toxicity studies nor in the acute neurotoxicity study in rats.

Toxicological reference values (TRVs) have been derived for bensulfuron-methyl.[14] The **acceptable daily intake** (**ADI**) is 0.2 mg/kg bw per day, based on the effects observed in the liver (increased weight, presence of brown pigment in the biliary canaliculi, and increased alanine aminotransferase (ALT) and alkaline phosphatase (ALP) activities) in the 1-year dog study, applying a standard uncertainty factor (UF) of 100. The **acceptable operator exposure level** (**AOEL**) is 0.12 mg/kg bw per day, based on the 1-year dog study, applying a standard uncertainty factor (UF) of 100 and correcting for the limited oral absorption of 60%. The allocation of an **acute reference dose** (**ARfD**) and an **acute AOEL** (**AAOEL**) is deemed unnecessary based on the low acute toxicological profile of bensulfuron-methyl.

Based on the EFSA guidance (EFSA, 2017), and in the absence of experimental data with the formulation for representative uses 'Londax 60 DF', the default **dermal absorption** values to be used for risk assessment are 10% for the concentrate and 50% for the dilution.

For the representative uses on rice (also covering the use on spring cereals), the **non-dietary exposure** estimates for the operators (wearing standard workwear) are below the AOEL based on the EFSA calculator (EFSA, 2014c). For the workers, considering re-entry exposure from entry into flooded paddy fields combined with exposure to dry residues on the plants,[15] the predicted estimates are below the AOEL. Similarly, the estimated exposure for residents (covering also bystanders) is below the AOEL without specific risk mitigation measures.

Metabolites of bensulfuron-methyl found in groundwater and/or in animals/plants were discussed at peer review experts' meeting.[16] The ones requiring further toxicological considerations are presented and discussed in the following

[11]Refer to experts' consultation 2.4 in the Report of Pesticides Peer Review Experts' Meeting TC 125 (EFSA, 2024).

[12]Refer to experts' consultations 2.5 and 2.6 in the Report of Pesticides Peer Review Experts' Meeting TC 125 (EFSA, 2024).

[13]Refer to experts' consultation 2.8 in the Report of Pesticides Peer Review Experts' Meeting TC 125 (EFSA, 2024).

[14]Same toxicological reference values were agreed in the former EFSA peer review (EFSA, 2008b).

[15]Refer to experts' consultation 2.13 in the Report of Pesticides Peer Review Experts' Meeting TC 125 (EFSA, 2024).

[16]Refer to experts' consultation 2.10 and 2.11 in the Report of Pesticides Peer Review Experts' Meeting TC 124-TC 125 (EFSA, 2024).

table. Further assessment of the toxicological profile of metabolites bensulfuron (IN-R9419), IN-DAT97 and IN-N5297 found in groundwater is needed (**data gap** leading to an **issue not finalised,** see Sections 3, 4 and 9.1.1). For the residue metabolites IN-N8989, IN-B6895, IN-F78184 and IN-N5297 genotoxicity data are missing (**data gap**, see Section 10) (Table 1).

TABLE 1 Summary of the toxicological profile of the metabolites requiring further toxicological data.

		Genotoxicity			
Metabolite	**Source(s)**	**Gene mutation**	**Chromosome aberrations**	**General toxicity**	**Reference values/Data gap(s)**
IN-DAT97	**GW**	Open No experimental data/in silico analysis inconclusive (and in any case not sufficient as a GW metabolite)	Open No experimental data/in silico analysis inconclusive (and in any case not sufficient as a GW metabolite)	No conclusion No experimental data/in silico analysis inconclusive (and in any case not sufficient as a GW metabolite)	No conclusion, pending data gap in genotoxicity (mutagenicity, clastogenicity and aneugenicity) and general toxicity
Bensulfuron (IN-R9419)	GW and residues	Negative Ames test negative	Open No experimental data/in silico analysis inconclusive (and in any case not sufficient as a groundwater metabolite)	No conclusion The structural similarity of bensulfuron to the parent molecule would support the application of the parent's TRVs to this metabolite; however its genotoxic potential should be first clarified	Reference values of bensulfuron-methyl might apply, pending clarification on genotoxic potential (clastogenicity and aneugenicity)
IN-N5297	GW and residues	Negative Ames test negative	Open No experimental data/in silico analysis inconclusive (and in any case not sufficient as a groundwater metabolite)	No conclusion	No conclusion, pending data gap in genotoxicity (clastogenicity and aneugenicity) and general toxicity
IN-B6895 (homosaccharin)	Residues	Negative Ames test negative	Open No experimental data/in silico analysis inconclusive	No conclusion	No conclusion, pending data gap in genotoxicity (clastogenicity and aneugenicity)
IN-N8989	Residues	Negative based on in silico analysis	Open No experimental data/in silico analysis inconclusive	No conclusion	No conclusion, pending data gap in genotoxicity (clastogenicity and aneugenicity)
IN-F78184	Residues	Open No experimental data/in silico analysis inconclusive	Open No experimental data/in silico analysis inconclusive	No conclusion	No conclusion, pending data gap in genotoxicity (mutagenicity, clastogenicity and aneugenicity)

3 | RESIDUES

The assessment in the residue section is based on the following guidance documents: OECD (2009, 2011), European Commission (2011) and JMPR (2004, 2007).

Bensulfuron-methyl was discussed at the Pesticides Peer Review Experts' Meeting TC 128 on 30–31 January 2024.

Metabolism of bensulfuron-methyl was studied in wheat and rice. The two studies on rice were not acceptable due to the lack of identification of residues in the study with foliar application despite sufficiently high residues and they do not support the EU GAP and the rice growing practices in the EU (the study with application to paddy rice). In the study with wheat, bensulfuron-methyl together with IN-N5297 and IN-F7880 accounted for ca 10% TRR in grain; whereas bensulfuron-methyl was the major residue in straw (28% TTR) followed by IN-F78148 (12% TRR), IN-N5297 (11% TRR) and IN-F7880 (5% TRR). Based on comparability of the application scenario and the extrapolation rules according to current guidelines, the

use of foliar application to rice (after sowing) can therefore still be supported by this wheat study. In contrast, the representative use on rice with pre-sowing application is not supported by a relevant primary crop metabolism study and a **data gap** is set for a scientifically based justification to address the expected metabolic pattern in rice with regard to the GAP with pre-sowing application (see Section 10).

A sufficient number of valid residue field trials analysing for bensulfuron-methyl supporting the representative uses with foliar application on wheat (NEU and SEU zones) and on rice (both on flooded and on saturated soil) in the SEU zone were presented. A complete set of residue trials in rice with foliar application (both flooded and saturated soil) in the NEU zone are requested to support the GAP requested for Hungary (**data gap,** see Section 10). The GAPs with pre-sowing application to rice, both to flooded and saturated soil, were not supported by data (**data gap**, see Section 10). Some of the wheat and rice trials also included analysis of metabolites. IN-F7880 and IN-N5297 were found only in rice straw (HR for both 0.02 mg/kg) and N-78184 in rice and wheat straw (HR 0.06 and 0.03 mg/kg, respectively). It should be noted that for IN-N5297 data on stability in cereals are not yet available as the study was ongoing at the time of the peer-review. The stability data for IN-N5297 are necessary to validate the results from the residue field trials and hence the relevance assessment of this metabolite for the livestock dietary burden is pending (data gap, see Section 10).

Three studies investigating the metabolism of bensulfuron-methyl in **rotational crops** were submitted. Two of them provided only limited information as the residue levels were too low to allow for identification. In the more recent and valid study applying the maximal seasonal application rate, residues above 0.01 mg/kg were only found in wheat plant parts (in straw, at all three PBIs and up to 0.24 mg/kg in the first PBI) and in oilseed rape straw at 120 days after application (DAA). Only the metabolite IN-N5297 was present at all three PBIs in wheat straw with initial concentrations of 0.024 mg/kg. To fully validate the study further evidence on the storage stability is requested (**data gap,** see Section 10).

Overall, metabolism in primary and rotational crops can be considered as similar. On this basis the **risk assessment** and **enforcement residue definitions for foliar applications in cereal crops** are proposed as bensulfuron-methyl. Whether these definitions are appropriate to extend to the pre-sowing application is pending submission of a scientifically based justification to address the expected metabolic pattern in rice with regard to this GAP scenario (see **data gap** above).

According to livestock burden assessment and considering only residues of bensulfuron-methyl, livestock studies are triggered for ruminants (sheep, all diets) for the representative uses. Metabolite IN-F78184 contributes to the dietary burden and it was not clarified whether it is also a metabolite formed by ruminants (see below). Therefore, a **data gap** is set to address the genotoxic potential of IN-F78184 (see Sections 2 and 10). The residue definition of risk assessment for feed items is provisionally set as bensulfuron-methyl.[17]

Metabolism studies with ruminants and poultry were submitted. The poultry study was not considered acceptable due to shortcomings (no identification of residues) and residue definitions for poultry commodities could not be proposed and they are currently not triggered with regard to the representative uses. The ruminant study with the phenyl label was considered acceptable while a study addressing the metabolism of the pyrimidyl-moiety part of bensulfuron-methyl was not available (**data gap**, Section 10). The main residue in milk and liver was IN-F7880. Additional metabolites above 10% TRR were observed in milk (IN-N8989, IN-B6895 and IN-N5297) and in liver (bensulfuron (GLU1)); in other tissues the residues levels were below the LOQ. It was noted that in this study the cereal straw major metabolite IN-F78184 was not analysed.

On the basis of this study, a **residue definition for risk assessment for ruminants** is proposed as bensulfuron-methyl and O-desmethyl bensulfuron-methyl (IN-F7880) expressed as bensulfuron-methyl. The residue definition is provisional and should be revisited once the ruminant study with pyrimidyl-label and toxicological information (genotoxicity) of the metabolites IN-N8989, IN-B6895 and IN-N5297 become available (**data gap,** see Sections 2 and 10). Based on the marker approach the **residue definition for enforcement** for **ruminant commodities** is proposed as O-desmethyl bensulfuron-methyl (IN-F7880). It should be noted that an analytical method for this metabolite is not available (see data gap in Sections 1 and 10) but it is for bensulfuron-methyl which is still recovered in milk.

The chronic consumer dietary intake assessment could be concluded with the available data and resulted in a consumer exposure corresponding to 0.3% ADI (NL, toddler) when using the revision 3.1 of the EFSA Pesticide Residue Intake Model (PRIMo).

The peer review conclusions do not trigger the need to review the assessment of existing MRLs for bensulfuron-methyl according to Article 12 of Regulation (EC) No 396/2005. The uses reported in the framework of the Art.12 MRL review (EFSA, 2016) were on rice only (same GAPs).

The consumer risk assessment for groundwater metabolites could not be finalised due to a missing refined groundwater exposure assessment for metabolite IN-N5297 and missing toxicological information for metabolites IN-R9419 and IN-N5297 (for data gaps see Sections 2, 4 and 9.1.1).

The consumer risk assessment from the consumption of drinking water is not finalised considering the lack of appropriate information to address the effect of water treatment processes on the nature of residues of bensulfuron-methyl, potentially present in surface water, when surface water is abstracted for drinking water (**issue not finalised**, see Sections 4 and 9.1.1).

[17]See experts' consultation point 3.2 in the evaluation table section 3 (EFSA, 2024).

4 | ENVIRONMENTAL FATE AND BEHAVIOUR

Bensulfuron-methyl was discussed at the Pesticides Peer Review Meeting Teleconference (TC) 127 in 24 January 2024.

The rates of dissipation and degradation in the environmental matrices investigated were estimated in agricultural soils using FOCUS (2006) kinetics guidance. In unflooded **soil laboratory incubations** under aerobic conditions in the dark, bensulfuron-methyl exhibited moderate to high persistence, forming the major (> 10% applied radioactivity (AR)) metabolites bensulfuron (max. 26% AR) and IN-D1R84 (max. 18% AR), which exhibited low to moderate persistence and the metabolites aminopyrimidine/IN-J0290 (max. 21% AR) and IN-N5297 (max. 12% AR), which exhibited low to medium persistence. Mineralisation of the ^{14}C-phenyl and ^{14}C-pyrimidine radiolabels to carbon dioxide accounted for 0.6%–13% AR after 90–95 days. The formation of unextractable residues (not extracted by ammonium carbonate/acetone, acetonitrile, acetonitrile/water and ammonium hydroxide) for these radiolabels accounted for 17%–26% AR after 90–95 days. A reliable flooded aerobic soil degradation study for bensulfuron-methyl was not provided. In consequence, experts agreed that the definition of residues triggering assessment in rice is unknown, as well as the required degradation endpoints for bensulfuron-methyl and metabolites (**issue not finalised**, see Section 9.1.1).[18] In anaerobic soil incubations, bensulfuron-methyl degraded more slowly than under aerobic conditions, however the route of degradation was similar to the one in aerobic investigations, with the major difference being the formation of a major anaerobic metabolite IN-DAT97 (max. 44% AR) formed at early stages of flooding conditions. Under soil photolysis conditions, bensulfuron-methyl was transformed to the major metabolites IN-N5297 (max. 25% AR) and aminopyrimidine/IN-J0290 (max. 8% AR).

Bensulfuron-methyl exhibited high **mobility in soil**. However, reliable adsorption endpoints for bensulfuron-methyl in two additional soils (including soils in acidic conditions) are missing (**issue not finalised**, see Section 9.1.1). Metabolites bensulfuron, IN-N5297 and IN-DAT97 exhibited high to very high soil mobility, aminopyrimidine/IN-J0290 exhibited very high to immobile soil mobility and IN-D1R84 exhibited low to medium mobility. In the Pesticides Peer Review TC 127, experts agreed that adsorption of soil metabolites was not pH dependent.[19] Reliable field dissipation studies were unavailable for bensulfuron-methyl and its soil metabolites IN-N5297 and aminopyrimidine/IN-J0290 (**data gap**, see Section 10). In two satisfactory paddy field dissipation studies carried out at five sites from Italy and the US (spray application to flooded soil plots at the end of tillering rice growth and spray application to non-cropped bare ground flooded test plots), bensulfuron-methyl exhibited low persistence in paddy water. No reliable DT50 values could be obtained in paddy soil. Sample analyses were carried out for the parent bensulfuron-methyl only. Due to some limitations of the studies, only persistence endpoints could be derived for bensulfuron-methyl in paddy field dissipation studies.

A reliable water/sediment study for bensulfuron-methyl is not available and, therefore, potential metabolites only formed in water/sediment systems could not be assessed (**issue not finalised**, see Section 9.1.1). In a laboratory sterile aqueous photolysis experiment, bensulfuron-methyl exhibited low to medium persistence. Chromatographically resolved components accounting for > 10% AR were IN-T5831 (max. 14% AR) and IN-YY142 (max. 14.7% AR). The necessary **surface water and sediment exposure assessments** (Predicted environmental concentrations (PEC) calculations) for the representative use in spring cereal fields were carried out for the metabolites bensulfuron (IN-R9419), IN-D1R84, IN-N5297, aminopyrimidine/IN-J0290, IN-DAT97 and IN-T5831 using the FOCUS (FOCUS, 2001) step 1 and step 2 approach (version 3.2 of the Steps 1–2 in FOCUS calculator) and for the metabolite IN-YY142 up to Step 3, derived from the max Step 3 of bensulfuron-methyl. For the active substance bensulfuron-methyl, appropriate step 3 (FOCUS, 2001) and step 4 calculations were available.[20] The step 4 calculations appropriately followed the FOCUS (FOCUS, 2007) guidance, with no-spray drift buffer zones of up to 20 m for both drainage and run-off scenarios (representing a 72%–93% spray drift reduction). The SWAN tool (version 5.0.1) was appropriately used to implement these mitigation measures in the simulations. Experts of the Pesticides Peer Review TC 127 agreed that current PEC surface water and PEC sediment calculations are based on reliable adsorption endpoints for bensulfuron-methyl investigated only in alkaline soil conditions and they may need to be recalculated once new adsorption endpoints of bensulfuron-methyl for acidic soils are provided and the pH dependency on adsorption becomes clear (**data gap**, see Section 10).[21] However, based on the literature on soil adsorption assessed as supportive, a conclusion that the available PEC calculations for the active substance are conservative for acidic soil conditions would result. In addition, the available PEC calculations for the known metabolites were carried out up to Step 2, and thus are independent from the parent adsorption, or up to Step 3 based on PEC from the active substance, and thus are conservative enough. Surface water and sediment exposure assessments for the representative uses in rice fields are currently missing, pending on data gaps (**issue not finalised**, see above and see Section 9.1.1).

The necessary **groundwater exposure assessments** for the representative use on spring cereals were appropriately carried out using FOCUS (European Commission, 2014a) scenarios and the models PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4.[22] Bensulfuron-methyl 80th percentile annual average concentrations moving below 1-m depth were predicted to be above the parametric drinking water limit of 0.1 µg/L in 6/6 of the pertinent FOCUS groundwater scenarios for the representative use on spring cereals (**critical area of concern**, see Section 9.1.2). Concentrations expressed in this basis were estimated to be > 0.1 µg/L for metabolites bensulfuron (IN-R9419) and IN-N5297 in 5/6 scenarios and IN-DAT97 in 6/6

[18] See experts' consultation point 4.1 of the Peer Review Meeting Report TC 127 (EFSA, 2024).

[19] See experts' consultation point 4.1 of the Peer Review Meeting Report TC 127 (EFSA, 2024).

[20] Simulations utilised the agreed Q10 of 2.58 (following EFSA, 2008a) and Walker equation coefficient of 0.7.

[21] See experts' consultation point 4.6 of the Peer Review Meeting Report TC 127 (EFSA, 2024).

[22] Simulations utilised the agreed Q10 of 2.58 (following EFSA, 2008a) and Walker equation coefficient of 0.7.

scenarios. Based on the information available in the mammalian toxicity section, the human health relevance assessment for these metabolites could not be finalised (see Sections 2 and 9.1.1). Information on the aerobic soil degradation rate of IN-DAT97 and soil formation fraction of IN-DAT97 and IN-N5297 would support a refined groundwater assessment (**issue not finalised**, see Section 9.1.1). Current PEC groundwater calculations are based on reliable adsorption endpoints for bensulfuron-methyl investigated only in alkaline soil conditions and may need to be recalculated once new adsorption endpoints of bensulfuron-methyl for acidic soils are provided and the pH dependency on adsorption becomes clear (**data gap**, see Section 10).[23] As discussed above for surface water, a conclusion that the available PEC calculations for the active substance are conservative for acidic soil conditions would result. Conversely, the leaching potential of metabolites that may occur under acidic conditions may be underestimated by the results at alkaline pH because of potential higher leaching of the active substance to deeper soil layers under alkaline soil conditions, where metabolite formation might be lower (**issue not finalised**, see Section 9.1.1). Groundwater exposure assessments for the representative uses in rice fields are currently missing, pending on **data gaps** (**issue not finalised**, see above and see Section 9.1.1).

The applicant 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 (see Sections 3 and 9.1.1).

The PEC in soil, surface water, sediment and groundwater covering the representative uses assessed on spring cereals can be found in Appendix B of this conclusion. A key to the wording used to describe the persistence and mobility of the compounds assessed can be found in Appendix C of this conclusion.

5 | ECOTOXICOLOGY

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

Bensulfuron methyl was discussed at the Pesticides Peer Review meeting (TC 124 and 129 from January 22nd to February 2nd 2024).

The batches used in the ecotoxicity studies were sufficiently comparable to the reference specification.

Acute and reproductive toxicity studies with **birds** and **mammals** with the active substance (a.s.) were available. The reproductive endpoint selection for birds[24] and wild mammals[25] was agreed at the experts' meeting. A low risk to birds and mammals from exposure to bensulfuron methyl and relevant plant metabolites was concluded on the basis of screening or Tier-1 assessment and considered relevant for all representative uses under the assumption that cereals are a suitable surrogate crop for the uses in rice. However, the RMS pointed out that the use of cereals as surrogate for rice paddies would be uncertain. An assessment of the risk to birds and mammals from secondary poisoning was not required (under the assumption that the log K_{OW} is below 3).

Suitable **aquatic** acute and chronic toxicity data (fish, aquatic invertebrates, algae and macrophytes) were available with the active substance. Toxicity data for fish (acute only) and aquatic invertebrates (acute and chronic) were available for the metabolites aminopyrimidine/IN-J0290 and IN-N5297. Toxicity data for algae and aquatic macrophytes were available for the metabolites aminopyrimidine/IN-J0290, IN-F7880, bensulfuron (IN-R9419), IN-T5831, IND1R84, IN-N5297 (macrophytes only) and IN-DAT97 (macrophytes only). Acute toxicity data for fish and aquatic invertebrates as well as toxicity data for algae and aquatic plants were available with the formulation for representative uses (Londax 60 DF HCG01).

The aquatic risk assessment for bensulfuron-methyl was driven by the regulatory acceptable concentration (RAC) derived for macrophytes. Toxicity data were available with 10 macrophyte species for bensulfuron-methyl, which allowed calculating a Tier-2 RAC based on a Species Sensitivity Distribution.[26] The Tier-2 RAC for macrophytes was still protective for all other groups of aquatic organisms.

In the absence of suitable PECs for the uses on rice, no risk assessment could be performed for such uses for either the active substance or the metabolites (**issue not finalised**, see Sections 4 and 9.1.1). For the use on spring cereals, the comparison of the available PEC with either the Tier-1 or the Tier-2 RAC for bensulfuron-methyl revealed a high risk in all scenarios, when mitigation measured were not applied. No-spray buffer zones of 10 meters were sufficient to achieve a low risk in three out of five FOCUS scenarios (see Section 8.1), while a high risk was still concluded for two out of five scenarios (D1 and D4), even when the buffer zones were increased to 20 meters.

The risk assessment for metabolites was carried out for every group of aquatic organisms either using available toxicity data for the individual metabolites or, when these were missing, toxicity data related to bensulfuron-methyl (i.e. screening assessment). For the use on spring cereals, a low risk to all metabolites could be concluded based on Step 2 PECs (step 3 for metabolite IN-YY142), with the only exception of IN-N5297 and IN-DAT97. For these two metabolites, the screening assessment for algae did not result in a low risk when the endpoint from bensulfuron-methyl and Step 2 PEC were used (data gap, see Section 10).

[23]See experts' consultation point 4.4 of the Peer Review Meeting Report TC 127 (EFSA, 2024).

[24]See Expert's consultation points 5.1 at the Pesticide Peer Review Experts' TC 124–139 (January and February 2024), (EFSA, 2024).

[25]See Expert's consultation points 5.2 at the Pesticide Peer Review Experts' TC 124–139 (January and February 2024), (EFSA, 2024).

[26]See Expert's consultation points 5.5 at the Pesticide Peer Review Experts' TC 124–139 (January and February 2024), (EFSA, 2024).

For **honey bees** acute studies with the a.s. or formulation 'BSM 600 WG (product code HCG04)' and chronic and larval studies with the formulation for representative uses were available. Toxicity data with bumble bees or solitary bees were not available. The acute risk for honey bees was quantified as low according to the European Commission (2002). Additionally, a risk assessment based on EFSA (2013) was provided, indicating low risk for honey bees from exposure to the active substance and relevant plant metabolites. No assessment of the risks to honeybees from consumption of contaminated drinking water was provided. A suitable assessment of accumulative and sublethal effects was not available (data gap, see Section 10).

Low risk for **non-target arthropods** other than bees was concluded for all representative uses.

Valid **earthworm** and **soil microorganism** studies were carried out with the formulation for representative uses and the metabolites IN-N5297; aminopyrimidine/IN-J0290; IN-F7880; bensulfuron (IN-R9419); IN-T5831 and IN-D1R84. The study with soil microorganisms with IN-N5297 was not conducted in full compliance with the OECD guideline 216. Nonetheless, a screening assessment assuming 10 times higher toxicity than bensulfuron methyl indicated low risk for soil organisms to this metabolite. Overall, based on the available information low risk for soil organisms to bensulfuron methyl and the relevant soil metabolites was concluded for all representative uses.

For the uses in cereals a revised exposure assessment was provided by the RMS after the experts' meeting, based on which a low risk to soil organisms was identified. For the uses in rice no risk assessment could be performed due to the lack of reliable exposure estimates (**issue not finalised**, see Section 4 and 9.1.1).

Effects on **non-target terrestrial plants** (NTTPs) were investigated in vegetative vigour and seedling emergence study designs with the formulation for representative uses. The seedling emergence study was discussed at the meeting,[27] where experts agreed on its use in risk assessment while highlighting uncertainties related to the species selection; statistical aspects of the endpoint derivation and overcrowding of seeds in the test units. Based on the available information, a low risk to NTTPs could only be concluded with mitigation measures comparable to a 5 m no-spray vegetated buffer zone or 75% drift reduction.

No concern was highlighted on the potential impacts on **biological methods for sewage treatment** of the representative uses of bensulfuron-methyl.

6 | ENDOCRINE DISRUPTION PROPERTIES

The endocrine disruption properties of bensulfuron methyl were discussed at the Pesticides Peer Review Joint Mammalian Toxicology-Ecotoxicology Experts' Teleconference (TC) 124 (22nd – 30th January 2024).

With regard to the assessment of the **human** endocrine disruption potential of bensulfuron-methyl for humans, according to the ECHA/EFSA ED Guidance (2018), in determining whether bensulfuron-methyl interacts with the oestrogen, androgen and steroidogenesis (EAS) and thyroid (T) mediated pathways, the number and type of effects induced and the magnitude and pattern of responses observed across studies were considered. Additionally, the conditions under which effects occur were considered, in particular, whether or not endocrine-related responses occurred at dose(s) that also resulted in overt toxicity. The assessment is therefore providing a weight-of-evidence analysis of the potential interaction of bensulfuron-methyl with the EAS- and T-signalling pathways using the available evidence in the data set.

For the **T modality**, T parameters were considered sufficiently investigated and a pattern of T-mediated adversity was not identified. Therefore, based on the available and sufficient dataset, it was concluded that the ED criteria are not met for the T modality (**Scenario 1a** of the ECHA/EFSA (2018) ED Guidance).

Regarding the **EAS-modalities**, EAS parameters were not sufficiently investigated and no EAS-mediated adversity was observed in the available dataset. Overall, since the endocrine activity was considered sufficiently investigated and negative there is no need for further investigation. Therefore, it was concluded that the ED criteria are not met for the EAS modalities (**Scenario 2a(ii)** of the ECHA/EFSA (2018) ED Guidance).

The outcome of the assessment reported above for humans also applies to **wild mammals as non-target organisms**.

For non-target organisms other than mammals, the valid and available fish short-term reproduction assay (FSTRA, OECD TG 229) and amphibian metamorphosis assay (AMA, OECD TG 231)[28] were considered negative and as such, a pattern of EATS-mediated endocrine activity was not identified in the available dataset.

Based on the available evidence, it can be concluded that bensulfuron-methyl is not an endocrine disruptor, according to point 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.

7 | OVERVIEW OF THE RISK ASSESSMENT OF COMPOUNDS LISTED IN RESIDUE DEFINITIONS TRIGGERING ASSESSMENT OF EFFECTS DATA FOR THE ENVIRONMENTAL COMPARTMENTS (TABLES 2–5)

Residue definitions triggering assessment for representative uses in rice fields is unknown, pending on flooded aerobic soil degradation and water/sediment studies to be provided. The rates of degradation in flooded conditions of the active substance and the potential metabolites are unknown. Therefore, the following tables apply **only** to the overview of risk

[27]See Expert's consultation points 5.6 at the Pesticide Peer Review Experts' TC 124–129 (January and February 2024), (EFSA, 2024).

[28]See point 5.7 of the report of the Peer-review meeting TC 124–129 for further information, (EFSA, 2024).

assessment of the representative use in **spring cereal fields**. In addition, for groundwater, surface water and sediment, the current assessment is based on reliable adsorption endpoints for bensulfuron-methyl only investigated in **alkaline soil conditions** and may need to be recalculated once new adsorption endpoints of bensulfuron-methyl are provided and the pH dependency on adsorption becomes clear (see further details in Section 4).

TABLE 2 Soil – Covering only spring cereal uses.

Compound (name and/or code)	Ecotoxicology
Bensulfuron-methyl	Low risk for soil organisms
Bensulfuron (IN-R9419)	Low risk for soil organisms
IN-D1R84	Low risk for soil organisms
IN-N5297	Low risk for soil organisms
Aminopyrimidine/IN-J0290	Low risk for soil organisms
IN-DAT97	Low risk for soil organisms

TABLE 3 Groundwater[a] – Covering only spring cereal uses.

Compound (name and/or code)	> 0.1 µg/L at 1 m depth for the representative uses[b] Step 2	Biological (pesticidal) activity/relevance Step 3a	Hazard identified Steps 3b. and 3c	Consumer RA triggered Steps 4 and 5	Human health relevance
Bensulfuron-methyl	Yes Spring cereals: 6/6 FOCUS scenarios (0.19–**0.94** µg/L)	Yes	–	Yes	Yes
Bensulfuron (IN-R9419)	Yes Spring cereals: 5/6 FOCUS scenarios (0.19–0.40 µg/L)	Data gap	Open No data for clastogenicity and aneugenicity	Open	Open
IN-D1R84	No	Assessment not triggered	Open No data available for genotoxicity and general toxicity	No	Open
IN-N5297	Yes Spring cereals: 5/6 FOCUS scenarios (0.17–0.32 µg/L)	Data gap	Open No data available for genotoxicity and general toxicity	Open	Open
Aminopyrimidine/IN-J0290	No	Assessment not triggered	Open No data for clastogenicity and aneugenicity	No	Open
IN-DAT97[c]	Yes Spring cereals: 6/6 FOCUS scenarios (**9.32**–**23.6** µg/L)	Data gap	Open No toxicological data/assessment available	Open	Open

[a]Assessment according to European Commission guidance of the relevance of groundwater metabolites (2003).

[b]FOCUS scenarios or relevant lysimeter. Ranges indicated for FOCUS scenarios include the result from the model giving the highest concentration at each scenario, as needed to comply with European Commission (2014a, 2014b) guidance.

[c]Triggering assessment in member states where anaerobic conditions cannot be excluded.

TABLE 4 Surface water and sediment[a] - Covering only spring cereal uses.

Compound (name and/or code)	Ecotoxicology
Bensulfuron-methyl	Low risk to aquatic organisms for the majority of the representative FOCUS surface water scenarios, but high risk for scenario D1 and D4
Bensulfuron (IN-R9419)	Low risk to aquatic organisms
IN-D1R84	Low risk to aquatic organisms
IN-N5297	Data gap for algae study
Aminopyrimidine/IN-J0290	Low risk to aquatic organisms
IN-DAT97[b]	Data gap for algae study
IN-T5831	Low risk to aquatic organisms
IN-YY142	Low risk to aquatic organisms

[a]Potential metabolites only formed in water/sediment systems are unknown (pending on the data gap for a water/sediment study, see Section 4).

[b]Triggering assessment in member states where anaerobic conditions cannot be excluded.

TABLE 5 Air.

Compound (name and/or code)	Toxicology
Bensulfuron-methyl	Rat LC_{50} inhalation > 7.5 mg/L for 4 h (nose-only)

8 | PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT BY RISK MANAGERS

Risk mitigation measures (RMMs) identified following consideration of Member State (MS) and/or applicant's proposal(s) during the peer review, if any, are presented in this section. These measures applicable for human health and/or the environment leading to a reduction of exposure levels of operators, workers, bystanders/residents, environmental compartments and/or non-target organisms for the representative uses are listed below. The list may also cover any RMMs as appropriate, leading to an acceptable level of risks for the respective non-target organisms.

It is noted that final decisions on the need of RMMs to ensure the safe use of the plant protection product containing the concerned active substance will be taken by risk managers during the decision-making phase. Consideration of the validity and appropriateness of the RMMs remains the responsibility of MSs at product authorisation, taking into account their specific agricultural, plant health and environmental conditions at national level.

8.1 | Particular conditions proposed for the representative uses evaluated (Table 6)

TABLE 6 Risk mitigation measures proposed for the representative uses assessed.

Representative use	Rice (pre-sowing, flooded) Spray	Rice (post-emergence, flooded) Spray	Rice (pre-sowing, saturated soil) Spray	Rice (post-emergence, saturated soil) Spray	Spring cereals Spray
Operator risk	–	–	–	–	–
Worker exposure	–	–	–	–	–
Bystander/resident exposure	–	–	–	–	–
Risk to aquatic organisms					RMM comparable to a 10 m no-spray buffer strip for three scenarios[a]
Risk to non-target terrestrial plants	RMM comparable to a 5 m no-spray vegetated buffer zone or 75% drift reduction				

[a]D3 (ditch); D5(stream); R4(stream).

9 | CONCERNS AND RELATED DATA GAPS

9.1 | Concerns and related data gaps for the representative uses evaluated

9.1.1 | 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 one or more of 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[29] 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.

The following issues or assessments that could not be finalised have been identified, together with the reasons including the associated data gaps where relevant, which are reported directly under the specific issue to which they are related:

[29]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. The **consumer risk assessment** is not finalised with regard to the unknown nature of residues that might be present in **drinking water**, consequent to water treatment following abstraction of surface water that might contain the active substance and its metabolites (see Sections 3 and 4).

   a. Further data and information were not available to demonstrate that residues of bensulfuron-methyl will have no immediate or delayed harmful effects on human health, including that of vulnerable groups or animal health, through drinking water (taking into account substances resulting from water treatment) (relevant to comply with the conditions of approval, not dependent of any specific use, see Section 4).

2. **Groundwater** exposure to the active substance and relevance assessment of metabolites (if any) for uses **on rice** could not be finalised:

   a. A reliable flooded aerobic soil degradation study for bensulfuron-methyl is missing. In consequence, the definition of residues triggering assessment in rice is unknown, as well as the required degradation endpoints for this substance and any metabolites that are formed, and their groundwater exposure (relevant for representative uses in rice fields, see Section 4).

3. **Groundwater** exposure and relevance assessment of **aerobic** soil metabolites for uses **on spring cereals** could not be finalised (and consequently the potential consumer risk assessment, see Section 3):

   a. Reliable adsorption endpoints for bensulfuron-methyl in two additional soils (including acidic soils) are missing. In consequence, PECgw for representative uses on spring cereals for metabolites in acidic soil conditions were unavailable. The leaching potential of metabolites that may occur under acidic conditions may be underestimated by the results at alkaline pH because of potential higher leaching of the active substance to deeper soil layers under alkaline soil conditions, where metabolite formation might be lower (relevant for representative uses in spring cereals, see Section 4).
   b. There is a need for a more refined groundwater exposure assessment for the metabolite IN-N5297. Information on the soil formation fraction of this metabolite would support a refined groundwater assessment (relevant for representative uses in spring cereals, see Section 4).
   c. Further assessment is needed for the toxicological profile of metabolites bensulfuron (IN-R9419) (clastogenicity and aneugenicity potential) and IN-N5297 (genotoxicity and general toxicity) (see Section 2).

4. **Groundwater** exposure and relevance assessment of **anaerobic** soil metabolites for uses **on spring cereals** could not be finalised:

   a. There is a need for a more refined groundwater exposure assessment for the anaerobic metabolite IN-DAT97. Information on the aerobic soil degradation rate and formation fraction of this metabolite would support a refined groundwater assessment (relevant for member states where anaerobic conditions cannot be excluded, see Section 4).
   b. Further assessment is needed for the toxicological profile of IN-DAT97 (genotoxicity and general toxicity), should the refined exposure assessment indicate the parametric value of 0.1 µg/L is exceeded (see Sections 2 and 3).

5. **Soil** and **surface water/sediment** exposure and risk assessment for non-target organisms (i.e. soil and aquatic organisms) for the uses on **rice** could not be finalised:

   a. A reliable flooded aerobic soil degradation study for bensulfuron-methyl is missing. In consequence, the definition of residues triggering assessment in rice is unknown, as well as the required degradation endpoints for this substance and any metabolites that are formed (relevant for representative uses in rice fields, see Section 4).
   b. Consequent to data gaps 5.a and 6.a, PECsoil, PECsw and PECsed for active substance and potential metabolites are not available (relevant for representative uses in rice fields, see Section 4).

6. **Surface water/sediment** exposure for **potential metabolites** only formed in these two compartments for the uses on **spring cereals** could not be finalised:

   a. A reliable water/sediment study for bensulfuron-methyl is missing. In consequence, PECsw/sed for potential metabolites only formed in water/sediment systems were unavailable (relevant for representative uses in spring cereals, see Section 4).

9.1.2 | 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.

The following critical areas of concern are identified, together with any associated data gaps, where relevant, which are reported directly under the specific critical area of concern to which they are related:

7. The potential for groundwater exposure by bensulfuron-methyl above the legal parametric drinking water limit of 0.1 μg/L is high over a wide range of geo-climatic conditions represented by 6 out of 6 of the modelled FOCUS groundwater scenarios for uses on spring cereals. Since groundwater exposure for bensulfuron-methyl for uses on rice could not be finalised, the current risk assessment does not permit the conclusion to be drawn, that at least one of the representative uses will not result in the legal parametric drinking water limit being exceeded. It cannot be excluded that the legal parametric drinking water is being exceeded also for the representative use in rice using current scientific and technical knowledge. (Considering the degradation rate in the available aerobic mineralisation study (DT_{50} ~ 500 days), when used as input for both paddy water and paddy soil in calculations, bensulfuron-methyl exceeds 0.1 μg/L in the less vulnerable MED-RICE clay scenario. In the more vulnerable MED-RICE sand scenario, to achieve a bensulfuron-methyl concentration below 0.1 μg/L, the aerobic DT_{50} needs to be less than 22.5 days).

9.1.3 | Overview of the concerns identified for each representative use considered (Table 7)

TABLE 7 Overview of concerns reflecting the issues not finalised, critical areas of concerns and the risks identified that may be applicable for some but not for all uses or risk assessment scenarios.

Representative use		Rice Pre-sowing flooded water	Rice BBCH 12–29 flooded water	Rice Pre-sowing saturated soil	Rice BBCH 12–29 saturated soil	Spring cereals (spring wheat, spring barley, oat, rye and triticale) BBCH 13–39
		Spray				
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[1]	x[1]	x[1]	x[1]	x[1]
Risk to wild non-target terrestrial vertebrates	Risk identified					
	Assessment not finalised					
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified					
	Assessment not finalised	X[5]	X[5]	X[5]	X[5]	
Risk to aquatic organisms	Risk identified					2/5 scenarios
	Assessment not finalised	X[5]	X[5]	X[5]	X[5]	
Groundwater exposure to active substance	Legal parametric value breached					X[7]
	Assessment not finalised	X[2,7]	X[2,7]	X[2,7]	X[2,7]	
Groundwater exposure to metabolites	Legal parametric value breached					
	Parametric value of 10 μg/L[a] breached					
	Assessment not finalised	X[2]	X[2]	X[2]	X[2]	X[3,4]

Notes: The superscript numbers relate to the numbered points indicated in Sections 9.1.1 and 9.1.2. Where there is no superscript number, see Sections 2–7 for further information.

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

10 | LIST OF OTHER OUTSTANDING ISSUES

Remaining data gaps not leading to critical areas of concern or issues not finalised but considered necessary to comply with the data requirements, and which are relevant for some or all of the representative uses assessed at EU level. Although not critical, these data gaps may lead to uncertainties in the assessment and are considered relevant.

These data gaps refer only to the representative uses assessed and are listed in the order of the sections:

- For two of the components of the formulation for representative uses 'Londax 60 BF, (HCG01)', in order to allow a final conclusion on the safety assessment of 'Londax 60 BF, (HCG01)', further information on these components in relation to their specifications/composition and repeated-dose toxicity information over the long-term might be considered for further assessment (to be confirmed by Member States when assessing applications for PPP authorisation; relevant for all representative uses evaluated; see Section 'Conclusions of the evaluation' under 'General aspects').
- Octanol water partition coefficient data for the metabolites IN-DAT97 and IN-YY142 were missing (relevant for all representative uses evaluated; see Section 1).
- Biological activity (herbicide screening data) for the groundwater metabolites IN-R9419, IN-N5297 and IN-DAT97 with a predicted groundwater concentration higher than 0.1 µg/L was unavailable (relevant for at least the representative uses evaluated on spring cereals; see Section 7).
- An analytical method for monitoring metabolite O-desmethyl bensulfuron-methyl (IN-F7880) in food and feed of animal origin (relevant for all representative uses evaluated; see Section 1).
- Toxicological data/information are missing to conclude on the relevance of one significant impurity present in the technical grade active ingredient (relevant for all representative uses evaluated; see Sections 1 and 2 and confidential evaluation table point 0.4)
- A literature review for the assessment of the toxicological relevance of groundwater metabolites is lacking; a literature review for the assessment of the genotoxicity and/or general toxicity of the residue metabolites is also lacking (for further details and the specific metabolites concerned, see data requirements 2.18 and 2.19 in the evaluation table Section 2 respectively).
- Bensulfuron-methyl was not phototoxic in the OECD 3T3 NRU-PT test. However, the OECD 3T3 NRU-PT might not allow concluding properly on the phototoxicity potential of bensulfuron-methyl since this test might not be suitable to test UVB absorbers such as bensulfuron-methyl. It is noted however that phototoxicity testing applying the OECD TG 498 test would allow for proper assessment of UVB absorbers as well (relevant for all representative uses evaluated; see Section 2).
- A scientifically based justification, considering the specific agricultural conditions of the GAP in rice with pre-sowing application, the environmental fate data applicable to saturated and/or flooded soil and the available data on metabolism in cereals, to address the expected metabolic pattern in rice with regard to the GAP with pre-sowing application (relevant for representative uses on rice with pre-sowing on flooded water and on saturated soil; see Section 3).
- A complete set of residue trials with application at growth stage of BBCH 12–29 to rice in the NEU zone in order to support the GAP requested for Hungary (relevant for representative uses on rice with at growth stage of BBCH 12–29 on flooded water and on saturated soil; see Section 3).
- A complete set of residue trials in NEU and SEU to support the proposed use on rice with pre-sowing application (relevant for representative uses on rice on flooded water and on saturated soil with pre-sowing application; see Section 3).
- Storage stability data for IN-N5297 in cereal straw and grain to support the storage period of the specimen of the current residue field trials (stability study is ongoing). (Relevant for representative uses on rice on flooded water and on saturated soil; see Section 3).
- Evidence is requested that residue composition in samples and sample extracts from the recent rotational crop metabolism study (KCA6.6.1/03) were not changing over the storage period of the specimen (relevant for all representative uses evaluated; see Section 3).
- Further assessment is needed for the toxicological profile (genotoxicity) of metabolites IN-F78184 (mutagenicity, clastogenicity and aneugenicity), IN-N8989 (clastogenicity and aneugenicity) and IN-B6895 (clastogenicity and aneugenicity) and IN-N5297 (clastogenicity and aneugenicity) (relevant for all representative uses; see Sections 2 and 3)
- A ruminant metabolism study with pyrimidyl-labelled bensulfuron-methyl or a study addressing the metabolism of the pyrimidyl-moiety part of bensulfuron-methyl is requested (relevant for all representative uses evaluated; see Section 3).
- An appropriate identification of the radioactivity of the two unidentified peaks (RT = 14min, R = 15 min) detected in the aqueous photolysis study (2003) was unavailable (relevant for all representative uses evaluated, see Evaluation Table for Section 4 (experts' consultation 4.6), (EFSA, 2024)).
- Reliable field dissipation studies for bensulfuron-methyl and the soil metabolites IN-N5297 and aminopyrimidine/IN-J0290 are needed, according to the results of laboratory incubations and the data requirements (relevant for the representative uses in spring cereal fields and other possible non rice uses, see Section 4).
- PEC gw, PECsw and PECsed for bensulfuron-methyl in acidic soil conditions are not available. The available PEC calculations for bensulfuron-methyl may only cover alkaline soil conditions and may need to be recalculated once new adsorption endpoints of bensulfuron-methyl for acidic soils are provided and the pH dependency on adsorption becomes clear

(pending on the data gap for reliable adsorption endpoints for bensulfuron-methyl in two additional (acidic) soils, see Section 9.1.1) (relevant for all representative uses evaluated, see Section 4).
- A valid study with algae should be provided for metabolites IN-N5297 (relevant for all representative uses evaluated; see Section 5) and IN-DAT97 (relevant for member states where anaerobic conditions cannot be excluded, see Sections 4 and 5).
- A study investigating sublethal effects to honeybees is needed (relevant for all representative uses evaluated; see Section 5).

ABBREVIATIONS

a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AMA	Amphibian Metamorphosis Assay
AOEL	acceptable operator exposure level
AOP	adverse outcome pathway
AP	alkaline phosphatase
AR	applied radioactivity
AR	androgen receptor
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming units
CI	confidence interval
CL	confidence limits
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DDD	daily dietary dose
DM	dry matter
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemicals Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
ERO	ecological recovery option
ETO	ecological threshold option
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	Time-weighted average factor
FAO	Food and Agriculture Organization of the United Nations
FID	flame ionisation detector
FIR	food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FSTRA	fish short-term reproduction assay
GAP	Good Agricultural Practice
GC	gas chromatography
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
HGPRT	hypoxanthine-guanine phosphoribosyl transferase

HPLC	high-pressure liquid chromatography or high-performance liquid chromatography
HPLC–MS	high-pressure liquid chromatography–mass spectrometry
HPG	hypopharygeal glands
HQ	hazard quotient
$HQ_{contact}$	hazard quotient for contact exposure
HR	hazard rate
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
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification
MCV	mean corpuscular volume
MOA	mode of action
MRL	maximum residue level
MS	mass spectrometry
MTD	maximum tolerated dose
NESTI	national estimated short-term intake
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NPD	nitrogen–phosphorus detector
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
PD	proportion of different food types
PEC	predicted environmental concentration
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure–activity relationship
r^2	coefficient of determination
RAC	regulatory acceptable concentration
RAR	Renewal Assessment Report
REACH	Registration, Evaluation, Authorisation of Chemicals Regulation
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SPG	specific protection goal
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TK	technical concentrate
TLV	threshold limit value
Tmax	time until peak blood levels achieved
ToxCAST	(US EPA) Toxicity Forecaster
TWA	time-weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor

UV ultraviolet
WG water-dispersible granule
WHO World Health Organization

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CONFLICT OF INTEREST
If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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APPENDIX A

Consideration of cut-off criteria for bensulfuron-methyl according to Annex II of Regulation (EC) No 1107/2009 of the European Parliament and of the Council

Properties		Conclusion[a]
CMR	**Carcinogenicity (C)**	Bensulfuron-methyl is not classified as carcinogen category 1A or 1B from Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process (Table 4.1 of Annex VI of Regulation (EC) No 1272/2008 as amended): CLP 00
	Mutagenicity (M)	Bensulfuron-methyl is not classified as mutagen category 1A or 1B from Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process (Table 4.1 of Annex VI of Regulation (EC) No 1272/2008 as amended): CLP 00
	Toxic for Reproduction (R)	Bensulfuron-methyl is not classified as toxic for reproduction category 1A or 1B from Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process (Table 4.1 of Annex VI of Regulation (EC) No 1272/2008 as amended): CLP 00
Endocrine disrupting properties		Bensulfuron-methyl is not considered to meet the criteria for endocrine disruption for humans and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II of Regulation No 1107/2009, as amended by Commission Regulation (EU) 2018/605
POP	**Persistence** **Bioaccumulation** **Long-range transport**	Bensulfuron-methyl is not considered to be a persistent organic pollutant (POP) according to point 3.7.1 of Annex II of Regulation (EC) 1107/2009
PBT	**Persistence** **Bioaccumulation** **Toxicity**	Bensulfuron-methyl is not considered to be a persistent, bioaccumulative and toxic (PBT) substance according to point 3.7.2 of Annex II of Regulation (EC) 1107/2009
vPvB	**Persistence** **Bioaccumulation**	Bensulfuron-methyl is not considered to be a very persistent, very bioaccumulative substance according to point 3.7.3 of Annex II of Regulation (EC) 1107/2009

[a]Origin of data to be included where applicable (e.g. EFSA, ECHA RAC, Regulation).

APPENDIX B

List of end points for the active substance and the formulation for representative uses

Appendix B can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2024.8999

APPENDIX C

Wording EFSA used in Section 4 of this conclusion, in relation to DT and Koc 'classes' exhibited by each compound assessed

Wording	DT_{50} normalised to 20°C for laboratory incubations[30] or not normalised DT_{50} for field studies (SFO equivalent, when biphasic, the DT_{90} was divided by 3.32 to estimate the DT50 when deciding on the wording to use)
Very low persistence	< 1 day
Low persistence	1–< 10 days
Moderate persistence	10–< 60 days
Medium persistence	60–< 100 days
High persistence	100 days to < 1 year
Very high persistence	A year or more

Note: These classes and descriptions are unrelated to any persistence class associated with the active substance cut-off criteria in Annex II of Regulation (EC) No 1107/2009. For consideration made in relation to Annex II, see Appendix A.

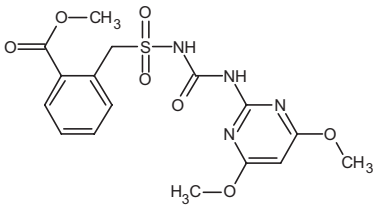
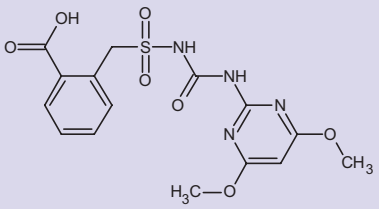
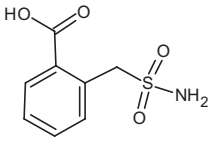
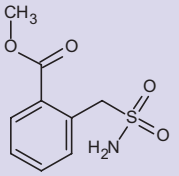
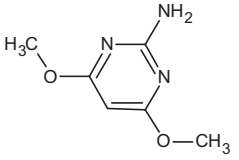
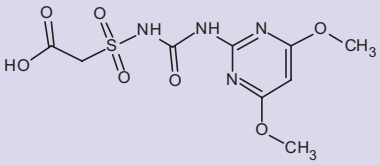
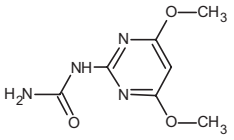
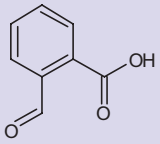
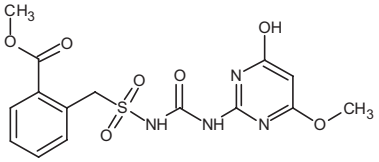
Wording	K_{oc} (either K_{Foc} or K_{doc}) mL/g
Very high mobility	0–50
High mobility	51–150
Medium mobility	151–500
Low mobility	501–2000
Slight mobility	2001–5000
Immobile	> 5000

Note: Based on McCall et al. (1980).

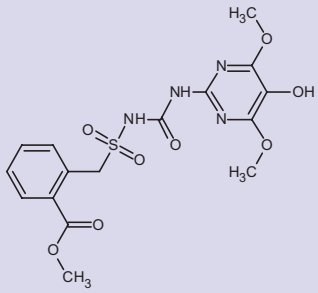
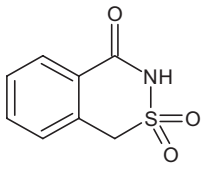
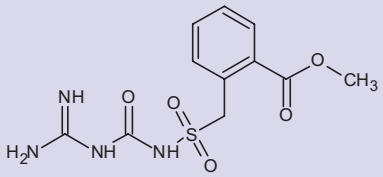
[30] For laboratory soil incubations normalisation was also to field capacity soil moisture (pF2/10 kPa). For laboratory sediment water system incubations, the whole system DT values were used.

APPENDIX D

Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Bensulfuron-methyl	methyl 2-({[[(4,6-dimethoxypyrimidin-2-yl)carbamoyl] sulfamoyl}methyl)benzoate O=C(Nc1nc(cc(OC)n1)OC)NS(=O)(=O)Cc1ccccc1C(=O)OC XMQFTWRPUQYINF-UHFFFAOYSA-N	
Bensulfuron (IN-R9419)	2-({[[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl} methyl)benzoic acid O=C(Nc1nc(cc(OC)n1)OC)NS(=O)(=O)Cc1ccccc1C(=O)O PPWBRCCBKOWDNB-UHFFFAOYSA-N	
IN-D1R84	2-(sulfamoylmethyl)benzoic acid O=S(N)(=O)Cc1ccccc1C(=O)O KBNYDFWKRBLDRQ-UHFFFAOYSA-N	
IN-N5297	methyl 2-(sulfamoylmethyl)benzoate O=S(N)(=O)Cc1ccccc1C(=O)OC DBOUFTHAEAVMJC-UHFFFAOYSA-N	
Aminopyrimidine, IN-J0290 (AEF092944, Hoe 092944, A-ADMP IN-J290, IN-J90-17, IN-J290-17, ADMP, SSRE-002, BCS-AA25052, AP, BCS-AA25052, CP 17477)	4,6-dimethoxypyrimidin-2-amine COc1cc(OC)nc(N)n1 LVFRCHIUUKWBLR-UHFFFAOYSA-N	
IN-DAT97	{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}acetic acid O=C(Nc1nc(cc(OC)n1)OC)NS(=O)(=O)CC(=O)O JGCJQNVBSXPBTM-UHFFFAOYSA-N	
IN-T5831 (DMPU, SSRE-003, AEF099095, UDPM, BCS-AB40283, IR7825, DOP urea, CP 240483)	1-(4,6-dimethoxypyrimidin-2-yl)urea O=C(N)Nc1nc(cc(OC)n1)OC BNOVYBVKWYHEMQ-UHFFFAOYSA-N	
IN-YY142	2-formylbenzoic acid OC(=O)c1ccccc1C=O DYNFCHNNOHNJFG-UHFFFAOYSA-N	
IN-F7880	methyl 2-({[[(4-hydroxy-6-methoxypyrimidin-2-yl)carbamoyl] sulfamoyl}methyl)benzoate O=C(Nc1nc(O)cc(OC)n1)NS(=O)(=O)Cc1ccccc1C(=O)OC YUXVFHAQFIJDOL-UHFFFAOYSA-N	

(Continued)

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
IN-N8989	methyl 2-({[(5-hydroxy-4,6-dimethoxypyrimidin-2-yl) carbamoyl]sulfamoyl}methyl)benzoate O=C(Nc1nc(OC)c(O)c(OC)n1)NS(=O)(=O)Cc1ccccc1C(=O)OC DALVUZRRYITKRP-UHFFFAOYSA-N	
IN- B6895	1*H*-2,3-benzothiazin-4(3H)-one 2,2-dioxide O=C1NS(=O)(=O)Cc2ccccc21 UYXCSOAMZMOWRY-UHFFFAOYSA-N	
IN-F78184	methyl 2-{[(carbamimidoylcarbamoyl)sulfamoyl]methyl} benzoate O=S(=O)(Cc1ccccc1C(=O)OC)NC(=O)NC(=N)N SVDMGUDDCUQUPY-UHFFFAOYSA-N	

[a]The name in bold is the name used in the conclusion. Name codes in brackets refer to common metabolites from other sulfonylureas active substances (see also Appendix B).

[b]ACD/Name 2021.1.3. ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 7 July 2021).

[c]ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 29 August 2021).