REASONED OPINION

EFSA Journal

ADOPTED: 9 December 2021

doi: 10.2903/j.efsa.2022.7048

Modification of existing maximum residue levels in various crops and evaluation of confirmatory data following the Article 12 MRL review for trifloxystrobin

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Bayer CropScience submitted two applications to the competent national authorities appointed in the United Kingdom and Greece to modify the existing maximum residue levels (MRLs) for the active substance trifloxystrobin in various crops and in sweet peppers/bell peppers, respectively. Moreover, in the application submitted to the United Kingdom, the applicant also included a request to evaluate the confirmatory data identified in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 as not available. In the framework of the assessment process, these applications were re-allocated to the Netherlands. The data submitted in support of the requests were found to be sufficient to derive MRL proposals for sweet peppers/bell peppers, kales, escaroles, herbs and edible flowers, beans with pods, oat and chicory roots. Since the data gaps identified in the MRL review were not addressed, risk managers might consider lowering the tentative MRLs in passion fruits/maracujas and leafy brassica other than kales to the limit of quantification (LOQ), and the implementation of the Codex MRL (CXL) in the EU legislation for cucumbers and gherkins. The new intended use on witloof/Belgian endives was not adequately supported by residue data and therefore an MRL proposal cannot be derived. Adequate analytical methods for enforcement are available to control the residues of trifloxystrobin on the commodities under consideration. Based on the results of the risk assessment performed, considering the exposure to residues of trifloxystrobin and its metabolites CGA 321113 (apart for passion fruits), EFSA concluded that the short-term and long-term intake of residues resulting from the uses of trifloxystrobin under consideration is unlikely to present a risk to consumer health, except for escaroles. For the intended indoor use on escaroles, a risk from short-term intake cannot be excluded, hence a modification of the existing EU MRL is not proposed for this commodity. The consumer risk assessment shall be regarded as indicative and affected by uncertainties.

Keywords: trifloxystrobin, various crops, fungicide, MRL, consumer risk assessment, MRL review confirmatory data

Requestor: European Commission

Question numbers: EFSA-Q-2020-00037; EFSA-Q-2020-00036; EFSA-Q-2020-00038

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Declaration of interest: The declarations of interest of all scientific experts active in EFSA's work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch.

Acknowledgement: EFSA wishes to thank: Stathis Anagnos, Laszlo Bura, Aija Kazocina, Andrea Mioč, Marta Szot, Aikaterini Vlachou for the support provided to this scientific output.

Suggested citation: 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, 2022. 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, 48 pp. https://doi.org/10.2903/j.efsa.2022.7048

ISSN: 1831-4732

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 CropScience submitted two applications to the competent national authorities appointed in the United Kingdom and Greece to modify the existing maximum residue levels (MRLs) for the active substance trifloxystrobin in various crops and in sweet peppers/bell peppers, respectively. In the framework of the application submitted to the United Kingdom, the applicant also requested to evaluate the confirmatory data identified in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005. The competent national authorities drafted two evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which were submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 13 January 2020. In the framework of the assessment process, the applications were re-allocated to the Netherlands as new evaluating Member State (EMS).

In the context of the MRL review under Article 12 in 2014, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified. The following data gaps were noted:

1) An analytical method fully validated and its independent laboratory validation (ILV) for the determination of trifloxystrobin and its metabolite CGA 321113 in animal commodities;
2) Four residue trials on raspberry complying with the northern Good Agricultural Practice (GAP) on blackberry and raspberry;
3) Six residue trials on currants complying with the northern GAP on currants and gooseberries and including results in accordance with the residue definition for risk assessment;
4) Four residue trials complying with the import tolerance on passion fruits;
5) Eight trials complying with the southern GAP and three additional trials complying with the indoor GAP on pepper;
6) Eight residue trials on cucumbers complying with the northern GAP on cucurbits with edible peel and eight residue trials complying with the indoor GAP on cucumber;
7) Two additional trials on kale complying with the northern GAP on leafy brassica, including residue data in accordance with the residue definition for risk assessment;
8) Four trials on lettuce (open leaves variety) complying with the indoor GAP and four trials on lettuce (open leaves variety) complying with the northern GAP on escarole and herbs;
9) Four residue trials complying with the northern GAP on witloof;
10) Eight trials complying with the indoor GAP and six additional trials complying with the northern GAP on beans (fresh, with pods) (including residue data in accordance with the residue definition for risk assessment);
11) Eight residue trials complying with the indoor GAP on peas (fresh, with pods);
12) Eight residue trials complying with the southern GAP on olives for oil production;
13) Eight residue trials complying with the northern GAP on oats;
14) Four residue trials complying with the northern GAP on chicory roots.

Tentative MRL proposals have been implemented in the MRL legislation by Commission Regulation (EU) No 2015/1200, including footnotes related to data gaps number 1, 3, 4, 5, 6, 7, 8, 10, 13, indicating the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRL by 23 July 2017. Data gaps number 2, 9, 11, 12, 14 were not implemented in the MRL regulation, either because an MRL of 3 mg/kg fully supported by data was assessed by EFSA in a further opinion concerning an MRL application on cane fruits (blackberry and raspberry) or because risk managers decided to set the MRL at the specific limit of quantification (LOQ) without requesting additional residue trials (witloof, peas with pods, olives for oil production and chicory roots). The footnotes related to data gap number 1 and 3 were deleted later by Commission Regulation (EU) No 2018/832, since the missing information on analytical methods for products of animal origin and data on currants covering not only gooseberries but the whole group of small fruits and berries were provided in the framework of an MRL application. On that occasion the footnote related to data gap number 8 was cancelled for escaroles because the results from an adjusted indoor GAP were considered instead.

The Netherlands proposed to confirm the tentative MRL of 0.4 mg/kg in oat and to modify the MRLs in sweet peppers/bell peppers, kales, herbs and edible flowers, beans with pods and chicory roots; the EMS recommended risk management decision to lowering the MRL to the LOQ in passion fruits/maracujas and leafy brassica different than kales, and proposed to implement the Codex MRL

(CXL) for cucumbers and gherkins. For escaroles/broad-leaved endives and witloofs/Belgian endives, a change of the existing MRL was not proposed.

EFSA assessed the applications and the evaluation reports as required by Articles 9 and 10 of the MRL regulation and in accordance with the agreed procedure set out in the working document SANTE/10235/2016 for the MRL confirmatory data. For reasons of efficiency, the applications were assessed in one EFSA output.

EFSA identified data requirements which were requested from the EMSs. On 5 July 2021, the EMS the Netherlands, which took over the responsibility of these applications, submitted two revised evaluation reports, which replaced the previously submitted evaluation reports.

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 these applications, the following conclusions are derived.

The metabolism of trifloxystrobin following foliar applications was investigated in crops belonging to the group of fruit crops, root crops, cereals and pulses/oilseeds, indicating that trifloxystrobin is the relevant residue in primary crops; metabolite CGA 321113 was present but at low concentrations. Studies investigating the effect of processing on the nature of trifloxystrobin (hydrolysis studies) demonstrated that the active substance is likely to degrade to CGA 321113 only under sterilisation conditions. In rotational crops, the major residue identified was the metabolite trifluoroacetic acid (TFA).

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of relevant metabolites, the MRL review proposed a general residue definition for enforcement in plant products as parent 'trifloxystrobin'; the risk assessment residue definition was set as the 'sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin'. It is noted that in the framework of the assessment on the renewal of the approval of the active substance, the residue definition for risk assessment was proposed to be enlarged to the 'sum of trifloxystrobin, its three structural isomers (CGA 357262, CGA 357261, CGA 331409) and its metabolite CGA 321113 (M5), expressed as trifloxystrobin'. However, the European Commission clarified that the applications were submitted prior to the renewal decision and that the new data requirements brought by the renewal decision could not be considered applicable, as the applicant could not anticipate the outcomes of the risk management decision when submitting the data.

EFSA concluded that the metabolism of trifloxystrobin in primary and in rotational crops and its possible degradation in processed products have been sufficiently addressed. For the crops assessed in present applications the residue definition for risk assessment derived in the framework of the MRL review is to be applied.

Sufficiently validated analytical methods are available to quantify residues in the crops under assessment according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg (LOQ).

The data submitted in support of the requests were found to be sufficient to derive MRL proposals for sweet peppers/bell peppers, kales, escaroles, herbs and edible flowers, beans with pods, oat and chicory roots. Since the data gaps identified in the MRL review were not addressed, risk managers may consider lowering the tentative MRLs in passion fruits/maracujas and leafy brassica other than kales to the LOQ, and the implementation of the CXL in the EU legislation for cucumbers and gherkins. The new intended use on witloof/Belgian endives was not adequately supported by residue data and therefore an MRL proposal cannot be derived.

Specific studies investigating the magnitude of trifloxystrobin residues in processed commodities are not required as the individual theoretical maximum daily intake (TMDI) for the crops under assessment is below the trigger value of 10% of the acceptable daily intake (ADI). Processing studies on tomato juice, paste, puree, preserve and dried fruit were provided in the MRL application on sweet peppers.

Based on the available information on the nature and magnitude of residues in rotational crops, it is concluded that significant residue levels are unlikely to occur in rotational crops, provided that the active substance is used according to the proposed GAPs.

As oat and kale products are used as feed items, the potential carry-over of trifloxystrobin residues into food of animal origin was assessed. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all relevant animal species but remained comparable to previous calculations. Therefore, a modification of the existing MRLs for commodities of animal origin is not proposed.

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 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 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 plants. Lacking further information on their toxicity and magnitude in all crops, the results of the present risk assessment should be regarded as indicative and affected by uncertainty.

In the framework of the MRL review, the metabolite CGA 321113 was assumed to be of the same toxicity as parent trifloxystrobin and the same approach was taken for the present assessment.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). No long-term consumer intake concerns were identified for any of the diets included in the EFSA PRIMo as the estimated maximum long-term dietary intake accounted for 12% of the ADI (NL toddler diet). The individual contribution of residues in the crops under assessment was below 1.2% of the ADI. The short-term exposure did not exceed the ARfD for the crops under consideration, except for escaroles (145% of the ARfD).

Based on the results of the risk assessment performed considering the exposure to residues of trifloxystrobin and its metabolites CGA 321113 (apart for passion fruits; where exposure to the active substance only was considered) and assuming the toxicity of the metabolite is covered by the toxicological profile of the parent, EFSA concluded that the short-term and long-term intake of residues resulting from the uses under assessment and the existing uses of trifloxystrobin is unlikely to present a risk to consumer health, except for escaroles. For this commodity, a potential acute consumer health risk could not be excluded for the intended indoor use and therefore the existing MRL should not be revised. The consumer risk assessment shall be regarded as indicative since affected by uncertainties due to the data gaps identified in the framework of the EU pesticides peer review renewal of the active substance.

EFSA proposes to amend the existing MRLs 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 MRL[(b)]	Proposed MRL	Conclusion/recommendation
Enforcement residue definition: Trifloxystrobin				
0162030	Passion fruits/ maracujas	4 (ft 1)	Further risk management considerations required	The data gap identified in the MRL review has not been addressed. The tentative MRL of 4 mg/kg based on underdosed residue trials analysed for trifloxystrobin only is not confirmed. Risk managers may consider lowering of the existing MRL to the LOQ of 0.01 mg/kg. Lacking information on the occurrence of the metabolite CGA 321113, an indicative consumer risk assessment was conducted considering exposure to the active substance only. Based on the available information, risk for consumer unlikely
0231020	Sweet peppers/ bell peppers	0.4 (ft 1)	0.9	The data gaps identified in the MRL review have not been addressed. The tentative MRL of 0.4 mg/kg is not confirmed. However, the new intended SEU use is sufficiently supported by residue data requiring a higher MRL proposal of 0.9 mg/kg. Risk for consumer unlikely
0232010	Cucumbers	0.3 (ft 1)	Further risk management considerations	The data gap identified in the MRL review has not been addressed. The EMS proposed to retain the same MRL of 0.3 mg/kg reflecting the level of the Codex MRL (CXL), which was set by the JMPR 2006 for cucurbits from merged residue data on cucumbers, courgettes (edible peel) and melons (inedible peel).
0232020	Gherkins	0.3 (ft 1)	Further risk management considerations	

Code[(a)]	Commodity	Existing MRL[(b)]	Proposed MRL	Conclusion/recommendation
				It is noted that the extrapolation applied to derive the CXL value is not fully in line with the EU requirements, although based on the same data set, the existing MRL (CXL) of 0.3 mg/kg is set for cucurbits with inedible peel and for courgettes in the EU legislation. Therefore, the risk manager decision is required. Risk for the consumer unlikely
0243020	Kales	3 (ft1)	2	The data gap identified in the MRL review has not been addressed. The tentative MRL of 3 mg/kg is not confirmed. However, an adjusted NEU use, authorised in the Netherlands, is fully supported by residue data, resulting in a lower MRL proposal. Risk for consumer unlikely
0243010	Chinese cabbages/pe-tsai	3 (ft1)	Further risk management considerations required	The data gap identified in the MRL review has not been addressed. The tentative MRL of 3 mg/kg is not confirmed. Risk managers may consider lowering of the existing MRL to the LOQ of 0.01 mg/kg
0243990	Others leafy brassica	3 (ft1)	Further risk management considerations required	
0251030	Escaroles/broad-leaved endives	15	No change	The submitted residue data are sufficient to support the intended indoor use and to derive by extrapolation an MRL proposal of 30 mg/kg. However, for this use, an acute consumer health risk cannot be excluded (145% of the ARfD). Thus, a modification of the existing EU MRL is not proposed
0256000	Herbs and edible flowers	15 (ft 1)	30	The data gap identified in the MRL review has been addressed and the new residue data submitted lead to a higher MRL proposal. Risk for consumer unlikely
0260010	Beans (with pods)	1 (ft 1)	0.8	The data gap identified in the MRL review has been addressed and the additional residue data lead to a lower MRL proposal. Risk for consumer unlikely
0500050	Oat	0.4 (ft 1)	0.3	The data gap identified in the MRL review has been addressed and the additional residue data lead to a lower MRL proposal. Risk for consumer unlikely
0255000	Witloofs/Belgian endives	0.01*	No change	The intended NEU use is not adequately supported by GAP-complaint residue trials. Therefore, a change of the existing MRL is not proposed
0900030	Chicory roots	0.01*	0.02*	The submitted data are sufficient to derive an MRL proposal for the intended NEU use. Risk for consumer unlikely

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice; LOQ: limit of quantification; ARfD: acute reference dose.

ft 1: The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 23 July 2017, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gaps No 4, 5, 6, 7, 8, 10, 13).

*Indicates that the MRL is proposed at the limit of quantification.

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

(b): Existing EU MRL set on a tentative basis with corresponding footnote on confirmatory data.

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Assessment

The European Food Safety Authority (EFSA) received two applications to modify the existing maximum residue levels (MRLs) for trifloxystrobin in various crops and sweet peppers/bell peppers, respectively. One of the two application also included information to evaluate the confirmatory data identified in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 as not available. The detailed description of the intended uses of trifloxystrobin and the uses assessed in the framework of the MRL review that were not fully supported by data and for which confirmatory data were requested is listed in Appendix A.

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 structure 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 (2017). The approval of trifloxystrobin for the use as fungicide was renewed[2] on 1 August 2018.

The EU MRLs for trifloxystrobin are established in Annex 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 (EFSA, 2014a). Under the MRL 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. Following the review of existing MRLs, the legal limits have been modified by Commission Regulation (EU) No 2015/1200[4], including footnotes for tentative MRLs that specified the type of information that was identified as missing. Any party having an interest in maintaining the proposed tentative MRL was requested to address the confirmatory data by 23 July 2017.

After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for trifloxystrobin. The proposals from these reasoned opinions have been also considered in recent MRL regulations.[5] In addition, certain Codex maximum residue limits (CXLs) have been taken over in the EU MRL legislation.[5]

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer CropScience submitted two applications to the competent national authorities, appointed in the United Kingdom (original RMS) and Greece (evaluating Member State, EMS), to modify the existing MRLs for the active substance trifloxystrobin in various crops and in sweet peppers/bell peppers, respectively. The application submitted to the United Kingdom, also included information to evaluate the confirmatory data identified in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005. The RMS and the EMS drafted two evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which were submitted to the European Commission and forwarded to the EFSA on 13 January 2020. It is noted that after the withdrawal of the United Kingdom from the European Union on 1 February 2020, the UK applications was reallocated to the Netherlands as new RMS. Subsequently, also the other application (EL-EMS) was re-allocated from Greece to the Netherlands during the risk assessment phase.

EFSA assessed the applications and evaluation reports as required by Articles 9 and 10 of the MRL regulation and in accordance with the agreed procedure set out in the working document SANTE/10235/2016 (European Commission, 2020). EFSA identified data requirements which were requested from the EMSs. On 5 July 2021, the EMS the Netherlands submitted two revised evaluation reports which replaced the previously submitted evaluation reports.

[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] Commission Regulation (EU) 2015/1200 of 22 July 2015 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 amidosulfuron, fenhexamid, kresoxim-methyl, thiacloprid and trifloxystrobin in or on certain products. OJ L 195, 23.7.2015, p. 1–36.

[5] 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

EFSA based its assessment on the evaluation report submitted by the EMS the Netherlands (Netherlands, 2021a,b) the renewal assessment report (RAR) and its revision (United Kingdom, 2016, 2017) prepared under Regulation (EC) No 1107/2009, the conclusion on the peer review of the pesticide risk assessment of the active substance trifloxystrobin (EFSA, 2017), the Commission review report on trifloxystrobin (European Commission, 2018) as well as the conclusions from previous EFSA opinions and scientific reports on trifloxystrobin, including the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2014a,b, 2016a,b, 2018c,d, 2019b).

For these applications, the data requirements established in Regulation (EU) No 544/2011[6] and the guidance documents applicable at the date of submission of the application to the (former) RMS and the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013). 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[7].

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

The evaluation reports submitted by the EMS (Netherlands, 2021a,b) 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.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of trifloxystrobin after foliar applications in primary crops belonging to the group of fruit crops, root crops, cereals/grass and pulses/oilseeds has been investigated in the framework of the MRL review and the EU pesticides peer review renewal (EFSA, 2014a, 2017). In the crops tested, the metabolism was found to be similar with trifloxystrobin (*E,E*-isomer) representing the major component of the total radioactive residues (TRRs). The other three structural isomers of trifloxystrobin, namely CGA 357262 (*Z,Z*-isomer), CGA 357261 (*E,Z*-isomer), CGA 331409 (*Z,E*-isomer) were not found at levels higher than 10% of the TRR. Metabolite CGA 321113 was found accounting for < 10% of the TRR, but in individual low absolute amounts: up to 0.05 mg/kg (apples and cucumbers) and below 0.1 mg/kg (peanut hay and wheat straw).

For the intended uses assessed in these applications, no further information is required.

1.1.2. Nature of residues in rotational crops

The crops under consideration in the MRL applications may be grown in rotation. Unlike trifloxystrobin (DT_{90} is < 100 days), its metabolite CGA 321113 is moderate to very high persistent in soil (DT_{90} is more than 500 days) and the major soil metabolite CGA 373466 is moderately persistent in soil (DT_{90} up to 290 days) (EFSA, 2017). Therefore, the residues in rotational crops were further investigated in the framework of the MRL review and the EU pesticides peer review renewal (EFSA, 2014a, 2017).

In the rotational crop metabolism studies, trifloxystrobin and its isomers accounted for a maximum of 15% of TRR. Trifluoroacetic acid (TFA) was the main metabolite, representing 12%, 23% and 13% of the TRR in radish root, top and wheat straw, respectively (EFSA, 2014a, 2017). Due to the low level of the TRR in rotational crops, EFSA did not considered necessary to include TFA in the risk assessment residue definition (EFSA, 2017). 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).

For the intended uses assessed in these applications, no further information is required.

[6] Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

[7] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

1.1.3. Nature of residues in processed commodities

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).

For the intended uses assessed in these applications, no further information is required.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of trifloxystrobin residues in plants were assessed in the framework of the MRL review and the EU pesticides peer review renewal (EFSA, 2014a, 2017). The QuEChERS multiresidue method using high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) is validated for the determination of residues of trifloxystrobin in all four plant commodity groups (high water, high acid, high oil and dry content matrices). The method allows quantifying residues at or above the limit of quantification (LOQ) of 0.01 mg/kg in the crops under consideration in these applications.

1.1.5. Storage stability of residues in plants

The storage stability of trifloxystrobin and CGA 321113 in plants under frozen conditions was investigated in the framework of the MRL review with additional data assessed during the EU pesticides peer review (EFSA, 2014a, 2017). Overall, residues of trifloxystrobin and CGA 321113 were stable for at least 24 months in high water, high acid, high oil, high protein/high starch content commodities, when stored at −18°C. In processed potato granules/flakes and grape juice residues were stable up to 18.5 months. Since significant variations in the concentrations of CGA 321113 in apple fruit, apple wet pomace, peanut nutmeat and peanut hay over various timepoints were observed in the storage stability studies, the EU pesticides peer review could not conclude on the stability of this metabolite in these specific commodities (EFSA, 2017). However, none of the crops under consideration in the present assessment belongs to the group of pome fruits or oilseeds, therefore the data gap is not applicable.

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 and the capabilities of enforcement analytical methods, the following general residue definitions were proposed in the framework of the MRL review (EFSA, 2014a):

- residue definition for enforcement: Trifloxystrobin
- residue definition for risk assessment: sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin.

The same residue definition 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.

In the framework of the renewal of the approval of trifloxystrobin (EFSA, 2017), based on the metabolism studies, supported by findings in field trials on pome fruits, grapes and strawberries where the three trifloxystrobin isomers were found in quantifiable concentrations, the EU pesticides peer review proposed to revise the residue definitions for risk assessment for plant commodities as follows:

- 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

Upon the request of the applicant, the European Commission clarified that the residue definition for risk assessment as proposed by the EU pesticides peer review and related data requirements[8] do not apply to the present MRL applications (Netherlands, 2021a,b) which were submitted before the conclusion on the renewal of approval, hence the applicant could not anticipate the outcomes of the risk management decision.

EFSA therefore considered in this opinion the residue definition for risk assessment as set in the framework of the MRL review (EFSA, 2014a).

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To address the data gaps identified by EFSA in the framework of the MRL review, the applicant provided new residue trials on sweet peppers and kales to support an adjusted SEU and NEU use, respectively, on open leaf lettuces for extrapolation purposes to herbs and edible flowers, on beans and peas with pods and on oat (SEU use), whereas no new information was submitted to confirm the tentative MRLs derived in the framework of the MRL review for passion fruits, sweet peppers, cucumbers, gherkins, leafy brassica and oat (NEU use). Additionally, residue trials were submitted which support new intended uses on sweet peppers, escaroles and chicory roots, whereas the data submitted do not supported the intended use on witloof/Belgian endive and the intended NEU use on oat. The results are presented in the Table B.1.2.1 of the Appendix B.

The samples from the new residue trials were analysed for the parent compound and the metabolite CGA 321113, which is included in the plant residue definitions for risk assessment proposed in the MRL review (EFSA, 2014a). Prior to be summed up for risk assessment purpose, the individual residue values of CGA 321113 above the LOQ of 0.01 mg/kg were recalculated to express them as trifloxystrobin using a conversion factor of 1.036 based on molecular weights.[9]

The new residue data submitted on trifloxystrobin and CGA 321113 residues are valid with regard to storage stability. According to the assessment of the EMS, the analytical methods used in the residue trials were sufficiently validated and fit for purpose (Netherlands, 2021a,b).

Passion fruits/maracujas

The applicant did not provide any new residue data to address the data gap number 4[10] identified during the MRL review and implemented as footnote in the MRL Regulation.

In addition to the lack of Good Agricultural Practice (GAP)-compliant residue trials analysed according to the residue definition for risk assessment, the applicant could not confirm that an authorisation is actually granted in the exporting country (Kenya) for the less critical GAP based on which the tentative MRL of 4 mg/kg was derived.

EFSA concludes that the tentative MRL cannot be confirmed and the risk managers can consider lowering the tentative MRL to the enforcement LOQ of 0.01 mg/kg.

Sweet peppers/bell peppers

The applicant did not provide any new residue data to address the data gap number 5[11] identified during the MRL review and implemented as footnote in the MRL Regulation.

Instead, the applicant submitted residue trials performed according to an adjusted, less critical SEU use (Netherlands, 2021a) which would support a lower MRL proposal of 0.15 mg/kg.

Additionally, the applicant applied for new, intended SEU and indoor uses and provided new sets of residue data (Netherlands, 2021a,b). The intended indoor use was sufficiently supported by eight GAP-compliant residue trials; an MRL proposal of 0.5 mg/kg was derived. All eight trials submitted to support the intended SEU use were compliant to the intended GAP in terms of number of applications and preharvest interval (PHI) but were conducted at a higher application rate of 200 g/ha instead of

[8] A data gap was identified to assess the toxicological profile of the three isomers (CGA 357261, CGA 357262, CGA 331409) and the metabolite CGA 321113 and their exposure, and, pending information on the toxicological profile of CGA 321113, feeding studies on ruminants including measurement of the conjugated residues of CGA 321113 (EFSA, 2017).

[9] Conversion factor obtained based on molecular weight (MW) ratio (trifloxystrobin: CGA 321113) (408.38:394.34 g/mol).

[10] Data gap number 4: Four residue trials complying with the import tolerance on passion fruit.

[11] Data gap number 5: Eight trials complying with the southern GAP and three additional trials complying with the indoor GAP on pepper.

150 g/ha. The residue levels were therefore proportionally scaled down to estimate the MRL proposal of 0.9 mg/kg (EFSA, 2018a).

EFSA concludes that sufficient residue data are available to propose an MRL of 0.9 mg/kg on sweet peepers/bell peppers in support of the new intended SEU use of trifloxystrobin, which showed to be more critical for residues.

Cucumbers, gherkins

The applicant did not provide any new residue data to address the data gap number 6[12] identified during the MRL review and implemented as footnote in the MRL Regulation. Thus, the tentative MRL cannot be confirmed.

Instead, the EMS proposed to consider the CXL of 0.3 mg/kg since the enforcement residue definitions set by the JMPR and the EU are comparable (Netherlands, 2021a). The CXL was derived from a combined set of residue data on cucumbers (16 trials), courgettes (5 trials) and melons (13 trials) supporting various indoor/outdoor GAPs in Europe and US (FAO, 2004). Although a sufficient number of trials on cucumbers and courgettes is available to extrapolate results to cucurbits with edible peel, EFSA notes that the use of indoor/outdoor data and the inclusion of residue data in melons (cucurbits with inedible peel) is not in line with the EU extrapolation guidance (European Commission, 2017).

Leafy brassica (kales, Chinese cabbages, others leafy brassica)

The applicant did not provide the requested two additional trials on kales compliant with the NEU GAP and additional results on CGA 321113 to address the data gap number 7[13] identified during the MRL review and implemented as footnote in the MRL Regulation.

Instead, the applicant submitted four GAP-compliant residue trials on kales for an adjusted NEU GAP (authorised in the Netherlands); the residue trials data lead to a lower MRL proposal of 2 mg/kg for kales.

As noted by the RMS, the data set of four trials does not support the extrapolation to the whole group of leafy brassica (Netherlands, 2021a). According to the extrapolation guidance, at least six trials are required to extrapolate results to a group with only minor crops (European Commission, 2017). Anyhow, the NEU use was reported to be authorised in kales and not on the other members of the leafy brassica group (Chinese cabbages/pe-tsai and others leafy brassica).

EFSA propose to lower the tentative MRL in kales to 2 mg/kg based on an adjusted NEU GAP. For the others leafy brassica, the tentative MRL of 3 mg/kg is not confirmed and risk managers might consider lowering it to the enforcement LOQ of 0.01 mg/kg.

Escaroles/broad-leaved endives, Herbs and edible flowers

Herbs and edible flowers: The applicant addressed the data gap number 8[14] by submitting completely new sets of residue trials on open leaf lettuces compliant with the authorised indoor and NEU uses on herbs and edible flowers.

Escaroles/broad leaved endives: The same residue data were proposed to be used in support of the new intended indoor and NEU uses of trifloxystrobin on escaroles.

The applicant proposed to extrapolate these newly submitted residue data on open-leaf lettuces to herbs and edible flowers group and to escarole/broad leaved endives; such an extrapolation is acceptable (European Commission, 2017). The results from the residue trials on lettuces assessed during the MRL review were disregarded and not combined with the results from these newly submitted trails since the applicant failed to provide confirmation they were performed on open leaf lettuces and thus, appropriate for extrapolation purpose.

For the NEU use, the new set of data leads to an MRL of 7 mg/kg.

For the indoor use, the new set of residue trials lead to an MRL of 30 mg/kg, which is higher than the tentative MRL set in the MRL review for herbs and edible flowers and the existing MRL for escaroles.

[12] Data gap number 6: Eight residue trials on cucumbers complying with the northern GAP on cucurbits with edible peel and eight residue trials complying with the indoor GAP on cucumber.

[13] Data gap number 7: Two additional trials on kale complying with the northern GAP on leafy brassica, including residue data in accordance with the residue definition for risk assessment.

[14] Data gap number 8: Four trials on lettuce (open leaves variety) complying with the indoor GAP and four trials on lettuce (open leaves variety) complying with the northern GAP on (scarole) and herbs.

It shall be noted that in the indoor data set, the highest residue value of 18 mg/kg was statistically detected as potential outlier (Dixon's Q test). The EMS reported that, although the size of the plant in this trial was smaller in comparison to other trials, it was still of commercial size, and that the active substance was applied to a fully developed crop (Netherlands, 2021a). Since no information or experimental evidence suggested that this value is likely unreliable, it was included in the calculation.

The data submitted are sufficient to derive by extrapolation an MRL proposal of 30 mg/kg for escaroles and herbs and edible flowers based on the more critical indoor use.

Witloofs/Belgian endives

The intended NEU use on witloof/Belgium endives is not supported by GAP-compliant residue trials (Netherlands, 2021a) and was not further discussed in the present reasoned opinion. No modification of the existing MRL set at the LOQ of 0.01 mg/kg is proposed.

Beans with pods

To address the data gap number 10[15] identified during the MRL review and implemented as footnote in the MRL Regulation, the applicant provided the results in accordance with the residue definition for risk assessment for the indoor residue trials on beans with pods compliant with the authorised indoor use assessed in the MRL review. The updated information allows to confirm the tentative MRL of 0.6 mg/kg.

Regarding the authorised NEU use assessed in the MRL review, based on which the tentative MRL of 1 mg/kg was set in the legislation, the applicant provided new residue trials on beans (7) and peas (10) with pods analysed according to the residue definition for enforcement and risk assessment. Extrapolation of residue data from peas with pods to beans with pods is possible (European Commission, 2017). Since in three trials on peas with pods the last application was performed at a BBCH growing stage (BBCH 79/80) largely deviating from the authorised GAP, results from these trials were excluded from the calculation.

EFSA concludes that the combined data set of new (14) and previously assessed residue trials (8) is sufficient to derive a lower MRL of 0.8 mg/kg based on the more critical NEU use, which is lower than the tentative MRL set in the MRL review.

Oat

The applicant did not provide new residue data to address the data gap number 13[16] identified during the MRL review and implemented as footnote in the MRL Regulation. Therefore, the authorised NEU GAP on oat assessed in the MRL review is not supported by any data.

However, for the authorised SEU use on oat assessed in the MRL review based on which the tentative MRL of 0.4 mg/kg was set in the legislation, additional residue trials on barley were provided for the present assessment, which, together with the results available from the MRL review, were assessed for independency and full compliance with the authorised SEU GAP on oat (Netherlands, 2021a). Overall, nine residue trials were selected and are sufficient to derive by extrapolation an MRL proposal of 0.3 mg/kg, which is lower than the tentative MRL set in the MRL review.

Samples were analysed also for residues in straw and input values derived for the update of the livestock dietary burden calculations.

Chicory roots

In order to support the intended NEU use of trifloxystrobin, the applicant provided four GAP compliant residue trials on sugar beets, which are sufficient to derive by extrapolation an MRL proposal of 0.02* mg/kg for the intended use on chicory roots in the NEU.

1.2.2. Magnitude of residues in rotational crops

The crops under consideration for which new intended uses were reported, can be grown in rotation with other crops. The possible transfer of trifloxystrobin residues to crops that are grown in crop rotation has been assessed in the MRL review and the EU pesticides peer review (EFSA, 2014a, 2017). The available studies demonstrated that trifloxystrobin and CGA 321113 residues were not

[15] Data gap number 10: Eight trials complying with the indoor GAP and six additional trials complying with the northern GAP on beans (fresh, with pods) (including residue data in accordance with the residue definition for risk assessment).
[16] Data gap number 13: Eight residue trials complying with the northern GAP on oat.

found (< LOQ 0.02 mg/kg) in succeeding crops (lettuce, turnip and wheat) planted in soil treated with 1128 g/ha of trifloxystrobin.

Since the maximum application rate for the crops under consideration (i.e. 3 × 200 g/ha) is lower than the application rate tested in the rotational crop studies, it is concluded that no residues are expected in rotational crops, provided that the active substance is applied according to the intended GAPs.

1.2.3. Magnitude of residues in processed commodities

Specific processing studies for the crops under assessment were not submitted with the MRL applications and are not required. The individual total theoretical maximum daily intake (TMDI) is expected below the trigger value of 10% of the acceptable daily intake (ADI) (European Commission, 1997d).

Processing studies with cooked broccoli, spinaches and celery stalk were assessed in a previous EFSA opinion (EFSA, 2019b). In the framework of the present MRL application on peppers, the results of 2 processing studies with tomato juice, preserve, paste, puree and dried fruit were provided for possible extrapolation to other vegetables (Netherlands, 2021b). The samples of unprocessed and processed products were analysed for trifloxystrobin and CGA 321113. Except for dried tomatoes, a reduction of residues was observed. Processing factors for enforcement (PF) and conversion factors for risk assessment (CF) were derived and are reported in Appendix B.1.

1.2.4. Proposed MRLs

The data submitted are sufficient to derive MRL proposals as well as risk assessment values for the commodities under evaluation for either the authorised, adjusted or new uses under assessment, except for passion fruits/maracujas, leafy brassica other than kales and witloof/Belgium endives.

No data were submitted to confirm the tentative MRL in cucumbers and gherkins derived based on the authorised use assessed in the MRL review; for these crops the CXL value (at the same level as the tentative MRL) could be considered by risk managers for implementation in the EU legislation. It is noted that the extrapolation applied to derive the CXL value of 0.3 mg/kg is not fully in line with the EU requirements but for courgettes and for the group of cucurbits with inedible peel this CXL was already included in Regulation (EC) No 396/2005 as MRL.

In Section 3, EFSA assessed whether residues on the crops resulting from either the intended uses (MRL applications) or the authorised/adjusted uses (MRL confirmatory data) supported by data are likely to pose a consumer health risk.

2. Residues in livestock

Oat grain and straw and kale leaves are used as feed items. Hence, EFSA updated the most recent dietary burden calculations for livestock performed in the framework of a previous MRL application (EFSA, 2018c). The input values for the exposure calculations for livestock are presented in Appendix D.1 and the results of the dietary burden calculation are presented in Appendix B.2.

Although exposure for all livestock species exceeded the trigger values of 0.1 mg/kg dry matter (DM) set under Regulation (EU) No 544/2011, the median and maximum animal burden remained of comparable range for sheep and poultry, or they were even slightly lower for cattle and swine compared to the previous calculations.

Since the updated livestock dietary burden has not been significantly changed, EFSA is not proposing a modification the existing EU MRLs in products of animal origin.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018b, 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 in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference values for trifloxystrobin used in the risk assessment (i.e. ADI and acute reference dose (ARfD) values) were agreed during the EU pesticides peer review renewal of the active substance where an ARfD was set (European Commission, 2018). EFSA performed the consumer risk assessment under the assumption of the MRL review that the toxicity of the metabolite CGA 321113 is considered covered by the toxicological profile of parent trifloxystrobin (EFSA, 2014a).

It is noted that the EU pesticides peer review for the renewal of the approval identified data gaps as regards toxicological studies to conclude on the 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 plants (EFSA, 2017). Lacking further information on their toxicity and magnitude in all crops, the results of the present risk assessment should be regarded as indicative and affected by uncertainty.

Although the existing tentative MRL for passion fruit/maracujas could not be confirmed and information on the occurrence of the metabolite CGA 321113 is not available, EFSA included this crop in the indicative consumer risk assessment, considering exposure to the active substance only.

Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed for the commodities assessed in these applications using the highest residue (HR) derived from the residue trials except for oat, where the supervised trials median residue (STMR) was used. The complete list of input values can be found in Appendix D.2.

With the exception of escaroles, the short-term exposure did not exceed the ARfD for the crops under assessment. EFSA confirmed the exceedance of the ARfD identified by the EMS for escaroles, accounting for 145% of the ARfD[17] (Netherlands, 2021a). Escaroles are also consumed cooked and a potential exceedance was also observed for boiled escaroles (240% of the ADI) but specific processing factor and conversion factor for risk assessment are not available to refine the exposure calculation.

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 EU level and the acceptable CXLs (EFSA, 2014a). EFSA updated the calculation with the relevant STMR values derived from the residue trials submitted in support of the present MRL applications and, in addition, with the STMRs derived in EFSA opinions issued after the MRL review (EFSA, 2014b, 2016a, 2018c, 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, 2015, 2017; EFSA, 2016b, 2018d). The complete list of input values can be found in Appendix D.2. The crops on which no uses have been reported in the MRL review or in subsequent EFSA assessments, were not considered in the consumer exposure calculations.

The estimated long-term dietary intake accounted for a maximum of 12% of the ADI (NL toddler diet). The contribution of residues expected in the individual commodities assessed in this opinion to the overall long-term exposure is presented in more detail in Appendix B.3.

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.

Overall conclusion on risk assessment

Based on the results of the risk assessment performed considering the exposure to residues of trifloxystrobin and its metabolites CGA 321113 (apart for passion fruits) and assuming the toxicity of the metabolite is covered by the toxicological profile of the parent, EFSA concluded that the short term and long-term intake of residues resulting from the uses under assessment and the existing uses of trifloxystrobin is unlikely to present a risk to consumer health, except for escaroles. The consumer risk assessment shall however be regarded as indicative since affected by uncertainties due to the data gaps identified in the framework of the EU pesticides peer review renewal of the active substance (EFSA, 2017).

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

4. Conclusion and Recommendations

The data submitted in support of the requests were found to be sufficient to derive MRL proposals for sweet peppers/bell peppers, kales, escaroles, herbs and edible flowers, beans with pods, oat and

[17] The EMS reported that for this reason the applicant subsequently removed the request for an increase of the MRL on escaroles. The Netherlands is also recommending all EU member states that authorisations of trifloxystrobin on protected escaroles in line with the cGAP considered in the MRL review (3 × 200 g/ha, PHI 7 days) are withdrawn (Netherlands, 2021a).

chicory roots. Since the data gaps identified in the MRL review were not addressed, risk managers might consider lowering the tentative MRLs in passion fruits/maracujas and leafy brassica other than kales to the LOQ, and the implementation of the CXL in the EU legislation for cucumbers and gherkins. The new intended use on witloof/Belgian endives was not adequately supported by residue data and therefore an MRL proposal cannot be derived.

Based on the results of the risk assessment performed considering the consumer exposure to residues of trifloxystrobin and its metabolites CGA 321113 (apart for passion fruits) and assuming the toxicity of the metabolite is covered by the toxicological profile of the parent, EFSA concluded that the short-term and long-term intake of residues resulting from the uses under assessment and the existing uses of trifloxystrobin is unlikely to present a risk to consumer health, except for escaroles. For this commodity, a potential acute consumer health risk could not be excluded for the intended indoor use and therefore the existing MRL should not be revised. The consumer risk assessment shall be regarded as indicative since affected by uncertainties due to the data gaps identified in the framework of the EU pesticides peer review renewal of the active substance.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CCPR	Codex Committee on Pesticide Residues
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
CF	conversion factor for enforcement to risk assessment residue definition
cGAP	critical GAP
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DT_{90}	period required for 90% dissipation (define method of estimation)
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
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MW	molecular weight
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
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
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WG	water-dispersible granule
WHO	World Health Organization

Appendix A – Summary of GAPs assessed in the evaluation of confirmatory data and intended GAP triggering the amendment of existing MRL

Crop and/or situation	NEU, SEU, MS or country	F G or I (a)	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)(d)	Remarks
				Type(b)	Conc. a.s. (g/kg)	Method kind	Range of growth stages & season(c)	Number min–max	Interval between application (days) min–max	g a.s./hL min–max	Water (L/ha) min–max	Rate min–max	Unit		
A.1 MRL review GAPs (authorised uses (EFSA, 2014a**)/adjusted uses)**															
Passion fruits	Non-EU (KE)	F	*Alternaria septorium*, *Cladosporium*	WG	500	Foliar spraying		2	7			0.4	kg a.i./ha	3	
Sweet peppers/ bell peppers	EU	I	*Leveillula taurica*	WG	500	Foliar spraying		1–3	7			100	g a.s/ha	1	
Sweet peppers/ bell peppers	SEU	F	*Oidium*	WG	500	Foliar spraying		3–7	–		–	100	g a.s/ha	1	
Sweet peppers/ bell peppers	SEU	F	LEVETA	WG	250	SPI	BBCH 29–89	1–3	8–12		1,000	75	g a.s/ha	3	Adjusted GAP
Cucumbers	EU	I	*Erysiphe cichoracearum Sphaerotheca fuliginea Didymella bryoniae*	WG	500	Foliar spraying		2	7–14			0.13–0.25	Kg a.s./ha	3	
Cucumbers	NEU	F	*Erysiphe cichoracearum Sphaerotheca fuliginea Didymella bryoniae*	WG	500	Foliar spraying		1				0.25	Kg a.s./ha	3	

Crop and/or situation	NEU, SEU, MS or country	F G or I (a)	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)(d)	Remarks
				Type(b)	Conc. a.s. (g/kg)	Method kind	Range of growth stages & season(c)	Number min–max	Interval between application (days) min–max	g a.s./hL min–max	Water (L/ha) min–max	Rate min–max	Unit		
Gherkins	EU	I	*Erysiphe cichoracearum Sphaerotheca fuliginea Didymella bryoniae*	WG	500	Foliar spraying		2	7–14			0.13–0.25	Kg a.s./ha	3	
Gherkins	NEU	F	*Erysiphe cichoracearum Sphaerotheca fuliginea Didymella bryoniae*	WG	500	Foliar spraying		1				0.25	Kg a.s./ha	3	
Chinese cabbages/ pe-tsai	NEU	F	*Erysiphe cruciferarum* Fungal leaf sport disease	WG	500	Foliar spraying	BBCH 16–45	1				200	g a.s./ha	14	
Kales	NEU	F		WG	500	SPI	BBCH 16–45	1	–			200	g a.s/ha	14	
Kales	NEU	F	ALTEBA, ALBUCA	WG	500	SPI	BBCH 12–49	1–2	21		200–800	100	g a.s/ha	21	adjusted GAP
Escaroles/ broad-leaved endives	NEU	F	*Botrytis, Sclerotinia*	WG	500	Foliar Spray	BBCH 19–49	1–3	7–10		200–800	200	g a.s/ha	7	
Herbs and edible flowers	NEU	F	Downey mildew	WG	500	Foliar spraying	BBCH 20–49	3				200	g a.s/ha	7	
Herbs and edible flowers	EU	I	Powdery mildew	WG	500	Foliar spraying		3	7–10			200	g a.s/ha	7	

Crop and/or situation	NEU, SEU, MS or country	F G or I (a)	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)(d)	Remarks
				Type(b)	Conc. a.s. (g/kg)	Method kind	Range of growth stages & season(c)	Number min–max	Interval between application (days) min–max	g a.s./hL min–max	Water (L/ha) min–max	Rate min–max	Unit		
Beans with pods	NEU	F	*Sclerotinia*, *Uromyces*	SC	250	Foliar spraying	BBCH 59–69	2	7–14		400–600	200	g a.s/ha	7	
Beans with pods	EU	I	Powdery mildew	WG	500	Foliar spray		3	7–10		1,000	30–130	g a.s/ha	1	
Oat	NEU	F	Mildew, rust, oat leaf sport	EC	250	Foliar spray		1				130	g a.s/ha	35	
Oat	SEU	F	PUCCCA	SC	500	Foliar spray						250	g a.s/ha	42	
A.2 New intended uses															
Sweet peppers/bell peppers	SEU	F	*Alternaria solani* (ALTESO) *Leveillula taurica* (LEVETA)	SC	250	Foliar spray	BBCH 51–89	2	10		200–800	150	g a.s/ha	3	
Escaroles/broad-leaved endives	EU	I	SEPTILA, MARSPA	WG	500	SPI	BBCH 19–49	1–3	7–10		200–800	200	g a.s/ha	7	
Witloofs/Belgian endives	NEU	F	ERYSCI	WG	500	Fdoliar Spray	BBCH 12–49	1–2	14		200–800	125	g a.s/ha	21	
Chicory roots	NEU	F	ERYSCI	WG	500	SPI	BBCH 12–49	1–2	21		200–800	125	g a.s/ha	21	

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; WG: water-dispersible granule; SC: suspension concentrate.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and methods of analysis in plants

B.1.1.1. Metabolism studies, methods of analysis 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	Radiolabelled active substance: [trifluoromethyl-phenyl-UL-^{14}C] trifloxystrobin and [glyoxyl-phenyl-UL-^{14}C] trifloxystrobin (EFSA, 2014a)
	Root crops	Sugar beets	Foliar, 3 × 130 or 690 g/ha	0, 21, 45	Radiolabelled active substance: [trifluoromethyl-phenyl-UL-^{14}C] trifloxystrobin and [glyoxyl-phenyl-UL-^{14}C] trifloxystrobin (EFSA, 2014a)
	Cereals	Wheat	Foliar, 1 × 500 g/ha	49	Radiolabelled active substance: [trifluoromethyl-phenyl-UL-^{14}C] trifloxystrobin and [glyoxyl-phenyl-UL-^{14}C] trifloxystrobin (EFSA, 2014a)
			Foliar, 2 × 250 g/ha	24, 52	Radiolabelled active substance: [trifluoromethyl-phenyl-UL-^{14}C] trifloxystrobin and [glyoxyl-phenyl-UL-^{14}C] trifloxystrobin (EFSA, 2014a)
			Foliar, 2 × 250 g/ha	3, 32	[trifluoromethyl-phenyl-UL-^{14}C] trifloxystrobin (EFSA, 2014a)
	Pulses/ oilseeds	Peanuts	Foliar, 4 × 560 g/ha	0, 14	Samples collected after 1st treatment: +0 and 14 days; after last treatment: 14 days; Radiolabelled active substance: [trifluoromethyl-phenyl-UL-^{14}C] trifloxystrobin and [glyoxyl-phenyl-UL-^{14}C] 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	Radiolabelled active substance: [trifluoromethyl-phenyl-UL-^{14}C] trifloxystrobin and [glyoxyl-phenyl-UL-^{14}C] trifloxystrobin (EFSA, 2014a)
	Cereal (small grain)	Wheat	Bare soil, 1 × 500 g/ha	Spring wheat: 31, 365; Winter wheat: 174	Radiolabelled active substance: [trifluoromethyl-phenyl-UL-^{14}C] trifloxystrobin and [glyoxyl-phenyl-UL-^{14}C] trifloxystrobin (EFSA, 2014a)
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 CGA 321113 (EFSA, 2014a)
	Other processing conditions			–	–

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; BBCH: growth stages of mono- and dicotyledonous plants; a.s.: active substance; MRL: maximum residue level; GC-MS: gas chromatography with mass spectrometry; LC-MS/MS: liquid chromatography with tandem mass spectrometry; HPLC-MS/MS: high performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; 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	TrifloxystrobinCGA 321113	EFSA (2017)
		Corn, green material	≤ −18	24	Months	TrifloxystrobinCGA 321113	EFSA (2017)
		Wheat, whole plant	≤ −18	24	Months	TrifloxystrobinCGA 321113	EFSA (2017)
		Apple, fruit	≤ −18	18	Months	Trifloxystrobin	EFSA (2017)
	High oil content	Oilseed rape, seed	≤ −18	24	Months	TrifloxystrobinCGA 321113	EFSA (2017)
		Peanut, nutmeat	≤ −18	18.5	Months	Trifloxystrobin	EFSA (2017)
	High protein content	Dry bean	≤ −18	24	Months	TrifloxystrobinCGA 321113	EFSA (2017)
	High starch	Rye, grain	≤ −18	24	Months	TrifloxystrobinCGA 321113	EFSA (2017)
		Wheat, grain	≤ −18	24	Months	TrifloxystrobinCGA 321113	EFSA (2017)
		Potato, tuber	≤ −18	24	Months	TrifloxystrobinCGA 321113	EFSA (2017)
	High acid content	Orange, fruit	≤ −18	24	Months	TrifloxystrobinCGA 321113	EFSA (2017)
		Grape, fruit	≤ −18	24	Months	TrifloxystrobinCGA 321113	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	TrifloxystrobinCGA 321113	EFSA (2017)
		Grape. juice	≤ −18	18.5	Months	TrifloxystrobinCGA 321113	EFSA (2017)
	Others	Wheat straw	≤ −18	24	Months	TrifloxystrobinCGA 321113	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

B.1.2.1. 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]
Passion fruits/ maracujas	Non-EU (KE)	EFSA (2014a) **Mo/RA**: –	No GAP-compliant residue trials on passion fruits submitted to support the use assessed in the MRL review	–			
		EFSA (2014a) **Mo:** 0.46; 0.51; 0.72; 1.30; 1.90 **RA**: –	Residue trials on passion fruits performed at two times lower application rate (0.2 kg/ha) in comparison to the reported GAP (0.4 kg/ha). CGA 321113: not analysed for	4	1.90	0.72	n.c.
Sweet peppers/ bell peppers	EU	EFSA (2014a): **Mo:** 0.04; 0.07; 0.08; 0.09; 0.19 **RA:** 0.06; 0.07; 0.09; 0.10; 0.20	No additional residue data submitted to complete the set of residue trials on peppers assessed in the MRL review insufficient to derive a MRL proposal. CGA 321113: 5 × < LOQ	–	0.20	0.09	1.2
		Mo: 0.06; 0.08; 0.12; 2 × 0.13; 0.19; 0.21; 0.24 **RA:** 0.07; 0.09; 0.13; 2 × 0.14; 0.02; 0.22; 0.25	Residue trials on peppers compliant with new intended indoor GAP. The minor deviation in the interval among applications is concluded as acceptable. CGA 321113: 8 × < LOQ. Samples analysed also for CGA 357261, CGA 357262 and CGA 331409	0.5	0.25	0.14	1.08
	SEU	EFSA (2014a) **Mo/RA**: –	No GAP-compliant residue trials on peppers submitted to support the use assessed in the MRL review	–	–	–	–
		Mo: 2 × 0.01; 0.02; 3 × 0.03; 0.04; 0.07 **RA:** 2 × 0.02; 0.03; 3 × 0.04; 0.05; 0.08	Residue trials on peppers compliant with an adjusted SEU GAP. CGA 321113: 8 × < LOQ of 0.01 mg/kg. Samples analysed also for CGA 357261, CGA 357262 and CGA 331409	0.15	0.08	0.04	1.35

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]
		Mo: 0.02; 0.02; 0.04; 0.10; 0.11; 0.15; 0.31; 0.72 (unscaled) 0.01; 0.02; 0.03; 0.07 0.08; 0.11; 0.23; 0.54 (scaled) **RA:** 2 × 0.02; 0.04; 0.08; 0.09; 0.12; 0.24; 0.55	Residue trials on peppers compliant with new intended SEU GAP scaled down by a factor of 0.75 to match the new intended SEU use. Higher residue at a longer PHI of 7 days is underlined. CGA 321113: 8 × < LOQ of 0.01 mg/kg. Samples analysed also for CGA 357261, CGA 357262 and CGA 331409	**0.9**	0.55	0.09	1.13
Cucumbers, courgettes	EU	EFSA (2014a) **Mo/RA**: –	No GAP-compliant residue trials on cucurbits submitted to support the use assessed in the MRL review	–	0.17	0.06	1.7
	NEU	EFSA (2014a) **Mo/RA**: –	No GAP-compliant residue trials on cucurbits submitted to support the use assessed in the MRL review	–	–	–	–
Leafy brassica	NEU	EFSA (2014a) **Mo**: 0.07; 0.21; 0.66; 0.77; 1.20 **RA**: 0.22; 0.81	No additional GAP-compliant residue trials submitted to complete the set of residue trials on kales insufficient to derive by extrapolation a MRL proposal to the group. CGA 321113: 2 × (individual values not available)	–	–	–	–
Kales	NEU	**Mo:** 0.04; 0.27; 0.35; 1.00 **RA:** 0.05; 0.29; 0.40; 1.05	Residue trials on kales compliant with an adjusted NEU GAP. CGA 321113: < 0.01; 0.02; 2 × 0.05 mg/kg. Samples analysed also for CGA 357261, CGA 357262 and CGA 331409	2	1.05	0.35	1.11
Escaroles, Herbs and edible flowers	EU	**Mo:** 2.1; 3.0; 4.0; 4.1; 5.2; 6.9, 7.6; 18 **RA:** 2.21; 3.20; 4.20; 4.29; 5.24; 6.94; 7.63; 18.09[e]	Residue trials on open leaf lettuces compliant with the indoor use in herbs and edible flowers assessed in the MRL review and with the new intended use on escaroles. Extrapolation of residue data to the groups of herbs and edible flowers and to escarole possible. CGA 321113: 0.03; 2 × 0.04; 0.09; 0.11; 0.18; 2 × 0.19 mg/kg.	**30**	18.09	4.77	1.03

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]
			Samples analysed also for CGA 357261, CGA 357262 and CGA 331409				
	NEU	**Mo:** 0.29; 0.62; 0.84; 0.93; 1.90; 2.30; 2.60; 3.70 **RA**: 0.37; 0.69; 0.90; 1.09; 2.06; 2.33; 2.65; 3.75	Residue trials on open leaf lettuces compliant with the NEU use assessed in the MRL review and with the new intended use on escaroles. Extrapolation of residue data to the groups of herbs and edible flowers and to escarole possible. CGA 321113: 0.03; 2 × 0.05; 0.06; 0.07; 0.08; 2 × 0.15 mg/kg. Samples analysed also for CGA 357261, CGA 357262 and CGA 331409	7	3.75	1.58	1.08
Bean with pods	EU	EFSA (2014a) and Netherlands (2021a) **Mo**: 0.10; 0.15; 2 × 0.16; 0.17; 0.18; 0.22; 0.35 **RA:** 0.12; 0.17; 2 × 0.18; 0.19; 0.20; 0.24; 0.37	Residue trials on beans with pods compliant with indoor use assessed in the MRL review completed with the results in accordance with the residue definition for risk assessment. CGA 321113: 8 × < LOQ of 0.02 mg/kg	0.6	0.37	0.19	1.12
	NEU	EFSA (2014a) **Mo:** 0.06; 0.07; 0.08; 0.16; 0.23; 0.29; 0.50; 0.51 **RA**: 0.08; 0.10 Netherlands (2021a) **Mo:** 0.03; 2 × 0.03; 0.04; 0.06; 0.06; 0.07; 2 × 0.08; 0.08; 0.16; 0.21; 0.23; 0.49 **RA:** 2 × 0.04; 2 × 0.04; 0.05; 0.07; 0.08; 0.08; 0.09; 2 × 0.10; 0.19; 0.23; 0.24; 0.51	Combined data set of residue trials on beans with pods (8) assessed in the MRL review and additional residue trials on beans (7) and peas (7, underlined). Extrapolation from peas with pods to beans with pods possible. CGA 321113: 8 × < 0.01; 2 × 0.01; 2 × < 0.02; 3 × < 0.02; 0.03 mg/kg Samples of new trials analysed also for CGA 357261, CGA 357262 and CGA 331409	**0.8**	0.51	0.08	1.22

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]
Oat, grain	NEU	EFSA (2014a) **Mo/RA:** –	No GAP-compliant residue trials submitted to support the use assessed in the MRL review		–	–	
	SEU	EFSA (2014a) and Netherlands (2021a) **Mo**: 2 × 0.01; 4 × < 0.02; 0.06; 0.12; 0.18 **RA:** 2 × 0.02; 4 × < 0.04; 0.08; 0.14; 0.20	Residue trials on barley compliant with the SEU use on oat assessed in the MRL review. The data set combines also results from trials previously reported in the MRL review which were concluded as independent. Extrapolation to oat possible. CGA 321113: 2 × < 0.01; 14 × < 0.02; 0.03 mg/kg	0.3	0.20	0.04	1.77
Oat, straw	NEU	EFSA (2014a) **Mo/RA:** –	See oat grain		–	–	
	SEU	EFSA (2014a)/ Netherlands (2021a) **Mo**: 0.15; 0.19; 0.22; 0.29; 0.45; 0.70; 1.00; 1.30; 2.40 **RA:** 0.24; 0.25; 0.27; 0.36; 0.49; 0.90; 1.08; 1.52; 2.57	See oat grain. CGA 321113: 2 × 0.03; 0.05; 0.07; 0.09; 0.12; 0.16; 0.20; 0.21	–	2.57	0.49	1.17
Chicory roots	NEU	**Mo:** 4 × < 0.02 **RA:** 4 × < 0.04	Residue trials on sugar beets compliant with intended new use on chicory roots. Extrapolation from sugar beets to chicory roots possible. CGA 321113: 4 × < 0.02 mg/kg	< 0.02	0.04	0.04	2

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment.
The value in bold is the final MRL proposal.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: indoor EU trials; 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. Individual residue values of CGA 321113 above the LOQ were recalculated to express them as trifloxystrobin using a conversion factor of 1.036 based on molecular weights (MW) ratio (trifloxystrobin: CGA 321113) (408.38:394.34 g/mol).
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion. Individual residue values of CGA 321113 above the LOQ were recalculated to express them as trifloxystrobin using a conversion factor of 1.036 based on molecular weights (MW) ratio (trifloxystrobin: CGA 321113) (408.38:394.34 g/mol).
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
(e): Statistically detected as potential outlier (Dixon's Q-test) but no information and no obvious defects in the trial justified the exclusion of the value from the calculation (European Commission, 1997g; FAO, 2009).

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	no	Based on the results from metabolism studies in rotational crops, which were performed with an application rate of 500 g/ha (max. rate for the intended uses 3 x 200 g/ha) but considering the application was to bare soil (interception by the plants is expected in practice), relevant residue levels are unlikely to occur in rotational crops. (EFSA, 2014a, 2017)
Residues in rotational and succeeding crops expected based on field rotational crop study?	no	Three rotational field trials in lettuce, turnip and wheat conducted with 1128 g/ha (1.88N maximum total treatment of the crop under assessment) at 30-day PBI are available. Samples were analysed for trifloxystrobin and CGA321113 and all the results were below LOQ (0.02 mg/kg). (EFSA, 2014a, 2017)

PBI: plant-back interval.

B.1.2.3. Processing factors

Processed commodity	Number of valid studies[a]	Processing Factor (PF)		CF_P[b]	Comment/Source
		Individual values	Median PF_{Enf}		
Tomato, juice	2	0,19; 0.23	0.21	0.24	Netherlands (2021b)
Tomato, paste	2	0.33; 0.74	0.54	0.59	Netherlands (2021b)
Tomato, puree	2	0.16; 0.37	0.27	0.29	Netherlands (2021b)
Tomato, preserve	2	0.10; 0.12	0.11	0.13	Netherlands (2021b)
Tomato, dried fruit	2	1.69; 1.81	1.75	1.82	Netherlands (2021b)

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Conversion factor for risk assessment in the processed commodity; median/mean of the individual conversion factors for each processing residues trial. Individual residue values of CGA 321113 above the LOQ of 0.01 mg/kg were recalculated to express them as trifloxystrobin using a conversion factor of 1.036 based on molecular weights(MW) ratio (trifloxystrobin: CGA 321113) (408.38:394.34 g/mol).

B.2. Residues in livestock

Dietary burden calculation according to OECD (2013).

Relevant groups[a]	Dietary burden expressed in				Most critical commodity [b]		Trigger exceeded (Yes/No)	Previous assessment (EFSA, 2018c)
	mg/kg bw per day		mg/kg DM					
	Median	Maximum	Median	Maximum				Max burden mg/kg DM
Cattle (all diets)	0.032	0.069	1.15	2.12	Kale	Leaves	Yes	3.88
Cattle (dairy only)	0.032	0.069	0.83	1.78	Kale	Leaves	Yes	3.56
Sheep (all diets)	0.054	0.111	1.27	2.60	Rye	Straw	Yes	2.57
Sheep (ewe only)	0.042	0.087	1.27	2.60	Rye	Straw	Yes	2.57
Swine (all diets)	0.012	0.024	0.51	1.02	Kale	Leaves	Yes	1.88
Poultry (all diets)	0.024	0.047	0.35	0.68	Wheat	Straw	Yes	0.67
Poultry (layer only)	0.024	0.047	0.35	0.68	Wheat	Straw	Yes	0.67
Fish	N/A							

bw: body weight; DM: dry matter.

(a): When one group of livestock includes several subgroups (e.g. poultry 'all' including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

B.3. Consumer risk assessment

ARfD	0.5 mg/kg bw (European Commission, 2018)
Highest IESTI, according to EFSA PRIMo	Escaroles/broad-leaved endives: 145.3% of the ARfD Sweet peppers/bell peppers: 6.5% Passion fruits/maracuja: 2.6% of ARfD Cucumbers: 3.1% of the ARfD Gherkins: 0.3% of the ARfD Kales: 9.2% of the ARfD Chervil: 4.7% of the ARfD Chives: 3.0% of the ARfD Celery leaves: 1.7% of the ARfD Parsley: 4.3% of the ARfD Sage: 2.7% of the ARfD Rosemary: 0.4% of the ARfD Thyme: 0.4% of the ARfD Basil and edible flowers: 2.6% of the ARfD Laurel/bay leaves: 0.4% of the ARfD Tarragon: 0.4% of ARfD Beans (with pods): 1.2% of the ARfD Oat: 0.01% of the ARfD Chicory roots: 0.003% of ARfD
Assumptions made for the calculations	The calculation is based on the highest residue levels expected in raw agricultural commodities according to the residue definition for risk assessment, except for oat, where the median residue level was applied. For passion fruits, the tentative MRL is not supported by GAP-complaint residue trials analysed also for CGA321113; nevertheless this commodity was re-considered in the exposure assessment now performed with PRIMo 3.1 version, using the highest residue value for parent trifloxystrobin as derived in the MRL review. For commodities not included in the present applications, the short-term exposure assessment was performed using the risk assessment values according to the residue definition for risk assessment derived in previous EFSA reasoned opinions and scientific reports issued after the MRL review (EFSA, 2014a,b, 2016a,b, 2018c,d, 2019b), except for spring onions where the highest residue value according to the enforcement residue definition was multiplied by the conversion factor (CF) for risk assessment of 2.6 (EFSA, 2012, 2014a). 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% of ADI (NL toddler diet) Contribution of crops assessed: Passion fruits/maracuja: 0.17% of ADI Sweet peppers/bell peppers: 0.05% of ADI Cucumbers: 0.16% of ADI Gherkins: 0.02% of ADI Kales: 0.07% of ADI Escaroles/broad-leaved endives: 1.16% of ADI Chervil: 0.05% of ADI Chives: 0.05% of ADI Celery leaves: 0.05% of ADI Parsley: 0.20% of ADI Sage: 0.05% of ADI Rosemary: 0.05% of ADI Thyme: 0.05% of ADI Basil and edible flowers: 0.16% of ADI Laurel/bay leaves: 0.05% of ADI Tarragon: 0.05% of ADI Beans (with pods): 0.07% of ADI Oat: 0.02% of ADI Chicory roots: 0.01% of ADI
Assumptions made for the calculations	The calculation is based on the median residue levels derived for raw agricultural commodities according to the risk assessment residue definition, except for spring onions where the median residue value according to the enforcement residue definition was multiplied by the conversion factor (CF) for risk assessment of 2.6 (EFSA, 2012. 2014a) and for passion fruits where information on the magnitude of CGA321113 to derive a CF was not available. The contributions of commodities not supported by confirmatory data (apart for passion fruits) or for which no adjusted/new use could be proposed (Chinese cabbages, other leafy brassica except kales) as well as where no GAP or safe CXL was reported in the framework of the MRL review or in EFSA opinions and scientific reports issued after the MRL review (EFSA, 2014a,b, 2016a,b, 2018c,d, 2019b) were not included in the calculation. 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.4. Recommended MRLs

Code[(a)]	Commodity	Existing MRL[(b)]	Proposed MRL	Conclusion/recommendation
Enforcement residue definition: Trifloxystrobin				
0162030	Passion fruits/ maracujas	4 (ft 1)	Further risk management considerations required	The data gap identified in the MRL review has not been addressed. The tentative MRL of 4 mg/kg based on underdosed residue trials analysed for trifloxystrobin only is not confirmed. Risk managers may consider lowering of the existing MRL to the LOQ of 0.01 mg/kg. Lacking information on the occurrence of the metabolite CGA 321113, an indicative consumer risk assessment was conducted considering exposure to the active substance only. Based on the available information, risk for consumer unlikely
0231020	Sweet peppers/ bell peppers	0.4 (ft 1)	0.9	The data gaps identified in the MRL review have not been addressed. The tentative MRL of 0.4 mg/kg is not confirmed. However, the new intended SEU use is sufficiently supported by residue data requiring a higher MRL proposal of 0.9 mg/kg. Risk for consumer unlikely
0232010	Cucumbers	0.3 (ft 1)	Further risk management considerations	The data gap identified in the MRL review has not been addressed. The EMS proposed to retain the same MRL of 0.3 mg/kg reflecting the level of the Codex MRL (CXL), which was set by the JMPR 2006 for cucurbits from merged residue data on cucumbers, courgettes (edible peel) and melons (inedible peel). It is noted that the extrapolation applied to derive the CXL value is not fully in line with the EU requirements, although based on the same data set, the existing MRL (CXL) of 0.3 mg/kg is set for cucurbits with inedible peel and for courgettes in the EU legislation. Therefore, the risk manager decision is required. Risk for the consumer unlikely
0232020	Gherkins	0.3 (ft 1)	Further risk management considerations	
0243020	Kales	3 (ft1)	2	The data gap identified in the MRL review has not been addressed. The tentative MRL of 3 mg/kg is not confirmed. However, an adjusted NEU use, authorised in the Netherlands, is fully supported by residue data, resulting in a lower MRL proposal. Risk for consumer unlikely
0243010	Chinese cabbages/ pe-tsai	3 (ft1)	Further risk management considerations required	The data gap identified in the MRL review has not been addressed. The tentative MRL of 3 mg/kg is not confirmed. Risk managers may consider lowering of the existing MRL to the LOQ of 0.01 mg/kg
0243990	Others leafy brassica	3 (ft1)	Further risk management considerations required	

Code[(a)]	Commodity	Existing MRL[(b)]	Proposed MRL	Conclusion/recommendation
0251030	Escaroles/broad-leaved endives	15	No change	The submitted residue data are sufficient to support the intended indoor use and to derive by extrapolation an MRL proposal of 30 mg/kg. However, for this use, an acute consumer health risk cannot be excluded (145% of the ARfD). Thus, a modification of the existing EU MRL is not proposed
0256000	Herbs and edible flowers	15 (ft 1)	30	The data gap identified in the MRL review has been addressed and the new residue data submitted lead to a higher MRL proposal. Risk for consumer unlikely
0260010	Beans (with pods)	1 (ft 1)	0.8	The data gap identified in the MRL review has been addressed and the additional residue data lead to a lower MRL proposal. Risk for consumer unlikely
0500050	Oat	0.4 (ft 1)	0.3	The data gap identified in the MRL review has been addressed and the additional residue data lead to a lower MRL proposal. Risk for consumer unlikely
0255000	Witloofs/Belgian endives	0.01*	No change	The intended NEU use is not adequately supported by GAP-complaint residue trials. Therefore, a change of the existing MRL is not proposed
0900030	Chicory roots	0.01*	0.02*	The submitted data are sufficient to derive an MRL proposal for the intended NEU use. Risk for consumer unlikely

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice; LOQ: limit of quantification; ARfD: acute reference dose.
ft 1: The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 23 July 2017, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gaps No 4, 5, 6, 7, 8, 10, 13).
*Indicates that the MRL is proposed at the limit of quantification.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): Existing EU MRL set on a tentative basis with corresponding footnote on confirmatory data.

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:	0.05

Toxicological reference values

ADI (mg/kg bw/day):	0.1	ARfD (mg/kg bw):	0.5
Source of ADI:	Eur Comm	Source of ARfD:	Eur Comm
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 - acute risk 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 : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

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)
12%	NL toddler	12.25	5%	Spinaches	1%	Milk: Cattle	1%	Apples		12%
7%	DE child	6.58	2%	Spinaches	1%	Apples	0.4%	Milk: Cattle		7%
6%	NL child	5.90	2%	Spinaches	0.6%	Apples	0.5%	Milk: Cattle		6%
4%	FR child 3 15 yr	3.64	0.8%	Spinaches	0.5%	Milk: Cattle	0.3%	Oranges		4%
4%	FR toddler 2 3 yr	3.62	1%	Spinaches	0.6%	Milk: Cattle	0.3%	Apples		4%
4%	GEMS/Food G10	3.62	0.9%	Lettuces	0.4%	Spinaches	0.2%	Parsley		4%
3%	SE general	3.46	1%	Lettuces	0.5%	Spinaches	0.2%	Milk: Cattle		3%
3%	ES child	3.44	1%	Lettuces	0.6%	Spinaches	0.2%	Milk: Cattle		3%
3%	IE adult	3.42	1.0%	Spinaches	0.2%	Lettuces	0.2%	Wine grapes		3%
3%	IT adult	3.35	1%	Lettuces	0.7%	Spinaches	0.4%	Other lettuce and other salad plants		3%
3%	GEMS/Food G06	3.32	0.4%	Spinaches	0.3%	Wheat	0.3%	Lettuces		3%
3%	NL general	3.32	1%	Spinaches	0.5%	Escaroles/broad-leaved endives	0.3%	Lettuces		3%
3%	GEMS/Food G11	3.27	0.7%	Spinaches	0.2%	Lamb's lettuce/corn salads	0.2%	Lettuces		3%
3%	FR infant	3.26	2%	Spinaches	0.3%	Milk: Cattle	0.2%	Apples		3%
3%	ES adult	3.20	2%	Lettuces	0.6%	Spinaches	0.1%	Oranges		3%
3%	GEMS/Food G07	3.11	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	2.77	0.8%	Lettuces	0.4%	Spinaches	0.3%	Other lettuce and other salad plants		3%
3%	DE women 14-50 yr	2.75	0.4%	Spinaches	0.3%	Lettuces	0.3%	Apples		3%
3%	DE general	2.59	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	2.18	0.4%	Other lettuce and other salad plants	0.4%	Spinaches	0.3%	Wine grapes		2%
2%	UK toddler	2.17	0.4%	Milk: Cattle	0.2%	Spinaches	0.2%	Oranges		2%
2%	UK infant	2.15	0.8%	Milk: Cattle	0.2%	Apples	0.1%	Oranges		2%
2%	RO general	2.02	0.3%	Wine grapes	0.2%	Head cabbages	0.2%	Milk: Cattle		2%
2%	PT general	1.81	0.4%	Wine grapes	0.3%	Lettuces	0.2%	Wheat		2%
2%	FI 3 yr	1.76	0.5%	Spinaches	0.1%	Strawberries	0.1%	Raspberries (red and yellow)		2%
2%	UK vegetarian	1.57	0.4%	Lettuces	0.3%	Spinaches	0.1%	Wine grapes		2%
2%	FI 6 yr	1.52	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	1.04	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	0.88	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
9%	Apples	0.7/0.44	47
9%	Kales	2/1.05	46
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

Expand/collapse list

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
4%	Apricots	3/2	22
4%	Parsley	30/18.09	22
4%	Kales	2/1.05	20
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

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
6%	Kales/boiled	2/1.05	29
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	0.8/0.51	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. Livestock dietary burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin (EFSA, 2014a)				
Barley straw	1.33	STMR (EFSA, 2014a)	2.88	HR (EFSA, 2014a)
Beet, mangel fodder	0.08	STMR (EFSA, 2014a)	0.44	HR (EFSA, 2014a)
Beet, sugar tops	0.08	STMR (EFSA, 2014a)	0.44	HR (EFSA, 2014a)
Cabbage, heads leaves	0.05	$STMR_{Mo}$ × CF (1.7) (EFSA, 2014a)	0.31	HR_{Mo} × CF (1.7) (EFSA, 2014a)
Kale leaves (forage)	0.35	STMR	1.05	HR
Oat straw	0.49	STMR	2.57	HR
Rye straw	1.92	$STMR_{Mo}$ × CF (1.2) (EFSA, 2014a)	4.8	HR_{Mo} × CF (1.2) (EFSA, 2014a)
Triticale straw	1.92	$STMR_{Mo}$ × CF (1.2) (EFSA, 2014a)	4.8	HR_{Mo} × CF (1.2) (EFSA, 2014a)
Wheat straw	1.92	$STMR_{Mo}$ (EFSA, 2014a) × CF (1.2)	4.8	HR_{Mo} × CF (1.2) (EFSA, 2014a)
Carrot culls	0.04	STMR (EFSA, 2014a)	0.05	HR (EFSA, 2014a)
Swede roots	0.04	STMR (EFSA, 2014a)	0.05	HR (EFSA, 2014a)
Turnip roots	0.04	STMR (EFSA, 2014a)	0.05	HR (EFSA, 2014a)
Barley grain	0.06	$STMR_{Mo}$ × CF (1.5) (EFSA, 2014a)	0.06	$STMR_{Mo}$ × CF (1.5) (EFSA, 2014a)
Bean seed (dry)	0.04	STMR (EFSA, 2018c)	0.04	STMR (EFSA, 2018c)
Lupin seed	0.04	STMR (EFSA, 2018c)	0.04	STMR (EFSA, 2018c)
Oat grain	0.04	STMR	0.04	STMR
Pea (Field pea) seed (dry)	0.04	STMR (EFSA, 2018c)	0.04	STMR (EFSA, 2018c)
Rye grain	0.03	$STMR_{Mo}$ × CF (1.5) (EFSA, 2014a)	0.03	$STMR_{Mo}$ × CF (1.5) (EFSA, 2014a)
Soybean seed	0.01	STMR (EFSA, 2014a)	0.01	STMR (EFSA, 2014a)
Triticale grain	0.02	STMR (EFSA, 2014a)	0.02	STMR (EFSA, 2014a)
Wheat grain	0.03	$STMR_{Mo}$ × CF (1.5) (EFSA, 2014a)	0.03	$STMR_{Mo}$ × CF (1.5) (EFSA, 2014a)
Apple pomace, wet	1.02	$STMR_{Mo}$ (EFSA, 2014a) × CF (1.2) × default PF (5)(a)	1.02	$STMR_{Mo}$ (EFSA, 2014a) × CF (1.2) × default PF (5)(a)
Beet, sugar dried pulp	0.36	STMR (EFSA, 2014a) × default PF (18)(a)	0.36	STMR (EFSA, 2014a) × default PF (18)(a)
Beet, sugar ensiled pulp	0.06	STMR (EFSA, 2014a) × default PF (3)(a)	0.06	STMR (EFSA, 2014a) × default PF (3)(a)
Beet, sugar molasses	0.56	STMR (EFSA, 2014a) × default PF (28)(a)	0.56	STMR(EFSA, 2014a) × default PF (28)(a)
Brewer's grain dried	0.2	$STMR_{Mo}$ (EFSA, 2014a) × CF (1.5) × default PF (3.3)(a)	0.2	$STMR_{Mo}$ (EFSA, 2014a) × CF (1.5) × default PF (3.3)(a)
Distiller's grain dried	0.1	$STMR_{Mo}$ × CF (1.5) × default PF (3.3)(a)	0.1	$STMR_{Mo}$ (EFSA, 2014a) × CF (1.5) × default PF (3.3)(a)
Lupin seed meal	0.04	STMR (EFSA, 2014a) × default PF (1.1)(a)	0.04	STMR (EFSA, 2014a) × default PF (1.1)(a)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Soybean meal	0.01	STMR (EFSA, 2014a) × default PF (1.3)(a)	0.01	STMR (EFSA, 2014a) × default PF (1.3)(a)
Soybean hulls	0.13	STMR (EFSA, 2014a) × default PF (13)(a)	0.13	STMR (EFSA, 2014a) × default PF (13)(a)
Wheat gluten meal	0.05	$STMR_{Mo}$ × CF (1.5) (EFSA, 2014a) × default PF (1.8)(a)	0.05	$STMR_{Mo}$ × CF (1.5) (EFSA, 2014a) × default PF (1.8)(a)
Wheat milled by-pdts	0.21	$STMR_{Mo}$ × CF (1.5) (EFSA, 2014a) × default PF (7)(a)	0.21	$STMR_{Mo}$ × CF (1.5) (EFSA, 2014a) × default PF (7)(a)
Barley straw	1.33	STMR (EFSA, 2014a)	2.88	HR (EFSA, 2014a)
Beet, mangel fodder	0.08	STMR (EFSA, 2014a)	0.44	HR (EFSA, 2014a)

STMR: supervised trials median residue; HR: highest residue; PF: processing factor; Mo: monitoring.
(a): In the absence of processing factors supported by data, default processing factors (in bracket) were included in the calculation to consider the potential concentration of residues in these commodities.

D.2. Consumer risk assessment

Commodity	Existing/ proposed MRL (mg/kg)	Source/ type of MRL	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment[(a)]
Risk assessment residue definition: 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	0.23	HR-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	0.02	HR-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/J. medlars	0.7	EFSA (2014a)	0.11	STMR-RAC	0.44	HR-RAC
Other pome fruit	0.7	EFSA (2014a)	0.11	STMR-RAC	0.44	HR-RAC

Commodity	Existing/ proposed MRL (mg/kg)	Source/ type of MRL	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment[a]
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	2	HR-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
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 (2018c)	0.33	STMR-RAC	2.11	HR-RAC
Cranberries	3	EFSA (2018c)	0.33	STMR-RAC	2.11	HR-RAC
Currants (red, black and white)	3	EFSA (2018c)	0.33	STMR-RAC	2.11	HR-RAC
Gooseberries (green, red and yellow)	3	EFSA (2018c)	0.33	STMR-RAC	2.11	HR-RAC
Rose hips	3	EFSA (2018c)	0.33	STMR-RAC	2.11	HR-RAC
Mulberries (black and white)	3	EFSA (2018c)	0.33	STMR-RAC	2.11	HR-RAC
Azarole/Med. medlar	3	EFSA (2018c)	0.33	STMR-RAC	2.11	HR-RAC
Elderberries	3	EFSA (2018c)	0.33	STMR-RAC	2.11	HR-RAC
Other small fruit & berries	3	EFSA (2018c)	0.33	STMR-RAC	2.11	HR-RAC
Table olives	0.3	EFSA (2014a)	0.095	STMR-RAC	0.14	HR-RAC
Passion fruits/ maracujas	4/< 0.01	Under assessment	0.72	STMR-RAC[b]	1.90	HR-RAC[b]
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

Commodity	Existing/ proposed MRL (mg/kg)	Source/ type of MRL	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment[(a)]
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	0.13	HR-RAC × CF
Tomatoes	0.7	EFSA (2014a)	0.08	STMR-RAC	0.49	HR-RAC
Sweet peppers/bell peppers	0.9	Under assessment	0.09	STMR-RAC	0.55	HR-RAC
Aubergines/egg plants	0.7	EFSA (2014a)	0.08	STMR-RAC	0.49	HR-RAC
Cucumbers	0.3	Under assessment (FAO, 2004)	0.095	STMR-RAC	0.24	HR-RAC
Gherkins	0.3	Under assessment (FAO, 2004)	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	0.24	HR-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	0.24	HR-RAC
Broccoli	0.6	EFSA, 2019b	0.1	STMR-RAC	0.43	HR-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	0.39	HR-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
Kales	2	Under assessment	0.35	STMR-RAC	1.05	HR-RAC
Lamb's lettuce/ corn salads	15	EFSA (2018c)	2.85	STMR-RAC	10	HR-RAC
Lettuces	15	EFSA (2018c)	2.85	STMR-RAC	10	HR-RAC
Escaroles/ broad-leaved endives	15	Under assessment	4.77	STMR-RAC	18.09	HR-RAC
Cress and other sprouts and shoots	15	EFSA (2018c)	2.85	STMR-RAC	10	HR-RAC
Land cress	15	EFSA (2018c)	2.85	STMR-RAC	10	HR-RAC
Roman rocket/ rucola	15	EFSA (2018c)	2.85	STMR-RAC	10	HR-RAC
Red mustards	15	EFSA (2018c)	2.85	STMR-RAC	10	HR-RAC
Baby leaf crops (including brassica species)	15	EFSA (2018c)	2.85	STMR-RAC	10	HR-RAC

Commodity	Existing/ proposed MRL (mg/kg)	Source/ type of MRL	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment[(a)]
Other lettuce and other salad plants	15	EFSA (2018c)	2.85	STMR-RAC	10	HR-RAC
Spinaches	20	EFSA (2018d)	7.6	STMR-RAC	10	HR-RAC
Purslanes	15	EFSA (2018c)	2.85	STMR-RAC	10	HR-RAC
Chervil	30	Under assessment	4.77	STMR-RAC	18.09	HR-RAC
Chives	30	Under assessment	4.77	STMR-RAC	18.09	HR-RAC
Celery leaves	30	Under assessment	4.77	STMR-RAC	18.09	HR-RAC
Parsley	30	Under assessment	4.77	STMR-RAC	18.09	HR-RAC
Sage	30	Under assessment	4.77	STMR-RAC	18.09	HR-RAC
Rosemary	30	Under assessment	4.77	STMR-RAC	18.09	HR-RAC
Thyme	30	Under assessment	4.77	STMR-RAC	18.09	HR-RAC
Basil and edible flowers	30	Under assessment	4.77	STMR-RAC	18.09	HR-RAC
Laurel/bay leaves	30	Under assessment	4.77	STMR-RAC	18.09	HR-RAC
Tarragon	30	Under assessment	4.77	STMR-RAC	18.09	HR-RAC
Other herbs	30	Under assessment	4.77	STMR-RAC	18.09	HR-RAC
Beans (with pods)	0.8	Under assessment	0.08	STMR-RAC	0.51	HR-RAC
Beans (without pods)	0.09	EFSA (2018c)	0.03	STMR-RAC	0.07	HR-RAC
Peas (with pods)	1.5	EFSA (2018c)	0.26	STMR-RAC	0.84	HR-RAC
Peas (without pods)	0.09	EFSA (2018c)	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 (2018c)	0.04	STMR-RAC	0.04	STMR-RAC
Lentils	0.2	EFSA (2018c)	0.04	STMR-RAC	0.04	STMR-RAC
Peas	0.2	EFSA (2018c)	0.04	STMR-RAC	0.04	STMR-RAC
Lupins/lupini beans	0.2	EFSA (2018c)	0.04	STMR-RAC	0.04	STMR-RAC
Other pulses	0.2	EFSA (2018c)	0.04	STMR-RAC	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 (2018d)	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	0.3	Under assessment	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

Commodity	Existing/ proposed MRL (mg/kg)	Source/ type of MRL	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment[a]
Ginseng root	0.05	EFSA (2018d)	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	Under assessment	0.04	STMR-RAC	0.04	HR-RAC
Risk assessment residue definition: sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin (ruminant muscle, fat, milk); trifloxystrobin, CGA 321123 and its conjugates, expressed as trifloxystrobin (ruminant liver, kidney) (EFSA, 2014a)						
Swine: Muscle/ meat[c]	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[c]	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: 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
Bovine: Edible offal (other than liver and kidney)	0.07	EFSA (2014a)	0.04	STMR-RAC	0.07	HR-RAC
Sheep: Muscle/ meat[c]	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: 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
Sheep: Edible offal (other than liver and kidney)	0.07	EFSA (2014a)	0.04	STMR-RAC	0.07	HR-RAC
Goat: Muscle/ meat[c]	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: 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
Goat: Edible offal (other than liver and kidney)	0.07	EFSA (2014a)	0.04	STMR-RAC	0.07	HR-RAC
Equine: Muscle/ meat[c]	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/ type of MRL	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment[a]
Equine: Edible offal (other than liver and kidney)	0.07	Reg No 2015/1200	0.04	STMR-RAC	0.07	HR-RAC
Poultry: Muscle/ meat[c]	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
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		
Other farmed animals: Muscle/ meat[c]	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
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	0.04	HR-RAC

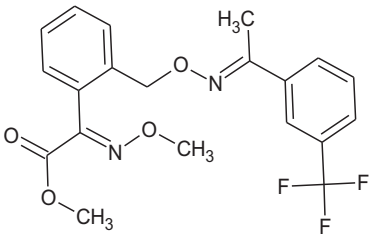
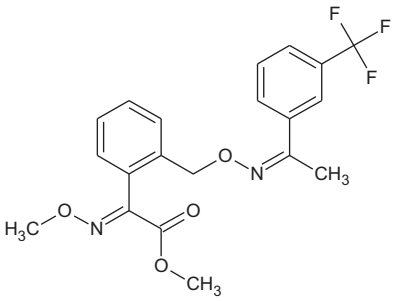
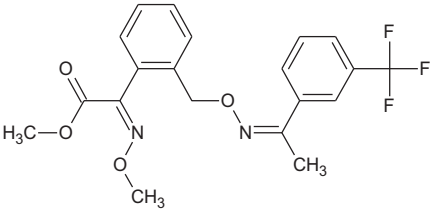
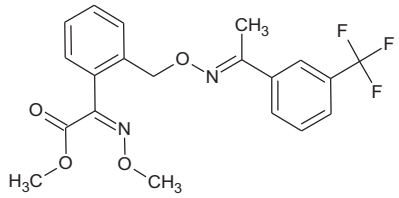
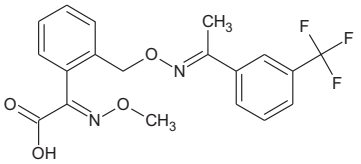
STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; PeF: Peeling factor.

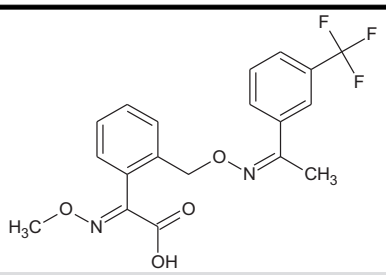
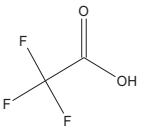
(a): Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.

(b): Input values refer to trifloxystrobin as reported in the MRL review, since information on potential exposure to metabolite CGA 321113 is not available.

(c): 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 an 80%/90% muscle and 20%/10% fat content for mammal/poultry meat respectively (FAO, 2016).

Appendix E – Used compound codes

Code/trivial name[a]	Chemical 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	

Code/trivial name[a]	Chemical name/SMILES notation/ InChiKey[b]	Structural formula[c]
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	
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).