CONCLUSION ON PESTICIDES PEER REVIEW

efsa JOURNAL

APPROVED: 5 July 2023

doi: 10.2903/j.efsa.2023.8142

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

European Food Safety Authority (EFSA),
Fernando Álvarez, Maria Arena, Domenica Auteri, Sofia Batista Leite, Marco Binaglia, Anna Federica Castoldi, Arianna Chiusolo, Ana-Andreea Cioca, Angelo Colagiorgi, Mathilde Colas, Federica Crivellente, Chloe De Lentdecker, Isabella De Magistris, Mark Egsmose, Gabriella Fait, Franco Ferilli, Varvara Gouliarmou, Katrin Halling, Laia Herrero Nogareda, Alessio Ippolito, Frederique Istace, Samira Jarrah, Dimitra Kardassi, Aude Kienzler, Anna Lanzoni, Roberto Lava, Renata Leuschner, Alberto Linguadoca, Jochem Louisse, Christopher Lythgo, Oriol Magrans, Iris Mangas, Ileana Miron, Tunde Molnar, Laura Padovani, Vincenzo Padricello, Martina Panzarea, Juan Manuel Parra Morte, Simone Rizzuto, Anamarija Romac, Agnès Rortais, Rositsa Serafimova, Rachel Sharp, Csaba Szentes, Andrea Terron, Anne Theobald, Manuela Tiramani, Giorgia Vianello and Laura Villamar-Bouza

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, Slovenia, and co-rapporteur Member State, Austria, for the pesticide active substance tritosulfuron 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 tritosulfuron as a herbicide on spring and winter cereals, spring cereals with undersown grasses and maize (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: tritosulfuron, peer review, risk assessment, pesticide, herbicide

Requestor: European Commission

Question number: EFSA Q-2016-00479

Correspondence: pesticides.peerreview@efsa.europa.eu

Declaration 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.

Acknowledgements: EFSA wishes to thank the rapporteur Member State, Slovenia, for the preparatory work on this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Álvarez, F., Arena, M., Auteri, D., Batista Leite, S., Binaglia, M., Castoldi, A. F., Chiusolo, A., Cioca, A.-A., Colagiorgi, A., Colas, M., Crivellente, F., De Lentdecker, C., De Magistris, I., Egsmose, M., Fait, G., Ferilli, F., Gouliarmou, V., Halling, K. … Villamar-Bouza, L. (2023). Peer review of the pesticide risk assessment of the active substance tritosulfuron. *EFSA Journal, 21*(8), 1–37. https://doi.org/10.2903/j.efsa.2023.8142

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.

Summary

Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659, lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012 as amended by Commission Implementing Regulation (EU) No 2016/183. Tritosulfuron is one of the active substances listed in that Regulation.

In accordance with Article 1 of Regulation (EU) No 844/2012, the rapporteur Member State (RMS), Slovenia, and co-rapporteur Member State (co-RMS), Austria, received an application from BASF SE for the renewal of approval of the active substance tritosulfuron.

An initial evaluation of the dossier on tritosulfuron 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. Subsequently, additional data were notified by the applicant BASF SE and considered as information on potentially harmful or unacceptable effects according to Article 56 of Regulation (EC) No 1107/2009. The RMS provided the assessment of additional information falling under Article 56 in a revised RAR which was peer reviewed by Member States and EFSA. The following conclusions are derived following the peer review of the renewal including the assessment conducted under Article 56 of Regulation (EC) No 1107/2009.

The uses of tritosulfuron according to the representative uses as a herbicide on spring and winter cereals, spring cereals with undersown grasses, and maize (field uses), 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 could not be finalised or that need to be included as critical areas of concern with respect to **identity, physical/chemical properties, and analytical methods**.

For the **mammalian toxicity** section, no critical areas of concern were identified. Following assessment conducted under Article 56 of Regulation (EC) No 1107/2009 concerning information on potentially harmful or unacceptable effects, the (geno)toxicity potential of metabolites M635H020 and M635H019 and the aneugenicity potential of metabolite trifluoroacetic acid (TFA) might need to be further investigated, pending confirmation of their levels in groundwater and in rotational crops, leading to an issue not finalised (see also Sections 3 and 4).

In the area or **residues**, no critical areas of concern were identified. Several data gaps were identified for rotational crops field trials and storage stability for tritosulfuron, and metabolites AMTT and TBSA. An additional data gap for field rotational trials analysing for TFA was identified in the framework of the Article 56 assessment. Overall, the consumer risk assessment performed is not finalised in view of lacking data on the magnitude of residues in rotational crops for all relevant compounds (tritosulfuron, AMTT, TBSA and TFA).

The data available on **environmental fate and behaviour** were sufficient to carry out the required environmental exposure assessments at EU level. However, based on Article 56 procedure, the environmental exposure assessment could not be finalised as a full data package (e.g. rate of degradation, field studies, soil adsorption) together with an environmental exposure assessment were not provided for metabolites M635H020 and TFA. Furthermore, the soil degradation endpoints and the environmental exposure assessment were not updated for tritosulfuron and metabolites M635H001, TBSA and M635H003 leading to a provisional environmental exposure assessment in soil, groundwater and surface water for these metabolites.

For the **ecotoxicology** section, no critical areas of concern were identified. Following the Article 56 assessment, the risk assessment for birds and mammals, aquatic organisms, bees and soil organisms could not be finalised for the metabolite TFA. The risk assessment for aquatic and soil organisms could not be finalised also for the metabolite M635H020.

Tritosulfuron is not an **endocrine disruptor** 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.

Table of contents

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, Slovenia, and co-RMS, Austria, received an application from BASF SE for the renewal of approval of the active substance tritosulfuron. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS, Austria, the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on tritosulfuron in the RAR, which was received by EFSA on 30 March 2018 (Slovenia, 2018).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, BASF SE, for consultation and comments on 11 September 2018. 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 14 November 2018. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of reporting table. In addition, the applicant was invited to respond to the comments received. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 13(3) of the Regulation were considered in a telephone conference between EFSA and the RMS on 14 January 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 and ecotoxicology.

In addition, following a consultation with Member States in the Pesticides Peer Review Expert meeting PREV 06 (June 2019), it was considered necessary to apply an additional clock stop of 19 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[4], are met.

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 tables. All points that

[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] 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.

were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in an expert consultation, were compiled by EFSA in the format of an evaluation table.

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

In the context of the renewal of approval of tritosulfuron, the Conclusion is also addressing the outcome of the assessment of the additional information submitted in the framework of the procedure laid down in Article 56 of Regulation (EC) No 1107/2009.

The toxicity of the metabolite trifluoroacetic acid (TFA) was the subject of a notification falling under Article 56 of Regulation (EC) No 1107/2009 concerning information on potentially harmful or unacceptable effects, submitted on 7 January 2021 to EFSA, the European Commission and Member States by the notifier Bayer of the REACH registration dossier on TFA and the REACH lead registrant and producer of TFA under Regulation (EC) No 1907/2006[5]. The notification concerned adverse developmental effects in rabbits after exposure to the metabolite TFA observed in a development toxicity study. In view of determining the human relevance of these developmental effects specific to rabbits, follow-up *in vitro* and *in vivo* studies were carried out under Regulation (EC) No 1907/2006. Since at the time of conducting the peer review process on the renewal of approval of tritosulfuron, these follow-up investigations were still ongoing at ECHA level, the data submitted as part of the Article 56 notification were not taken into account in this present conclusion.

In 2018, drinking water producers and local German authorities inquired BASF SE if TFA as a metabolite of tritosulfuron can be the cause of increased TFA levels in German drinking water catchments and drinking waters. In this context, BASF SE initiated new studies on tritosulfuron to investigate the formation of TFA from tritosulfuron.

In July 2021, during the ongoing peer review process, the applicant BASF SE informed the RMS on the presence of two new metabolites, M635H020 and TFA, in soil identified from additional aerobic soil degradation study and the confined rotational crop study on tritosulfuron.

On 10 December 2021, the applicant BASF SE formally notified to the Member States, EFSA and the European Commission of the additional data on the two new metabolites.

As part of the peer review process on tritosulfuron, the additional data notified by the applicant BASF SE were considered as information on potentially harmful or unacceptable effects and directly linked to the Article 56 notification submitted by Bayer and the REACH lead registrant.

On 10 May 2022, the applicant submitted the additional studies, i.e. an aerobic degradation study of tritosulfuron in four soils, a confined rotational crop study with tritosulfuron and a residue analysis of selected samples on TFA, to the RMS, the Member States and EFSA. The RMS provided its evaluation of the Article 56 data in a revised RAR, which was received by EFSA on 7 October 2022. EFSA distributed the revised RAR to the Member States and the applicant, BASF SE, for consultation and comments on 16 October 2022. EFSA also provided comments. EFSA collated and forwarded all comments received to the RMS for compilation and evaluation in the format of reporting table. In addition, the applicant was invited to respond to the comments received. The comments and the applicant's response were evaluated by the RMS in column 3 and subsequently any follow-up considerations together with their outcome were included in the evaluation tables.

A final consultation on the conclusions arising from the peer review of the risk assessment following the renewal process including the assessment conducted in the framework of Article 56 of Regulation (EC) No 1107/2009 took place with Member States via a written procedure in May–June 2023.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the formulation for representative uses, evaluated on the basis of the representative uses of tritosulfuron as a herbicide on spring and winter cereals, spring cereals with undersown grasses, and maize, 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.

In addition, the peer review also provided considerations on whether the additional information submitted by BASF SE on the newly available metabolites of tritosulfuron in the context of Article 56 of Regulation (EC) 1107/2009 can be considered as adverse effect.

[5] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

A list of the relevant end points for the active substance and the formulation is provided in Appendix B. In addition, the considerations as regards the cut-off criteria for tritosulfuron 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, 2023), 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 (15 January 2019, 30 August 2021[6] and 7 December 2022[7]);
- the evaluation table (4 July 2023);
- 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 (Slovenia, 2022), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

It is recommended that this conclusion 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(s) for representative uses

Tritosulfuron[8] is the ISO common name for *N*-{[4-methoxy-6-(trifluoromethyl)-1,3,5-triazin-2-yl] carbamoyl}-2-(trifluoromethyl)benzenesulfonamide (IUPAC).

The formulated product for the evaluation was 'BAS 635 00H', a water dispersible granule (WG) containing 714 g/kg of tritosulfuron.

The representative uses evaluated were spray applications for the control of wide range of dicotyledonous weeds (including *Galium aparine*) in maize and all types of small grain cereals like wheat, rye, triticale, barley, durum wheat, spelt wheat and oat (field uses). It should be noted that for some uses, the addition of an adjuvant is recommended. It should be considered at Member State level that the adjuvant proposed for the representative uses contains a component classified as Asp. Tox. 1. H304 at a level higher than 0.1%. Full details of the good agricultural practices (GAPs) can be found in the list of end points in Appendix B.

Data were submitted to conclude that the uses of tritosulfuron 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).

Conclusions of the evaluation

1. Identity, physical/chemical/technical properties and methods of analysis

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

The proposed specification for tritosulfuron is based on batch data from industrial plant production. The proposed minimum purity of the technical material is 992 g/kg. AMTT and TBSA were considered relevant impurities with maximum contents of 0.1 and 4.2 g/kg, respectively (see Section 2). It should be noted that the evaluation of the toxicological relevance of one impurity is open (see Section 2) and, as a consequence, new data such as spectral data, content of the impurity before and after storage of the formulation and method of analysis of the relevant impurity in the formulation might be required.

[6] Reporting table following consultation on the revised RAR on the assessment of the endocrine-disrupting properties and negligible exposure assessment made available after the 19-month clock stop.

[7] Reporting table following consultation on the revised RAR made available for the assessment of the additional information submitted in the framework of the procedure laid down in Article 56 of Regulation (EC) 1107/2009.

[8] It should be noted that tritosulfuron is identified as a pesticide active substance that meets the definition of per- and polyfluoroalkyl substances (PFAS) based on its chemical structure as reported on the ECHA website at the following link: https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas

The batches used in the (eco)toxicological assessment support the proposed new specification but do not support the original reference specification (see Sections 2 and 5). Based on the data for the renewal, the reference specification is proposed to be updated (i.e. higher minimum purity of the active substance, lower maximum level for AMTT and a new relevant impurity TBSA). There is no FAO specification available for tritosulfuron.

The main data regarding the identity of tritosulfuron and its physical and chemical properties are given in Appendix B. For the relevant impurity TBSA, a data gap for spectra data and for the content of the impurity before and after storage of the formulation was set (**data gap, see Section 10**).

Adequate analytical methods are available for the generation of data required for the risk assessment. Methods of analysis are available for the determination of the active substance and the relevant impurities in the technical material and for the active substance and AMTT in the formulation for representative uses. An analytical method for determination of TBSA in the formulation was not provided (**data gap, see Section 10**).

The components of the residue definition (tritosulfuron and AMTT) in food and feed of plant origin can be monitored by liquid chromatography with tandem mass spectrometry (LC–MS/MS) with a limit of quantification (LOQ) of 0.001 mg/kg in edible matrices and 0.01 mg/kg in wheat forage and straw. Another validated LC–MS/MS exists for determination of AMTT in dry, high water and high acid content commodities with LOQs of 0.0001 mg/kg. The efficiency of the extraction procedures used in these methods was demonstrated for straw (dry commodity) and high-water content commodities (forage); however, extraction efficiency for high acid and high oil content commodities was not demonstrated because of lack of metabolism study in these commodities (not required considering the representative uses).

Residues of tritosulfuron in food of animal origin can be determined by LC–MS/MS with an LOQ of 0.01 mg/kg in all animal matrices. Residues of AMTT in animal products can be monitored by LC–MS/MS with an LOQ of 0.0005 mg/kg in milk and 0.001 mg/kg in all other matrices.

Tritosulfuron residues in soil, water and air can be monitored by LC–MS/MS with LOQs of 0.0005 mg/kg, 0.05 μg/L and 0.044 mg/m^3, respectively.

LC–MS/MS method can be used for monitoring of tritosulfuron residues in body fluids with an LOQ 0.01 mg/kg. Tritosulfuron residues in tissues can be determined by using the monitoring methods for residues in food of animal origin.

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: European Commission (2003, 2012), EFSA (2014b, 2017), and ECHA (2017).

Tritosulfuron was discussed at the Pesticide Peer Review Experts' Meeting 07 – session 2 (June 2019).

In the reference specification, **AMTT** and **TBSA** are identified as toxicologically relevant **impurities**. The proposed levels of 0.1 and 4.2 g/kg (AMTT and TBSA, respectively) for the new reference specification are supported. With regard to the material tested in the critical toxicity studies, it can be considered representative of the new reference specification but not of the original specification (see Section 1). For one impurity, the toxicological relevance could not be concluded (**data gap, see Section 10**); however, the tested levels were considered sufficiently representative of the new reference specification.

Tritosulfuron is rapidly and almost completely **absorbed** (based on mainly urinary, and biliary excretion) after oral administration in rats. Tritosulfuron is widely **distributed** (highest levels in gut, kidney and liver) and no evidence is found of potential bioaccumulation.

Tritosulfuron **metabolism** is limited, the parent is the main compound **excreted** while numerous metabolites were detected in low amounts. Major urinary rat metabolite identified is M635H015. The hydroxylated metabolite M635H017 was only detected in human hepatocytes in the *in vitro* comparative metabolism study.[9] M635H017 is considered covered by the toxicological profile of the major urinary rat metabolite M635H015, based on structural similarity. The residue definition for body fluids (plasma and urine) should include tritosulfuron for the purpose of human biomonitoring.

[9] Please refer to Pesticide Peer Review Experts' TC 07 (expert consultation point 2.1) (EFSA, 2023).

Tritosulfuron is of low **acute toxicity** after oral, dermal and inhalation exposure and it is not an eye or skin irritant. Tritosulfuron has a harmonised classification as Skin Sens.1 H317 'May cause an allergic skin reaction'.[10] Tritosulfuron is not phototoxic in the 3 T3 NRU-PT test. However, tritosulfuron is mainly a UVB absorber and the 3 T3 NRU-PT test might not be suitable to test UVB absorbers (**data gap, see Section 10**).

In **short-term** dietary studies conducted in rat, mouse and dog, the dog was the most sensitive species.[11] The overall oral short-term no-observed adverse effect level (NOAEL) is 6 mg/kg bw per day based on a decreased body weight gain, an increased alkaline phosphatase (ALP) and a decreased urea concentration observed at 31 mg/kg body weight (bw) per day in the 12-month oral dog study. In the 90-day oral dog study, the NOAEL is established at 15 mg/kg bw per day based on a decreased body weight gain (also observed in the first days of treatment), a decreased albumin, an increased ALP, an increased adrenal and liver weight and a hepatocellular hypertrophy observed at 92 mg/kg bw per day.

Genotoxicity of tritosulfuron was studied *in vivo* and *in vitro*. Negative results were obtained in bacteria and mammalian cell gene mutation assays. In an *in vitro* chromosomal aberration study, positive results were obtained in the presence of metabolic activation, while negative results were obtained in an *in vivo* micronucleus study conducted in mice with proof of bone marrow exposure. Based on the available evidence, tritosulfuron is unlikely to be genotoxic.[12]

The relevant **long-term** NOAEL is 48 mg/kg bw per day in the 24-month carcinogenicity study in rat, based on effects (ano-genital region smeared with urine, increased water consumption) observed at 170.4 mg/kg bw per day. No increased incidences of tumours were seen in rat (testing tritosulfuron with AMTT level of 0.024%) and mouse (testing tritosulfuron with AMTT level of 2.46%). The carcinogenicity NOAEL is 327 mg/kg bw per day from the 24-month carcinogenicity study in rat.[13]

In the multigeneration **reproductive toxicity** study in rat,[14] fertility and overall reproductive performance were not impaired; clinical signs of toxicity (urine smeared fur) and an increased water consumption were observed in parental animals while a decreased body weight gain and an increased incidence of dilated renal pelvis were observed in F2 and in F1b pups, respectively. The relevant parental and offspring NOAEL is 65 mg/kg bw per day. The reproductive NOAEL is 352 mg/kg bw per day. In the **developmental toxicity** studies, there was no evidence of teratogenicity, and the relevant maternal NOAELs are 120 mg/kg bw per day for the rat and 150 mg/kg bw per day for the rabbit, based on a reduced body weight gain accompanied by a decreased food intake and a discoloured urine/haematuria in rabbit. Based on the increased total visceral variations, hydroureters, dilation of renal pelvis in rats and a slightly increased incidence of incompletely ossified skull bones in rabbits, the developmental NOAELs are 120 mg/kg bw per day for the rat and 150 mg/kg bw per day for the rabbit.

In the acute **neurotoxicity**, subchronic neurotoxicity or developmental neurotoxicity studies, no clinical, behavioural or histopathological signs indicating a neurotoxic potential of tritosulfuron were observed. Potential for immunotoxicity was not observed in the available toxicity studies.[15]

The acceptable daily intake (**ADI**) of tritosulfuron[16] is 0.06 mg/kg bw per day, based on the 12-month study in dog, supported by the carcinogenicity rat study, and applying an uncertainty factor (UF) of 100. In the previous assessment, the same ADI was derived on the same basis (European Commission, 2008).

The acute reference dose (**ARfD**)[15] is 0.15 mg/kg bw, based on the 90-day study in dog and applying the default UF of 100. In the previous assessment, an ARfD was considered not necessary.

The systemic acceptable operator exposure level (**AOEL**)[15] is 0.15 mg/kg bw per day based on the 90-day dog study and using the UF 100. No correction for oral absorption is needed. The same AOEL was derived in the first approval.

The acute acceptable operator exposure level (**AAOEL**)[15] is 0.15 mg/kg bw per day on the same basis as the ARfD and no correction for oral absorption is needed.

[10] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355.
[11] Please refer to Pesticide Peer Review Experts' TC 07 (expert consultation point 2.2) (EFSA, 2023).
[12] Please refer to Pesticide Peer Review Experts' TC 07 (expert consultation point 2.3) (EFSA, 2023).
[13] Please refer to Pesticide Peer Review Experts' TC 07 (expert consultation point 2.4) (EFSA, 2023).
[14] Please refer to Pesticide Peer Review Experts' TC 07 (expert consultation point 2.5) (EFSA, 2023).
[15] Please refer to Pesticide Peer Review Experts' TC 07 (expert consultation point 2.6) (EFSA, 2023)
[16] Please refer to Pesticide Peer Review Experts' TC 07 (expert consultation point 2.9) (EFSA, 2023)

For the assessment of the toxicological profile of the **metabolites**,[17] a grouping approach was applied taking into account the metabolic pathways, the chemical similarity and the information on chemical reactivity (structural alerts). Based on the available evidence, M635H004 (AMTT), M635H001, M635H003 and M635H002 (TBSA) are considered unlikely to be genotoxic; however, the aneugenicity potential has not been specifically tested for M635H001 and M635H003 (**data gap; see Section 10**).[18] Based on the implemented SANCO Guidance (European Commission, 2003), these four metabolites, M635H001, M635H002, M635H003 and M635H004, are considered not toxicologically relevant groundwater metabolites.

In the context of additional information on potentially harmful or unacceptable effects submitted by the applicant BASF SE and falling under Article 56 of Regulation (EC) No 1107/2009, two new metabolites M635H020 and trifluoroacetic acid (TFA) were identified from the new aerobic soil degradation study and the new confined rotational crop study (see Background section). Pending on the data gaps identified in Sections 3 and/or 4, the assessment of the (geno)toxicity profile for metabolite **M635H020** and **M635H019** might be needed (**data gap; see Section 9.1**). For the metabolite trifluoroacetic acid (**TFA**),[19] it was found not mutagenic or clastogenic; however, aneugenicity was not investigated (**data gap; see Section 9.1**); the toxicological reference values agreed during the peer review of flurtamone (EFSA, 2016) are applicable: an ADI of 0.05 mg/kg bw per day based on a 90-day rat study, applying an increased UF of 200 for the extrapolation from subchronic to chronic toxicity, and an ARfD of 0.05 mg/kg bw based on a 14-day rat study, applying an UF of 200 for the incomplete data package.[20] Adverse developmental effects after exposure to TFA (higher incidence of major fetal abnormalities) identified in a developmental toxicity study in rabbits were not taken into account in the renewal of approval of tritosulfuron since at the time of conducting the peer review process, these follow-up investigations were still ongoing at ECHA level (see Background section).

Concerning M635H004 (**AMTT**), the ADI/ARfD/AOEL/AAOEL is 0.0012 mg/kg bw (per day), derived from the specific 32-week study in rat, applying a default uncertainty factor (UF) of 100 as well as an additional factor of 10 due to the incomplete data package and a factor of 3 due to the use of a LOAEL. It is noted that the previous ADI/ARfD/AOEL was 0.0001 mg/kg bw (per day) based on the two-generation rat study and applying a default UF of 100 and an additional factor of 5 (European Commission, 2008).

Concerning **M635H001**, the ADI is 0.34 mg/kg bw per day, derived from a specific 28-days rat study, applying a default UF of 100 and an additional factor of 10 due to the uncomplete data package. Concerning **M635H003**, the ADI is 1.2 mg/kg bw per day, based on a specific 90-day dietary rat study, applying a default UF of 100 and an additional factor of 10 due to the incomplete data package.

Concerning M635H002 (**TBSA**), the ADI is 0.0058 mg/kg bw per day based on a specific one-generation reproductive toxicity study, and applying the default UF of 100, an additional factor of 10 for extrapolation of study duration (subacute to chronic) and an additional assessment factor of 3 for using the LOAEL instead of the NOAEL. The ARfD is 0.9 mg/kg bw based on a specific subacute rat study, applying a default UF of 100.

Pending the data gaps regarding the rotational crops field trials, and confirmation of their levels in groundwater for **M635H020**, **M635H19** and trifluoroacetic acid (**TFA**), further toxicological data for these potentially relevant metabolites might be needed (see Sections 3 and 4).

Dermal absorption values for the formulation for representative uses 'BAS 635 00H' (WG) are 10% and 50%, corresponding to the default values for the concentrate and spray dilution, respectively, according to the Guidance on dermal absorption (EFSA, 2017).

[17] Please refer to Pesticide Peer Review Experts' TC 07 (expert consultation point 2.8) (EFSA, 2023).

[18] EFSA noted that the lack of aneugenicity investigations might have an impact on the setting of reference values and could have triggered an additional UF. However, this has not been discussed during the peer review. Please see also the conclusion for triflusulfuron-methyl (EFSA, 2022).

[19] It should be noted that trifluoroacetic acid is identified as a metabolite that meets the definition of per- and polyfluoroalkyl substances (PFAS) based on its the chemical structure as reported on the ECHA website at the following link: https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas.

[20] Note: Adverse developmental effects in rabbits after exposure to TFA were observed in a development toxicity study (2021) conducted by the applicant Bayer and the REACH lead registrant producer of TFA under Regulation (EC) No 1907/2006 (REACH); As investigations on TFA revealed potential adverse effects, a notification under Article 56 of Regulation (EC) 1107/2009 was submitted on 7 January 2021. Further follow-up investigations are currently underway.

The dermal absorption value for AMTT has been set at 24%[21] based on the *in vitro* human skin study testing 'BAS 635 00H' for the concentrate. For the in-use dilution, the dermal absorption value is set at 50% which is the default value according to the Guidance on dermal absorption (EFSA, 2017).

For the **non-dietary exposure assessment**, predictions were also provided for AMTT since, in addition of being a toxicologically relevant impurity, it can also be formed during storage of the product (0.2% for mixing/loading) and spray dilution (0.216% for chronic and 0.3% for acute exposure). Considering these levels of AMTT,[22] the exposure estimates were extrapolated from the predicted exposure levels for tritosulfuron and compared to the respective (A)AOEL.

For all categories of the exposed population (operators, workers, residents and bystanders), the exposure estimates were below the (A)AOEL for the representative uses in cereals and maize (low crops) for both tritosulfuron and AMTT, without the use of personal protective equipment (only workwear) for operators and workers. Therefore, the results of the field study where operator exposure to AMTT was measured were not further considered, while based on the air concentrations of AMTT, the measured exposures for bystanders and residents were all below 10% of the (A)AOEL.

3. Residues

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

Tritosulfuron was discussed at the Pesticides Peer Review Experts' Meeting 09 (24–28 June 2019).

Metabolism studies in primary crops were conducted with phenyl- and triazine-labelled tritosulfuron in cereals (maize and wheat) after post-emergence foliar treatment.

Tritosulfuron was found to be the major compound in maize grain, with up to 29% total radioactive residues (TRR) while in wheat grain occurring at only 7.3% TRR. Metabolite **M635H001** was found far below 10% TRR in wheat grain and above 10% TRR in maize grain, but its absolute concentration was low (0.001 mg/kg). Metabolites **M635H006**, **M635H013**, **M635H017**, M635H002 (**TBSA**) and M635H004 (**AMTT**) occurred at levels far below 10% TRRs in grain.

In forage and straw, **tritosulfuron** was the major component up to 59% TRRs (maize forage), 53% TRRs (wheat straw), 25% TRRs (maize straw) and 20% TRRs (maize silage), while **M635H013** was present up to 29% TRRs in maize forage and 22% TRRs in wheat straw. Metabolites **AMTT** and **TBSA** occurred at levels 6% and 4% TRRs, respectively, in wheat straw.

Sufficient GAP compliant field trials in cereals (wheat, barley, rye and maize) analysing for the parent compound and metabolites, AMTT and TBSA in grain, forage and straw were submitted. In grains, only residues of **AMTT** and **TBSA** were detected up to 0.00042 and 0.0015 mg/kg, respectively. In forage and straw, only **parent** and **AMTT** were present.

Confined rotational metabolism studies were conducted with both phenyl and triazine rings labelled tritosulfuron at a max rate of 60 g/ha (in bare soil) at three plant back intervals (PBI) of 30, 120, 365 days, covering four crop groups (roots/tuber, leafy, cereals, pulses/oilseeds). The metabolic pathway in the edible parts of the rotational crops was found similar to the primary crops. In October 2022, a new confined rotational crops metabolism study conducted on spinach, radish and wheat with tritosulfuron labelled on the triazine ring was submitted and assessed by the RMS under Article 56 of Regulation (EC) No 1107/2009 concerning information on potentially harmful or unacceptable effects (see Background section). This study covers all three PBIs showing the formation of trifluoroacetic acid (TFA) at significant amounts in all investigated crops up to 87.3% TRRs in wheat forage and 109.2% of TRRs in white radish.

Field rotational crop studies on spinach, carrots, cauliflower and wheat, at 50 g a.s./ha (in bare soil) and analysing for tritosulfuron, TBSA and AMTT residues at PBI of 30 days or 120 days (spinach) were available; M365H006 (predominant metabolite mainly in feed items) was not determined in these trials. At harvest, **tritosulfuron** residues were below the LOQ of 0.001 mg/kg in all mature plant parts and below the LOQ of 0.01 mg/kg in wheat straw, except for one trial on cauliflower and spinach (0.002 mg/kg and 0.0011 mg/kg, respectively). Residue levels above the LOQ were recovered for **TBSA** in wheat grain (0.004 mg/kg) and for **AMTT** on spinach (0.0017–0.002 mg/kg). Since tritosulfuron was applied to bare soil and the interception by the plants has not been considered, rotational crops were sown at PBI of 30 days (unlikely scenario for cereals use), while the PEC soil for parent, TBSA and AMTT was not covered.[23] Besides, storage stability data for tritosulfuron and AMTT

[21] Please refer to Pesticide Peer Review Experts' TC 07 (expert consultation point 2.10) (EFSA, 2023).
[22] Please refer to Pesticide Peer Review Experts' TC 07 (expert consultation point 2.11) (EFSA, 2023).
[23] Please refer to Pesticide Peer Review Experts' TC 09 (expert consultation point 3.1) (EFSA, 2023).

in tomato, cucumber, cauliflower and spinach, and for TBSA in tomato and cucumber do not cover the storage time of samples (**data gap; see Section 10**). Due to the above uncertainties and since metabolite AMTT may accumulate in soil, sufficient rotational crop field trials at all PBIs (30 days, 90–270 days, and 365 days) covering the PECs soil for the parent, TBSA, AMTT and M365H006 are still required (**data gap; see Sections 4 and 9.1**). Additionally, field rotational crops trials analysing for TFA resulting from the use of tritosulfuron covered by storage stability data and validated analytical met for TFA resulting from the use of tritosulfuron covered by storage stability data and validated analytical method are triggered by the new rotational crop metabolism study (**data gap; see Section 9.1**).

Based on the above and considering the different toxicological properties observed for tritosulfuron, TBSA and AMTT, the residue definition for **monitoring** is proposed as 'tritosulfuron and AMTT' separately, whereas for **risk assessment (RA)**, the inclusion of **TBSA** was considered provisionally, pending the outcome of the requested rotational crop field trials (see data gap above).[23] Regarding metabolite **M365H006**, its inclusion in the RA residue definition is pending the outcome of the requested rotational crop field trials. Therefore, **the residue definition for risk assessment (RD-RA)**, is proposed provisionally as 'tritosulfuron, AMTT and TBSA' to be considered separately. For rotational crops only additionally TFA is included in the RD-RA. Both proposals for RD for monitoring and RA are restricted to cereals by foliar application and rotational crops.

The stability of **tritosulfuron** residues was demonstrated in several matrices when stored at temperature below −5°C while the stability of **AMTT** and **TBSA** was also demonstrated when stored < −10°C and at −20°C, respectively (see details in Appendix B).

Under the standard hydrolysis conditions representative of processing (pasteurisation, baking, sterilisation), tritosulfuron was degraded to **AMTT**, **TBSA** and 4-amino-6-(trifluoromethyl)-1,3,5-triazin-2-ol **(AHTT)**, the latter was formed at (13% TRR) under sterilisation.[23] The experts agreed that AHTT is not relevant for consumer intake for the representative uses; however, it should be reconsidered in case of any future additional uses. Considering the representative uses on wheat and maize, under hydrolytic conditions for boiling/brewing/baking (60 min at 100°C, pH 5), **AMTT** and **TBSA** were formed at 12.7% and 14.4% TRR, respectively; thus, the **same residue definitions as for primary crops** are applicable to the processed commodities.

As regards processing trials, they were not submitted since the residues in grains were all below 0.01 mg/kg. However, the magnitude of residues in rotational crops for tritosulfuron, AMTT, TBSA and TFA is still pending, and therefore, additional data on processing trials might be also needed.

Livestock metabolism studies with both phenyl- and triazine-labelled tritosulfuron were available at exaggerated rate (147–440 N) for ruminants and (910–2275 N) for poultry when compared with dietary burden intake. Tritosulfuron, TBSA and AMTT were the most predominant compounds in all animal matrices.

In milk, tritosulfuron was found up to (102% TRR), AMTT up to (42% TRR) and TBSA (1% TRR) identified in lower amounts. Similarly, in tissues (kidney, liver, muscle), tritosulfuron accounted for up to 87% TRR and for up to 55% TRR in fat. Metabolites TBSA and AMTT were found in tissues for up to 21% and 61% TRR, respectively.

In eggs, tritosulfuron was found up to (44% TRR), TBSA (42% TRR), AMTT (44% TRR) and M635H009 (22% TRR). Similarly, in tissues, tritosulfuron accounted for up to 53% TRR, whereas TBSA for up to 66% TRR, AMTT for up to 71% TRR and metabolite M635H009 for 25% TRR in muscle and less than 10% TRR in other tissues.

It is noted that the metabolite **M635H009** was not recovered in the rat metabolism. Nevertheless, the studies were conducted at exaggerated rates and the actual levels of the identified metabolites TBSA, AMTT and M635H009 are expected at a trace level (< 0.001 mg/kg). Thus, the residue definition for **monitoring** and **risk assessment** for animal commodities is proposed as 'tritosulfuron and AMTT', to be considered separately.

Metabolism studies in fish were not available, since tritosulfuron, AMTT and TBSA are not fat soluble and significant residues were not detected in grains.

Regarding the magnitude of residues in pollen and bee products for human consumption, no data were submitted and the impact from primary crops is not expected. However, the magnitude of residues in rotational crops is still not elucidated. Therefore, pending the results from the rotational field trials, the magnitude of residues in pollen and other bee products may my need to be addressed.

Two indicative consumer risk assessment calculations were performed by using EFSA PRIMo rev.2 and EFSA PRIMo rev 3.1 for tritosulfuron, AMTT and TBSA separately with the toxicological reference values (see Section 2). As input values for residue levels for tritosulfuron LOQ of 0.01 mg/kg for RC,

cereals and animal commodities, for AMTT, LOQs of 0.001 mg/kg (cereals, milk) and 0.01 mg/kg (RC, other animal commodities) and for TBSA HR values from primary and RCs were used.

The results with PRIMO rev.2 were as follows: TMDIs were 0.8% of the ADI (FR toddler) for tritosulfuron, 7.2% of the ADI (FR toddler) for AMTT, 1.2% of the ADI (WHO cluster diet B) for TBSA. The maximum IESTI were 0.8% of the ARfD (milk, UK infant) for tritosulfuron, 72.9% of the ARfD (scarole, NL diet, rotational crops) for AMTT and 0.02% of the ARfD for TBSA (for melons, rotational crops).

The results with PRIMO rev 3.1 were as follows: TMDIs were, 13% of the ADI (NL toddler) for tritosulfuron, 10% of the ADI (NL toddler) for AMTT, 1% of the ADI (NL toddler) for TBSA. The maximum IESTI were 0.8% of the ARfD (milk, UK infant) for tritosulfuron; 34% of the ARfD (scarole BE toddler, rotational crops) for AMTT; and 0.02% of the ARfD (for melons rotational crops) for TBSA.

As regards the consumer exposure via drinking water the input values used for M635H001, M635H002 (TBSA), M635H003 were 2.4; 2.4; 6.9 μg/L, respectively (see Section 4). For **TBSA,** the intake is 1.4% of the ADI for adults, 4.1% of the ADI for children and 6.2% of the ADI for infants. For the metabolites **M635H001** and **M635H003,** the intake is below 0.11% of the ADI for all three population groups. **No consumer risk assessment was performed for TFA since no data were available neither for dietary intake nor for drinking water (see the data gaps on RC and in Section 4)**. Overall, the consumer risk assessment is provisional pending the data required on rotational crops for all the relevant metabolites **(data gap; see Section 9.1**).

It is noted that in the framework of the peer review for the renewal of the approval of tritosulfuron, different residue definition for risk assessment for plant was provisionally proposed compared to the Article 12 MRL review (EFSA, 2015). The toxicological reference values were also changed: for AMTT, the ARfD was increased to 0.0012 mg/kg bw, while for tritosulfuron, an ARfD of 0.15 mg/kg bw was set. Therefore, the MRLs derived under Article 12 of the Regulation (EC) No 396/2005 may need to be revised (EFSA, 2015).

The data gaps identified in the MRL Article 12 review for a confirmatory method and an ILV for the determination of AMTT residues in livestock matrices are fulfilled (EFSA, 2015). The data gaps related to the estimation of the soil plateau concentration of AMTT and conducting additional field RC on cereals, leafy and root vegetables at a dose rate covering this plateau, was not addressed and a data gap for RC studies was set as described above.

4. Environmental fate and behaviour

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, tritosulfuron exhibited moderate persistence, forming the major (> 10% applied radioactivity (AR)) metabolites **M635H001** (max. 62.5% AR), M635H002 (**TBSA**, max. 25.5% AR), **M635H003** (max. 17.3% AR), which exhibited medium to high persistence, and metabolite M635H004 (**AMTT**, max. 6% AR), which exhibited moderate to medium persistence. No mineralisation of the phenyl ring ^{14}C radiolabel to carbon dioxide accounted after 122 days, while mineralisation of the triazine ring ^{14}C radiolabel to carbon dioxide accounted for 4.7% AR after 90 days. The formation of unextractable residues for the phenyl ring ^{14}C radiolabel accounted for 28.4% AR after 122 days and for the triazine ring ^{14}C radiolabel accounted for 17.2% AR after 90 days. In a new aerobic soil degradation study submitted in the framework of the procedure under Article 56 of Regulation (EC) No 1107/2009 concerning information on potentially harmful or unacceptable effects (see Background section), metabolite **M635H020** was formed (max. 9% AR); however, a full data package (e.g. rate of degradation, possible field studies, soil adsorption) together with an environmental exposure assessment was not provided for this new metabolite (**data gap; see Section 9.1**). Consequently, the soil degradation endpoints and the environmental exposure assessment should have been updated for tritosulfuron and metabolites M635H001, TBSA (M635H002) and M635H003 (**data gap; see Section 9.1**). Furthermore, in this new study, it was shown that trifluoroacetic acid (**TFA)** was formed (max. ca. 22% of applied tritosulfuron). However, a kinetic evaluation to derive degradation rate and formation fraction in soil for TFA together with analysis results from field studies, soil adsorption information and an environmental exposure assessment were not provided (**data gap, see Section 9.1**). In anaerobic soil incubations, tritosulfuron formed the major (> 10% AR) metabolite **M635H019** (max. 16% AR) which was not formed under aerobic conditions. Considering that anaerobic conditions may occur during the winter season, anaerobic degradation of tritosulfuron is relevant for uses on winter cereals following winter application. Therefore, a data gap is identified to address the exposure assessment of metabolite M635H019 (**data gap; see Section 10**).

Tritosulfuron exhibited very high mobility in soil. Metabolite M635H001 exhibited very high to medium soil mobility, metabolites M635H002 and M635H003 exhibited very high to high soil mobility and M635H004 exhibited very high soil mobility. It was concluded that the adsorption of tritosulfuron was not pH dependent.

In satisfactory field dissipation studies carried out at two sites in Germany, one in Denmark, one in Bulgaria and one in Italy (spray application to the soil surface on bare soil plots in spring) tritosulfuron exhibited low to moderate persistence. Field study DegT50 values were derived following normalisation to FOCUS reference conditions (20°C and PF2 soil moisture) following the EFSA DegT50 guidance (EFSA, 2014a). The field data endpoints were not combined with lab values to derive modelling endpoints. Furthermore, satisfactory field dissipation studies carried out at three sites in Germany, at two in Spain, one in Sweden and at four sites in the US (spray application to the soil surface on bare soil plots in late spring) tritosulfuron exhibited moderate persistence. The endpoints derived from these studies were not used to derive modelling endpoints.

In lysimeter studies of 2-year duration, the maximum concentration of tritosulfuron was 0.04 μg/L. Metabolites M635H001, TBSA (M635H002) and M635H003 were found to reach a maximum annual average concentration of 1.04 μg/L, 0.11 μg/L and 0.57 μg/L, respectively. Metabolite AMTT (M635H004) μg/L was not detected at level > 0.05 μg/L. Metabolite M635H017 was detected only in lysimeter studies at a level < 0.1 μg/L.

In laboratory incubations in dark aerobic natural sediment water systems, tritosulfuron formed the major metabolites **M635H001** (max. 29% AR in water and 35% AR in sediment) and **TBSA** (M635H002) (max. ca. 15% AR in water but only 1% max. in sediment). The unextractable sediment fraction for the phenyl ring ^{14}C radiolabel accounted for 3.8–9.8% AR at study end (100 days) and for the triazine ring ^{14}C radiolabel accounted for 4.8–9.3% AR at study end (100 days). Mineralisation accounted for only 0.7–1.2% AR for the phenyl ring ^{14}C radiolabel and for 1.3–5.0% AR for the triazine ring ^{14}C radiolabel at the end of the study. The rate of decline of tritosulfuron in a laboratory sterile aqueous photolysis experiment was stable. No chromatographically resolved component (excluding tritosulfuron) accounted for > 10% AR.

Considering the data gap for an updated exposure assessment for metabolites M635H001, TBSA (M635H002) and M635H003, predicted environmental concentrations (PEC) calculations are not considered acceptable as these soil metabolites were found at higher levels than in the original soil incubation database (**data gap; see Section 9.1**). Therefore, the existing PEC for metabolites M635H001, TBSA (M635H002) and M635H003 have been deleted from the list of endpoints but are reported in the RAR as being reliable when considering the original study database.

The necessary surface water and sediment exposure assessments PEC calculations were carried out for the metabolites M635H001, TBSA (M635H002), M635H003 and AMTT (M635H004), 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 tritosulfuron, appropriate step 3 (FOCUS, 2001) was available.[24]

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.[24] Two sets of calculations were performed using plant uptake factor of 0 at Tier 0 and of 0.5 at Tier 1. The potential for groundwater exposure from the representative uses by tritosulfuron above the parametric drinking water limit of 0.1 μg/L was concluded to be low in geoclimatic situations that are represented by all nine FOCUS groundwater scenarios for representative uses on maize and spring cereals. For the representative use on winter cereals, the 80th percentile annual average recharge concentrations of tritosulfuron leaving the top 1 m soil layer were estimated to be > 0.1 μg/L at three out of eight scenarios at tier 0 and at one out of eight scenarios at tier 1. For the representative uses on maize, the 80th percentile annual average recharge concentrations leaving the top 1 m soil layer were estimated to be > 0.1 μg/L at eight out of eight scenarios for metabolites M635H001, M635H002, M635H003 (exceedingly also 0.75 μg/L) at both Tier 0 and Tier 1, and one out of eight scenarios for metabolite M635H004 Tier 0.

For the representative uses on spring cereals (BBCH 13), the 80th percentile annual average recharge concentrations leaving the top 1 m soil layer were estimated to be > 0.1 μg/L at six of six scenarios for metabolites M635H001, M635H002, M635H003 (exceedingly also 0.75 μg/L) at both Tier 0 and Tier 1, and three out of six scenarios for metabolite M635H004 at Tier 0 and two out of six scenarios at Tier 1.

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

For the representative uses on winter cereals (BBCH 13), the 80th percentile annual average recharge concentrations leaving the top 1 m soil layer were estimated to be > 0.1 μg/L at nine of nine scenarios for metabolites M635H001, M635H002, M635H003 (exceedingly also 0.75 μg/L) at both Tier 0 and Tier 1, and four of nine scenarios for metabolite M635H004 at Tier 0 and two out of nine scenarios at Tier 1.

Considering the toxicology assessment of the available data, M635H001, M635H002, M635H003 and M635H004 are not considered relevant for groundwater (see Section 2).

The applicant provided appropriate information to address the effect of water treatment processes on the nature of the residues that might be present in surface water and groundwater when surface water or groundwater is abstracted for drinking water. The conclusion of this consideration was that neither tritosulfuron nor any of its degradation products that trigger assessment would be expected to undergo any substantial transformation due to oxidation at the disinfection stage of usual water treatment processes.

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

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002), SETAC (2001), EFSA (2009), EFSA PPR Panel (2013) and EFSA (2013). Some parts of the risk assessment were discussed in the Pesticide Peer Review Experts' meeting 6 in June 2019.

The ecotoxicological batches were considered sufficiently representative of the new technical specification but do not support the original reference specification (see Section 1).

Toxicity data for the active substance were available for **birds and mammals** and used to assess the acute and reproductive risks. For mammals, toxicity data with rats for the metabolite M635H004 (AMTT) were also available. On the basis of the available risk assessments, a low acute and reproductive dietary risk, from tritosulfuron, to birds and mammals was concluded. The dietary risk assessment for metabolite M635H004 (AMTT) was discussed at the experts' meeting[25] where the available assessment was agreed. On this basis, a low risk to birds and mammals from metabolite M635H004 (AMTT) was concluded. A low risk to birds and mammals from tritosulfuron and pertinent metabolites from secondary poisoning and consumption of contaminated water was concluded. Following the procedure under Article 56 of Regulation (EC) No 1107/2009 and the new studies submitted concerning information on potentially harmful or unacceptable effects (see Background section and Section 4), a risk assessment for birds and mammals when exposed to the metabolite **TFA** was triggered (see Section 3). However, this was not presented (**data gap; see Section 9.1**).

Acute and chronic toxicity data were available for the relevant taxa of **aquatic organisms** for the active substance. Acute toxicity data were also available for pertinent aquatic metabolites (M635H001, TBSA (M635H002), M635H003, AMTT (M635H004)) for fish, aquatic invertebrates and algae. A further study investigating the effects of metabolite M635H0019 to aquatic plants was also available. Toxicity data were also available for the formulation for representative uses with, and without the adjuvant.

Based on the available risk assessment using FOCUS step 1 exposure estimates a low acute and chronic risk to **fish, aquatic invertebrates and algae**, from tritosulfuron, was concluded for all representative uses. Using FOCUS step 3 exposure estimates, a low risk to aquatic plants was concluded for the representative uses to maize and spring sown cereals. For the representative use to winter sown cereals, a low risk was indicated for all FOCUS surface water scenarios except for the D2 scenario. A tier-2 risk assessment was performed using a refined endpoint derived from a species sensitivity distribution (SSD). The appropriateness of the data used for the SSD was discussed and agreed by the experts during the experts' meeting.[26] The experts agreed on the proposed the refined endpoint, together with an assessment factor of 3, which resulted in a Regulatory Acceptable Concentration (RAC). Using the tier 2-RAC in the risk assessment, a low risk to aquatic plants was concluded.

A low risk for fish and aquatic invertebrates and algae was concluded for the pertinent surface water metabolites (M635H001, TBSA (M635H002), M635H003, AMTT (M635H004)) at FOCUS Step 1.

[25] Please refer to Pesticide Peer Review Experts' TC 06 (expert consultation point 3.2) (EFSA, 2023).
[26] Please refer to Pesticide Peer Review Experts' TC 06 (expert consultation point 5.3) (EFSA, 2023).

No aquatic plant toxicity data were available for these metabolites. Nevertheless, a low risk was concluded given the low toxicity of these metabolites to other aquatic organisms. It has to be noted that following the submission of new data under Article 56 procedure, the available PEC values were not updated for the metabolites M635H001, TBSA (M635H002) and M635H003 (see Section 4). However, based on the identified margin of safety of the risk assessment, low risk can still be concluded. No exposure assessment for metabolite M635H019 was available (see Sections 4 and 10) and as such no quantitative risk assessment could be performed. Nevertheless, given that the endpoint from the study with metabolite M635H019 is substantially higher than that for tritosulfuron (more than 3,000 times higher), it is possible to conclude a low risk. Pending on the data gap identified in Section 4 triggered by the assessment of the additional data submitted under Article 56 procedure, a risk assessment for the metabolites M635H020 and TFA is needed (**data gap; see Section 9.1).** The risk to aquatic organisms from the formulated product was considered to be addressed by the available assessment for the active substance.

Toxicity data were available for both **honey bees and bumble bees**. For honey bees, acute data were available for the active substance and for the formulation for representative uses with an adjuvant ('BAS 152 00 S') different to that specified in the GAP. Chronic toxicity data for adult honey bees and honey bee larvae were available for the formulation for representative uses. For bumble bees, acute data were available with the active substance. No data were available investigating accumulative toxicity nor sublethal effects (hypopharyngeal gland (HPG)) (**data gap; see Section 10**). No chronic toxicity data were available for bumble bees. Furthermore, no toxicity data were available for solitary bees.

The available risk assessments, based on both EFSA (2013) and European Commission (2002) guidance, indicated a low acute risk to honeybees for all proposed uses. The chronic risk to adult honeybees and honeybee larvae was assessed according to EFSA (2013) and a low risk was concluded. Based on a risk assessment according to EFSA (2013), the acute risk to bumblebees was assessed to be low. The risk to bees from metabolites was concluded to be low for the representative uses and considering the toxicity profile of the parent substance. No risk assessment to honey bees was available for exposure via residues in water. Following the Article 56 procedure and the new studies submitted, a risk assessment for honeybees when exposed to the metabolite TFA was triggered (see Section 3). However, this was not presented (**data gap; see Section 9.1**).

For **non-target arthropods**, data were available for the formulation for representative uses together with an adjuvant (BAS 9047 0 S) different to that specified in the GAP for the standard tier 1 species and several additional tier 2 species. On the basis of the available tier 1 and tier 2 risk assessment, a low in-field and off-field risk to non-target arthropods was concluded.

Studies with **non-target soil micro, meso- and macrofauna, including earthworms**, were available for the formulation with and without adjuvant in the case of earthworms and soil microorganisms and for the metabolites (TBSA (M635H002), M635H003, M635H001 and AMTT (M635H004)). Additionally, for earthworms, data were available with the active substance. No toxicity data were available with metabolite M635H0019. On the basis of the available risk assessment, it was concluded that tritosulfuron and its pertinent metabolites, TMSA (M635H002), M635H003, M635H001 and AMTT (M635H004) pose a low risk to non-target soil macro-organisms. A low risk to soil nitrogen transformation processes from tritosulfuron and metabolites TBSA (M635H002), M635H003, M635H001 and AMTT (M635H004) was concluded for all representative uses. It has to be noted that following the submission of new data under Article 56 procedure, the available PEC values were not updated for the metabolites M635H001, TBSA (M635H002) and M635H003 (see Section 4). However, based on the identified margin of safety of the risk assessment, low risk can still be concluded. No quantitative risk assessment was available for metabolite M635H019; however, given the high margin of safety obtained in the risk assessment for the parent (greater than a factor of 10), a low risk to soil macro- and microorganisms was concluded. Pending on the data gap identified in Section 4 triggered by the assessment of the additional data submitted under Article 56 procedure, a risk assessment for soil organisms for the metabolites M635H020 and TFA is needed (**data gap; see Section 9.1**).

Data were available assessing the toxicity of the formulation for representative uses (with- and without adjuvant) to **non-target terrestrial plants**. On the basis of the available risk assessments, a high risk for non-target terrestrial plants was identified at tier 1. A refined risk assessment using a refined endpoint, i.e. hazardous concentration for 5 % of the species (HC5), derived from a species sensitivity distribution (SSD), was available and indicated low risk for the formulation without adjuvant. The risk assessment for the formulation for representative uses with the adjuvant indicated that risk mitigation measures were needed to reach a low risk (see Section 8).

On the basis of the available data and risk assessment, low risk to organisms in **sewage treatment processes** was concluded for all representative uses.

6. Endocrine disruption properties

With regard to the oestrogen, androgen, steroidogenesis and thyroid (EATS) modalities for humans, the data set was considered complete and a pattern of EATS-mediated adversity was not identified. Therefore, based on the available and sufficient data set, it was concluded that the ED criteria for humans are not met for the EATS modalities (Scenario 1a of the EFSA/ECHA (2018) ED Guidance).[27]

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, two level 3 studies, one according to OECD TG 248 (Xenopus Eleutheroembryonic Thyroid Assay) and one according to OECD TG 230 (21-day Fish Assay) were conducted to sufficiently investigate the endocrine activity through the T and EAS-modalities, respectively. No positive evidence for endocrine activity was observed in any of the two available studies.

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, it can be concluded that tritosulfuron is not an endocrine disruptor.

[27] Please refer to Pesticide Peer Review Experts' TC 07 (expert consultation point 2.7) (EFSA, 2023).

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[(a)]

Compound (name and/or code)	Ecotoxicology
Tritosulfuron	Provisionally low risk to soil organisms.
M635H001*	
TBSA (M635H002)*	
M635H003*	
M635H004 (AMTT)	
M635H019 (anaerobic)	
M635H020	Data gap
Trifluoroacetic acid (TFA)	Data gap

(a): Consideration of effects data in soil for metabolites M635H020 and TFA are triggered by the assessment of additional information on potentially harmful or unacceptable effects submitted by the applicant BASF SE and falling under Article 56 of Regulation (EC) No 1107/2009.

*: Considering the data gap for an updated exposure assessment for metabolites M635H001, M635H002 and M635H003 PECsoil are not considered acceptable. Therefore, existing PECsoil for these metabolites are deleted from the LoEP but are left in the RAR as informative values. Moreover, based on the high margin of safety in the risk assessment and the related endpoints, the outcome is not considered to be affected by any change in the PEC values.

Table 2: Groundwater[(a),(c)]

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
Tritosulfuron	No maize and spring cereals. Winter cereals: 3/9 FOCUS scenarios (Tier 0: 0.107–0.188 µg/L; Tier 1 0.167 µg/L)	Yes	–	–	Yes
M635H001*	Yes Maize: 8/8 FOCUS scenarios (Tier 0: 0.45 –1.73 µg/L; Tier 1 0.27–1.4*8 µg/L) Spring cereals: 6/6 FOCUS scenarios (Tier 0: 1.16–2.76 µg/L; Tier 1 0.92–2.37 µg/L) Winter cereals: 9/9 FOCUS scenarios (Tier 0: 0.24–2.60 µg/L; Tier 1 0.18–2.28 µg/L)	No	Genotoxicity: not mutagenic, not clastogenic, aneugenicity not investigated (data gap) General toxicity: 28-day rat study NOAEL = 344 mg/kg bw per day (high dose) Reference values: ADI: 0.34 mg/kg bw per day	Yes Provisional Consumer intake: 0.02% ADI (adult), 0.07% ADI (child), 0.11% ADI (infant)	No

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
M635H002 (TBSA)*	Yes Maize: 8/8 FOCUS scenarios (Tier 0: 0.42–1.95 μg/L; Tier 1 0.37–1.68 μg/L) Spring cereals: 6/6 FOCUS scenarios (Tier 0: 0.64–1.76 μg/L; Tier 1 0.56–1.56 μg/L) Winter cereals: 9/9 FOCUS scenarios (Tier 0: 0.76–2.73 μg/L; Tier 1 0.71–2.43 μg/L)*	No	Genotoxicity: not mutagenic, not clastogenic, not aneugenic General toxicity: 1-generation rat study LOAEL = 17.3 mg/kg bw per day; Sub-acute rat study NOAEL = 90.7 mg/kg bw per day Reference values: ADI: 0.0058 mg/kg bw per day ARfD: 0.9 mg/kg bw	Yes Provisional Consumer intake: 1.4% ADI (adult), 4.1% ADI (child), 6.2% ADI (infant)	No
M635H003*	Yes Maize: 8/8 FOCUS scenarios (Tier 0: 1.41–5.85 μg/L; Tier 1 1.27–5.03 μg/L) Spring cereals: 6/6 FOCUS scenarios (Tier 0: 2.17–5.76 μg/L; Tier 1 1.90–5.14 μg/L) Winter cereals: 9/9 FOCUS scenarios (Tier 0: 2.22–7.86 μg/L; Tier 1 1.98–6.95 μg/L)*	No	Genotoxicity: not mutagenic, not clastogenic, aneugenicity not investigated (data gap) General toxicity: 90-day rat study NOAEL = 1187 mg/kg bw per day (high dose) Reference values: ADI: 1.2 mg/kg bw per day	Yes Provisional Consumer intake: 0.02% ADI (adult), 0.06% ADI (child), 0.09% ADI (infant)	No
M635H004 (AMTT)	Yes Maize: 1/8 FOCUS scenarios (Tier 0: 0.11 μg/L); Spring cereals: 3/6 FOCUS scenarios (Tier 0: 0.10–0.16 μg/L); 2/6 FOCUS scenarios (Tier 1 0.10–0.14 μg/L) Winter cereals: 4/9 FOCUS scenarios (Tier 0: 0.11–0.13 μg/L); 2/9 FOCUS scenarios (Tier 1 0.11–0.12 μg/L)	No	Genotoxicity: not mutagenic, not clastogenic, not aneugenic General toxicity: 32-week rat study LOAEL = 3.6 mg/kg per day Reference values: ADI/ARfD/AOEL/ AAOEL: 0.0012 mg/kg bw (per day)	Provisionally no	No
M635H019 (anaerobic)	Data gap	Open**	Data gap	Open	Open
M635H020	Data gap	Open**	Data gap	Open	Open

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
Trifluoroacetic acid (TFA)	Data gap, but values > 0.1 µg/L likely	Open**	Genotoxicity: not mutagenic, not clastogenic, aneugenicity not investigated (data gap) General toxicity: 14-day rat study NOAEL = 43 mg/kg per day 90-day rat study NOAEL = 9.9 mg/kg bw per day Developmental toxicity: open[28] Reference values[29]: ADI 0.05 mg/kg bw per day ARfD of 0.05 mg/kg bw	Open	Open

(a): Assessment according to European Commission guidance of the relevance of groundwater metabolites (2003).
(b): FOCUS scenarios or relevant lysimeter.
(c): Consideration of effects data in groundwater for metabolites M635H020 and TFA is triggered by the assessment of additional information on potentially harmful or unacceptable effects submitted by the applicant BASF SE and falling under Article 56 of Regulation (EC) No 1107/2009.
*: Considering the data gap for an updated exposure assessment for metabolites M635H001, M635H002 and M635H003 PECgw are not considered acceptable. Therefore, existing PECgw for these metabolites are deleted from the LoEP, but are left in the RAR as informative values.
**: Pending submission of the environmental fate and behaviour data screening for biological (pesticidal) activity might be required.

Table 3: Surface water and sediment[(a)]

Compound (name and/or code)	Ecotoxicology
Tritosulfuron	Low risk to aquatic organisms.
M635H001*	Provisionally low risk to aquatic organisms.
TBSA (M635H002)*	Provisionally low risk to aquatic organisms.
M635H003*	Provisionally low risk to aquatic organisms.
M635H004 (AMTT)	Provisionally low risk to aquatic organisms.
M635H019 (soil anaerobic)	Provisionally low risk to aquatic organisms.
M635H020	Data gap
Trifluoroacetic acid (TFA)	Data gap

(a): Consideration of effects data in surface water and sediment for metabolites M635H020 and TFA are triggered by the assessment of additional information on potentially harmful or unacceptable effects submitted by the applicant BASF SE and falling under Article 56 of Regulation (EC) No 1107/2009.
*: Considering the data gap on an updated exposure assessment for metabolites M635H001, M635H002 and M635H003 PECsw, sed are not considered acceptable. Therefore, existing PECsw,sed for these metabolites are deleted from the LoEP, but are left in the RAR as informative values. Moreover, based on the high margin of safety in the risk assessment, the outcome is not considered to be affected by any change in the PEC values.

[28] Adverse developmental effects in rabbits after exposure to TFA were observed in a development toxicity study (2021) conducted by the applicant Bayer and the REACH lead registrant producer of TFA under Regulation (EC) No 1907/2006 (REACH); As investigations on TFA revealed potential adverse effects, a notification under Article 56 of regulation (EC) 1107/2009 was submitted on 7 January 2021. Further follow-up investigations are currently underway.
[29] Values agreed during the peer review of flurtamone (EFSA, 2016).

Table 4: Air

Compound (name and/or code)	Toxicology
Tritosulfuron	Rat LC_{50} inhalation > 5.4 mg/L air/4 h (head/nose inhalation)

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 (Table 5). These measures applicable for human health and/or the environment leading to a reduction of exposure levels of operators, workers, bystanders/residents, environmental compartments and/or non-target organisms for the representative uses are listed below. The list may also cover any RMMs as appropriate, leading to an acceptable level of risks for the respective non-target organisms.

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

8.1. Particular conditions proposed for the representative uses evaluated

Table 5: Risk mitigation measures proposed for the representative uses assessed

Representative use	Winter cereals	Spring cereals	Spring cereals with under sown grasses	Winter cereals, Spring cereals	Maize
Operator risk	RMM not required	RMM not required	RMM not required	RMM not required	RMM not required
Worker exposure	RMM not required	RMM not required	RMM not required	RMM not required	RMM not required
Bystander/ resident exposure	RMM not required	RMM not required	RMM not required	RMM not required	RMM not required
Risk to non-target terrestrial plants	RMM to 5 m buffer zone or 75% drift reduction	RMM to 5 m buffer zone or 75% drift reduction	RMM to 5 m buffer zone or 75% drift reduction	RMM to 5 m buffer zone or 75% drift reduction	RMM to 5 m buffer zone or 75% drift reduction

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[30] 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) The consumer risk assessment could not be finalised due to the following issues:
   a) Rotational crop field trials in the representative crops analysing for tritosulfuron and metabolites TBSA, AMTT and M365H006 at all PBIs (30 days, 90–270 days and 365 days) and covering the PECs soil, respectively, for the relevant compounds are required (relevant for the representative uses evaluated; see Section 3).
   b) Sufficient field rotational crop trials analysing for TFA[31] resulting from the use of tritosulfuron covered by storage stability data and validated analytical method are required (relevant for all representative uses evaluated, see Section 3).
   c) Pending on the results of the rotational crop trials, further assessment of the aneugenicity potential of metabolite TFA should be provided (relevant for all representative use evaluated; see Section 2)
2) Based on the additional data submitted in the context of the Article 56 procedure, the environmental exposure assessment could not be finalised due to the following issues:
   a) A full data package (e.g. rate of degradation, possible field studies, soil adsorption) together with an environmental exposure assessment was not provided for metabolite M635H020 (relevant for all representative uses evaluated; see Section 4).[31]
   b) A kinetic evaluation to derive degradation endpoints in soil together with field studies, soil adsorption and an environmental exposure assessment were not provided for TFA (relevant for all representative uses evaluated; see Section 4).[31]
   c) The soil degradation endpoints and the environmental exposure assessment were not updated for tritosulfuron and metabolites M635H001, TBSA (M635H002) and M635H003 (relevant for all representative uses evaluated; see Section 4).[31]
   d) Pending confirmation of levels in groundwater, further assessment of the (geno)toxicity profile of metabolite M635H020 and M635H019 should be provided (relevant for all representative uses evaluated; see Section 2).[31]
   e) Pending confirmation of levels in groundwater, further assessment of the aneugenicity potential of metabolite TFA should be provided (relevant for all representative uses evaluated; see Section 2).[31]
3) A risk assessment for birds and mammals and bees when exposed to the metabolite TFA[30] was not available (relevant for all representative uses evaluated; see Section 5).
4) A risk assessment for aquatic and soil organisms when exposed to the metabolites M635H020[30] and TFA was not available (relevant for all representative uses evaluated; see Section 5).

[30] 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.

[31] This data gap is triggered by the assessment of additional data submitted under Article 56 procedure. Note that PEC for the active substance tritosulfuron have been retained in appendix B where field DegT50 endpoints were the basis for the calculations.

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:

No critical areas of concern have been identified.

9.3. Overview of the concerns identified for each representative use considered (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	Spring cereals	Spring cereals with under sown grasses	Winter cereals, Spring cereals	Maize
Operator risk	Risk identified					
	Assessment not finalised					
Worker risk	Risk identified					
	Assessment not finalised					
Resident/bystander risk	Risk identified					
	Assessment not finalised					
Consumer risk	Risk identified					
	Assessment not finalised	X[1]	X[1]	X[1]	X[1]	X[1]
Risk to wild non-target terrestrial vertebrates	Risk identified					
	Assessment not finalised	X[3]	X[3]	X[3]	X[3]	X[3]
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified					
	Assessment not finalised	X[2,3,4]	X[2,3,4]	X[2,3,4]	X[2,3,4]	X[2,3,4]
Risk to aquatic organisms	Risk identified					
	Assessment not finalised	X[2,4]	X[2,4]	X[2,4]	X[2,4]	X[2,4]

Representative use		Winter cereals	Spring cereals	Spring cereals with under sown grasses	Winter cereals, Spring cereals	Maize
Groundwater exposure to active substance	Legal parametric value breached					
	Assessment not finalised					
Groundwater exposure to metabolites	Legal parametric value breached[(a)]					
	Parametric value of 10 µg/L[(b)] breached					
	Assessment not finalised	X[1,3]	X[1,3]	X[1,3]	X[1,3]	X[1,3]

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

(a): Based on classification made in the context of this evaluation procedure under Regulation (EC) No 1107/2009. It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Or it should be noted that the classification proposed in the context of this evaluation procedure under Regulation (EC) No 1107/2009 concurs with the harmonised classification and labelling in accordance with Regulation (EC) No 1272/2008.

(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:

- Spectra data for the relevant impurity TBSA (relevant for all representative uses evaluated; see Section 1).
- Analytical method for determination of the relevant impurity TBSA in the formulation for representative uses (relevant for all representative uses evaluated; see Section 1).
- Content of the relevant impurity TBSA before and after storage of the formulation for representative uses (relevant for all representative uses evaluated; see Section 1).
- The toxicological relevance of one impurity should be addressed (relevant for all representative uses evaluated; see Section 2).
- Phototoxicity testing applying the new version of the OECD TG 432 (June, 2019) that would allow for proper assessment of UVB absorbers is required (relevant for all representative uses evaluated; see Section 2).
- The aneugenicity potential of metabolites M635H001 and M635H003 should be further investigated (relevant for all representative uses evaluated; see Section 2).
- Storage stability data for tritosulfuron and AMTT in tomato, cucumber, cauliflower, spinach and for TBSA in tomato and cucumber are needed, covering the maximum storage time interval of the residue samples from the field rotational crop studies (relevant for all representative use evaluated; see Section 3).
- Exposure assessment of metabolite M635H019 formed in soil under anaerobic conditions (relevant for the representative use in winter cereals; see Section 4).
- Data investigating the sublethal effects to honey bees (relevant for all representative uses evaluated; see Section 5).

References

ECHA (European Chemicals Agency), 2017. Guidance on the Application of the CLP Criteria; Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures. Version 5.0 July 2017. Reference: ECHA-17-G-21-EN; ISBN: 978–92–9020-050-5. Available online: https://echa.europa.eu/guidance-documents/guidance-on-clp

ECHA and EFSA (European Chemicals Agency and European Food Safety Authority) with the technical support of the Joint Research Centre (JRC), Andersson N, Arena M, Auteri D, Barmaz S, Grignard E, Kienzler A, Lepper P, Lostia AM, Munn S, Parra Morte JM, Pellizzato F, Tarazona J, Terron A and Van der Linden S, 2018. Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. EFSA Journal 2018;16(6):5311, 135 pp. https://doi.org/10.2903/j.efsa.2018.5311

EFSA (European Food Safety Authority), 2008. Opinion on a request from EFSA related to the default Q10 value used to describe the temperature effect on transformation rates of pesticides in soil. EFSA Journal 2008;6 (1):622, 32pp. https://doi.org/10.2903/j.efsa.2008.622

EFSA (European Food Safety Authority), 2009. Guidance on Risk Assessment for Birds and Mammals on request from EFSA. EFSA Journal 2009;7(12):1438, 358 pp. https://doi.org/10.2903/j.efsa.2009.1438

EFSA (European Food Safety Authority), 2013. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera, Bombus* spp. and solitary bees). EFSA Journal 2013;11(7):3295, 268 pp. https://doi.org/10.2903/j.efsa.2013.3295

EFSA (European Food Safety Authority), 2014a. EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 37 pp. https://doi.org/10.2903/j.efsa.2014.3662

EFSA (European Food Safety Authority), 2014b. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874, 55 pp. https://doi.org/10.2903/j.efsa.2014.3874. Available online: www.efsa.europa.eu/efsajournal

EFSA (European Food Safety Authority), 2015. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for tritosulfuron according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13 (1):3964, 48 pp. https://doi.org/10.2903/j.efsa.2015.3964

EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance flurtamone. EFSA Journal 2016;14(6):4498, 24 pp. https://doi.org/10.2903/j.efsa.2016.4498

EFSA (European Food Safety Authority), 2017. Guidance on dermal absorption. EFSA Journal 2017;10(4):2665, 60 pp. https://doi.org/10.2903/j.efsa.2017.4873

EFSA (European Food Safety Authority), 2023. Peer review report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance tritosulfuron. Available online: www.efsa.europa.eu

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290, 186 pp. https://doi.org/10.2903/j.efsa.2013.3290

European Commission, 2000a. Residues: guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (Part A, Section 4) and Annex III (Part A, Section 5) of Directive 91/414. SANCO/3029/99-rev. 4, 11 July 2000.

European Commission, 2000b. Technical material and preparations: guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (Part A, Section 4) and Annex III (Part A, Section 5) of Directive 91/414. SANCO/3030/99-rev. 4, 11 July 2000.

European Commission, 2002. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002-rev. 2 final, 17 October 2002.

European Commission, 2003. Guidance Document on Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Council Directive 91/414/EEC. SANCO/221/2000-rev. 10 final, 25 February 2003.

European Commission, 2008. Review report for the active substance tritosulfuron. SANCO/1256/08 – final. 20 May 2008.

European Commission, 2010. Guidance Document on residue analytical methods. SANCO/825/00-rev. 8.1, 16 November 2010.

European Commission, 2011. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. SANCO 7525/VI/95-rev. 9 March 2011. pp. 1–46.

European Commission, 2012. Guidance document on the assessment of the equivalence of technical materials of substances regulated under Regulation (EC) No 1107/2009. SANCO/10597/2003-rev. 10.1, 13 July 2012.

European Commission, 2014a. Assessing potential for movement of active substances and their metabolites to ground water in the EU. Report of the FOCUS Workgroup. EC Document Reference SANCO/13144/2010-v. 3, 613 pp., as outlined in Generic guidance for tier 1 FOCUS groundwater assessment, v. 2.2 May 2014.

European Commission, 2014b. Guidance document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No 844/2012. SANCO/2012/11251-rev. 4, 12 December 2014.

FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use), 2001. FOCUS surface water scenarios in the EU evaluation process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios. EC Document Reference SANCO/4802/2001-rev. 2, 245 pp., as updated by Generic guidance for FOCUS surface water scenarios, v. 1.4 May 2015.

FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use), 2006. Guidance document on estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU Registration Report of the FOCUS Work Group on Degradation Kinetics. EC Document Reference SANCO/10058/2005-v. 2.0, 434 pp., as updated by the Generic guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, v. 1.1 December 2014.

JMPR (Joint Meeting on Pesticide Residues), 2004. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues, Rome, Italy, 20–29 September 2004, 383 pp.

JMPR (Joint Meeting on Pesticide Residues), 2007. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues, Geneva, Switzerland, 18–27 September 2007, 164 pp.

McCall P J, Laskowski D A, Swann R L, Dishburger H J, 1980. Measurements of sorption coefficients of organic chemicals and their use in environmental fate analysis. In: Test Protocols for Environmental Fate and Movement of Toxicants. In: Proceedings of the 94th Annual Meeting of the American Association of Official Analytical Chemists (AOAC). October 21–22, Washington, DC. pp. 89-109.

OECD (Organisation for Economic Co-operation and Development), 2009. Guidance document on overview of residue chemistry studies. ENV/JM/MONO(2009)31, 28 July 2009.

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: www.oecd.org

SETAC (Society of Environmental Toxicology and Chemistry), 2001. Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods. ESCORT, 2.

Slovenia, 2018. Renewal Assessment Report (RAR) on the active substance tritosulfuron prepared by the rapporteur Member State Slovenia, in the framework of Commission Implementing Regulation (EU) No 844/2012, March 2018. Available online: www.efsa.europa.eu

Slovenia, 2022. Revised Renewal Assessment Report (RAR) on tritosulfuron prepared by the rapporteur Member State Slovenia in the framework of Commission Implementing Regulation (EU) No 844/2012 and in the context of the Article 56 of Regulation (EC) No 1107/2009, December 2022. Available online: www.efsa.europa.eu

Abbreviations

1/*n*	slope of Freundlich isotherm
a.s.	active substance
AAOEL	acute acceptable operator exposure level
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
bw	body weight
CI	confidence interval
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
dw	dry weight
EAS	oestrogen, androgen and steroidogenesis modalities
ECHA	European Chemicals Agency
EEC	European Economic Community
FAO	Food and Agriculture Organization of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
HC5	hazardous concentration for 5 % of the species
HR	hazard rate
IESTI	international estimated short-term intake
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
iv	intravenous
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
K_{Foc}	Freundlich organic carbon adsorption coefficient
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC–MS	liquid chromatography–mass spectrometry
LC–MS-MS	liquid chromatography with tandem mass spectrometry
LOD	limit of detection
LOQ	limit of quantification
mm	millimetre (also used for mean measured concentrations)
mN	milli-Newton
MRL	maximum residue level
MS	mass spectrometry
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
Pa	pascal
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
pF2	pF value of 2 (suction pressure that defines field capacity soil moisture)
ppm	parts per million (10^{-6})
PT	proportion of diet obtained in the treated area
r^2	coefficient of determination
RAC	regulatory acceptable concentration
RAR	Renewal Assessment Report
REACH	Registration, Evaluation, Authorisation of Chemicals Regulation

SC	suspension concentrate
SFO	single first-order
SMILES	simplified molecular-input line-entry system
SSD	species sensitivity distribution
$t_{1/2}$	half-life (define method of estimation)
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UF	uncertainty factor
UV	ultraviolet
W/S	water/sediment
w/v	weight per unit volume
w/w	weight per unit weight
WG	water-dispersible granule
WHO	World Health Organization

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

Properties		Conclusion[(a)]
CMR	Carcinogenicity (C)	Tritosulfuron is not considered to be a carcinogenic according to point 3.6.2 of Annex II of Regulation (EC) No 1107/2009.
	Mutagenicity (M)	Tritosulfuron is not considered to be a mutagen according to point 3.6.3 of Annex II of Regulation (EC) No 1107/2009.
	Toxic for Reproduction (R)	Tritosulfuron is not considered to be a reproductive toxicant according to point 3.6.4 of Annex II of Regulation (EC) No 1107/2009.
Endocrine disrupting properties		Tritosulfuron is not considered to meet the criteria for endocrine disruption for humans and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II of Regulation No 1107/2009, as amended by Commission Regulation (EU) 2018/605.
POP	**Persistence**	Tritosulfuron is not considered to be a persistent organic pollutant (POP) according to point 3.7.1 of Annex II of Regulation (EC) 1107/2009.
	Bioaccumulation	
	Long-range transport	
PBT	**Persistence**	Tritosulfuron 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.
	Bioaccumulation	
	Toxicity	
vPvB	**Persistence**	Tritosulfuron 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.
	Bioaccumulation	

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

Appendix B – List of end points for the active substance and the formulation(s) for representative uses

Appendix B can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2023.8142

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

Wording	DT_{50} normalised to 20°C for laboratory incubations[32] 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 to < 10 days
Moderate persistence	10 to < 60 days
Medium persistence	60 to < 100 days
High persistence	100 days to <1 year
Very high persistence	A year or more

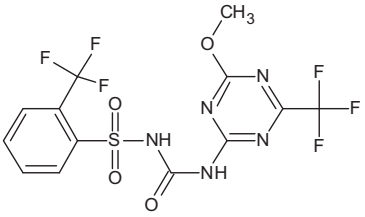
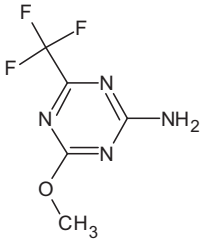
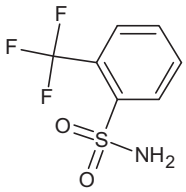
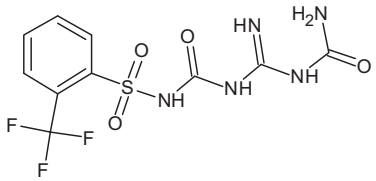
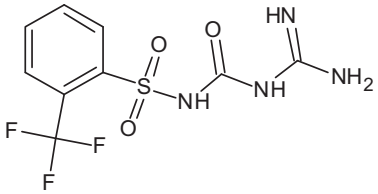
Note these classes and descriptions are unrelated to any persistence class associated with the active substance cut-off criteria in Annex II of Regulation (EC) No 1107/2009. For consideration made in relation to Annex II, see Appendix A.

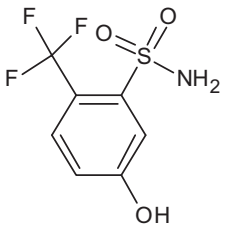
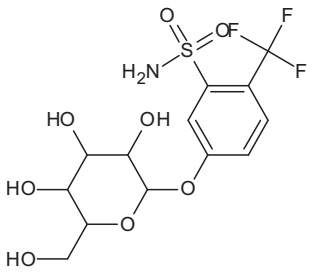
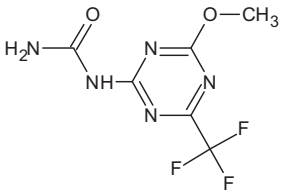
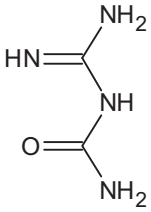
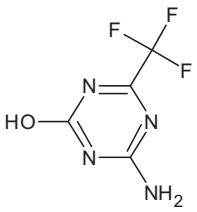
Wording	K_{oc} (either K_{Foc} or K_{doc}) mL/g
Very high mobility	0–50
High mobility	51–150
Medium mobility	151–500
Low mobility	501–2,000
Slight mobility	2,001–5,000
Immobile	> 5,000

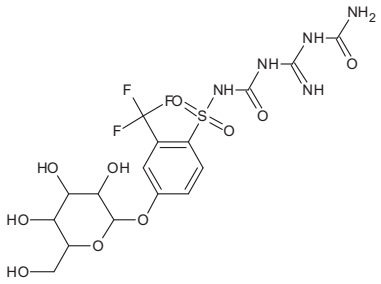
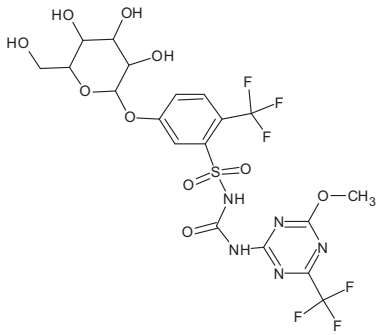
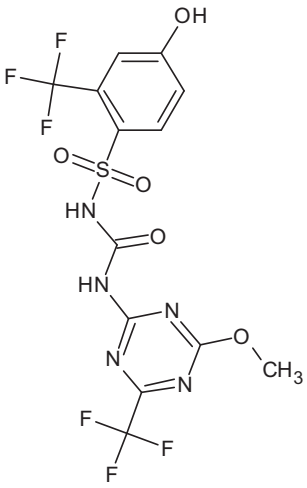
Based on McCall et al. (1980).

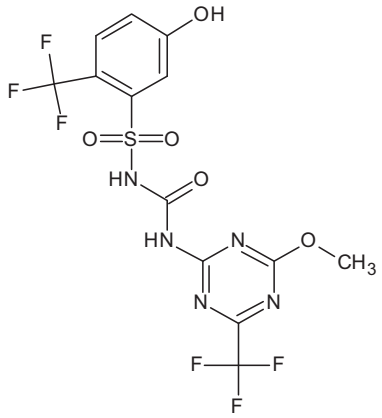
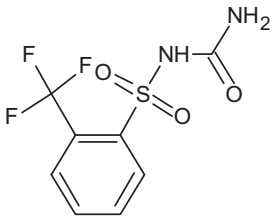
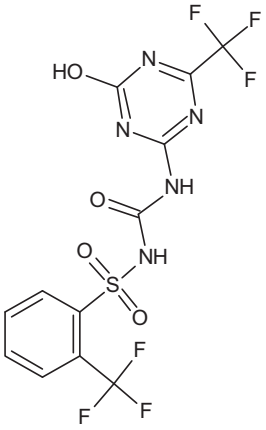
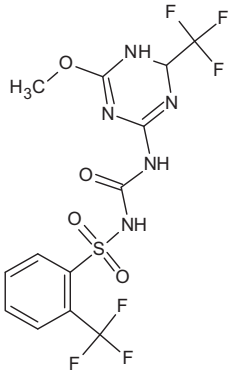
[32] For laboratory soil incubations normalisation was also to field capacity soil moisture (pF2/10 kPa). For laboratory sediment water system incubations, the whole system DT values were used.

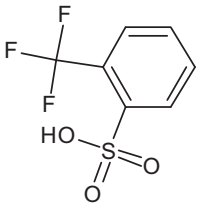
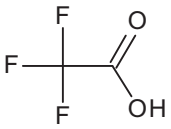
Appendix D – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
tritosulfuron	*N*-{[4-methoxy-6-(trifluoromethyl)-1,3,5-triazin-2-yl]carbamoyl}-2-(trifluoromethyl) benzenesulfonamide COc1nc(nc(NC(=O)NS(=O)(=O)c2ccccc2C(F)(F)F)n1)C(F)(F)F KVEQCVKVIFQSGC-UHFFFAOYSA-N	
M635H004 (AMTT)	4-methoxy-6-(trifluoromethyl)-1,3,5-triazin-2-amine COc1nc(nc(N)n1)C(F)(F)F DTVMLDILWYLGLA-UHFFFAOYSA-N	
M635H002 (TBSA)	2-(trifluoromethyl)benzene-1-sulfonamide O=S(N)(=O)c1ccccc1C(F)(F)F AFFPZJFLSDVZBV-UHFFFAOYSA-N	
M635H001	*N*-[(*N*-carbamoylcarbamimidoyl)carbamoyl]-2-(trifluoromethyl)benzene-1-sulfonamide O=S(=O)(NC(=O)NC(=N)NC(N)=O)c1ccccc1C(F)(F)F WBSGOTBBRAWAJI-UHFFFAOYSA-N	
M635H003	*N*-(carbamimidoylcarbamoyl)-2-(trifluoromethyl) benzene-1-sulfonamide O=S(=O)(NC(=O)NC(=N)N)c1ccccc1C(F)(F)F VPHWAXAVJXQLJQ-UHFFFAOYSA-N	

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
M635H006	5-hydroxy-2-(trifluoromethyl)benzene-1-sulfonamide O=S(N)(=O)c1cc(O)ccc1C(F)(F)F BIHYUHLBDZGXJG-UHFFFAOYSA-N	
M635H007	5-(hexopyranosyloxy)-2-(trifluoromethyl)benzene-1-sulfonamide FC(F)(F)c1ccc(cc1S(N)(=O)=O)OC1OC(CO)C(O)C(O)C1O WGFMDBVXLYWRLZ-UHFFFAOYSA-N	
M635H009	*N*-[4-methoxy-6-(trifluoromethyl)-1,3,5-triazin-2-yl] urea COc1nc(nc(NC(N)=O)n1)C(F)(F)F MVRGPGBKLDXXSC-UHFFFAOYSA-N	
M635H010	*N*-carbamimidoylurea N=C(N)NC(N)=O SQSPRWMERUQXNE-UHFFFAOYSA-N	
M635H011 (AHTT)	4-amino-6-(trifluoromethyl)-1,3,5-triazin-2-ol FC(F)(F)c1nc(N)nc(O)n1 FDFFUNMRNUMHCU-UHFFFAOYSA-N	

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
M635H012	*N*-[(*N*-carbamoylcarbamimidoyl)carbamoyl]-4-(hexopyranosyloxy)-2-(trifluoromethyl)benzene-1-sulfonamide NC(=O)NC(=N)NC(=O)NS(=O)(=O)c1ccc(OC2OC(CO)C(O)C(O)C2O)cc1C(F)(F)F JSGVBZMSBORTMZ-UHFFFAOYSA-N	
M635H013	5-(hexopyranosyloxy)-*N*-{[4-methoxy-6-(trifluoromethyl)-1,3,5-triazin-2-yl]carbamoyl}-2-(trifluoromethyl)benzene-1-sulfonamide FC(F)(F)c1nc(nc(OC)n1)NC(=O)NS(=O)(=O)c1cc(OC2OC(CO)C(O)C(O)C2O)ccc1C(F)(F)F JWCJLMQYLNYELA-UHFFFAOYSA-N	
M635H015	4-hydroxy-*N*-{[4-methoxy-6-(trifluoromethyl)-1,3,5-triazin-2-yl]carbamoyl}-2-(trifluoromethyl) benzene-1-sulfonamide COc1nc(nc(NC(=O)NS(=O)(=O)c2ccc(O)cc2C(F)(F)F)n1)C(F)(F)F FYTPZEUMOWMTMD-UHFFFAOYSA-N	

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
M635H017	5-hydroxy-*N*-{[4-methoxy-6-(trifluoromethyl)-1,3,5-triazin-2-yl]carbamoyl}-2-(trifluoromethyl) benzene-1-sulfonamide COc1nc(nc(NC(=O)NS(=O)(=O)c2cc(O)ccc2C(F)(F)F)n1)C(F)(F)F XGSJEJGOUIZOBV-UHFFFAOYSA-N	
M635H018	*N*-carbamoyl-2-(trifluoromethyl)benzene-1-sulfonamide O=S(=O)(NC(N)=O)c1ccccc1C(F)(F)F MLDADJREQBSUSX-UHFFFAOYSA-N	
M635H019	*N*-{[4-hydroxy-6-(trifluoromethyl)-1,3,5-triazin-2-yl] carbamoyl}-2-(trifluoromethyl)benzene-1-sulfonamide FC(F)(F)c1nc(NC(=O)NS(=O)(=O)c2ccccc2C(F)(F)F)nc(O)n1 UROJKYURKZSQBJ-UHFFFAOYSA-N	
M635H020	*N*-{[6-methoxy-4-(trifluoromethyl)-4,5-dihydro-1,3,5-triazin-2-yl]carbamoyl}-2-(trifluoromethyl) benzene-1-sulfonamide FC(F)(F)C1N=C(NC(=O)NS(=O)(=O)c2ccccc2C(F)(F)F)N=C(OC)N1 YWSOBHDUSJYOKT-UHFFFAOYSA-N	

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
M635H023	2-(trifluoromethyl)benzene-1-sulfonic acid OS(=O)(=O)c1ccccc1C(F)(F)F IXSGUIFSMPTAGW-UHFFFAOYSA-N	
Trifluoracetic acid (TFA)	trifluoroacetic acid FC(F)(F)C(=O)O DTQVDTLACAAQTR-UHFFFAOYSA-N	

(a): The name in bold is the name used in the conclusion.
(b): ACD/Name 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 7 July 2021).
(c): ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 28 August 2021).