Modification of the existing maximum residue levels for trifloxystrobin in various crops

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Bayer CropScience submitted a request to the competent national authority in the Netherlands to modify the existing maximum residue levels (MRL) for the active substance trifloxystrobin in small fruits and berries (whole group), lettuce and salad plants (whole group), purslanes, beans (without pods) and peas (with and without pods) and pulses. The data submitted in support of the request were found to be sufficient to derive MRL proposals for all crops under consideration. Adequate analytical methods for enforcement are available to control the residues of trifloxystrobin on the commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg and in animal matrices at the validated LOQ of 0.01 mg/kg. The risk assessment included a preliminary assessment considering the acute reference dose proposed during the peer review. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of trifloxystrobin according to the reported agricultural practices is unlikely to present a risk to consumer health, except for escaroles. For escaroles, based on the recently proposed acute reference dose, EFSA concluded that a risk from short-term intake cannot be excluded. Therefore, no MRL has been proposed for this use.

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the company Bayer CropScience submitted an application to the competent national authority in the Netherlands (evaluating Member State (EMS)) to modify the maximum residue levels (MRLs) for the active substance trifloxystrobin in small fruits and berries, for whole subgroup of lettuce and salad plants, purslanes, beans without pods, peas with and without pods and pulses. The Netherlands drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 23 January 2017. To accommodate for the intended uses of trifloxystrobin, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) of 0.01 mg/kg to:

- 3 mg/kg for other small fruits and berries;
- 15 mg/kg for lettuce and salad plants (no current MRL for the whole group);
- 15 mg/kg for purslanes,
- 0.09 mg/kg for beans without pods,
- 0.09 mg/kg for peas without pods,
- 1.5 mg/kg for peas with pods and
- 0.2 mg/kg for pulses.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. In the course of the detailed assessment, EFSA identified points which needed further clarifications. The EMS provided the requested information on 18 December 2017. Based on the conclusions derived by EFSA in the framework of Regulation (EC) No 1107/2009 and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

EFSA concludes that based on the available information for the uses assessed in this application, the proposed residue definitions are still applicable.

The current residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above mentioned residue definition.

It is noted that in the framework of the assessment on the renewal of the approval the risk assessment residue definition for plant commodities was proposed to be expanded to the sum of trifloxystrobin, its three isomers CGA 357262, GA 357261, CGA 331409 and its metabolite CGA321113, expressed as trifloxystrobin. The proposal was based on the metabolism studies, supported by field trials on pome fruits, grapes and strawberries. Thus, once the new residue definition for risk assessment is approved, the existing EU MRLs will have to be reconsidered. However, for this MRL application, the risk assessment is performed with the residue definition derived in the MRL review.

Sufficiently validated analytical methods based on high-performance liquid chromatography (HPLC) are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in the crops assessed (LOQ).

The available residue trials are sufficient to derive MRL proposals for all crops under consideration.

Specific studies investigating the magnitude of trifloxystrobin residues in processed commodities are not required, as the long-term exposure is low and the contribution of residues in the crops under consideration to the total consumer exposure is insignificant (below 0.1% of the acceptable daily intake (ADI) per crop).

The occurrence of trifloxystrobin residues in rotational crops was investigated in the framework of the MRL review. Based on the available information on the nature and magnitude of residues, it was concluded that significant residue levels are unlikely to occur in rotational crops, provided that the active substance is used according to the proposed good agricultural practice (GAP).

As dry pulse is used as a feed product, a potential carry-over 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 animal species. However, the contribution of trifloxystrobin residues in the crops under consideration in this MRL application to the total livestock exposure was insignificant and therefore further investigation and modification of the existing MRLs for commodities of animal origin was considered unnecessary.
The toxicological profile of trifloxystrobin was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.1 mg/kg body weight (bw) per day. An acute reference dose (ARFD) was deemed unnecessary. During the process of renewal of the approval under Regulation (EC) No 1107/2009, the ADI was confirmed while an ARFD of 0.5 mg/kg bw has been set. Although this ARFD has not yet been noted by the European Commission, an acute dietary intake calculation considering the ARFD of 0.5 mg/kg bw has been performed.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO).

A concern for short-term intake was identified for escaroles, based on the highest residue observed in residue trials representative for open leaf varieties of lettuce; the highest intake was calculated to account for 175% of the ARFD (NL children diet). For the other crops for which an amendment of the existing MRL was requested, no risk for the consumers was identified.

For information, the short-term intake calculation was also performed using PRIMO revision 3 (EFSA, under publication). Although no intake concern for any of the raw agricultural commodities were identified (up to 80% of ARFD for escaroles, BE toddler), for processed escaroles the ARFD was exceeded (133%, NL toddler); a more refined risk assessment would be possible if a processing factor for boiled escaroles was available.

The estimated long-term dietary intake accounted for up to 5.3% of the ADI for WHO Cluster diet B, including escaroles contributing to the ADI by 0.2%. The highest contribution of escaroles to the diet was up to 0.4% of the ADI (NL general population). Among the crops under consideration, lettuce was the major contributor to the total consumer exposure accounting for a maximum of 1.2% of the ADI for WHO Cluster diet B. EFSA concludes that the long-term intake of residues of trifloxystrobin resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

Based on these calculations, EFSA concludes that the proposed use of trifloxystrobin on the crops assessed, except for escaroles is unlikely to pose a risk for the consumers. For escaroles, the setting of a MRL for a fall-back GAP may be possible based on an existing outdoor use; further risk management considerations are required.

It is noted that the above assessment does not yet take into consideration the isomers of trifloxystrobin. The isomers of the parent compound were agreed to be included in the residue definition for risk assessment during the process of renewal and further toxicological data was requested related to these isomers and CGA 32111; however, these amendments and data gaps have not yet been noted by the European Commission. In view of this, the consumer risk assessment may need to be revised together with a comprehensive review of all authorised uses.

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

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

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|------------------------|------------------------|-----------------------|
| 0154000 | Other small fruits and berries (whole group) | 0.01* – 2 | 3 | The submitted data are sufficient to derive a MRL proposal for the NEU/SEU use. Risk for consumers unlikely |
| 0251010 | Lamb’s lettuce | 0.01* | 15 | The MRL proposal reflects the EU indoor use. It relates to all commodities within subgroup 0251000 as applied for, except escaroles. For lettuces and baby leaf crops (including brassica species), the existing MRL is already 15 mg/kg. Risk for consumers unlikely |
| 0251040 | Cress and other sprouts and shoots | 0.01* | 15 | The MRL proposal reflects the EU indoor use. It relates to all commodities within subgroup 0251000 as applied for, except escaroles. For lettuces and baby leaf crops (including brassica species), the existing MRL is already 15 mg/kg. Risk for consumers unlikely |
| 0251050 | Roman rocket | 15 | | Further risk management considerations required |
| 0251060 | Red mustard | 15 | | The indoor use on escarole is supported by 7 trials on open variety lettuce. The short-term exposure exceeded the recently derived ARFD. The lowering of the existing MRL set at the level of 15 mg/kg or other risk management options should be considered |
| 02510700 | Others | 15 | | |
| 251990 | | | | |

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| Code\(^{(a)}\) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|------------|-----------|------------------------|-------------------------|-----------------------|
| 0251020    | Purslanes | 0.01*                  | 15                      | The submitted data are sufficient to derive a MRL proposal for the EU indoor use. Risk for consumers unlikely |
| 0260020    | Beans (without pods) | 0.01*                  | 0.09                    | The MRL proposal reflects the more critical residue situation of the SEU use. Risk for consumers unlikely |
| 0260030    | Peas (with pods) | 0.01*                  | 1.5                     | The MRL proposal reflects the more critical residue situation of the SEU use. Risk for consumers unlikely |
| 0260040    | Peas (without pods) | 0.01*                  | 0.09                    | The MRL proposal reflects the more critical residue situation of the SEU use. Risk for consumers unlikely |
| 0300000    | Pulses (whole group) | 0.01*                  | 0.2                     | The MRL proposal reflects the SEU use. Risk for consumers unlikely |

NEU: northern Europe; SEU: southern Europe; MRL: maximum residue level; ARfD: acute reference dose.

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
\(^{(a)}\): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
\((F)\): Fat soluble.
\((R)\) = The residue definition differs for the following combinations pesticide-code number:
- Trifloxystrobin- code 1000000 except 1040000: the sum of trifloxystrobin and its metabolite \((E, E)\)-methoxymino-\{2-[1-(3-trifluoromethyl-phenyl)-ethylideneamino-oxyethyl(1-phenyl)-acetic acid (CGA 321113).\)

\(^{(A)\} = The EU reference labs identified the reference standard for CGA321113 as commercially not available. When reviewing the MRL, the Commission will take into account the commercial availability of the reference standard referred to in the first sentence by 23 July 2016, or, if that reference standard is not commercially available by that date, the unavailability of it.
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Assessment

The applicant applied for raising the existing maximum residue levels (MRLs) for trifloxystrobin for the crop group of 'other small fruits and berries'; lamb's lettuce; cress and other sprouts and shoots; land cress; Roman rocket; red mustard; purslane; beans (without pods), peas (with and without pods) and pulses. Considering that according to the evaluating Member State (EMS), the MRLs required for lamb's lettuce, cress and other sprouts and shoots, land cress, Roman rocket and red mustards are at the same level as the existing MRLs for escaroles, lettuce and baby leaf crops, the EMS proposed to set a group MRL for the whole group of lettuces and salad plants. The detailed description of the intended uses in the crops under assessment is reported in Appendix A.

Trifloxystrobin is the ISO common name for methyl \((E)-\text{methoxyiminono-}\{(E)-\text{o-tolyl)-methoxyimino-}\{(E)-\text{-tri-fluoro-m-tolyl\}}(\text{ethylideneaminoxy})\text{-o-tyl\}}\text{acetate (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.}

Trifloxystrobin was evaluated in the framework of Directive 91/414/EEC\(^1\) with the United Kingdom designated as rapporteur Member State (RMS) for the representative uses (follar applications) on apples, grapes, melons, cucumbers, wheat and barley. The draft assessment report (DAR) prepared by the RMS was not peer reviewed by the European Food Safety Authority (EFSA). Therefore no EFSA conclusion is available. Trifloxystrobin was approved\(^2\) for the use as fungicide on 1 October 2003.

The process of renewal of the first approval is currently ongoing; EFSA has completed the assessment (EFSA, 2017) but a decision on the renewal of the approval has not yet been taken.

The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2014a). In 2015, the proposed modifications have been implemented in Annex II of Regulation (EC) No 396/2005\(^3\). After completion of the MRL review, EFSA has issued two reasoned opinions on the modification of MRLs for trifloxystrobin. The proposals from these reasoned opinions have been considered in recent regulations\(^4\) for the European Union (EU) MRLs. In addition, certain Codex MRLs have been included in the EU MRL legislation.

In accordance with Article 6 of Regulation (EC) No 396/2005, the company Bayer CropScience submitted an application to the competent national authority in the Netherlands (evaluating Member State, EMS) to modify the MRLs for the active substance trifloxystrobin in small fruits and berries, for whole subgroup of lettuce and salad plants, purslanes, beans without pods, peas with and without pods and pulses. The Netherlands drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 23 January 2017. To accommodate for the intended uses of trifloxystrobin, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) of 0.01 mg/kg to:

- 3 mg/kg for other small fruits and berries;
- 15 mg/kg for lettuce and salad plants (no current MRL for the whole group);
- 15 mg/kg for purslanes;
- 0.09 mg/kg for beans without pods;
- 0.09 mg/kg for peas without pods;
- 1.5 mg/kg for peas with pods and
- 0.2 mg/kg for pulses.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. In the course of the detailed assessment, EFSA identified points which needed further clarifications. The EMS provided the requested information on 18 December 2017. Based on the conclusions derived by EFSA in the framework of Regulation (EC) No 1107/2009 and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

EFSA based its assessment on the updated evaluation report submitted by the EMS (Netherlands, 2017), the DAR (United Kingdom, 2000) prepared under Council Directive 91/414/EEC, the Commission review report on trifloxystrobin (European Commission, 2003), the JMPR Evaluation reports (FAO, 2012, 2015), the revised renewal assessment report (RAR) (United Kingdom, 2017) and

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\(^1\) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.

\(^2\) Commission Directive 2003/68/EC of 11 July 2003 amending Council Directive 91/414/EEC to include trifloxystrobin, carfentrazone-ethyl, mesotrione, fenamidone and isoxaflutole as active substances. OJ L 177, 16.7.2003, p. 12–16.

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

\(^4\) For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/ep-pesticides-database/public/?event=pesticide.residue.selection&language=EN
the conclusion on the peer review of the pesticide risk assessment of the active substance trifloxystrobin (EFSA, 2017), as well as the conclusions from a previous EFSA reasoned opinions on trifloxystrobin, including the one on the MRL review (EFSA, 2014a,b, 2016).

For this application, the data requirements established in Regulation (EU) No 544/2011\(^5\) and the guidance documents applicable at the date of submission of the application to 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\(^6\).

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

The evaluation report submitted by the EMS (Netherlands, 2017) 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

In the framework of the Article 12 MRL review and the renewal of the approval (EFSA, 2014a, 2017), the metabolism of trifloxystrobin following foliar treatment was investigated in primary crops belonging to the groups of fruits and fruiting vegetables (apple, cucumber), root and tuber vegetables (sugar beet), cereals (wheat) and pulses and oilseeds (peanut). In the metabolism studies, the parent compound was the major component of the total radioactive residues (TRR) in all crops. Besides trifloxystrobin, its three isomers CGA 357262, GA 357261, CGA 331409 and its metabolite CGA321113 were also present, all individually accounting for less than 10% of TRRs, but in absolute amounts up to 0.05 mg/kg in apple and cucumbers and > 0.1 mg/kg in peanut hay and wheat straw.

1.1.2. Nature of residues in rotational crops

All crops under consideration, except small fruits and berries may be grown in rotation. As field degradation studies showed that unlike trifloxystrobin, its metabolite CGA321113 and the major soil metabolite CGA 373466 are persistent in soil (DT\(_{90}\) CGA321113 > 500 days and CGA 373466 up to 290 days) the residues in rotational crops was further investigated. During the Article 12 MRL review, the metabolism of trifloxystrobin was assessed in lettuce, radish and wheat grown in rotation after application to bare soil at a rate of 500 g a.s./ha. Based on these studies, it was concluded that metabolism in primary and rotational crops is similar (EFSA, 2014a).

1.1.3. Nature of residues in processed commodities

Studies investigating the effect of processing on the nature of trifloxystrobin (hydrolysis studies) showed that under conditions simulating pasteurisation trifloxystrobin remained stable, whereas under baking/brewing/boiling conditions minor and under sterilisation significant degradation to CGA 321113 (approximately 20%) occurred. It was concluded that the metabolic pattern of trifloxystrobin in raw commodities is similar to that as in processed commodities (EFSA, 2014a).

1.1.4. Methods of analysis in plants

The most comprehensive set of analytical methods for the determination of trifloxystrobin residues in plant commodities was assessed during the peer review for the renewal, which concluded that adequately validated analytical methods in all major crop groups (high water, high acid, high oil, high protein content, dry and difficult to analyse matrices) are available for enforcement (EFSA, 2017).

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\(^5\) 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.

\(^6\) 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.
A multiresidue Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) method using high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) quantification (CEN, 2008) is applicable to enforce trifloxystrobin in high water and high protein content commodities, to which the crops under consideration belong, with a LOQ of 0.01 mg/kg (EFSA, 2014a).

1.1.5. Stability of residues in plants

The storage stability of trifloxystrobin in plants stored under frozen conditions was investigated comprehensively in the framework of the EU pesticides peer review (EFSA, 2017). According to these studies, trifloxystrobin and its metabolite CGA 321113 are stable for up to 24 months in high water, high oil, high protein, high starch and high acid content commodities (EFSA, 2017).

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in primary crops, rotational crops and in processing studies, the Article 12 MRL review concluded on a residue definition for enforcement as parent trifloxystrobin and for risk assessment as the sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin. These residue definitions were suggested for all plant commodities (EFSA, 2014a).

EFSA concludes that based on the available information for the uses assessed in this application, the proposed residue definitions are still applicable.

The current residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above mentioned residue definition.

It is noted that in the framework of the assessment on the renewal of the approval (EFSA, 2017) the risk assessment residue definition for plant commodities was proposed to be expanded to the sum of trifloxystrobin, its three isomers CGA 357262, GA 357261, CGA 331409 and its metabolite CGA321113, expressed as trifloxystrobin. The proposal was based on the metabolism studies, supported by field trials on pome fruits, grapes and strawberries. Thus, once the new residue definition for risk assessment is approved, the existing EU MRLs will have to be reconsidered. However, for this MRL application the risk assessment is performed with the residue definition derived in the MRL review (EFSA, 2014a).

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, residue trials on currants, grapes, lettuce (head forming and open leaf varieties), peas and beans (fresh with and without pods, and dry) were provided. Residue data were presented for the parent compound and CGA321113, but not on residues of the isomers of the parent compound (CGA 357262, GA 357261, CGA 331409). According to the assessment of the EMS, the analytical methods used were sufficiently validated and fit for purpose and samples were taken and stored in compliance with the demonstrated storage conditions.

The results of the residue trials, the related risk assessment input values (highest residue (HR), median residue) and the MRL proposals are summarised in Appendix B.1.2.1.

Other small fruits and berries

In total, 10 outdoor trials on currants compliant with the northern Europe (NEU) good agricultural practice (GAP) were provided; however, three trials were considered replicates as they were carried out at nearby locations during the same period of time. Thus, in total seven independent outdoor trials on currants are available for the NEU GAP.

The southern Europe (SEU) GAP was supported by eight GAP-compliant outdoor trials, four on currants and four on grapes. For grapes, the treatment interval exceeded 7 days; however, this was considered to have a minor impact on the overall residues and the trials were accepted.

For the indoor GAP, six valid trials on currants were provided.

In accordance with the EU guidance document (European Commission, 2017), extrapolation from currants (at least six trials) or from a mixed data set of currants (minimum four trials) plus two trials on either grapes or two trials on any crop belonging to the group of small fruit and berries to the whole group of small fruits and berries is acceptable. Thus, the number of trials is sufficient to derive an MRL proposal for the whole group of other small fruit and berries.
Given that the SEU and NEU data sets are similar based on statistical analyses, the outdoor trials were merged to secure a more robust assessment. This merged data set was selected for the MRL proposal as it was more critical compared to the indoor use. For the consumer risk assessment, the most critical HR value of 2.11 mg/kg was derived from the merged data set, whereas the most critical supervised trials median residue (STMR) of 0.33 mg/kg was based on the indoor application. The HR and STMR values are reported based on the residue definition for risk assessment.

**Lettuces and salad plants (Whole subgroup 0251010)**

Seven residue trials on open leaf and three trials on varieties closer to head forming lettuce varieties were provided to support extrapolation to the whole group of 'lettuces and salad plants'. All trials were compliant with the indoor GAP. However, the trials that could not be unambiguously classified as open leaf lettuces were considered as supporting information and were not included in the calculation.

According to the EU guidance (European Commission, 2017), at least eight residue trials on open leaf varieties are required to set a MRL for the whole group; for extrapolation from a major crop to a single minor crop, at least four trials would be sufficient. The guidance document gives the option to extrapolate from a major crop to a group with only minor crops based on six valid residue trials.

For the present application, the seven trials on open leaf varieties on their own are not sufficient. However, considering that the residues in the three supporting residue trials in varieties that are not clearly classified as open or head forming lettuce varieties are in the same range and that for the extrapolations to the individual minor crops belonging to the group of lettuce and salad plants (all within the group, except lettuce), four residue trials would be sufficient, EFSA is of the opinion that the data set is sufficient to derive MRL proposals for the whole group, considering that for lettuce there is no need to amend the existing MRL.

Based on the seven residue trials, the OECD calculator suggests to set a MRL at the level of 20 mg/kg. Based on expert judgement, a MRL proposal of 15 mg/kg is deemed more appropriate considering that the unrounded MRL proposals of the OECD calculator is just slightly above 15 mg/kg (unrounded OECD MRL = 15.82 mg/kg), and that the results of the previously used EU MRL calculation methodology would also suggest a MRL proposal of 15 mg/kg ($R_{\text{max}} = 14.01$ and $R_{\text{ber}} = 9.00$). It is noted that the EMS also suggested a MRL proposal of 15 mg/kg which is at the same level as the existing MRLs for lettuces (251020), escaroles (251030) and baby leaf crops (including *Brassica* species) (251080). The STMR (3.24 mg/kg) and HR (10 mg/kg) values derived from these trials were used in the consumer risk assessment for all crops belonging to the group of lettuce and salad plants.

**Purslanes**

The above-mentioned GAP-compliant residue trials on open leave varieties of lettuce also support the MRL application for purslanes. The extrapolation from lettuce (open leaf varieties) to purslanes is acceptable (European Commission, 2017) and the data were sufficient to derive a MRL proposal of 15 mg/kg.

**Fresh beans and peas without pods**

Two residue trials on beans without pods and eight trials on peas without pods compliant with the NEU GAP and three trials on beans without pods and eight on peas without pods compliant with the SEU GAP were submitted. All trials were considered valid.

According to the EU guidance (European Commission, 2017), extrapolation from beans without pods to peas without pods and vice versa is possible; therefore, the data on peas or beans without pods were pooled and the mixed data set was considered appropriate to derive a MRL proposal for beans and peas without pods. As the statistical analyses showed that the residue trials for the SEU and NEU GAPs were not similar, the two data sets could not be merged. The MRL proposal of 0.09 mg/kg, the HR (0.05 mg/kg) and STMR (0.04 mg/kg) values used in the consumer risk assessment reflect the more critical residue situation of the SEU use.

**Peas with pods**

Eleven trials on beans with pods and 10 residue trials on peas with pods compliant with the SEU GAP and eight trials on beans with pods and one residue trial on peas with pods compliant with a less critical NEU GAP (longer PHI) were submitted in support of the MRL application. Extrapolation from beans with pods to peas with pods is possible. Based on the mixed SEU data set, a MRL proposal of 1.5 mg/kg was derived. The NEU use is also fully supported by data, but is less critical than the SEU GAP.
Dry pulses

Eight residue trials on dry pea and bean seeds compliant with the SEU GAP support the MRL application. Extrapolation is possible from beans and peas to whole category pulses. The data was sufficient to derive a MRL proposal of 0.2 mg/kg based on the SEU GAP.

1.2.2. Magnitude of residues in rotational crops

The possible transfer of trifloxystrobin residues to crops that are grown in crop rotation has been assessed in the MRL review (EFSA, 2014a). Three rotational field trials in lettuce, turnip and wheat conducted with 1.13 kg/ha (2.8N) at 30 days plant back interval were available. They were analysed for trifloxystrobin and CGA 321113 and the results were all below the LOQ of 0.02 mg/kg.

Since the maximum annual application rate for the crops under consideration (i.e. 0.4 kg a.s./ha) is lower than the application rate tested in the rotational crop studies, it is concluded that no residues are expected, provided that the active substance is applied according to the proposed GAPs.

1.2.3. Magnitude of residues in processed commodities

Specific processing studies for the crops under assessment are not available. As the long-term exposure accounted for is 5.3%\(^7\) of the acceptable daily intake (ADI) and the contribution of residues in the crops under consideration to the total consumer exposure is insignificant (below 0.1% of the ADI per crop) additional processing studies for the crops under consideration are not necessary.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for the commodities under evaluation (see Appendix B.1.2.1). In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

EFSA concludes that the submitted residue trials are sufficient to derive MRL proposals for all the crops under assessment.

2. Residues in livestock

2.1. Nature of residues and methods of analysis in livestock

Metabolism studies in livestock (goat, laying hen) have been assessed previously in the framework of the MRL review (EFSA, 2014a). EFSA concluded that the residue definition proposed for enforcement and risk assessment in poultry, ruminant and pig products is trifloxystrobin and CGA321113, expressed as trifloxystrobin. A fully validated analytical method and its ILV for the determination of trifloxystrobin and its metabolite in products of animal origin with a limit of quantification (LOQ) of 0.01 mg/kg is available (Netherlands, 2017).

2.2. Magnitude of residues in livestock

As pulses may be used for feed purposes, the dietary burden calculation for livestock performed in the framework of the MRL review (EFSA, 2014a) was updated. 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 species exceeded the trigger values defined in the relevant guidance, the median and maximum animal burden remained unchanged compared to the previous calculation. Thus, it is not expected that the intended uses currently assessed has an impact on the residues in food of animal origin (EFSA, 2014a). EFSA concluded that following the intended use, pulses as a feed item does not contribute significantly to the livestock dietary burden (see Appendix B.2) and there is no need to modify the existing EU MRLs in products of animal origin listed in Regulation (EU) 2017/626\(^8\).

\(^7\) The calculation includes also intake from escaroles.
\(^8\) Commission Regulation (EU) No 2017/626 of 31 March 2017 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, cyantraniliprole, cypermethrin, cyproflo, difenoconazole, ethoprop, fluopyram, flutriafol, fluoxipyr, imazapyr, imazaquin, imazethapyr, lambda-cyhalothrin, mesotrione, profenofos, propiconazole, pyrimethanil, spirotetramat, tebuconazole, triazophos and trifloxystrobin in or on certain products. OJ L 96, 7.4.2017, p. 1-43.
3. **Consumer risk assessment**

The toxicological profile of trifloxystrobin was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.1 mg/kg body weight (bw) per day. An acute reference dose (ARfD) was deemed unnecessary (European Commission, 2003). During the process of renewal of the approval under Regulation (EC) No 1107/2009, the previously derived ADI was confirmed, while an ARfD of 0.5 mg/kg bw has been set (EFSA, 2017). Although this ARfD has not yet been noted by the European Commission, an acute dietary intake calculation has been performed for the crops under consideration, using the ARfD of 0.5 mg/kg bw.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo (EFSA, 2007). The complete list of input values is presented in Appendix D.2.

The short-term exposure assessment was performed for the various crops in accordance with the internationally agreed methodology. It was performed only with regard to the commodities under consideration assuming the consumption of a large portion of the food items as reported in the national food surveys and that these items contained residues at the HR level as observed in supervised field trials (Appendix B.1.2.1).

A concern for short-term intake was identified for escaroles, based on the highest residue observed in residue trials representative for open leaf varieties of lettuce; the highest intake was calculated to account for 175% of the ARfD (NL children diet). For the other crops for which an amendment of the existing MRL was requested, no risk for the consumers was identified.

As additional information to assist risk managers, the short-term intake calculation was also performed using PRIMo revision 3 (EFSA, under publication). Although no intake concern for any of the raw agricultural commodities were identified (up to 80% of ARfD for escaroles, BE toddler), the ARfD was exceeded for processed escaroles (133%, NL toddler); a more refined risk assessment would be possible if a processing factor for boiled escaroles was available. It is noted that the HR value may be an outlier in the data set, yet there is no reason to disregard it.

The long-term exposure assessment was performed, taking into account the STMR values derived for the commodities assessed in this application; for the remaining commodities STMR values derived in the MRL review and the following MRL applications (EFSA, 2014b, 2016) were selected as input values.

The estimated long-term dietary intake accounted for up to 5.3% of the ADI for WHO Cluster diet B, including escaroles, having a contribution of 0.2% of the ADI. The highest contribution of escaroles to the diet was up to 0.4% of the ADI (NL general population). Among the crops under consideration, lettuce was the major contributor to the total consumer exposure accounting for a maximum of 1.2% of the ADI for WHO Cluster diet B (see Appendix C). EFSA concludes that the long-term intake of residues of trifloxystrobin resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

Based on these calculations, EFSA concludes that the proposed use of trifloxystrobin on the crops assessed, except for escaroles is unlikely to pose a risk for the consumers. For escaroles, the setting of a MRL for a fall-back GAP may be possible based on existing outdoor use (EFSA, 2014a); further risk management considerations are required.

It is noted that the above assessment does not take into consideration the isomers of trifloxystrobin. The isomers of the parent compound were agreed to be included in the residue definition for risk assessment during the process of renewal and further toxicological data was requested related to these isomers and CGA 321113 (EFSA, 2017); however, these amendments have not yet been noted by the European Commission and Member States. In view of this, the consumer risk assessment is considered tentative and may need to be revised together with a comprehensive review of the existing uses.

4. **Conclusion and recommendations**

The data submitted in support of this MRL application were found to be sufficient to derive a MRL proposal for:

- the whole group of small fruits and berries;
- the whole group of lettuce and other salad plants, except escaroles;
- purslanes;
- beans (without pods);
- peas (without pods);

The complete list of input values is presented in Appendix D.2.
EFSA concluded that the proposed use of trifloxystrobin on the above commodities, except for escaroles, will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

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
CEN European Committee for Standardisation (Comité Européen de Normalisation)
CF conversion factor for enforcement to risk assessment residue definition
CXL Codex maximum residue limit
DAR draft assessment report
DAT days after treatment
DM dry matter
DT90 period required for 90% dissipation (define method of estimation)
EMS evaluating Member State
EURL EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
HPLC high-performance liquid chromatography
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
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
QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
Rber statistical calculation of the MRL by using a non-parametric method
Rmax statistical calculation of the MRL by using a parametric method
RA risk assessment
RD residue definition
RMS rapporteur Member State
SANCO Directorate-General for Health and Consumers
SC suspension concentrate
SEU southern Europe
| Acronym | Description                        |
|---------|-----------------------------------|
| STMR    | supervised trials median residue  |
| TRR     | total radioactive residue         |
| WHO     | World Health Organization         |
## Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country (F or G or I) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|--------------------------------------|------------------------------------|-------------|-------------|------------------------------|---------------|---------|
| Purslanes (sea aster, sea lavender, other purslanes) | NEU F | Botrytis cinerea, Sclerotinia sclerotiorum | SC 250 | Foliar spraying | BBCH 12-49 1–2 | 7 days | 200–1,000 | 0.20 kg a.i./ha | 7 | – |
| Bean without pod | SEU F | Botrytis fuckeliana Sclerotinia sclerotiorum | SC 250 | Foliar spraying | BBCH 55-89 2 | 7 days | 0.025–0.100 | 300–1,000 | 0.20 kg a.i./ha | 7 | – |
| Pea without pod | NEU F | Botryotinia fuckeliana/ Botrytis cinerea Sclerotinia sclerotiorum | SC 250 | Foliar spraying | BBCH 59-79 1–2 | 7 days | 0.025–0.100 | 300–1,000 | 0.20 kg a.i./ha | 14 | – |
| Pea without pod | SEU F | Botrytis cinerea Sclerotinia sclerotiorum Ascochyta sp. (pinodes ou pisi) Erysiphe pisi | SC 250 | Foliar spraying | BBCH 55-89 1–2 | 7 days | 0.020–0.067 | 200–800 | 0.20 kg a.i./ha | 7 | – |
| Crop and/or situation | NEU, SEU, MS or country | F G or I<sup>(a)</sup> | Pests or group of pests controlled | Preparation | Conc. a.s. | Method kind | Application | Application rate per treatment | Remarks |
|-----------------------|-------------------------|----------------------|-----------------------------------|-------------|-----------|-------------|-----------------|-----------------|---------|
| Pea with pod         | NEU F                   | Botryotinia fuckeliana/ Botrytis cinerea Sclerotinia sclerotiorum | SC 250 | Foliar spraying | BBCH 59-79 | 2 | 7 days | 0.025-0.100 | 200-800 | 0.20 kg a.i./ha | 14 – |
| Pea with pod         | SEU F                   | Botrytis cinerea Sclerotinia sclerotiorum Ascochytasp. (pinodes ou pisi) Erysiphe pisi | SC 250 | Foliar spraying | BBCH 55-89 | 1-2 | 7 days | 0.020-0.067 | 300-1,000 | 0.20 kg a.i./ha | 7 – |
| Pulses (whole group) | SEU F                   | Botrytis cinerea Sclerotinia sclerotiorum Ascochytasp. (pinodes ou pisi) Erysiphe pisi | SC 250 | Foliar spraying | BBCH 55-89 | 1-2 | 7 days | 0.050 | 400 | 0.20 kg a.i./ha | 21 – |
| Lettuce and other salad plants (whole group) | G | Botrytis cinerea/ Botryotinia fuckeliana Sclerotinia sclerotiorum Sclerotinia minor | SC 250 | Foliar spraying | BBCH 40-49 | 1-2 | 7 days | 0.020-0.067 | 300-1,000 | 0.20 kg a.i./ha | 7 – |
### Modification of existing MRLs for trifloxystrobin in various crops

| Crop and/or situation | NEU, SEU, MS or country | F or G or I | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | Remarks |
|-----------------------|-------------------------|-------------|-----------------------------------|-------------|-------------|-------------------------------|---------|
| **NEU** Other small fruits and berries (whole group) | NEU | F | Botryotinia fuckeliana Cronartium ribicola Drepanopeziza ribis f. sp. nigri Sphaerotheca mors-uvae | SC | Foliar spraying | BBCH 15-89 | 7 days | 0.0133–0.100 | 200–1,500 | 0.20 kg a.i./ha | 7 | – |
| **SEU** Other small fruits and berries (whole group) | SEU | F | Botrytis cinerea Sphaerotheca mors-uvae Colletotrichum sp. | SC | Foliar spraying | BBCH 13-89 | 7 days | 0.0133–0.067 | 300–1,500 | 0.20 kg a.i./ha | 7 | – |
| **G** Other small fruits and berries (whole group) | G | Botryotinia fuckeliana Cronartium ribicola Colletotrichum sp. Drepanopeziza ribis f. sp. nigri Sphaerotheca mors-uvae | SC | Foliar spraying | BBCH 15-89 | 7 days | 0.0133–0.100 | 200–1,500 | 0.20 kg a.i./ha | 7 | – |

NEU: northern Europe; SEU: southern Europe; MS: Member State; a.s.: active substance; a.i.: active ingredient; SC: suspension concentrate.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).

(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. 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 | Crop(s) | Application(s) | Sampling (DAT) | Comment/source |
|-----------------------------------|-------------|---------|----------------|----------------|----------------|
| Fruit crops                       | Apple       | Foliar (4 \times 100 g/ha) | 0, 14          | [Tri fluoromethyl-phenyl-UL-\textsuperscript{14}C] trifloxystrobin and [glyoxyl-phenyl-UL-\textsuperscript{14}C] trifloxystrobin; EFSA (2014a) |
|                                  | Cucumber    | Foliar (3 \times 312 g/ha)  | 1, 7           | [Tri fluoromethyl-phenyl-UL-\textsuperscript{14}C] trifloxystrobin and [glyoxyl-phenyl-UL-\textsuperscript{14}C] trifloxystrobin; EFSA (2014a) |
| Root crops                        | Sugar beet  | Foliar (3 \times 130 or 690 g/ha) | 0, 21, 45     | [Tri fluoromethyl-phenyl-UL-\textsuperscript{14}C] trifloxystrobin and [glyoxyl-phenyl-UL-\textsuperscript{14}C] trifloxystrobin; EFSA (2009) |
| Cereals                           | Wheat       | Foliar (1 \times 500 g/ha)  | 49             | [Tri fluoromethyl-phenyl-UL-\textsuperscript{14}C] trifloxystrobin and [glyoxyl-phenyl-UL-\textsuperscript{14}C] trifloxystrobin; EFSA (2014a) |
|                                  |             | Foliar (2 \times 250 g/ha)  | 24, 52         | [Tri fluoromethyl-phenyl-UL-\textsuperscript{14}C] trifloxystrobin and [glyoxyl-phenyl-UL-\textsuperscript{14}C] trifloxystrobin; EFSA (2014a) |
|                                  |             | Foliar (2 \times 250 g/ha)  | 3, 32          | [Tri fluoromethyl-phenyl-UL-\textsuperscript{14}C] trifloxystrobin; EFSA (2014a) |
| Pulses/oilseeds                   | Peanut      | Foliar (4 \times 560 g/ha)  | 0, 14          | + 0 and 14 days after 1st treatment; 14 days after last treatment [Tri fluoromethyl-phenyl-UL-\textsuperscript{14}C] trifloxystrobin and [glyoxyl-phenyl-UL-\textsuperscript{14}C] trifloxystrobin; EFSA (2014a) |

| Rotational crops (available studies) | Crop groups       | Crop(s) | Application(s) | PBI (DAT) | Comment/source |
|--------------------------------------|-------------------|---------|----------------|-----------|----------------|
| Root/tuber crops                     | Radish            | 1 \times 0.5 kg/a.s. per ha; bare soil, outdoor/field | 31, 120, 365 | EFSA (2014a) |
| Leafy crops                          | Lettuce           | 1 \times 0.5 kg/a.s. per ha; bare soil, outdoor/field | 31, 120, 365 | EFSA (2014a) |
| Cereal (small grain)                 | Wheat             | 1 \times 0.5 kg/a.s. per ha; bare soil, outdoor/field | Spring wheat: 31, 365; Winter wheat: 174 | EFSA (2014a) |
| Other                                |                   |         |                |           |                |
### Processed commodities (hydrolysis study)

| Conditions                                      | Stable? | Comment/source                                      |
|------------------------------------------------|---------|-----------------------------------------------------|
| Pasteurisation (20 min, 90°C, pH 4)             | Yes     | EFSA (2014a)                                        |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes     | EFSA (2014a)                                        |
| Sterilisation (20 min, 120°C, pH 6)             | No      | 21.5% degradation, mainly (ca. 20%) to CGA321113; EFSA (2014a) |

**Other processing conditions**

DAT: days after treatment; PBI: plant-back interval; a.s.: active substance.

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**Can a general residue definition be proposed for primary crops?**
- Yes

**Rotational crop and primary crop metabolism similar?**
- Yes

**Residue pattern in processed commodities similar to residue pattern in raw commodities?**
- Yes

**Plant residue definition for monitoring (RD-Mo)**
- Trifloxystrobin

**Plant residue definition for risk assessment (RD-RA)**
- Trifloxystrobin and metabolite CGA 321113

**Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)**
- HPLC–MS/MS, LOQ 0.01 mg/kg in high water (corn, green materials; broccoli head), high protein (kidney bean, dry seed), high starch (wheat grain), high oil (rape seed), and high acid (orange fruit, grape bunch). LOQ 0.05 in difficult matrix to analyse (hops kiln-dried cone). Determined: parent and metabolite CGA 321113
- QuEChERS (HPLC–MS/MS) method; LOQ of 0.01 mg/kg in high oil (olive), high protein (kidney bean) and hops, green cone (difficult matrix to analyse) and an LOQ of 0.05 mg/kg in hops, kiln-dried cone; determined: parent trifloxystrobin
- QuEChERS (HPLC–MS/MS) method; LOQ of 0.01 mg/kg in high acid, dry, high sugar and high water content (EURL data pool); determined: parent trifloxystrobin
- Confirmatory method and ILV available for all matrices
- Netherlands (2017); EFSA (2017)
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period | Compounds covered | Comment/source |
|------------------------------------|----------|-----------|--------|------------------|-------------------|---------------|
|                                    | High water content | Cucumber  | ≤ −18  | 24 Months       | Trifloxystrobin CGA 321113 | EFSA (2017)    |
|                                    |          |           |        |                 |                   |               |
|                                    |           | Corn, green material | ≤ −18  | 24 Months       | Trifloxystrobin CGA 321113 | EFSA (2017)    |
|                                    |          | Wheat whole plant | ≤ −18  | 24 Months       | Trifloxystrobin CGA 321113 | EFSA (2017)    |
|                                    |          | Apple fruit   | ≤ −18  | 18 Months       | Trifloxystrobin    | EFSA (2017)    |
|                                    | High oil content | Oilseed rape seed | ≤ −18  | 24 Months       | Trifloxystrobin CGA 321113 | EFSA (2017)    |
|                                    |          | Peanut nutmeat | ≤ −18  | 18.5 Months     | Trifloxystrobin    | EFSA (2017)    |
|                                    | High protein content | Dry bean | ≤ −18  | 24 Months       | Trifloxystrobin CGA 321113 | EFSA (2017)    |
|                                    | High starch | Rye grain   | ≤ −18  | 24 Months       | Trifloxystrobin CGA 321113 | EFSA (2017)    |
|                                    |           | Wheat grain  | ≤ −18  | 24 Months       | Trifloxystrobin CGA 321113 | EFSA (2017)    |
|                                    |           | Potato tuber | ≤ −18  | 24 Months       | Trifloxystrobin CGA 321113 | EFSA (2017)    |
|                                    | High acid content | Oranges   | ≤ −18  | 24 Months       | Trifloxystrobin CGA 321113 | EFSA (2017)    |
|                                    |           | Grapes      | ≤ −18  | 24 Months       | Trifloxystrobin CGA 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     | Trifloxystrobin CGA 321113 | EFSA (2017)    |
|                                    |           | Grape juice  | ≤ −18  | 18.5 Months     | Trifloxystrobin CGA 321113 | EFSA (2017)    |
|                                    | Others    | Wheat straw  | ≤ −18  | 24 Months       | Trifloxystrobin CGA 321113 | EFSA (2017)    |
|                                    |           | Peanut hay   | ≤ −18  | 18.5 Months     | Trifloxystrobin    | 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/indoor(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) |
|-----------|------------------|---------------------------------------------------------------|----------------|------------------------|---------------|-----------------|
| Other small fruits and berries (whole group) | NEU | Mo: 0.13, 0.22, 0.25, 0.27, 0.31, 0.77, 0.92 RA: 0.14, 0.23, 0.27, 0.29, 0.32, 0.78, 0.93 | Residue trials on currants and grapes (indicated as (gr)) compliant with GAP, except the treatment interval for grapes exceeded seven days. The NEU and SEU data sets could be merged. Extrapolation to the whole group of other small fruits and berries possible. The most critical MRL and HR derived from the merged NEU and SEU residue data sets | 3 | 2.11 | 0.29 |
| | SEU | Mo: 0.04(gr), 0.1(gr), 0.14, 0.26(gr), 0.29, 0.46, 0.66(gr), 2.1 RA: 0.05(gr), 0.12(gr), 0.15, 0.27(gr), 0.3, 0.47, 0.68(gr), 2.11 | | | |
| | EU/Indoor | Mo: 0.15, 0.27, 0.31, 0.35, 0.36, 0.51 RA: 0.16, 0.28, 0.32, 0.36, 0.37, 0.52 | Residue trials on currants compliant with GAP. Extrapolation to the whole group of other small fruits and berries possible. The most critical STMR was based on the indoor use | 1 | 0.52 | 0.33 |
| Lettuces and other salad plants (whole group) | EU/Indoor | Mo: 0.85, 1.20, 2.60, 3.10, 3.80, 4.50, 9.90 RA: 0.90, 1.30, 2.84, 3.24, 3.83, 4.69, 10.00 | Extrapolation from seven residue trials on open leaf lettuce varieties compliant with the indoor GAP. Extrapolation to the whole group accepted based on expert judgement as data set small, but supporting information considered. The MRL proposal is based on the EU-MRL, unrounded-OECD MRL and expert judgement. No MRL is proposed for escaroles | 15(d),(e) | 10 | 2.85 |
| Purslanes | EU/Indoor | Mo: 0.85, 1.20, 2.60, 3.10, 3.80, 4.50, 9.90 RA: 0.90, 1.30, 2.84, 3.24, 3.83, 4.69, 10.00 | Extrapolation from residue trials on open leaf lettuce varieties compliant with the indoor GAP. Extrapolation to purslanes possible. The MRL proposal is based on the EU-MRL, unrounded-OECD MRL and expert judgement | 15(d) | 10 | 2.85 |
| Commodity | Region/ indoor(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) |
|-----------|------------------|---------------------------------------------------------------|-----------------|-----------------------|---------------|-----------------|
| Beans (without pods) Peas (without pods) | NEU | Beans (without pods) Mo: 0.02, 0.04 RA: 0.04, 0.05 Peas (without pods) Mo: 6 × < 0.01, 2 × 0.01 RA: 8 × < 0.02 | Residue trials on beans without pods and peas without pods compliant with NEU GAP. Extrapolation is possible from beans without pods to peas without pods and vice versa | 0.06 | 0.05 | 0.02* |
| Beans (without pods) Peas (without pods) | SEU | Beans (without pods) Mo: 2 × < 0.01, 0.06 RA: 2 × < 0.02, 0.07 Peas (without pods) Mo: 2 × 0.01, 2 × 0.02, 2 × 0.03, 2 × 0.04 RA: 2 × 0.02, 2 × 0.03, 2 × 0.04, 2 × 0.05 | Residue trials on beans without pods and peas without pods compliant with SEU GAP. Extrapolation is possible from beans without pods to peas without pods and vice versa. The most critical MRL, STMR and HR derived from the mixed data set compliant with the SEU GAP | 0.09 | 0.07 | 0.03 |
| Peas (with pods) | NEU | Beans (with pods) Mo: 0.01, 2 × 0.02, 2 × 0.03, 0.05, 0.06, 0.08 RA: 0.02, 2 × 0.03, 2 × 0.05, 0.07, 0.08, 0.09 Peas (with pods) Mo: 0.23 RA: 0.24 | Residue trials on beans with pods and peas without pods compliant with GAP. Extrapolation is possible from beans with pods to peas with pods | 0.40 | 0.24 | 0.05 |
| Peas (with pods) | SEU | Beans (with pods) Mo: 0.02, 0.03, 0.05, 0.06, 0.08, 0.09, 2 × 0.12, 0.21, 0.34, 0.65 RA: 0.03, 0.04, 0.06, 0.07, 0.09, 0.10, 0.13, 0.14, 0.26, 0.35, 0.69 Peas (with pods) Mo: 0.06, 0.25, 0.26, 0.28, 2 × 0.36, 0.37, 0.41, 0.65, 0.83 RA: 0.07, 0.26, 0.27, 0.29, 0.37, 2 × 0.38, 0.43, 0.66, 0.84 | Residue trials on peas and beans with pods compliant with GAP. Extrapolation is possible from beans to peas with pods. The most critical MRL, STMR and HR derived from mixed data set compliant with the SEU GAP | 1.5 | 0.84 | 0.26 |
| Commodity | Region/ indoor\(^{(a)}\) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/source | Calculated MRL (mg/kg) | HR\(^{(b)}\) (mg/kg) | STMR\(^{(c)}\) (mg/kg) |
|-----------|---------------------------|-------------------------------------------------------------|-----------------|------------------------|------------------|------------------|
| Pulses (whole group) | SEU | Mo: 2 × < 0.01, 2 × 0.02, 0.03, 0.05, 2 × 0.09  
RA: 2 × 0.02, 2 × 0.03, 0.04, 0.06, 0.11, 0.14 | Residue trials on dry pea and dry bean seeds compliant with GAP. Extrapolation is possible to whole pulses group | 0.2 | 0.14 | 0.04 |

MRL: maximum residue level; Mo: monitoring; RA: risk assessment; GAP: good agricultural practice; OECD: Organisation for Economic Co-operation and Development.

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

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.

(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.

(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.

(d): Based on EU-MRL, unrounded-OECD MRL and expert judgement.

(e): MRL proposal excludes escaroles, due to potential short-term intake concern for the consumers.
B.1.2.2. Residues in rotational crops

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | No | Based on bare soil rotational crop study (1.25N) with lettuce, radish and wheat, significant residues are not expected in rotational crops following the intended uses |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | No | Three rotational field trials with lettuce, turnip and wheat (2.8N) performed, and residues were below the LOQ of 0.02 mg/kg |

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application.

B.2. Residues in livestock

B.2.1. Nature of residues and methods of analysis in livestock

B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) |
|-----------------------------|---------------------------------------------|---------------------------|----------------------------|-----------------------|
| Cattle (all)                | Median 0.082 Maximum 0.137                  | Dairy cattle              | Kale leaves                | Yes                   |
| Cattle (dairy only)         | Median 0.082 Maximum 0.137                  | Dairy cattle              | Kale leaves                | Yes                   |
| Sheep (all)                 | Median 0.054 Maximum 0.109                  | Lamb                      | Rye straw                 | Yes                   |
| Sheep (ewe only)            | Median 0.042 Maximum 0.086                  | Ram/Ewe                   | Rye straw                 | Yes                   |
| Swine (all)                 | Median 0.027 Maximum 0.043                  | Swine (breeding)          | Kale leaves                | Yes                   |
| Poultry (all)               | Median 0.024 Maximum 0.046                  | Poultry layer             | Wheat straw                | Yes                   |
| Poultry (layer only)        | Median 0.024 Maximum 0.046                  | Poultry layer             | Wheat straw                | Yes                   |
| 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.2.2. Residues in processed commodities

B.2.3. Residues in plants

B.2.3.1. Nature of residues and methods of analysis in plants

B.2.3.2. Metabolism studies, methods of analysis and residue definitions in plants

| Livestock (available studies) | Animal | Dose (mg/kg bw per day) | Duration (days) | Comment/source |
|-------------------------------|--------|-------------------------|-----------------|---------------|
|                               | Laying hen | 7.7 6.7 | 4 | Label position: $[^{14}\text{C}\text{-TP}]$ and $[^{14}\text{C}\text{-GP}]$, respectively |
|                               | Lactating ruminants | 4.24 4.13 | 4 | Goat. Label position: $[^{14}\text{C}\text{-TP}]$ and $[^{14}\text{C}\text{-GP}]$, respectively |

bw: body weight.
Time needed to reach a plateau concentration in milk and eggs (days)

|                  | Milk: cannot be established | Lactating goats were dosed with 4 mg/kg bw per d of trifloxystrobin, (29N ruminant). TRR in milk was 0.09 mg/kg. Study too short to reach plateau |
|------------------|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                  | Eggs: cannot be established | Plateau in egg yolk not reached                                                                                                                                                                   |

Metabolism in rat and ruminant similar

Can a general residue definition be proposed for animals?

Yes

Animal residue definition for monitoring (RD-Mo)

Sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin

Animal residue definition for risk assessment (RD-RA)

Sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin

Fat soluble residues

Yes

Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs)

Method for trifloxystrobin and CGA 321113

- Milk, eggs, muscle, fat, liver, kidney: HPLC–MS/MS, LOQ 0.01 mg/kg.
- Confirmatory method available.
- ILV available (Netherlands, 2017)

B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability period | Compounds covered | Comment/source |
|------------------------------------|--------|-----------|--------|-----------------|-------------------|---------------|
|                                    | Cow    | Muscle    | ≤ −20  | 12 Months       | Trifloxystrobin, CGA 321113 | EFSA (2017)    |
|                                    | Cow    | Liver     | ≤ −20  | 3 Months        | Trifloxystrobin | EFSA (2017)    |
|                                    | Cow    | Liver     | ≤ −20  | 12 Months       | CGA 321113      | EFSA (2017)    |
|                                    | Cow    | Milk      | ≤ −20  | 7 Months        | Trifloxystrobin | EFSA (2017)    |
|                                    | Cow    | Milk      | ≤ −20  | 12 Months       | CGA 321113      | EFSA (2017)    |
|                                    | Hen    | Eggs      | ≤ −20  | 6 Months        | Trifloxystrobin | EFSA (2017)    |
|                                    | Hen    | Eggs      | ≤ −20  | 12 Months       | CGA 321113      | EFSA (2017)    |

B.2.2. Magnitude of residues in livestock

Not relevant.
## B.3. Consumer risk assessment

| ARfD | 0.5 mg/kg bw (EFSA, 2017) |
|------|--------------------------|
| Highest IESTI, according to EFSA PRIMo | Other small fruit and berries (whole group): up to 3.9% of ARfD (currants, DE child)  
Escaroles: 175% (NL child)  
Lettuce: 54% of ARfD (NL child)  
Lamb's lettuce: 5.6% of ARfD (BE child)  
Cress: 0.6% (UK 4–6 years old)  
Roman rocket/rucola: 6.2% of ARfD (DE child)  
Purslanes: 30.2% of ARfD (DE child)  
Beans without pods: 0.1% of ARfD (UK toddler)  
Peas without pods: 0.1% of ARfD (UK infant)  
Peas with pods: 0.6% of ARfD (UK 4–6 years old)  
Pulses (whole group): up to 0.5% of ARfD (dry beans; UK infant) |
| Assumptions made for the calculations | The calculation is based on the highest residue levels expected in raw agricultural commodities |

| ADI | 0.1 mg/kg bw per day (EFSA, 2017) |
|------|--------------------------|
| Highest IEDI, according to EFSA PRIMo | 5.3% of ADI of which escaroles contributed to 0.2% of ADI (WHO Cluster diet B)  
Highest contribution of crops assessed:  
Other small fruit and berries (whole group): up to 0.07% of ADI (gooseberry, WHO Cluster diet B)  
Lettuce: 1.2% ADI (lettuce, WHO Cluster diet B)  
Escaroles: 0.38% ADI (NL general population)  
Lamb's lettuce: 0.02% ADI (FR all population)  
Cress: 0.02% ADI (NL child)  
Roman rocket/rucola: 0.02% ADI (DE child)  
Other lettuce and other salad plants others: 0.6% of ADI (FR all population)  
Purslanes: 0.02% of ADI  
Beans without pods: below 0.01% of ADI (UK toddler)  
Peas without pods: below 0.01% of ADI (UK infant)  
Peas with pods: 0.06% of ADI (UK 4–6 year)  
Pulses (whole group): up to 0.01% of ADI (beans, UK infant) |
| Assumptions made for the calculations | The calculation is based on the median residue levels derived for raw agricultural commodities, using the input values derived from the Article 12 MRL review (EFSA, 2014a), from Article 10 (EFSA, 2016), CXL (FAO, 2015) and derived in the present evaluation (see input values in Appendix D.2) |
## B.4. Recommended MRLs

| Code\(^{(a)}\) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|----------------|-----------|-------------------------|-------------------------|-----------------------|
| 0154000        | Other small fruits and berries (whole group) | 0.01* – 2 | 3 | The submitted data are sufficient to derive a MRL proposal for the NEU/SEU use. Risk for consumers unlikely |
| 0251010        | Lamb's lettuce | 0.01* | 15 | The submitted data are considered sufficient to derive a MRL proposal. The MRL proposal reflects the EU indoor use. It relates to all commodities within subgroup 0251000 as applied for, except escaroles. For lettuces and baby leaf crops (including Brassica species), the existing MRL is already 15 mg/kg. Risk for consumers unlikely |
| 0251040        | Cress and other sprouts and shoots | Land cress | 0.01* | 15 | The submitted data are considered sufficient to derive a MRL proposal. The MRL proposal reflects the EU indoor use. It relates to all commodities within subgroup 0251000 as applied for, except escaroles. For lettuces and baby leaf crops (including Brassica species), the existing MRL is already 15 mg/kg. Risk for consumers unlikely |
| 0251050        | Roman rocket  | Red mustards | Others | 0.01* | 15 | The submitted data are considered sufficient to derive a MRL proposal. The MRL proposal reflects the EU indoor use. It relates to all commodities within subgroup 0251000 as applied for, except escaroles. For lettuces and baby leaf crops (including Brassica species), the existing MRL is already 15 mg/kg. Risk for consumers unlikely |
| 0251070        | Escaroles | 15 | Further risk management considerations required | The indoor use on escarole is supported by seven trials on open variety lettuce. The short-term exposure exceeded the recently derived ARfD. The lowering of the existing MRL set at the level of 15 mg/kg or other risk management options should be considered |
| 0251090        | Purslanes | 0.01* | 15 | The submitted data are sufficient to derive a MRL proposal for the EU indoor use. Risk for consumers unlikely |
| 0260020        | Beans (without pods) | 0.01* | 0.09 | The MRL proposal reflects the more critical residue situation of the SEU use. Risk for consumers unlikely |
| 0260030        | Peas (with pods) | 0.01* | 1.5 | The MRL proposal reflects the more critical residue situation of the SEU use. Risk for consumers unlikely |
| 0260040        | Peas (without pods) | 0.01* | 0.09 | The MRL proposal reflects the more critical residue situation of the SEU use. Risk for consumers unlikely |
| 0300000        | Pulses (whole group) | 0.01* | 0.2 | The MRL proposal reflects the SEU use. Risk for consumers unlikely |

NEU: northern Europe; SEU: southern Europe; MRL: maximum residue level; ARfD: acute reference dose.

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).

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

(F): Fat soluble.

(R) = The residue definition differs for the following combinations pesticide-code number: Trioxystrobin code 100000 except 1040000: the sum of trifloxystrobin and its metabolite \((E, E)\)-methoxyimino- \[2\{1-(3-trifluoromethyl-phenyl)-ethylideneamino-oxymethyl\}-phenyl\]-acetic acid (CGA 321113).

(A) = The EU reference labs identified the reference standard for CGA321113 as commercially not available. When re-viewing the MRL, the Commission will take into account the commercial availability of the reference standard referred to in the first sentence by 23 July 2016, or, if that reference standard is not commercially available by that date, the unavailability of it.
# Appendix C – Pesticide Residue Intake Model (PRIMO)

## Trifloxystrobin

| Toxicological end points | LOQ (mg/kg bw) | Proposed LOQ |
|--------------------------|----------------|--------------|
| ADI (mg/kg bw per day)   | 0.1            | 0.5          |
| Source of ADI            | EU             | EFSA         |
| Year of evaluation       | 2003           | 2017         |

### Status of the active substance: Approved Code no.

- LOQ (mg/kg bw): Proposed LOQ
- ADI (mg/kg bw): 0.1
- ARfD (mg/kg bw): 0.5
- Source of ADI: EU
- Source of ARfD: EFSA
- Year of evaluation: 2003
- Year of evaluation: 2017

### Chronic risk assessment – refined calculations

| Commodity/group of commodities | TMDI (range) in % of ADI |
|-------------------------------|--------------------------|
|                               | minimum – maximum        |

| No of diets exceeding ADI   | Commodity/group of commodities |
|-----------------------------|--------------------------------|
|                             |                               |

### Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

For processed commodities, no exceedance of the ARfD/ADI was identified.

The estimated short term intake (ESTI 1) exceeded the ARfD/ADI for 1 commodities.

Also, the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 1 commodities.

Conclusion:

For Trifloxystrobin, IESTI 1 and IESTI 2 were calculated for food commodities for which pMRLs were submitted and for which consumption data are available.

The estimated short term intake (ESTI 1) exceeded the ARfD/ADI for 1 commodities.

Also, the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 1 commodities.

For processed commodities, no exceedance of the ARfD/ADI was identified.

| No of commodities for which ARfD/ADI is exceeded (ESTI 1): | No of commodities for which ARfD/ADI is exceeded (ESTI 2): |
|------------------------------------------------------------|------------------------------------------------------------|
| IESTI 1 | 1 | IESTI 2 | 1 |
| ***) | **) | ***) | **) |
| Highest % of ARfD/ADI Commodities | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodities | pTMRL/ threshold MRL (mg/kg) |
| 174.9 Scarole (broad-leaf) | 10/- | 174.9 Scarole (broad-leaf) | 10/- |
| 53.8 Lettuce | 10/- | 32.3 Lettuce | 10/- |
| 30.2 Purslane | 10/- | 22.9 Purslane | 10/- |
| 6.2 Rocket, Rucola | 10/- | 6.2 Rocket, Rucola | 10/- |
| 5.8 Lamb’s lettuce | 10/- | 5.6 Lamb’s lettuce | 10/- |

| No of critical MRLs (ESTI 1): 1 |

| No of critical MRLs (ESTI 2): 1 |

| No of commodities for which ARfD/ADI is exceeded: --- |

| No of commodities for which ARfD/ADI is exceeded: --- |

| Highest % of ARfD/ADI Commodity | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodity | pTMRL/ threshold MRL (mg/kg) |
|---------------------------------|-----------------------------|---------------------------------|-----------------------------|
| 14.5 Grape juice | 2.2/- | 1.7 Wine | 2.2/- |
| 6.6 Peach juice | 1.9/- | 0.8 Peach preserved with syrup | 1.9/- |
| 5.3 Plum juice | 1.9/- | 0.6 Apple juice | 0.44/- |
| 4.5 Apple juice | 0.44/- | 0.5 Orange juice | 0.23/- |
| 3.5 Passion fruit juice | 2.28/- | 0.2 Tomato (preserved- fresh) | 0.49/- |

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARD is exceeded for more than 5 commodities, all IESTI values > 90% of ARD are reported.

**) pTMRL: provisional temporary MRL.

***) pTMRL: provisional temporary MRL for unprocessed commodity.
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                |
| Barley straw           | 1.33 STMR             | 2.88 HR                |
| Beet fodder            | 0.08 STMR             | 0.44 HR                |
| Sugar beet tops        | 0.08 STMR             | 0.44 HR                |
| Head cabbage leaves    | 0.05 STMR             | 0.31 HR                |
| Kale leaves (forage)   | 1.32 STMR             | 1.20 HR                |
| Oat straw              | 1.33 STMR             | 2.88 HR                |
| Rye straw              | 1.92 STMR             | 4.80 HR                |
| Triticale straw        | 1.92 STMR             | 4.00 HR                |
| Wheat straw            | 1.92 STMR             | 4.80 HR                |
| Carrot culls           | 0.04 STMR             | 0.02 HR                |
| Swede roots            | 0.04 STMR             | 0.04 HR                |
| Turnip roots           | 0.04 STMR             | 0.04 HR                |
| Barley grain           | 0.06 STMR             |                        |
| Oat grain              | 0.06 STMR             |                        |
| Pea, bean seed (dry)  | 0.04 STMR             |                        |
| Rye grain              | 0.03 STMR             |                        |
| Soya bean              | 0.01 STMR(b)          |                        |
| Triticale grain        | 0.03 STMR             |                        |
| Wheat grain            | 0.03 STMR             |                        |
| Apple pomace, wet      | 1.02 STMR × PF(a)     |                        |
| Sugar beet dried pulp  | 0.36 STMR × PF(a)     |                        |
| Sugar beet ensiled pulp| 0.06 STMR × PF(a)     |                        |
| Sugar beet molasses    | 0.56 STMR × PF(a)     |                        |
| Brewer’s grain dried   | 0.20 STMR × PF(a)     |                        |
| Distiller’s grain dried| 0.10 STMR × PF(a)     |                        |
| Soya bean meal         | 0.01 STMR(b) × PF(a)  |                        |
| Soya bean hulls        | 0.13 STMR(b) × PF(a)  |                        |
| Wheat gluten meal      | 0.05 STMR × PF(a)     |                        |
| Wheat milled by-products| 0.21 STMR × PF(a) |                        |

Risk assessment residue definition: Sum of trioxystrobin and its metabolite CGA 321113

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.

(a): For fruit pomace, dried pulp, ensiled pulp, molasses, dried grain, soya bean meal and hull, wheat meal, and cereal bran, in the absence of processing factors supported by data, default processing factors of 5, 18, 3, 28, 3.3, 1.3, 13, 1.8, and 7 were, respectively, included in the calculation to consider the potential concentration of residues in these commodities.

(b): FAO (2015).

D.2. Consumer risk assessment

| Commodity                                           | Chronic risk assessment | Acute risk assessment |
|-----------------------------------------------------|-------------------------|-----------------------|
|                                                     | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Other small fruits and berries (all commodities     | 0.33 STMR, current      | 2.11 HR               |
| within whole group)                                 | assessment              |                       |
| Lettuces and salad plants (whole group)             | 3.24 STMR, current      | 10 HR                 |
|                                                     | assessment              |                       |
| Commodity                          | Chronic risk assessment | Acute risk assessment |
|-----------------------------------|-------------------------|-----------------------|
|                                   | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment                      |
| Purslanes                         | 2.85                    | STMR, current assessment | 10                | HR                           |
| Beans without pod, peas without pod | 0.03                    | STMR, current assessment | 0.07              | HR                           |
| Peas with pods                    | 0.26                    | STMR, current assessment | 0.84              | HR                           |
| Pulses (all commodities within whole group) | 0.04                    | STMR, current assessment | 0.04              | STMR, current assessment     |
| Olives for oil production         | 0.06                    | STMR, based on CXL     |                   | Acute risk assessment only for the crops under consideration |
| Soya beans                        | 0.01                    | STMR, based on CXL     |                   |                              |
| Celeriac                          | 0.04                    | STMR, EFSA (2016)      |                   |                              |
| All other commodities             | See EFSA (2014a)         |                       |                   |                              |

STMR: supervised trials median residue; HR: highest residue; CXL: Codex maximum residue limit.
# Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | Chemical name/SMILES notation | Structural formula |
|-------------------------------|-------------------------------|-------------------|
| **Trifloxystrobin**           | methyl (E)-methoxyimino- ((E)-α-[1-(α,α,α-trifluoro-m-toly]ethylideneaminoxy]-α-toly) acetate | ![Structural formula](image) |
| **CGA 357261**               | methyl (2E)-(methoxyimino)[2-((Z)-1-[3-(trifluoromethyl)phenyl]ethylideneaminoxy]-methyl)phenyl]acetate | ![Structural formula](image) |
| **CGA 357262**               | methyl (2Z)-(methoxyimino)[2-((Z)-1-[3-(trifluoromethyl)phenyl]ethylideneaminoxy]-methyl)phenyl]acetate | ![Structural formula](image) |
| **CGA 331409**              | methyl (2Z)-(methoxyimino)[2-((E)-1-[3-(trifluoromethyl)phenyl]ethylideneaminoxy]-methyl)phenyl]acetate | ![Structural formula](image) |
| **CGA 321113 M5**           | (2E)-(methoxyimino)[2-((E)-1-[3-(trifluoromethyl)phenyl]ethylideneaminoxy]-methyl)phenyl]acetic acid | ![Structural formula](image) |
| **CGA 373466**              | (2E)-(methoxyimino)[2-((Z)-1-[3-(trifluoromethyl)phenyl]ethylideneaminoxy]-methyl)phenyl]acetic acid | ![Structural formula](image) |

SMILES: simplified molecular-input line-entry system.
(a): (ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).