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CONCLUSION ON PESTICIDES PEER REVIEW

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

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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, Finland, and co-rapporteur Member State, Croatia, for the pesticide active substance amidosulfuron and the assessment of confirmatory data following the Article 12 MRL review 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 amidosulfuron as a post-emergence herbicide on winter cereals, spring cereals, flax and grass/pasture (all field uses). The reliable end points, appropriate for use in regulatory risk assessment are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are reported where identified.

KEYWORDS

amidosulfuron, Article 12 confirmatory data, 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. Amidosulfuron is one of the active substances listed in Regulation (EU) No 686/2012.

In accordance with Article 1 of Regulation (EU) No 844/2012, the rapporteur Member State (RMS), Finland, and co-rapporteur Member State (co-RMS), Croatia, received an application from Bayer AG for the renewal of approval of the active substance amidosulfuron. In addition, Bayer AG submitted an application for the assessment of confirmatory data following the Article 12 MRL review.

An initial evaluation of the dossier on amidosulfuron 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 amidosulfuron according to the representative uses as field spray application for the control of annual broad-leaved weeds in winter and spring cereals, flax and grass/pasture as proposed at EU level result in a sufficient herbicidal efficacy against the target weeds.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the **identity, physical, chemical and technical properties** of amidosulfuron or the representative formulation and analytical methods. A new relevant impurity has been identified that requires to be specified with a maximum content of 0.0036 g/kg. It should be noted that the levels of this impurity in the representative batches were above this level.

In the area of **mammalian toxicology**, certain issues were identified that could not be finalised. Specifically, it has not been demonstrated that the technical specification is covered by the batches used in the toxicological studies. The comparative in vitro metabolism has not been addressed.

With respect to the **residues** in food and feed, the consumer dietary risk assessment is considered not finalised due to data gaps identified with respect to unprocessed and processed animal matrices and the lack of toxicological data of the metabolites N-{[(5-hydroxy-4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-N-methylmethanesulfonamide and AE F128721 potentially formed under drinking water treatments chlorination processes. Only a tentative consumer's risk assessment is presented in Appendix B. The methods provided in the dossier allow to monitor amidosulfuron in food and feed of plant and animal origin in all representative commodities, including dry commodities (cereals). Therefore, the confirmatory data required in the MRL review (EFSA, 2014a) has been addressed.

The data available on **environmental fate and behaviour** are sufficient to carry out the required environmental exposure assessments at EU level for the representative uses, with the notable exception that a data gap was identified for information on the effect of water treatment processes via chlorination on the nature of residues potentially present in surface water and groundwater (e.g. metabolites N-{[(5-hydroxy-4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-N-methylmethanesulfonamide and AE F128721), when surface water and groundwater are abstracted for the production of drinking water. This data gap leads to the consumer risk assessment from the consumption of drinking water being not finalised for all the representative uses.

The assessment of the data package revealed no issues that could not be finalised or that need to be included as critical areas of concern with respect to **ecotoxicology** section.

With regard to the assessment of the **endocrine disruption (ED) properties**, based on the available data and assessment, it can be concluded that amidosulfuron does not meet the ED criteria for humans and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605. Although further confirmation is needed regarding the conclusion for the T-modality in non-mammalian species, based on the available data, it is unlikely that amidosulfuron is an endocrine disruptor.

BACKGROUND

Commission Implementing Regulation (EU) No 844/2012,[1] as amended by Commission Implementing Regulation (EU) No 2018/1659,[2] (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.[3] 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, Finland, and co-RMS, Croatia, received an application from Bayer AG for the renewal of approval of the active substance amidosulfuron. In addition, Bayer AG submitted an application for the assessment of confirmatory data following the Article 12 MRL review of Regulation (EC) No 396/2005.[4] Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Croatia), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on amidosulfuron in the RAR, which was received by EFSA on 31 October 2018 (Finland, 2018). The RAR included a proposal to set MRLs, submitted under Article 7 of Regulation (EC) No 396/2005.

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Bayer AG, for consultation and comments on 21 January 2019. 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 31 March 2019. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of a reporting table. The applicant was invited to respond to the comments in column 3 of the reporting table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for experts' 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 telephone conference between EFSA, the RMS on 16 May 2019. 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 telephone conference, together with EFSA's further consideration of the comments, is reflected in the conclusions set out in column 4 of the reporting table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in an expert consultation, were compiled by EFSA in the format of an evaluation table.

In addition, following a consultation with Member States in the Pesticides Peer Review Experts' meeting PREV 18 and 21 (November 2019), it was considered necessary to apply an additional clock stop of 30 months in accordance with Commission Implementing Regulation (EU) No 2018/1659, to be able to conclude whether the approval criteria for endocrine disruption in line with the scientific criteria for the determination of endocrine-disrupting properties, as laid down in Commission Regulation (EU) 2018/605,[5] are met.

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, and on confirmatory data following the MRL review under Article 12 of Regulation (EC) No 396/2005 took place with Member States via a written procedure in April 2023.

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

[2]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.

[3]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.

[4]Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

[5]Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the representative formulation, evaluated on the basis of the representative uses of amidosulfuron as a herbicide as a post-emergence herbicide on winter cereals, spring cereals, flax and grass/pasture (all field uses) 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. Confirmatory data following the MRL review under Article 12 MRL of Regulation (EC) No 396/2005 were evaluated.

A list of the relevant end points for the active substance and the formulation and the assessment of confirmatory data following the Article 12 MRL review are provided in Appendix B. In addition, the considerations as regards the cut-off criteria for amidosulfuron according to Annex II of Regulation (EC) No 1107/2009 are summarised in Appendix A.

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:

- the comments received on the RAR;
- the reporting table (16 May 2019 and 24 April 2023[6]);
- the evaluation table (27 June 2024);
- the report(s) 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 (Finland, 2023), 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

Amidosulfuron is the ISO common name for *N*-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-*N*-methylmethanesulfonamide (IUPAC).

The formulation for representative uses was 'Amidosulfuron WG 75', a water dispersible granule (WG) containing 750 g/kg amidosulfuron.

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;[7] however, one of the co-formulants of 'Amidosulfuron WG 75' is a currently approved active substance under Regulation (EC) 1107/2009.[8] 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 were applications by ground boom sprayer for the control of annual broad-leaved weeds in winter and spring cereals, flax and grass/pasture (all field uses) in the EU. Full details of the GAPs can be found in the list of end points in Appendix B.

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

[6]Reporting table following consultation on the revised RAR on the assessment of the endocrine-disrupting properties made available after the clock stop applied in accordance with Commission Regulation (EU) No 2018/1659.

[7]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.

[8]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

CONCLUSIONS OF THE EVALUATION

General aspects

With regard to the mammalian toxicity information available for the formulation for representative uses 'Amidosulfuron WG 75', studies were performed for acute toxicity endpoints. With regard to the co-formulants contained in 'Amidosulfuron WG 75', sufficient toxicological data were available for all components, but one (present in significant amount in the final formulation). For this co-formulant, EFSA considered that insufficient information about its specification/composition was available and the available toxicological information did not sufficiently address the repeated dose toxicity potential of 'Amidosulfuron WG 75' over long-term exposure and might be considered for further assessment. 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 (see Section 10).

Regarding ecotoxicology, suitable ecotoxicity data with the formulation for representative uses were available for the assessment of non-target organisms according to the requirements of Regulation (EU) No 284/2013.[9] Acute toxicity data with the formulation for representative uses were available with all groups of organisms. No chronic data with the formulation for representative uses were available with the exception of aquatic invertebrates, algae, aquatic plants, bees, earthworms and soil macroorganisms. Based on the available toxicity data, it is noted that the formulation for representative uses is not more toxic than the active substance. For those groups of organisms for which chronic data were not available, available data for the individual components of the formulation for representative uses were retrieved. Data on single components were limited[10] with the exception of one of the components. Pending on the outcome on identified missing data for toxicology for one of the components in the formulation for representative uses, further consideration to non-target organisms may be necessary.

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

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

The minimum purity of amidosulfuron technical material is 980 g/kg. The proposed specification is based on batch data from industrial scale production and on quality control (QC) data to support the specification for the impurities. 1,2-dichloroethane was considered a new relevant impurity (not included in the current reference specification) with a maximum level of 0.0036 g/kg (see Section 2). It should be noted that the levels of this impurity in the representative batches were above this level. In addition, the toxicological relevance of one impurity could not be concluded (see Section 2), and as a consequence, new data such as spectral data, content of the impurities before and after the storage of the formulation and methods for analysis of the relevant impurities in the formulation might be required. Considering the data submitted on the renewal, the changes in the minimum purity, the impurity profile and the identification of a new relevant impurity, it is proposed to update the reference specification to the specification proposed by the RMS. The batches used in the (eco)toxicological assessment do not support the current reference and the newly proposed reference specification (see Sections 2 and 5). An FAO specification does not exist for the active substance.

The main data regarding the identity of amidosulfuron and its physical and chemical properties are given in Appendix B.

Adequate analytical methods were available for the generation of data required for the risk assessment expect for the analytical method used in the rat developmental toxicity study, for which no validation data were provided (**data gap**, see Section 10). Methods of analysis are available for the determination of amidosulfuron in the technical material and in the representative formulation. A data gap for validated methods for analysis of the relevant impurity in the technical material and in the formulation with LOQs suitable for the proposed max level of 0.0036 g/kg is identified.

Amidosulfuron can be monitored in food and feed of plant and animal origin with high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) with limit of quantification (LOQ) of 0.01 mg/kg in all representative commodities. Pending on the final residue definition for monitoring in food and feed of animal origin, additional analytical methods might be required.

Amidosulfuron residues in soil can be monitored using HPLC–MS/MS with an LOQ of 1 µg/kg. An appropriate HPLC–MS/MS method with an LOQ of 0.05 µg/L exists for monitoring amidosulfuron in surface water. A **data gap** was identified for monitoring method for the determination of the components of the residue definition for drinking water (see Section 10). Residues of amidosulfuron in air can be monitored by HPLC-UV with an LOQ of 1 µg/m^3.

An HPLC–MS/MS method was submitted for the determination of amidosulfuron and desmethyl-amidosulfuron (AE F101630) in body tissues with an LOQ 0.01 mg/kg for each analyte and for the determination of amidosulfuron in body fluids with an LOQ 50 µg/L. A data gap was identified for monitoring method for the determination of desmethyl-amidosulfuron (AE F101630) in body fluids (see Section 10).

[9]Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with 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 93, 3.4.2013, p. 85–152.

[10]Studies were not evaluated for the current assessment.

2 | MAMMALIAN TOXICITY

The toxicological profile of the active substance amidosulfuron was discussed at the Pesticides Peer Review Experts' Meeting PREV 18 (4–8 November 2019) based on the following guidance documents: European Commission (2003, 2012), EFSA (2014b), EFSA PPR Panel (2012), ECHA (2017) and draft Technical Guidance Document on assessment of negligible exposure (European Commission, 2015).

Regarding the proposed **reference specification,** the impurity 1,2-dichloroethane is identified as toxicologically relevant (Carcinogenic 1B). Applying the lowest TTC value of 0.0025 µg/kg bw per day (for genotoxic compounds), and considering the exposure at the ADI, the maximum acceptable level from the toxicological point of view is 0.0036 g/kg. For one impurity, the toxicological relevance could not be concluded on the basis of the available data (**data gap**). The batches used in toxicity studies are not fully representative of the original and newly proposed reference specification for the active substance and associated impurities (see Sections 1 and 9.1).

The analytical methods for the generation of pre-approval data required for the risk assessment were considered adequate except for the rat developmental toxicity study (**data gap**, see Sections 1 and 10).

In the toxicokinetic studies in rats, amidosulfuron was well **absorbed** after oral administration (> 80% based on urine and cage wash, no data on biliary excretion). The calculated bioavailability is 95.2% based on the oral/intravenous study. Amidosulfuron is widely distributed with no evidence of bioaccumulation, poorly metabolised and rapidly and extensively excreted mainly via urine. Insufficient data were provided for comparative in vitro metabolism (see Section 9.1). The residue definition for body fluids and tissues should include amidosulfuron and desmethyl amidosulfuron for the purpose of human biomonitoring.

Amidosulfuron has low acute toxicity when administered orally, dermally and by inhalation to rats and moderate acute toxicity via intraperitoneal route. The active substance is neither a skin or eye irritant nor a skin sensitiser. In the maximisation test, amidosulfuron showed non-sensitising potential. Since amidosulfuron is an UVB absorber, a new OECD 3T3 NRU-PT test may be suitable to conclude on its phototoxicity potential, with use of appropriate UVB filters and UVB absorbing compound as positive control (data gap, see Section 10).

In the short-term oral toxicity studies, the target organ was the liver in rats whereas no adverse effects were observed at the highest dose in mouse studies. In the 1-year dog study, the critical effects observed were changes in clinical chemistry and urinalysis, with a relevant oral NOAEL of 66.4 mg/kg bw per day.

Regarding the **genotoxicity potential** of amidosulfuron, available in vitro studies were negative, with the chromosome aberration test considered not acceptable. An in vivo micronucleus test was negative in mice. Despite some uncertainties for this last test (no bone marrow toxicity, short exposure duration of the bone marrow), the majority of the experts agreed that the active substance was sufficiently investigated and was unlikely to be genotoxic. The RMS disagreed.[11] Photomutagenicity testing is not required.

In **long-term** dietary studies, the most sensitive finding was the decreased body weight gain in the 2-year rat study with a relevant long-term NOAEL of 495.42 mg/kg bw per day. In mice, no adverse effects were observed at the highest dose level tested. No carcinogenic effects were observed in both species. Amidosulfuron is concluded as unlikely to be carcinogenic.

Regarding the **reproductive** toxicity studies, no adverse effects were observed in the dams and offspring in a rat two-generation study. The agreed parental, reproductive and offspring NOAEL is 568 mg/kg bw per day (highest dose tested). Based on developmental toxicity studies in rats and in rabbits, no treatment-related effects were observed for dams and for pups. The relevant maternal and developmental NOAEL is up to 1000 mg/kg bw per day in rats and in rabbits. There was no teratogenic effect observed in both species.

Amidosulfuron is not expected to be **neurotoxic** based on the available data and its chemical structure.

The acceptable daily intake (**ADI**) and acceptable operator exposure level (**AOEL**) are 0.7 mg/kg bw per day based on the 1-year dog study. An uncertainty factor (UF) of 100 was applied to the relevant NOAEL, and no correction for oral absorption. Based on the low toxicity profile of amidosulfuron, the experts agreed that the acute reference dose (**ARfD**) and acute acceptable operator exposure level (**AAOEL**) are not necessary. The previous toxicological reference values were: ADI 0.2 mg/kg bw per day based on the two-generation study (UF of 100) and AOEL 1.4 mg/kg bw per day based on the 3-month dog study together with the 1-year dog study (UF of 100); and no ArfD was allocated (European Commission, 2008).

Dermal absorption studies were not performed with the representative formulation 'Amidosulfuron WG 75'; therefore, the default **dermal absorption** values of 25% for the concentrate and 75% for the spray dilution apply (EFSA PPR Panel, 2012). With the EFSA calculator, the **non-dietary exposure** estimates for operators, workers, bystanders and residents for the representative uses in cereals and grasslands are below the AOEL without the use of risk mitigation measures (such as PPE for operators and workers).

With regard to the metabolites identified in plant metabolism and processed commodities (see Section 3), **amidosulfuron-desmethyl** being a major rat metabolite is considered covered by the parent compound. For the metabolite **amidosulfuron-guanidine**, an ADI of 0.8 mg/kg bw per day was derived on the basis of a 28-day rat study and applying an UF of 1000. EFSA notes that a data gap was identified due to the lack of investigations of the aneugenicity of the compound (data gap, see Section 10).[12] According to the latest scientific state of the art (EFSA Scientific Committee, 2021), the derivation of reference values could be affected by the conclusion on aneugenicity. However, this has not been

[11]Refer to experts' consultation 2.6 in the Report of Pesticides Peer Review Meeting 192 (EFSA, 2024).

[12]Refer to experts' consultation 2.13 in the Report of the Pesticides Peer Review Experts' Meeting 18 in November 2019 (EFSA, 2024).

discussed during the peer review of Amidosulfuron since the EFSA Scientific Opinion on the guidance on aneugenicity assessment (2021) was not available at the time of the dossier submission. For the metabolite **aminopyrimidine**, aneugenicity and clastogenicity could not be concluded and no data for repeat dose toxicity were provided (**data gap**, see Section 10 and 3). For the metabolite **amidosulfuron sulfamic acid**, no toxicological data were reported (**data gap**, see Sections 10 and 3).

With regard to the additional metabolites identified in groundwater, it was concluded that **amidosulfuron-desmethyl chloropyrimidine** has no genotoxic potential and is not toxicologically relevant (see Table 2). For **amidosulfuron biuret** and **amidosulfuron ADHP**, a **data gap** has been identified for aneugenicity. In particular, the aneugenicity has not been addressed according to the latest state of the art since the revised guidance on the assessment of the relevance of metabolites in groundwater (European Commission, 2021), including the assessment of aneugenicity, was not available/implemented during the peer review of amidosulfuron (**data gap**, see Section 10). Therefore, on the basis of the available data and applicable guidance during the peer review (European Commission, 2003), these two metabolites can be considered as not toxicologically relevant. For the metabolites **AE F128721** and N-{[(5-hydroxy-4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-N-methylmethanesulfonamide, potentially formed during processing of drinking water with chlorine-based reagents, no toxicological assessment has been provided (see Section 9.1).

3 | RESIDUES

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

Amidosulfuron was discussed by the experts in residues in Pesticide Peer Review Meeting 20 (November 2019).

3.1 | Representative use residues

The plant metabolism of radiolabelled amidosulfuron has been investigated in wheat and linseed under appropriate conditions to reflect the supported representative uses (cereals, oilseed–flax and grass). Two additional studies on wheat and potatoes are available but considered only as supportive information. The compound is extensively metabolised and amidosulfuron represents only 10% of the total radioactive residues (TRR) in plant after 2 weeks. The metabolic pathway consists in demethylation of the pyrimidine ring leading to the metabolite desmethyl-amidosulfuron (AE F101630) and subsequent hydrolysis to the metabolite amidosulfuron guanidine (BCS-CO41839).

As residues of compounds structurally related to the active substance are extremely low in commodities used for human consumption, the **residue definitions** in **plant** food items for **risk assessment** are proposed by default as amidosulfuron (restricted to foliar use on cereals and oilseeds). Considering that there is a significant exposure of ruminants to metabolite desmethyl-amidosulfuron (AE F101630) through consumption of treated pasture or hay, the **residue definition for risk assessment** in **feed** items (grass, cereal forage/straw) is proposed as the sum of amidosulfuron and its metabolite desmethyl-amidosulfuron (AE F101630), expressed as amidosulfuron. As concluded by the toxicological evaluation, the same toxicological reference values are applicable to amidosulfuron and to the metabolite desmethyl-amidosulfuron (AE F101630) (see Section 2). For **monitoring and enforcement**, the residue definition is proposed as amidosulfuron by default both for food and feed items. Residue definitions are applicable only to cereals (and pulses) and oilseeds via foliar treatment only and should be confirmed subsequently on the identification of two major metabolites in rotational crops (see below). If, in the future, additional uses on different crop categories are intended, metabolism data on a third crop group will be required.

It is noted that, in the reasoned opinion of the review of the existing MRL (EFSA, 2014a), the inclusion of the metabolite amidosulfuron-guanidine (BCS-CO41839) in the residue definition for risk assessment of feed was proposed. This proposal is not confirmed by the peer review, based on levels found in supervised residue trials and the lower toxicity of this metabolite with respect to parent and desmethyl-amidosulfuron (AE F101630).

A sufficient number of supervised residue trials were conducted supporting all representative uses. Numerous magnitude residue trials were also conducted in pasture/meadow and grassland for post application intervals of relevance. Results of these trials were used for derivation of livestock dietary burden intake (see Appendix B). The reliability of these residue trials is supported by storage stability studies.

From available processing studies, amidosulfuron was totally degraded into aminopyrimidine (AE F092944 or ADMP) (79.6%–99.5% AR) for all processing procedures and into BCS-AW41401 (amidosulfuron sulfamic acid) (19.6% AR) at pasteurisation. Toxicity data are limited or not available for any of these compounds. Based on the calculated dietary burden, residue levels of amidosulfuron and desmethyl-amidosulfuron are expected in milk and in other edible food of animal origin. Processing residue trials with aminopyrimidine and amidosulfuron-sulfamic acid in milk and other animal matrices under all standard processing conditions are therefore required (data gap, see Section 9.1). Pending upon the outcome of these residue trials and whether quantifiable residues are observed for these metabolites, an appropriate toxicological data set for aminopyrimidine and amidosulfuron-sulfamic acid will have to be provided. Currently, the residue definitions for monitoring and risk assessment remain open for processed commodities.

Persistence in soil of amidosulfuron and several of its soil metabolites does not allow to exclude the potential build-up of residues in rotational crops. Metabolism in rotational crops with soil applied amidosulfuron (1.4 N when compared to the cereal GAP) are available. Metabolism at PBI 30 days was evaluated in potatoes (root and tuber crops) and in wheat (cereals). In addition to wheat, carrots and cabbage were studied at PBI of 150 days, and carrots and spinach at PBI of 365 days. Trials in leafy crops (spinach) were only successful at the long PBIs of 365 days due to phytotoxicity. Thus, minimum 365-day rotation limitation for leafy crops is proposed. The results demonstrate that no residues above 0.01 mg/kg are expected in rotational edible crop parts and no MRL is required for rotational crops. However, cereal straw (dry), contained two metabolites, at levels above 0.01 mg/kg: 0.013 and 0.026 mg/kg (21% and 41% of TRR) at PBI of 30 days, respectively. The identity of these metabolites was not clarified. Further identification of the residues in cereal straw and husks is needed for metabolites exceeding 0.01 mg/kg (both > 20% of TRR), and possibly field trials to confirm the residue levels (data gap, see Section 9.1).

A significant exposure of livestock (ruminants) to the parent and its main metabolite desmethyl-amidosulfuron (AE F101630) may be expected through feed items. Metabolism studies of amidosulfuron in lactating goats and laying hens are available and adequate to conclude on the nature of the residues in animal commodities. No metabolism study is available for desmethyl-amidosulfuron (AE F101630) and no information can be deduced from the metabolism study with the parent compound as it is not produced from amidosulfuron in the goat metabolism (**data gap**, see Section 9.1). Therefore, the proposed **residue definition in animal commodities for risk assessment** as the sum of amidosulfuron and desmethyl-amidosulfuron (AE F101630), expressed as amidosulfuron cannot be confirmed pending on the information needed with respect to residues in rotational crops feed items and desmethyl-amido sulfuron ruminants' metabolism. For **monitoring and enforcement of food of animal origin**, the residue definition in animal matrices is proposed as amidosulfuron by default pending the information on the metabolism of desmethyl-amidosulfuron (AE F101630) and the identification of the metabolites in husk and straw in rotational crops.

In a feeding study in goat, amidosulfuron was found in kidney at the lower dose and in kidney, liver, milk and fat at the higher dose. No feeding study is required in poultry according to dietary burden calculations.

Amidosulfuron is not a fat-soluble substance and metabolism in fish is not triggered.

Cereals and rye grass for forage and silage have no melliferous capacity (European Commission, 2018). Therefore, the MRL in honey for the uses on cereals and grass is set by default at 0.05mg/kg. Concerning the use on flax, the application time (BBCH 49) is before flowering and very low residues in seed and straw were observed at harvest. Consequently, the MRL in honey for the intended use in flax is also proposed at 0.05mg/kg.

Consumer dietary risk assessment is considered not finalised due to data gaps identified with respect to unprocessed and processed animal matrices and the lack of toxicological data on the metabolite N-{[(5-hydroxy-4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-N-methylmethanesulfonamide and AE F128721 potentially formed under drinking water treatments chlorination processes (see Sections 4, 2 and 9.1). A tentative consumer's risk assessment is presented in Appendix B without considering the uncertainty associated with these data gaps. Tentative theoretical maximum daily intake (TMDI) calculations with PRIMo revision 3.1 have been presented and the resulting calculated TMDI amounted to 0.3% of the ADI (NL toddler, highest contributor: cattle milk).

Acute exposure assessments were not conducted as no ARfD is necessary for amidosulfuron. Calculated MRLs (based on the data evaluated in the present RAR) are lower than currently set MRLs. No change in the current MRLs is considered necessary.

3.2 | Confirmatory data MRL review

In EFSA (2014a), the need for a confirmatory analytical method for enforcement in dry commodities was identified. Methods provided with the renewal dossier allow to monitor amidosulfuron in food and feed of plant and animal origin in all representative commodities (see Section 1), which include dry commodities (cereals). Therefore, the confirmatory data required in the MRL review have been satisfactorily addressed.

4 | ENVIRONMENTAL FATE AND BEHAVIOUR

Amidosulfuron was discussed at the Pesticides Peer Review Experts' Meeting PREV 19 (11–14 November 2019).

The rates of dissipation and degradation in the environmental matrices investigated were estimated using FOCUS (2006) kinetics guidance. In soil laboratory incubations under aerobic conditions in the dark, amidosulfuron exhibited low to medium persistence, forming the major (> 10% applied radioactivity (AR)) metabolites **amidosulfuron-desmethyl** (AE F101630; max. 49.6% AR; low to moderate persistence in soil), **amidosulfuron-guanidine** (BCS-CO41839; max. 38.6% AR; high to very high persistence in soil) and **amidosulfuron-desmethyl-chloropyrimidine** (BCS-CO41838, max. occurrence 12.2% AR; moderate to high persistence in soil). Other metabolites triggering an environmental exposure assessment were **amidosulfuron-biuret** (BCS-CQ51287; max. occurrence 6.3% AR; moderate persistence in soil) and **aminopyrimidine** (AE F092944 or ADMP; max. occurrence 9.9% AR; low to high persistence in soil). Mineralisation of the pyrimidyl ring ^{14}C radiolabel to carbon dioxide accounted for 12%–43% AR after 100–120 days. The formation of unextractable residues for this radiolabel accounted for 17%–30% AR after 100–120 days. In anaerobic soil incubations, amidosulfuron was essentially stable, forming the major metabolite amidosulfuron-desmethyl (AE F101630; max. 14.5% AR), and the novel metabolite

compared to aerobic conditions **amidosulfuron-ADHP** (AE F094206, max 10.9% AR at 90 days). It should be noted, however, that such prolonged (i.e. 90 days) anaerobic conditions in soil are unlikely to occur even under representative use on winter cereals. Consequently, the formation of metabolite amidosulfuron-ADHP can be excluded under real field conditions. Under aerobic conditions, the metabolite amidosulfuron-ADHP exhibited very low to very high persistence in soil. Amidosulfuron is not significantly photodegraded on the soil surface.

Amidosulfuron exhibited very high to high mobility in soil. The metabolites amidosulfuron-desmethyl, amidosulfuron-desmethyl-chloropyrimidine, amidosulfuron-guanidine and amidosulfuron-biuret exhibited very high soil mobility, and aminopyrimidine was immobile or exhibited very high soil mobility. It was concluded that the adsorption of amidosulfuron and its soil metabolites was not pH dependent. Field dissipation studies were carried out at three sites in Germany. None of these legacy studies was considered suitable for determination of persistence or modelling endpoints. Sample analyses were only carried out for the parent amidosulfuron. According to the data requirements, field soil dissipation investigations should be made for the parent active substance and metabolites in at least four different geographical locations when laboratory period required for 50% (DT50) or 90% (DT90) degradation are greater than 60 and 200 days, respectively. Therefore, a **data gap** was identified for soil dissipation studies to provide estimates of DisT50field and DisT90field and or DegT50field and DegT90field of amidosulfuron (one additional study to the three available studies) and its metabolites amidosulfuron-desmethyl-chloropyrimidine, amidosulfuron-guanidine and aminopyrimidine (four different geographical locations) under field conditions (see Section 10). However, the exposure assessment for the EU representative uses was completed using the available laboratory kinetic endpoints.

In a 3-year study conducted with two lysimeters (post-emergence application in spring to winter wheat at ca. 54 g a.s./ha) under outdoor conditions (Germany), amidosulfuron and amidosulfuron-desmethyl were present in leachates leaving the 1.3 m soil monolith at annual average concentrations <0.021 µg/L for amidosulfuron and not detected for amidosulfuron-desmethyl. Two metabolites amidosulfuron-guanidine and amidosulfuron-ADHP were present in individual leachate samples at up to 0.53 µg/L and 0.25 µg/L with these highest concentrations occurring in the second year of the experiment. The metabolite amidosulfuron-ADHP was included in the groundwater exposure assessment.

In laboratory incubations in dark aerobic natural sediment water systems, amidosulfuron remained primarily in the watercolumn. Metabolites amidosulfuron-desmethyl, amidosulfuron-guanidine and **amidosulfuron-(guanidinocarbonyl) sulfamic acid (BCS-BI49539)** were formed in the water up to 12.3% AR, 14.8% AR and 17.1% AR, respectively. The unextractable sediment fraction was the major sink for the pyrimidyl ring ^{14}C radiolabel, accounting for 2%–61% AR at study end (100–180 days). Mineralisation of this radiolabel accounted for 6%–25% AR at the end of the study. The rate of decline of amidosulfuron in a laboratory sterile aqueous photolysis experiment was slow relative to that occurred in the aerobic sediment water incubations. No chromatographically resolved component (excluding amidosulfuron) accounted for > 6% AR. The necessary surface water and sediment exposure assessments (predicted environmental concentrations (PEC) calculations) were carried out for the metabolites amidosulfuron-desmethyl, amidosulfuron-guanidine, amidosulfuron-desmethyl-chloropyrimidine, aminopyrimidine, amidosulfuron-biuret and amidosulfuron-(guanidinocarbonyl)sulfamic acid, using the FOCUS (FOCUS, 2001) step 1 and step 2 approach (version 3.2 of the Steps 1–2 in FOCUS calculator). For the active substance amidosulfuron, appropriate Step 3 (FOCUS, 2001) PECsw/PECsed was available.[13]

The necessary groundwater exposure assessments 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.[14] The degradation pathway used in the simulations included an intermediate (ghost) compartment to model the formation of the secondary metabolites amidosulfuron-desmethyl-chloropyrimidine, amidosulfuron-guanidine and amidosulfuron-biuret. Two sets of simulations were carried out based on different extreme adsorption properties of the intermediate compartment: one set with a K_{oc} value of 2000 mL/g and one set with a K_{oc} value of 0 mL/g. The maximum PECgw values for the three secondary metabolites were slightly higher in modelling with a K_{oc} value of 0 mL/g for the intermediate compartment. Specific PECgw simulation for metabolite amidosulfuron-ADHP was carried out by handling this metabolite as a pseudo-parent applied and correcting the application rate of the parent for the maximum occurrence of amidosulfuron-ADHP and its molar mass correction factor. The potential for groundwater exposure by amidosulfuron above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by all the relevant FOCUS groundwater scenarios for the representative uses assessed, except for:

- winter cereals (30 g/ha): 2/9 scenarios (max. 0.154 µg/L Okehampton scenario);
- spring cereals and flax (30 g/ha): 1/6 scenarios (max. 0.115 µg/L Hamburg scenario);
- permanent grass (autumn, 45 g/ha): 1/9 scenarios (max. 0.108 µg/L Porto scenario).

For the representative use on winter cereals at 30 g/ha, concentrations expressed on this basis were estimated to be > 0.1 µg/L in all scenarios for amidosulfuron-guanidine (max. 4.280 µg/L Thiva scenario), in one out of nine scenarios for amidosulfuron-desmethyl (max. 0.12 µg/L Okehampton scenario), in eight out of nine scenarios for amidosulfuron-desmethyl-chloropyrimidine (max. 0.35 µg/L Hamburg scenario), and in five out of nine scenarios for amidosulfuron-biuret (max. 0.489 µg/L Jokioinen scenario).

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

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

For the representative use on winter cereals at 15 g/ha, concentrations expressed on this basis were estimated to be > 0.1 μg/L in all scenarios for amidosulfuron-guanidine (max. 2.637 μg/L Thiva scenario), in seven out of nine scenarios for amidosulfuron-desmethyl-chloropyrimidine (max. 0.21 μg/L Hamburg scenario), and in two out of nine scenarios for amidosulfuron-biuret (max. 0.305 μg/L Jokioinen scenario).

For the representative use on spring cereals and flax at 30 g/ha, concentrations expressed on this basis were estimated to be > 0.1 μg/L in all scenarios for amidosulfuron-guanidine (max. 3.68 μg/L Hamburg scenario), in one out of six scenarios for amidosulfuron-desmethyl (max. 0.102 μg/L Hamburg scenario), and for amidosulfuron-desmethyl-chloropyrimidine (max. 0.52 μg/L Hamburg scenario), and in four out of six scenarios for amidosulfuron-biuret (max. 0.61 μg/L Jokioinen scenario).

For the representative use on permanent grass (spring) at 45 g/ha, concentrations expressed on this basis were estimated to be > 0.1 μg/L in all scenarios for amidosulfuron-guanidine (max. 0.548 μg/L Jokioinen scenario), and in one out of nine scenarios for amidosulfuron-biuret (max. 0.11 μg/L Jokioinen scenario).

For the representative use on permanent grass (autumn) at 45 g/ha, concentrations expressed on this basis were estimated to be > 0.1 μg/L in all scenarios for amidosulfuron-guanidine (max. 0.598 μg/L Jokioinen scenario), in one out of nine scenarios for amidosulfuron-biuret (max. 0.157 μg/L Jokioinen scenario) and in two out of nine scenarios for amidosulfuron-desmethyl-chloropyrimidine (max. 0.116 μg/L Jokioinen scenario).

For metabolites aminopyrimidine and amidosulfuron-ADHP, the parametric drinking water limit of 0.1 μg/L was concluded not to be breached under the representative uses assessed in all geoclimatic situations that are represented by all the relevant FOCUS groundwater scenarios.

In conclusion, PECgw exceeding 0.1 μg/L in more than half of the relevant FOCUS scenarios by metabolites are calculated for the following uses:

- Winter cereals (30 g/ha): amidosulfuron-desmethyl-chloropyrimidine, amidosulfuron-guanidine and amidosulfuron-biuret.
- Winter cereals (15 g/ha): amidosulfuron-desmethyl-chloropyrimidine and amidosulfuron-guanidine.
- Spring cereals and flax (30 g/ha): amidosulfuron-desmethyl-chloropyrimidine, amidosulfuron-guanidine and amidosulfuron-biuret.
- Permanent grass (spring application at 45 g/ha): amidosulfuron-guanidine.
- Permanent grass (autumn application at 45 g/ha): amidosulfuron-guanidine.

It should be noted that PECgw were > 0.75 μg/L for amidosulfuron-guanidine for the representative uses on winter cereals (both application rates) and for spring cereals and flax. None of the metabolites exceed 10 μg/L for all uses. Based on the available information in the mammalian toxicology section, metabolites amidosulfuron-desmethyl-chloropyrimidine, amidosulfuron-guanidine and amidosulfuron-biuret are considered not toxicological relevant (see Section 2).

The applicant provided 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. The conclusion of this consideration was that neither amidosulfuron nor any of its degradation products that trigger assessment (amidosulfuron-desmethyl, amidosulfuron-guanidine, amidosulfuron-desmethyl-chloropyrimidine, aminopyrimidine, amidosulfuron-biuret, amidosulfuron-ADHP and amidosulfuron-(guanidinocarbonyl)sulfamic acid) would be expected to undergo any substantial transformation due to oxidation with ozone at the disinfection stage of usual water treatment processes. The applicant provided also some argumentation to address the risk of forming potentially toxic conversion products upon the processing of drinking water with the chlorine-based reagents.[15] Based on chemico-structural considerations on the negative partial charge at pyrimidine 5-poisition two amidosulfuron derivatives might be formed: amidosulfuron-desmethyl-chloropyrimidine (BCS-CO41838/sodium salt: BCS-CO78570), and N-{[(5-hydroxy-4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-N-methylmethanesulfonamide. Amidosulfuron-desmethyl-chloropyrimidine is a major soil metabolite, with no genotoxic potential (see Section 2), while no satisfactory information was submitted to address the toxicological relevance of N-{[(5-hydroxy-4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-N-methylmethanesulfonamide. In addition, another potential chlorinated amidosulfuron derivative identified based on toxicological considerations is the 5-chlorinated variant of parent amidosulfuron **AE F128721**. No toxicological assessment is available for AE F128721 (see Section 2). This leads to a consumer risk assessment not finalised (see Section 9.1).

The PEC in soil, surface water, sediment and groundwater covering the representative uses assessed can be found in Appendix B. A key to the persistence and mobility class wording used, relating these words to numerical DT and K_{oc} endpoint values can be found in Appendix C.

5 | ECOTOXICOLOGY

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

Amidosulfuron was discussed at the Pesticide Peer Review Experts' Meeting PREV 21 (18–22 November 2019).

[15]Please, refer to data requirement 4.20 in the evaluation report (EFSA, 2024).

The available data were insufficient to confirm the compliance of the batches used in the ecotoxicity studies with reference or the proposed reference specification (**data gap**).

Based on the available data and risk assessment, low acute and chronic risk to birds and **wild mammals** was concluded for the relevant routes of exposure for all the representative uses. The available subchronic study with birds was not fully compliant with the data requested under Regulation EU No 283/2013 as the exposure period was only 6 weeks. Although this leads to uncertainty, the endpoint was used in the risk assessment and low risk was concluded for all the representative uses with a high margin of safety. A new reproduction study with standard exposure duration may be needed in future risk assessments in case the margin of safety is considered insufficient to balance the uncertainties identified (study with a shorter exposure duration).

Acute and chronic data were available for **aquatic organisms** with the active substance and the formulated product. Based on the available data, showing *Lemna* sp. To be the driver of the aquatic risk assessment, low risk to aquatic organisms was concluded for spring cereals and flax by using FOCUS step 3 PECsw estimations. High risk was indicated in situations represented by scenario D2 for all the other representative uses (grass and winter cereals at 15 g a.s./ha) except for winter cereals at 30 g a.s./ha showing high risk for D1, D2 and D6 scenarios (3 out of 9 FOCUS scenarios) by using FOCUS step 3 PECsw. The lack of reliable data on rooted macrophytes and the two available refined exposure studies with *Lemna* sp. Were discussed at the Peer Review Experts' meeting 21.[16] Overall, the experts agreed that the two refined exposure studies are valid but cannot be used for risk assessment in the absence of a comparison of the exposure in the study with the FOCUS exposure profiles. A scientific publication from the open literature was available with *Myriophillum* sp. The experts considered that, although not fully reliable, the study could be used to conclude that *Lemna* sp. Is more sensitive than *Myriophillum* sp. Therefore, further data for macrophytes were considered unnecessary. Low risk to aquatic organisms was concluded from exposure to the pertinent aquatic metabolites.

Acute oral and contact toxicity data were available with the active substance and the formulation with **honey bees.** Chronic toxicity data with the formulations and larval toxicity data with the active substance were also available. Additionally, acute toxicity data were available with bumble bees. Acute toxicity data (oral and contact) were available with the metabolites amidosulfuron-desmethyl and amidosulfuron-guanidine. Based on the available data and risk assessment conducted according to SANCO Guidance (2002) and EFSA (2013), low risk to honeybees was concluded for the routes of exposure assessed, and representative uses. Low acute risk to bumble bees was also concluded. Two higher tier studies, i.e. a study according to Oomen et al. (1992) and a semi-field test according to OECD 75, were available and were discussed at the Peer Review Experts' meeting 21.[17] Overall, the experts concluded that a clear pattern of effects was not evident from the higher tier studies and, therefore, the outcome of the lower tier assessment could be confirmed. Assessment of accumulative and sublethal effects was not available (**data gap**, see Section 10). Data on solitary bees were no available. A risk assessment was not presented for exposure to all relevant metabolites (**data gap**, see Section 10).

Tier 1 toxicity studies and an extended laboratory study were available with non-target arthropods standard species. Based on the available data and Tier 1 risk assessment, low risk to **non-target arthropods** was concluded for all the representative uses.

Low risk to **earthworms, other soil macroorganisms** and **soil microorganisms** was concluded for amidosulfuron and the pertinent soil metabolites for all the representative uses.

Laboratory studies, semi-field and field studies with sunflower were available for **non-target terrestrial plants.** The experts considered the semi-field and field study available as supportive only and the probabilistic approach was considered the preferred approach to conclude. Based on the probabilistic assessment, low risk was concluded for the representative uses on winter cereals at 15 g a.s./ha with the implementation of mitigation measures, i.e. 5-m buffer zone and 75% drift reduction. For the other representative uses, the mitigation measures proposed to conclude low risk went above the maximum allowed spray drift reduction of 95% and therefore could not be accepted. Based on this, high risk was concluded for all the other representative uses other than winter cereals at 15 g a.s./ha. Uncertainties were identified in the available risk assessment as phytotoxic effects were observed in the available laboratory studies but not quantified and therefore not properly covered in the risk assessment.

Low risk to **organisms involved in biological methods for sewage treatment** was concluded.

6 | ENDOCRINE DISRUPTION PROPERTIES

The assessment of the endocrine disruption (ED) potential of amidosulfuron was initially discussed at the Pesticides Peer Review Meeting 18 for Mammalian Toxicology (04–08 November) and at the PREV 21 in November 2019 and at TC 104 for Ecotoxicology in April 2023 after the submission of further data.[18]

With regard to the assessment of the endocrine disruption (ED) potential of amidosulfuron **for humans** according to the ECHA/EFSA guidance (EFSA, 2018), in determining whether amidosulfuron interacts with the oestrogen, androgen and

[16]Refer to experts' consultation 5.3 in the Report of the Pesticides Peer Review Experts' Meeting 21 in November 2019 (EFSA, 2024).

[17]Refer to experts' consultation 5.3 in the Report of the Pesticides Peer Review Experts' Meeting 21 in November 2019 (EFSA, 2024).

[18]In the context of the mandate from the European Commission and following submission of additional information on the ED potential by the applicant during a 30-month stop-of-the-clock procedure, new data became available for the purpose of the ED assessment in line with the request as indicated in the Experts consultation 5.6 as reflected in the report of the peer-review meeting PREV 21.

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 amidosulfuron with the EAS and T signalling pathways using the available evidence in the data set.

With regard to the T modality the data set was considered complete, and a pattern of T-mediated adversity was not identified. Therefore, based on the available and sufficient data set, it was concluded that the ED criteria are not met for the T modality (Scenario 1a of the EFSA/ECHA (2018) ED Guidance).[19]

With regard to EAS modalities, the data set was considered complete based on endocrine activity and a pattern of EATS-mediated adversity was not identified in the existing data set. Therefore, based on the available and sufficient data set, it was concluded that the ED criteria are not met for the EAS modalities (Scenario 2a-ii of the EFSA/ECHA (2018) ED Guidance).[20]

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, a Xenopus Eleutheroembryonic Thyroid Assay (XETA, OECD TG 248) and a Fish Short-Term Reproduction Assay (FSTRA, OECD TG 229) were available. It was noted that a part of the available XETA was not conducted under GLP conditions, as indicated in the provisions of the principles laid down in Directive 2004/10/EC of the European Parliament and of the Council and as implemented by the Commission Regulation (EU) No 283/2013. The study was considered fully reliable by experts at the meeting[21] and no evidence of T-mediated endocrine activity was observed. Nevertheless, a **data gap** is identified to further confirm the findings in the available study by performing a study in line with the legal requirements, i.e. under GLP. (see Section 10). For EAS-modalities, the available FSTRA did not show any evidence suggesting EAS-mediated endocrine activity.[22]

Based on the available assessment, it could be concluded that amidosulfuron does not meet the ED criteria as laid down in the points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605. Although further confirmation is needed regarding the conclusion for the T-modality in non-mammalian species, based on the available data, it is unlikely that amidosulfuron is an endocrine disruptor.

7 | OVERVIEW OF THE RISK ASSESSMENT OF COMPOUNDS LISTED IN RESIDUE DEFINITIONS TRIGGERING ASSESSMENT OF EFFECTS DATA FOR THE ENVIRONMENTAL COMPARTMENTS (TABLES 1–4)

TABLE 1 Soil.

Compound (name and/or code)	Ecotoxicology
Amidosulfuron	Low risk to soil organisms
Amidosulfuron-desmethyl (AE F101630)	Low risk to soil organisms
Amidosulfuron-desmethyl-chloropyrimidine (BCS-CO41838)	Low risk to soil organisms
Amidosulfuron-guanidine (BCS-CO41839)	Low risk to soil organisms
Amidosulfuron-biuret (BCS-CQ51287)	Low risk to soil organisms
Aminopyrimidine (AE F092944 or ADMP)	Low risk to soil organisms

TABLE 2 Groundwater.[a]

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
Amidosulfuron	Yes Winter cereals (30 g a.s./ha): 2/9 FOCUS scenarios (< 0.001–0.154 μg/L) Spring cereals and flax (30 g a.s./ha): 1/6 FOCUS scenarios (0.012–0.115 μg/L) Permanent grass (autumn, 45 g a.s./ha): 1/9 FOCUS scenarios (< 0.005–0.108 μg/L)	Yes	Yes	Not pertinent	Yes

(Continues)

[19]Refer to experts' consultation 2.8 in the Report of the Pesticides Peer Review Experts' Meeting 18 (EFSA, 2024).

[20]Refer to experts' consultation 2.8 in the Report of the Pesticides Peer Review Experts' Meeting 18 (EFSA, 2024).

[21]Refer to experts' consultation point 5.8 in the Report of Pesticides Peer Review meeting TC 104 (EFSA, 2024).

[22]See experts' consultation point 5.7 in the report of Pesticides Peer Review meeting TC 104 (EFSA, 2024).

TABLE 2 (Continued)

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
Amidosulfuron-desmethyl (AE F101630)	Yes Winter cereals (30 g a.s./ha): 1/9 FOCUS scenarios (< 0.001–0.120 μg/L) Spring cereals and flax (30 g a.s./ha): 1/6 FOCUS scenarios (0.012–0.102 μg/L)	No	No Ames test negative Unlikely to be genotoxic covered by parent as major rat metabolite Acute oral LD_{50} > 5000 mg/kg bw ADI of the parent can apply	Not triggered	Not relevant
Amidosulfuron-desmethyl-chloropyrimidine (BCS-CO41838)	Yes Winter cereals (30 g a.s./ha): 8/9 FOCUS scenarios (0.007–0.350 μg/L) Winter cereals (15 g a.s./ha): 7/9 FOCUS scenarios (0.003–0.210 μg/L) Spring cereals and flax (30 g a.s./ha): 6/6 FOCUS scenarios (0.145–0.516 μg/L) Permanent grass (autumn, 45 g a.s./ha): 2/9 FOCUS scenarios (0.027–0.116 μg/L)	No	No (Sodium salt) Acute oral LD_{50} > 2000 mg/kg bw; Ames -ve In vitro GM (V79 cells) -ve In vitro CA (V79 cells) -ve In vivo MN -ve In vivo UDS -ve	Not triggered	Not relevant
Amidosulfuron-guanidine (BCS-CO41839)	Yes Winter cereals (30 g a.s./ha): 9/9 FOCUS scenarios (1.255–4.280 μg/L) Winter cereals (15 g a.s./ha): 9/9 FOCUS scenarios (0.778–2.637 μg/L) Spring cereals and flax (30 g a.s./ha): 6/6 FOCUS scenarios (1.307–3.676 μg/L) Permanent grass (spring, 45 g a.s./ha): 9/9 FOCUS scenarios (0.170–0.548 μg/L) Permanent grass (autumn, 45 g a.s./ha): 9/9 FOCUS scenarios (0.168–0.598 μg/L)	No	No Acute oral LD_{50} > 2000 mg/kg bw; Ames -ve In vitro GM (V79 cells) -ve In vitro CA (V79 cells) -ve Aneugenicity not concluded (data gap); 28-days NOAEL = 778 mg/kg bw per day ADI 0.8 mg/kg bw per day; ArfD not necessary	Consumers risk assessment with respect to drinking water consumption the basis of the ADI 0.8 mg/kg bw per day do not indicate risk for consumers.	Not relevant[23]
Amidosulfuron-biuret (BCS-CQ51287)	Yes Winter cereals (30 g a.s./ha): 5/9 FOCUS scenarios (0.008–0.489 μg/L) Winter cereals (15 g a.s./ha): 2/9 FOCUS scenarios (0.005–0.305 μg/L) Spring cereals and flax (30 g a.s./ha): 4/6 FOCUS scenarios (0.063–0.613 μg/L) Permanent grass (spring, 45 g a.s./ha): 1/9 FOCUS scenarios (0.005–0.110 μg/L) Permanent grass (autumn, 45 g a.s./ha): 1/9 FOCUS scenarios (0.015–0.157 μg/L)	No	No Acute oral LD50 > 2000 mg/kg bw Ames -ve In vitro GM (V79 cells) -ve In vitro CA (V79 cells) -ve Aneugenicity not concluded (data gap)	Not triggered	Not relevant[24]

[23]The aneugenicity has not been addressed according to the latest state of the art since the revised guidance on the assessment of the relevance of metabolites in groundwater (European Commission, 2021), including the assessment of aneugenicity, was not available/implemented during the peer review of amidosulfuron (data gap, see Section 10).

[24]The aneugenicity has not been addressed according to the latest state of the art since the revised guidance on the assessment of the relevance of metabolites in groundwater (European Commission, 2021), including the assessment of aneugenicity, was not available/implemented during the peer review of amidosulfuron (data gap, see Section 10).

TABLE 2 (Continued)

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
aminopyrimidine (AE F092944 or ADMP)	No	No	Not triggered Acute oral LD50 = 2669 mg/kg bw Ames test negative	Not triggered	Not triggered
Amidosulfuron-ADHP (AE F094206) (soil metabolite under anaerobic conditions and also formed in the lysimeter study)	FOCUS modelling: no Lysimeter: max detected in individual lysimeter leachate: 0.25 μg/L (annual average data unavailable for a formal trigger comparison)	No	No Acute oral LD50 > 5000 mg/kg bw Ames -ve In vitro GM (V79 cells) -ve In vitro CA (V79 cells) -ve Aneugenicity not concluded (data gap).	Not triggered	Not relevant[25]

[a]Assessment according to European Commission guidance of the relevance of groundwater metabolites (2003).
[b]FOCUS scenarios or relevant lysimeter.

TABLE 3 Surface water and sediment.

Compound (name and/or code)	Ecotoxicology
Amidosulfuron	High risk identified in 3 out of 9 FOCUS scenarios for the presentative use on winter cereals at 30 g a.s./ga and 1 FOCUS scenario for the other representative uses on grass and winter cereals at 15 g a.s./ha
Amidosulfuron-desmethyl (AE F101630)	Low risk to aquatic organisms
Amidosulfuron-desmethyl-chloropyrimidine (BCS-CO41838) (from soil)	Low risk to aquatic organisms
Amidosulfuron-guanidine (BCS-CO41839)	Low risk to aquatic organisms
Amidosulfuron-biuret (BCS-CQ51287) (from soil)	Low risk to aquatic organisms
aminopyrimidine (AE F092944 or ADMP) (from soil)	Low risk to aquatic organisms
amidosulfuron-(guanidinocarbonyl)sulfamic acid (BCS-BI49539)	Low risk to aquatic organisms

TABLE 4 Air.

Compound (name and/or code)	Toxicology
Amidosulfuron	Low acute toxicity by inhalation to rats. (Rat LC_{50} > 1.8 mg/L air/4 h (nose only) (the technically highest administrable dose)[a]

[a]LC50: lethal concentration, median.

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).

No particular conditions are proposed for the representative uses evaluated for aquatic organisms (Table 5).

[25]The aneugenicity has not been addressed according to the latest state of the art since the revised guidance on the assessment of the relevance of metabolites in groundwater (European Commission, 2021), including the assessment of aneugenicity, was not available/implemented during the peer review of amidosulfuron (data gap, see Section 10).

TABLE 5 Risk mitigation measures proposed for the representative uses assessed.

Representative use	Winter cereals (15 g a.s./ha)
	Foliar spray
Non target terrestrial plants	5 metre buffer zone +75% drift reduction[26]

9 | CONCERNS AND RELATED DATA GAPS

9.1 | Issues that could not be finalised

An issue is listed as 'could not be finalised' if there is not enough information available to perform an assessment, even at the lowest tier level, for 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[27] 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:

1. Current and newly proposed reference specification have not been demonstrated to be covered by the batches used in the toxicological studies (see Section 2).

   a. Assessment of the toxicological relevance of one impurity should be provided.

2. Comparative in vitro metabolism data were not sufficient to identify possible unique human metabolites (see Section 2).

   a. Additional investigations of in vitro comparative metabolism should be provided.

3. The consumer dietary risk assessment could not be concluded in view of the identified data gaps with respect to unprocessed and processed animal matrices and the lack of toxicological data on the metabolite N-{[(5-hydroxy-4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-N-methylmethanesulfonamide and AE F128721 potentially formed under drinking water treatments chlorination processes.

   a. Further identification of the residues in cereal straw of rotational crops is needed for metabolites exceeding 0.01 mg/kg, and possibly field trials to confirm the residue levels. Animal dietary burden of such metabolites and impact on residue in animal matrices will need to be further assessed (relevant for all representative uses evaluated; see Section 3).
   b. Metabolism information or data for desmethyl-amidosulfuron (AE F101630) in ruminants (relevant for all representative uses evaluated; see Section 3).
   c. Processing residue trials on the magnitude of residues of aminopyrimidine and amidosulfuron-sulfamic acid in milk and other animal matrices under all standard processing conditions are required. It is highlighted that the applicant should conduct these trials with sufficient levels of residues in the matrices under consideration. Pending upon the outcome of these residue trials and whether quantifiable residues are observed for these metabolites, an appropriate toxicological dataset for aminopyrimidine and amidosulfuron-sulfamic acid will have to be provided (relevant for all representative uses evaluated; see Sections 2 and 3).
   d. Further toxicological data and assessment of the metabolites N-{[(5-hydroxy-4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-N-methylmethanesulfonamide and AE F128721 potentially formed under drinking water treatment chlorination processes (relevant for all representative uses evaluated; see Sections 2 and 4).

[26]The RMS presented a risk assessment for non-target terrestrial plants using mitigation measures up to 10 m buffer zone and 90% drift reduction. Those mitigation measures were needed to conclude low risk for the other uses than winter cereals at 15 g a.s/ha. However, those mitigations go beyond the maximum allowed spray drift reduction and could not be considered.

[27]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.

9.2 | Critical areas of concern

An issue is listed as a critical area of concern if there is enough information available to perform an assessment for the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and if this assessment does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if the assessment at a higher tier level could not be finalised due to lack of information, and if the assessment performed at the lower tier level does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

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:

Critical areas of concern were not identified.

9.3 | Overview of the concerns identified for each representative use considered (Table 6)

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in Section 8, has been evaluated as being effective, then 'risk identified' is not indicated in Table 6.)

TABLE 6 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		Winter cereals (15 g a.s./ha)	Winter cereals (30 g a.s./ha)	Flax (30 g a.s./ha)	Grass/pasture	Spring cereals
			Foliar 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[3]	X[3]	X[3]	X[3]	X[3]
Risk to wild non-target terrestrial vertebrates	Risk identified					
	Assessment not finalised					
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified		X	X	X	X
	Assessment not finalised					
Risk to aquatic organisms	Risk identified	1 out of 5 FOCUS scenarios	3 out of 9 FOCUS scenarios		1 out of 7 FOCUS scenarios	
	Assessment not finalised					
Groundwater exposure to active substance	Legal parametric value breached		2 out of 9 FOCUS scenarios	1 out of 6 FOCUS scenarios	1 out of 9 FOCUS scenarios	1 out of 6 FOCUS scenarios
	Assessment not finalised					
Groundwater exposure to metabolites	Legal parametric value breached[a]					
	Parametric value of 10 µg/L[b] breached					
	Assessment not finalised					

Notes: The superscript numbers relate to the numbered points indicated in Sections 9.1 and 9.2. Where there is no superscript number, see Sections 2–7 for further information.

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

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

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 one of the components of the formulation for representative uses 'Amidosulfuron WG 75', in order to allow a final conclusion on the safety assessment of 'Amidosulfuron WG 75', further information on this component in relation to its specification/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 'the active substance and the formulation for representative uses').
- A validated monitoring method for the determination of desmethyl-amidosulfuron (AE F101630) in body fluids (relevant for all representative uses, see Section 1).
- Validation data for the analytical method used in the rat developmental toxicity study (relevant for all representative uses, see Section 1).
- Validated methods for analysis of the relevant impurity in the technical material and in the formulation with LOQs suitable for the proposed max level of 0.0036 g/kg (relevant for all representative uses, see Section 1).
- A validated monitoring method for the determination of the components of the residue definition for drinking water as reported in Appendix B (relevant for all representative uses, see Section 1).
- Since amidosulfuron is an UVB absorber, the OECD 3T3 NRU-PT test may not be suitable to conclude on its phototoxicity potential (relevant for all representative uses evaluated; see Section 2).
- Investigation of the aneugenic potential of **amidosulfuron-guanidine** (relevant for all representative uses evaluated; see Section 2).
- Investigation of the aneugenic and clastogenic potential of **aminopyrimidine**, as well as of its repeat dose toxicity profile (relevant for all representative uses evaluated; see Section 2).
- Investigation of the (geno)toxicity potential of **amidosulfuron sulfamic acid** (relevant for all representative uses evaluated; see Section 2).
- Investigation of the aneugenic potential of **amidosulfuron biuret** and **amidosulfuron ADHP** (relevant for all representative uses evaluated; see Section 2)
- Soil dissipation studies to provide estimates of DisT50field and DisT90field and/or DegT50field and DegT90field of amidosulfuron (one additional study to the three available studies) and its metabolites amidosulfuron-desmethyl-chloropyrimidine, amidosulfuron-guanidine and aminopyrimidine (four different geographical locations) under field conditions were not available (relevant for all representative uses evaluated; see Section 4).
- A fully transparent kinetic evaluation of the laboratory aerobic degradation data in soil in line with the recommendations of the FOCUS (2006) kinetics guidance (i.e. the sequential fitting steps that should have been done for the three schemes and that need to be reported) were not available (relevant for all representative uses evaluated; see Section 4).[28]
- Further data to address the risk to honey bees from sublethal effects (e.g. effects on HPG) (relevant for all representative uses, see Section 5).
- A risk assessment for bees when exposed to pertinent metabolites (relevant for all representative uses, see Section 5).
- Further data on the compliance of the batches used in the ecotoxicity studies with reference to the proposed technical specification was unavailable (relevant for all representative uses, see Section 5).
- A new study compliant with the GLP requirement as indicated in the provisions of the principles laid down in Directive 2004/10/EC[29] of the European Parliament and of the Council and as implemented by the Commission Regulation (EU) No 283/2013 is needed to further confirm the findings in the available non-GLP XETA study (relevant for all representative uses, see Section 5).

ABBREVIATIONS

1/*n*	slope of Freundlich isotherm
AAOEL	acute acceptable operator exposure level
AMA	Amphibian Metamorphosis Assay
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level

[28]Refer to Data Requirement 4.10 of the Evaluation table in Section 4 (EFSA, 2024).

[29]Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances. OJ L 50, 20.2.2004, p. 44–59.

AOP	adverse outcome pathway
AP	alkaline phosphatase
AR	applied radioactivity
AR	androgen receptor
ARfD	acute reference dose
ARSTTA	Stably Transfected Human Androgen Receptor Activation Assay
AST	aspartate aminotransferase (SGOT)
AUC	area under the blood concentration/time curve
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming units
CHO	Chinese hamster ovary cells
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
C&L	classification and labelling
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)
EAS	oestrogen, androgen and steroidogenesis modalities
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
ERSTTA	Stably Transfected Human Oestrogen Receptor-alpha Transcriptional Activation Assay
ETO	ecological threshold option
EUROPOEM	European Predictive Operator Exposure Model
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
GCPF	Global Crop Protection Federation (formerly known as International Group of National Associations of Manufacturers of Agrochemical Products; GIFAP)
GM	geometric mean
GS	growth stage
GSH	glutathione
Hct	haematocrit
HGPRT	hypoxanthine-guanine phosphoribosyl transferase
HPLC	high-pressure liquid chromatography, or high-performance liquid chromatography
HPLC-MS	high-pressure liquid chromatography–mass spectrometry
HQ	hazard quotient
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)
LD_{50}	lethal dose, median; dosis letalis media
LDD_{50}	lethal dietary dose; median
LDH	lactate dehydrogenase
LH	luteinizing hormone
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
MEOGRT	Medaka Extended One-Generation Reproduction Test
M&K	Maximisation test of Magnusson & Kligman
mm	millimetre (also used for mean measured concentrations)
mN	milli-Newton
MOA	mode of action
MRL	maximum residue level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water-holding capacity
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
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in groundwater
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
r^2	coefficient of determination
RAC	regulatory acceptable concentration
RAR	Renewal Assessment Report
RBC	red blood cells
SC	suspension concentrate
SFO	single first-order
SMILES	simplified molecular-input line-entry system
SPG	specific protection goal
SSD	species sensitivity distribution
STMR	supervised trials median residue
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue

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 amidosulfuron according to Annex II of Regulation (EC) No 1107/2009 of the European Parliament and of the Council

Properties		Conclusion[a]
CMR[30]	Carcinogenicity (C)	Amidosulfuron is not considered to be a carcinogen (category 1A or 1B) according to point 3.6.3 of Annex II of Regulation (EC) No 1107/2009
	Mutagenicity (M)	Amidosulfuron is not considered to be a mutagen according to point 3.6.2 of Annex II of Regulation (EC) No 1107/2009
	Toxic for Reproduction (R)	Amidosulfuron is not considered to be toxic for reproduction according to point 3.6.4 of Annex II of Regulation (EC) No 1107/2009
Endocrine-disrupting properties		Amidosulfuron is not considered to meet the criteria for endocrine disruption for human health 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**	Amidosulfuron 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**	Amidosulfuron 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**	Amidosulfuron 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).

[30]Harmonised classification and labelling (COMMISSION REGULATION (EU) 2018/669 of 16 April 2018 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures) does not include hazards for human health.

APPENDIX B

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

Appendix B can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2024.8984

APPENDIX C

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

Wording	DT_{50} normalised to 20°C for laboratory incubations[31] 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.

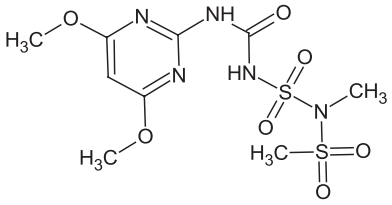
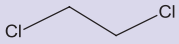
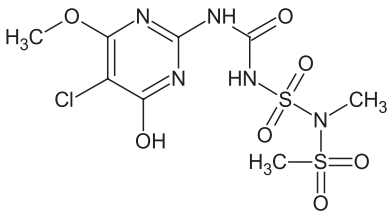
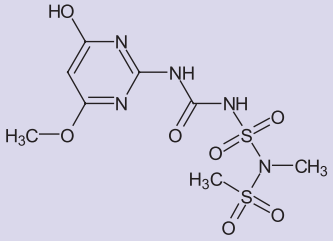
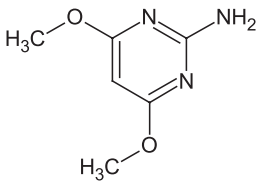
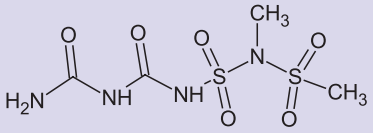
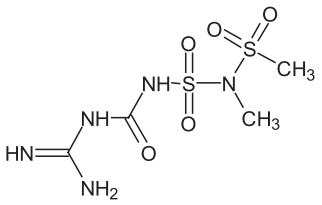
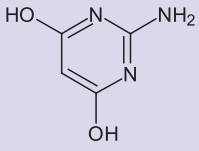
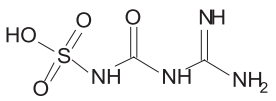
Wording	K_{oc} (either K_{Foc} or K_{doc}) mL/g
Very High Mobility	0–50
High Mobility	51–150
Medium Mobility	151–500
Low Mobility	501–2000
Slight Mobility	2001–5000
Immobile	> 5000

Note: Based on McCall et al. 1980).

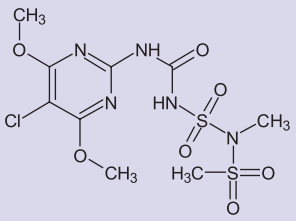
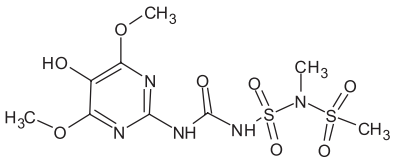
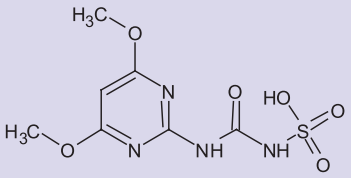
[31]For laboratory soil incubations, normalisation was also to field capacity soil moisture (pF2/10 kPa). For laboratory sediment water system incubations, the whole system DT values were used.

APPENDIX D

Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
amidosulfuron	*N*-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl] sulfamoyl}-*N*-methylmethanesulfonamide O=C(Nc1nc(cc(OC)n1)OC)NS(=O)(=O)N(C)S(C)(=O)=O CTTHWASMBLQOFR-UHFFFAOYSA-N	
1,2-dichloroethane	1,2-dichloroethane ClCCC WSLDOOZREJYCGB-UHFFFAOYSA-NI	
amidosulfuron-desmethyl-chloropyrimidine (BCS-CO41838)	*N*-{[(4-hydroxy-5-chloro-6-methoxypyrimidin-2-yl) carbamoyl]sulfamoyl}-*N*-methylmethanesulfonamide O=C(Nc1nc(O)c(Cl)c(OC)n1)NS(=O)(=O)N(C)S(C)(=O)=O QGOBGTMFEGVCTQ-UHFFFAOYSA-N	
desmethyl-amidosulfuron O-desmethyl amidosulfuron, Hoe 101630, AE F101630	*N*-{[(4-hydroxy-6-methoxypyrimidin-2-yl)carbamoyl] sulfamoyl}-*N*-methylmethanesulfonamide O=C(Nc1nc(O)cc(OC)n1)NS(=O)(=O)N(C)S(C)(=O)=O QAYZUYJYJXIVLF-UHFFFAOYSA-N	
aminopyrimidine AE F092944 Hoe 092944 ADMP IN-J290 IN-J0290 IN-J90-17 SSRE-002 BCS-AA25052 CP17477 AP	4,6-dimethoxypyrimidin-2-amine COc1cc(OC)nc(N)n1 LVFRCHIUUKWBLR-UHFFFAOYSA-N	
amidosulfuron-biuret (BCS-CQ51287)	*N*-[(carbamoylcarbamoyl) sulfamoyl]-*N*-methylmethanesulfonamide O=C(NS(=O)(=O)N(C)S(=O)(C)=O)NC(N)=O MDRMRZIDXYIOKR-UHFFFAOYSA-N	
Amidosulfuron guanidine BCS-CO41839 AE F128870	*N*-[(carbamimidoylcarbamoyl) sulfamoyl]-*N*-methylmethanesulfonamide O=C(NS(=O)(=O)N(C)S(=O)(C)=O)NC(=N)N IXGXOTQMSXNTSZ-UHFFFAOYSA-N	
Amidosulfuron-ADHP AE F094206	2-aminopyrimidine-4,6-diol Oc1cc(O)nc(N)n1 AUFJTVGCSJNQIF-UHFFFAOYSA-N	
Amidosulfuron-(guanidinocarbonyl)sulfamic acid BCS-BI49539	(carbamimidoylcarbamoyl)sulfamic acid O=C(NC(=N)N)NS(=O)(=O)O PJRKIOAWDWYUEV-UHFFFAOYSA-N	

(Continued)

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
AE F128721	*N*-{[(5-chloro-4,6-dimethoxypyrimidin-2-yl)carbamoyl] sulfamoyl}-*N*-methylmethanesulfonamide O=C(Nc1nc(OC)c(Cl)c(OC)n1)NS(=O)(=O)N(C)S(C)(=O)=O KDZUALKJCKUHBO-UHFFFAOYSA-N	
N-{[(5-hydroxy-4,6-dimethoxypyrimidin-2-yl) carbamoyl]sulfamoyl}-N-methylmethanesulfonamide	*N*-{[(5-hydroxy-4,6-dimethoxypyrimidin-2-yl)carbamoyl] sulfamoyl}-*N*-methylmethanesulfonamide O=C(Nc1nc(OC)c(O)c(OC)n1)NS(=O)(=O)N(C)S(C)(=O)=O JWXHOFCJFXZJMN-UHFFFAOYSA-N	
BCS-AW41401 Amidosulfuron-sulfamic acid	[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamic acid O=C(Nc1nc(cc(OC)n1)OC)NS(=O)(=O)O DHRJAVBSNPEYMP-UHFFFAOYSA-N	

[a]The metabolite name in bold is the name used in the conclusion.

[b]ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 July 2019).

[c]ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 July 2019).