CONCLUSION ON PESTICIDES PEER REVIEW

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

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Abstract

The conclusions of the EFSA following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State, France, and co-rapporteur Member State, Denmark, for the pesticide active substance triflusulfuron-methyl are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The conclusions were reached on the basis of the evaluation of the representative uses of triflusulfuron-methyl as a herbicide on sugar beet, fodder beet, red beet, chicory and witloof (field uses). The peer review also provided considerations on whether exposure to humans and the environment from the representative uses of triflusulfuron-methyl can be considered negligible, taking into account the European Commission's draft guidance on this topic. The reliable end points, appropriate for use in regulatory risk assessment, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified. An evaluation of data concerning the necessity of triflusulfuron-methyl as herbicide to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods is also presented.

Keywords: triflusulfuron-methyl, peer review, risk assessment, pesticide, herbicide

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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. Triflusulfuron is one of the active substances listed in that Regulation. It should be noted that for the renewal the applicant proposed, the name of the active substance to be specified as triflusulfuron-methyl. The rapporteur Member State (RMS) and EFSA agreed on this proposal considering the manufacturing process and available data.

In accordance with Article 1 of Regulation (EU) No 844/2012, the RMS, France, and co-rapporteur Member State (co-RMS), Denmark, received an application from FMC Agricultural Solutions A/S for the renewal of approval of the active substance triflusulfuron-methyl.

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

It has been concluded that triflusulfuron-methyl meets the cut-off criteria for non-approval, laid down in Annex II, points 3.6.5 and 3.8.2 of Regulation (EC) No 1107/2009 as amended by Commission Regulation (EU) No 2018/605 concerning endocrine disrupting potential. As part of the renewal procedure, the applicant provided further information aimed at demonstrating that the exposure of humans and/or the environment to triflusulfuron-methyl was negligible under realistic conditions of use. Triflusulfuron-methyl has therefore been assessed under the provisions of negligible exposure to satisfy points 3.6.5 and 3.8.2 of Annex II of Regulation 1107/2009 as amended by Commission Regulation (EU) No 2018/605. Furthermore, the applicant requested a derogation under Article 4(7) of Regulation (EC) 1107/2009, submitting evidence regarding the necessity of triflusulfuron-methyl to control a serious danger to plant health. The evaluation of the data regarding this derogation request is presented in Appendices C and D of this conclusion. Overall, derogation is scientifically supported in the following uses and related Member States as follows: (a) Sugar beet & fodder beet: Austria, Belgium, Denmark, France, Hungary, Germany, Netherlands, Sweden, Poland, Finland; (b) Red beet: Austria, Belgium, Denmark, France, Germany, Netherlands, Sweden; (c) Chicory: Austria, Belgium, Denmark, France, Germany, Sweden; (d) Large rooted chicory: Netherlands; (e) Witloof chicory roots: Netherlands, Belgium; (f) Tuberous begonia: Belgium.

Following completion of the peer review process, the following conclusions are derived.

The use of triflusulfuron-methyl according to the representative uses as a herbicide on sugar beet, fodder beet, red beet, chicory and witloof applied by broadcast and band medium-low volume field spraying, as proposed at EU level, results 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 and chemical properties and analytical methods**.

Regarding **mammalian toxicology**, the toxicological relevance of some impurities in the technical specification could not be concluded due to an incomplete assessment of their general toxicity profile. For the groundwater metabolites IN-M7222 and IN-E7710, the data were not sufficient to conclude on their toxicological relevance, while the groundwater metabolites IN-JM000 and IN-JU122 were concluded as toxicologically relevant. With regard to negligible exposure assessment according to the draft technical guidance on assessment of negligible exposure, levels of exposure below 10% of the (acute) acceptable operator exposure level ((A)AOEL) were identified for operators, workers, residents and bystanders with relevant risk mitigation measures where necessary.

The **consumer dietary risk assessment** could not be finalised in view of the identified data gaps in Sections 2, 3 and 4. The provisional calculated chronic intake according to the EFSA PRIMo rev. 3.1 model accounted for 11% of the acceptable daily intake (ADI) (NL child), whilst an exceedance of the acute reference dose (ARfD) was shown for sugar beet roots/sugar (147%) and for witloofs/boiled (118%) for children. The exceedance of the ARfD for sugar beet root/sugar can be explained by using a processing factor (PF) of 12 for sugar which is highly conservative in the specific case of the 'zero' residue situation established in sugar beet root. The exceedance of the ARfD for witloofs/boiled is linked to the higher consumption data for this processed commodity whilst the residue levels were all below the LOQ of 0.01 mg/kg in witloofs. IESTI calculated for beetroots and for

witloof, Belgian endives amounted to 76% and 53% of the ARfD, respectively. According to EFSA PRIMo rev. 2A model, the calculated chronic intake accounted for 30.5% of the ADI (UK Toddler) whilst the highest acute intake was 85.1% of the ARfD (sugar beet root). Since IN-E7710 and IN-M7222 are major plant and groundwater metabolites, a global exposure of the consumers to these metabolites through dietary intake (according to PRIMo rev.3.1 model) and drinking water was carried out and amounted up to 24%, 64.5% and 88.3% of the ADI, respectively, for adults, children and infants. This assessment is, however, not finalised considering the provisional PECgw values that were calculated for both compounds. The consumer risk assessment is also not finalised with regard to the unknown nature of residues that might be present in drinking water, consequent to water treatment processes following abstraction of surface water or groundwater that might contain the active substance and its metabolites. As for the assessment of **negligible exposure** according to the draft technical guidance on assessment of negligible exposure, residue concentrations above 0.01 mg/kg for the compounds that could be relevant in rotational crops and a potential carry-over of these residues to food items of animal origin cannot be excluded based on the assessment of the submitted residue data.

The data available on **environmental fate and behaviour** were not sufficient to carry out the required environmental exposure assessments at EU level for the representative uses. Based on provisional available groundwater modelling, for the representative uses evaluated, the PECgw for metabolites IN-E7710, IN-M7222, IN-W6725 and IN-JU122 are $>$ 0.1 μg/L in all relevant FOCUS scenarios. Considering the toxicology assessment of the available data, metabolites IN-JU122 and IN-JM000 (for IN-JM000 final groundwater modelling was available) are considered relevant for groundwater which resulted in a critical area of concern being identified. PECsw/PECsed for triflusulfuron-methyl are also provisional since validated adsorption/desorption values for triflusulfuron-methyl are not available.

Low risk to **non-target organisms** i.e. birds and mammals, bees, non-target arthropods, soil organisms, non-target terrestrial plants and organisms involved in biological methods for sewage treatment has been concluded. The risk assessment for aquatic organisms could not be finalised due to lack of validated PECsw values, and therefore, the presented risk assessment should only be considered provisional.

Triflusulfuron-methyl is an **endocrine disruptor** for both humans and wild mammals as non-target organisms according to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605, leading to a critical area of concern.

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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 France and co-RMS Denmark received an application from FMC Agricultural Solutions A/S for the renewal of approval of the active substance triflusulfuron-methyl. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Denmark), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on triflusulfuron-methyl in the RAR, which was received by EFSA on 26 July 2019 (France, 2019).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, FMC Agricultural Solutions A/S, for consultation and comments on 31 October 2019. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 13 January 2020. 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.

It should be noted that for the renewal, the applicant proposed the name of the active substance to be specified as triflusulfuron-methyl. The RMS and EFSA agreed on this proposal considering the manufacturing process and available data.

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 agreed between EFSA and the RMS on 16 April 2020. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicant and that EFSA should conduct an expert consultation in the areas of mammalian toxicology, residues, environmental fate and behaviour and ecotoxicology.

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

[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.

In addition, in accordance with the provisions of Commission Implementing Regulation (EU) No 2018/1659, following a consultation with Member States in the Pesticides Peer Review Expert meeting TC 32 (mammalian toxicology, 9–11 November 2020) and TC 37 (ecotoxicology, 23–24 November 2020), the applicant was given the opportunity to submit, within a period of 3 months, additional information to address the approval criteria set out in point 3.6.5 and/or point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605[4], and/or documentary evidence demonstrating that triflusulfuron-methyl may be used such that exposure is negligible, or the conditions for the application of the derogation under Art.4(7) of Regulation (EC) No 1107/2009 are met.

Subsequently, the applicant provided further information aimed at demonstrating that the exposure of humans and/or the environment to triflusulfuron-methyl was negligible under realistic conditions of use. Triflusulfuron-methyl has therefore been assessed under the provisions of negligible exposure to satisfy points 3.6.5 and 3.8.2 of Annex II of Regulation 1107/2009. Furthermore, the applicant requested a derogation under Article 4(7) of Regulation (EC) 1107/2009, submitting evidence regarding the necessity of triflusulfuron-methyl to control a serious danger to plant health. The evaluation of the data regarding this derogation request is presented in Appendices C and D of this conclusion. A public consultation on the draft Art 4(7) scientific report and the revised RAR on the endocrine disruption and negligible exposure assessments made available after the 3-month clock stop was conducted between 25 August 2021 and 25 October 2021. All comments received, including from the applicant and Member States, were collated in the format of a commenting table (on the draft Art 4(7) scientific report) and reporting table (on the revised RAR on the assessment of the endocrine-disrupting properties and negligible exposure assessment).

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

A final consultation on the conclusions arising from the peer review of the risk assessment, including the negligible exposure assessment and the evaluation of the data regarding the necessity of triflusulfuron-methyl to control a serious danger to plant health which cannot be contained by other available means, took place with Member States via a written procedure in February–March 2022.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the representative formulation, evaluated on the basis of the representative uses of triflusulfuron-methyl as a herbicide on sugar beet, fodder beet, red beet, chicory and witloof (field uses). 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 exposure to humans and the environment from the representative uses of triflusulfuron-methyl can be considered negligible, taking into account the European Commission's draft guidance on this topic. An evaluation of data concerning the necessity of triflusulfuron-methyl as herbicide to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods, is also presented (see Appendices C and D).

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 triflusulfuron-methyl 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, 2022), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report comprises the following documents, in which all views expressed during the course of the peer review, including minority views, where applicable, can be found:

- the comments received on the RAR;
- the comments received on the applicant's report submitted for the evaluation of data concerning the necessity of triflusulfuron-methyl to control a serious danger to plant health (May 2021);

[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.

- the reporting tables (16 April 2020 and 8 December 2021[5]);
- the evaluation table (21 March 2022);
- the reports of the scientific consultation with Member State experts (where relevant);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft Art 4(7) scientific report;
- the comments received on the draft EFSA conclusion.

Given the importance of the RAR, including its revisions France, 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 formulated product

Triflusulfuron-methyl is the modified ISO common name for methyl 2-({[4-(dimethylamino)-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-yl]carbamoyl}sulfamoyl)-3-methylbenzoate (IUPAC).

The representative formulated product for the evaluation was 'Triflusulfuron methyl 50WG', a water dispersible granule (WG) containing 500 g/kg triflusulfuron-methyl.

The representative uses evaluated were broadcast and band medium–low volume spray application to control broadleaf weeds in sugar beet, fodder beet, red beet, chicory and witloof with or without use of an adjuvant (non-ionic surfactant or oil). 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 use of triflusulfuron-methyl according to the representative uses proposed at EU level results in a sufficient herbicidal efficacy against the target weeds, following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014b).

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

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 triflusulfuron-methyl is based on batch data from industrial plant production and quality control (QC) data. The proposed minimum purity of the technical material based on the data submitted for the renewal is 978 g/kg. N,N-dimethyl-6-(2,2,2-trifluoroethoxy)-1,3,5-triazine-2,4-diamine (**IN-D8526**) and dimethylcarbamoyl chloride (**DMCC**) are considered relevant impurities with maximum levels of 5 g/kg and 1.7 mg/kg, respectively. Toxicological relevance of the other impurities could not be concluded (see Section 2). The RMS proposed to update the reference specification to include the two relevant impurities and higher minimum purity of 978 g/kg for the active substance to be set (min. purity in the original reference specification is 960 g/kg). In addition, levels of some of the significant impurities might be lowered. EFSA agrees with the RMS's proposal. The batches used in the toxicological assessment support the proposed updated reference specification but not the original specification (see Section 2). The batches used in ecotoxicological assessment support both original and updated reference specification (see Section 5). There is no FAO specification available for triflusulfuron-methyl.

[5] Reporting table following consultation on the revised RAR on the assessment of the endocrine-disrupting properties and negligible exposure assessment made available after the 3-month clock stop.

The main data regarding the identity of triflusulfuron-methyl and its physical and chemical properties are given in Appendix B. The content of the relevant impurities before and after storage of the plant protection product at ambient temperature for 2 years was not provided (data gap, see Section 10). It is noted that the content of the relevant impurities was analysed in an accelerated storage stability study (8 weeks at 40°C) and showed an increase of the content of impurity IN-D8526 at the end of the study. In addition, it should be noted that evaluation of the toxicological relevance of the other impurities is open and as a consequence, new data such as spectral data, content of the impurities before and after the storage of the formulation and methods for analysis of the relevant impurities in the formulation might be required.

Adequate methods are available for the generation of data required for the risk assessment. Methods of analysis are available for the determination of the active substance in the technical material and in the representative formulation and the impurities in the technical material. An analytical method for determination of the relevant impurities in the plant protection product was submitted by the applicant; however, the method was not assessed and included in the RAR; therefore, a formal data gap remains (see Section 10).

6-(2,2,2-trifluoroethoxy)-1,3,5-triazine-2,4-diamine (**IN-M7222**) residue in food and feed of plant origin can be monitored by DGF S19 using high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) with a limit of quantification (LOQ) of 0.01 mg/kg in all commodity groups. However, the efficiency of the extraction procedure used in the method was not demonstrated (data gap, see Section 10). Triflusulfuron-methyl residue in food of animal origin can be determined by HPLC–MS/MS with an LOQ of 0.01 mg/kg in all animal matrices. It should be noted that extraction efficiency of the method was not addressed. Pending the need to set a residue definition for monitoring for products of animal origin (see Section 3), additional validation data (extraction efficiency) for the available method and/or new validated methods might be required.

Triflusulfuron-methyl in soil and water could be monitored by HPLC-MS/MS with LOQs of 0.05 μg/kg and 0.05 μg/L, respectively. Appropriate HPLC-UV method exists for monitoring of triflusulfuron-methyl in air with a LOQ of 1.1 μg/m^3.

HPLC-MS/MS method can be used for monitoring of triflusulfuron-methyl and its metabolite IN-M7222 in body fluids (plasma and urine) with an LOQ of 0.01 mg/kg. However, the residue definition in body fluids was concluded as triflusulfuron-methyl, IN-M7222 and IN-66036, consequently a **data gap** for validated analytical methods for monitoring of IN-66036 in body fluids was identified (see Section 10). Triflusulfuron-methyl residue in body tissues can be determined by using the monitoring methods for residues in food of animal origin, however considering the lack of bioaccumulation (see Section 2), no body tissue biomonitoring is needed.

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion (European Commission, 2003, 2012a, 2015; EFSA, 2014b, 2017; ECHA, 2017).

Triflusulfuron-methyl was discussed at the Pesticides Peer Review Expert's TC 32 in November 2020.

The impurities IN-D8526 and DMCC are toxicologically relevant with respective acceptable levels of 5 g/kg and 1.7 mg/kg in the technical specification. The other impurities are unlikely to be genotoxic, whereas their general toxicity was not sufficiently assessed,[6] and therefore, their toxicological relevance could not be concluded (data gap and issue not finalised). It is noted that at the proposed levels in the technical specification, they are concluded to be of no toxicological concern. Concerning the test material used in the toxicity studies, it can be considered as representative of the technical specification proposed for the renewal, but not of the original technical specification.

In rats, the oral **absorption** of triflusulfuron-methyl is rapid and accounts for ≥ 80% following a single low dose of 25 mg/kg body weight (bw) per day, based on urinary and bile excretions, and residues in carcasses and cage wash. The compound is widely distributed and extensively metabolised. The major **metabolic pathway** is via hydroxylation/demethylation on the triazine ring and cleavage of the sulfonyl urea bridge. Tissue clearance is rapid from tissues, slower from liver and blood. **Excretion** occurs mainly in bile and urine, and to a limited extent in faeces. There is no evidence of bioaccumulation. The major metabolites are IN-66036 and IN-W6725 in urine and/or plasma in rats. No unique human metabolites have been identified in the *in vitro* comparative metabolism studies.

[6] See Experts' consultation point 2.7 at the Pesticides Peer Review Expert's TC 32 (EFSA, 2022).

Triflusulfuron-methyl has low **acute oral** and **dermal** toxicity. In the rat, inhalation LD_{50} was > 5.1 mg/L (4 h and nose-only). The active substance is neither a skin/eye irritant nor a skin sensitiser or a phototoxicant.

Concerning **short-term** dietary exposure to triflusulfuron-methyl, the relevant oral subchronic no observed adverse effect level (NOAEL) in the rat was 6.6 mg/kg bw per day, based on decreased body weight/gain and food efficiency, increased liver weight and blood anaemia. Liver (clinical chemistry parameters, increased weight, hypertrophy), blood and testes were the target organs in the 1-year dog study, with a relevant oral NOAEL of 26.9 mg/kg bw per day. Liver (histopathological changes associated with increased liver weight) was also the target organ in mice exposed for 90 days.

In vitro and *in vivo* evidence supports that triflusulfuron-methyl is unlikely to be **genotoxic**.

In a **long-term** dietary exposure study, the critical systemic effects in rats were a decrease in body weight and body weight gain, testes changes (increased weight, interstitial cell (Leydig cells) hyperplasia and adenoma) and blood anaemia. The relevant long-term NOAEL was 2.54 mg/kg bw per day (2-year carcinogenicity study). In mice, liver (increased weight, histopathological changes) was the target organ, with an NOAEL of 20.9 mg/kg bw per day in an 18-month study.

Regarding **carcinogenicity**, in rats, there was a significant increase in the incidence of Leydig cell adenoma in male rats at the two higher doses. The mode of action underlying Leydig cell hyperplasia and adenoma seems to involve the perturbation of the hypothalamus-pituitary testis (HPT) axis, via aromatase inhibition and as such it is considered relevant to humans. Accordingly, triflusulfuron-methyl has been classified by ECHA as a Carcinogen Category 2 (H351) (see ECHA RAC Opinion, 2013).

The relevant NOAEL for carcinogenicity from the 2-year rat study is the same as that for the long-term effects, i.e. 2.54 mg/kg bw per day. In the 18-month mouse study, on the other hand, no tumours were considered treatment-related.

With respect to **reproductive toxicity**, the parental NOAEL in a two-generation rat study was 5.81 mg/kg bw per day based on reduced parental body weight and body weight gain and nutritional parameters. The same NOAEL is also applied to offspring effects (reduced body weight in the F1 generation). No adverse reproductive effects were detected in the rat two-generation study, with this resulting in a relevant reproductive NOAEL of 89.5 mg/kg bw per day.

The most critical **developmental toxicity** effect of triflusulfuron-methyl was the increased incidence of abortions and decreased fetal weight observed in rabbit offspring, with an NOAEL of 90 mg/kg bw per day. In the same study, the maternal NOAEL was 15 mg/kg bw per day for body weight loss, decreased body weight gain. Signs of developmental and maternal toxicity of triflusulfuron-methyl were also detected in rats at 1.3- and 8-fold higher doses, respectively, than in rabbits.

There is no indication of **neurotoxicity** based on both acute and repeated neurotoxicity studies.

Concerning the **reference values**, the acceptable daily intake (**ADI)** was set at **0.025 mg/kg bw/day**, based on the NOAEL of 2.54 mg/kg bw per day for decrease in body weight and body weight gain, increased testis weight, Leydig cell adenoma and anaemia in male rats from the 2-year study, applying the default 100-fold uncertainty factor. This ADI value is slightly lower than that of 0.04 mg/kg bw per day set during the first EU approval (European Commission, 2012b) on the basis of the same study and dose level. However, due to the degradation of the test material during the study, the dose levels were adjusted to the lowest concentration level measured in the cage-side feeder samples, resulting in a decrease of the NOAEL from 4.06 to 2.54 mg/kg bw per day in males.

It is noteworthy that triflusulfuron-methyl has harmonised classification as Carcinogenic Cat 2 according to Regulation (EC) No 1272/2008[7] (ECHA, 2013) due to increased incidence of interstitial cell tumours from the dose level of 30.6 mg/kg bw per day (LOAEL) onwards. Therefore, the margin of safety between the ADI and the LOAEL for carcinogenic effects is approx. 1200, which is considered sufficient for this type of effect.

The acute reference dose (**ARfD)** was agreed at **0.15 mg/kg bw**, based on the **maternal NOAEL of 15 mg/kg bw per day** in the **developmental rabbit toxicity study** (based on body weight loss during the first days of dosing), and a 100-fold uncertainty factor. This value replaces the ARfD previously set during the first EU approval (European Commission, 2012b) of 1.2 mg/kg bw, based on the NOAEL from the developmental toxicity study of 120 mg/kg bw in rats.

[7] 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.

The acceptable operator exposure level (**AOEL)** was established at **0.06 mg/kg bw per day**, on the basis of the **NOAEL of 5.8 mg/kg bw per day from the two-generation study** (critical effects: decreased parental and pup body weight, body weight gains), supported by the slightly higher NOAEL of 6.6 mg/kg bw per day from the 90-day rat study (critical effects: decreased body weight, body weight gain and food efficiency, increased mean relative liver weight and haemolytic anaemia), to which a 100-fold uncertainty factor was applied.

As the ARfD, the acute AOEL (**AAOEL)** was also set at **0.15 mg/kg bw**, based on the maternal NOAEL of 15 mg/kg bw per day in the developmental rabbit toxicity study where body weight loss was noted during the first days of dosing, applying a 100-fold uncertainty factor.

IN-M7222 (both a plant and a groundwater metabolite, see also Sections 3 and 4) is unlikely to be mutagenic or clastogenic. However, the available data are not sufficient to conclude on its aneugenic potential (data gap); therefore, its toxicological relevance in groundwater cannot be concluded according to the European Commission guidance of 2003 (issue not finalised; see Section 9.1). IN-M7222 was negative for aromatase inhibition and, as such, considered as not sharing the same carcinogenic properties of the parent. Compared to the parent compound, IN-M7222 had qualitatively similar toxicity but higher potency (for acute and 90-day oral toxicity). In the absence of data on aneugenicity, the approach of applying a relative potency factor to derive the ADI and ARfD for IN-M7222 from those of triflusulfuron-methyl was not considered applicable[8]. Instead, the ADI and ARfD of IN-M7222 were both set at 0.0015 mg/kg bw (per day) on the basis of the NOAEL of 3 mg/kg bw per day in the 90-day toxicity study with IN-M7222, divided by an overall uncertainty factor (UF) of 2000 (including 2 additional factors i.e. 10 for the lack of data on the metabolite and 2 to address the uncertainty regarding aneugenicity).

IN-E7710 (both a plant and a groundwater metabolite) bears structural similarities to IN-M7222. IN-E7710 has a similar lethal dose as IN-M7222, it is negative for mutagenicity and clastogenicity *in vitro*, and its potential for aneugenicity was not investigated (data gap) leading to the inability to conclude on its toxicological relevance as groundwater metabolite according to the European Commission guidance of 2003 (issue not finalised; see Section 9.1). Like IN-M7222, it was negative for aromatase inhibition, therefore was concluded as being devoid of the carcinogenic properties of triflusulfuron-methyl. On the basis of its structural similarity to IN-M7222, the same ADI and ARfD of 0.0015 mg/kg bw (per day) set for IN-M7222 are also considered applicable to IN-E7710.

The plant and potential groundwater metabolite **IN-D8526** has a similar acute toxicity as IN-M7222, and was negative for *in vitro* mutagenicity and clastogenicity, with no investigation of its aneugenic potential. Read across with IN-M7222 was agreed and the same ADI and ARfD of 0.0015 mg/kg bw (per day) applied, in view of their structural similarity.

IN-W6725 (methyl saccharin) is a plant and groundwater metabolite and also major rat metabolite in urine (7.3–11.2% of the administered dose). *In vitro* and *in vivo*, IN-W6725 did not show any genotoxic potential. It is also negative for aromatase inhibition, and therefore, it is not concluded to be toxicologically relevant. Structurally, it is closely related to saccharin (addition of a methyl group on the phenyl ring) and the same ADI value of saccharin of 3.8 mg/kg bw per day (expressed as the free acid, by the European Scientific Committee for Food (EU Commission, 1997)) can be considered applicable also to IN-W6725. No ARfD is needed.

For metabolite **IN-JM000** (groundwater metabolite), no genotoxicity or general toxicity data were provided. In the absence of mechanistic data demonstrating that this metabolite is devoid of any aromatase inhibition potential, the same mode of action (MoA) underlying the carcinogenic effect of the parent active substance (classified as Carcinogen 2) is assumed also for IN-JM000, leading to the conclusion that it is a toxicologically relevant groundwater metabolite according to the European Commission guidance of 2003 (critical area of concern, see Sections 4 and 9.2).

For the metabolite **IN-JU122** (groundwater/plant metabolite), it was shown to be of low acute toxicity and unlikely to be mutagenic or clastogenic *in vitro*. However, its potential for aneugenicity and general toxicity profile (in comparison with triflusulfuron-methyl's) were not investigated. As the same MoA underlying the carcinogenic effect of triflusulfuron-methyl cannot be excluded, this metabolite is concluded to be toxicologically relevant in groundwater according to the European Commission guidance of 2003 (critical area of concern, see Sections 4 and 9.2).

Concerning **IN-JK555** (a residue metabolite), negative results were obtained in an Ames test. Given the close structural similarity between triflusulfuron-methyl (methyl ester) and IN-JK555 (acid form), it was considered likely that both the lack of aneugenic and clastogenic potential and the

[8] See Expert consultation 2.5 at the Pesticides Peer Review Expert's Meeting TC 32 (EFSA, 2022).

reference values of triflusulfuron-methyl could apply to IN-JK555 (ADI = 0.025 mg/kg bw per day; ARfD = 0.15 mg/kg bw). **IN-JJ987** is an intermediate in the formation of the major rat metabolite IN-W6725. Based on the available genotoxicity data, it is concluded unlikely to be genotoxic (as well as its glucose conjugate). Its general toxicity profile is considered to be covered by triflusulfuron-methyl (with applicability of its reference values). For **IN-KA557** (residue/plant metabolite), no genotoxicity data are available. A read-across to IN-E7710 is considered appropriate for both genotoxicity and general toxicity based on structural similarities and metabolic pathway. Therefore, the IN-E7710's ADI = ARfD of 0.0015 mg/kg bw (per day), which includes an additional UF covering for the lack of aneugenicity assessment, is considered applicable also to IN-KA557. For **IN-JH260**, no genotoxicity data are available but a read-across to IN-JJ987 is considered appropriate for genotoxicity as well as for general toxicity based on structural similarities and metabolic pathway. IN-JH260 has thus been assigned the same reference values as IN-JJ987 (ADI = 0.025 mg/kg bw per day; ARfD = 0.15 mg/kg bw). For **T5** (residue/plant metabolite), no toxicity data are available and the same concern for aneugenicity as for IN-D8526, IN-M7222, IN-E7710 and IN-KA557 applies. Likewise, the reference values of IN-D8526, IN-E7710 and IN-M7222 are also considered applicable to T5, in view of structural similarities and considering the rat metabolic pathway.

The **dermal absorption** values applicable to triflusulfuron-methyl in the representative formulation 'Triflusulfuron-methyl 50WG' are the default values of 10% for the concentrate and 50% for the in-use dilution. In case a non-ionic surfactant or oil is added to the tank mix (as mentioned in the summary table of representative uses), a default dermal absorption value of 70% will have to be applied for the in-use dilution.

With regard to the **standard exposure** assessment for the representative uses on sugar and fodder beet (covering also red beet and chicory/witloof), only tractor-mounted applications have been considered. For **operators**, the exposure estimates are 9.5% of the AOEL and 30% of the AAOEL without use of PPE/RPE. For **bystanders** (child and adult), the exposure estimates are up to 6% of the AAOEL with a buffer strip of 2–3 m. For **residential** children, the exposure estimates are up to 12% of the AOEL (mean of all pathways). For **workers**, the exposure estimate is 6.5% of the AOEL with use of workwear (no gloves).

With regard to the **negligible exposure** assessment for **operators**, as first-tier approach according to the draft Commission guidance document (European Commission, 2015), the exposure estimates are below 10% of the (A)AOEL when the application is by tractor with drift reduction, and the operators are wearing gloves during mixing/loading and application. For **workers** (with workwear), the exposure estimates during inspection activity are below 10% of the AOEL without the use of gloves, while for reaching/picking activity (chicory), the predictions are below or equal to 10% of the AOEL in the case of three and four applications of 0.020 and 0.015 kg a.s./ha, respectively, with the use of gloves, and no addition of surfactant in the tank mixture. For **bystanders** (adults and children) and adult **residents**, the exposure estimates are below 10% of the AAOEL when considering a buffer zone of 2–3 m. For residential children, the exposure estimates are 10% of the AOEL with no drift reduction and a buffer zone of minimum 10 m, and without addition of surfactant in the tank mixture.

3. Residues

The assessment in the residue section is based on the following guidance documents (OECD, 2009, 2011; European Commission, 2003, 2011; JMPR, 2004, 2007).

Triflusulfuron-methyl was discussed at the Pesticides Peer Review Experts' Teleconference TC 36 (November 2020).

The metabolism of triflusulfuron-methyl was investigated in sugar beet tops and leaves following foliar treatment, using either the triazine or the ester-carbonyl ^{14}C-labelling form of the parent molecule (1.7 N rate). For both labelling forms, the parent compound was found only in the immature whole plant of sugar beet. The predominant compounds of the total residues were identified as **IN-E7710** and **IN-M7222** in whole plants (up to 50.5% total radioactive residue (TRR) – 0.24 mg eq./kg and 27.5% TRR – 0.013 mg eq./kg, respectively) and in mature tops and leaves (up to 12% TRR – 0.01 mg eq./kg and 53% TRR – 0.042 mg eq./kg, respectively). The metabolite **JJ987**, free and glucoside conjugated was also recovered in significant levels in the whole plant (up to 70% TRR – 0.525 mg eq./kg) or only as glucoside conjugate in tops/leaves (up to 46% TRR – 0.025 mg eq./kg). The total radioactive residues in sugar beet roots were too low for further metabolites' investigation (< 0.01 mg eq./kg for triazine ^{14}C label and 0.01–0.038 mg eq./kg for the

ester-carbonyl ^{14}C label). The shortcomings identified in the metabolism study, i.e. treatment at a BBCH growth stage of 14–18 instead of 39 and the lack of information to demonstrate acceptable extraction efficiency of the method, were concluded not to have a significant impact on the metabolism study that was found to be suitable to fully elucidate the metabolic pathway of triflusulfuron-methyl in sugar beet. Considering the specific growth conditions of witloofs/Belgian endives, the metabolism depicted in sugar beet tops/leaves can be considered representative for this crop. It should, however, be highlighted that if in the future the uses are extended to other leafy crops, a metabolism study representative of this crop category should be provided. The current residue definitions remain unchanged. The **residue definition** for **monitoring** is set as *'IN-M7222'* and for **risk assessment** the residue definition is proposed as the *'Sum of IN-M7222 and IN-E7710, expressed as IN-M7222'*. The experts agreed by a majority opinion that these residue definitions are applicable not only to the sugar beet tops and leaves but also to the roots and can be extrapolated to the whole category of root crops.

In the rotational crops (wheat, lettuce, beetroot) following bare soil treatment with ^{14}C-triazine labelled triflusulfuron-methyl, the predominant compounds of the total residues at all plant back intervals (PBIs) were **IN-M7222** and **IN-E7710** in wheat forage (up to 13.9% TRR – 0.03 mg eq./kg and 28.5% TRR – 0.07 mg eq./kg, respectively), in straw (up to 27.8% TRR – 0.19 mg eq./kg and 30.3% TRR – 0.21 mg eq./kg, respectively), and in beet root foliage (up to 34.2% TRR – 0.08 mg eq./kg and 27.2% TRR – 0.06 mg eq./kg, respectively). Metabolites **IN-KA557** and **T5** (N-hydroxymethyl, N-methyl triazine amine) were also found in wheat forage (up to 14.3% TRR – 0.01 mg eq./kg and 16.8% TRR – 0.04 mg eq./kg, respectively) and in straw (up to 19.4% TRR – 0.14 mg eq./kg and 11.5% TRR – 0.16 mg eq./kg, respectively). In beet root foliage, only a metabolite **T3** (assumed to be IN-KA557) was found up to 22.8% TRR but since its absolute amount recovered in the overdosed metabolism study is low (≤0.05 mg eq./kg), no further elucidation of the exact structure of T3 was needed.

For the ^{14}C-ester carbonyl labelling, methyl saccharin (**IN-W6725**) was found at 27.8% TRR – 0.02 mg eq./kg at 30-d PBI only in wheat forage and a mixture of **E1/E2** (assumed to be **IN-JU122/IN-JH260**) was found at levels of 40.2% TRR – 0.03 mg eq./kg and 42.3% TRR – 0.13 mg eq./kg in wheat forage and straw, respectively, at 30-day PBI only. A complete elucidation of the structure of E1/E2 was not deemed necessary in view of its low actual concentration level considering the overdosed metabolism study and the expected low contribution of this compound to the livestock dietary burden. The total radioactive residues in wheat grain, lettuce and beet roots were too low (< 0.01–0.04 mg eq./kg) to allow for further metabolites' identification.

Regarding the moderate to high/very high persistence of the soil metabolites **IN-M7222**, **IN-E7710**, **IN-JL000, IN-JU122, IN-W6725** and the low to high persistence of **IN-D8526** (see Section 4), their respective concentration in soil at application, at sowing and at harvest of the rotational crops were determined and it was noted that the measured concentrations, respectively, of IN-M7222 and IN-E7710 in soil at sowing were lower compared to the maximal PECaccu calculated for these compounds according to the representative uses. The maximal PECaccu values calculated for the other metabolites were covered. Despite this shortcoming, the metabolism study was considered as sufficiently dosed to fully elucidate the metabolic pathway of triflusulfuron-methyl in rotational crops that is similar to the metabolic pattern depicted in primary crops.

NEU and SEU field residue trials analysed for triflusulfuron-methyl and metabolites IN-M7222 and IN-E7710 in rotational crops planted after sugar beet was treated with triflusulfuron-methyl, in compliance with the representative uses. Residues were below the LOQ (0.01 mg/kg) in all crop parts except for IN-M7222 in cereal straw and hay (0.037 mg/kg and 0.019 mg/kg, respectively) and IN-E7710 in spinaches immature (0.026 mg/kg). Since the soil concentrations of these metabolites were not provided, whether the calculated max PECaccu for these two persistent metabolites was reached in these trials could not be concluded on. Furthermore, these trials were not supported by storage stability data with regard to several crops. Finally and considering also the toxicity profile of metabolites IN-KA557 and T5 (N-hydroxymethyl, N-methyl triazine amine) (see Section 2) that were identified in significant levels and concentrations in wheat straw, their respective magnitude in the rotational crops should also be addressed. The experts of the meeting were therefore of the opinion that sufficient NEU and SEU rotational crops residue field trials, analysing for IN-M7222, IN-E7710, IN-KA557 and T5 using an appropriate analytical method, supported by acceptable storage stability data for all these compounds in food and feed edible parts of the rotational crops and conducted at a dose rate covering the max PECaccu, respectively, for IN-M7222 and IN-E7710 should be provided (data gap, see Section 9.1). Meanwhile, the same residue definitions as for primary crops are provisionally set for rotational crops.

Studies to address the nature of residues in processed commodities at representative hydrolysis conditions are not triggered considering the representative uses and the residues < LOQ (0.01 mg/kg) for IN-M7222 and IN-E7710 in the raw agricultural commodities.

Six NEU and four SEU GAP compliant residue trials analysing for triflusulfuron-methyl, IN-D8526, IN-M7222 and IN-E7710 residues have been submitted on sugar beet with a possible extrapolation to fodder beet, beet root and chicory root. These residue trials were conducted without surfactant. The residue levels in the roots were below the LOQ (0.01 mg/kg) for each analysed compound whilst in sugar beet tops/leaves, a residue value above the LOQ for IN-M7222 (0.019 mg/kg) was found in one SEU trial only. The experts considered by majority opinion that sufficient residue trials were available as a 'zero' residue situation is demonstrated for sugar beet root from the metabolism data and there is currently no general agreement on the number of residue trials to be required for feed items (sugar beet tops and leaves). Sufficient residue trials, respectively, for chicory roots and witloof, Belgian endives and compliant with the NEU GAP have been provided. Although the residue levels of IN-M7222 and IN-E7710 are expected to be below the LOQ in witloof, Belgian endives considering the specific growth conditions for witloofs, sufficient residue trials on witloof, Belgian endives and compliant with the SEU GAP should be provided to confirm this assumption. EFSA highlights that this data gap does not lead to an issue not finalised but considered necessary to comply with the data requirements (see Section 10). It is noted that the RMS expressed its disagreement on this data gap as witloofs, Belgian endives are crops that are grown mainly in Northern Europe. Comparative residue trials (with and without adjuvants) on the crops under consideration were not provided. However, additional Northern European residue trials on sugar beet and conducted with a formulation containing a surfactant were made available and indicated that the use of the surfactant had no impact on the magnitude of the residues in sugar beet root and tops/leaves.

The **livestock** dietary burden calculation should consider the residue levels of IN-M7222 and IN-E7710 both in primary and in rotational crops. Furthermore, this calculation should be revised and finalised pending upon the outcome of the requested rotational crops field trials (see data gap above-mentioned) and finalisation of the risk assessment residue definition for rotational crops.

Poultry metabolism studies were not provided and are not required based on the current provisional dietary burden calculation. The goat metabolism study was conducted following dosing with triflusulfuron-methyl only (180N rate - provisional). For the ^{14}C triazine labelling, the parent compound was extensively metabolised into mainly metabolites **IN-D8526**, **IN-M7222** and **IN-E7710,** which were found to be the predominant compounds of the total residues in milk (24.4% TRR – 0.015 mg eq./kq, 22.2% TRR – 0.013 mg eq./kq and 12.3% TRR – 0.007 mg eq./kq, respectively) along with minor metabolites (< 10% TRR and < 0.01 mg eq./kg). A similar metabolic pattern was observed in liver and kidney, but all the identified metabolites occurred at a level < 10% TRR. For the ester-^{14}C-carbonyl label, **triflusulfuron-methyl** and methyl saccharin (**IN-W6725)** were the predominant compounds of the total residues in liver and kidney (up to 57% TRR – 0.069 mg/kg and 21% TRR – 0.025 mg eq./kg), respectively). It is noted that no metabolites' investigation was performed in muscle and fat although the total radioactive residues accounted for 0.17 mg eq./kg and 0.09 mg eq./kg, respectively. Despite this shortcoming, the total residues are expected to be very low (< 0.01 mg eq./kg) in all matrices at the provisional calculated dietary burden. Provided that the livestock dietary burden calculation will have to be finalised once the data gap on the magnitude of the residues of the relevant metabolites in rotational crops is addressed (data gap, see Section 9.1), the compliance of the submitted ruminant metabolism study with the current data requirements and the need to derive robust residue definitions for products of animal origin should be reconsidered accordingly.

Fish metabolism studies are not triggered considering that the representative uses are not feed items and the calculated Log P_{ow} for IN-E7110 and IN-M7222 is below 3. However, the fish dietary intake should be recalculated once the residue definition for rotational crops is finalised and considering the magnitude of the residues of IN-KA557 and T5 in rotational crops (data gap, see Section 9.1) in order to conclude on the need for a metabolism study or alternatively to demonstrate that these compounds have a low lipophilicity (Log P*o/w* ≤ 3).

Sugar/fodder beet, beet root and chicory root/witloof as representative uses have no melliferous capacity. However, and pending upon the magnitude of residues of the relevant metabolites in rotational crops (see data gap above), the **residues in pollen and bee products** might need to be addressed.

In view of the identified data gap to finalise the residue definition for risk assessment in rotational crops, the livestock exposure assessment not being finalised and the outstanding data to address the

aneugenicity potential of IN-M7222 and IN-E7710 (see Section 2), a **provisional consumer dietary intake calculation** has been carried out considering the risk assessment input values for the sum of IN-M7222 and IN-E7710, expressed as IN-M7222 for the representative uses and the ADI/ARfD for IN-M7222 and IN-E7710 of 0.0015 mg/kg bw (per day). The calculated chronic dietary intake according to the EFSA PRIMo rev. 3.1 model accounted for 11% of the ADI (NL child) whilst an exceedance of the ARfD was shown for sugar beet roots/sugar (147%) and for witloofs/boiled (118%) for children; IESTI calculated for beetroots and for witloof, Belgian endives amounted to 76% and 53% of the ARfD, respectively. EFSA highlights that the exceedance of the ARfD as observed for sugar beet root/sugar can be explained by using a processing factor (PF) of 12 for sugar in the calculation and considered as highly conservative in the specific case of the 'zero' residue situation established in sugar beet root. Also, no residues above the LOQ are expected in sugar and a PF of 1 should therefore be more suitable. In this case, the calculated IESTI would account for 12% of the ARfD for sugar. The exceedance of the ARfD observed for witloofs/boiled is linked to the higher consumption data for this processed commodity compared to the raw agricultural commodity (RAC), whilst the residue levels were all below the LOQ of 0.01 mg/kg in witloofs as it is expected considering the specific growth conditions of this crop. It is therefore suggested that the requested residue trials on witloof, Belgian endives (see data gap) should be conducted according to an analytical method validated at an LOQ lower than 0.01 mg/kg. According to EFSA PRIMo rev. 2A model, the calculated chronic intake accounted for 30.5% of the ADI (UK Toddler) whilst the highest acute intake was 85.1% of the ARfD (sugar beet root).

The PECgw values calculated for the respective metabolites **IN-D8526**, **IN-66036** and **IN-JL000** were below 0.1 μg/L and therefore did not trigger to conduct the consumer intake through drinking water. For metabolites **IN-JM000** and **IN-JU122** (PECgw: 0.262 and 0.783 μg/L, respectively, see Section 4), data to address their genotoxicity and general toxicity were not available and are therefore assumed to share the carcinogenic properties of the parent compound and were concluded as toxicologically relevant in compliance with the Guidance document SANCO/221/2000 – rev.10 (European Commission, 2003). Based on these considerations, the consumer risk assessment through drinking water has been carried out regarding the metabolites **IN-E7710** and **IN-M7222** only that exceeded the concentration of 0.75 μg/L in groundwater (see Section 4). The theoretical maximum daily intake (TMDI) accounted for 2.2% and 15.7% of the ADI (0.0015 mg/kg bw per day) for adults, 6.5% and 47% of the ADI for children and 9.8% and 70.5% of the ADI for infants, respectively. This assessment is, however, not finalised as for both compounds, the PECgw calculations are provisional and the aneugenicity potential is not addressed (see data gaps in Sections 2 and 4). Furthermore, since IN-E7710 and IN-M7222 are also major plant metabolites, a global exposure of the consumers to these metabolites through dietary intake (according to PRIMo rev.3.1) and drinking water was carried out and amounted up to 24%, 64.5% and 88.3% of the ADI, respectively, for adults, children and infants. Considering PRIMo rev.2A model, the total exposure through dietary intake and drinking water accounted for 23.2%, 84% and 93.7% of the ADI, respectively, for adults, children and infants. The consumer risk assessment is also not finalised as appropriate information to address the effect of water treatment processes on the nature of the residues that might be present in surface water and groundwater, when surface water or groundwater are abstracted for drinking water is missing (see Sections 4 and 9.1).

As an outcome of the renewal peer review, specifically leading to a lowered ADI value and the setting of an ARfD value for IN-M7222 and IN-E7710 considering that the potential aneugenicity is not addressed for IN-M7222 (see Section 2), a screening assessment for all maximum residue levels (MRLs) as recommended for witloof, Belgian endives, beet root, sugar beet root and chicory root in the framework of the Art.12 MRL review did not indicate any chronic or acute dietary intake concern, considering the input residue value for risk assessment of 0.01 mg/kg (HR/STMR) instead of 0.02 mg/kg as a 'zero' residue situation for IN-M7222 and IN-E7710 can be established for these crops (see EFSA, 2015). Using the EFSA PRIMo rev.3.1, the total TMDI accounted for 6% of the ADI (NL child) and the maximum IESTI was 38% of the ARfD (beetroots).

As for the assessment if the provisions of **negligible exposure** according to Regulation (EC) 1107/2009 are met, considering the draft technical guidance on assessment of negligible exposure (European Commission, 2015), the following can be concluded: For the representative uses of triflusulfuron-methyl, residue concentrations of, respectively, IN-M7222 and IN-E7710 in sugar beet root (with a possible extrapolation to beet root, fodder beet root and chicory root) were determined by data and are less than 0.01 mg/kg for each compound whilst residues above 0.01 mg/kg are found in sugar beet tops and leaves only. For witloof, Belgian endives, a data gap was identified for residue

trials compliant with the SEU GAP. A complete assessment of the magnitude of the residues of the compounds IN-M7222, IN-E7710, IN-KA557 and T5 that could be relevant in food and feed items from the potential succeeding crops cannot be finalised and there is a data gap to address the aneugenicity potential of the metabolites IN-M7222 and IN-E7710 (see data gaps in Sections 2, 3 and 9.1). Based on the quantitative information on primary and rotational crops to support the representative uses, potential livestock exposure and carry-over of triflusulfuron-methyl derived residues in animal matrices cannot be excluded. Finally, consumer exposure through drinking water is not finalised for the representative uses, pending robust PECgw calculations for IN-M7222 and IN-E7710 and a complete toxicological assessment in accordance with the European Commission guidance document of 2003 for the assessment of the relevance of these metabolites in groundwater.

4. Environmental fate and behaviour

Triflusulfuron-methyl was discussed at the Pesticides Peer Review Experts' Teleconference TC 34 (November 2020).

The rates of dissipation and degradation in the environmental matrices investigated were estimated using FOCUS (2006) kinetics guidance. The route of degradation of triflusulfuron-methyl under dark aerobic laboratory conditions was investigated in five soils with two labels ([^{14}C-triazine] and [^{14}C-ester carbonyl]). In the soil laboratory incubations under aerobic conditions in the dark, triflusulfuron-methyl exhibited low to moderate persistence. The main degradation pathway involved hydrolysis of the sulfonylurea bridge to yield the major (> 10% applied radioactivity (AR)) metabolites **IN-D8526** (max. 92.3% AR after 101 days, triazine radiolabel) which exhibited low to **high persistence** and **IN-W6725** (max. of 88.1% AR after 30 days, ester carbonyl label) which exhibited moderate to **high persistence**. The metabolite IN-D8526 was further degraded via N-desmethylation to form **IN-E7710** (max. 54.7% AR after 120 days) that exhibited moderate to **high persistence**, undergoing further N-desmethylation to form **IN-M7222** (max. 31.7% AR after 91 days) which exhibited moderate to **very high persistence**. IN-W6725 was further degraded to **IN-JU122** (max. 15.8% AR after 91 days) having moderate to **high persistence**.

Maximum amounts of carbon dioxide formed from samples treated with triazine and ester carbonyl-labelled triflusulfuron-methyl were 0.8–11.3% AR and 17–70.7% AR after 120 days, respectively. The formation of unextractable residues for the [^{14}C-triazine] label accounted for 12.6–61.5% AR after 120 days and for the [^{14}C-ester carbonyl] radiolabel accounted for 4.6–39.5% AR after 120 days.

In anaerobic soil incubations, triflusulfuron-methyl formed the major (> 10% AR) metabolite **IN-D8526** (max. 56.9% AR at 62 days, [^{14}C-triazine]-label) and **IN-W6725** (max. 74.6% AR at 62 days, [^{14}C- ester carbonyl]-label). There was no formation of metabolite specific to anaerobic conditions. Soil photolysis was investigated in one soil under dry conditions and in one soil under moist conditions, with the two labels (triazine and ester carbonyl). Degradation rates were similar between irradiated samples and dark control. However, the metabolic pathway was different, with the following metabolites formed only under irradiated conditions: **IN-JM000** (max. 13.5% AR after 15 days) which exhibited medium to **very high persistence**, **IN-JL000** (max. 9.6% AR after 15 days, ≥ 5% on 2 consecutive sampling points) which exhibited moderate to **very high persistence** and **IN-66036** (max. 14.0% AR after 10 days) which exhibited low persistence.

The rates of degradation of triflusulfuron-methyl and its metabolites were evaluated following the recommendations of the FOCUS Kinetic guidance (FOCUS, 2006) and EFSA DegT50 guidance (EFSA, 2014a). 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). In satisfactory field dissipation studies carried out at four sites in Northern Germany, Southern Germany, Spain and Northern France, triflusulfuron-methyl, IN-D8526, IN-E7710, IN-M7222 and IN-W6725 were monitored. The field data endpoints were combined with laboratory values to derive modelling endpoints for IN-D8526, IN-E7710 and IN-M7222. IN-JU122, IN-JL000 and IN-JM000 were not investigated in field. Since they have laboratory DT_{50} > 60 days (DT_{90} > 200 days), according to Regulation (EU) No 283/2013 a data gap is set for field DT_{50} at three different locations for these metabolites (see Section 10). Metabolites IN-E7710 and IN-M7222 were monitored in the four sites investigated in the field studies conducted with parent substance; however, this was not considered sufficiently addressing the data requirement for terrestrial field dissipation studies addressing the degradation rate for the metabolites IN-E7710 and IN-M7222 leading to a data gap[9] (see Section 10).

[9] See Data requirement 4.3 in the Evaluation table (EFSA, 2022).

The adsorption of triflusulfuron-methyl and its metabolites was investigated using the batch equilibrium method. For the transformation products IN-D8526, IN-E7710, IN-M7222, IN-W6725, IN-JU122, IN-66036, IN-JL000 and IN-JM000 although mass balance was not determined as recommended in the OECD 106 guideline, there was sufficient evidence of the stability of the metabolites in the corresponding studies. For triflusulfuron-methyl, however, there is a data gap for a batch adsorption study to be conducted according to OECD 106 guideline (see Section 9.1). From the available studies, triflusulfuron-methyl may be considered to exhibit high to very high mobility, triazine amine (IN-D8526) very high to low mobility, *N*-desmethyl triazine amine (IN-E7710) very high to medium mobility, *N*,*N*-bis-desmethyl triazine amine (IN-M7222) very high to high mobility, methyl saccharin (IN-W6725), IN-66036 and IN-JU122 very high mobility, and IN-JL000 and IN-JM000 high to low mobility.

pH dependence of degradation and adsorption was not identified for triflusulfuron-methyl or its metabolites.

Hydrolytic degradation of triflusulfuron-methyl was investigated in buffer solutions with two labels (triazine and ester carbonyl). The rate of hydrolysis was affected by pH, with most rapid degradation occurring under acidic conditions. The hydrolysis of the sulfonylurea bridge of triflusulfuron-methyl resulted in the main degradation products **IN-D8526** (max. 98.4 and 47.7% AR after 30 days at 25°C, at pH 5 and 7, respectively) for the triazine label and **IN-W6725** (max. 99.4 and 46.4% AR after 30 days at 25°C, at pH 5 and 7, respectively) for the ester carbonyl label. The aerobic mineralisation and degradation of triflusulfuron-methyl in surface water were determined in the laboratory under dark conditions with two labels (triazine and ester carbonyl). Triflusulfuron-methyl was degraded by hydrolysis into IN-D8526 (maximum 44.4% AR after 60 days) and IN-W6725 (maximum 56.4% AR after 60 days).

In laboratory incubations in dark aerobic natural sediment water systems, triflusulfuron-methyl formed the metabolites IN-JK555 (max. 29% AR in water and 20% AR in sediment), IN-D8526 (max. ca. 30% AR in water and 38% max. in sediment), IN-E7710 (max. ca. 11% AR in water and 10% max. in sediment), IN-JL000 (max. ca. 4% AR in water and 9% max. in sediment) and IN-W6725 (max. ca. 66% AR in water and 32% max. in sediment). Mineralisation accounted for only 0.6–2.8% AR after 100 days and the maximum amount of non-extractable residue reached 3.0–16.1% AR after 100 days.

Since no adsorption/desorption values could be validated for triflusulfuron-methyl, the PECsw/PECsed presented for triflusulfuron-methyl are provisional. A data gap is set for new PECsw/PECsed calculations for triflusulfuron-methyl once validated adsorption/desorption parameters are available thus leading to an issue that could not be finalised regarding the risk assessment for aquatic organisms (see Sections 5 and 9.1).

The necessary surface water and sediment exposure assessments (predicted environmental concentrations (PEC) calculations) were carried out for PECsw and PECsed for triflusulfuron-methyl (provisional) and its metabolites IN-D8526, IN-E7710, IN-M7222, IN-W6725, IN-JU122, IN-66036, IN-JL000, IN-JM000 and IN-JK555 for the uses on sugar and fodder beets using the FOCUS (FOCUS, 2001) step 1 and step 2 approach (version 3.2 of the Steps 1–2 in FOCUS calculator). The exposure calculations have been provided for the uses on sugar beets covering also the uses on fodder beet, red beet, chicory and witloof. For the active substance triflusulfuron-methyl, provisional step 3 (FOCUS, 2001) and step 4 calculations were available.[10] The step 4 calculations appropriately followed the FOCUS (FOCUS, 2007) guidance, regarding no-spray buffer zones and vegetated buffer strips of up to 20 m were implemented for the run-off scenarios (these no spray buffer zones representing a 88–95% drift reduction). The SWAN tool (version 5.0.1) was appropriately used to implement these mitigation measures in the simulations. However, risk managers and others may wish to note that whilst run-off mitigation is included in the step 4 calculations available, the FOCUS (FOCUS, 2007) report acknowledges that for substances with K_{Foc} < 2,000 mL/g (i.e. triflusulfuron-methyl), the general applicability and effectiveness of run-off mitigation measures had been less clearly demonstrated in the available scientific literature, than for more strongly adsorbed compounds.

The 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.[10] Since no adsorption values could be validated for triflusulfuron-methyl, the PECgw presented for triflusulfuron-methyl and its subsequent metabolites IN-D8526, IN-E7710, IN-M7222, IN-W6725 and IN-JU122 are considered provisional. A **data gap** is set for new PECgw calculations for

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

triflusulfuron-methyl and its metabolites IN-D8526, IN-E7710, IN-M7222, IN-W6725 and IN-JU122 once validated adsorption/desorption parameters for triflusulfuron-methyl are available leading to an issue that could not be finalised (for metabolites IN-D8526, IN-E7710 and IN-M7222, calculations for both microbial degradation and photodegradation pathways should be provided) (see Section 9.1). PECgw for photodegradates IN-66036, IN-JL000 and IN-JM000 were calculated with FOCUS PEARL and PELMO models assuming a pseudo-application of the metabolites and are considered acceptable (adsorption of triflusulfuron-methyl has no impact on these calculations). The exposure calculations have been provided for the uses on sugar beets. However, they cover also the uses on fodder and red beet, chicory and witloof. Two sets of calculations were performed, at Tier 1 (a worst-case approach) IN-66036, IN-JL000 and IN-JM000 applied as active substance, with application rate corrected for molar ratio where at Tier 2 IN-66036 and IN-JL000 applied as active substance, with application rate corrected for molar ratio and maximum occurrence of 14% and 50%, respectively. The acceptability of Tier 2 approach used for PECgw modelling in particular for photolysis transformation compounds was discussed in the expert meeting. The experts agreed on using the Tier 2 approach, i.e. to follow the assumed application rate at the soil surface for both photolysis products IN-JL000 and IN-66036 as described in the RAR.[11]

Based on the provisional results, the potential for groundwater exposure from the representative uses by triflusulfuron-methyl 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.

The 80th percentile annual average recharge concentrations leaving the top 1 m soil layer were estimated to be < 0.1 μg/L for metabolites **IN-D8526, IN-66036** (in Tier 2 only) and **IN-JL000** in all nine FOCUS groundwater scenarios for all representative uses. PECgw for metabolite **IN-JM000** are > 0.1 μg/L for eight of nine scenarios in Tier 1, and six of nine scenarios in Tier 2 (max. 0.435 μg/L and 0.262 μg/L in Châteaudun at 4 × 15 g/ha in sugar beets in Tier 1 and Tier 2, respectively). PECgw for **IN-E7710, IN-M7222, IN-W6725 and IN-JU122** are > 0.1 μg/L in all scenarios, with maximum PECgw of 0.975 μg/L (Tier 2, Châteaudun at 4 × 15 g/ha in sugar beets), 7.050 μg/L (Tier 2, Thiva at 4 × 15 g/ha in sugar beets), 0.572 μg/L (Châteaudun at 4 × 15 g/ha in sugar beets) and 0.783 μg/L (Jokioinen at 4 × 15 g/ha in sugar beets), respectively. For IN-W6725 and IN-JU122 Tier 2 calculations were not available. Considering the toxicology assessment of the available data, metabolites IN-JU122 and IN-JM000 are considered relevant for groundwater according to the European Commission guidance of 2003 (see Section 2) and therefore a critical area of concern was identified (see Section 9.2).

The applicant did not provide appropriate information to address the effect of water treatment processes on the nature of the residues that might be present in surface water and groundwater, when surface water or groundwater are abstracted for drinking water. This has led to the identification of a **data gap** and results in the consumer risk assessment not being finalised (see Sections 3 and 9.1).

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

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2000a,b), SETAC (2001), EFSA (2009, 2013), EFSA PPR Panel (2013). Triflusulfuron-methyl was discussed at the Pesticides Peer Review Experts' Teleconference TC 37 (November 2020).

The batches used in ecotoxicological studies were considered compliant with the technical specifications (original ones and proposed for the renewal).

Suitable acute and reproductive toxicity data for **birds and mammals** were available for the active substance. The reproductive endpoint for birds was agreed at the Pesticides Peer Review Experts' Teleconference TC 37.[12] Furthermore, acute toxicity data with the formulated product were available for birds and mammals. The data showed that the active substance is not more acutely toxic when formulated. On the basis of the available screening risk assessment, a low acute risk to birds and mammals was indicated for all representative uses. A low reproductive risk to birds and mammals was indicated with the available Tier 1 risk assessment for all representative uses. A low risk to birds

[11] See experts' consultation point 4.2 at the Pesticide Peer Review Experts' TC 34 (EFSA, 2022).
[12] See experts' consultation point 5.1 at the Pesticides Peer Review Experts' Teleconference TC 37 (EFSA, 2022).

and mammals was indicated from secondary poisoning and from consumption of contaminated water. The available assessment to birds and mammals from plant metabolites was considered not to be adequate, and therefore, a data gap was identified for an updated and complete assessment (see Section 10).[13]

Acute toxicity data with all the standard **aquatic species** were available with the active substance, the representative formulation (with and without surfactant). Chronic toxicity data were available with the active substance for fish and aquatic invertebrates and with the active substance and the representative formulation (with and without surfactant) with aquatic plants. For algae, data were available with the active substance and the representative formulation with a surfactant. No data were available on green algae with the active substance. At the Pesticides Peer Review Experts' Teleconference TC 37, it was agreed that the available endpoint on green algae with the formulation and the tested surfactant may provisionally be used for risk assessment. This conclusion was reached considering (i) the available data on aquatic plants showing that the formulation with the surfactant is expected to be as toxic as the active substance and the formulation without the surfactant; (ii) aquatic plants are driving the risk assessment. However, to comply with the data requirements as laid down in the Regulation (EU) No 283/2013, a data gap for a new study with green algae and the active substance is identified (see Section 10).

As reported in Section 4, a data gap and an issue not finalised were identified and the available exposure estimates are only considered provisional. Consequently, the risk assessment for aquatic organisms could not be finalised either and presented for illustrative purposes only and thus, the outcome has to be considered provisional only.

By considering the available data and the provisional risk assessment, low risk (acute and chronic) to fish, aquatic invertebrates and algae was indicated by using PEC step 1&2 for all the representative uses. Several studies with algae and aquatic plants were discussed at the Pesticides Peer Review Experts' Teleconference TC 37.[14]

For aquatic plants and the representative uses on sugar and fodder beet, red beet and chicory witloof at 4 × 15 g a.s./ha, low risk was indicated for two of four FOCUS scenarios using worst-case PECsw Step 3 (worst case between single and multiple applications). High risk was indicated in situation represented by the FOCUS scenario R1 and R3 (two of four FOCUS Scenarios) even with the application of the maximum mitigation measures. It is noted that low risk for all the relevant FOCUS scenarios was indicated using PECsw step 3 for a single application on sugar and fodder beet, red beet and chicory witloof at 15 g a.s./ha. For the representative use on sugar and fodder beet at 3 × 20 g a.s/ha, low risk was indicated for two of four relevant FOCUS scenarios (D3 and D4) when using worst-case PECsw Step 3 and 4 (worst case between single and multiple applications) with mitigation measures up to 10 m no-spray buffer zone and vegetative filter strip. It is noted that the implementation of mitigation measures up to 10 m no-spray buffer zone and vegetative filter strip is sufficient to indicate low risk for all the relevant FOCUS scenarios when considering a single application on sugar and fodder beet at 20 g a.s./ha. Low risk was indicated for the representative use on sugar and fodder beet at 2 × 30 g a.s/ha using provisional PECsw Step 4 with mitigation measures up to 20 m no-spray buffer zone and vegetative filter strip for all the relevant FOCUS scenarios when considering both single and multiple applications. No other suitable refinements were available. Two studies with *Myriophyllum* sp. were provided aiming at demonstrating reciprocity which is one of the criteria for the use of time-weighted average PEC. However, the study design of those studies was not considered suitable for its scope.[15]

Toxicity data with the most sensitive aquatic organism, i.e. plants, were available for all the pertinent surface water metabolites. Based on the available data, low risk to aquatic organisms was concluded for all the pertinent surface water metabolites by using PECsw Step 1&2. It was noted that for the pertinent metabolites, only data on *Lemna* sp. were available while *Myriophyllum* sp. was more sensitive when exposed to the parent compound. However, considering the margin of safety in the risk assessment for metabolites and the difference in sensitivity between *Lemna* sp. and *Myriophyllum* sp. (by a factor of 3), the available data were considered suitable for risk assessment.

Tier 1 laboratory studies with honey **bees** and bumble bees were available. Specifically, the acute oral and contact toxicity to honey bees and bumble bees were investigated using the representative formulation and the active substance, respectively. Additionally, for both species, the combined toxicity

[13] See the response to data requirement 5.3 in the Evaluation table (EFSA, 2022).
[14] See experts' consultation point 5.2 at the Pesticides Peer Review Experts' Teleconference TC 37 (EFSA, 2022).

of the representative formulation and the surfactant DPX-KG691 was characterised. Moreover, honey bee chronic and larval data were produced using the representative formulation alone.

Based on EFSA guidance document (2013), a low acute risk to honey bees and bumble bees was identified at the screening step, with or without the surfactant. Additionally, the low risk to honey bee adults and brood was identified for the representative formulation alone. However, owing to the lack of effect studies, chronic (adult and larval) risks from the combined exposure to triflusulfuron-methyl and the surfactant were not addressed. Nonetheless, considering the margin of safety in the dietary risk assessment with the representative formulation or the active substance, this might be considered a minor issue. Therefore, it is suggested that further consideration may be given to this matter at MS level, if needed.

A low risk from exposure to contaminated surface and puddle water was concluded, while a high chronic risk for honeybee larvae consuming contaminated guttation water could not be excluded at the screening step. A further risk assessment was not available (data gap, see Section 10).

A quantitative risk assessment from exposure to metabolites occurring in nectar and pollen was not performed (data gap, see Section 10).

A suitable assessment of accumulative effects and sublethal effects (e.g. hypopharyngeal glands (HPGs)) was not available (data gap, see Section 10). Finally, toxicity data and risk assessment were not available for solitary bees.

For **non-target arthropods** other than bees, Tier 1 (glass-plate) studies were conducted with the standard species (*Aphidius rhopalosiphi* and *Typhlodromus pyri*) for the representative formulation with and without surfactant (i.e. 'Triflusulfuron methyl 50WG' and 'Triflusulfuron methyl 50WG + DPX-KG691'). Glass-plate studies were also available for the *Chrysoperla carnea* and *Poecilus cupreus* for the representative formulation 'Triflusulfuron methyl 50WG'. The risk assessment was discussed at the Pesticides Peer Review Experts' Teleconference TC 37.[15] Based on toxicity data and the Tier 1 risk assessment, a low in-field risk for *A. rhopalosiphi* was indicated for all representative uses with 'Triflusulfuron methyl 50WG' whereas a high in-field risk was concluded for all uses with the formulation containing the surfactant. Therefore, several higher tier studies using 'Triflusulfuron methyl 50WG + DPX-KG691' were submitted: extended laboratory studies with *A. rhopalosiphi*, *C. carnea* and *T. pyri* and an aged residue study with *A. rhopalosiphi*. When considering the extended laboratory studies, a low in-field risk could be concluded for the uses on sugar and fodder beet and chicory at 4 × 0.015 kg a.s./h with 'Triflusulfuron methyl 50WG + DPX-KG691'. The experts at the meeting agreed that a low in-field risk to non-target arthropods could also be concluded for the uses on sugar and fodder beet at 2 × 0.03 and 3 × 0.02 kg a.s./h considering that in the aged residue study, effects on reproduction were below 50% and no mortality was observed 22 days after 'Triflusulfuron methyl 50WG + DPX-KG691' application. A low off-field risk was concluded for all representative uses with both formulations at Tier 1.

Suitable reproductive toxicity data for **earthworms**, **soil macroorganisms other than earthworms** and **soil microorganism** were available for the formulation with the surfactant and the relevant soil metabolites (IN-D8526, IN-E7710, IN-M7222, IN-W6725, IN-JU122, IN-JM000, IN-JL000 and IN-66036). The risk assessment based on data obtained with 'Triflusulfuron methyl 50WG + DPX-KG691' was considered to cover that for the representative formulation 'Triflusulfuron methyl 50WG' since toxicity studies performed with other non-target organisms indicated that the formulation with the surfactant is of equal or higher toxicity than the active substance or than the formulation without the surfactant. A low risk was indicated at Tier 1 for all representative uses of triflusulfuron-methyl.

For **non-target terrestrial plants**, data were available for the active substance, the formulated product with and without (only for two species) the surfactant ('Triflusulfuron methyl 50WG + DPX-KG691') and for the active substance with Ortho X-77 surfactant. The lowest endpoint was derived from a study performed with the active substance and X-77 surfactant. Two separate risk assessments were available. The first was for the formulated product with the surfactant ('Triflusulfuron methyl 50WG + DPX-KG691') resulted in a low risk to non-target plants without the need for risk mitigation. The second assessment used data for the active substance with surfactant Ortho X-77. The results of this assessment indicated that risk mitigation measures, such as a 5 m buffer zone, are required for applications of 15, 20 and 30 g a.s./ha (see Section 8).

A low risk to organisms involved in **biological methods for sewage treatment** was concluded for all the representative uses.

[15] See experts' consultation point 5.3 at the Pesticides Peer Review Experts' Teleconference TC 37 (EFSA, 2022).

6. Endocrine disruption properties

With regard to the assessment of the endocrine disruption potential of triflusulfuron-methyl **for humans** according to the ECHA/EFSA guidance (2018), in determining whether triflusulfuron-methyl interacts with the **oestrogen, androgen, steroidogenesis and thyroid (EATS) modalities**, the number and type of effects induced, the magnitude and pattern of responses observed across studies and sexes were considered. Additionally, the conditions under which effects occur were considered, in particular, whether or not endocrine-related responses occurred at dose(s) that also resulted in general systemic toxicity or overt toxicity. The assessment done for triflusulfuron-methyl is therefore providing a weight of evidence analysis of the potential interaction of triflusulfuron-methyl with the EATS signalling pathways using all the available evidence in the data set. There was no evidence of a pattern of adversity for the **T-modality** and the ED criteria for the T-modality are not met.

The available evidence in the data set for the **EAS-modalities** for triflusulfuron-methyl was sufficient to conclude that triflusulfuron-methyl induces a pattern of adversity characterised by an increased incidence of testicular interstitial (Leydig) cell hyperplasia and adenomas in rat and testicular changes i.e. decrease in absolute and relative testicular weight, atrophy of tubular seminiferous epithelium and cytoplasmic vacuolation in the testes and aspermatogenesis and oligospermia in the epididymides, in dog. There are several possible molecular initiating events (MIEs) triggering these histological changes (including non EAS-modalities), with deregulation of the hypothalamus–pituitary–gonads (HPG) axis as a common key event (KE). *In vivo* endocrine activity was characterised by a decrease in the circulating levels of oestradiol, an increase in testosterone and an increase in luteinising hormone (LH) and FSH. In the available data set, there is indication for decrease in aromatase activity *in vivo* and *in vitro*. Therefore, a link between the endocrine activity and the pattern of observed adversity can be postulated[16], meeting the ED criteria, which represents a critical area of concern.

The outcome of the assessment for humans also applies to **wild mammals as non-target organisms for oestrogen, androgen, steroidogenesis and thyroid (EATS) modalities**. Triflusulfuron-methyl is not considered to be an endocrine disruptor for wild mammals, in line with the assessment for humans, through the **T-modality**. Conversely, as indicated for humans, for the **EAS-modalities**, triflusulfuron-methyl also meets the ED criteria for wild mammals as effects on reproductive organs linked to the same mode of action (MoA) (aromatase inhibition) were observed in two species (rat and dog) and the MoA is relevant for wild mammals and not specific for aged animals. The lack of reproductive effects in the two-generation study with rats was not considered sufficient to exclude the population relevance of the above-mentioned adverse effects (increased incidence of interstitial (Leydig) cell hyperplasia and adenomas in rat and testicular changes, i.e. tubular seminiferous epithelium and epididymides in dog) for several reasons: (i) some EAS-mediated parameters were not measured in the two-generation study with rats conducted based on the old OECD TG 416 protocol and this was considered an uncertainty regarding the lack of reproductive effects in the rat; (ii) in the dog, reproduction is not assessed, and therefore, it is not possible to argue on the lack of reproductive effects; the MoA is indicating a perturbation of the HPG axis in two mammalian species.

For **non-target organisms other than mammals**, no data were available for the assessment of the ED properties though the T-modality. Regarding, EAS-modalities, a Fish Short-Term Reproduction assay was available. No effects were observed in any of the available parameters.

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 triflusulfuron-methyl is an endocrine disruptor, which represents a critical area of concern.

In view of the fact that ED is an approval criterion, the applicant provided further information aimed at demonstrating that the exposure of humans and/or the environment to triflusulfuron-methyl was negligible under realistic conditions of use. Triflusulfuron-methyl has therefore been assessed under the provisions of **negligible exposure** to satisfy points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009.

Regarding human health, considerations on negligible exposure are reported in Section 2 (mammalian toxicology) and Section 3 (residues).

Regarding the environment, it might be considered that exposure was not negligible, as the available PEC in soil, surface water and sediment for all the representative uses assessed are above levels that can be routinely measured.[17] There will be exposure from triflusulfuron-methyl via food

[16] See experts' consultation point 2.3 at the Pesticides Peer Review Experts' Teleconference TC 32 (EFSA, 2022).

[17] In line with the ethos of FAO/WHO (2009) further discussed in EFSA Scientific Committee (2012) and limits of analytical quantification needed for monitoring methods set out in European Commission (2021).

items of non-target organisms for the representative field uses, as these organisms will enter fields on the same day an application is made.

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

Table 1: Soil

Compound (name and/or code)	Ecotoxicology
Triflusulfuron-methyl	Low risk to soil organisms
IN-D8526	
IN-E7710	
IN-M7222	
IN-W6725	
IN-JU122	
IN-JM000	
IN-JL000	
IN-66036	

Table 2: Groundwater[a]

Compound (name and/or code)	> 0.1 µg/L at 1 m depth for the representative uses[b] Step 2	Biological (pesticidal) activity/ relevance Step 3a.	Hazard identified Steps 3b. and 3c.	Consumer RA triggered Steps 4 and 5	Human health relevance
Triflusulfuron-methyl	Assessment not finalised	Yes	–	–	Yes
IN-D8526	No[a]	No	Open Genotoxicity – Unlikely to be mutagenic or clastogenic. – **Aneugenicity not investigated**. General toxicity – Rat acute oral lethal dose: 670 mg/kg bw. – Carcinogenic potential via aromatase inhibition excluded. Reference values – same as for IN-M7222 (read across).	Not triggered based on provisional PEC GW calculations for the representative uses	Not triggered based on provisional PEC GW calculations for the representative uses

Compound (name and/or code)	> 0.1 µg/L at 1 m depth for the representative uses[b] Step 2	Biological (pesticidal) activity/ relevance Step 3a.	Hazard identified Steps 3b. and 3c.	Consumer RA triggered Steps 4 and 5	Human health relevance
IN-E7710	Yes in 9/9 FOCUS scenarios in Tier 2 (sugar beet 4 × 15 g/ha, 3 × 20 g/ha, and 2 × 30 g/ha)[a] In 3/9 scenarios in Tier 2 provisional PECgw is exceeding 0.75 µg/L (sugar beet 4 × 15 g/ha, 3 × 20 g/ha and 2 × 30 g/ha)	No	Open Genotoxicity – Unlikely to be mutagenic or clastogenic. – **Aneugenicity not investigated**. General toxicity – Rat acute lethal dose: 670 mg/kg bw per day. – Carcinogenic potential via aromatase inhibition excluded. Reference values – same as for IN-M7222 (read across).	Yes The TMDI accounted for 2.2% of the ADI (0.0015 mg/kg bw per day) for adults, 6.5% of the ADI for children and 9.8% of the ADI for infants.	Not concluded Aneugenicity potential not excluded
IN-M7222	Yes in 9/9 FOCUS scenarios in Tier 1 and Tier 2 (sugar beet 4 × 15 g/ha, 3 × 20 g/ha and 2 × 30 g/ha)[a] In 9/9 scenarios in Tier 1 and Tier 2 provisional PECgw is exceeding 0.75 µg/L (sugar beet 4 × 15 g/ha, 3 × 20 g/ha, and 2 × 30 g/ha)	No	Open Genotoxicity – Unlikely to be mutagenic or clastogenic. – **aneugenicity not investigated**. General toxicity – Rat acute oral lethal dose: 450 mg/kg bw. – Rat 90 days NOAEL: 3 mg/kg bw per day. – **Carcinogenic potential via aromatase inhibition excluded**. Reference values – ADI = ARfD: 0.0015 mg/kg bw per day.	Yes The TMDI accounted for 15.7% of the ADI (0.0015 mg/kg bw per day) for adults, 47% of the ADI for children and 70.5% of the ADI for infants.	Not concluded Aneugenicity potential not excluded

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
IN-W6725 (methyl saccharin)	Yes in 9/9 FOCUS scenarios in Tier 1* (sugar beet 4 × 15 g/ha, 3 × 20 g/ha, and 2 × 30 g/ha) [a]	No	No Genotoxicity No genotoxic potential. General toxicity – Read across with saccharin based on structural similarities – Carcinogenic potential via aromatase inhibition excluded. Reference values Same as for saccharin ADI: 3.8 mg/kg bw day (European Scientific Committee for Food, 1997) ARfD: not needed	No based on provisional PEC GW calculations for the representative uses (Provisional PEC*gw* = 0.572 µg/L)	No based on provisional PEC GW calculations.
IN-JU122	Yes in 9/9 FOCUS scenarios in Tier 1* (sugar beet 4 × 15 g/ha, 3 × 20 g/ha, and 2 × 30 g/ha)[a]	No	Yes Genotoxicity – Unlikely to be mutagenic or clastogenic. – **Aneugenicity not investigated** General toxicity – Rat acute oral LD_{50} > 2,000 mg/kg bw – **Carcinogenic potential cannot be excluded** (possibly same Carc 2 properties as parent)	No With the available toxicity data considered relevant at Steps 3b and 3c.	Yes
IN-66036	No (in Tier 2)	Not triggered	Not triggered	Not triggered for the representative uses assessed	Not triggered for the representative uses assessed
IN-JL000	No (in Tier 2)	Not triggered	Not triggered	Not triggered for the representative uses assessed	Not triggered for the representative uses assessed

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
IN-JM000	Yes, in 6/9 FOCUS scenarios in Tier 2 (sugar beet 4 × 15 g/ha, 3 × 20 g/ha and 2 × 30 g/ha)	Data gap	Yes Genotoxicity – **No data available**. General toxicity – **No data available**. – Carcinogenic potential cannot be excluded (possibly same Carc 2 properties as parent).	No With the available toxicity data considered relevant at Steps 3b and 3c.	Yes

*: Tier 2 not available.
(a): Assessment according to European Commission guidance of the relevance of groundwater metabolites (2003). PECgw for parent and its soil metabolites IN-D8526, IN-E7710, IN-M7222, IN-W6725 and IN-JU122 are provisional pending a batch adsorption study for parent according to OECD 106 guideline.
(b): FOCUS scenarios or relevant lysimeter.

Table 3: Surface water and sediment (outcome based on provisional PECsw for the parent)

Compound (name and/or code)	Ecotoxicology
Triflusulfuron-methyl	High risk for 2 out of 4 FOCUS scenarios for the representative uses at 4 × 15 g a.s./ha and 3 × 20 g a.s./ha. Low risk with the implementation of mitigation measures for the representative use at 2 × 30 g a.s./ha.
IN-D8526	Low risk
IN-E7710	
IN-M7222	
IN-W6725	
IN-JU122	
IN-JM000	
IN-JL000	
IN-66036	
IN-JK555	

Table 4: Air

Compound (name and/or code)	Toxicology
Triflusulfuron-methyl	Inhalation LD_{50} (rat) > 5.1 mg/L air (4 h and nose-only)

8. Particular conditions proposed to be taken into account by risk managers

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

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

Mitigation measures are needed to conclude low risk for aquatic organisms based on provisional PECsw, see below.

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

Representative use	Sugar and fodder beet 1–4 applications of 15 g a.s./ha	Sugar and fodder beet 1–3 applications of 20 g a.s./ha	Sugar and fodder beet 1–2 applications of 30 g a.s./ha	Red beet 1–4 applications of 15 g a.s./ha	Chicory, Witloof 1–4 applications of 15 g a.s./ha
Operator standard* exposure	No RMM is required	No RMM is required	No RMM is required	No RMM is required	No RMM is required
Operator negligible exposure**	Drift reduction + use of gloves	Drift reduction + use of gloves	Drift reduction + use of gloves	Drift reduction + use of gloves	Drift reduction + use of gloves
Worker standard* exposure	No RMM is required	No RMM is required	No RMM is required	No RMM is required	No RMM is required
Worker negligible exposure**	No RMM is required for inspection	No RMM is required for inspection	No RMM is required for inspection	No RMM is required for inspection	Use of gloves for reaching/ picking[a]
Bystander/ Resident standard* exposure	Buffer strip 2–3 m	Buffer strip 2–3 m	Buffer strip 2–3 m	Buffer strip 2–3 m	Buffer strip 2–3 m
Bystander negligible exposure**	Buffer strip 2–3 m	Buffer strip 2–3 m	Buffer strip 2–3 m	Buffer strip 2–3 m	Buffer strip 2–3 m
Resident negligible exposure**	Adult: buffer strip 2–3 m Child: drift reduction + buffer strip 10 m	Adult: buffer strip 2–3 m Child: drift reduction + buffer strip 10 m + no addition of surfactant in the tank mixture	Adult: buffer strip 2–3 m Child: no drift reduction + buffer strip 10 m + no addition of surfactant in the tank mixture	Adult: buffer strip 2–3 m Child: drift reduction + buffer strip 10 m	Adult: buffer strip 2–3 m Child: drift reduction + buffer strip 10 m
Risk to aquatic organisms	–	RMM equivalent to 10 m no-spray buffer zone and 10 m vegetative buffer strip for the relevant FOCUS scenario D3[b] when considering worst-case PECsw	RMM equivalent to 10 m no-spray buffer zone and 10 m vegetative filter strip for the relevant FOCUS scenario D3, D4 and R1, and 20 m no-spray buffer zone and 20 m vegetative filter strip for the FOCUS scenario R3[c]	–	–
Risk to non-target terrestrial plants	RMM equivalent to 5 m no-spray buffer zone[d]	RMM equivalent to 5 m no-spray buffer zone[d]	RMM equivalent to 5 m no-spray buffer zone[d]	RMM equivalent to 5 m no-spray buffer zone[d]	RMM equivalent to 5 m no-spray buffer zone[d]

*: For standard exposure, exposure calculations have been done with a dermal absorption value for the in use dilution of 50%. Considering the available results, the same conclusions can be applied to the value of 70%, applicable when surfactant is added to the tank mixture.
**: For negligible exposure, according to EC 2015, RMMs are reflected in the table in case they would lead to exposure below or equal to 10% of the (A)AOEL. In order to give a clear overview, it is also mentioned when RMMs are not needed or are insufficient to lead to an exposure level meeting the criteria for standard or negligible exposure. For further details and considerations as regards negligible exposure assessment please refer to Section 2 and Appendix B.
(a): For the activity of reaching/picking in chicory, the use of gloves is required for workers in the case of 3 or 4 applications of 20 g a.s./ha and 15 g a.s./ha, respectively, and when no surfactant is added in the tank mixture.
(b): When considering a single application, low risk for all the relevant FOCUS scenarios was concluded with the implementation of mitigation measures up to 10 m no-spray buffer zone and vegetative filter strip.
(c): When considering a single application, 10 m no-spray buffer zone and 10 m vegetative filter strip are sufficient for concluding low risk for the FOCUS scenario R3.
(d): Based on a risk assessment with active substance with surfactant Ortho X-77.

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[18] 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) Toxicological relevance of three impurities could not be concluded (see Section 2).
    a) General toxicity potential was not sufficiently investigated, e.g. for developmental and reproductive toxicity endpoints (relevant for all representative uses evaluated; see Section 2).
2) Groundwater relevance of metabolites IN-E7710 and IN-M7222 (which are also the major plant metabolites included in the residue definition for risk assessment) could not be concluded (see Section 2), considering the identified data gap:
    a) The aneugenicity potential of the groundwater metabolites IN-M7222 and IN-E7710 was not investigated (relevant for all representative uses evaluated; see Section 2).
3) The consumer dietary risk assessment could not be finalised in view of the outstanding data to address the aneugenicity potential of IN-M7222 and IN-E7710, the provisional risk assessment residue definition for rotational crops and consequently, the livestock and fish exposure assessments being not finalised (see Section 3), considering the identified data gaps:
    a) NEU and SEU rotational crops field trials, analysing for IN-M7222, IN-E7710, IN-KA557 and T5 according to an appropriate analytical method, conducted at a dose rate covering the max PECaccu, respectively, for IN-M7222 and IN-E7710 and supported by acceptable storage stability data for all these compounds in food and feed edible parts of the rotational crops (relevant for all representative uses evaluated; see Section 3).

[18] 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.

b) The livestock and fish dietary burden calculations should be finalised considering the actual residue levels of the relevant compounds identified in primary and rotational crops (relevant for all representative uses evaluated; see Section 3).
c) The PECgw calculations are provisional (see data gap at 5.a.) and the aneugenicity potential is not addressed for the metabolites IN-M7222 and IN-E7710 (see data gap at 2.a.) (relevant for all representative uses evaluated; see Sections 2 and 4).

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

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

5) PECgw for triflusulfuron-methyl and its metabolites IN-D8526, IN-E7710, IN-M7222, IN-W6725, IN-JU122 are provisional since no validated adsorption/desorption values for triflusulfuron-methyl are available (for metabolites IN-D8526, IN-E7710 and IN-M7222, calculations for both microbial degradation and photodegradation pathways should be provided) (see Section 4).
6) A data gap is identified for new PECgw calculations for triflusulfuron-methyl and its metabolites IN-D8526, IN-E7710, IN-M7222, IN-W6725, IN-JU122 once validated adsorption/desorption parameters for triflusulfuron-methyl are available following a batch adsorption study conducted according to OECD 106 guideline (relevant for all representative uses evaluated, see Section 4).
7) Reliable data on adsorption/desorption of triflusulfuron-methyl in soil were not available. A batch adsorption study conducted according to OECD 106 guideline is needed (relevant for all representative uses evaluated; see Section 4).
8) PECsw/PECsed for triflusulfuron-methyl are provisional since no validated adsorption/ desorption values for triflusulfuron-methyl are available. Consequently, the risk assessment for aquatic organisms is also provisional and presented only for illustration purpose (see Sections 4 and 5).
9) A data gap is identified for new PECsw/PECsed calculations for triflusulfuron-methyl once validated adsorption/desorption parameters are available. The data gap at 5.b. above is also relevant here (relevant for all representative uses evaluated, see Section 4).

9.2. Critical areas of concern

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

An issue is also listed as a critical area of concern if the assessment at 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:

1) Potential for groundwater contamination by relevant metabolites. Based on provisional available PECgw calculations, PECgw for metabolite IN-JU122 are > 0.1 μg/L in all FOCUS scenarios for all representative uses. Based on final PECgw calculations, PECgw for metabolite IN-JM000 are > 0.1 μg/L for the majority (6/9) FOCUS scenarios for all representative uses. Since these metabolites are considered as relevant (see Section 2), this represents a critical area of concern.
   a) Reliable data on adsorption/desorption of triflusulfuron-methyl in soil were not available. A batch adsorption study conducted according to OECD 106 guideline is needed (relevant for all representative uses evaluated; see Section 4).
   b) The absence of genotoxic and carcinogenic potential of the metabolites predicted to be found in groundwater (IN-JU122 and IN-JM000) has not been demonstrated (relevant for all representative uses evaluated; see Section 2).
2) Triflusulfuron-methyl is an endocrine disruptor for both humans and wild mammals as non-target organisms, according to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.

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

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

In addition to the issues indicated below, triflusulfuron-methyl is considered to meet the criteria for endocrine disruption for humans and wild mammals as non-target organisms according to points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605. For the considerations as regards negligible exposure assessment, please refer to Sections 2, 3, 6, Table 5 and Appendix B.

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

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		**Sugar and fodder beet**	**Sugar and fodder beet**	**Sugar and fodder beet**	**Red beet**	**Chicory, witloof**
		Medium–low volume spraying, broadcast or band application Field				
		1–4 applications of 15 g a.s./ha	**1–3 applications of 20 g a.s./ha**	**1–2 applications of 30 g a.s./ha**	**1–4 applications of 15 g a.s./ha**	**1–4 applications of 15 g a.s./ha**
Operator risk	Risk identified					
	Assessment not finalised					
Worker risk	Risk identified					
	Assessment not finalised					
Resident/ bystander risk	Risk identified					
	Assessment not finalised					

Representative use		Sugar and fodder beet	Sugar and fodder beet	Sugar and fodder beet	Red beet	Chicory, witloof
		Medium–low volume spraying, broadcast or band application Field				
		1–4 applications of 15 g a.s./ha	1–3 applications of 20 g a.s./ha	1–2 applications of 30 g a.s./ha	1–4 applications of 15 g a.s./ha	1–4 applications of 15 g a.s./ha
Consumer risk	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 wild non-target terrestrial vertebrate	Risk identified					
	Assessment not finalised					
Risk to wild non-target terrestrial organisms other than vertebrate	Risk identified					
	Assessment not finalised					
Risk to aquatic organisms	Risk identified	X (2 out of 4 scenarios) based on provisional PECsw with 4 appl	X (2 out of 4 scenarios) based on provisional PECsw with 3 appl		X (2 out of 4 scenarios) based on provisional PECsw with 4 appl	X (2 out of 4 scenarios) based on provisional PECsw with 4 appl
	Assessment not finalised	X[6]	X[6]	X[6]	X[6]	X[6]
Groundwater exposure to active substance	Legal parametric value breached					
	Assessment not finalised	X[5]	X[5]	X[5]	X[5]	X[5]
Groundwater exposure to metabolites	Legal parametric value breached	X[7]	X[7]	X[7]	X[7]	X[7]
	Parametric value of 10 μg/L[(a)] breached					
	Assessment not finalised	X[2,5]	X[2,5]	X[2,5]	X[2,5]	X[2,5]

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

- A data gap has been identified for a search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites, dealing with side effects on non-target species and published within the 10 years before the date of submission of the dossier, to be conducted and reported in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011). The search terms used for the targeted search strategy were considered incomplete and source of bias (relevant for all representative uses evaluated; see section on 'The active substance and formulated product' and Evaluation table, section 5, Open point 5.40; EFSA, 2022).
- Screening for the biological activity against the target weeds according to SANCO/221/2000-rev.10-final (European Commission, 2003) Step 3a Stage 1, for IN-JM000 was not provided (relevant for all representative uses evaluated; see Section 7, Table 2).

- Information on the content of the relevant impurities before and after storage of the plant protection product at ambient temperature for 2 years was not available (relevant for all representative uses evaluated; see Section 1).
- An analytical method for determination of the relevant impurities in the plant protection product was submitted by the applicant; however, the method was not assessed and included in the RAR; therefore, a formal data gap remains (relevant for all representative uses evaluated; see Section 1).
- Extraction efficiency of the procedure used in the monitoring method for food/feed of plant origin was not addressed (relevant for all representative uses evaluated; see Section 1).
- Validated analytical method for monitoring of IN-66036 in body fluids was not available (relevant for all representative uses evaluated; see Section 1).
- Sufficient residue trials on witloof, Belgian endives compliant with the SEU GAP are needed (relevant for the representative use on chicory root and witloof, Belgian endives evaluated; see Section 3).
- Field degradation rates at three locations for metabolites IN-JU122, IN-JL000, IN-JM000, IN-E7710 and IN-M7222 were not available. This is required for metabolites having laboratory DT_{50} > 60 days (DT_{90} > 200 days), according to Regulation (EU) No 283/2013 (relevant for all representative uses, see Section 4).
- A complete assessment of the risk to birds and mammals from plant metabolites is needed (relevant for the representative uses evaluated; see Section 5).
- Further data on the toxicity of triflusulfuron-methyl on green algae should be provided (relevant for all the representative uses evaluated; submission date proposed by the applicant: 3rd quarter of 2021, see Section 5).
- Information to address the risk to honeybees from sublethal effects (e.g. effects on hypopharyngeal glands), the risk via guttation water and via exposure to metabolites formed in pollen and nectar were not available (relevant for the representative uses evaluated; see Section 5).

References

ECHA (European Chemicals Agency), 2013. Committee for Risk Assessment (RAC) Opinion proposing harmonised classification and labelling at EU level of Triflusulfuron-methyl; methyl 2-({[4-(dimethylamino)-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-yl]carbamoyl}sulfamoyl)-3-methylbenzoate, EC number: N/A, CAS Number, 126535–15-7. CLH-O-0000001709-67-02/F. Adopted 5 December 2013. Available at www.echa.europa.eu

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. ECHA-18-G-01-EN.

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, 32 pp. 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), 2011. Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009. EFSA Journal 2011;9(2):2092, 49 pp. https://doi.org/10.2903/j.efsa.2011.2092

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 triflusulfuron according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13 (7):4190, 31 pp. https://doi.org/10.2903/j.efsa.2015.4190
EFSA (European Food Safety Authority), 2017. Guidance on dermal absorption. EFSA Journal 2017;15(6):4873, 60 pp. https://doi.org/10.2903/j.efsa.2017.4873
EFSA (European Food Safety Authority), 2022. Peer review report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance rape seed oil. 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
EFSA Scientific Committee, 2012. Scientific Opinion on risk assessment terminology. EFSA Journal 2012;10 (5):2664, 43 pp. https://doi.org/10.2903/j.efsa.2012.2664
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, 2002a. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002-rev. 2 final, 17 October 2002.
European Commission, 2002b. Guidance Document on Aquatic Ecotoxicology Under Council Directive 91/414/EEC. SANCO/3268/2001-rev. 4 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, 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, 2012a. 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, 2012b. Review report for the active substance triflusulfuron. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 26 February 2009 in view of the inclusion of triflusulfuron in Annex I of Council Directive 91/414/EEC. SANCO/4439/09 – final rev. 1, 9 March 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.
European Commission, 2015. Technical guidance on the interpretation of points 3.6.3. to 3.6.5, and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, in particular regarding the assessment of negligible exposure to an active substance in a plant protection product under realistic conditions of use. SANCO-2014-12096, May 2015.
European Commission, 2021. Guidance document on pesticide analytical methods for risk assessment and post-approval control and monitoring purposes. SANTE/2020/12830-rev. 1, 24 February 2021.
European Commission Scientific Committee for Food, 1997. Opinion on saccharin and its sodium, potassium and calcium salts. Annex III to Document III/5157/97. CS/ADD/EDUL/148-FINAL, February 1997. Available online: https://ec.europa.eu/food/system/files/2020-12/sci-com_scf_7_out26_en.pdf
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.
FAO /WHO (Food and Agriculture Organization of the United Nations/World Health Organization). 2009. Risk Characterization of Microbiological Hazards in Food: Guidelines. Microbiological Risk Assessment Series No. 17. Rome. 116 pp.
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.

FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use), 2007. Landscape and mitigation factors in aquatic risk assessment. Volume 1. Extended summary and recommendations. Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment. EC Document Reference SANCO/10422/2005 v. 2.0, 169 pp.

France, 2019. Renewal Assessment Report (RAR) on the active substance triflusulfuron prepared by the rapporteur Member State France, in the framework of Commission Implementing Regulation (EU). No 844/2012, July 2019. Available online: www.efsa.europa.eu

France, 2022. Revised Renewal Assessment Report (RAR) on triflusulfuron-methyl prepared by the rapporteur Member State France in the framework of Commission Implementing Regulation (EU). No 844/2012, February 2022. Available online: www.efsa.europa.eu

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.

SETAC (Society of Environmental Toxicology and Chemistry), Candolfi MP, Barrett KL, Campbell PJ, Forster R, Grandy N, Huet MC, Lewis G, Oomen PA, Schmuck R and Vogt H (eds.), 2001. Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods. ESCORT 2 workshop.

McCall PJ, Laskowski DA, Swann RL and Dishburger HJ, 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). Oct 21–22, Washington, DC, pp. 89–109.

OECD (Organisation for Economic Co-operation and Development), 2009. Guidance document on overview of residue chemistry studies.

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

Abbreviations

1/*n*	slope of Freundlich isotherm
Λ	wavelength
E	decadic molar extinction coefficient
AMA	Amphibian Metamorphosis Assay
a.s.	active substance
ADI	acceptable daily intake
AAOEL	acute acceptable operator exposure level
AOEL	acceptable operator exposure level
AR	applied radioactivity
AR	androgen receptor
ARfD	acute reference dose
Bw	body weight
CAS	Chemical Abstracts Service
C&L	classification and labelling
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
EAS	oestrogen, androgen and steroidogenesis modalities
EATS	oestrogen, androgen, steroidogenesis and thyroid 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
HPLC	high-pressure liquid chromatography or high-performance liquid chromatography
HPLC-MS	high-pressure liquid chromatography–mass spectrometry
HPG	hypopharygeal glands
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
LD_{50}	lethal dose, median; dosis letalis media
LH	luteinising hormone
LOAEL	lowest observable adverse effect level
LOQ	limit of quantification
MIE	molecular initiating events
Mm	millimetre (also used for mean measured concentrations)
mN	milli-newton
MoA	mode of action
MRL	maximum residue level
MS	mass spectrometry
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
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)
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
Ppm	parts per million (10^{-6})
r^2	coefficient of determination
RAC	regulatory acceptable concentration
RAR	Renewal Assessment Report
RPE	respiratory protective equipment
SFO	single first-order
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
T	thyroid
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UF	uncertainty factor
WG	water-dispersible granule
WHO	World Health Organization

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

Properties		Conclusion[(a)]
CMR	**Carcinogenicity (C)**	Triflusulfuron-methyl is classified as a Carcinogen 2 (H351) (ECHA RAC, 2013)
	Mutagenicity (M)	Triflusulfuron-methyl is not considered to be a mutagen according to point 3.6.2 of Annex II of Regulation (EC) No 1107/2009.
	Toxic for Reproduction (R)	Triflusulfuron-methyl is not considered to be toxic for reproduction according to point 3.6.4 of Annex II of Regulation (EC) No 1107/2009.
Endocrine disrupting properties		Triflusulfuron-methyl is considered to meet the criteria for endocrine disruption for humans and wild mammals as non-target organisms according to points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) No 2018/605.
POP	**Persistence**	Triflusulfuron-methyl is not considered to be a persistent organic pollutant (POP) according to point 3.7.1 of Annex II of Regulation (EC) No 1107/2009.
	Bioaccumulation	
	Long-range transport	
PBT	**Persistence**	Triflusulfuron-methyl is not considered to be a persistent, bioaccumulative and toxic (PBT) substance according to point 3.7.2 of Annex II of Regulation (EC) No 1107/2009.
	Bioaccumulation	
	Toxicity	
vPvB	**Persistence**	Triflusulfuron-methyl is not considered to be a very persistent, very bioaccumulative substance according to point 3.7.3 of Annex II of Regulation (EC) No 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 representative formulation

Appendix B can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2022.7303

Appendix C – Evaluation of data concerning the necessity of triflusulfuron-methyl as herbicide to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods

Appendix C can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2022.7303

Appendix D – Data collection set

Validated Excel files submitted by MS and evaluated by EFSA in the context of the assessment of the evaluation of data under Art 4(7) of Regulation (EC) No 1107/2009 concerning the necessity of triflusulfuron-methyl as herbicide to control a serious danger to plant health which cannot be contained by other available means.

Appendix D can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2022.7303

Appendix E – 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[19] 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

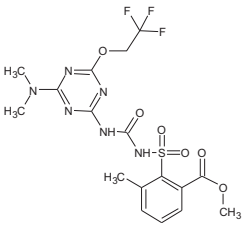
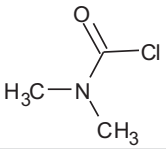
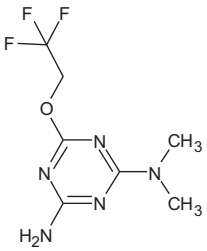
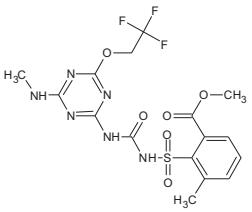
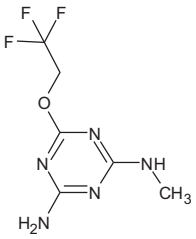
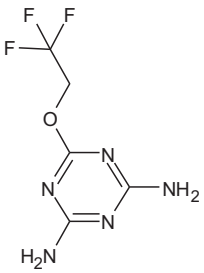
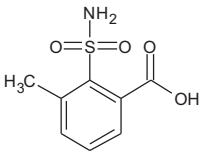
Note these classes and descriptions are unrelated to any persistence class associated with the active substance cut-off criteria in Annex II of Regulation (EC) No 1107/2009. For consideration made in relation to Annex II, see Appendix A.

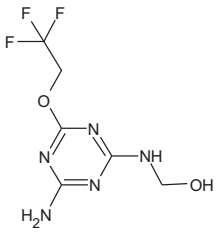
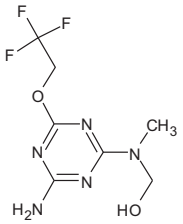
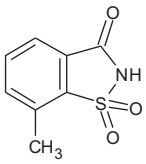
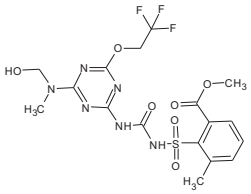
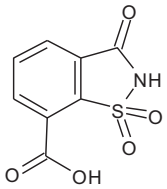
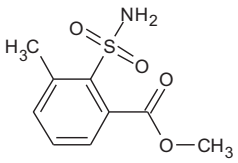
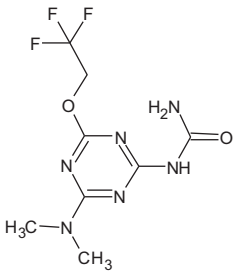
Wording	K_{oc} (either K_{Foc} or K_{doc}) mL/g
Very high mobility	0–50
High mobility	51–150
Medium mobility	151–500
Low mobility	501–2,000
Slight mobility	2,001–5,000
Immobile	> 5,000

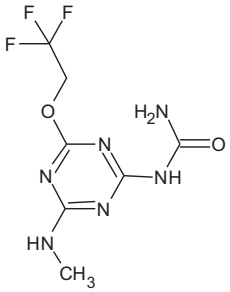
Based on McCall et al. (1980).

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

Appendix F – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/ InChiKey[b]	Structural formula
triflusulfuron-methyl	methyl 2-({[4-(dimethylamino)-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-yl]carbamoyl} sulfamoyl)-3-methylbenzoate O=C(OC)c1cccc(C)c1S(=O)(=O)NC(=O)Nc1nc(nc(OCC(F)(F)F)n1)N(C)C IMEVJVISCHQJRM-UHFFFAOYSA-N	
DMCC (dimethylcarbamoyl chloride)	dimethylcarbamoyl chloride CN(C)C(Cl)=O YIIMEMSDCNDGTB-UHFFFAOYSA-N	
IN-D8526 (N,N-dimethyl-6-(2,2,2-trifluoroethoxy)-1,3,5-triazine-2,4-diamine) (triazine amine)	N^2,N^2-dimethyl-6-(2,2,2-trifluoroethoxy)-1,3,5-triazine-2,4-diamine CN(C)c1nc(N)nc(OCC(F)(F)F)n1 CDIMJMNYIJEGBW-UHFFFAOYSA-N	
IN-66036	methyl 3-methyl-2-({[4-(methylamino)-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-yl] carbamoyl}sulfamoyl)benzoate O=C(OC)c1cccc(C)c1S(=O)(=O)NC(=O)Nc1nc(nc(OCC(F)(F)F)n1)NC OIQKIVWRCNEADB-UHFFFAOYSA-N	
IN-E7710 (N-desmethyl triazine amine)	N^2-methyl-6-(2,2,2-trifluoroethoxy)-1,3,5-triazine-2,4-diamine FC(F)(F)COc1nc(N)nc(NC)n1 JNLDCQPAUYHHTN-UHFFFAOYSA-N	
IN-M7222 (6-(2,2,2-trifluoroethoxy)-1,3,5-triazine-2,4-diamine) (N,N-bis-desmethyl triazine amine)	6-(2,2,2-trifluoroethoxy)-1,3,5-triazine-2,4-diamine FC(F)(F)COc1nc(N)nc(N)n1 HJZAYYJWOHOQSM-UHFFFAOYSA-N	
JJ987	3-methyl-2-sulfamoylbenzoic acid O=S(N)(=O)c1c(C)cccc1C(=O)O HPSFLQXVHGVYEU-UHFFFAOYSA-N	

Code/trivial name[a]	IUPAC name/SMILES notation/ InChiKey[b]	Structural formula
IN-KA557 T3 (assumed to be IN-KA557)	{[4-amino-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-yl]amino}methanol FC(F)(F)COc1nc(N)nc(NCO)n1 KECLXHXTMUALOB-UHFFFAOYSA-N	
T5 (N-hydroxymethyl, N-methyl triazine amine)	{[4-amino-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-yl](methyl)amino}methanol CN(CO)c1nc(N)nc(OCC(F)(F)F)n1 WGTHLECBXCIZCH-UHFFFAOYSA-N	
IN-W6725 (methyl saccharin)	7-methyl-1H-1λ^6,2-benzothiazole-1,1,3(2*H*)-trione Cc1cccc2c1S(=O)(=O)NC2=O XCKNHXNNXXBHNF-UHFFFAOYSA-N	
IN-JW767	methyl 2-[({4-[(hydroxymethyl)(methyl) amino]-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-yl}carbamoyl)sulfamoyl]-3-methylbenzoate O=C(OC)c1cccc(C)c1S(=O)(=O)NC(=O)Nc1nc (nc(OCC(F)(F)F)n1)N(C)CO WNGWDZSQMSDWMB-UHFFFAOYSA-N	
IN-JU122	1,1,3-trioxo-2,3-dihydro-1H-1λ^6,2-benzothiazole-7-carboxylic acid O=C(O)c1cccc2c1S(=O)(=O)NC2=O YDEWSNNYZLNJDA-UHFFFAOYSA-N	
IN-JH260	methyl 3-methyl-2-sulfamoylbenzoat O=S(N)(=O)c1c(C)cccc1C(=O)OC CEMRUYMUINNTSO-UHFFFAOYSA-N	
IN-JL000	*N*-[4-(dimethylamino)-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-yl]urea CN(C)c1nc(nc(OCC(F)(F)F)n1)NC(N)=O YJPXNZXGNKUQPR-UHFFFAOYSA-N	

Code/trivial name[a]	IUPAC name/SMILES notation/ InChiKey[b]	Structural formula
IN-JM000	*N*-[4-(methylamino)-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-yl]urea NC(=O)Nc1nc(nc(OCC(F)(F)F)n1)NC GFRGMDSOGPTEER-UHFFFAOYSA-N	

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116563, 15 June 2020).
(c): ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C25H41, Build 121153, 22 March 2021).