Modification of the existing maximum residue level for trifloxystrobin in broccoli

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Bayer Hellas AG submitted a request to the competent national authority in Greece to modify the existing maximum residue level (MRL) for the active substance trifloxystrobin in broccoli. The data submitted in support of the request were found to be sufficient to derive an MRL proposal for broccoli. Adequate analytical methods for enforcement are available to control the residues of trifloxystrobin on the commodity under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. EFSA performed a tentative risk assessment in which the calculated exposure to residues of trifloxystrobin and one of its metabolites CGA 321113 did not exceed the toxicological reference values derived for trifloxystrobin. The risk assessment is tentative since the toxicological properties of certain metabolites identified in some metabolism studies are not fully elucidated and data on the occurrence of metabolites CGA 357262, CGA 357261, CGA 331409 in crops for which MRLs were established in the past are not available.

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer Hellas AG submitted an application to the competent national authority in Greece (evaluating Member State (EMS)) to modify the existing maximum residue level (MRL) for the active substance trifloxystrobin in broccoli. The EMS 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 11 July 2018. To accommodate for the intended use of trifloxystrobin, the EMS proposed to raise the existing MRL from 0.5 to 0.6 mg/kg.

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

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

The metabolism of trifloxystrobin following foliar application was investigated in crops belonging to the groups of fruit crops, root crops, leafy crops, cereals, pulses/oilseeds. Besides the parent compound, its isomers (CGA 357262, CGA 357261, CGA 331409) and metabolite CGA 321113 were identified in the metabolism studies in fruits and fruiting vegetables.

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 conversion to CGA 321113 (approximately 20%) occurred.

The occurrence of trifloxystrobin residues in rotational crops was investigated in the framework of the European Union (EU) pesticides peer 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).

Based on the metabolic pattern identified in primary crops, rotational crops and in processing studies, the Article 12 MRL review confirmed the current residue definition for enforcement set in Regulation (EC) No 396/2005 for plant products which covers parent trifloxystrobin only and proposed the residue definition for risk assessment as the ‘sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin’. In the framework of the assessment on the renewal of the approval the residue definition for risk assessment was proposed to be expanded to the ‘sum of trifloxystrobin, its three isomers CGA 357262, CGA 357261, CGA 331409 and its metabolite CGA321113, expressed as trifloxystrobin’. For processed plant products, the risk assessment residue definition was proposed as the ‘sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin’. For the crop assessed under this application, the residue definitions for enforcement and the new residue definitions for risk assessment are applicable. Although data to assess the toxicological profile of the metabolites included in the residue definition for risk assessment (CGA 357262, CGA 357261, CGA 331409 and its metabolite CGA321113) were identified as missing, further confirmatory data were not requested in the framework of the renewal of the approval for trifloxystrobin.

Sufficiently validated analytical methods are available to quantify residues of trifloxystrobin in broccoli at or above the limit of quantification (LOQ) of 0.01 mg/kg.

The available residue trials are sufficient to derive an MRL proposal of 0.6 mg/kg for broccoli. The residue trials submitted in support of the application residues of the metabolites were analysed for the full residue definition for risk assessment; quantifiable residues of CGA321113 were found in almost all trials, the other metabolites were not present in quantifiable concentrations except in two samples where low concentrations of CGA 357262 and CGA 331409 were found.

Residues of trifloxystrobin in commodities of animal origin were not assessed since the crop under consideration in this MRL application is normally not fed to livestock.

The toxicological profile of trifloxystrobin was assessed in the framework of the EU pesticides peer review of the renewal assessment report under Regulation (EC) No 1107/2009 and the data were sufficient to derive an acceptable daily intake (ADI) of 0.1 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.5 mg/kg bw. The toxicological properties of the three isomers of trifloxystrobin and CGA 321113 included in the residue definition for risk assessment for plants, have not been fully addressed in the framework of the peer review and new information has not been provided under the current application.
The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). Due to data gaps related to the toxicological assessment of the three isomers of trifloxystrobin and CGA 321113 and missing information on the occurrence of the metabolites in crops for which MRLs have been established in the past, the consumer risk assessment is tentative only. Assuming that metabolite CGA 321113 has a similar toxicity to parent trifloxystrobin, the calculated short-term and long-term exposure did not exceed the toxicological reference values derived for trifloxystrobin. The estimated tentative long-term dietary intake accounted for up to 5.3% of the ADI for WHO cluster diet B. In the tentative short-term risk assessment, residues in broccoli accounted for 8.3% of the ARfD. The missing information on the residue levels related to the three isomers (CGA 357262, CGA 357261, CGA 331409) and CGA 321113 in crops for which MRLs have been established in the past and the lack of information on the toxicological properties of these compounds are a source of non-standard uncertainty.

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

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

| Code\(^{(a)}\) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---|---|---|---|---|
| 0241010 | Broccoli | 0.5 | Further risk management considerations needed | The submitted data are sufficient to derive a MRL proposal of 0.6 mg/kg for the intended NEU/SEU use. The tentative risk assessment did not reveal potential short-term or long-term consumer health risks. The risk assessment is tentative since the toxicological properties of certain metabolites identified in some metabolism studies are not fully elucidated and data on the occurrence of metabolites CGA 357262, CGA 357261, CGA 331409 in crops for which MRLs were established in the past are not available |

NEU: northern Europe; SEU: southern Europe; MRL: maximum residue level.

\(^{(a)}\): 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 \((E, E)\)-methoxyimino- \(2\-[1-(3\text{-trifluoromethyl-phenyl})\text{-ethylideneamino-oxymethyl}]\text{-phenyl})\)-acetic acid (CGA 321113).
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Assessment

EFSA received an application to modify the existing maximum residue level (MRL) for the active substance trifloxystrobin in broccoli. The detailed description of the intended use of trifloxystrobin in broccoli, which is the basis for the current MRL application, is reported in Appendix A.

Trifloxystrobin is the ISO common name for methyl \((E)-\text{methoxyimino}-\{(E)-\alpha-[1-(\alpha,\alpha,\alpha-\text{trifluoro-}m\text{-}
\text{tolyl})\text{ethylideneaminoxy})-\text{c}-\text{tolyl}\}\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 with the United Kingdom designated as rapporteur Member State (RMS) for the representative uses (foliar applications) on apples, grapes, melons, cucumbers, wheat and barley. Since the draft assessment report (DAR) prepared by the RMS was not peer reviewed by the European Food Safety Authority (EFSA), no EFSA conclusion is available. Trifloxystrobin was approved for the use as a fungicide on 1 October 2003. The process of renewal of the first approval with the United Kingdom designated as rapporteur Member State (RMS) for the representative uses on apple, pear, quince, grapes and strawberry has been completed (EFSA, 2017). Trifloxystrobin renewal was approved on 1 August 2018.

The EU MRLs for trifloxystrobin are established in Annexes II of Regulation (EC) No 396/2005. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2014a) and the proposed modifications have been implemented in the MRL legislation. After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for trifloxystrobin, which have been considered in regulations modifying the EU MRL legislation. A number of Codex maximum residue limits (CXLs) for trifloxystrobin have been taken over in the EU legislation.

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer Hellas AG submitted an application to the competent national authority in Greece (evaluating Member State (EMS)) to modify the existing MRL for the active substance trifloxystrobin in broccoli. The EMS 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 11 July 2018. To accommodate for the intended use of trifloxystrobin, the EMS proposed to raise the existing MRL from 0.5 to 0.6 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS (Greece, 2018), the renewal assessment report (RAR) (and its revision) (United Kingdom, 2016, 2017) prepared under Regulation (EC) 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 on trifloxystrobin including the one on the MRL review (EFSA, 2014a,b, 2016, 2018).

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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 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.
4 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.
5 For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN
6 Commission Regulation (EU) 2016/67 of 19 January 2016 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, chlorothalonil, diphenylamine, flonicamid, flusilazole, flumioxazin, haloxifen, haloxifen-methyl, propamocarb, prothioconazole, thiacloprid and trifloxystrobin in or on certain products. OJ L 15, 22.1.2016, p. 2–50.
7 Commission Regulation (EU) 2017/506 of 4 March 2017 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, cyantraniliprole, cypermethrin, cyprodinil, difenoconazole, ethphon, fluopyram, flutriafol, fluxapyroxad, imazapic, imazapyr, lambda-cyhalothrin, mesotrione, profenofos, propiconazole, pyrimethanil, spirotetramat, tebuconazole, triazophos and trifloxystrobin in or on certain products. OJ L 96, 7.4.2017, p. 1–43.
8 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.
For this application, the data requirements established in Regulation (EU) No 283/2013\(^9\) 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\(^10\).

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

The evaluation report submitted by the EMS (Greece, 2018) 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 MRL review under Article 12 of Regulation (EC) No 396/2005 and the renewal of the approval under Regulation (EC) No 1107/2009 (EFSA, 2014a, 2017), the metabolism of trifloxystrobin following foliar treatment was investigated in primary crops belonging to the groups of fruits 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. Overall, the metabolism of trifloxystrobin was found to be similar in all crops and involves a cis-trans isomerisation of trifloxystrobin (\(E,E\)-isomer) to its \(E,Z\), \(Z,Z\) and \(Z,E\) isomers as well as hydrolysis of the methyl esters of the parent and its isomers to carboxylic acids and a cis-trans isomerisation of the \(E,E\)-carboxylic acid leading to CGA 321113. The three isomers CGA 357262 (\(Z,Z\)-isomer), GA 357261 (\(E,Z\)-isomer), CGA 331409 (\(Z,E\)-isomer) and metabolite CGA321113 were found 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

The crop under consideration may be grown in rotation. As field degradation studies showed that unlike trifloxystrobin (\(DT_{90}\) trifloxystrobin: 0.8–160 days), 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 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).

\(^9\) Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 93, 3.4.2013, p. 1-84.

\(^10\) 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.
1.1.4. Methods of analysis in plants

Analytical methods for the determination of trifloxystrobin residues in plant commodities were assessed during the peer review for the renewal of the approval of the active substance, 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). A multi-residue QuEChERS method using 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 limit of quantification (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).

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

In the framework of the assessment on the renewal of the approval (EFSA, 2017), the residue definition for enforcement for unprocessed products was confirmed as parent ‘trifloxystrobin’, whereas the risk assessment residue definition for unprocessed plant commodities was proposed to be expanded to the ‘sum of trifloxystrobin, its three isomers CGA 357262, CGA 357261, CGA 331409 and its metabolite CGA321113, expressed as trifloxystrobin’. The proposal was based on the metabolism studies, supported by findings in field trials on pome fruits, grapes and strawberries where the three isomers were found in quantifiable concentrations.

For processed products, the peer review proposed the same enforcement residue definition as for unprocessed products; for risk assessment (processed products), the residue definition was proposed as the ‘sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin’.

The new residue definitions derived in the peer review have been noted (European Commission, 2018).11 EFSA concluded that for the crop assessed under this application the previously derived residue definitions for enforcement and the new residue definitions for risk assessment are applicable.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, in total 12 good agricultural practice (GAP)-compliant residue trials on broccoli were provided (6 trials performed in northern Europe (NEU), 6 trials in southern Europe (SEU)). Residue data were presented for the parent compound, its metabolite CGA321113 and the isomers of the parent compound (CGA 357262, CGA 357261, CGA 331409). It was noted that the residue concentrations of CGA 357262, CGA 357261, CGA 331409 were below the LOQ in all trials except two, where low concentrations of CGA 357261 and CGA 331409 were found in broccoli curd.

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, median residue) and the MRL proposals are summarised in Appendix B.1.2.1.

11 It is noted that risk managers decided not to request the toxicological data identified for metabolite CGA321113 and the three isomers CGA 357262, CGA 357261, CGA 331409 as data gaps to be submitted as confirmatory data.
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 framework of the peer review (EFSA, 2017) and the MRL review (EFSA, 2014a). Three rotational field trials in lettuce, turnip, and wheat conducted with 1,128 g/ha (4.5N seasonal application rate) at 30-day plant-back interval were available. Samples were analysed for trifloxystrobin and CGA 321113; all the results were below the LOQ (0.02 mg/kg). Since the maximum annual application rate for the crops under consideration (i.e. 2 × 0.125 kg a.s./ha) is lower than the application rate tested in the rotational crop studies, residues of trifloxystrobin and its metabolite CGA 321113 are not expected to exceed the limit of quantification in rotational crops, provided that trifloxystrobin is applied in compliance with the GAP reported in Appendix A.

1.2.3. Magnitude of residues in processed commodities

Processing data with cooked vegetables are available for broccoli curd, spinach leaves and celery stalk (Greece, 2018); the samples of unprocessed and the processed products were analysed for trifloxystrobin and CGA 321113. An additional study was available with head cabbage, but since residues were < LOQ in the raw agricultural commodity and in the processed commodities, no processing factors were calculated (Greece, 2018).

Indicative processing factors (PF) and conversion factors for risk assessment (CF) for cooked vegetables are reported in B.1.2.3. To derive robust PF, additional studies would be required.

1.2.4. Proposed MRLs

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

2. Residues in livestock

Residues of trifloxystrobin in commodities of animal origin were not assessed since the crop under consideration in this MRL application is normally not fed to livestock.

3. Consumer risk assessment

During the process of renewal of the approval under Regulation (EC) No 1107/2009, the originally set acceptable daily intake (ADI) of 0.1 mg/kg body weight (bw) per day was confirmed; it was also found appropriate to set an acute reference dose (ARfD) of 0.5 mg/kg bw (EFSA, 2017) which was not yet in place when the MRL review was performed. The toxicological reference values have been taken note of (European Commission, 2018). It is noted that EFSA identified data gaps as regards toxicological studies to conclude on the toxicity of the three isomers and CGA 321113. Lacking data on the toxicological properties of the three isomers of trifloxystrobin and CGA 321113, EFSA performed the risk assessment under the assumption that these compounds are of similar toxicity as parent trifloxystrobin. The results of the risk assessment are therefore considered to be tentative only.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. The PRIMo model contains the relevant European food consumption data for different sub-groups of the EU population (EFSA, 2007). The long-term exposure assessment was performed, taking into account the STMR values derived for broccoli, compliant with the residue definition for risk assessment derived in the recently published EFSA conclusion (EFSA, 2017); for the remaining commodities the STMR values derived in the MRL review and the following MRL applications (EFSA, 2014b, 2016, 2018) were selected as input values. For these commodities, the risk assessment was performed with the residue definition derived in the MRL review (i.e. the ‘sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin’). The missing information on the residue levels related to the three isomers (CGA 357262, CGA 357261, CGA 331409) and CGA 321113 in crops for which MRLs have been established in the past and the lack of information on the toxicological properties of these compounds are a source of non-standard uncertainty. The estimated long-term dietary intake accounted for up to 5.3% of the ADI for (WHO cluster diet B). Broccoli was accounted for up to 0.15% of the ADI (FR infant).

An acute dietary intake calculation has been performed for broccoli only, assuming the consumption of a large portion of the food item as reported in the national food surveys which contained residues at the highest residue level (HR) as observed in supervised field trials (Appendix B.1.2.1). Since the
toxicological assessment of CGA 357262, CGA 357261, CGA 331409 and CGA 321113 is pending (EFSA, 2017), also the acute risk assessment is tentative. The calculated maximum short-term (acute) exposure accounted for 8.3% of the ARfD in children and 5.1% in adults.

The complete list of input values is presented in Appendix D.1.

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 this MRL application were found to be sufficient to derive an MRL proposal for broccoli.

EFSA concluded, based on the tentative calculations, that the expected exposure to residues of trifloxystrobin and its metabolite CGA 321113 are not expected to exceed the toxicological reference values derived for trifloxystrobin. However, the risk assessment is tentative since the toxicological properties of certain metabolites identified in some metabolism studies are not fully elucidated and data on the occurrence of metabolites CGA 357262, CGA 357261, CGA 331409 in crops for which MRLs were established in the past are not available. The missing information on the residue levels related to the three isomers (CGA 357262, CGA 357261, CGA 331409) and CGA 321113 in crops for which MRLs have been established in the past and the lack of information on the toxicological properties of these compounds are a source of non-standard uncertainty.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

| Abbreviation | Description |
|--------------|-------------|
| a.s. | active substance |
| 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 |
| 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–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 |
| Acronym | Definition |
|---------|------------|
| 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) |
| RA      | risk assessment |
| RAC     | raw agricultural commodity |
| RAR     | renewal assessment report |
| 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 |
| 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 T | Pests or group of pests controlled | Preparation | Application | Application rate per treatment |
|-----------------------|-------------------------|--------|----------------------------------|-------------|-------------|--------------------------------|
|                       |                         |        |                                  | Type(b) Conc. a.s. Method kind Range of growth stages & season(c) Number min–max Interval between application (min) g a.s./hl min–max Water L/ha min–max Rate Unit | PHI (days)(d) | Remarks |
| **Broccoli**          | NEU                     | F      | Alternaria brassicae/Alternaria brassicola (ALTEBA/ALTEBI) Erysiphe cruciferarum (ERYSCR) Mycosphaerella brassicola (MYCOBR) Leptosphaeria maculans (LEPTMA) | SC 500 Foliar appl. BBCH 41–49 2 14 | 0.016–0.063 | 200–800 0.125–0.125 kg a.s./ha | 14 |
| **Broccoli**          | SEU                     | F      | Alternaria brassicae/Alternaria brassicola (ALTEBA/ALTEBI) Erysiphe cruciferarum (ERYSCR) Mycosphaerella brassicola (MYCOBR) Leptosphaeria maculans (LEPTMA) | SC 500 Foliar appl. BBCH 41–49 2 14 | 0.016–0.063 | 200–800 0.125–0.125 kg a.s./ha | 14 |
Modification of the existing maximum residue level for trifloxystrobin in broccoli

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; 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 × 100 g/ha) | 0, 14          | [trifluoromethyl-phenyl-UL-^{14}C] triflloxystrobin and [glyoxyl-phenyl-UL-^{14}C] triflloxystrobin (EFSA, 2014a) |
|                                  | Cucumber    | Foliar  | (3 × 312 g/ha) | 1, 7           | [trifluoromethyl-phenyl-UL-^{14}C] triflloxystrobin and [glyoxyl-phenyl-UL-^{14}C] triflloxystrobin (EFSA, 2014a) |
| Root crops                        | Sugar beet  | Foliar  | (3 × 130 or 690 g/ha) | 0, 21, 45 | [trifluoromethyl-phenyl-UL-^{14}C] triflloxystrobin and [glyoxyl-phenyl-UL-^{14}C] triflloxystrobin (EFSA, 2014a) |
| Cereals                           | Wheat       | Foliar  | (1 × 500 g/ha) | 49             | [trifluoromethyl-phenyl-UL-^{14}C] triflloxystrobin and [glyoxyl-phenyl-UL-^{14}C] triflloxystrobin (EFSA, 2014a) |
|                                   |             | Foliar  | (2 × 250 g/ha) | 24, 52         | [trifluoromethyl-phenyl-UL-^{14}C] triflloxystrobin and [glyoxyl-phenyl-UL-^{14}C] triflloxystrobin (EFSA, 2014a) |
|                                   |             | Foliar  | (2 × 250 g/ha) | 3, 32          | [trifluoromethyl-phenyl-UL-^{14}C] triflloxystrobin (EFSA, 2014a) |
| Pulses/oilseeds                   | Peanut      | Foliar  | (4 × 560 g/ha) | 0, 14          | +0 and 14 days after 1st treatment; 14 days after last treatment [trifluoromethyl-phenyl-UL-^{14}C] triflloxystrobin and [glyoxyl-phenyl-UL-^{14}C] triflloxystrobin (EFSA, 2014a) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/source |
|-------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                    | Radish      | 1 × 0.5 kg/a.s./ha; Bare soil, outdoor/field | 31, 120, 365 | EFSA (2014a) |
| Leafy crops                        | Lettuce     | 1 × 0.5 kg/a.s./ha; Bare soil, outdoor/field | 31, 120, 365 | EFSA (2014a) |
| Cereal (small grain)               | Wheat       | 1 × 0.5 kg/a.s./ha; Bare soil, outdoor/field | Spring wheat: 31, 365; Winter wheat: 174 | 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 CGA321113 (EFSA, 2014a) |
| Other processing conditions                     | –       | –                                           |

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) **Sum of trifloxystrobin, its 3 isomers (CGA 357262, CGA 357261 and CGA 331409) and CGA 321113 (M5), expressed as trifloxystrobin (EFSA, 2017)**
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**

Greece (2018); EFSA (2017)

**DAT:** days after treatment; **PBI:** plant-back interval; **HPLC–MS/MS:** high-performance liquid chromatography with tandem mass spectrometry; **QuEChERS:** Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method); **LOQ:** limit of quantification; **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                                      | Comment/source |
|-----------------------------------|-----------------------------------|--------------------|--------|------------------|--------------------------------------------------------|---------------|
|                                   | High water content                | Cucumber           | ≤ −18  | 24 Months        | Trioxystrobin, CGA 321113                               | EFSA (2017)   |
|                                   | Corn, green material              | ≤ −18              | 24     |                  | Trioxystrobin, CGA 321113                               | EFSA (2017)   |
|                                   | Wheat whole plant                 | ≤ −18 ≤ −18        | 24     |                  | Trioxystrobin, CGA 321113                               | EFSA (2017)   |
|                                   | Apple fruit                       | ≤ −18              | 18     |                  | Trioxystrobin                                            | EFSA (2017)   |
|                                   | High oil content                  | Olseed rape seed   | ≤ −18  | 24 Months        | Trioxystrobin, CGA 321113                               | EFSA (2017)   |
|                                   | Peanut nutmeat                    | ≤ −18              | 18.5   | Months           | Trioxystrobin                                            | EFSA (2017)   |
|                                   | High protein content              | Dry bean           | ≤ −18  | 24 Months        | Trioxystrobin, CGA 321113                               | EFSA (2017)   |
|                                   | High starch                       | Rye grain          | ≤ −18  | 24 Months        | Trioxystrobin, CGA 321113                               | EFSA (2017)   |
|                                   | Wheat grain                       | ≤ −18              | 24     |                  | Trioxystrobin, CGA 321113                               | EFSA (2017)   |
|                                   | Potato tuber                      | ≤ −18              | 24     |                  | Trioxystrobin, CGA 321113                               | EFSA (2017)   |
|                                   | Oranges                           | ≤ −18              | 24     |                  | Trioxystrobin, CGA 321113                               | EFSA (2017)   |
|                                   | Grapes                            | ≤ −18              | 24     |                  | Trioxystrobin, CGA 321113                               | EFSA (2017)   |
|                                   | Processed products                | Apple, wet pomace   | ≤ −20  | 18.5 Months      | Trioxystrobin                                            | EFSA (2017)   |
|                                   | Peanut oil                        | ≤ −18              | 18.5   | Months           | Trioxystrobin                                            | EFSA (2017)   |
|                                   | Potato granules/flakes            | ≤ −18              | 18.5   | Months           | Trioxystrobin, CGA 321113                               | EFSA (2017)   |
|                                   | Grape juice                       | ≤ −18              | 18.5   | Months           | Trioxystrobin, CGA 321113                               | EFSA (2017)   |
|                                   | Others                            | Wheat straw        | ≤ −18  | 24 Months        | Trioxystrobin, CGA 321113                               | EFSA (2017)   |
|                                   | Peanut hay                        | ≤ −18              | 18.5   | Months           | Trioxystrobin                                            | 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) |
|-----------|-------------------------|---------------------------------------------------------------|----------------|------------------------|-----------------|-----------------|
| Broccoli  | NEU                     | Mo: < 0.01, 0.014, 0.036, 0.073, 0.15, 0.32 RA: 0.061, 0.056, 0.083, 0.12, 0.22, 0.43 | Residue trials on broccoli (curd) compliant with the GAP | 0.6         | Mo: 0.32             | Mo: 0.05         |
| Broccoli  | SEU                     | Mo: 2 × < 0.01, 0.048, 0.052, 0.065, 0.24 RA: < 0.05, 0.058, 0.095, 0.10, 0.12, 0.33 | Residue trials on broccoli (curd) compliant with the GAP | 0.5         | Mo: 0.24             | Mo: 0.05         |

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment.
(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.
B.1.2.2. Residues in rotational crops

| Question                                                                 | Response | Details                                                                                                                                                                                                 |
|--------------------------------------------------------------------------|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Residues in rotational and succeeding crops expected based on confined  | No       | Based on bare soil rotational crop study (4 N) with lettuce, radish and wheat, significant residues are not expected in rotational crops following the intended uses.                                              |
| rotational crop study?                                                   |          |                                                                                                                                                                                                        |
| Residues in rotational and succeeding crops expected based on field      | No       | Three rotational field trials in lettuce, turnip and wheat conducted with 1,128 g/ha (9N) at 30-day PBI were available (EFSA, 2014a, 2017). They were analysed for trifloxystrobin and CGA 321113. Residues are          |
| rotational crop study?                                                   |          | not expected to be above 0.01 mg/kg in broccoli cultivated as rotational crop.                                                                                                                                 |

B.1.2.3. Processing factors

| Processed commodity          | Number of valid studies\(^{(a)}\) | Processing factor (PF) | \(\text{CF}_P^{(b)}\) | Comment/source |
|------------------------------|-----------------------------------|------------------------|------------------------|---------------|
| Broccoli/cooked curd        | 1                                 | 0.88                   | –                      | 1.04          | Greece (2018) |
| Spinach/cooked leaves       | 1                                 | 0.36                   | –                      | 1.01          | Greece (2018) |
| Celery/cooked stem          | 1                                 | 0.017                  | –                      | 1.01          | Greece (2018) |

\(^{(a)}\): 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 of the individual conversion factors for each processing residues trial.

B.2. Residues in livestock

Not relevant since the crop under consideration is not fed to livestock.
### B.3. Consumer risk assessment

| **ARfD** | 0.5 mg/kg bw (EFSA, 2017) |
| --- | --- |
| **Highest IESTI, according to EFSA PRIMo** | Broccoli: 8.3% of ARfD children, 5.1% of ARfD adults |
| **Assumptions made for the calculations** | The calculation is based on the highest residue levels expected in raw agricultural commodities (residue definition: Sum of trifloxystrobin, its 3 isomers (CGA 357262, CGA 357261 and CGA 331409) and CGA 321113 (M5), expressed as trifloxystrobin) The tentative risk assessment is based on the assumption that the toxicological properties of the three isomers of trifloxystrobin and CGA 321113 are comparable with the parent compound trifloxystrobin |

| **ADI** | 0.1 mg/kg bw per day (EFSA, 2017) |
| --- | --- |
| **Highest IEDI, according to EFSA PRIMo** | 5.3% ADI (WHO cluster diet B) Contribution of crops assessed: Highest contribution to the diet: 0.24% ADI (FR toddler) |
| **Assumptions made for the calculations** | The calculation is based on the median residue levels derived in the framework of the MRL review under Article 12 (EFSA, 2014a), in MRL applications assessed by EFSA (EFSA, 2016, 2014b, 2018), STMR values derived by JMPR for CXLs that have been taken over in EU MRL legislation (FAO, 2015) and derived in the present evaluation (see input values in Appendix D.1) The tentative long-term exposure assessment was performed, taking into account the STMR values derived for broccoli, compliant with the residue definition for risk assessment derived in the recently published EFSA conclusion (EFSA, 2017); for the remaining commodities the STMR values derived in the MRL review and the following MRL applications (EFSA, 2014b, 2016, 2018) were used as input values (reflecting the residue definition 'sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin'). The assessment is based on the assumption that toxicological properties of the isomers of trifloxystrobin and CGA 321113 are similar to parent trifloxystrobin The missing information on the residue levels related to the three isomers (CGA 357262, CGA 357261, CGA 331409) and CGA 321113 in crops for which MRLs have been established in the past and the lack of information on the toxicological properties of these compounds are a source of non-standard uncertainty |

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.
B.4. **Recommended MRLs**

| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|------------------|-----------|------------------------|-------------------------|------------------------|
| 0241010          | Broccoli  | 0.5                    |                         | Further risk management considerations needed |

**Enforcement residue definition:** trifloxystrobin<sup>(F), (R)</sup>

The submitted data are sufficient to derive a MRL proposal of 0.6 mg/kg for the intended NEU/SEU use. The tentative risk assessment did not reveal potential short-term or long-term consumer health risks. The risk assessment is tentative since the toxicological properties of certain metabolites identified in some metabolism studies are not fully elucidated and data on the occurrence of metabolites CGA 357262, CGA 357261, CGA 331409 in crops for which MRLs were established in the past are not available.

NEU: northern Europe; SEU: southern Europe; MRL: maximum residue level.

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

<sup>(F)</sup> Fat soluble.

<sup>(R)</sup> 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)-methoxyimino- (2-[(1-(3-trifluoromethyl-phenyl)- ethyldeneamino-oxymethyl)-phenyl]-acetic acid (CGA 321113).
Appendix C – Pesticide Residue Intake Model (PRIMO)

Trifloxystrobin

| Status of the active substance: | Approved |
| LOQ (mg/kg b.w.) | Proposed LOQ |
| Toxicological end points |
| ADI (mg/kg b.w. per day) | 0.1 |
| Source of ADI: | EC |
| Year of evaluation: | 2017 |
| ARfD (mg/kg b.w.) | 0.5 |
| Source of ARfD: | EC |
| Year of evaluation: | 2017 |

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity, the highest national MRL was identified (proposed temporary MRL = pTMRL). The pTMRLs have been submitted to EFSA in September 2006.

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Trifloxystrobin is unlikely to present a public health concern.

| Commodity/ group of commodities | TMDI values in % of ADI |
|---------------------------------|------------------------|
|                                | Minimum – maximum      |
|                                |                       |

### Chronic risk assessment – refined calculations

| Commodity/ group of commodities | MS Diet |
|---------------------------------|---------|
|                                 |         |
|                                |         |
|                                |         |
|                                |         |
|                                |         |

| Commodity/ group of commodities | 2nd contributor to MS diet (in % of ADI) |
|---------------------------------|----------------------------------------|
|                                 | Commodity/ group of commodities         |
|                                |                                        |
|                                |                                        |
|                                |                                        |

| Commodity/ group of commodities | 3rd contributor to MS diet (in % of ADI) |
|---------------------------------|----------------------------------------|
|                                 | Commodity/ group of commodities         |
|                                |                                        |
|                                |                                        |
|                                |                                        |

| Commodity/ group of commodities | pTMRLs at LOQ (in % of ADI) |
|---------------------------------|-----------------------------|
|                                 |                            |
|                                |                            |
|                                |                            |

### Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Trifloxystrobin is unlikely to present a public health concern.
**Acute risk assessment/children – refined calculations**

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 calculation, 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.

| Highest % of ARfD/ADI Commodities pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodities pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodities pTMRL/ threshold MRL (mg/kg) |
|--------------------------------|--------------------------------|--------------------------------|
| 5.0 Broccoli 0.43 / - | 3.6 Broccoli 0.43 / - | 1.8 Broccoli 0.43 / - |

**Acute risk assessment/adults/general population – refined calculations**

| Highest % of ARfD/ADI Commodities pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodities pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodities pTMRL/ threshold MRL (mg/kg) |
|--------------------------------|--------------------------------|--------------------------------|
| 5.0 Broccoli 0.43 / - | 3.6 Broccoli 0.43 / - | 1.8 Broccoli 0.43 / - |

**Conclusion:**
For Trifloxystrobin IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

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.

**Acute risk assessment/children – refined calculations**

| No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): | No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): |
|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|
| --- | --- | --- | --- |

| No of commodities for which ARfD/ADI is exceeded (IESTI 2): | No of commodities for which ARfD/ADI is exceeded (IESTI 1): |
|-------------------------------------------------|-------------------------------------------------|
| --- | --- |

**Acute risk assessment/adults/general population – refined calculations**

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

**Conclusion:**
For Trifloxystrobin IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

**Processed commodities**

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.
Appendix D – Input values for the exposure calculations

### D.1. Consumer risk assessment

| Commodity                                      | Chronic risk assessment | Acute risk assessment |
|------------------------------------------------|-------------------------|-----------------------|
|                                                 | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Broccoli                                       | 0.60                    | Proposed MRL, current application | 0.43 | HR (Table B.1.2.1) |
| Other small fruits and berries (all commodities within whole group) | 0.33 | STMR, EFSA (2018) |                   | Acute risk assessment only for the crop under consideration |
| Lettuces and salad plants (whole group)        | 3.24                    | STMR, EFSA (2018)    |                   |                      |
| Purslanes                                      | 2.85                    | STMR, EFSA (2018)    |                   |                      |
| Beans without pod, peas without pod            | 0.03                    | STMR EFSA (2018)     |                   |                      |
| Peas with pods                                 | 0.26                    | STMR, EFSA (2018)    |                   |                      |
| Pulses (all commodities within whole group)   | 0.04                    | STMR, EFSA (2018)    |                   |                      |
| Olives for oil production                      | 0.06                    | STMR, based on CXL   |                   |                      |
| Soya beans                                     | 0.01                    | STMR, based on CXL   |                   |                      |
| Celeriac                                       | 0.04                    | STMR, EFSA (2016)    |                   |                      |
| Cane fruits                                    | 0.62                    | STMR, EFSA (2014b)   |                   |                      |
| All other commodities                          | See EFSA (2014a)        |                      |                   |                      |

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

| Code/trivial name | Chemical name/SMILES notation<sup>(a)</sup> | Structural formula<sup>(b)</sup> |
|-------------------|--------------------------------------------|---------------------------------|
| Trifloxystrobin   | methyl (E)-methoxyimino-((E)-α-[1-α,α,α-trifluoro-m-tolyl]ethylideneaminoxy]-o-toly) acetate | ![Trifloxystrobin](image1) |
|                   | FC(F)(F)c1cccc(c1)C(=NOCc2cccc2C (=N(OC))/C(=O)OC | ![Trifloxystrobin](image2) |
| CGA 357261        | methyl (2E)-(methoxyimino)[2-(([Z]-1-3-[trifluoromethyl]phenyl]ethylidene)amino]oxy)methyl)phenyl]acetate | ![CGA 357261](image3) |
|                   | FC(F)(F)c1ccccc(c1)C(=NOCc2cccc2C (=N(OC))/C(=O)OC | ![CGA 357261](image4) |
| CGA 357262        | methyl (2Z)-(methoxyimino)[2-(([Z]-1-3-[trifluoromethyl]phenyl]ethylidene)amino]oxy)methyl)phenyl]acetate | ![CGA 357262](image5) |
|                   | FC(F)(F)c1ccccc(c1)C(=NOCc2cccc2C (=N(OC))/C(=O)OC | ![CGA 357262](image6) |
| CGA 331409        | methyl (2Z)-(methoxyimino)[2-((E)-1-3-[trifluoromethyl]phenyl]ethylidene)amino]oxy)methyl)phenyl]acetate | ![CGA 331409](image7) |
|                   | FC(F)(F)c1ccccc(c1)C(=NOCc2cccc2C (=N(OC))/C(=O)OC | ![CGA 331409](image8) |
| CGA 321113 M5     | (2E)-(methoxyimino)[2-((E)-1-3-[trifluoromethyl]phenyl]ethylidene)amino]oxy)methyl)phenyl]acetic acid | ![CGA 321113](image9) |
|                   | FC(F)(F)c1ccccc(c1)C(=NOCc2cccc2C (=N(OC))/C(=O)OC | ![CGA 321113](image10) |
| CGA 373466        | (2E)-(methoxyimino)[2-((Z)-1-3-[trifluoromethyl]phenyl]ethylidene)amino]oxy)methyl)phenyl]acetic acid | ![CGA 373466](image11) |
|                   | FC(F)(F)c1ccccc(c1)C(=NOCc2cccc2C (=N(OC))/C(=O)OC | ![CGA 373466](image12) |

**SMILES:** simplified molecular-input line-entry system.

<sup>(a)</sup>: ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).
<sup>(b)</sup>: ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).