REASONED OPINION

efsa JOURNAL

ADOPTED: 12 July 2023

doi: 10.2903/j.efsa.2023.8189

Modification of the existing maximum residue level for trifloxystrobin in honey

EFSA (European Food Safety Authority),
Giulia Bellisai, Giovanni Bernasconi, Luis Carrasco Cabrera, Irene Castellan, Monica del Aguila, Lucien Ferreira, German Giner Santonja, Luna Greco, Samira Jarrah, Renata Leuschner, Javier Martinez Perez, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Silvia Ruocco, Miguel Santos, Alessia Pia Scarlato, Anne Theobald, Manuela Tiramani and Alessia Verani

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Bayer AG Crop Science Division submitted a request to the competent national authority in the Netherlands to set a maximum residue level (MRL) for the active substance trifloxystrobin in honey. The data submitted in support of the request were found to be sufficient to derive an MRL proposal for the commodity under assessment. An adequate analytical method for enforcement is available to control the residues of trifloxystrobin in honey at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the potential transfer of residues into honey assessed in the present MRL application of trifloxystrobin is unlikely to present a risk to consumer health. The consumer risk assessment shall be regarded as indicative and affected by uncertainties.

© 2023 European Food Safety Authority. *EFSA Journal* published by Wiley-VCH GmbH on behalf of European Food Safety Authority.

Keywords: trifloxystrobin, honey, pesticide, MRL, consumer risk assessment

Requestor: European Commission

Question number: EFSA-Q-2022-00407

Correspondence: pesticides.mrl@efsa.europa.eu

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

Acknowledgements: EFSA wishes to thank: Stathis Anagnos, Andrea Mioč, Marta Szot, for the support provided to this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Carrasco Cabrera, L., Castellan, I., del Aguila, M., Ferreira, L., Santonja, G. G., Greco, L., Jarrah, S., Leuschner, R., Perez, L. M., Miron, I., Nave, S., Pedersen, R., Reich, H., Ruocco, S., Santos, M., Scarlato, A. P., … Verani, A. (2023). Modification of the existing maximum residue level for trifloxystrobin in honey. *EFSA Journal, 21*(8), 1–33. https://doi.org/10.2903/j.efsa.2023.8189

ISSN: 1831-4732

© 2023 European Food Safety Authority. *EFSA Journal* published by Wiley-VCH GmbH on behalf of European Food Safety Authority.

This is an open access article under the terms of the Creative Commons Attribution-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

EFSA may include images or other content for which it does not hold copyright. In such cases, EFSA indicates the copyright holder and users should seek permission to reproduce the content from the original source.

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

Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer AG Crop Science Division submitted an application to the competent national authority in the Netherlands (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance trifloxystrobin in honey.

The application, alongside the dossier containing the supporting data in IUCLID format, was submitted through the EFSA Central Submission System on 22 February 2022. The appointed EMS the Netherlands assessed the dossier and declared its admissibility on 21 June 2022. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA, and a public consultation launched on the dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The consultation run from 24 March 2023 to 14 April 2023. No additional data nor comments were submitted in the framework of the consultation.

At the end of the commenting period, the EMS proceeded drafting the evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 3 May 2023. The EMS proposed to raise the existing MRL from the limit of quantification (LOQ) of 0.05–0.07 mg/kg in honey.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

Based on the conclusions derived by EFSA in the framework of Regulation (EC) No 1107/2009, the data evaluated under previous MRL assessments, and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

In the absence of specific metabolism studies on honey and considering that the metabolic profile of trifloxystrobin in primary and rotational crops was similar and no degradation products are formed under pasteurisation conditions, EFSA concludes that the same general residue definitions derived for plants in the renewal of the approval of the active substance are applicable for honey. That is:

- residue definition for enforcement: Trifloxystrobin;
- residue for risk assessment: Sum of trifloxystrobin, its three isomers (CGA 357262, CGA 357261 and CGA 331409) and CGA 321113 (M5), expressed as trifloxystrobin.

A sufficiently validated analytical method based on HPLC is available to quantify residues in honey according to the enforcement residue definition. The method enables quantification of residues at or above 0.01 mg/kg in the crops assessed (LOQ).

The applicant provided residue trials for honey with trifloxystrobin applied under semi-field conditions in tunnels. The applicant indicated that the application rate of the trials in *phacelia* adequately covers the most critical scenario for residues expected in honey from the authorised uses. The available residue trials are sufficient to derive an MRL proposal of 0.07 mg/kg for honey.

No information is available on the possible transfer of trifloxystrobin residues to the floral nectar of rotational crops. Based on the available information on the nature and magnitude of residues in rotational crops, EFSA concludes that significant residue levels of trifloxystrobin, trifloxystrobin isomers and CGA 321113 are unlikely to occur in honey as a result of transfer from succeeding crops.

Residues of trifloxystrobin in commodities of animal origin were not assessed since honey is not used for feed purposes.

The toxicological profile of trifloxystrobin was assessed in the framework of the EU pesticides peer review under Regulation (EC) No 1107/2009 and the data were sufficient to derive an acceptable daily intake (ADI) of 0.1 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.5 mg/kg bw. The EU pesticides peer review on the renewal of approval of the active substance could not conclude on the general toxicity of CGA 321113 and of the other three structural isomers of trifloxystrobin, which were added to a revised residue definition for risk assessment in plant and animal products (CGA 321113 only), and further data were requested. The data gap is considered relevant for the present MRL application in honey. Nevertheless, since the genotoxic potential of these compounds was ruled out, they were not quantified in any of the residue trials (LOQ 0.01 mg/kg) and considering the very low human exposure to residues of trifloxystrobin in honey, EFSA is of the opinion that the lack of this information is not negatively impacting the risk assessment for honey. In the future, should additional uses lead to quantifiable residues of CGA 357262, CGA 357261 and CGA 331409 and CGA 321113 in honey this conclusion should be revised.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The estimated short-term exposure for honey was 0.06% of the ARfD while the estimated long-term dietary intake accounted for a maximum of 12% of ADI (Dutch toddler diet). The contribution of residues expected in honey to the overall long-term exposure accounted for less than 0.01% of the ADI.

Based on the results of the risk assessment performed considering the exposure to residues of trifloxystrobin, the three isomers (CGA 357262, CGA 357261, CGA 331409) and metabolite CGA 321113 and assuming the toxicity of the metabolite and the isomers is covered by the toxicological profile of the parent, EFSA concluded that the short-term and long-term intake of residues resulting from the potential transfer of residues into honey of trifloxystrobin assessed in the present MRL application is unlikely to present a risk to consumer health.

The consumer risk assessment shall be regarded as indicative and affected by uncertainties due to missing information on the general toxicological properties of the three isomers of trifloxystrobin and CGA 321113 and the lack of a full data set of residue trials analysed according to the residue definition for risk assessment for almost all commodities.

EFSA proposes to amend the existing MRL as reported in the summary table below.

Full details of all end points and the consumer risk assessment can be found in Appendices B–D.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: trifloxystrobin[(F)]				
1040000	Honey and other apiculture products[(b)]	0.05*	0.07	The submitted data are sufficient to derive an MRL proposal for honey. Risk for consumers is unlikely. The consumer risk assessment shall be regarded as indicative and affected by uncertainties due to the lack of further information on the general toxicity of trifloxystrobin structural isomers and metabolites CGA 321113 (data gaps of the EU pesticides peer review) and their magnitude in all crops

MRL: maximum residue level.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): According to Regulation (EC) No 396/2005 MRLs are not applicable to other apiculture products until individual products have been identified and listed within this group.
(F): Fat soluble.

Table of contents

Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for trifloxystrobin in honey. The current MRL application is not linked to one specific good agricultural practice (GAP) but is related to the existing uses in crops that might be attractive to bees and that are a potential source for residues of trifloxystrobin in honey. The worst-case GAP was identified by the applicant (Netherlands, 2023).

Trifloxystrobin is the ISO common name for methyl(*E*)-methoxyimino-{(*E*)-α-[1-(α,α,α-trifluoro-*m*-tolyl)ethylideneaminooxy]-*o*-tolyl}acetate (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Trifloxystrobin was evaluated in the framework of Regulation (EC) No 1107/2009[1] with United Kingdom designated as rapporteur Member State (RMS) for the representative uses (foliar applications) on apples, pears, quinces, grapes and strawberries. The renewal assessment report (RAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2017). The approval of trifloxystrobin for the use as fungicide was renewed[2] for the use as on 1 August 2018.

The EU MRLs for trifloxystrobin are established in Annexes II of Regulation (EC) No 396/2005[3]. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed. During this review, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses not fully supported by data, but for which no risk to consumers was identified (EFSA, 2014a). The proposed modifications have been implemented in the MRL legislation. After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for trifloxystrobin, which have been considered in recent MRL regulations.[4] In addition, a number of Codex maximum residue limits (CXLs) for trifloxystrobin have been taken over in the EU legislation.[5,6] The evaluation of the MRL review confirmatory data on trifloxystrobin was performed in 2022 (EFSA, 2022a). The evaluation was combined with the request to modify existing MRLs in a number of crops. The MRL proposals have not been implemented yet in the MRL regulation.

In accordance with Article 6 of Regulation (EC) No 396/2005 and following the provisions set by the 'Transparency Regulation' (EU) 2019/1381[7], the applicant Bayer AG Crop Science Division submitted on 22 February 2022 an application to the competent national authority in the Netherlands, alongside the dossier containing the supporting data using the IUCLID format.

The appointed EMS the Netherlands assessed the dossier and declared its admissibility on 21 June 2022. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA, and a public consultation launched on the dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The consultation run from 24 March 2023 to 14 April 2023. No additional data nor comments were submitted in the framework of the consultation.

[1] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 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.

[2] Commission Implementing Regulation (EU) 2018/1060 of 26 July 2018 renewing the approval of the active substance trifloxystrobin in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.C/2018/4836. OJ L 190, 27.7.2018, p. 3–7.

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

[4] For an overview of all MRL Regulations on this active substance, please consult: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as

[5] Commission Regulation (EU) 2016/67 of 19 January 2016 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for ametoctradin, chlorothalonil, diphenylamine, flonicamid, fluazinam, fluoxastrobin, halauxifen-methyl, propamocarb, prothioconazole, thiacloprid and trifloxystrobin in or on certain products. OJ L 15, 22.1.2016, p. 2–50.

[6] Commission Regulation (EU) 2017/626 of 31 March 2017 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, cyantraniliprole, cypermethrin, cyprodinil, difenoconazole, ethephon, fluopyram, flutriafol, fluxapyroxad, imazapic, imazapyr, lambda-cyhalothrin, mesotrione, profenofos, propiconazole, pyrimethanil, spirotetramat, tebuconazole, triazophos and trifloxystrobin in or on certain products. OJ L 96, 7.4.2017, p. 1–43.

[7] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, PE/41/2019/REV/1. OJ L 231, 6.9.2019, p. 1–28.

At the end of the commenting period, the EMS proceeded drafting the evaluation report, accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 3 May 2023. The EMS proposed to raise the existing MRL from the limit of quantification (LOQ) of 0.05–0.07 mg/kg. EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

EFSA based its assessment on the evaluation report submitted by the EMS (Netherlands, 2023), the RAR and its revisions (United Kingdom, 2016, 2017) prepared under Regulation (EC) No 1107/2009, the Commission review report on trifloxystrobin (European Commission, 2018a), the conclusion on the peer review of the pesticide risk assessment of the active substance trifloxystrobin (EFSA, 2017), the JMPR report (FAO, 2004, 2013, 2015, 2017), as well as the conclusions from previous EFSA opinions on trifloxystrobin, including the reasoned opinion on the MRL review according to Article 12 of Regulation No 396/2005 and its evaluation (EFSA, 2014a,b, 2016a,b, 2018b,c, 2022a,b; EFSA, 2019b).

For this application, the data requirements established in Regulation (EU) No 283/2013[8] and the guidance documents applicable at the date of submission of the IUCLID application are applicable (European Commission, 2010, 2018b, 2021, 2023; OECD, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[9].

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously, is presented in Appendix B.

The evaluation report submitted by the EMS (Netherlands, 2023) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.[10]

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

Information on the nature of residues in primary crops is relevant to support the present MRL application in honey (see Section 3.1).

In the framework of the MRL review and the renewal of the approval under Regulation (EC) No 1107/2009 (EFSA, 2014a, 2017), the metabolism of trifloxystrobin following foliar treatment was investigated in primary crops belonging to the groups of fruits crops (apple, cucumber), root crops (sugar beet), cereals (wheat) and pulses and oilseeds (peanut). Overall, the metabolism of trifloxystrobin was found to be similar in all crops. The parent compound was the major component of the total radioactive residues (TRR) in all crops. In addition, in all investigated crops the three isomers (CGA 357262, CGA 357261 and CGA 331409) and the metabolite CGA 321113 were also present. Although recovered at < 10% of TRR, the absolute amount was significant (0.05 mg/kg in apples and cucumbers and > 0.1 mg/kg in peanut hay and wheat straw).

1.1.2. Nature of residues in rotational crops

Information on the nature of residues in rotational crops is relevant to support the present MRL application in honey (see Section 3.1).

The metabolism of trifloxystrobin was assessed in confined rotational crops metabolism studies on leafy crops (lettuce), root crops (radish) and cereals (wheat) (EFSA, 2014a, 2017). Trifloxystrobin and its isomers accounted for a maximum of 15% of TRR, however the detectable fraction was less than 0.01 mg eq/kg. Trifluoroacetic acid (TFA) occurred in significant proportion of the TRR in radish root,

[8] Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plantprotection products on the market. OJ L 93, 3.4.2013, p. 1–84.

[9] 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.

[10] Background documents to this reasoned opinion are published on OpenEFSA portal and are available at the following link: https://open.efsa.europa.eu/study-inventory/EFSA-Q-2022-00407

top and wheat straw but the TRR in food items was very low. It should be noted that the metabolite TFA, which is very persistent in soil (DT_{50} > 1,000 days), is a breakdown product common with other pesticides and occurs ubiquitously in the environment from a variety of other sources (EFSA, 2021).

1.1.3. Nature of residues in processed commodities

Information on the degradation products formed during pasteurisation conditions is relevant to support the present MRL application in honey (see Section 3.1).

The effect of processing on the nature of trifloxystrobin was investigated in the framework of the MRL review and the EU pesticides peer review renewal (EFSA, 2014a, 2017). These studies (hydrolysis studies) showed that trifloxystrobin remained stable under pasteurisation and baking/brewing/boiling conditions but degraded significantly under sterilisation conditions into CGA 321113 (up to 21.5% degradation).

1.1.4. Analytical methods for enforcement purposes in plant commodities

As the current MRL application is on honey, evaluation of analytical methods for enforcement of residues in primary crops is not required.

Anyway, analytical enforcement methods, including a multi-residue QuEChERS method, have been fully validated for the determination of residues of trifloxystrobin in plant commodities at or above the LOQ of 0.01 mg/kg (EFSA, 2014a, 2017).

1.1.5. Storage stability of residues in plants

As the current MRL application is on honey, investigations of storage stability in primary crops are not required.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites, the following general residue definitions were proposed for plants in the framework of the EU pesticides peer review (EFSA, 2017):

- residue definition for enforcement: Trifloxystrobin.
- residue definition for risk assessment (primary and rotational crops): Sum of trifloxystrobin, its three isomers (CGA 357262, CGA 357261 and CGA 331409) and CGA 321113 (M5), expressed as trifloxystrobin.
- residue definition for risk assessment (processed products): Sum of trifloxystrobin and CGA 321113 (M5), expressed as trifloxystrobin.

The same residue definition for enforcement was proposed for rotational crops and processed products. The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

As the current MRL application is on honey, investigations of residues in primary crops are not required.

1.2.2. Magnitude of residues in rotational crops

No information is available on the possible transfer of residues of trifloxystrobin and its structural isomers and of CGA 321113 (M5) from the soil to the floral nectar of rotational crops. However, the possible transfer of trifloxystrobin residues to crops that are grown in crop rotation has been assessed in the framework of the peer review (EFSA, 2017) and the MRL review (EFSA, 2014a). Three rotational field trials in lettuce, turnip and wheat conducted with 1,128 g/ha at 30-day plant-back intervals were available (EFSA, 2014a, 2017). Samples were analysed for trifloxystrobin and CGA 321113; all the results were below the LOQ (0.02 mg/kg). It is noted that the trifloxystrobin isomers CGA 357262, CGA 357261 and CGA 331409, included in the residue definition for risk assessment in rotational crops, were not measured. However, the amount of trifloxystrobin and its isomers detected in the metabolism

studies on rotational crops was very minor (0.0011–0.006 mg eq/kg). Although the maximum annual application rate for the representative worst-case GAP with respect to residues in honey (i.e. 3 × 250 g/ha) is lower (0.66 N) than the application rate tested in the confined rotational crop studies, trifloxystrobin was applied to bare soil, and an additional interception of residues is expected in practice. Based on the results from the confined and the field study, residues in honey as a result of transfer from succeeding crops are not expected.

1.2.3. Magnitude of residues in processed commodities

As the current MRL application is on honey, investigations on the magnitude of residues in processed crops are not required.

1.2.4. Proposed MRLs

Not relevant.

2. Residues in livestock

Not relevant as honey is not used for feed purposes.

3. Residues in honey

3.1. Nature of residues in honey

A metabolism study with trifloxystrobin in honeybees is not available and is not required. According to the technical guidelines, in the absence of specific metabolism studies with honey bees, studies investigating the nature of residues in primary crops and rotational crops and studies investigating the degradation during pasteurisation standard conditions should be considered to determine the nature of residues in honey (European Commission, 2018b). The available studies showed that the metabolism of trifloxystrobin in primary and rotational plants is similar and that the active substance was stable under pasteurisation (EFSA, 2014a; EFSA, 2017). Honey is produced by bees from sugary secretions of plants (floral nectar mainly) through regurgitation, enzymatic conversion and water evaporation and followed by storage in the beehives for a certain time period. It is likely that the nature of residues in pollen and nectar collected from primary and rotational crops, as well as in honey (resulting from the residues in floral nectar), is the same as in primary and rotational crops.

Considering that sufficient data investigating the metabolic profile in primary and rotational crops and the degradation of the active substance under standard hydrolysis conditions are available (see Sections 1.1.1, 1.1.2 and 1.2.3, respectively), no further information is required for the current application according to the guidelines (European Commission, 2018b). However, it would be recommended to further investigate whether enzymatic processes involved in the production of honey occurring in the bee gut or during the storage in the beehive have an impact on the nature of residues in honey.

3.1.1. Analytical methods for enforcement in honey

In the framework of the present assessment, the applicant submitted the validation results of an analytical method for enforcement of trifloxystrobin residues in honey (Netherlands, 2023). The method, based on HPLC-MS/MS is sufficiently validated according to SANTE/2020/12830 rev. 1 for the determination (quantification and simultaneous confirmation) of trifloxystrobin (CGA 279202) according to the residue definition for enforcement, at or above the limit of quantification (LOQ) of 0.01 mg/kg. The method proposed is supported by a validated independent laboratory validation (ILV) (Netherlands, 2023).

Validation data in honey were provided also for its three isomers (CGA 357262, CGA 357261 and CGA 331409), the metabolite CGA 321113 and its isomer CGA 373466 in honey. LOQ achieved was at or above of 0.01 mg/kg for each individual analyte.

Since the existing guidance document on extraction efficiency (European Commission, 2023)[11] cannot be applied to the honey matrix and since no other guidance on how to investigate extraction efficiency in honey is available, demonstration of extraction efficiency in honey matrix is not required for the present assessment.

3.1.2. Storage stability of residues in honey

The storage stability of residues of trifloxystrobin (CGA 279202), its three isomers (CGA 357262, CGA 357261 and CGA 331409), metabolite CGA 321113 and its isomer CGA 373466 in honey samples stored under frozen conditions was investigated in the current MRL application (Netherlands, 2023).

It was demonstrated that residues of trifloxystrobin (CGA 279202), its three isomers (CGA 357262, CGA 357261 and CGA 331409), metabolite CGA 321113 and its isomer CGA 373466 were stable for at least 6 months when stored at −18°C in honey.

3.1.3. Proposed residue definitions

In the absence of specific metabolism studies on honey, the studies investigating the nature of residues in primary and rotational crops and studies investigating the degradation of the active substance during pasteurisation are to be considered to derive the residue definitions for honey (European Commission, 2018b).

In the framework of the assessment on the renewal of the approval (EFSA, 2017), the residue definition for enforcement for primary and rotational crops was confirmed as parent 'trifloxystrobin', and the risk assessment residue definition was proposed to be expanded to the 'sum of trifloxystrobin, its three isomers CGA 357262, CGA 357261, CGA 331409 and its metabolite CGA321113, expressed as trifloxystrobin' (see Section 1.1.6). Studies investigating the effect of processing on the nature of trifloxystrobin (hydrolysis studies) showed that under conditions simulating pasteurisation trifloxystrobin remained stable.

It is noted that no residues of CGA 321113 or the trifloxystrobin isomers (CGA 357262, CGA 357261, CGA 331409) were found in the submitted residue trials in honey above the LOQ of 0.01 mg/kg. Based on these findings, and the stability of trifloxystrobin during pasteurisation conditions, the applicant and EMS proposed the residue definition for risk assessment in honey as parent trifloxystrobin only (Netherlands, 2023). However, EFSA does not consider this justification sufficient for establishing a different residue definition for risk assessment in honey compared to primary crops as there are no specific metabolism studies in honey and the observations rely on a limited dataset comprising only four residue trials linked to a specific use of the pesticide. Therefore, it cannot be ruled out that with a larger dataset or a more critical GAP, residues exceeding the LOQ may be quantified.

EFSA concludes that for honey, the same residue definitions for primary and rotational crops for enforcement and risk assessment as derived in the renewal of the approval (EFSA, 2017), are applicable.

3.2. Magnitude of residues in honey

In support of the current MRL application, the applicant submitted four independent residue trials performed in northern (two trials) and southern (two trials) Europe under semi-field conditions to investigate the residue carry-over of trifloxystrobin from plants to honey. The active substance was applied on *Phacelia tanacetifolia* (treated plot) in three foliar spray applications at a rate of 250 g/ha with a 7-day interval during the flowering phase in the growing season 2019. According to the applicant, the application rate tested in the residue trials is considered sufficiently representative of the worst-case authorised GAP with respect to residues in honey (Netherlands, 2023). Honey samples were collected when honey reached its commercial maturity (water content below 20% or after comb closure), 2–7 days after the last application. The trials are considered valid.

The honey samples were analysed for the parent compound and the metabolites included in the residue definitions for risk assessment. No residues of CGA 321113 or the trifloxystrobin isomers (CGA 357262, CGA 357261, CGA 331409) were found in honey above the LOQ of 0.01 mg/kg.

[11] The previous revision 4 of SANTE/2017/10632, the technical guidance on extraction efficiency, was applicable at the date of submission of the IUCLID application (European Commission, 2022). Since then, further precisions on its applicability were addressed in the revised version 5, applicable from 23 May 2023. Since the revision 5 does not contain any new elements or obligations, EFSA took into consideration this newly released version directly.

According to the assessment of the EMS, the method used in the residue trials is sufficiently validated for the quantification of residues of trifloxystrobin (CGA 279202), its three isomers (CGA 357262, CGA 357261 and CGA 331409), metabolite CGA 321113 and are fit for purpose. The samples of these residue trials were stored under conditions for which the integrity of the samples has been demonstrated in honey.

The available residue trials are sufficient to derive an MRL proposal of 0.07 mg/kg for honey.

3.2.1. Proposed MRLs

The available data are considered sufficient to derive an MRL proposal of 0.07 mg/kg as well as risk assessment values for honey (see Appendix B.3.2.1). In Section 4, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

It should be noted that currently, MRLs set for honey are not applicable to other apicultural products following Commission Regulation (EU) 2018/62[12].

4. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018a, 2019a). This exposure assessment model contains food consumption data for different sub-groups of the EU population and allows the acute and chronic exposure assessment to be performed following the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference values for trifloxystrobin used in the risk assessment (i.e. ADI and ARfD values) were agreed during the EU pesticides peer review renewal of the active substance where an ARfD was set (European Commission, 2018a).

The EU pesticides peer review for the renewal of the approval identified data gaps as regards to general toxicological studies (after repeated dose exposure) to conclude on the toxicity of the three isomers of trifloxystrobin and the metabolite CGA 321113 included in the residue definition for risk assessment in unprocessed plant commodities. In addition, CGA 321113 is also included in the residue definition for risk assessment for animal commodities (EFSA, 2017). The data gap is considered relevant for the present MRL application in honey. Nevertheless, since the genotoxic potential of these compounds is ruled out (EFSA, 2017), they were not quantified in any of the residue trials (LOQ 0.01 mg/kg) and considering the very low human exposure to residues of trifloxystrobin in honey (see Appendix B.4) EFSA is of the opinion that the lack of this information is not negatively impacting the risk assessment for honey. In the future, should additional uses lead to quantifiable residues of CGA 357262, CGA 357261, CGA 331409 and CGA 321113 in honey this conclusion should be revised.

Lacking further information on the toxicity of these compounds and their occurrence in crops for which MRLs were established in the past, the results of the present risk assessment should be regarded as indicative and affected by uncertainty. EFSA performed the risk assessment under the assumption that CGA 321113 and the trifloxystrobin isomers (CGA 357262, CGA 357261, CGA 331409) are of similar toxicity as parent trifloxystrobin.

The input values used in the exposure calculations are summarised in Appendix D.1.

Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed for honey using the highest residue value (HR) derived from the residue trials submitted.

The estimated short-term exposure for honey was 0.06% of the ARfD (see Appendix B.4).

Long-term (chronic) dietary risk assessment

In the framework of the MRL review a comprehensive long-term exposure assessment was performed, taking into account the existing uses at the EU level and the acceptable CXLs (EFSA, 2014a). EFSA updated the calculation with the relevant supervised trials median residue (STMR) values derived from the residue trials in honey submitted in support of the present MRL application and, in addition, with the STMRs derived in EFSA opinions issued after the MRL review (EFSA, 2014b, 2016a, 2018b, 2019b). For those commodities where the CXLs have been implemented in the EU legislation after the MRL review, the respective STMR values as derived by the JMPR were used (FAO, 2004, 2013, 2015, 2017; EFSA, 2016b, 2018c). In addition, EFSA issued an opinion on the

[12] Commission Regulation (EU) 2018/62 of 17 January 2018 replacing Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council. C/2018/0138. OJ L 18, 23.1.2018, p. 1–73.

evaluation of MRL review confirmatory data following the MRL review and the modification of existing MRLs in various crops (EFSA, 2022a). The proposed MRLs of this opinion have not been implemented in the regulation. EFSA performed the chronic risk assessment under a worst-case scenario considering only STMR values derived from proposed MRLs in EFSA, 2022a higher than the MRLs in the current regulation (sweet peppers/bell peppers, herbs and edible flowers, chicory roots). For spring onions, the median residue was multiplied by the conversion factor (CF) for risk assessment of 2.6 (EFSA, 2012, 2014a). The crops on which no uses have been reported in the MRL review or subsequent EFSA assessments, were not considered in the consumer exposure calculations. The complete list of input values can be found in Appendix D.1.

The estimated long-term dietary intake accounted for a maximum of 12% of the ADI (NL toddler diet). The contribution of residues expected in honey to the overall long-term exposure was less than 0.01% (DE child diet) (see Appendix B.4).

EFSA concluded that the long-term intake of residues resulting from the use of trifloxystrobin under consideration is unlikely to present a risk to consumer health.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

5. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal of 0.07 mg/kg for honey.

Based on the results of the risk assessment, EFSA concluded that the short-term and long-term intake of residues resulting from the potential transfer of residues into honey and the existing uses of trifloxystrobin assessed in the present MRL application in honey of trifloxystrobin is unlikely to present a risk to consumer health. The consumer risk assessment shall be regarded as indicative and affected by uncertainties due to the data gaps identified in the framework of the EU pesticides peer review renewal of the active substance regarding missing information on the general toxicological properties of the three isomers (CGA 357262, CGA 357261, CGA 331409) and CGA 321113 and the lack of a full data set of residue trials analysed according to the residue definition for risk assessment for almost all commodities.

The MRL recommendations are summarised in Appendix B.5.

References

EFSA (European Food Safety Authority), 2012. Reasoned opinion on the modification of the existing MRLs for trifloxystrobin in spring onions and globe artichokes. EFSA Journal 2012;10(9):2873, 25 pp. https://doi.org/10.2903/j.efsa.2012.2873

EFSA (European Food Safety Authority), 2014a. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for trifloxystrobin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(2):3592, 81 pp. https://doi.org/10.2903/j.efsa.2014.3592

EFSA (European Food Safety Authority), 2014b. Reasoned opinion on the modification of the existing MRL for trifloxystrobin in cane fruits. EFSA Journal 2014;12(7):3751, 17 pp. https://doi.org/10.2903/j.efsa.2014.3751

EFSA (European Food Safety Authority), 2016a. Reasoned opinion on the modification of the existing maximum residue level (MRL) for trifloxystrobin in celeriacs. EFSA Journal 2016;14(1):4383, 17 pp. https://doi.org/10.2903/j.efsa.2016.4383

EFSA (European Food Safety Authority), 2016b. Scientific Report of EFSA on scientific support for preparing an EU position in the 48th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2016;14(8):4571, 166 pp. https://doi.org/10.2903/j.efsa.2016.4571

EFSA (European Food Safety Authority), Arena M, Auteri D, Barmaz S, Bellisai G, Brancato A, Brocca D, Bura L, Byers H, Chiusolo A, Court Marques D, Crivellente F, De Lentdecker C, De Maglie M, Egsmose M, Erdos Z, Fait G, Ferreira L, Goumenou M, Greco L, Ippolito A, Istace F, Janossy J, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Magrans JO, Medina P, Miron I, Molnar T, Nougadere A, Padovani L, Parra Morte JM, Pedersen R, Reich H, Sacchi A, Santos M, Serafimova R, Sharp R, Stanek A, Streissl F, Sturma J, Szentes C, Tarazona J, Terron A, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2017. Conclusion on the peer review of the pesticide risk assessment of the active substance trifloxystrobin. EFSA Journal 2017;15(10):4989, 29 pp. https://doi.org/10.2903/j.efsa.2017.4989

EFSA (European Food Safety Authority), Brancato A, Brocca D, Ferreira L, Greco L, Jarrah S, Leuschner R, Medina P, Miron I, Nougadere A, Pedersen R, Reich H, Santos M, Stanek A, Tarazona J, Theobald A and Villamar-Bouza L, 2018a. Guidance on use of EFSA pesticide residue intake model (EFSA PRIMo revision 3). EFSA Journal 2018;16(1):5147, 43 pp. https://doi.org/10.2903/j.efsa.2018.5147

EFSA (European Food Safety Authority), Brancato A, Brocca D, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Medina P, Miron I, Molnar T, Nougadere A, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2018b. Reasoned opinion on the modification of the existing maximum residue levels for trifloxystrobin in various crops. EFSA Journal 2018;16(1):5154, 33 pp. https://doi.org/10.2903/j.efsa.2018.5154

EFSA (European Food Safety Authority), 2018c. Scientific Report of EFSA on scientific support for preparing an EU position in the 50th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2018;16 (7):5306, 229 pp. https://doi.org/10.2903/j.efsa.2018.5306

EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Tarazona J, Theobald A, Verani A, 2019a. Pesticide Residue Intake Model- EFSA PRIMo revision 3.1 (update of EFSA PRIMo revision 3). EFSA supporting publication 2019;EN-1605, 15 pp. https://doi.org/10.2903/sp.efsa.2019.EN-1605

EFSA (European Food Safety Authority), Abdourahime H, Anastassiadou M, Brancato A, Brocca D, Carrasco Cabrera L, De Lentdecker C, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lostia A, Lythgo C, Medina P, Miron I, Molnar T, Nave S, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B, Verani A, and Villamar-Bouza L, 2019b. Reasoned opinion on the modification of the existing maximum residuelevel for trifloxystrobin in broccoli. EFSA Journal 2019;17(1):5576, 25 pp. https://doi.org/10.2903/j.efsa.2019.5576

EFSA (European Food Safety Authority), Bellisai G, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Giner G, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Ruocco S, Santos M, Scarlato AP, Theobald A, Vagenende B and Verani A, 2021. Reasoned opinion on the review of the existing maximum residue levels for cyflumetofen according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2021;19(8):6812, 51 pp. https://doi.org/10.2903/j.efsa.2021.6812

EFSA (European Food Safety Authority), Bellisai G, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Giner G, Greco L, Jarrah S, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Ruocco S, Santos M, Scarlato AP, Theobald A, Vagenende B and Verani A, 2022a. Reasoned Opinion on the modification of existing maximum residue levels in various crops and evaluation of confirmatory data following the Article 12 MRL review for trifloxystrobin. EFSA Journal 2022;20(1):7048, 50 pp. https://doi.org/10.2903/j.efsa.2022.7048

EFSA (European Food Safety Authority), 2022b. Scientific support for preparing EU position in the 53rd Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2022;20(9):7521, 310 pp. https://doi.org/10.2903/j.efsa.2022.7521

European Commission, 2010. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs) SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2018a. Final Renewal report for the active substance trifloxystrobin finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 25 May 2018 in view of the renewal of the approval of trifloxystrobin as active substance in accordance with Regulation (EC) No 1107/2009. SANTE/10107/2018, 25 May 2018.

European Commission, 2018b. Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey. SANTE/2016/11956 Rev. 9, 14 September 2018.

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, 2023. Technical Guideline on the Evaluation of Extraction Efficiency of Residue Analytical Methods SANTE 2017/10632, Rev. 5, 11 May 2023.

FAO (Food and Agriculture Organization of the United Nations), 2004. Trifloxystrobin. In: Pesticide residues in food – 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 FAO Plant Production and Protection Paper 178.

FAO (Food and Agriculture Organization of the United Nations), 2013. Trifloxystrobin. In: Pesticide residues in food – 2012. 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 FAO Plant Production and Protection Paper 215, p. 349–352.

FAO (Food and Agriculture Organization of the United Nations), 2015. Trifloxystrobin. In: Pesticide residues in food – 2015. 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. FAO Plant Prodyuction and Protection Paper 223.

FAO (Food and Agriculture Organization of the United Nations), 2016. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 3rd edn. FAO Plant Production and Protection Paper 225. 298 p.

FAO (Food and Agriculture Organization of the United Nations), 2017. Trifloxystrobin. In: Pesticide residues in food −2017. 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. FAO Plant Prodyuction and Protection Paper 232.

Netherlands, 2023. Evaluation report on the modification of MRLs for trifloxystrobin in honey. April 2023, 37 pp. Available online: www.efsa.europa.eu

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.

United Kingdom, 2016. Renewal Assessment Report (RAR) on the active substance trifloxystrobin prepared by the rapporteur Member State United Kingdom, in the framework of Commission Implementing Regulation (EU) No 844/2012, September 2016. Available online: www.efsa.europa.eu

United Kingdom, 2017. Revised Renewal Assessment Report (RAR) on the active substance trifloxystrobin prepared by the rapporteur Member State United Kingdom in the framework of Commission Implementing Regulation (EU) No 844/2012, July 2017. Available online: www.efsa.europa.eu

Abbreviations

a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
bw	body weight
CEN	European Committee for Standardization (Comité Européen de Normalisation)
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex maximum residue limit
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe

STMR	supervised trials median residue
TAR	total applied radioactivity
TRR	total radioactive residue
WHO	World Health Organization

Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

Since the MRL application is not linked to a specific intended GAP and applies to honey as food item for consumers, this Appendix is not relevant for the given application.[13]

[13] The use pattern of trifloxystrobin in *Phacelia tanacetifolia*, which was tested in the residue trials, was reported in the GAP table in the MRL application and in the evaluation report (Netherlands, 2023). However, the applicant clarified that a use in *Phacelia tanacetifolia* is not intended for trifloxystrobin.

Appendix B – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and analytical methods for enforcement purposes in plant commodities

B.1.1.1. Metabolism studies, analytical methods and residue definitions in plants

Primary crops (available studies)	**Crop groups**	**Crops**	**Applications**	**Sampling (DAT)**	**Comment/Source**
	Fruit crops	Apples	Foliar, 4 × 100 g/ha	0, 14	Radiolabelled active substance: [trifluoromethyl-phenyl-UL-^{14}C] trifloxystrobin and [glyoxyl-phenyl-UL-^{14}C] trifloxystrobin (EFSA, 2014a)
		Cucumbers	Foliar, 3 × 312 g/ha	1, 7	
	Root crops	Sugar beets	Foliar, 3 × 130 or 690 g/ha	0, 21, 45	
	Cereals	Wheat	Foliar,2 × 250 g/ha	24, 52	
			Foliar, 2 × 250 g/ha	3, 32	
			Foliar, 1 × 500 g/ha	49	Radiolabelled active substance: [trifluoromethyl-phenyl-UL-^{14}C] trifloxystrobin (EFSA, 2014a)
	Pulses/ oilseeds	Peanuts	Foliar, 4 × 560 g/ha	0, 14	Radiolabelled active substance: [trifluoromethyl-phenyl-UL-14C] trifloxystrobin and [glyoxyl-phenyl-UL-14C] trifloxystrobin (EFSA, 2014a)
Rotational crops (available studies)	**Crop groups**	**Crops**	**Applications**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Radishes	Bare soil, 1 × 500 g/ha	31, 120, 365	Radiolabelled active substance: [trifluoromethyl-phenyl-UL-^{14}C] trifloxystrobin and [glyoxyl-phenyl-UL-^{14}C] trifloxystrobin (EFSA, 2014a)
	Leafy crops	Lettuces	Bare soil, 1 × 500 g/ha	31, 120, 365	
	Cereal (small grain)	Wheat	Bare soil, 1 × 500 g/ha	Spring wheat: 31, 365; Winter wheat: 174	
Processed commodities (hydrolysis study)	**Conditions**			**Stable?**	**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)			Yes	EFSA, 2014a
	Baking, brewing and boiling (60 min, 100°C, pH 5)			Yes	EFSA, 2014a
	Sterilisation (20 min, 120°C, pH 6)			No	21.5% degradation, mainly (ca. 20%) to CGA321113 (EFSA, 2014a)

Can a general residue definition be proposed for primary crops?	Yes (EFSA, 2014a, 2017)
Rotational crop and primary crop metabolism similar?	Yes (EFSA, 2014a, 2017)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes (EFSA, 2014a, 2017)
Plant residue definition for monitoring (RD-Mo)	Trifloxystrobin
Plant residue definition for risk assessment (RD-RA)	MRL review (EFSA, 2014a): Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin. EU pesticides peer review (EFSA, 2017): Raw agricultural commodities: Sum of trifloxystrobin, its 3 isomers (CGA 357262, CGA 357261 and CGA 331409) and CGA321113 (M5), expressed as trifloxystrobin. Processed commodities: Sum of trifloxystrobin and CGA321113 (M5), expressed as trifloxystrobin.
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	• Matrices with high water content (corn, green materials; broccoli), high protein (kidney bean, dry seed), high starch (wheat grain), high oil (rapeseed), high acid (orange fruit, grape bunch): - HPLC–MS/MS, LOQ 0.01 mg/kg • Matrices with high oil (olive), high protein (kidney bean): - QuEChERS (HPLC–MS/MS); LOQ of 0.01 mg/kg • Matrices with high acid, dry, high sugar and high-water content (EURL data pool): - QuEChERS (HPLC–MS/MS); LOQ of 0.01 mg/kg (determined as parent trifloxystrobin) • Matrices difficult to analyse (hops, kiln-dried cone): - HPLC–MS/MS, LOQ 0.05 mg/kg (Determined as parent and metabolite CGA 321113) - QuEChERS (HPLC–MS/MS) LOQ 0.05 mg/kg (Determined as parent trifloxystrobin) Confirmatory method and ILV available for all matrices. (EFSA, 2014a, 2017, 2019b)

DAT: days after treatment; PBI: plant-back interval;; MRL: maximum residue level; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; EURL: European Union Reference Laboratories for Pesticide Residues; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; ILV: independent laboratory validation.

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**[(a)]	**Comment/ Source**
				Value	**Unit**		
	High-water content	Cucumber	≤ −18	24	Months	Trifloxystrobin CGA321113	EFSA (2017)
		Corn, green material	≤ −18	24	Months	Trifloxystrobin CGA321113 CGA 357262 CGA 357261 CGA 331409	EFSA (2017)

Plant products (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered[(a)]	Comment/ Source
				Value	Unit		
		Wheat, whole plant	≤ −18	24	Months	Trifloxystrobin CGA321113	EFSA (2017)
		Apple, fruit	≤ −18	18	Months	Trifloxystrobin	EFSA (2017)
	High-oil content	Oilseed rape, seed	≤ −18	24	Months	Trifloxystrobin CGA321113 CGA 357262 CGA 357261 CGA 331409	EFSA (2017)
		Peanut, nutmeat	≤ −18	18.5	Months	Trifloxystrobin	EFSA (2017)
	High-protein content	Dry bean	≤ −18	24	Months	Trifloxystrobin CGA321113CGA 357262 CGA 357261 CGA 331409	EFSA (2017)
	High starch	Rye, grain	≤ −18	24	Months	Trifloxystrobin CGA321113 CGA 357262 CGA 357261 CGA 331409	EFSA, 2017
		Wheat, grain	≤ −18	24	Months	Trifloxystrobin CGA321113	EFSA (2017)
		Potato, tuber	≤ −18	24	Months	Trifloxystrobin CGA321113	EFSA (2017)
	High-acid content	Orange, fruit	≤ −18	24	Months	Trifloxystrobin CGA321113 CGA 357262 CGA 357261 CGA 331409	EFSA (2017)
		Grape, fruit	≤ −18	24	Months	Trifloxystrobin CGA321113	EFSA (2017)
	Processed products	Apple, wet pomace	≤ −20	18.5	Months	Trifloxystrobin	EFSA (2017)
		Peanut, oil	≤ −18	18.5	Months	Trifloxystrobin	EFSA (2017)
		Potato, granules/ flakes	≤ −18	18.5	Months	Trifloxystrobin CGA321113	EFSA (2017)
		Grape juice	≤ −18	18.5	Months	Trifloxystrobin CGA321113	EFSA (2017)
	Others	Wheat straw	≤ −18	24	Months	Trifloxystrobin CGA321113	EFSA (2017)
		Peanut hay	≤ −18	18.5	Months	Trifloxystrobin	EFSA (2017)

(a): Since significant variations in the concentrations of CGA 321113 in apple fruit, apple wet pomace, peanut nutmeat, oil and peanut hay over various timepoints was observed in the storage stability studies, it was not possible to conclude on the stability of this metabolite in these specific commodities (EFSA, 2017).

B.1.2. Magnitude of residues in plants

Not relevant.

B.2. Residues in livestock

Not relevant.

B.3. Residues in honey

B.3.1. Nature of residues and analytical methods for enforcement purposes in honey

B.3.1.1. Metabolism studies, analytical methods and residue definitions in honey

Metabolism studies in honey	Metabolism studies in honey are not available. The nature of the residues in honey is based on the major components of the residue detected in primary crops, rotational crops and processed pasteurised commodities.
Honey residue definition for monitoring (RD-Mo)	Trifloxystrobin
Honey residue definition for risk assessment (RD-RA)	Sum of trifloxystrobin, its 3 isomers (CGA 357262, CGA 357261 and CGA 331409) and CGA321113 (M5), expressed as trifloxystrobin
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Honey: HPLC–MS/MS LOQ 0.01 mg/kg Confirmatory method and ILV available (Netherlands, 2023)

HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.3.1.2. Storage stability of residues in honey

Products of animal origin (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**	**Comment/ Source**
				Value	**Unit**		
	Bee products	Honey	≤ −18°C	6	Months	Trifloxystrobin CGA321113 CGA 357262 CGA 357261 CGA 331409 and CGA 373466	Netherlands (2023)

B.3.2. Magnitude of residues in honey

B.3.2.1. Summary of residues data from the supervised residue trials

Commodity	**Region[a]**	**Residue levels observed in the supervised residue trials (mg/kg)**	**Comments/ Source**	**Calculated MRL (mg/kg)**	**HR[b] (mg/kg)**	**STMR[c] (mg/kg)**	**CF[d]**
Honey	n.r.	**Mo**: 2 × < 0.01; 0.013; 0.037 **RA[e]**: 2 × < 0.05; 0.053; 0.077	Semi-field (tunnel) trials on *Phacelia tanacetifolia*. CGA 357262, CGA 357261, CGA 331409, CGA 321113: 4 × < 0.01 mg/kg	0.07	**Mo**: 0.037 **RA[e]**: 0.077	**Mo**: 0.012 **RA[e]**: 0.052	n.c.

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment; n.r.: not relevant; n.c.: not calculated.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment. EFSA has not calculated the median conversion factor, as residues of trifloxistrobing isomers and metabolite CGA 321113 we below 0.01 (LOQ).
(e): Risk assessment residue definition: Sum of trifloxystrobin, its three isomers (CGA 357262, CGA 357261 and CGA 331409) and CGA 321113 (M5), expressed as trifloxystrobin. Trifloxystrobin isomers (CGA 357262, CGA 357261, CGA 331409) and metabolite CGA 321113 were added as such without molecular weight (MW) conversion factor as residues were below the LOQ and the conversion factor for MW is very close to 1.

B.4. Consumer risk assessment

ARfD	0.5 mg/kg bw (European Commission, 2018)
Highest IESTI, according to EFSA PRIMo	Honey: 0.06% of ARfD
Assumptions made for the calculations	The calculation is based on the highest residue levels in honey derived from the residue trials according to the residue definition for risk assessment: Sum of trifloxystrobin, its 3 isomers (CGA 357262, CGA 357261 and CGA 331409) and CGA 321113, expressed as trifloxystrobin. It was assumed, that the toxicological properties of the three isomers of trifloxystrobin and CGA 321113 were comparable with the parent compound trifloxystrobin. Calculations performed with PRIMo revision 3.1

ADI	0.1 mg/kg bw per day (European Commission, 2018)
Highest IEDI, according to EFSA PRIMo	12% ADI (NL toddler diet) Contribution of crops assessed: Honey: 0.005% of ADI (DE child diet)
Assumptions made for the calculations	The calculation is based on the median residue levels derived in the framework of the MRL review (EFSA, 2014a), updated with the STMR value derived in the present MRL application in honey, the STMRs derived in EFSA opinions issued after the MRL review and from CXLs that have been taken over in EU MRL legislation (EFSA, 2014b, 2016a,b, 2018b,c, 2019b; FAO, 2004, 2013, 2015, 2017). In addition, EFSA issued an opinion on the evaluation of MRL review confirmatory data following the MRL review and the modification of existing MRLs in various crops (EFSA, 2022a). The proposed MRLs of this opinion have not been implemented in the regulation. EFSA performed the chronic risk assessment under a worst-case scenario considering only STMR values derived from proposed MRLs in EFSA

	2022a higher than the MRLs in the current regulation (sweet peppers/bell peppers, herbs and edible flowers, chicory roots) (see input values in Appendix D.1). The STMR values resulting from honey and broccoli (Netherlands, 2023; EFSA, 2019b) are fully compliant with the residue definition for risk assessment derived in the EFSA conclusion (EFSA, 2017). For the remaining commodities, the STMR values reflect the previous residue definition derived in the MRL review (EFSA, 2014a). For spring onions, the median residue was multiplied by the conversion factor (CF) for risk assessment of 2.6 (EFSA, 2012, 2014a). The crops on which no uses have been reported in the MRL review or subsequent EFSA assessments were not considered in the consumer exposure calculations. The assessment assumes that the toxicological properties of the isomers of trifloxystrobin and CGA 321113 are similar to the parent trifloxystrobin. The missing information on the residue levels related to the three isomers (CGA 357262, CGA 357261, CGA 331409) and CGA 321113 in crops for which MRLs have been established in the past and the lack of information on the toxicological properties of these compounds are a source of non-standard uncertainty. Calculations performed with PRIMo revision 3.1

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; STMR: supervised trials median residue; CXL: codex maximum residue limit.

B.5. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: trifloxystrobin[(F)]				
1040000	Honey and other apiculture products[(b)]	0.05*	0.07	The submitted data are sufficient to derive an MRL proposal for honey. Risk for consumers is unlikely. The consumer risk assessment shall be regarded as indicative and affected by uncertainties due to the lack of further information on the general toxicity of trifloxystrobin structural isomers and metabolites CGA 321113 (data gaps of the EU pesticides peer review) and their magnitude in all crops.

MRL: maximum residue level.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): According to Regulation (EC) No 396/2005 MRLs are not applicable to other apiculture products until individual products have been identified and listed within this group.
(F): Fat soluble.

Appendix C – Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Trifloxystrobin (F)

LOQs (mg/kg) range from:	0.01	to:	4.0
Toxicological reference values			
ADI (mg/kg bw per day):	0.1	ARfD (mg/kg bw):	0.5
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2018	Year of evaluation:	2018

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment | Details – acute risk assessment/children | Details – acuterisk assessment/adults

Comments: With input values on escarole derived from the indoor use leading to MRL propoal of 30 mg/kg

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	12%	NL toddler	12.37	5%	Spinaches	1%	Milk: Cattle	1%	Apples		12%
	7%	DE child	6.60	2%	Spinaches	1%	Apples	0.4%	Milk: Cattle		7%
	6%	NL child	5.97	2%	Spinaches	0.6%	Apples	0.5%	Milk: Cattle		6%
	4%	GEMS/Food G10	3.73	0.9%	Lettuces	0.4%	Spinaches	0.2%	Parsley		4%
	4%	FR toddler 2 3 yr	3.72	1%	Spinaches	0.6%	Milk: Cattle	0.3%	Apples		4%
	4%	FR child 3 15 yr	3.70	0.8%	Spinaches	0.5%	Milk: Cattle	0.3%	Oranges		4%
	4%	SE general	3.62	1%	Lettuces	0.5%	Spinaches	0.2%	Milk: Cattle		4%
	4%	IE adult	3.57	1.0%	Spinaches	0.2%	Lettuces	0.2%	Wine grapes		4%
	3%	ES child	3.47	1%	Lettuces	0.6%	Spinaches	0.2%	Milk: Cattle		3%
	3%	IT adult	3.39	1%	Lettuces	0.7%	Spinaches	0.4%	Other lettuce and other salad plants		3%
	3%	NL general	3.38	1%	Spinaches	0.5%	Escaroles/broad-leaved endives	0.3%	Lettuces		3%
	3%	GEMS/Food G06	3.35	0.4%	Spinaches	0.3%	Wheat	0.3%	Lettuces		3%
	3%	FR infant	3.32	2%	Spinaches	0.3%	Milk: Cattle	0.2%	Apples		3%
	3%	GEMS/Food G11	3.27	0.7%	Spinaches	0.2%	Lamb's lettuce/corn salads	0.2%	Lettuces		3%
	3%	ES adult	3.23	2%	Lettuces	0.6%	Spinaches	0.1%	Oranges		3%
	3%	GEMS/Food G07	3.12	0.7%	Lettuces	0.3%	Spinaches	0.2%	Wine grapes		3%
	3%	GEMS/Food G08	3.11	0.6%	Lettuces	0.2%	Spinaches	0.2%	Lamb's lettuce/corn salads		3%
	3%	IT toddler	2.80	0.8%	Lettuces	0.4%	Spinaches	0.3%	Other lettuce and other salad plants		3%
	3%	DE women 14-50 yr	2.76	0.4%	Spinaches	0.3%	Lettuces	0.3%	Apples		3%
	3%	DE general	2.61	0.3%	Spinaches	0.3%	Lettuces	0.3%	Apples		3%
	3%	GEMS/Food G15	2.58	0.3%	Lettuces	0.2%	Wheat	0.2%	Wine grapes		3%
	2%	DK child	2.26	0.4%	Lettuces	0.3%	Apples	0.3%	Milk: Cattle		2%
	2%	FR adult	2.21	0.4%	Other lettuce and other salad plants	0.4%	Spinaches	0.3%	Wine grapes		2%
	2%	UK toddler	2.18	0.4%	Milk: Cattle	0.2%	Spinaches	0.2%	Oranges		2%
	2%	UK infant	2.16	0.8%	Milk: Cattle	0.2%	Apples	0.1%	Oranges		2%
	2%	RO general	2.04	0.3%	Wine grapes	0.2%	Head cabbages	0.2%	Milk: Cattle		2%
	2%	PT general	1.87	0.4%	Wine grapes	0.3%	Lettuces	0.2%	Wheat		2%
	2%	FI 3 yr	1.78	0.5%	Spinaches	0.1%	Strawberries	0.1%	Raspberries (red and yellow)		2%
	2%	UK vegetarian	1.58	0.4%	Lettuces	0.3%	Spinaches	0.1%	Wine grapes		2%
	2%	FI 6 yr	1.55	0.4%	Spinaches	0.2%	Lettuces	0.1%	Strawberries		2%
	1%	UK adult	1.32	0.3%	Lettuces	0.2%	Wine grapes	0.1%	Spinaches		1%
	1%	DK adult	1.24	0.3%	Lettuces	0.1%	Wine grapes	0.1%	Milk: Cattle		1%
	1%	FI adult	1.05	0.4%	Lettuces	0.1%	Spinaches	0.1%	Apples		1%
	1.0%	LT adult	0.99	0.2%	Apples	0.2%	Lettuces	0.1%	Milk: Cattle		1.0%
	0.9%	PL general	0.90	0.2%	Apples	0.1%	Tomatoes	0.1%	Potatoes		0.9%
	0.4%	IE child	0.39	0.1%	Milk: Cattle	0.0%	Rice	0.0%	Wheat		0.4%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Trifloxystrobin (F) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 1

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
145%	Escaroles/broad-leaved endives	15/18.09	727
76%	Lettuces	15/10	381
45%	Spinaches	20/10	226
38%	Peaches	3/2	190
32%	Table grapes	3/2.2	160
17%	Plums	3/2	84
14%	Apricots	3/2	70
12%	Pears	0.7/0.44	61
11%	Kales	3/1.2	53
9%	Apples	0.7/0.44	47
8%	Chinese cabbages/pe-tsai	3/1.2	39
7%	Melons	0.3/0.24	36
7%	Sweet peppers/bell peppers	0.9/0.55	33
6%	Oranges	0.5/0.23	31
6%	Watermelons	0.3/0.24	29
6%	Leeks	0.7/0.49	29
6%	Tomatoes	0.7/0.49	28
6%	Lamb's lettuce/corn salads	15/10	28
5%	Roman rocket/rucola	15/10	27
5%	Cherries (sweet)	3/2	24
5%	Chervil	30/18.09	23
5%	Cauliflowers	0.5/0.39	23
4%	Wine grapes	3/2.2	20
4%	Parsley	30/18.09	20
4%	Grapefruits	0.5/0.23	18
4%	Broccoli	0.6/0.43	18
3%	Head cabbages	0.5/0.39	17
3%	Currants (red, black and white)	3/2.11	17
3%	Cucumbers	0.3/0.24	16
3%	Blackberries	3/1.44	15
3%	Chives	30/18.09	15
3%	Sage	30/18.09	14
3%	Mandarins	0.5/0.23	14
3%	Raspberries (red and yellow)	3/1.44	13
3%	Basil and edible flowers	30/18.09	13
3%	Papayas	0.6/0.31	13
3%	Passionfruits/maracujas	4/1.9	13
3%	Blueberries	3/2.11	13
2%	Gooseberries (green, red and yellow)	3/2.11	12
2%	Aubergines/egg plants	0.7/0.49	12
2%	Courgettes	0.3/0.24	11
2%	Quinces	0.7/0.44	11
2%	Cranberries	3/2.11	9.5
2%	Strawberries	1/0.56	9.2
2%	Celery leaves	30/18.09	8.7
2%	Lemons	0.5/0.23	7.9
2%	Celeries	1/0.21	7.9
1%	Peas (with pods)	1.5/0.84	6.8
1%	Pumpkins	0.3/0.24	6.4
1%	Medlar	0.7/0.44	6.1
1%	Beans (with pods)	1/0.51	5.8
1%	Carrots	0.1/0.08	5.1
0.9%	Limes	0.5/0.23	4.6
0.8%	Brussels sprouts	0.6/0.45	3.8
0.6%	Potatoes	0.02/0.02	3.1
0.6%	Cress and other sprouts and shoots	15/10	2.9
0.6%	Bananas	0.05/0.03	2.9
0.6%	Parsnips	0.04/0.08	2.9
0.5%	Swedes/rutabagas	0.04/0.05	2.6
0.5%	Dewberries	3/1.44	2.5
0.5%	Milk: Cattle	0.02/0.02	2.5
0.5%	Beetroots	0.02/0.04	2.3
0.4%	Celeriacs/turnip rooted celeries	0.03/0.04	2.2
0.4%	Globe artichokes	0.3/0.12	2.1
0.4%	Spring onions/green onions and Welsh onions	0.1/0.13	2.0
0.4%	Rice	5/0.16	2.0
0.4%	Azarole/Mediteranean medlar	3/2.11	1.9

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
73%	Escaroles/broad-leaved endives	15/18.09	365
24%	Lettuces	15/10	121
15%	Table grapes	3/2.2	75
11%	Red mustards	15/10	53
10%	Wine grapes	3/2.2	52
8%	Spinaches	20/10	40
7%	Peaches	3/2	37
7%	Plums	3/2	36
6%	Chinese cabbages/pe-tsai	3/1.2	30
5%	Kales	3/1.2	23
4%	Apricots	3/2	22
4%	Parsley	30/18.09	22
4%	Cherries (sweet)	3/2	20
4%	Blueberries	3/2.11	19
4%	Purslanes	15/10	19
4%	Lamb's lettuce/corn salads	15/10	19
3%	Head cabbages	0.5/0.39	16
3%	Currants (red, black and white)	3/2.11	14
3%	Pears	0.7/0.44	13
3%	Aubergines/egg plants	0.7/0.49	13
2%	Apples	0.7/0.44	12
2%	Roman rocket/rucola	15/10	12
2%	Blackberries	3/1.44	12
2%	Broccoli	0.6/0.43	10
2%	Watermelons	0.3/0.24	9.7
2%	Gooseberries (green, red and yellow)	3/2.11	9.5
2%	Melons	0.3/0.24	9.4
2%	Cauliflowers	0.5/0.39	9.0
2%	Sweet peppers/bell peppers	0.9/0.55	9.0
2%	Tomatoes	0.7/0.49	7.8
2%	Raspberries (red and yellow)	3/1.44	7.8
1%	Oranges	0.5/0.23	7.1
1%	Quinces	0.7/0.44	6.7
1%	Cucumbers	0.3/0.24	6.7
1%	Leeks	0.7/0.49	6.4
1%	Passionfruits/maracujas	4/1.9	6.3
1%	Celery leaves	30/18.09	5.9
1%	Courgettes	0.3/0.24	5.6
1%	HOPS (dried)	40/29	5.3
1%	Strawberries	1/0.56	5.2
0.9%	Rose hips	3/2.11	4.6
0.9%	Papayas	0.6/0.31	4.3
0.8%	Mandarins	0.5/0.23	4.1
0.8%	Grapefruits	0.5/0.23	4.1
0.8%	Beans (with pods)	1/0.51	3.9
0.8%	Cress and other sprouts and shoots	15/10	3.8
0.7%	Sage	30/18.09	3.6
0.7%	Pumpkins	0.3/0.24	3.5
0.7%	Celeries	1/0.21	3.4
0.6%	Chives	30/18.09	3.1
0.6%	Medlar	0.7/0.44	3.0
0.6%	Peas (with pods)	1.5/0.84	2.9
0.5%	Brussels sprouts	0.6/0.45	2.7
0.5%	Cranberries	3/2.11	2.4
0.4%	Basil and edible flowers	30/18.09	2.2
0.4%	Dewberries	3/1.44	2.1
0.4%	Lemons	0.5/0.23	2.1
0.4%	Rosemary	30/18.09	1.8
0.4%	Rosemary	30/18.09	1.8
0.4%	Rosemary	30/18.09	1.8
0.4%	Rosemary	30/18.09	1.8
0.3%	Swedes/rutabagas	0.04/0.05	1.7
0.3%	Limes	0.5/0.23	1.6
0.3%	Carrots	0.1/0.08	1.6
0.3%	Globe artichokes	0.3/0.12	1.6
0.3%	Chervil	30/18.09	1.5
0.3%	Gherkins	0.3/0.24	1.5

0.4%	Turnips	0.04/0.05	1.8	0.3%	Rice	5/0.16	1.4
0.3%	Radishes	0.08/0.07	1.7	0.2%	Parsnips	0.04/0.08	1.1
0.3%	Salsifies	0.04/0.05	1.6	0.2%	Beetroots	0.02/0.04	0.92
0.2%	HOPS (dried)	40/29	1.2	0.2%	Parsley roots/Hamburg roots parsley	0.08/0.08	0.82
0.2%	Thyme	30/18.09	1.1	0.2%	Milk: Cattle	0.02/0.02	0.77
0.2%	Asparagus	0.05/0.05	0.96	0.1%	Radishes	0.08/0.07	0.73
0.1%	Beans	0.2/0.04	0.73	0.1%	Bananas	0.05/0.03	0.63
0.1%	Poultry: Muscle/meat	0.04/0.04	0.68	0.1%	Potatoes	0.02/0.02	0.60
0.1%	Gherkins	0.3/0.24	0.67	0.1%	Spring onions/green onions and Welsh onions	0.1/0.13	0.58
0.1%	Wheat	0.3/0.04	0.58	0.1%	Horseradishes	0.08/0.08	0.58
0.1%	Peas (without pods)	0.09/0.07	0.57	0.1%	Turnips	0.04/0.05	0.56
0.1%	Bovine: Liver	0.07/0.07	0.56	0.1%	Salsifies	0.04/0.05	0.54
0.1%	Beans (without pods)	0.09/0.07	0.55	0.09%	Celeriacs/turnip rooted celeries	0.03/0.04	0.47
0.1%	Rosemary	30/18.09	0.54	0.09%	Poultry: Muscle	0.04/0.04	0.47
0.1%	Bovine: Edible offals (other than liver and	0.07/0.07	0.51	0.08%	Asparagus	0.05/0.05	0.38
0.10%	Eggs: Chicken	0.04/0.04	0.50	0.07%	Peas (without pods)	0.09/0.07	0.37
0.10%	Swine: Muscle/meat	0.04/0.04	0.48	0.07%	Milk: Goat	0.02/0.02	0.37
0.10%	Milk: Goat	0.02/0.02	0.48	0.07%	Wheat	0.3/0.04	0.34
0.09%	Table olives	0.3/0.14	0.47	0.06%	Milk: Sheep	0.02/0.02	0.30
0.09%	Onions	0.01/0.02	0.45	0.06%	Onions	0.01/0.02	0.30
0.07%	Parsley roots/Hamburg roots parsley	0.08/0.08	0.36	0.06%	Bovine: Liver	0.07/0.07	0.28
0.06%	Coconuts	0.02/0.02	0.29	0.05%	Beans (without pods)	0.09/0.07	0.27
0.06%	Bovine: Muscle/meat	0.04/0.04	0.29	0.05%	Beans	0.2/0.04	0.26
0.06%	Other farmed animals: Muscle/meat	0.04/0.04	0.28	0.05%	Lentils	0.2/0.04	0.25
0.06%	Honey and other apiculture products	0.07/0.08	0.28	0.05%	Bovine: Edible offals (other than liver and kidney)	0.07/0.07	0.23
0.05%	Lentils	0.2/0.04	0.27	0.05%	Bovine: Muscle	0.04/0.04	0.23
0.05%	Peas	0.2/0.04	0.26	0.04%	Other farmed animals: Muscle/meat	0.04/0.04	0.22
0.05%	Rye	0.3/0.04	0.25	0.04%	Sheep: Liver	0.07/0.07	0.20
0.05%	Equine: Muscle/meat	0.04/0.04	0.24	0.04%	Rye	0.3/0.04	0.19
0.04%	Barley	0.5/0.04	0.22	0.04%	Swine: Muscle/meat	0.04/0.04	0.19
0.04%	Sheep: Muscle/meat	0.04/0.04	0.22	0.04%	Barley	0.5/0.04	0.19
0.04%	Laurel/bay leaves	30/18.09	0.18	0.04%	Equine: Muscle/meat	0.04/0.04	0.19
0.03%	Bovine: Kidney	0.04/0.04	0.15	0.04%	Sheep: Muscle/meat	0.04/0.04	0.19
0.03%	Maize/corn	0.02/0.02	0.13	0.04%	Poultry: Liver	0.04/0.04	0.19
0.02%	Bovine: Fat tissue	0.06/0.06	0.12	0.03%	Coconuts	0.02/0.02	0.17
0.02%	Olives for oil production	0.3/0.1	0.12	0.03%	Eggs: Chicken	0.04/0.04	0.17
0.02%	Swine: Edible offals (other than liver and	0.04/0.04	0.12	0.03%	Table olives	0.3/0.14	0.14
0.02%	Pistachios	0.02/0.02	0.12	0.03%	Peas	0.2/0.04	0.13
0.02%	Chestnuts	0.02/0.02	0.08	0.03%	Swine: Other products	0.04/0.04	0.13
0.01%	Milk: Sheep	0.02/0.02	0.07	0.03%	Soyabeans	0.05/0.02	0.13
0.01%	Garlic	0.01/0.02	0.07	0.02%	Honey and other apiculture products	0.07/0.08	0.11
0.01%	Swine: Fat tissue	0.04/0.04	0.07	0.02%	Swine: Edible offals (other than liver and kidney)	0.04/0.04	0.10
0.01%	Walnuts	0.02/0.02	0.07	0.02%	Chestnuts	0.02/0.02	0.09
0.01%	Hazelnuts/cobnuts	0.02/0.02	0.07	0.02%	Swine: Kidney	0.04/0.04	0.09
0.01%	Peanuts/groundnuts	0.02/0.02	0.06	0.02%	Bovine: Kidney	0.04/0.04	0.08
0.01%	Almonds	0.02/0.02	0.06	0.02%	Swine: Fat tissue	0.04/0.04	0.08
0.01%	Pecans	0.02/0.02	0.06	0.01%	Olives for oil production	0.3/0.1	0.07
0.01%	Soyabeans	0.05/0.02	0.05	0.01%	Goat: Muscle	0.04/0.04	0.06
0.01%	Cashew nuts	0.02/0.02	0.05	0.01%	Bovine: Fat tissue	0.06/0.06	0.06
0.01%	Swine: Kidney	0.04/0.04	0.05	0.01%	Swine: Liver	0.04/0.04	0.06
0.01%	Swine: Liver	0.04/0.04	0.05	0.01%	Eggs: Quail	0.04/0.04	0.06
0.01%	Oat	0.4/0.04	0.04	0.01%	Pistachios	0.02/0.02	0.05
0.01%	Poultry: Liver	0.04/0.04	0.04	0.01%	Poultry: Kidney	0.04/0.04	0.05
0.01%	Horseradishes	0.08/0.08	0.03	0.01%	Sheep: Edible offals (other than liver and kidney)	0.07/0.07	0.05
0.00%	Brazil nuts	0.02/0.02	0.02	0.01%	Peanuts/groundnuts	0.02/0.02	0.05
0.00%	Macadamia	0.02/0.02	0.01	0.01%	Pecans	0.02/0.02	0.05
0.00%	Pine nut kernels	0.02/0.02	0.01	0.01%	Walnuts	0.02/0.02	0.04
0.00%	Ginseng root	0.05/0.03	0.01	0.01%	Maize/corn	0.02/0.02	0.04
0.00%	Poultry: Fat tissue	0.04/0.04	0.00	0.01%	Macadamia	0.02/0.02	0.04
				0.01%	Cashew nuts	0.02/0.02	0.03
				0.01%	Almonds	0.02/0.02	0.03
				0.01%	Oat	0.4/0.04	0.03
				0.00%	Hazelnuts/cobnuts	0.02/0.02	0.02
				0.00%	Pine nut kernels	0.02/0.02	0.02
				0.00%	Pine nut kernels	0.02/0.02	0.02
				0.00%	Ginseng root	0.05/0.03	0.02
				0.00%	Chicory roots	0.02/0.04	0.02
				0.00%	Brazil nuts	0.02/0.02	0.01
				0.00%	Garlic	0.01/0.02	0.01
				0.00%	Poultry: Fat tissue	0.04/0.04	0.01
				0.00%	Sheep: Kidney	0.04/0.04	0.00

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)	1

Processed commodities

Results for children

No of processed commodities for which ARfD/ADI is exceeded (IESTI): 1

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
240%	Escaroles/broad-leaved endives/boiled	15/18.09	1199
28%	Spinaches/frozen; boiled	20/10	139
10%	Peaches/canned	3/2	52
7%	Broccoli/boiled	0.6/0.43	34
7%	Kales/boiled	3/1.2	33
6%	Leeks/boiled	0.7/0.49	28
5%	Cauliflowers/boiled	0.5/0.39	27
4%	Pumpkins/boiled	0.3/0.24	21
2%	Currants (red, black and white)/juice	3/0.33	9.4
2%	Courgettes/boiled	0.3/0.24	8.5
1%	Raspberries/juice	3/0.62	7.3
1%	Wine grapes/juice	3/0.15	6.5
1%	Beans (with pods)/boiled	1/0.51	6.4
1%	Peaches/juice	3/0.38	6.3
1%	Apples/juice	0.7/0.11	6.0

Expand/collapse list

Results for adults

No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
74%	Escaroles/broad-leaved endives/boiled	15/18.09	370
17%	Spinaches/frozen; boiled	20/10	83
8%	Purslanes/boiled	15/10	41
4%	Wine grapes/wine	3/2.2	21
3%	Peaches/canned	3/2	16
3%	Cauliflowers/boiled	0.5/0.39	16
3%	Pumpkins/boiled	0.3/0.24	13
3%	Table grapes/raisins	3/10.34	13
2%	Broccoli/boiled	0.6/0.43	10
2%	Leeks/boiled	0.7/0.49	8.5
1%	Celeries/boiled	1/0.21	7.1
1%	Courgettes/boiled	0.3/0.24	5.5
0.8%	Currants (red, black and white)/juice	3/0.33	4.2
0.7%	Apples/juice	0.7/0.11	3.7
0.6%	Wine grapes/juice	3/0.15	3.1

Conclusion:

The estimated short-term intake (IESTI) exceeded the toxicological reference value for 1 commodities.

For processed commodities, the toxicological reference value was exceeded in one or several cases.

Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Current risk assessment residue definition: Sum of trifloxystrobin, its three isomers CGA 357262, CGA 357261, CGA 331409 and its metabolite CGA321113, expressed as trifloxystrobin (EFSA, 2017)						
Broccoli	0.6	EFSA (2019b)	0.1	STMR-RAC	0.43	HR-RAC
Honey and other apiculture products[c]	0.07	MRL proposal	0.052	STMR-RAC	0.077	HR-RAC
Previous risk assessment residue definition plant products: Sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin (EFSA, 2014a)						
Grapefruits	0.5	EFSA (2014a)	0.095	STMR-RAC	0.23	HR-RAC
Oranges	0.5	EFSA (2014a)	0.095	STMR-RAC	0.23	HR-RAC
Lemons	0.5	EFSA (2014a)	0.095	STMR-RAC	0.23	HR-RAC
Limes	0.5	EFSA (2014a)	0.095	STMR-RAC	0.23	HR-RAC
Mandarins	0.5	EFSA (2014a)	0.095	STMR-RAC	0.23	HR-RAC
Other citrus fruit	0.5	EFSA (2014a)	0.095	STMR-RAC		
Almonds	0.02	EFSA (2014a)	0.02	STMR-RAC	0.02	HR-RAC
Brazil nuts	0.02	EFSA (2014a)	0.02	STMR-RAC	0.02	HR-RAC
Cashew nuts	0.02	EFSA (2014a)	0.02	STMR-RAC	0.02	HR-RAC
Chestnuts	0.02	EFSA (2014a)	0.02	STMR-RAC	0.02	HR-RAC
Coconuts	0.02	EFSA (2014a)	0.02	STMR-RAC	0.02	HR-RAC
Hazelnuts/cobnuts	0.02	EFSA (2014a)	0.02	STMR-RAC	0.02	HR-RAC
Macadamia	0.02	EFSA (2014a)	0.02	STMR-RAC	0.02	HR-RAC
Pecans	0.02	EFSA (2014a)	0.02	STMR-RAC	0.02	HR-RAC
Pine nut kernels	0.02	EFSA (2014a)	0.02	STMR-RAC	0.02	HR-RAC
Pistachios	0.02	EFSA (2014a)	0.02	STMR-RAC	0.02	HR-RAC
Walnuts	0.02	EFSA (2014a)	0.02	STMR-RAC	0.02	HR-RAC
Other tree nuts	0.02	EFSA (2014a)	0.02	STMR-RAC		
Apples	0.7	EFSA (2014a)	0.11	STMR-RAC	0.44	HR-RAC
Pears	0.7	EFSA (2014a)	0.11	STMR-RAC	0.44	HR-RAC
Quinces	0.7	EFSA (2014a)	0.11	STMR-RAC	0.44	HR-RAC
Medlar	0.7	EFSA (2014a)	0.11	STMR-RAC	0.44	HR-RAC
Loquats/Japanese medlars	0.7	EFSA (2014a)	0.11	STMR-RAC	0.44	HR-RAC
Other pome fruit	0.7	EFSA (2014a)	0.11	STMR-RAC		
Apricots	3	EFSA (2014a)	0.38	STMR-RAC	2	HR-RAC
Cherries (sweet)	3	EFSA (2014a)	0.38	STMR-RAC	2	HR-RAC
Peaches	3	EFSA (2014a)	0.38	STMR-RAC	2	HR-RAC
Plums	3	EFSA (2014a)	0.38	STMR-RAC	2	HR-RAC
Other stone fruit	3	EFSA (2014a)	0.38	STMR-RAC		
Table grapes	3	EFSA (2014a)	0.15	STMR-RAC	2.2	HR-RAC
Wine grapes	3	EFSA (2014a)	0.15	STMR-RAC	2.2	HR-RAC
Strawberries	1	EFSA (2014a)	0.335	STMR-RAC	0.56	HR-RAC
Blackberries	3	EFSA, 2014b	0.62	STMR-RAC	1.44	HR-RAC
Dewberries	3	EFSA, 2014b	0.62	STMR-RAC	1.44	HR-RAC

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Raspberries (red and yellow)	3	EFSA, 2014b	0.62	STMR-RAC	1.44	HR-RAC
Other cane fruit	3	EFSA, 2014b	0.62	STMR-RAC		
Blueberries	3	EFSA, 2018b	0.33	STMR-RAC	2.11	HR-RAC
Cranberries	3	EFSA, 2018b	0.33	STMR-RAC	2.11	HR-RAC
Currants (red, black and white)	3	EFSA, 2018b	0.33	STMR-RAC	2.11	HR-RAC
Gooseberries (green, red and yellow)	3	EFSA, 2018b	0.33	STMR-RAC	2.11	HR-RAC
Rose hips	3	EFSA, 2018b	0.33	STMR-RAC	2.11	HR-RAC
Mulberries (black and white)	3	EFSA, 2018b	0.33	STMR-RAC	2.11	HR-RAC
Azarole/ Mediteranean medlar	3	EFSA, 2018b	0.33	STMR-RAC	2.11	HR-RAC
Elderberries	3	EFSA, 2018b	0.33	STMR-RAC	2.11	HR-RAC
Other other small fruit & berries	3	EFSA, 2018b	0.33	STMR-RAC		
Table olives	0.3	EFSA (2014a)	0.095	STMR-RAC	0.14	HR-RAC
Passion fruit/ maracujas	4	EFSA (2014a)	0.72	STMR-RAC	1.9	HR-RAC
Bananas	0.05	EFSA (2014a)	0.02	STMR-RAC	0.03	HR-RAC
Papayas	0.6	EFSA (2014a)	0.2	STMR-RAC	0.31	HR-RAC
Potatoes	0.02	EFSA (2014a)	0.02	STMR-RAC	0.02	HR-RAC
Beetroots	0.02	EFSA (2014a)	0.04	STMR-RAC	0.04	HR-RAC
Carrots	0.1	EFSA (2014a)	0.035	STMR-RAC	0.08	HR-RAC
Celeriacs/turnip rooted celeries	0.03	EFSA (2016a)	0.04	STMR-RAC	0.04	HR-RAC
Horseradishes	0.08	EFSA (2016a)	0.04	STMR-RAC	0.08	HR-RAC
Parsnips	0.04	EFSA (2014a)	0.065	STMR-RAC	0.08	HR-RAC
Parsley roots/ Hamburg roots parsley	0.08	EFSA (2016a)	0.04	STMR-RAC	0.08	HR-RAC
Radishes	0.08	EFSA (2014a)	0.065	STMR-RAC	0.07	HR-RAC
Salsifies	0.04	EFSA (2014a)	0.04	STMR-RAC	0.05	HR-RAC
Swedes/rutabagas	0.04	EFSA (2014a)	0.04	STMR-RAC	0.05	HR-RAC
Turnips	0.04	EFSA (2014a)	0.04	STMR-RAC	0.05	HR-RAC
Garlic	0.01	EFSA (2014a)	0.02	STMR-RAC	0.02	HR-RAC
Onions	0.01	EFSA (2014a)	0.02	STMR-RAC	0.02	HR-RAC
Spring onions/ green onions and Welsh onions	0.1	EFSA (2012)	0.039	STMR-RAC*CF (2.6)	0.13	HR-RAC*CF (2.6)
Tomatoes	0.7	EFSA (2014a)	0.08	STMR-RAC	0.49	HR-RAC
Sweet peppers/bell peppers	0.9[c]	EFSA (2022a)	0.09	STMR-RAC	0.55	HR-RAC
Aubergines/egg plants	0.7	EFSA (2014a)	0.08	STMR-RAC	0.49	HR-RAC

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Cucumbers	0.3[c]	EFSA (2022a)	0.095	STMR-RAC	0.24	HR-RAC
Gherkins	0.3[c]	EFSA (2022a)	0.095	STMR-RAC	0.24	HR-RAC
Courgettes	0.3	EFSA (2014a)	0.095	STMR-RAC	0.24	HR-RAC
Other cucurbits - edible peel	0.3	EFSA (2014a)	0.095	STMR-RAC		
Melons	0.3	EFSA (2014a)	0.095	STMR-RAC	0.24	HR-RAC
Pumpkins	0.3	EFSA (2014a)	0.095	STMR-RAC	0.24	HR-RAC
Watermelons	0.3	EFSA (2014a)	0.095	STMR-RAC	0.24	HR-RAC
Other cucurbits - inedible peel	0.3	EFSA (2014a)	0.095	STMR-RAC		
Cauliflowers	0.5	EFSA (2014a)	0.17	STMR-RAC	0.39	HR-RAC
Other flowering brassica	0.5	EFSA (2014a)	0.17	STMR-RAC		
Brussels sprouts	0.6	EFSA (2014a)	0.16	STMR-RAC	0.45	HR-RAC
Head cabbages	0.5	EFSA (2014a)	0.17	STMR-RAC	0.39	HR-RAC
Chinese cabbages/ pe-tsai	3	EFSA (2014a)	0.66	STMR-RAC	1.2	HR-RAC
Kales	3	EFSA (2014a)	0.66	STMR-RAC	1.2	HR-RAC
Other leafy brassica	3	EFSA (2014a)	0.66	STMR-RAC		
Lamb's lettuce/ corn salads	15	EFSA (2018b)	2.85	STMR-RAC	10	HR-RAC
Lettuces	15	EFSA (2018b)	2.85	STMR-RAC	10	HR-RAC
Escaroles/broad-leaved endives	15	EFSA (2018b)	4.77	STMR-RAC	18.09	HR-RAC
Cress and other sprouts and shoots	15	EFSA (2018b)	2.85	STMR-RAC	10	HR-RAC
Land cress	15	EFSA (2018b)	2.85	STMR-RAC	10	HR-RAC
Roman rocket/ rucola	15	EFSA (2018b)	2.85	STMR-RAC	10	HR-RAC
Red mustards	15	EFSA (2018b)	2.85	STMR-RAC	10	HR-RAC
Baby leaf crops (including brassica species)	15	EFSA (2018b)	2.85	STMR-RAC	10	HR-RAC
Other lettuce and other salad plants	15	EFSA (2018b)	2.85	STMR-RAC		
Spinaches	20	EFSA (2018b)	7.6	STMR-RAC	10	HR-RAC
Purslanes	15	EFSA (2018b)	2.85	STMR-RAC	10	HR-RAC
Chervil	30[d]	EFSA (2022a)	4.77	STMR-RAC	18.09	HR-RAC
Chives	30[d]	EFSA (2022a)	4.77	STMR-RAC	18.09	HR-RAC
Celery leaves	30[d]	EFSA (2022a)	4.77	STMR-RAC	18.09	HR-RAC
Parsley	30[d]	EFSA (2022a)	4.77	STMR-RAC	18.09	HR-RAC
Sage	30[d]	EFSA (2022a)	4.77	STMR-RAC	18.09	HR-RAC
Rosemary	30[d]	EFSA (2022a)	4.77	STMR-RAC	18.09	HR-RAC
Thyme	30[d]	EFSA (2022a)	4.77	STMR-RAC	18.09	HR-RAC
Basil and edible flowers	30[d]	EFSA (2022a)	4.77	STMR-RAC	18.09	HR-RAC
Laurel/bay leaves	30[d]	EFSA (2022a)	4.77	STMR-RAC	18.09	HR-RAC

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Tarragon	30[d]	EFSA (2022a)	4.77	STMR-RAC	18.09	HR-RAC
Other herbs	30[c],[d]	EFSA (2022a)	4.77	STMR-RAC		
Beans (with pods)	1	EFSA (2014a)	0.2	STMR-RAC	0.51	HR-RAC
Beans (without pods)	0.09	EFSA (2018b)	0.03	STMR-RAC	0.07	HR-RAC
Peas (with pods)	1.5	EFSA (2018b)	0.26	STMR-RAC	0.84	HR-RAC
Peas (without pods)	0.09	EFSA (2018b)	0.03	STMR-RAC	0.07	HR-RAC
Asparagus	0.05	EFSA (2014a)	0.05	STMR-RAC	0.05	HR-RAC
Celeries	1	EFSA (2014a)	0.18	STMR-RAC	0.21	HR-RAC
Globe artichokes	0.3	EFSA (2014a)	0.09	STMR-RAC	0.12	HR-RAC
Leeks	0.7	EFSA (2014a)	0.31	STMR-RAC	0.49	HR-RAC
Beans	0.2	EFSA (2018b)	0.04	STMR-RAC	0.04	STMR-RAC
Lentils	0.2	EFSA (2018b)	0.04	STMR-RAC	0.04	STMR-RAC
Peas	0.2	EFSA (2018b)	0.04	STMR-RAC	0.04	STMR-RAC
Lupins/lupini beans	0.2	EFSA (2018b)	0.04	STMR-RAC	0.04	STMR-RAC
Other pulses	0.2	EFSA (2018b)	0.04	STMR-RAC		
Peanuts/ groundnuts	0.02	EFSA (2014a)	0.02	STMR-RAC	0.02	STMR-RAC
Soyabeans	0.05	EFSA (2016b)	0.023	STMR-RAC	0.023	STMR-RAC
Cotton seeds	0.4	EFSA (2018c)	0.03	STMR-RAC	0.03	STMR-RAC
Olives for oil production	0.3	EFSA (2014a)	0.095	STMR-RAC	0.095	STMR-RAC
Barley	0.5	EFSA (2014a)	0.04	STMR-RAC	0.04	STMR-RAC
Maize/corn	0.02	EFSA (2014a)	0.02	STMR-RAC	0.02	STMR-RAC
Oat	0.4	EFSA (2014a)	0.04	STMR-RAC	0.04	STMR-RAC
Rice	5	EFSA (2014a)	0.16	STMR-RAC	0.16	STMR-RAC
Rye	0.3	EFSA (2014a)	0.04	STMR-RAC	0.04	STMR-RAC
Wheat	0.3	EFSA (2014a)	0.04	STMR-RAC	0.04	STMR-RAC
Ginseng root	0.05	EFSA (2018c)	0.03	STMR-RAC	0.03	HR-RAC
HOPS (dried)	40	EFSA (2014a)	9.95	STMR-RAC	29	HR-RAC
Sugar beet roots	0.02	EFSA (2014a)	0.04	STMR-RAC	0.04	HR-RAC
Chicory roots	0.02[d]	EFSA (2022a)	0.04	STMR-RAC	0.04	HR-RAC
Current risk assessment residue definition: Swine/Ruminants (liver and kidney)/Equine: Sum of trifloxystrobin and CGA 321113 (M5) (free and conjugated), expressed as trifloxystrobin); Poultry: Sum of trifloxystrobin and CGA 321113 (M5) (only free), expressed as trifloxystrobin						
Bovine: Liver	0.07	EFSA (2014a)	0.04	STMR-RAC	0.07	HR-RAC
Bovine: Kidney	0.04	EFSA (2014a)	0.04	STMR-RAC	0.04	HR-RAC
Sheep: Liver	0.07	EFSA (2014a)	0.04	STMR-RAC	0.07	HR-RAC
Sheep: Kidney	0.04	EFSA (2014a)	0.04	STMR-RAC	0.04	HR-RAC
Goat: Liver	0.07	EFSA (2014a)	0.04	STMR-RAC	0.07	HR-RAC
Goat: Kidney	0.04	EFSA (2014a)	0.04	STMR-RAC	0.04	HR-RAC
Poultry: Muscle/ meat[e]	0.04	EFSA (2014a)	0.04	STMR-RAC	0.04	HR-RAC
Poultry: Fat tissue	0.04	EFSA (2014a)	0.04	STMR-RAC	0.04	HR-RAC

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Poultry: Liver	0.04	EFSA (2014a)	0.04	STMR-RAC	0.04	HR-RAC
Poultry: Kidney	0.04	EFSA (2014a)	0.04	STMR-RAC	0.04	HR-RAC
Poultry: Edible offal (other than liver and kidney)	0.04	EFSA (2014a)	0.04	STMR-RAC	0.04	HR-RAC
Poultry: Other products	0.04	EFSA (2014a)	0.04	STMR-RAC		
Eggs: Chicken	0.04	EFSA (2014a)	0.04	STMR-RAC	0.04	HR-RAC
Eggs: Duck	0.04	EFSA (2014a)	0.04	STMR-RAC	0.04	HR-RAC
Eggs: Goose	0.04	EFSA (2014a)	0.04	STMR-RAC	0.04	HR-RAC
Eggs: Quail	0.04	EFSA (2014a)	0.04	STMR-RAC	0.04	HR-RAC
Eggs: Others	0.04	EFSA (2014a)	0.04	STMR-RAC		
Previous risk assessment residue definition animal products: Swine/Ruminants (except liver and kidney)/Equine: Sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin						
Swine: Muscle/ meat[d]	0.04	EFSA (2014a)	0.04	STMR-RAC	0.04	HR-RAC
Swine: Fat tissue	0.04	EFSA (2014a)	0.04	STMR-RAC	0.04	HR-RAC
Swine: Liver	0.04	EFSA (2014a)	0.04	STMR-RAC	0.04	HR-RAC
Swine: Kidney	0.04	EFSA (2014a)	0.04	STMR-RAC	0.04	HR-RAC
Swine: Edible offal (other than liver and kidney)	0.04	EFSA (2014a)	0.04	STMR-RAC	0.04	HR-RAC
Swine: Other products	0.04	EFSA (2014a)	0.04	STMR-RAC	0.04	HR-RAC
Bovine: Muscle/ meat[e]	0.04	EFSA (2014a)	0.04	STMR-RAC	0.04	HR-RAC
Bovine: Fat tissue	0.06	EFSA (2014a)	0.04	STMR-RAC	0.06	HR-RAC
Bovine: Edible offal (other than liver and kidney)	0.07	EFSA (2014a)	0.04	STMR-RAC	0.07	HR-RAC
Sheep: Muscle/ meat[e]	0.04	EFSA (2014a)	0.04	STMR-RAC	0.04	HR-RAC
Sheep: Fat tissue	0.06	EFSA (2014a)	0.04	STMR-RAC	0.06	HR-RAC
Sheep: Edible offal (other than liver and kidney)	0.07	EFSA (2014a)	0.04	STMR-RAC	0.07	HR-RAC
Goat: Muscle/ meat[e]	0.04	EFSA (2014a)	0.04	STMR-RAC	0.04	HR-RAC
Goat: Fat tissue	0.06	EFSA (2014a)	0.04	STMR-RAC	0.06	HR-RAC
Goat: Edible offal (other than liver and kidney)	0.07	EFSA (2014a)	0.04	STMR-RAC	0.07	HR-RAC
Equine: Muscle/ meat[e]	0.04	Reg No 2015/1200	0.04	STMR-RAC	0.04	HR-RAC
Equine: Fat tissue	0.06	Reg No 2015/1200	0.04	STMR-RAC	0.06	HR-RAC
Equine: Liver	0.07	Reg No 2015/1200	0.04	STMR-RAC	0.07	HR-RAC
Equine: Kidney	0.04	Reg No 2015/1200	0.04	STMR-RAC	0.04	HR-RAC

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[(a)] (mg/kg)	Comment	Input value[(a)] (mg/kg)	Comment[(b)]
Equine: Edible offal (other than liver and kidney)	0.07	Reg No 2015/1200	0.04	STMR-RAC	0.07	HR-RAC
Other farmed animals: Muscle/ meat[(e)]	0.04	Reg No 2015/1200	0.04	STMR-RAC	0.04	HR-RAC
Other farmed animals: Fat tissue	0.06	Reg No 2015/1200	0.04	STMR-RAC	0.06	HR-RAC
Other farmed animals: Liver	0.07	Reg No 2015/1200	0.04	STMR-RAC	0.07	HR-RAC
Other farmed animals: Kidney	0.04	Reg No 2015/1200	0.04	STMR-RAC	0.04	HR-RAC
Other farmed animals: Edible offal (other than liver and kidney)	0.07	Reg No 2015/1200	0.04	STMR-RAC	0.07	HR-RAC
Milk: Cattle	0.02	EFSA (2014a)	0.02	STMR-RAC	0.02	STMR-RAC
Milk: Sheep	0.02	EFSA (2014a)	0.02	STMR-RAC	0.02	STMR-RAC
Milk: Goat	0.02	EFSA (2014a)	0.02	STMR-RAC	0.02	STMR-RAC
Milk: Horse	0.02	EFSA (2014a)	0.02	STMR-RAC	0.02	STMR-RAC
Milk: Others	0.02	EFSA (2014a)	0.02	STMR-RAC	0.02	STMR-RAC

STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; CF: conversion factor.

(a): Figures in the table are rounded to two digits, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce dietary burden calculations, the unrounded values need to be used.

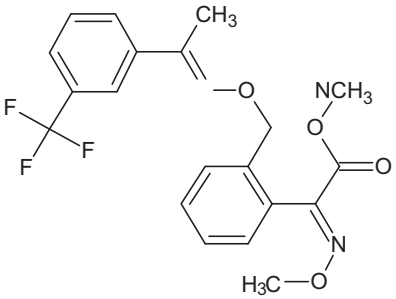
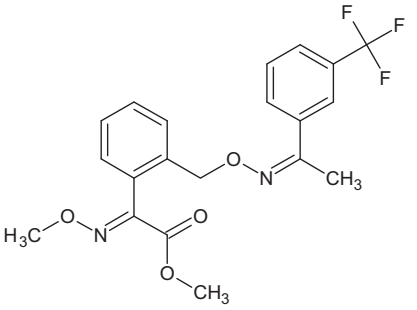
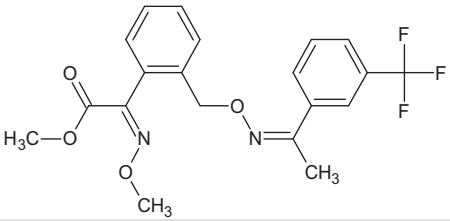
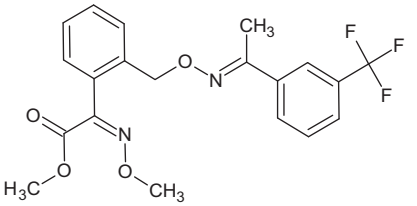
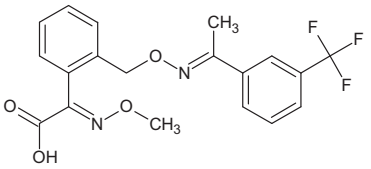
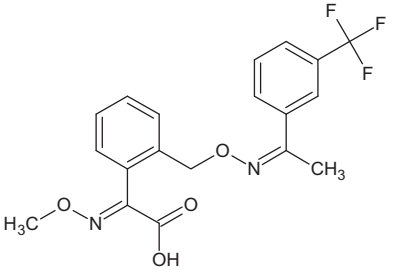
(b): Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.

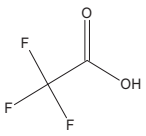
(c): MRL proposal and input values for risk assessment refer to honey only.

(d): MRL proposals based on a recently assessed opinion (EFSA, 2022a) not yet considered for implementation in the EU MRL regulation.

(e): Consumption figures in the EFSA PRIMo are expressed as meat. Since the a.s. is a fat-soluble pesticide, STMR and HR residue values were calculated considering a 80%/90% muscle and 20%/10% fat content for mammal/poultry meat respectively (FAO, 2016).

Appendix E – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/ InChiKey[b]	Structural formula[c]
Trifloxystrobin	methyl (*E*)-methoxyimino-{(*E*)-α-[1-(α,α,α-trifluoro-*m*-tolyl)ethylideneaminooxy]-*o*-tolyl} acetate FC(F)(F)c1cccc(c1)C(\C)=N\OCc2ccccc2C(=N\OC)/C(=O)OC ONCZDRURRATYFI-TVJDWZFNSA-N	
CGA 357261	methyl (2*E*)-(methoxyimino)[2-({[(*Z*)-{1-[3-(trifluoromethyl)phenyl]ethylidene}amino]oxy} methyl)phenyl]acetate FC(F)(F)c1cccc(c1)C(/C)=N\OCc1ccccc1C(=N\OC)/C(=O)OC ONCZDRURRATYFI-KEEMFBDKSA-N	
CGA 357262	methyl (2*Z*)-(methoxyimino)[2-({[(*Z*)-{1-[3-(trifluoromethyl)phenyl]ethylidene}amino]oxy} methyl)phenyl]acetate FC(F)(F)c1cccc(c1)C(/C)=N\OCc1ccccc1C(=N\OC)\C(=O)OC ONCZDRURRATYFI-JCLPZYRYSA-N	
CGA 331409	methyl (2*Z*)-(methoxyimino)[2-({[(*E*)-{1-[3-(trifluoromethyl)phenyl]ethylidene}amino]oxy} methyl)phenyl]acetate FC(F)(F)c1cccc(c1)C(\C)=N\OCc2ccccc2C(=N\OC)\C(=O)OC ONCZDRURRATYFI-QTCHDTBASA-N	
CGA 321113 M5	(2*E*)-(methoxyimino)[2-({[(*E*)-{1-[3-(trifluoromethyl)phenyl]ethylidene}amino]oxy} methyl)phenyl]acetic acid FC(F)(F)c1cccc(c1)C(\C)=N\OCc2ccccc2C(=N\OC)/C(=O)O ISZQNKFXNXQTTF-NACSPRHISA-N	
CGA 373466	(2*E*)-(methoxyimino)[2-({[(*Z*)-{1-[3-(trifluoromethyl)phenyl]ethylidene}amino]oxy} methyl)phenyl]acetic acid FC(F)(F)c1cccc(c1)C(/C)=N\OCc2ccccc2C(=N\OC)/C(=O)O ISZQNKFXNXQTTF-NFNXJDIJSA-N	

Code/trivial name[(a)]	IUPAC name/SMILES notation/ InChiKey[(b)]	Structural formula[(c)]
Trifluoroacetic acid (TFA)	trifluoroacetic acid FC(F)(F)C(=O)O DTQVDTLACAAQTR-UHFFFAOYSA-N	

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