**REASONED OPINION**

# Reasoned Opinion on the review of the existing maximum residue levels (MRLs) for trifloxystrobin according to Article 12 of Regulation (EC) No 396/2005[1]

**European Food Safety Authority**[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

## ABSTRACT

According to Article 12 of Regulation (EC) No 396/2005, the European Food Safety Authority (EFSA) has reviewed the Maximum Residue Levels (MRLs) currently established at European level for the pesticide active substance trifloxystrobin. In order to assess the occurrence of trifloxystrobin residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission as well as the import tolerances and European authorisations reported by Member States (incl. the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was found to be missing. Hence, the consumer risk assessment is considered indicative only and some MRL proposals derived by EFSA still require further consideration by risk managers.

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## KEY WORDS

trifloxystrobin, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, strobilurins, fungicide

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## SUMMARY

Trifloxystrobin was included in Annex I to Directive 91/414/EEC on 01 October 2003, which is before the entry into force of Regulation (EC) No 396/2005 on 02 September 2008. EFSA is therefore required to provide a reasoned opinion on the review of the existing MRLs for that active substance in compliance with Article 12(2) of the aforementioned regulation. In order to collect the relevant pesticide residues data, EFSA asked United Kingdom, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile). The requested information was submitted to EFSA on 21 July 2011 and, after having considered several comments made by EFSA, the RMS provided on 02 November 2012 a revised PROFile.

Based on the conclusions derived in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission and the additional information provided by the RMS, EFSA issued on 20 August 2013 a draft reasoned opinion that was circulated to Member States' experts for consultation. Comments received by 18 October 2013 were considered in the finalisation of this reasoned opinion. The following conclusions are derived.

The toxicological profile of trifloxystrobin was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI being established at 0.1 mg/kg bw per d. An ARfD was not deemed necessary.

Primary crop metabolism of trifloxystrobin was investigated in three different crop groups following foliar applications. Based on these studies, EFSA proposes to define the residue for enforcement in all plant commodities as parent trifloxystrobin while for risk assessment the relevant residue is defined as the sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin. Validated analytical methods for enforcement of this residue definition are available with an LOQ of 0.01 mg/kg.

Regarding the magnitude of residues in primary crops, at least one GAP is fully supported by data for most of the crops reported and the available residue data were considered acceptable to derive MRL proposals as well as risk assessment, except for cherry, apricot, peach, currants, gooseberries, passion fruit, pepper, cucurbits with edible peel, leafy brassica, scarole, herbs, beans (fresh, with pods), leek, barley and oats where additional data are required (residue trials compliant with GAP) and only tentative MRLs are derived. For blackberries, raspberries, pumpkins, witloof, peas (fresh, with pods), olives for oil production and chicory roots, the available data were insufficient to derive tentative MRLs.

The hydrolysis studies demonstrated that under pasteurisation, baking/boiling/brewing and sterilisation conditions, trifloxystrobin remained stable in processed commodities. Consequently, the residue definitions proposed for enforcement and risk assessment of raw commodities also apply to processed commodities. Studies investigating the magnitude of residues in processed commodities of apple and wines were also reported. As data on trifloxystrobin and CGA 321113 residue levels in raw and processed commodities were not reported, it was not possible to derive processing factors according to the proposed residue definitions.

The potential incorporation of soil residues into succeeding and rotational crops was investigated in lettuce, radish and wheat during the peer review and the residue definition set for the primary crops also applies to the rotational crops. Trifloxystrobin residue levels are also not expected to exceed 0.01 mg/kg in rotational commodities, provided that trifloxystrobin is applied in compliance with the GAPs reported in Appendix A.

Based on the uses reported by the RMS, significant intakes were calculated for ruminants, poultry and pigs. Metabolism in lactating ruminants and poultry was sufficiently investigated and findings in ruminants can be extrapolated to pigs. The relevant residue definition for enforcement in all commodities of animal origin was defined as sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin. For risk assessment, the residue definition is the same, except in ruminant liver and

kidney, where EFSA proposes to define the residue as the sum of trifloxystrobin, CGA321113 and its conjugates, expressed as trifloxystrobin. Fully validated analytical methods for enforcement of the residue definition are not available and they are therefore still required. Feeding studies also allowed to derive MRLs in ruminants and pigs. Considering however that no fully validated analytical method is available, these MRLs are tentative.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure represented 5.9 % of the ADI (WHO Cluster diet B). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for trifloxystrobin. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out. The highest chronic exposure represented 6.1 % of the ADI (WHO Cluster diet B).

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D of the reasoned opinion (see summary table). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see summary table footnotes for details). In particular, some tentative MRLs and existing EU MRLs need to be confirmed by the following data:

- an analytical method fully validated and its ILV for the determination of trifloxystrobin and its metabolite CGA 321113 in animal commodities;
- 4 residue trials on raspberry complying with the northern GAP on blackberry and raspberry;
- 6 residue trials on currants complying with the northern GAP on currants and gooseberries and including results in accordance with the residue definition for risk assessment;
- 4 residue trials complying with the import tolerance on passion fruit;
- 8 trials complying with the southern GAP and 3 additional trials complying with the indoor GAP on pepper;
- 8 residue trials on cucumbers complying with the northern GAP on cucurbits with edible peel and 8 residue trials complying with the indoor GAP on cucumber;
- 2 additional trials on kale complying with the northern GAP on leafy brassica, including residue data in accordance with the residue definition for risk assessment;
- 4 trials on lettuce (open leaves variety) complying with the indoor GAP and 4 trials on lettuce (open leaves variety) complying with the northern GAP on scarole and herbs;
- 4 residue trials complying with the northern GAP on witloof;
- 8 trials complying with the indoor GAP and 6 additional trials complying with the northern GAP on beans (fresh, with pods) (including residue data in accordance with the residue definition for risk assessment);
- 8 residue trials complying with the indoor GAP on peas (fresh, with pods);
- 8 residue trials complying with the southern GAP on olives for oil production;
- 8 residue trials complying with the northern GAP on oats;
- 4 residue trials complying with the northern GAP on chicory roots.

It is highlighted, however, that some of the MRLs derived result from a CXL or from a GAP in one climatic zone only, while other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gaps which are not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- 7 additional residue trials (with a minimum of 4 trials on apricots) complying with the northern outdoor GAP on apricot and peaches and 8 residue trials (with a minimum of 4 trials on apricots) complying with the southern outdoor GAP on apricot and peaches;
- 8 residue trials on cherries complying with the northern GAP, 1 additional trial on cherries complying with the southern GAP and 4 residue trials on cherries complying with the indoor GAP;
- 8 residue trials on grapes complying with the indoor GAP;
- 6 additional residue trials on strawberries complying with the northern GAP and 8 trials complying with the southern GAP;
- 8 residue trials complying with the southern GAP on tomato;
- 4 additional residue trials complying with the southern GAP on courgettes;
- 8 residue trials complying with the northern GAP on melons;
- 4 residue trials complying with the northern GAP and 4 residue trials complying with the indoor GAP on pumpkin;
- 2 additional residue trials complying with the southern GAP on watermelon;
- 8 residue trials complying with the northern GAP and 6 additional residue trials complying with the southern GAP on leek (including residue data in accordance with the residue definition for risk assessment);
- 2 additional residue trials on wheat complying with the southern GAP on wheat and rye;
- 2 additional residue trials complying with the southern GAP on barley;
- 4 residue trials complying with the northern GAP on grass.

If the above reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

Minor deficiencies were also identified in the assessment but these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data are therefore considered desirable but not essential:

- data on the toxicological relevance and magnitude of the compound SA04271 in cereal grain;
- a detailed evaluation report of the latest storage stability studies as well as the storage conditions of the residues trials samples for which storage conditions were not yet reported;
- 1 additional residue trial on plum complying with the northern GAP;
- 1 additional residue trial on melon complying with the southern GAP;
- 1 additional residue trial on barley supporting the northern GAP;
- 1 additional residue trial on wheat complying with the northern GAP on wheat and rye;
- information on the storage conditions of the samples from livestock feeding studies.

**SUMMARY TABLE**

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | |
|---|---|---|---|---|---|
| | | | | MRL (mg/kg) | Comment |
| **Enforcement residue definition :** trifloxystrobin | | | | | |
| 110000 | Citrus fruit | 0.3 | 0.5 | 0.5 | Recommended [(a)] |
| 120000 | Tree nuts | 0.02* | 0.02* | 0.02 | Recommended [(a)] |
| 130000 | Pome fruit | 0.5 | 0.7 | 0.7 | Recommended [(b)] |
| 140010 | Apricots | 1 | 3 | 3 | Recommended [(c)] |
| 140020 | Cherries | 1 | 3 | 3 | Recommended [(c)] |
| 140030 | Peaches | 1 | 3 | 3 | Recommended [(c)] |
| 140040 | Plums | 0.2 | 3 | 3 | Recommended [(b)] |

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | |
|---|---|---|---|---|---|
| | | | | MRL (mg/kg) | Comment |
| 151000 | Table and wine grapes | 5 | 3 | 3 | Recommended [b] |
| 152000 | Strawberries | 0.5 | 1 | 1 | Recommended [b] |
| 153010 | Blackberries | 0.02* | - | 0.02 | Further consideration needed [d] |
| 153030 | Raspberries | 0.02* | - | 0.02 | Further consideration needed [d] |
| 154010 | Blueberries | 2 | - | 2 | Recommended [e] |
| 154030 | Currants (red, black and white) | 1 | - | 1.5 | Further consideration needed [f] |
| 154040 | Gooseberries | 1 | - | 1.5 | Further consideration needed [f] |
| 1610030 | Table olives | 0.3 | 0.3 | 0.3 | Recommended [b] |
| 162030 | Passion fruit | 4 | - | 4 | Further consideration needed [f] |
| 163020 | Bananas | 0.05 | 0.05 | 0.05 | Recommended [b] |
| 162030 | Papaya | 1 | 0.6 | 0.6 | Recommended [a] |
| 211000 | Potatoes | 0.02* | 0.02* | 0.02 | Recommended [a] |
| 213010 | Beetroot | 0.02* | - | 0.02 | Recommended [e] |
| 213020 | Carrots | 0.05 | 0.1 | 0.1 | Recommended [b] |
| 213030 | Celeriac | 0.02* | - | 0.02 | Recommended [e] |
| 213040 | Horseradish | 0.02* | - | 0.08 | Recommended [e] |
| 213060 | Parsnips | 0.04 | - | 0.04 | Recommended [e] |
| 213070 | Parsley root | 0.04 | - | 0.08 | Recommended [e] |
| 213080 | Radishes | 0.02* | 0.08 | 0.08 | Recommended [a] |
| 213090 | Salsify | 0.04 | - | 0.04 | Recommended [e] |
| 213100 | Swedes | 0.04 | - | 0.04 | Recommended [e] |
| 213110 | Turnips | 0.04 | - | 0.04 | Recommended [e] |
| 220010 | Garlic | 0.02* | - | 0.01* | Recommended [e] |
| 220020 | Onions | 0.02* | - | 0.01* | Recommended [e] |
| 231010 | Tomatoes | 0.5 | 0.7 | 0.7 | Recommended [b] |
| 231020 | Peppers | 0.3 | 0.3 | 0.4 | Further consideration needed [g] |
| 231030 | Aubergines (egg plants) | 0.3 | 0.7 | 0.7 | Recommended [b] |
| 232010 | Cucumbers | 0.2 | 0.3 | 0.3 | Further consideration needed [g] |
| 232020 | Gherkins | 0.2 | 0.3 | 0.3 | Further consideration needed [g] |
| 232030 | Courgettes | 0.2 | 0.3 | 0.3 | Recommended [c] |
| 233010 | Melons | 0.3 | 0.3 | 0.3 | Recommended [b] |
| 233020 | Pumpkins | 0.2 | 0.3 | 0.3 | Recommended [h] |
| 233030 | Watermelons | 0.2 | 0.3 | 0.3 | Recommended [b] |
| 241000 | Flowering brassica | 0.05 | 0.5 | 0.5 | Recommended [b] |
| 242010 | Brussels sprouts | 0.5 | 0.1 | 0.6 | Recommended [i] |
| 242020 | Head cabbage | 0.3 | 0.5 | 0.5 | Recommended [b] |

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | |
|---|---|---|---|---|---|
| | | | | MRL (mg/kg) | Comment |
| 243000 | Leafy brassica | 3 | - | 3 | Further consideration needed [f] |
| 251020 | Lettuce | 10 | - | 15 | Recommended [e] |
| 251030 | Scarole (broad-leaf endive) | 10 | - | 15 | Further consideration needed [f] |
| 251080 | Leaves and sprouts of Brassica spp | 0.02* | 15 | 15 | Recommended [a] |
| 255000 | Witloof | 0.02* | - | 0.02 | Further consideration needed [d] |
| 256000 | Herbs | 10 | - | 15 | Further consideration needed [f] |
| 260010 | Beans (fresh, with pods) | 0.5 | - | 1 | Further consideration needed [f] |
| 260030 | Peas (fresh, with pods) | 0.02* | - | 0.02 | Further consideration needed [d] |
| 270010 | Asparagus | 0.02* | 0.05* | 0.05 | Recommended [a] |
| 270030 | Celery | 1 | 1 | 1 | Recommended [b] |
| 270050 | Globe artichokes | 0.2 | - | 0.3 | Recommended [e] |
| 270060 | Leek | 0.2 | 0.7 | 0.7 | Recommended [c] |
| 401020 | Peanuts | 0.05* | 0.02* | 0.02 | Recommended [a] |
| 402010 | Olives for oil production | 0.3 | - | 0.3 | Further consideration needed [d] |
| 500010 | Barley grain | 0.3 | 0.5 | 0.5 | Recommended [c] |
| 500030 | Maize grain | 0.02* | 0.02* | 0.02 | Recommended [a] |
| 500050 | Oats grain | 0.02* | - | 0.4 | Further consideration needed [f] |
| 500060 | Rice grain | 0.02* | 5 | 5 | Recommended [a] |
| 500070 | Rye grain | 0.05 | - | 0.3 | Recommended [e] |
| 500090 | Wheat grain | 0.05 | 0.2 | 0.3 | Recommended [i] |
| 700000 | Hops (dried), including hop pellets and unconcentrated powder | 30 | 40 | 40 | Recommended [i] |
| 900010 | Sugar beet (root) | 0.05 | - | 0.02 | Recommended [e] |
| 900030 | Chicory roots | 0.02* | - | 0.02 | Further consideration needed [d] |
| - | Other products of plant origin | See App. C.1 | - | - | Further consideration needed [j] |
| **Enforcement residue definition:** sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin. | | | | | |
| 1011010 | Swine muscle | 0.04* | 0.05 | 0.04 | Further consideration needed [g] |
| 1011020 | Swine fat (free of lean meat) | 0.04* | 0.05 | 0.04 | Further consideration needed [g] |
| 1011030 | Swine liver | 0.04* | 0.05 | 0.04 | Further consideration needed [g] |
| 1011040 | Swine kidney | 0.04* | 0.04* | 0.04 | Further consideration needed [g] |
| 1012010 | Bovine muscle | 0.04* | 0.05 | 0.04 | Further consideration needed [g] |
| 1012020 | Bovine fat | 0.04* | 0.05 | 0.06 | Further consideration needed [g] |
| 1012030 | Bovine liver | 0.04* | 0.05 | 0.07 | Further consideration needed [g] |

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | |
|---|---|---|---|---|---|
| | | | | MRL (mg/kg) | Comment |
| 1012040 | Bovine kidney | 0.04* | 0.04* | 0.04 | Further consideration needed [g] |
| 1013010 | Sheep muscle | 0.04* | 0.05 | 0.04 | Further consideration needed [g] |
| 1013020 | Sheep fat | 0.04* | 0.05 | 0.06 | Further consideration needed [g] |
| 1013030 | Sheep liver | 0.04* | 0.05 | 0.07 | Further consideration needed [g] |
| 1013040 | Sheep kidney | 0.04* | 0.04* | 0.04 | Further consideration needed [g] |
| 1014010 | Goat muscle | 0.04* | 0.05 | 0.04 | Further consideration needed [g] |
| 1014020 | Goat fat | 0.04* | 0.05 | 0.06 | Further consideration needed [g] |
| 1014030 | Goat liver | 0.04* | 0.05 | 0.07 | Further consideration needed [g] |
| 1014040 | Goat kidney | 0.04* | 0.04* | 0.04 | Further consideration needed [g] |
| 1016010 | Poultry muscle | 0.04* | 0.04* | 0.04 | Further consideration needed [g] |
| 1016020 | Poultry fat | 0.04* | 0.05 | 0.04 | Further consideration needed [g] |
| 1016030 | Poultry liver | 0.04* | 0.04* | 0.04 | Further consideration needed [g] |
| 1020010 | Cattle milk | 0.02* | 0.02* | 0.02 | Further consideration needed [g] |
| 1020020 | Sheep milk | 0.02* | 0.02* | 0.02 | Further consideration needed [g] |
| 1020030 | Goat milk | 0.02* | 0.02* | 0.02 | Further consideration needed [g] |
| 1030000 | Birds' eggs | 0.04* | 0.04* | 0.04 | Further consideration needed [g] |
| - | Other product of animal origin | See App. C.1 | - | - | Further consideration needed [j] |

(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix D).
(b): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination G-VII in Appendix D).
(c): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower tentative MRL (combination E-VII in Appendix D).
(d): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL; no CXL is available (combination C-I in Appendix D).
(e): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).
(f): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available (combination E-I in Appendix D).
(g): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; existing CXL is covered by the tentative MRL (combination E-III in Appendix D).
(h): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level is not supported by data but the existing EU MRL is lower than the existing CXL (combination C-VII in Appendix D).
(i): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination G-III in Appendix D).
(j): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).

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## BACKGROUND

Regulation (EC) No 396/2005[4] establishes the rules governing the setting and the review of pesticide MRLs at European level. Article 12(2) of that regulation stipulates that EFSA shall provide by 01 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC[5] before 02 September 2008. As trifloxystrobin was included in Annex I to the above mentioned directive on 01 October 2003, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2008-644 was included in the EFSA Register of Questions.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC. It should be noted, however, that in the framework of Directive 91/414/EEC only a few representative uses are evaluated, while MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the EU, and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Directive 91/414/EEC is therefore insufficient for the assessment of all existing MRLs for a given active substance.

In order to gain an overview of the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residues Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities;
- the analytical methods for enforcement of the proposed MRLs.

United Kingdom, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for trifloxystrobin. The requested information was submitted to EFSA on 21 July 2011 and subsequently checked for completeness. On 02 November 2012, after having clarified some issues with EFSA, the RMS provided a revised PROFile.

A draft reasoned opinion was issued by EFSA on 20 August 2013 and submitted to Member States (MS) for commenting. All MS comments received by 18 October 2013 were considered by EFSA in the finalisation of the reasoned opinion.

## TERMS OF REFERENCE

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;

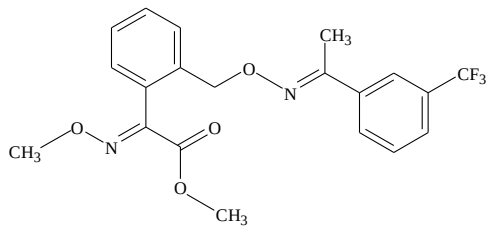
[4] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1-16.

[5] 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.

- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

## THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Trifloxystrobin is the ISO common name for methyl (*E*)-methoxyimino-{(*E*)-α-[1-(α,α,α-trifluoro-*m*-tolyl)ethylideneaminooxy]-*o*-tolyl}acetate (IUPAC).




Trifloxystrobin belongs to the group of strobilurin compounds which are used as fungicide. Trifloxystrobin possesses penetrative properties and is a synthetic derivative of the naturally occurring strobilurins found in several genera of wood decaying fungi such as *Strobilurus tenacellus*. The mode of action of trifloxystrobin involves inhibition of mitochondrial respiration in fungi.

Trifloxystrobin was evaluated in the framework of Directive 91/414/EEC with the United Kingdom being the designated rapporteur Member State (RMS). The representative use supported for the peer review process was the outdoor foliar treatment on cereals, grapes, pome fruits and cucurbits, 35 to 3 days before harvest. Following the peer review, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2003/68/EC[6], which entered into force on 01 October 2003. According to Regulation (EU) No 540/2011[7], trifloxystrobin is deemed to have been approved under Regulation (EC) No 1107/2009[8]. This approval is restricted to uses as fungicide only. As EFSA was not yet involved in the peer review of trifloxystrobin, an EFSA Conclusion on this active substance is not available.

The EU MRLs for trifloxystrobin are established in Annexes II and IIIB of Regulation (EC) No 396/2005. Since the entry into force of that regulation, EFSA recommended the modifications of the existing MRLs for various crops (EFSA, 2008, 2009a, 2009b, 2010, 2011, 2012, 2013a) which were legally implemented in Regulations (EU) No 459/2010[9], 508/2011[10], 813/2011[11], 35/2013[12] and

[6] 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, 16.07.2003, p. 12-16.

[7] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1-186.

[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 309, 24.11.2009, p. 1-50.

[9] Commission Regulation (EU) No 459/2010 of 27 May 2010 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for certain pesticides in or on certain products. OJ L 129, 28.5.2010, p. 3-49.

[10] Commission Regulation (EU) No 508/2011 of 24 May 2011 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 abamectin, acetamiprid, cyprodinil, difenoconazole, dimethomorph, fenhexamid, proquinazid, prothioconazole, pyraclostrobin, spirotetramat, thiacloprid, thiamethoxam and trifloxystrobin in or on certain products. OJ L 137, 25.5.2011, p. 3–52.

[11] Regulation (EU) No 813/2011 of 11 August 2011 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 acequinocyl, emamectin benzoate, ethametsulfuronmethyl, flubendiamide, fludioxonil, kresoxim-methyl, methoxyfenozide, novaluron, thiacloprid and trifloxystrobin in or on certain products. OJ L 208, 13.8.2011, p. 23–79.

[12] Regulation (EU) No 35/2013 of 18 January 2013 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 dimethomorph, indoxacarb, pyraclostrobin and trifloxystrobin in or on certain products. OJ L 25, 26.1.2013, p. 49–73.

1004/2013[13]. EFSA also recommended the modification of the existing MRLs for horseradish and parsley root (EFSA, 2013b) which was not yet reviewed by the meeting of the Standing Committee on the Food Chain and Animal Health. All existing EU MRLs, which are established for the parent compound only in plant commodities and for the sum of trifloxystrobin and its metabolite CGA 321113[14] in animal commodities, are summarised in Appendix C.1 to this document. CXLs for trifloxystrobin were also established by the Codex Alimentarius Commission and are reported in Appendix C.2 to this reasoned opinion. These CXLs refer to the same residue definition as the EU MRLs.

For the purpose of this MRL review, the critical uses of trifloxystrobin currently authorised within the EU as well as uses authorised in third countries that might have a significant impact on international trade, have been collected by the RMS and reported in the PROFile. The additional GAPs reported during the consultation of Member States were also considered (see Appendix A). Trifloxystrobin is authorised for foliar application on various crops, both under indoor and outdoor conditions.

## ASSESSMENT

EFSA bases its assessment on the PROFile submitted by the RMS, the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (United Kingdom, 2000), the Review Report on trifloxystrobin (EC, 2003), the JMPR Evaluation report (FAO, 2004), the previous reasoned opinions on trifloxystrobin (EFSA, 2008, 2009a, 2009b, 2010, 2011, 2012, 2013a, 2013b) as well as the evaluation reports submitted during the consultation of Member States (Belgium, 2013; Finland, 2013; France, 2013; Germany, 2013; Italy, 2013; Portugal, 2013; Spain, 2013; Netherlands, 2013; United Kingdom, 2013a and 2013b). The assessment is performed in accordance with the legal provisions of the Uniform Principles for Evaluation and Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[15] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011 and OECD, 2011).

## 1. Methods of analysis

### 1.1. Methods for enforcement of residues in food of plant origin

During the peer review under Directive 91/414/EEC, an analytical method using HPLC-UV, and its ILV were evaluated and validated for the determination of parent trifloxystrobin in plant matrices with an LOQ of 0.02 mg/kg in high water content (potatoes and apples), acidic (grapes) and dry (wheat and barley grains) commodities (United Kingdom, 2000).

The multi-residue QuEChERS method in combination with HPLC-MS/MS, as described by CEN (2008), is also reported for analysis of parent with an LOQ of 0.01 mg/kg in high water content, high oil content, acidic and dry commodities (EURL, 2013).

[13] Regulation (EU) No 1004/2013 of 15 October 2013 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 8-hydroxyquinoline, cyproconazole, cyprodinil, fluopyram, nicotine, pendimethalin, penthiopyrad and trifloxystrobin in or on certain products. OJ L 279, 19.10.2013, p. 10–56.

[14] CGA 321113: (E, E)-methoxyimino- {2-[1-(3-trifluoromethyl-phenyl)-ethylideneamino-oxymethyl]-phenyl}-acetic acid. See Appendix E.

[15] 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, 11.06.2011, p. 127-175.

**Table 1-1:** Recovery data for the analysis of trifloxystrobin in different crop groups using the QuEChERS method in combination with HPLC-MS/MS (EURL, 2013)

| Commodity group | Spiking levels (mg/kg) | Recoveries | | | No of labs |
|---|---|---|---|---|---|
| | | Mean (%) | RSD (%) | n | |
| Acidic | 0.01<br>0.10 | 103.9<br>98.4 | 6.9<br>11.4 | 10<br>10 | 2 |
| Dry (cereals, dry pulses) | 0.01<br>0.10 | 104.4<br>105.5 | 8.3<br>5.0 | 10<br>10 | 2 |
| Fatty (oils) | 0.01<br>0.10 | 96.6<br>98.0 | 7.5<br>9.4 | 5<br>5 | 1 |
| Watery | 0.01<br>0.10 | 110.7<br>102.9 | 15.0<br>4.7 | 15<br>10 | 2 |

Hence it is concluded that trifloxystrobin can be enforced in food of plant origin with an LOQ of 0.01 mg/kg in high water content, high oil content, acidic and dry commodities. As the active substance does not contain a chiral center, the analytical method is considered specific to the active substance.

### 1.2. Methods for enforcement of residues in food of animal origin

During the peer review under Directive 91/414/EEC, an analytical method using GC-ECD, and its ILV were evaluated for the determination of parent trifloxystrobin and its metabolite CGA 321113 in food of animal origin with an LOQ of 0.02 mg/kg for each analyte (United Kingdom, 2000). Nevertheless, this analytical method was not adequately validated according to the current guidance document on analytical methods (EC, 2010b).

Consequently, an analytical method fully validated and its ILV are required for the determination of residues of trifloxystrobin (trifloxystrobin and its metabolite CGA 321113) in foodstuff of animal origin (including fat, meat, liver/kidney, milk and eggs). Hence the residue cannot be enforced in food of animal origin.

## 2. Mammalian toxicology

The toxicological assessment of trifloxystrobin was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by the European Commission (2003). These toxicological reference values are summarised in Table 2-1.

The metabolite CGA321113 is also encountered in the rat metabolism and it is considered covered by the toxicological profile of parent trifloxystrobin. The RMS concluded that the metabolites NOA443152[16], BO172741[17], NOA414412[18], NOA413163[19] and NOA413161[20] identified in wheat were not of toxicological concern and overall the toxicological reference values of the parent are expected to be applicable to all compounds structurally related to the parent compound. The toxicity of

[16] NOA443152: 2-[2-hydroxy-1-(3-trifluoromethyl-phenyl)-ethylideneaminooxy-methyl]-phenyl}-methoxyimino-acetic acid. See Appendix E.
[17] BO172741: (2-[2-hydroxy-1-(3-trifluoromethyl-phenyl)-ethylideneaminooxy-methyl]-phenyl}-methoxyimino-acetic acid. See Appendix E (E,E isomer of NOA443152).
[18] NOA414412: 2-[1-(3-hydroxy-5-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-phenyl}-methoxyimino-acetic acid. See Appendix E.
[19] NOA413163: (E,E)-{2-[carboxy-(3-trifluoromethyl-phenyl)-methyleneaminooxy-methyl]-phenyl}-methoxyiminoacetic acid. See Appendix E.
[20] NOA413161: (E,Z)-{2-[carboxy-(3-trifluoromethyl-phenyl)-methyleneaminooxy-methyl]-phenyl}-methoxyiminoacetic acid. See Appendix E.

the trifloxystrobin isomers (ZZ, EZ and ZE) was not discussed in the DAR, as their levels in plant commodities are not expected to be of concern (United Kingdom, 2000).

**Table 2-1:** Overview of the toxicological reference values

| | Source | Year | Value | Study relied upon | Safety factor |
|---|---|---|---|---|---|
| **Trifloxystrobin** | | | | | |
| ADI | EC | 2003 | 0.1 mg/kg bw per d | 2-year rat study | 100 |
| ARfD | EC | 2003 | Not necessary | | |

# 3. Residues

## 3.1. Nature and magnitude of residues in plant

### 3.1.1. Primary crops

#### 3.1.1.1. Nature of residues

Metabolism of trifloxystrobin was investigated for foliar application on cereals (wheat), fruits and fruiting vegetables (apple, cucumber) (United Kingdom, 2000) and in root and tuber vegetables (sugar beet) (EFSA, 2009), using either trifluoro-phenyl-$^{14}$C-labelled trifloxystrobin or glyoxyl-phenyl-$^{14}$C-labelled trifloxystrobin. In addition, supplementary metabolism studies on cereals (wheat) and pulses and oilseeds (peanuts) were evaluated by JMPR (FAO, 2004). The characteristics of these studies are summarised in Table 3-1.

*Apples*

The TRR in apple 14 DAT was 0.83 and 1.3 mg eq/kg for TP- and GP-labels, respectively. Most of the TRR was recovered in the surface washes of the fruits (82-87 % TRR), the remaining concentrating in peel (11- 17 % TRR; 0.7-0.75 mg eq/kg) rather than in pulp (1.2-1.9 % TRR; 0.01-0.03 mg eq/kg). Parent trifloxystrobin was the major compound in whole fruit, accounting for 81-83 % TRR (0.7-1.1 mg/kg). Other isomers of trifloxystrobin were individually quantified at up to 5.2 % TRR (0.04 mg eq/kg). No other compound was detected at level above 0.01 mg eq/kg.

*Cucumber*

In cucumber, the TRR decreased from 0.4-0.9 mg eq/kg to 0.2-0.6 mg eq/kg 7 days after the last application. The metabolic profile was similar to the one in apple, with the parent compound accounting for 80-89.5 % TRR (0.2-2 mg eq/kg). Other isomers of trifloxystrobin were individually quantified at up to 2.2 % TRR (0.04 mg eq/kg) while metabolite CGA321113 accounted for up to 4.2 % TRR (0.053 mg eq/kg). An unidentified component ($II_{24}$) was quantified at levels up to 6.9 % TRR (0.01 mg eq/kg). No other compound was present above 0.01 mg eq/kg.

*Sugar beet*

The highest TRR in sugar beets was found in tops, ranging from 2.3 to 4.1 mg eq/kg after each treatment and decreasing to 1.4-1.5 mg eq/kg and to 0.45-0.73 mg eq/kg 21 DAT and 45 DAT, respectively. TRR in roots was significantly lower, ranging from 0.05-0.1 mg eq/kg after each treatment to 0.04-0.1 mg eq/kg and to 0.02-0.03 mg eq/kg 21 DAT and 45 DAT, respectively.

In leaves and roots parent trifloxystrobin was the main component of the TRR 45 DAT, accounting for 21-34 % TRR (0.16 mg eq/kg) and for 24-48 % TRR (at or below 0.01 mg eq/kg), respectively. In

roots, the two metabolites CGA 321113 and $II_{19a}$[21] were found at levels exceeding the trigger value of 10 %: CGA 321113 accounted for 10.8 % TRR (0.01 mg eq/kg) 21 DAT (GP-label) and for 9.5 % TRR (<0.01 mg eq/kg) 45 DAT (TP-label), while $II_{19a}$ represented 19.6 % TRR (<0.01 mg eq/kg) at 0 DAT (GP-label) and 14.9 % TRR (<0.01 mg eq/kg) 45 DAT (TP-label). In tops, no single compound other than parent was detected above 10 % TRR. However, some metabolites were detected at levels above 0.05 mg eq/kg: CGA 321113 found at 0.07 mg eq/kg (5.2 % TRR) in the sample from the GP- label taken 45 DAT; NOA443152, under free and conjugated forms found at up to 0.08 mg eq/kg (8.7 % TRR) and $II_{21a}$[22] under free and conjugated forms found at up to 0.06 mg eq/kg (4 % TRR).

*Wheat*

In the studies conducted on wheat and reported in the DAR, the highest TRR was identified in forage and straw (3.9-5.5 mg eq/kg). TRR was lower in husk (0.1-0.8 mg eq/kg) and in grain (0.06-0.1 mg eq/kg).

In forage and straw, parent trifloxystrobin was present at 1-4 % TRR (0.04-0.2 mg eq/kg). Each of its isomers accounted for less than 1 % TRR. NOA443152, its isomer BO172741 and NOA414412, under their free and conjugated form, as well as NOA413163 and its isomer NOA413161 accounted for 24-39 % TRR (1.1-2.2 mg eq/kg) in forage and for 15-24 % TRR (0.8-0.9 mg eq/kg) in straw. Unidentified compounds represented 33 % of the TRR in forage (with single compound accounting for up to 12 % TRR; 0.6 mg eq/kg) and 9-17 % of the TRR in straw (with single compound accounting for up to 8 % TRR; 0.4 mg eq/kg).

In straw 39-44 % TRR (ca. 2 mg eq/kg) was not extracted, among which 1-6 % TRR was found to be incorporated as lignin, 0.3-3 % TRR as cellulose and 0.1-0.2 % TRR as pectin.

In grain, results showed an extensive metabolism resulting in several individual compounds, none of them accounting for more than 0.01 mg eq/kg or 10 % TRR. Parent trifloxystrobin accounted for less than 0.01 mg eq/kg and less than 3 % TRR. 61 % TRR was not extracted, among which 3.5–13.4 % TRR was incorporated as starch, 6 % TRR as pectin (TF label only) and 3.5 % TRR as protein (GP label only).

Additional studies on cereals were summarised by JMPR (FAO, 2004). Results are reported below as the tested GAP is compliant with the EU authorised uses on cereals.

The highest TRR were detected in straw (6.1 mg eq/kg, for both labels) and in hay (5.2-6 mg eq/kg). TTR in grain was significantly lower, with 0.1 and 0.3 mg eq/kg, respectively for each label.

In hay and straw, parent trifloxystrobin was the major compound, accounting for 31-40 % TRR (1.6-2.4 mg eq/kg) and for 14-19 % TRR (1 mg eq/kg), respectively. Parent isomers were altogether present at levels of 11-13 % TRR (0.7-0.8 mg eq/kg). CGA321113 and its isomer CGA373466 accounted for 1.5-2 % TRR (0.1 mg eq/kg) in hay and for 6 % TRR (0.35-0.4 mg eq/kg) in straw. NOA443152, its isomer BO172741 and NOA414412, under their free and conjugated form, as well as NOA413163 and its isomer NOA413161 accounted for 25-31 % TRR in hay (1.5-1.6 mg eq/kg) and 26-30 % TRR in straw (1.6-1.9 mg eq/kg). No other compound was deemed significantly present.

In grain, parent trifloxystrobin was the major compound, accounting for 11-20 % TRR (0.02-0.03 mg eq/kg). Parent isomers were altogether present at levels of 7-21 % TRR

[21] $II_{19a}$: {2-[1-(2,3-dihydroxy-5-methyl-phenyl)-2-hydroxy-ethylideneamino-oxymethyl]-phenyl}-methoxy-imino-acetic acid. See Appendix E.

[22] II21a: 2-[[[[(1E)-1-[2,3-dihydroxy-5-(trifluoromethyl)phenyl]ethylidene]amino]oxy]-methyl]-a-(methoxyimino)-benzeneacetic acid. See Appendix E.

(0.02-0.03 mg eq/kg). Metabolite SA04271[23], tentatively identified, was detected in grain at 9.5 % TRR (0.03 mg eq/kg). No other compound was detected at level above 0.01 mg eq/kg.

*Peanuts*

In the metabolism study on peanuts reviewed by JMPR, residues were investigated in immature vines, mature hay, hull and kernels. Considering that only seeds are considered as raw agricultural commodities in Europe, only results on kernels are presented and discussed.

TRR in kernels was 0.18 mg eq/kg for GP label and 0.31 mg eq/kg for TF-label. 52-53 % TRR was extracted in kernels and no further investigation was reported in the JMPR report. 24-29 % TRR (0.05-0.07 mg eq/kg) was incorporated as triglycerides. Parent and its isomers accounted for less than 0.01 mg eq/kg and for less than 2 % TRR in each label. CGA347242[24] under conjugated form accounted for 8.8 % TRR (0.02 mg eq/kg) and phthalic acid for 6 % TRR (0.02 mg eq/kg).

*Overall assessment*

Parent trifloxystrobin is the most important single compound in fruits, root and tuber vegetables and in straw from the JMPR metabolism study. Significant levels of metabolite CGA321113 were observed in sugar beet root and to a minor extend in cereal straw. In straw, metabolites NOA413163, NOA414412, NOA443152 occurred at a global level of 30 % TRR. The metabolic pathway of trifloxystrobin was considered similar in fruits, root and tuber vegetables and in cereal straw. The main route of degradation consisted of successive demethylation (leading to the formation of CGA321113) and hydroxylation. These metabolites are then conjugated to sugar compounds. Parent and metabolites appear to undergo minor isomerisation, except in cereal where isomerisation occurred at the same proportion as the parent trifloxystrobin. In peanuts and in wheat grain, a different route of degradation was observed involving cleavage of the parent molecule with the formation of metabolites CGA347242 and phthalic acid in peanuts and of SA04271 in cereal grain. It is noted that cleavage of the parent molecule was observed in the rat metabolism, resulting especially in the formation of CGA347242 and phthalic acid (United Kingdom, 2000). SA04271 was not observed in rat and therefore its toxicological relevance and its magnitude in cereal grain should in principle be further addressed. However, considering that the identification of this compound in cereal grain was only tentative, the lack of this information can be considered as a minor deficiency. The metabolism study in peanuts gave limited information on the metabolism of trifloxystrobin in pulses and oilseeds since only 15 % TRR was identified and 30 % TRR was characterised as natural compounds. For the time being, considering that only uses on peas and beans are authorised, additional metabolism data are not deemed necessary. If additional uses on pulses and oilseeds are intended in the future, these data should be required.

Based on the above findings, EFSA concludes that for the time being a general residue definition for enforcement purposes which includes parent trifloxystrobin only can be proposed. Validated analytical methods for enforcement of the proposed residue definition are available (see also section 1.1). These methods distinguish trifloxystrobin from its ZZ, EZ and ZE isomers, hereby allowing the specific enforcement of the proposed residue definition.

[23] SA04271: 8-hydroxybicyclo[4.2.0]octa-1,3,5-trien-7-one. See Appendix E.
[24] CGA347242: (2-hydroxyethyl-phenyl)-methoxyimino-acetic acid. See Appendix E.

**Table 3-1:** Summary of available metabolism studies in plants

| Group | Crop | Label position | Application and sampling details | | | | |
|---|---|---|---|---|---|---|---|
| | | | Method, F or G [(a)] | Rate (kg a.s./ha) | No | Sampling (DAT) | Remarks |
| Fruits and fruiting vegetable | Apple | TP-$^{14}$C [(b)] | Foliar spray, G | 0.1 | 4 | 0, 14 | UK, 2000 |
| | | GP-$^{14}$C [(b)] | | | | | |
| | Cucumber | TP-$^{14}$C [(b)] | Foliar spray, G | 0.312 | 3 | 1, 7 | UK, 2000 |
| | | GP-$^{14}$C [(b)] | | | | | |
| Root and tuber vegetables | Sugar beet | TP-$^{14}$C [(b)] | Foliar spray, F | 0.13 | 3 | 0, 21, 45 | EFSA, 2009 |
| | | GP-$^{14}$C [(b)] | | | | | |
| | | TP-$^{14}$C [(b)] | Foliar spray, F | 0.69 | 3 | 0, 21, 45 | |
| | | GP-$^{14}$C [(b)] | | | | | |
| Cereals | Wheat | TP-$^{14}$C [(b)] | Foliar spray, F | 0.25 | 2 | Forage: 24 Straw: 52 | UK, 2000 |
| | | TP-$^{14}$C [(b)] | | 0.5 | 1 | Grain: 49 | |
| | | GP-$^{14}$C [(b)] | | 0.25 | 2 | Forage: 24 Straw, grain: 52 | |
| | | TP-$^{14}$C [(b)] | Foliar spray, F | 0.25 | 2 | Hay: 3 Straw, Grain: 32 | FAO, 2004 |
| | | GP-$^{14}$C [(b)] | | | | | |
| Pulses and oilseeds | Peanut | TP-$^{14}$C [(b)] | Foliar spray, F | 0.56 | 4 | Vines: 0, 14 Hay, hulls, kernels: 14 | FAO, 2004 |
| | | GP-$^{14}$C [(b)] | | | | | |

n.r.: not reported.
(a): Outdoor or field use (F) or glasshouse/protected crops/indoor application (G).
(b): TP = trifluoro-phenyl-14C trifloxystrobin; GP = glyoxyl-phenyl-14C trifloxystrobin.

Based on the available residue data (see section 3.1.1.2.), where CGA 321113 was found at significant levels in brassicas, cucurbits with edible peel and in some root and tuber vegetables, and considering that this metabolite was not analysed in all crops, EFSA proposes to include CGA321113 in the residue definition for risk assessment for all plant commodities.

In addition, EFSA noted that in straw the sum of trifloxystrobin isomers other than the parent, CGA321113 isomers, NOA413163, NOA414412, NOA443152, their isomers and their conjugates was found to be higher than the parent compound. However as none of them represented more than 10 % TRR and considering that straw is not an important contributor to the livestock dietary burden, they were not considered for inclusion in the residue definition for risk assessment.

#### 3.1.1.2. Magnitude of residues

According to the RMS, the active substance trifloxystrobin is authorised in northern and southern Europe for foliar application in a large number of crops, both under outdoor and indoor conditions (see Appendix A). To assess the magnitude of trifloxystrobin residues resulting from these GAPs, EFSA considered all residue trials reported in the PROFile, including residue trials evaluated in the framework of previous MRL applications (EFSA, 2008, 2009a, 2009b 2010, 2011, 2012, 2013a and 2013b) and additional data submitted during the consultation of Member States (Belgium, 2013; Finland, 2013; France, 2013; Germany, 2013; Italy, 2013; Portugal, 2013; Spain, 2013; Netherlands, 2013; United Kingdom, 2013a, 2013b). All available residue trials that, according to the RMS, comply with the authorised GAPs are summarised in Table 3-2. The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (EC, 2011). A sufficient number of trials complying with the GAP was reported by the RMS for all crops under assessment, except in the following cases:

- Apples, pears: the number of residue trials supporting northern and southern outdoor GAP is compliant with the data requirements but trials were carried out with a more critical GAP than the one authorised (10 applications instead of 4 for northern Europe and 6 instead of 3 for southern Europe) and southern trials were not compliant with the residue definition for risk assessment. However, as first applications are done at an early growth stage, the number of applications is not expected to impact on the final residue. Moreover, as residues for northern and southern Europe are expected to be in the same range, northern data compliant with the risk assessment residue definition are considered sufficient to derive an overall conversion factor for risk assessment in pome fruits. Therefore, appropriate MRL and risk assessment values can be derived and further trials are not required.

- Cherries: residue trials supporting northern outdoor GAP were carried out with a more critical GAP (3 applications instead of 1), only 3 residue trials are available to support the southern outdoor use and no residue trial is available to support the indoor use. Therefore, although tentative MRL and risk assessment values can be derived from the northern residue trials, 8 trials complying with the northern GAP, 1 additional trial complying with the southern GAP and 4 residue trials complying with the indoor GAP are still required.

- Peaches, apricots: the number of residue trials supporting the northern GAP is not compliant with the data requirements for these crops (4 trials on peaches, only 1 being compliant with the residue definition for risk assessment). Moreover, no residue trials are available to support the southern use. Although tentative MRL and risk assessment values can be derived from the available northern data, 8 trials complying with the southern GAP (with a minimum of 4 trials on apricots) and 7 additional trials complying with the northern GAP (with a minimum of 4 trials on apricots) are still required. All trials should include residue data in accordance with the residue definition for risk assessment.

- Plums: residue trials supporting northern outdoor GAP were carried out with a more critical GAP (3 applications instead of 2) and the number of residue trials is not compliant with the data requirement on this crop (7 residue trials instead of 8). However, the first application out of 3 is not expected to impact on the final residue and one additional trial would not modify significantly the risk assessment values. Therefore, appropriate MRL and risk assessment values can be derived from available data. One additional trial complying with the northern use is still desirable (minor deficiency).

- Table and wine grapes: no residue trials are available to support the indoor GAP and residue trials supporting the southern outdoor GAP were carried out with a more critical GAP (6 applications instead of 3). However, as first applications are done at an early growth stage, they are not expected to impact on the final residue. Therefore, appropriate MRL and risk

assessment values can be derived from the southern trials, but 8 residue trials complying with the indoor GAP are still required.

- Strawberries: the number of residue trials supporting the northern GAP is not compliant with the data requirements for this crop (3 trials, only 2 being compliant with the residue definition for risk assessment, instead of 8) and no residue trials are available to support the southern use. Although MRL and risk assessment values can be derived from indoor data, 6 additional trials complying with the northern GAP and 8 trials complying with the southern GAP are still required.

- Blackberries, raspberries: no residue trials are available to support the northern use. Considering that it is a minor crop in northern Europe, 4 residue trials complying with the GAP are required. Meanwhile, neither MRLs nor risk assessment values can be derived.

- Currant, gooseberries: residue trials supporting the northern outdoor GAP on these crops were not compliant with the residue definition for risk assessment. Although tentative MRL and risk assessment values can be derived from the available data, 6 residue trials on currants compliant with the residue definition for risk assessment are still required.

- Table olives: residue trials supporting the southern outdoor use were carried out with 2 applications instead of 1. However, as the first application was done at an early growth stage, it is not expected to impact on the final residue. Therefore, appropriate MRL and risk assessment values can be derived from the available trials.

- Passion fruit: no residue trials are available to support the import tolerance. Although tentative MRL and risk assessment values were derived from the underdosed trials already evaluated by EFSA in 2008, 4 trials complying with the import tolerance are still required.

- Bananas: the number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for this crop. However, the reduced number of residue trials is considered acceptable in this case because all results were below the LOQ and a no residues situation is expected. Further residue trials are therefore not required.

- Onions, garlic: the number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements on these crops (4 instead of 8); moreover trials were carried out with a more critical GAP (3 applications instead of 1). However, the higher number of applications and the reduced number of residue trials is considered acceptable in this case because all results were below the LOQ and a no residues situation is expected. Further residue trials are therefore not required.

- Tomatoes: no residue trials are available to support the southern use. Although appropriate MRL and risk assessment values can be derived from the indoor data, 8 trials complying with the southern GAP are still required.

- Peppers: no residue trials are available to support the southern use and the number of residue trials supporting the indoor use is not compliant with the data requirements for this crop (5 trials instead of 8). Although tentative MRL and risk assessment values can be derived from the indoor data, 8 trials complying with the southern GAP and 3 additional trials complying with the indoor GAP are still required.

- Cucumbers, courgettes, gherkins: the number of residue trials supporting northern GAP on the whole group and southern GAP on courgette is not compliant with the data requirements (4 trials instead of 8). In addition, northern trials were carried out with a more critical GAP (3 applications instead of 1) and residue trials supporting the indoor use on cucumber and gherkin were carried out with a more critical GAP (5 applications instead of 2). Therefore,

although tentative MRL and risk assessment values can be derived from the indoor data (cucumber and gherkin) or from the northern data (courgette), 8 trials on cucumbers complying with the northern GAP on cucurbits with edible peel, 4 additional trials on cucumbers complying with the southern GAP on cucurbits with edible peel and 8 trials on cucumbers complying with the indoor GAP on cucumber and gherkins are still required.

- Melons: the number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements on this crop (7 instead of 8) and trials were carried out with a more critical GAP (5 applications instead of 4). However, as the first application done at an early growth stage is not expected to impact on the final residue, these trials were accepted. In addition, no residue trials are available to support the northern use. Therefore, although appropriate MRL and risk assessment values can be derived from the indoor data, 8 trials complying with the northern GAP are still required and one additional trial complying with the southern outdoor GAP is desirable.

- Pumpkins: no residue trials are available to support northern and indoor uses. Considering that it is a minor crop, 4 residue trials complying with the northern GAP and 4 residue trials complying with the indoor GAP are required. Meanwhile, neither MRLs nor risk assessment values can be derived.

- Watermelons: the number of residue trials supporting the southern GAP is not compliant with the data requirements for this crop (6 trials instead of 8). Although appropriate MRL and risk assessment values can be derived from the indoor data, 2 additional trials complying with the southern GAP are still required.

- Kale, Chinese cabbage: only 2 of the 5 residue trials supporting the northern use include results in accordance with the residue definition for risk assessment. Although tentative MRL can be derived from available data, at least 2 additional trials complying with the northern use and including results on CGA321113 are still required.

- Scarole, herbs: as information is not available whether or not the northern and indoor data on lettuce refer to open leaves varieties, those data are extrapolated to scarole and herbs on a tentative basis only. Although tentative MRL and risk assessment values can be derived from the northern data, 4 trials complying with the northern GAP and 4 trials complying with the indoor GAP are still required (all carried out on open leaf varieties).

- Witloof: no residue trials are available to support the northern use. Considering that it is a minor crop, 4 residue trials complying with the northern GAP are required. Meanwhile, neither MRLs nor risk assessment values can be derived.

- Beans (fresh, with pods): only 2 of the residue trials supporting the northern use and none of the residue trials supporting the indoor use include results in accordance with the residue definition for risk assessment. Although tentative MRL and risk assessment values can be derived from the northern data, 8 trials complying with the indoor use and 6 additional residue trials complying with the northern use (including residue data in accordance with the residue definition for risk assessment) are required.

- Peas (fresh, with pods): no residue trials are available to support the indoor use. Considering that this is a major crop, 8 residue trials complying with the indoor GAP are required. Meanwhile, neither MRLs nor risk assessment values can be derived.

- Leek: none of the residue trials supporting the northern GAP included data compliant with the residue definition for risk assessment and the number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for this crop (2 trials instead of 8). Although tentative MRL and risk assessment values can be derived from the northern data, 8

residue trials complying with the northern GAP and 6 additional residue trials complying with the southern GAP, including residue data in accordance with the residue definition for risk assessment, are still required.

- Olives for oil production: no residue trials are available to support the southern use. Considering that it is a major crop, 8 residue trials complying with the southern GAP are required. Meanwhile, neither MRLs nor risk assessment values can be derived.

- Barley (grain): the number of residue trials supporting the northern GAP and the southern GAP are not compliant with the data requirements (respectively 7 and 6 residue trials instead of 8). However, one additional trial would not modify significantly the risk assessment values for the northern outdoor GAP. Therefore, appropriate MRL and risk assessment values can be derived from the northern data but 1 additional trial complying with the northern GAP is still desirable and 2 additional trials complying with the southern GAP are still required.

- Oats (grain): no residue trials are available to support the northern use. Although tentative MRL and risk assessment values can be derived from the southern data, 8 residue trials complying with the northern GAP are required.

- Wheat and rye (grain): the number of residue trials supporting the northern GAP and the southern GAP are not compliant with the data requirements (respectively 7 and 6 residue trials instead of 8). However, one additional trial would not modify significantly the risk assessment values for the northern outdoor GAP. Therefore, appropriate MRL and risk assessment values can be derived from the northern data but 1 additional trial complying with the northern GAP is still desirable and 2 additional trials complying with the southern GAP are still required.

- Hops: the number of residue trials supporting the northern GAP is compliant with the data requirements but trials were carried out with a more critical GAP than the one authorised (4 to 6 applications instead of 2). However, as the first applications were underdosed and done at an early growth stage, they are not expected to impact on the final residue. Therefore, appropriate MRL and risk assessment values can be derived from these trials.

- Sugar beet (root), fodder beet (root): the number of residue trials supporting the northern outdoor GAP is not compliant with the data requirements for this crop. However, the reduced number of residue trials is considered acceptable in this case because all results were all below the LOQ and a no residues situation is expected. Further residue trials are therefore not required.

- Sugar beet (tops), fodder beet (tops): residue trials supporting southern outdoor GAP were carried out with a less critical GAP than the one authorised (2 applications instead of 3) and they were not compliant with the residue definition for risk assessment. However, as first applications are done at an early growth stage, the number of applications is not expected to impact on the final residue. Moreover, as residues for northern and southern Europe are expected to be in the same range, northern data compliant with the risk assessment residue definition are considered sufficient to derive an overall conversion factor for risk assessment in sugar and fodder beet tops. Therefore, MRL and risk assessment values can be derived and further trials are not required.

- Chicory roots: no residue trials are available to support the northern use. Considering that this is a minor crop, 4 residue trials complying with the northern GAP are required. Meanwhile, neither tentative MRLs nor risk assessment values can be derived.

- Grass: no residue trials are available to support the northern use. Considering that this is a fodder crop, 4 residue trials complying with the northern GAP are required. Meanwhile, neither tentative MRLs nor risk assessment values can be derived.

The potential degradation of residues during storage of the residue trials samples was also assessed. In the framework of the peer review, storage stability of trifloxystrobin and CGA321113 was demonstrated for a period of 12 months at -20°C in high water content (cucumber, potato), acidic (grapes) and dry commodities (wheat grain) (United Kingdom, 2000). Following the peer review, the RMS evaluated additional data demonstrating storage stability of trifloxystrobin and CGA321113 for a period of 18 months in high acid content and dry matrices and for 24 months in high oil content matrices but a detailed evaluation of these data is not available to EFSA. Storage conditions are compliant with the demonstrated period of stability for the available residue trials supporting the uses on parsnips, parsley root, salsify, swedes, turnips, aubergines, melons, Brussels sprouts, head cabbage, kale, Chinese cabbage, lettuce, scarole, celery, globe artichokes, barley, wheat and sugar beet. In order to confirm validity of all available residues trials, a detailed evaluation report of the latest storage stability studies as well as the storage conditions of the residues trials samples (where such information is not yet available) are still desirable.

Consequently, the available residues data are considered sufficient to derive MRL proposals as well as risk assessment values for most of the commodities under assessment except for cherry, apricot, peach, currants, gooseberries, passion fruit, pepper, cucurbits with edible peel, leafy brassica, scarole, herbs, beans (fresh, with pods), leek, barley and oats where additional data are required (residue trials compliant with GAP) and only tentative MRLs are derived. For blackberries, raspberries, pumpkins, witloof, peas (fresh, with pods), olives for oil production and chicory roots, the available data were insufficient to derive tentative MRLs (see also Table 3-2). Median conversion factors for enforcement to risk assessment were derived for each commodity, considering only residues of both parent and CGA 321113 above the LOQ. When relevant, datasets on a same commodity but from different climatic conditions (NEU, SEU or indoor) were pooled for the calculation of a common CF. When several uses are authorised for one commodity, the final MRL proposal was derived from the most critical use and indicated in bold in Table 3-2. Tentative MRLs were also derived for feed crops in view of the future need to set MRLs in feed items except for grass where the available data were insufficient to derive tentative MRLs.

**Table 3-2:** Overview of the available residue trials data

| Commodity | Residue region [(a)] | Outdoor /Indoor | Individual trial results (mg/kg) | | Median residue (mg/kg) [(b)] | Highest residue (mg/kg) [(c)] | MRL proposal (mg/kg) | Median CF [(d)] | Comments |
|---|---|---|---|---|---|---|---|---|---|
| | | | Enforcement | Risk assessment | | | | | |
| **Enforcement residue definition:** trifloxystrobin<br>**Risk assessment residue definition:** sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin**.** | | | | | | | | | |
| Apples<br>Pears | NEU | Outdoor | 0.06; 0.19; 0.21; 0.10; 0.14; 0.06; 0.05; 0.04; 0.08; 0.06 | 0.08; 0.21; 0.23; 0.12; 0.16; 0.07; 0.08; 0.06; 0.10; 0.07 | 0.07 | 0.21 | 0.4 | 1.2[(e, f)] | Trials on apples performed with 10 applications instead of 4 accepted as first applications are not expected to impact on the final residue (United Kingdom, 2000); see also body text. CGA 321113 always <LOQ.<br>$MRL_{OECD}$=0.34<br>$R_{ber}$=0.31<br>$R_{max}$=0.28 |
| | SEU | Outdoor | 0.21; 0.07; 0.18; 0.15; 0.19; 0.09; 0.13; 0.20 | - | 0.17 | 0.21 | 0.5 | | Trials on apples performed with 6 applications instead of 3 accepted as first applications are not expected to impact on the final residue (United Kingdom, 2000); see also body text.<br>$MRL_{OECD}$=0.46<br>$R_{ber}$=0.4<br>$R_{max}$=0.32 |
| Medlar<br>Quinces<br>Loquat | NEU | Outdoor | 0.06; 0.19; 0.21; 0.10; 0.14; 0.06; 0.05; 0.04; 0.08; 0.06 | 0.08; 0.21; 0.23; 0.12; 0.16; 0.07; 0.08; 0.06; 0.10; 0.07 | 0.07 | 0.21 | 0.4 | 1.2 [(f)] | Direct extrapolation from the northern data on apples. |

| Commodity | Residue region [(a)] | Outdoor /Indoor | Individual trial results (mg/kg) | | Median residue (mg/kg) [(b)] | Highest residue (mg/kg) [(c)] | MRL proposal (mg/kg) | Median CF [(d)] | Comments |
|---|---|---|---|---|---|---|---|---|---|
| | | | Enforcement | Risk assessment | | | | | |
| Cherries | NEU | Outdoor | 0.07; 0.11; 0.1; 0.19; 0.11; 0.2; 0.31; 0.14; 0.05 | 0.09; 0.13; 0.12; 0.22; 0.13; 0.22; 0.33; 0.15; 0.07 | 0.11 | 0.31 | 0.5 (tentative) | 1.2 | Trials on cherries performed with 3 applications instead of 1.<br>$MRL_{OECD}$=0.46<br>$R_{ber}$=0.39<br>$R_{max}$=0.39 |
| | SEU | Outdoor | 0.06; 0.03; 0.10 | 0.08; 0.05; 0.12 | 0.06 | 0.10 | 0.4 (tentative) | | Trials on cherries compliant with GAP (Italy, 2013). CGA 321113 residues always <LOQ.<br>$MRL_{OECD}$= 0.20<br>$R_{ber}$= -<br>$R_{max}$= 0.33 |
| | EU | Indoor | - | - | - | - | - | - | No trials available |
| Peaches Apricots | NEU | Outdoor | 0.096; 0.42; 0.68; 0.31 | 0.098 | 0.37 | 0.68 | 1.5 (tentative) | - | Trials on peaches compliant with GAP, tentatively extrapolated to apricots.<br>$MRL_{OECD}$=1.35<br>$R_{ber}$=1.23<br>$R_{max}$=1.63 |
| | SEU | Outdoor | - | - | - | - | - | - | No trials available. |

| Commodity | Residue region [a] | Outdoor /Indoor | Individual trial results (mg/kg) | | Median residue (mg/kg) [b] | Highest residue (mg/kg) [c] | MRL proposal (mg/kg) | Median CF [d] | Comments |
|---|---|---|---|---|---|---|---|---|---|
| | | | Enforcement | Risk assessment | | | | | |
| Plums | NEU | Outdoor | 0.06; 0.04; 0.05; 0.06; 0.11; 0.09; 0.02 | 0.08; 0.06; 0.07; 0.08; 0.13; 0.10 | 0.06 | 0.11 | 0.2 | 1.2 [f] | Trials on plums performed with 3 applications instead of 2 accepted as first applications are not expected to impact on the final residue. CGA 321113 residues always <LOQ.<br>$MRL_{OECD}$=0.18<br>$R_{ber}$=0.18<br>$R_{max}$=0.16 |
| | SEU | Outdoor | 0.03; 0.04; 0.05; 0.03 | 0.05; 0.06; 0.07; 0.05 | 0.04 | 0.05 | 0.15 | | Trials on plums compliant with GAP (Italy, 2013). CGA 321113 residues always <LOQ.<br>$MRL_{OECD}$=0.11<br>$R_{ber}$=0.10<br>$R_{max}$=0.09 |
| Table grapes<br>Wine grapes | NEU | Outdoor | 0.04; 0.13; 0.06; 0.29; 0.27; 0.14; 0.036; 0.06 | 0.06; 0.16; 0.07; 0.30; 0.29; 0.16; 0.046; 0.07 | 0.10 | 0.29 | 0.6 | 1.2 | Trials on grapes compliant with GAP.<br>$MRL_{OECD}$=0.48<br>$R_{ber}$=0.45<br>$R_{max}$=0.53 |
| | SEU | Outdoor | 0.13; 0.05; 0.28; 0.08; 0.36; 0.11; 0.14; 0.07; 0.17 | 0.15; 0.07; 0.30; 0.10; 0.38; 0.13; 0.16; 0.09; 0.19 | 0.13 | 0.36 | 0.6 | | Trials on grapes performed with 6 applications instead of 3 accepted as first applications are not expected to impact on the final residue (United Kingdom, 2000); see also body text.<br>$MRL_{OECD}$=0.57<br>$R_{ber}$=0.45<br>$R_{max}$=0.47 |
| | EU | Indoor | - | - | - | - | - | - | No trials available. |

| Commodity | Residue region [a] | Outdoor /Indoor | Individual trial results (mg/kg) | | Median residue (mg/kg) [b] | Highest residue (mg/kg) [c] | MRL proposal (mg/kg) | Median CF [d] | Comments |
|---|---|---|---|---|---|---|---|---|---|
| | | | Enforcement | Risk assessment | | | | | |
| Strawberries | NEU | Outdoor | 0.16; 0.11; 0.48 | 0.21; 0.15 | - | - | - | - | Trials on strawberries compliant with GAP. Number of trials is not sufficient for deriving an MRL proposal. |
| | SEU | Outdoor | - | - | - | - | - | - | No trials available. |
| | EU | Indoor | 0.29; 0.09; 0.36; 0.05; 0.03; 0.10; 0.03; 0.23 | 0.31; 0.11; 0.39; 0.07; 0.05; 0.12; 0.05; 0.25 | 0.10 | 0.36 | 0.7 | 1.2 | Trials on strawberries compliant with GAP.<br>$MRL_{OECD}$= 0.66<br>$R_{ber}$= 0.55<br>$R_{max}$= 0.56 |
| Blackberries Raspberries | NEU | Outdoor | - | - | - | - | - | - | No trials available. |
| Blueberries | NEU | Outdoor | 0.76; 0.80; 0.43; 1.1; 0.34; 0.26 | 0.79; 0.82; 0.45; 1.12; 0.36; 0.28 | 0.60 | 1.10 | 2 | 1.0 | Trials on blackcurrants compliant with the GAP (Belgium, 2013). Extrapolation to blueberries possible.<br>$MRL_{OECD}$= 2.32<br>$R_{ber}$= 2.05<br>$R_{max}$= 2.18 |
| Currants (red, black and white) Gooseberries | NEU | Outdoor | Currants: 0.23; 0.52; 0.06; 0.05; 0.16; 0.60; 0.35<br>Gooseberries: 0.39 | - | 0.29 | 0.60 | 1.5 (tentative) | - | Combined dataset on currant and gooseberry (Germany, 2013) compliant with GAP.<br>$MRL_{OECD}$= 1.11<br>$R_{ber}$= 0.98<br>$R_{max}$= 0.95 |

| Commodity | Residue region [a] | Outdoor /Indoor | Individual trial results (mg/kg) | | Median residue (mg/kg) [b] | Highest residue (mg/kg) [c] | MRL proposal (mg/kg) | Median CF [d] | Comments |
|---|---|---|---|---|---|---|---|---|---|
| | | | Enforcement | Risk assessment | | | | | |
| Table olives | SEU | Outdoor | 0.1; 0.05; 0.02; 0.06; 0.09; 0.02; 0.03; 0.05 | 0.11; 0.06; 0.03; 0.07; 0.10; 0.03; 0.04; 0.06 | 0.05 | 0.10 | 0.2 | 1.2 [f] | Trials conducted with 2 applications instead of 1 (Portugal, 2013), deemed acceptable as first application is done at an early growth stage. CGA321113 always <LOQ.<br>$MRL_{OECD}$= 0.17<br>$R_{ber}$= 0.17<br>$R_{max}$= 0.15 |
| Passion fruit | Import (Kenya) | Outdoor/ Indoor | 0.46; 0.51; 0.72; 1.3; 1.9 | - | 0.72 | 1.90 | 4 (tentative) | - | Trials on passion fruits performed at a lower application rate, considered acceptable for supporting a less critical GAP of 0.2 kg a.s./ha (EFSA, 2008). |
| Bananas | SEU | Outdoor | 2x<0.01 | 2x<0.02 | 0.01 | 0.01 | 0.01* | 1.0 [g] | Trials on bagged bananas performed with 4 applications instead of 2, deemed acceptable to support the use on bananas (France, 2013). |
| Beetroot | NEU | Outdoor | 4 x <0.02 | 4 x <0.04 | 0.02 | 0.02 | 0.02 | 1.0 [g] | Trials on carrot compliant with GAP (United Kingdom, 2013a). CGA 321113 residues always <LOQ.<br>$MRL_{OECD}$= 0.02 |
| Carrots<br>Parsnips<br>Salsify<br>Swedes<br>Turnips | NEU | Outdoor | 0.02; <0.02; 0.02; <0.02; <0.02; <0.02; 0.02; 0.02 | 0.04; <0.04; 0.04; <0.04; <0.04; <0.04; 0.05; 0.03 | 0.02 | 0.02 | 0.04 | 2.0 | Trials on carrots compliant with GAP.<br>$MRL_{OECD}$= 0.04<br>$R_{ber}$= 0.04<br>$R_{max}$= 0.02 |
| Celeriac | NEU | Outdoor | 4x<0.02 | 4x<0.04 | 0.02 | 0.02 | 0.02 | 1.0 [g] | Trials on celeriac compliant with GAP.<br>$MRL_{OECD}$= 0.02 |

| Commodity | Residue region [a] | Outdoor /Indoor | Individual trial results (mg/kg) | | Median residue (mg/kg) [b] | Highest residue (mg/kg) [c] | MRL proposal (mg/kg) | Median CF [d] | Comments |
|---|---|---|---|---|---|---|---|---|---|
| | | | Enforcement | Risk assessment | | | | | |
| Horseradish Parsley root | NEU | Outdoor | <0.02; 0.02; 0.02; 0.03; 0.03; 0.04 | <0.04; <0.04; <0.03; 0.04; 0.05; 0.08 | 0.03 | 0.04 | 0.08 | 1.8 | Trials on carrots compliant with GAP (EFSA, 2013b).<br>$MRL_{OECD}$= 0.07<br>$R_{ber}$= 0.07<br>$R_{max}$= 0.06 |
| Garlic Onions | SEU | Outdoor | 4x<0.01 | 4x<0.02 | 0.01 | 0.01 | 0.01 | 1.0 [g] | Trials on onions conducted with 3 applications instead of 1 (Spain, 2013), acceptable because no residues of parent and CGA321113 were detected. Extrapolation to garlic possible. |
| Tomatoes | SEU | Outdoor | - | - | - | - | - | - | No trials available. |
| | EU | Indoor | 0.14; 0.08; 0.11; 0.13; 0.06; 0.08; 0.07; 0.04 | 0.16; 0.10; 0.13; 0.15; 0.08; 0.10; 0.09; 0.06 | 0.08 | 0.14 | 0.3 | 1.2 [f] | Trials on tomatoes compliant with GAP (Spain, 2013). CGA 321113 residues always <LOQ.<br>$MRL_{OECD}$= 0.27<br>$R_{ber}$= 0.25<br>$R_{max}$= 0.20 |
| Peppers | SEU | Outdoor | - | - | - | - | - | - | No trials available. |
| | EU | Indoor | 0.04; 0.07; 0.08; 0.19; 0.09 | 0.06; 0.07; 0.09; 0.20; 0.10 | 0.08 | 0.19 | 0.4 (tentative) | 1.2 [f] | Trials on peppers compliant with GAP (Spain, 2013). CGA 321113 residues always <LOQ.<br>$MRL_{OECD}$= 0.32<br>$R_{ber}$= 0.28<br>$R_{max}$= 0.33 |

| Commodity | Residue region [a] | Outdoor /Indoor | Individual trial results (mg/kg) | | Median residue (mg/kg) [b] | Highest residue (mg/kg) [c] | MRL proposal (mg/kg) | Median CF [d] | Comments |
|---|---|---|---|---|---|---|---|---|---|
| | | | Enforcement | Risk assessment | | | | | |
| Aubergines (egg plants) | EU | Indoor | 0.02; 0.05; 0.06; 0.07; 0.08; 0.10; 0.13; 0.13 | 0.04; 0.07; 0.08; 0.09; 0.10; 0.12; 0.15; 0.15 | 0.08 | 0.13 | 0.3 | 1.2 [f] | Trials on tomatoes compliant with GAP on aubergines (EFSA, 2011). CGA 321113 residues always <LOQ.<br>$MRL_{OECD}$= 0.24<br>$R_{ber}$= 0.25<br>$R_{max}$= 0.2 |
| Cucumbers Gherkins | NEU | Outdoor | 0.05; 0.07; <0.02; 0.03 | 0.07; 0.09; <0.04; 0.05 | 0.04 | 0.07 | 0.2 (tentative) | 1.7 | Trials on cucumbers performed with 3 applications instead of 1. CGA321113 always <LOQ.<br>$MRL_{OECD}$= 0.13<br>$R_{ber}$= 0.13<br>$R_{max}$= 0.16 |
| | SEU | Outdoor | 0.04; 0.01; 0.01; 0.06 | 0.05; 0.02; 0.02; 0.08 | 0.03 | 0.06 | 0.2 | | Trials on cucumber compliant with GAP (Spain, 2013). Not authorised for gherkins in SEU.<br>$MRL_{OECD}$= 0.13<br>$R_{ber}$= 0.11<br>$R_{max}$= 0.16 |
| | EU | Indoor | <0.02; 0.04; 0.06; 0.07; 0.02; 0.03; 0.03; 0.14; 0.14 | <0.04; 0.06; 0.10; 0.12; 0.04; 0.05; 0.05; 0.17; 0.17 | 0.04 | 0.14 | 0.3 (tentative) | | Trials on cucumber performed with 5 applications instead of 2.<br>$MRL_{OECD}$= 0.21<br>$R_{ber}$= 0.21<br>$R_{max}$= 0.25 |

| Commodity | Residue region [a] | Outdoor /Indoor | Individual trial results (mg/kg) | | Median residue (mg/kg) [b] | Highest residue (mg/kg) [c] | MRL proposal (mg/kg) | Median CF [d] | Comments |
|---|---|---|---|---|---|---|---|---|---|
| | | | Enforcement | Risk assessment | | | | | |
| Courgettes | NEU | Outdoor | 0.05; 0.07; <0.02; 0.03 | 0.07; 0.09; <0.04; 0.05 | 0.04 | 0.07 | 0.2 (tentative) | 1.9 | Direct extrapolation from cucumbers |
| | SEU | Outdoor | 0.04; 0.01; 0.01; 0.06 | 0.05; 0.02; 0.02; 0.08 | 0.03 | 0.06 | 0.2 (tentative) | | Direct extrapolation from cucumber. |
| | EU | Indoor | 0.03; 0.05; 0.02; <0.01; 0.03; 0.01; 0.01; 0.06 | 0.04; 0.06; 0.04; 0.03; 0.06; 0.06; 0.04; 0 .11 | 0.03 | 0.06 | 0.1 | | Trials on cucumbers compliant with GAP (Spain, 2013).<br>$MRL_{OECD}$= 0.10<br>$R_{ber}$= 0.09<br>$R_{max}$= 0.09 |
| Melons | NEU | Outdoor | - | - | - | - | - | - | No trials available. |
| | SEU | Outdoor | 0.07; 0.10; 0.09; <0.02; 0.11; 0.03; <0.02 | 0.09; 0.12; 0.11; <0.04; 0.13; 0.05; <0.04 | 0.07 | 0.11 | 0.2 (tentative) | 1.2 [f] | Trials on melons performed with 5 applications instead of 4 acceptable as first applications are not expected to impact on the final residue. CGA 321113 residues always <LOQ.<br>$MRL_{OECD}$= 0.22<br>$R_{ber}$= 0.2<br>$R_{max}$= 0.2 |
| | EU | Indoor | 0.06; 0.02; 0.05; <0.02; 0.05; 0.02; 0.03; 0.14 | 0.08; 0.04; 0.07; 0.04; 0.07; 0.04; 0.05; 0.16 | 0.04 | 0.14 | 0.2 | | Trials compliant with GAP (Italy, 2013). CGA 321113 residues always <LOQ.<br>$MRL_{OECD}$= 0.21<br>$R_{ber}$= 0.12<br>$R_{max}$= 0.18. |
| Pumpkins | NEU | Outdoor | - | - | - | - | - | - | No trials available. |
| | EU | Indoor | - | - | - | - | - | - | No trials available. |

| Commodity | Residue region [a] | Outdoor /Indoor | Individual trial results (mg/kg) | | Median residue (mg/kg) [b] | Highest residue (mg/kg) [c] | MRL proposal (mg/kg) | Median CF [d] | Comments |
|---|---|---|---|---|---|---|---|---|---|
| | | | Enforcement | Risk assessment | | | | | |
| Watermelons | SEU | Outdoor | <0.01; 0.01; <0.01; 0.06; <0.02; 0.08 | <0.03; 0.03; <0.03; 0.08; <0.04; 0.10 | 0.02 | 0.08 | 0.15 (tentative) | 1.2 [f] | Trials on melons compliant with GAP on watermelons. CGA 321113 residues always <LOQ.<br>$MRL_{OECD}$= 0.15<br>$R_{ber}$= 0.13<br>$R_{max}$= 0.15 |
| | EU | Indoor | 0.06; 0.02; 0.05; <0.02; 0.05; 0.02; 0.03; 0.14 | 0.08; 0.04; 0.07; 0.04; 0.07; 0.04; 0.05; 0.16 | 0.04 | 0.14 | 0.2 | | Direct extrapolation from melons. |
| Broccoli Cauliflower | NEU | Outdoor | Broccoli: <0.02; <0.02; 0.03; 0.02; Cauliflower: <0.02; <0.02; 0.02; <0.01 | Broccoli: 0.04; <0.04; 0.05; 0.04; Cauliflower: <0.04; 0.07; 0.08; 0.04 | 0.02 | 0.03 | 0.05 | 2.0 | Combined dataset on broccoli and cauliflower, compliant with GAP (Netherlands, 2013)<br>$MRL_{OECD}$= 0.04<br>$R_{ber}$= 0.04<br>$R_{max}$= 0.04 |
| Brussels sprouts | NEU | Outdoor | 0.02; 0.06; 0.06; 0.07; 0.13; 0.14; 0.24; 0.35 | 0.04; 0.15; 0.095; 0.15; 0.16; 0.21; 0.26; 0.45 | 0.10 | 0.35 | 0.6 | 1.5 | Trials compliant with GAP.<br>$MRL_{OECD}$= 0.58<br>$R_{ber}$= 0.43<br>$R_{max}$= 0.49 |
| Head cabbage | NEU | Outdoor | <0.01; 0.01; 0.02; 0.03; 0.03; 0.06; 0.16; 0.18 | 0.03; 0.02; 0.04; 0.05; 0.05; 0.1; 0.21; 0.2 | 0.03 | 0.18 | 0.4 | 1.7 | Trials compliant with GAP.<br>$MRL_{OECD}$= 0.34<br>$R_{ber}$= 0.27<br>$R_{max}$= 0.28 |
| Kale Chinese cabbage | NEU | Outdoor | 0.21; 0.77; 0.071; 0.66; 1.2 | 0.22; 0.81 | 0.66 | 1.20 | 3 (tentative) | - | Trials on kale compliant with GAP. Extrapolation to Chinese cabbage possible.<br>$MRL_{OECD}$= 2.4<br>$R_{ber}$= 1.97<br>$R_{max}$= 2.49 |

| Commodity | Residue region [a] | Outdoor /Indoor | Individual trial results (mg/kg) | | Median residue (mg/kg) [b] | Highest residue (mg/kg) [c] | MRL proposal (mg/kg) | Median CF [d] | Comments |
|---|---|---|---|---|---|---|---|---|---|
| | | | Enforcement | Risk assessment | | | | | |
| Lettuce | EU | Indoor | 2.4; 2.5; 2.7; 5.4; 5.6; 5.7; 6.6; 7.2 | 2.4; 2.7; 2.7; 5.4; 5.65; 5.8; 6.7; 7.2 | 5.50 | 7.20 | 15 | 1.0 | Trials on lettuce compliant with GAP.<br>$MRL_{OECD}$= 14.29<br>$R_{ber}$= 12.75<br>$R_{max}$= 10.94 |
| Scarole (broad-leaf endive)<br>Herbs | NEU | Outdoor | Lettuce:<br>0.43; 0.61; 1.1; 1.2; 1.3; 2.2 [h]<br><br>Scarole: 0.79 | Lettuce:<br>0.46; 0.63; 1.12; 1.2; 1.3; 2.2 [h]<br><br>Scarole: 0.85 | 1.1 | 2.2 | 4 (tentative) | 1.0 | Combined data on lettuce and scarole compliant with GAP, tentatively extrapolated to scarole and fresh herbs; see body text.<br>$MRL_{OECD}$= 3.42<br>$R_{ber}$= 2.60<br>$R_{max}$= 3.08 |
| | EU | Indoor | 2.4; 2.5; 2.7; 5.4; 5.6; 5.7; 6.6; 7.2 | 2.4; 2.7; 2.7; 5.4; 5.65; 5.8; 6.7; 7.2 | 5.50 | 7.20 | 15 (tentative) | 1.0 | Tentative extrapolation from lettuce |
| Witloof | NEU | Outdoor | - | - | - | - | - | - | No trials available. |
| Beans (fresh, with pods) | NEU | Outdoor | 0.06; 0.07; 0.08; 0.16; 0.23; 0.29; 0.50; 0.51 | 0.08; 0.10 | 0.20 | 0.51 | 1 (tentative) | - | Trials compliant with GAP (EFSA, 2013). When available, CGA 321113 residues < LOQ.<br>$MRL_{OECD}$= 0.97<br>$R_{ber}$= 0.90<br>$R_{max}$= 0.82 |
| | EU | Indoor | 0.10; 0.17; 0.18; 0.15; 0.35; 0.16; 0.22; 0.16 | - | 0.17 | 0.35 | 0.6 (tentative) | - | Trials compliant with GAP (Netherlands, 2013).<br>$MRL_{OECD}$= 0.56<br>$R_{ber}$= 0.42<br>$R_{max}$= 0.42 |
| Peas (fresh, with pods) | EU | Indoor | - | - | - | - | - | - | No trials available. |

| Commodity | Residue region [a] | Outdoor /Indoor | Individual trial results (mg/kg) | | Median residue (mg/kg) [b] | Highest residue (mg/kg) [c] | MRL proposal (mg/kg) | Median CF [d] | Comments |
|---|---|---|---|---|---|---|---|---|---|
| | | | Enforcement | Risk assessment | | | | | |
| Celery | NEU | Outdoor | 0.10; 0.06; 0.04; 0.17 | 0.12; 0.08; 0.06; 0.19 | 0.08 | 0.17 | 0.4 | 1.0 [f] | Trials on celery compliant with GAP. CGA321113 residues always < LOQ<br>$MRL_{OECD}$= 0.32<br>$R_{ber}$= 0.3<br>$R_{max}$= 0.39 |
| Globe artichokes | SEU | Outdoor | 0.06; 0.06; 0.07; 0.1 | 0.08; 0.08; 0.09; 0.12 | 0.07 | 0.10 | 0.3 | 1.0 [f] | Trials on artichokes compliant with GAP. CGA 321113 residues always < LOQ.<br>$MRL_{OECD}$= 0.22<br>$R_{ber}$= 0.19<br>$R_{max}$= 0.17 |
| Leek | NEU | Outdoor | 0.04; 0.06; 2x0.07; 2x0.08; 0.14 | - | 0.07 | 0.14 | 0.3 (tentative) | - | Trials on leek compliant with GAP.<br>$MRL_{OECD}$= 0.23<br>$R_{ber}$= 0.16<br>$R_{max}$= 0.18 |
| | SEU | Outdoor | <0.01; 0.01 | 0.03; 0.03 | - | - | - | - | Trials conducted with 3 applications instead of 2 (France, 2013). Number of trials insufficient to derive an MRL proposal. |
| Olives for oil production | SEU | Outdoor | - | - | - | - | - | - | No trials available. |

| Commodity | Residue region [a] | Outdoor /Indoor | Individual trial results (mg/kg) | | Median residue (mg/kg) [b] | Highest residue (mg/kg) [c] | MRL proposal (mg/kg) | Median CF [d] | Comments |
|---|---|---|---|---|---|---|---|---|---|
| | | | Enforcement | Risk assessment | | | | | |
| Barley grain | NEU | Outdoor | <0.02; 0.04; 0.04; 0.03; 0.04; 0.03; 0.07 | <0.04; 0.06; 0.06; 0.05; 0.06; 0.05; 0.09 | 0.04 | 0.07 | 0.1 | 1.5 | Trials on barley compliant with GAP. CGA 321113 residues always <LOQ.<br>$MRL_{OECD}$= 0.1<br>$R_{ber}$= 0.08<br>$R_{max}$= 0.09 |
| | SEU | Outdoor | 0.18; 0.02; 0.05; 0.11; <0.02; <0.02 | 0.20; 0.04; 0.07; 0.15; <0.04; <0.04 | 0.04 | 0.18 | 0.4 (tentative) | | Trials on barley compliant with GAP (France, 2013).<br>$MRL_{OECD}$= 0.33<br>$R_{ber}$= 0.26<br>$R_{max}$= 0.31 |
| Barley straw | NEU | Outdoor | 0.81; 0.68; 0.12; 0.41; 0.78; 0.17; 0.32 | 0.97; 0.80; 0.17; 0.46; 0.85; 0.22; 0.68 | 0.41 | 0.81 | 2 | 1.2 | Trials on barley compliant with GAP.<br>$MRL_{OECD}$= 1.62<br>$R_{ber}$= 1.56<br>$R_{max}$= 1.46 |
| | SEU | Outdoor | 2.4; 0.91; 0.81; 1.48; 0.15; 1.3 | 2.56; 1.11; 0.94; 1.64; 0.20; 1.51 | 1.11 | 2.40 | 2 (tentative) | | Trials on barley compliant with GAP (France, 2013).<br>$MRL_{OECD}$= 4.20<br>$R_{ber}$= 3.42<br>$R_{max}$= 3.98 |
| Oats grain | NEU | Outdoor | - | - | - | - | - | - | No trials available. |
| | SEU | Outdoor | 0.18; 0.02; 0.05; 0.11; <0.02; <0.02 | 0.20; 0.04; 0.07; 0.15; <0.04; <0.04 | 0.04 | 0.18 | 0.4 (tentative) | 1.5 | Direct extrapolation from barley. |
| Oats straw | NEU | Outdoor | - | - | - | - | - | - | No trials available. |
| | SEU | Outdoor | 2.4; 0.91; 0.81; 1.48; 0.15; 1.3 | 2.56; 1.11; 0.94; 1.64; 0.20; 1.51 | 1.11 | 2.40 | 2 (tentative) | 1.2 | Direct extrapolation from barley. |

| Commodity | Residue region [a] | Outdoor /Indoor | Individual trial results (mg/kg) | | Median residue (mg/kg) [b] | Highest residue (mg/kg) [c] | MRL proposal (mg/kg) | Median CF [d] | Comments |
|---|---|---|---|---|---|---|---|---|---|
| | | | Enforcement | Risk assessment | | | | | |
| Wheat grain<br>Rye grain | NEU | Outdoor | <0.02; 0.05; <0.02; <0.02; 0,14; 0.02; <0.02 | <0.04; 0.07; <0.04; <0.04;0.20; 0.03; <0.04 | 0.02 | 0.14 | 0.3 | 1.5 | Trials on wheat compliant with GAP. Extrapolation to rye possible.<br>$MRL_{OECD}$= 0.22<br>$R_{ber}$= 0.10<br>$R_{max}$= 0.19 |
| | SEU | Outdoor | <0.02; <0.02; <0.02; 0.03; <0.02; <0.02 | <0.04; <0.04; <0.04; 0.05; <0.04; <0.04 | 0.02 | 0.04 | 0.05 (tentative) | | Trials on wheat compliant with GAP. CGA 321113 residues always <LOQ. Not authorised on rye in southern Europe.<br>$MRL_{OECD}$= 0.04<br>$R_{ber}$= 0.05<br>$R_{max}$= 0.04 |
| Wheat straw<br>Rye straw | NEU | Outdoor | 2.3; 1.8; 2.0; 0.62; 0.16; 4; 1.3; 1.6; 0.35 | 2.63; 2.62; 2.14; 0.78; 0.21; 4.07; 1.61; 1.74; 0.42 | 1.60 | 4.00 | 7 (tentative) | 1.2 | Trials on wheat compliant with GAP.<br>$MRL_{OECD}$= 5.15<br>$R_{ber}$= 4.30<br>$R_{max}$= 6.29 |
| | SEU | Outdoor | 0.83; 0.17; 0.94; 1.3; 0.38; 0.7 | 1.0; 0.25; 1.07; 1.46; 0.43; 0.87 | 0.77 | 1.30 | 3 | | Trials on wheat compliant with GAP. Not authorised on rye in southern Europe.<br>$MRL_{OECD}$= 2.34<br>$R_{ber}$= 2.06<br>$R_{max}$= 2.22 |
| Hops (dried) | NEU | Outdoor | 4.7; 8.8; 5.4; 15.7; 9.5; 10.8; 11.4; 26.1 | 6.2; 9.2; 6.7; 17.7; 12.1; 12.5; 12.8; 28.6 | 10.15 | 26.10 | 40 | 1.1 | Trials performed with 4-6 applications instead of 2 accepted as first applications are not expected to impact on the final residue (United Kingdom, 2000); see also body text.<br>$MRL_{OECD}$= 38.85<br>$R_{ber}$= 29.25<br>$R_{max}$= 33.31 |

| Commodity | Residue region [a] | Outdoor /Indoor | Individual trial results (mg/kg) | | Median residue (mg/kg) [b] | Highest residue (mg/kg) [c] | MRL proposal (mg/kg) | Median CF [d] | Comments |
|---|---|---|---|---|---|---|---|---|---|
| | | | Enforcement | Risk assessment | | | | | |
| Sugar beet (root)<br>Fodder beet (root) | NEU | Outdoor | 4x<0.02 | 4x<0.04 | 0.02 | 0.02 | 0.02 | 1.0 [e, g] | Trials compliant with GAP (Netherlands, 2013; United Kingdom, 2013b). CGA 321113 residues always below the LOQ.<br>$MRL_{OECD}$= 0.02 |
| | SEU | Outdoor | 13x<0.02 | - | 0.02 | 0.02 | 0.02 | | Trials performed with 2 applications instead of 3. Not authorised on fodder beet in southern Europe<br>$MRL_{OECD}$= 0.02 |
| Sugar beet (tops)<br>Fodder beet (tops) | NEU | Outdoor | <0.02; 0.1; <0.05; 0.44 | <0.04; 0.15; <0.10; 0.49 | 0.08 | 0.44 | 1.5 (tentative) | 1.0 [e, f] | Trials compliant with GAP (Netherlands, 2013; United Kingdom, 2013b). CGA321113 residues always below the LOQ.<br>$MRL_{OECD}$= 0.93<br>$R_{ber}$= 0.71<br>$R_{max}$= 1.15 |
| | SEU | Outdoor | 4x<0.02; 5x<0.05; 0.05; 0.07; 0.09; 0.14; 0.33; 0.44 | - | 0.05 | 0.44 | 0.6 | | Trials performed with 2 applications instead of 3. Not authorised on fodder beet in southern Europe<br>$MRL_{OECD}$= 0.59<br>$R_{ber}$= 0.18<br>$R_{max}$= 0.41 |
| Chicory roots | NEU | Outdoor | - | - | - | - | - | - | No trials available. |
| Grass | NEU | Outdoor | - | - | - | - | - | - | No trials available. |

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e outdoor use) or Import (country code) (EC, 2011).
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.
(e): Although the number of residue data on CGA321113 in one of the climatic condition is in principle not sufficient to propose a reliable conversion factor, the residue data under other climatic condition is considered sufficient to derive an overall conversion factor.

(f): As CGA 321113 levels were all below the LOQ, the most occurring conversion factor for the other crops belonging to the same crop group was applied (CF of 1.2 for fruits and fruiting vegetables; CF of 1 for leafy, stem vegetables and sugar beet leaves; CF of 2 for root and tuber vegetables).
(g): As residues of both trifloxystrobin and CGA321113 were all at or below the LOQ, a conversion factor of 1 was derived for risk assessment.
(h): Although the trial was underdosed, this value was included in the dataset as it was found to be higher than any other value resulting from trials compliant with GAP.
(*): Indicates that the MRL is set at the limit of analytical quantification.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of trifloxystrobin was investigated in the framework of the peer review. A study was conducted with radiolabelled trifloxystrobin at pH ranging between 1 and 13 and at temperatures ranging between 25-60°C (United Kingdom, 2000). Trifloxystrobin was stable at pH 5 and no isomerisation of the parent compound occurred. In neutral and alkaline conditions, CGA 321113 was the major metabolite. In addition, a hydrolysis study performed at three test conditions (20 minutes at 90°C, pH 4; 60 minutes at 100°C pH 5; 20 minutes at 120°C, pH 6) was evaluated by the JMPR (FAO, 2004). Trifloxystrobin was hydrolytically stable under conditions simulating pasteurisation, showed minor degradation under baking/brewing/boiling conditions (2.6 % of TRR) and significant degradation under sterilisation (22.5 % of TRR). The main degradation product observed was the metabolite CGA 321113 (2 % at pH 5; 21 % at pH 6). Consequently, it can be concluded that the same residue definitions proposed for enforcement and risk assessment of raw commodities apply to processed commodities.

Studies investigating the magnitude of residues in processed commodities of apple and wines were also reported in the framework of the peer review (United Kingdom, 2000). As data on trifloxystrobin and CGA 321113 residue levels in raw and processed commodities were not reported, it was not possible to derive processing factors according to the proposed residue definitions.

### 3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

All crops under consideration, except pome fruits, stone fruits, berries, bananas, grapes and olives, may be grown in rotation. According to the soil degradation studies performed in the framework of the peer review, the $DT_{90}$ value of trifloxystrobin is less than 100 days. For the metabolite CGA 321113, the $DT_{90}$ value is more than 500 days and for CGA 373466[25], the major soil metabolite, the $DT_{90}$ value is up to 290 days (United Kingdom, 2000). According to the European guidelines on rotational crops (EC, 1997b), further investigation of residues in rotational crops is relevant.

3.1.2.2. Nature of residues

The metabolism of trifloxystrobin in lettuce, radish and wheat grown in rotation has been evaluated in the framework of the peer review (United Kingdom, 2000). The characteristics of the available studies are summarised in Table 3-3.

TRR were below 0.01 mg eq/kg in edible parts and below 0.05 mg eq/kg in feed items from all plants sown/planted more than 120 DAT. Consequently, no further investigation is required for those intervals and only results from 30 DAT plant-back intervals are discussed hereafter.

TRR were 0.02-0.03 mg eq/kg in lettuce heads and in radish roots and 0.04-0.06 mg eq/kg in wheat grain. In feed items, TRR was below 0.05 mg eq/kg in radish tops, 0.05 mg eq/kg in wheat forage and at about 0.12-0.13 mg eq/kg in straw. Trifluoroacetic acid was the most abundant compound identified in all samples from TP-label, accounting for 29 % TRR (0.046 mg eq/kg) in wheat forage, for 25 % TRR (0.015 mg eq/kg) in wheat grain and for 13 % TRR (0.016 mg eq/kg) in wheat straw. No other compound was detected at levels above 0.01 mg eq/kg in both labels. Extraction rate was generally low in the different samples (56-65 % TRR not extracted in straw; 55-85 % TRR not extracted in grain). Further investigation was conducted: 26 % TRR in grain was incorporated as starch and 11 % TRR as protein while in straw 8 % TRR was incorporated to natural compounds.

On the basis of the above findings, metabolisms in primary and rotational crops were found to be similar.

[25] CGA 373466: (Z, E)-methoxyimino-{2-[1-(3-trifluoro methyl-phenyl)-ethylideneaminooxymethyl]-phenyl}-acetic acid. See Appendix E.

**Table 3-3:** Summary of available metabolism studies in rotational crops

| Crop group | Crop | Label position | Application and sampling details | | | | |
|---|---|---|---|---|---|---|---|
| | | | Method, F or G [(a)] | Rate (kg a.s./ha) | Sowing intervals (DAT) | Harvest Intervals (DAT) | Remarks |
| Leafy vegetables | Lettuce | TP-$^{14}$C [(b)] | Bare soil, F | 0.5 | 31<br>120<br>365 | 69<br>181<br>419 | - |
| | | GP-$^{14}$C [(b)] | | | | | |
| Root and tuber vegetables | Radish | TP-$^{14}$C [(b)] | Bare soil, F | 0.5 | 31<br>120<br>365 | 69<br>181<br>419 | - |
| | | GP-$^{14}$C [(b)] | | | | | |
| Cereals | Wheat | TP-$^{14}$C [(b)]<br>GP-$^{14}$C [(b)] | Bare soil, F | 0.5 | Spring wheat:<br>31<br>365 | 76[(c)],<br>440[(c)],<br>120[(d)],<br>468[(d)] | - |
| | | | | | Winter wheat:<br>174 | 223[(c)],<br>419[(c)],<br>454[(d)] | - |

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b): TP = trifluoro-phenyl; GP = glyoxyl-phenyl
(c): sampling of forage
(d): sampling of grain, husk and straw

#### 3.1.2.3. Magnitude of residues

Based on the rotational confined crop study, considering that the application rate of trifloxystrobin within the EU ranges between 0.1-1.3 kg a.s./ha and that trifloxystrobin was applied to a bare soil (interception of trifloxystrobin by the plants is expected in practice), it can be concluded that trifloxystrobin residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that trifloxystrobin is applied in compliance with the GAPs reported in Appendix A.

## 3.2. Nature and magnitude of residues in livestock

### 3.2.1. Dietary burden of livestock

Trifloxystrobin is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens were therefore calculated for different groups of livestock using the agreed European methodology (EC, 1996). The input values for all relevant commodities have been selected according to the recommendations of JMPR (FAO, 2009) and are summarised in Table 3-4. For wheat bran and apple pomace, default processing factors of 8 and 2.5, respectively, have been included in the calculation in order to consider the potential concentration of residues in this commodity. For kale, since available data were not sufficient to derive a reliable CF for risk assessment, the worst case CF of 2 has been used. It is highlighted that for several feed items, no residue data were available (e.g. grass). The animal intake of trifloxystrobin residues via these commodities has therefore not been assessed and may have been underestimated.

**Table 3-4:** Input values for the dietary burden calculation

| Commodity | Median dietary burden | | Maximum dietary burden | |
|---|---|---|---|---|
| | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| **Risk assessment residue definition:** sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | | | | |
| Cabbage | 0.05 | Median residue x CF | 0.31 | Highest residue x CF |
| Kale | 1.32 | Median residue x 2 | 2.40 | Highest residue x 2 |
| Sugar and fodder beet leaves | 0.08 | Median residue x CF | 0.44 | Highest residue x CF |
| Apple, pomace | 0.51 | Median residue x CF x 2.5 | 0.51 | Median residue x CF x 2.5 |
| Wheat, rye grain | 0.03 | Median residue x CF | 0.03 | Median residue x CF |
| Wheat, rye bran | 0.24 | Median residue x CF x 8 | 0.24 | Median residue x CF x 8 |
| Wheat, rye straw | 1.92 | Median residue x CF | 4.80 | Highest residue x CF |
| Barley grain | 0.06 | Median residue x CF | 0.06 | Median residue x CF |
| Oats grain | 0.06 | Median residue x CF | 0.06 | Median residue x CF |
| Barley, oats straw | 1.33 | Median residue x CF | 2.88 | Highest residue x CF |
| Turnips, Swedes | 0.04 | Median residue x CF | 0.04 | Highest residue x CF |
| Sugar and fodder beets | 0.02 | Median residue x CF | 0.02 | Highest residue x CF |

The results of the calculations are reported in Table 3-5. The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation of residues is therefore required in all commodities of animal origin.

**Table 3-5:** Results of the dietary burden calculation

| | Median dietary burden (mg/kg bw per d) | Maximum dietary burden (mg/kg bw per d) | Highest contributing commodity | Max dietary burden (mg/kg DM) | Trigger exceeded (Y/N) |
|---|---|---|---|---|---|
| **Risk assessment residue definition:** sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | | | | | |
| Dairy ruminants | 0.142 | 0.265 | Kale | 7.34 | Y |
| Meat ruminants | 0.192 | 0.379 | Kale | 8.82 | Y |
| Poultry | 0.038 | 0.062 | Kale | 0.99 | Y |
| Pigs | 0.068 | 0.115 | Kale | 2.85 | Y |

### 3.2.2. Nature of residues

The nature of trifloxystrobin residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (United Kingdom, 2000). Reported metabolism studies include two studies in lactating goats and two studies in laying hens using $^{14}C$-labelled trifloxystrobin. The characteristics of these studies are summarised in Table 3-6.

**Table 3-6:** Summary of available metabolism studies in livestock

| Group | Species | Label position | No of animal | Application details | | Sample details | |
|---|---|---|---|---|---|---|---|
| | | | | Rate (mg/kg bw per d) | Duration (days) | Commodity | Time |
| Lactating ruminants | Goat | TP-$^{14}$C [(a)] | 2 | 4.2 | 4 | Milk | Twice, daily |
| | | | | | | Urine and faeces | Daily |
| | | | | | | Tissues | At sacrifice |
| | | GP-$^{14}$C [(a)] | | 4.1 | | Milk | Twice, daily |
| | | | | | | Urine and faeces | Daily |
| | | | | | | Tissues | At sacrifice |
| Laying poultry | Hens | TP-$^{14}$C [(a)] | 5 | 7.7 | 4 | Eggs | Twice, daily |
| | | | | | | Excreta | Daily |
| | | | | | | Tissues | At sacrifice |
| | | GP-$^{14}$C [(a)] | | 6.7 | | Eggs | Twice, daily |
| | | | | | | Excreta | Daily |
| | | | | | | Tissues | At sacrifice |

(a): TP = trifluoro-phenyl; GP = glyoxyl-phenyl

Lactating goats were dosed with 4 mg/kg bw per d of trifloxystrobin, corresponding to approximately 10 times the exposure of meat ruminant. Up to 63.4 % of the AR was excreted. TRR in milk was 0.09 mg/kg. The study was too short to conclude that a plateau was reached. After sacrifice, the highest TRR was found in liver and kidney (3.9-4.8 and 1.8-2.3 mg/kg, respectively). TRR in muscle and fat were 0.06-0.08 and 0.19-0.36 mg/kg, respectively.

Parent trifloxystrobin was the major compound in milk (52-74 % TRR, 0.04-0.07 mg eq/kg) and in fat (79-82 % TRR, 0.15-0.29 mg eq/kg) and was present at 21-27 % TRR (0.01-0.02 mg eq/kg) in muscle and at 1-3 % TRR in liver (0.04-0.14 mg eq/kg) and kidney (0.03-0.04 mg eq/kg). CGA 321113, under free and conjugated forms, was the major compound in liver (50 % TRR, *ca.* 2 mg eq/kg), kidney (72-80 % TRR, 1.3-1.9 mg eq/kg) and muscle (51-57 % TRR, 0.03-0.04 mg eq/kg). CGA 321113 was detected under acid form in fat at 10-11 % TRR (0.02-0.04 mg eq/kg) and under conjugated form in milk at 12 % TRR (0.01 mg eq/kg). Other identified metabolites did not individually exceed 5 % TRR. In liver, 31-33 % TRR remained unextracted and further investigation conducted did not allow a further characterisation of the residue in this tissue. Nevertheless, considering the overdosing factor and that CGA 321113 under acid and conjugated forms represented an important part of the TRR, no further investigation is deemed necessary.

Laying hens were dosed with 6.7-7.7 mg/kg bw per d of trifloxystrobin, corresponding to approximately 200 times the exposure of poultry. 80 % of the AR was excreted, but a plateau was not reached in egg yolk, as residue levels were almost doubled between the two last samplings. TRR in whole egg was 0.8-0.9 mg eq/kg. After sacrifice, the highest TRR was found in liver (*ca.*6 mg eq/kg); TRR was 0.8-1.5 mg eq/kg in fat and skin and 0.2 mg eq/kg in muscle. Results showed that the metabolism in poultry liver was very extensive, leading to several identified compounds, among which

only L13b[26] and BO172631[27] were detected at levels above 10 % TRR (11-13 % TRR for each compound). However, considering the overdosing factor, no significant residues are expected in poultry products.

Based on the above findings, EFSA concludes that the residue definition proposed for enforcement in ruminants is sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin. Since log $P_{o/w}$ of trifloxystrobin is higher than 3 (United Kingdom, 2000), EFSA concludes that the residue in commodities of animal origin is fat soluble. No fully validated analytical methods for enforcement of the proposed residue definition are available (see also section 1.2) and are therefore required. For risk assessment, EFSA proposes to also include the conjugates of CGA321113 in the residue definition for ruminant liver and kidney.

The general metabolic pathways in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to pigs. However, as the intake calculated for pigs is lower than the one for ruminants, no residue of trifloxystrobin nor CGA321113 is expected to occur in pig commodities. Consequently, EFSA considers not necessary to include conjugates of CGA321113 in the residue definition for risk assessment in pig liver and kidney. For poultry, as no residues are expected from the authorised uses, EFSA concludes that the residue definition proposed for enforcement and risk assessment in poultry products is trifloxystrobin and CGA321113, expressed as trifloxystrobin. No validated analytical methods for enforcement of this residue definition are available (see also section 1.2) and are therefore required.

### 3.2.3. Magnitude of residues

According to the above mentioned metabolism studies, it is concluded that, after exposure to the maximum dietary burden (about 200 times lower than the dose level of the metabolism studies; see also section 3.2.1), no residue above the LOQ is expected in poultry commodities (muscle, fat, eggs and liver). Hence, no poultry feeding study is required; MRLs and risk assessment values for the relevant commodities in poultry can be established at the LOQ level.

During the peer review under Directive 91/414/EEC, the magnitude of trifloxystrobin residues in ruminants was investigated in a feeding study with lactating cows (United Kingdom, 2000). Three groups of lactating cows, each consisting of three animals were dosed for 28 consecutive days with trifloxystrobin at levels of 2, 6, and 20 mg/kg in the diet (equivalent to 0.06, 0.19 and 0.64 mg/kg bw). The samples were analysed for trifloxystrobin and CGA321113. Results of ruminant livestock feeding studies are summarised in Table 3-7.

The storage stability of trifloxystrobin residues in animal products was evaluated under the peer review of Directive 91/414/EEC (United Kingdom, 2000). Study demonstrated storage stability of trifloxystrobin and CGA321113 in milk, muscle, fat, liver and kidney for up to 4 months when stored deep frozen. The storage conditions of the samples from the livestock feeding study were not reported by the RMS. Considering that storage stability in animal tissues and milk was only demonstrated for 4 months, this information would be desirable in order to confirm the validity of the reported livestock feeding studies.

Consequently, the available data are considered sufficient for deriving MRLs in ruminants and pigs. These MRLs were derived in compliance with the latest recommendations on this matter (FAO, 2009) and are summarised in Table 3-7. Significant residues in liver of ruminants are expected and MRLs for these commodities can be proposed. Significant residues in other tissues of ruminants and milk are not expected and MRLs for these commodities can be established at the LOQ of the analytical method used in livestock feeding studies. Considering that no validated analytical method is available for

[26] L13b: {2-[1-(hydroxy-5-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-phenyl}-methoxyimino-acetic acid methyl ester. See Appendix E.
[27] BO172631: 2-[2-hydroxy-1-(3-trifluoromethyl-phenyl)- ethylideneaminooxymethyl]-benzonitrile. See Appendix E.

enforcement purposes and information on the storage condition is still required for animal matrices, these MRLs are tentative only.

Based on the available metabolism studies, EFSA also derived tentative conversion factors of 1.3 and 3.3 for risk assessment in ruminant kidney and liver respectively. Although it is preferable to derive conversion factors for risk assessment from the livestock feeding studies, the conversion factors are considered appropriate in the framework of this review because the contribution of the products of animal origin to the chronic exposure is minor (see also section 4).

**Table 3-7:** Overview of the values derived from the livestock feeding studies

| Commodity | Dietary burden | | Results of the livestock feeding study | | | | | | Median residue (mg/kg)[(a)] | Highest residue (mg/kg)[(b)] | MRL proposal (mg/kg)[(c)] | CF for RA |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Med. (mg/kg bw per d) | Max. (mg/kg bw per d) | Dose Level (mg/kg bw per d) | No | Result for enf. | | Result for RA | | | | | |
| | | | | | Mean (mg/kg) | Max. (mg/kg) | Mean (mg/kg) | Max. (mg/kg) | | | | |
| **Enforcement and risk assessment residue definition:** sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin. | | | | | | | | | | | | |
| Pig muscle | 0.07 | 0.12 | 0.06 | 3 | n.a. | n.a. | n.a. | n.a. | 0.04 | 0.04 | 0.04 (tentative) | 1.00 |
| | | | 0.19 | 3 | n.a. | n.a. | n.a. | n.a. | | | | |
| | | | 0.64 | 3 | <0.04 | <0.04 | <0.04 | <0.04 | | | | |
| Pig fat | 0.07 | 0.12 | 0.06 | 3 | <0.04 | <0.04 | <0.04 | <0.04 | 0.04 | 0.04 | 0.04 (tentative) | 1.00 |
| | | | 0.19 | 3 | <0.04 | <0.04 | <0.04 | <0.04 | | | | |
| | | | 0.64 | 3 | 0.06 | 0.08 | 0.06 | 0.08 | | | | |
| Pig liver | 0.07 | 0.12 | 0.06 | 3 | <0.04 | <0.04 | <0.04 | <0.04 | 0.04 | 0.04 | 0.04 (tentative) | 1.00 |
| | | | 0.19 | 3 | <0.04 | <0.04 | <0.04 | <0.04 | | | | |
| | | | 0.64 | 3 | 0.08 | 0.11 | 0.08 | 0.11 | | | | |
| Pig kidney | 0.07 | 0.12 | 0.06 | 3 | <0.04 | <0.04 | <0.04 | <0.04 | 0.04 | 0.04 | 0.04 (tentative) | 1.00 |
| | | | 0.19 | 3 | <0.04 | <0.04 | <0.04 | <0.04 | | | | |
| | | | 0.64 | 3 | 0.04 | 0.04 | 0.04 | 0.04 | | | | |
| Ruminant muscle | 0.19 | 0.38 | 0.06 | 3 | n.a. | n.a. | n.a. | n.a. | 0.04 | 0.04 | 0.04 (tentative) | 1.00 |
| | | | 0.19 | 3 | n.a. | n.a. | n.a. | n.a. | | | | |
| | | | 0.64 | 3 | <0.04 | <0.04 | <0.04 | <0.04 | | | | |
| Ruminant fat | 0.19 | 0.38 | 0.06 | 3 | <0.04 | <0.04 | <0.04 | <0.04 | 0.04 | 0.06 | 0.06 (tentative) | 1.00 |
| | | | 0.19 | 3 | <0.04 | <0.04 | <0.04 | <0.04 | | | | |
| | | | 0.64 | 3 | 0.06 | 0.08 | 0.06 | 0.08 | | | | |

| Commodity | Dietary burden | | Results of the livestock feeding study | | | | | | Median residue (mg/kg)[(a)] | Highest residue (mg/kg)[(b)] | MRL proposal (mg/kg)[(c)] | CF for RA |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Med. (mg/kg bw per d) | Max. (mg/kg bw per d) | Dose Level (mg/kg bw per d) | No | Result for enf. | | Result for RA | | | | | |
| | | | | | Mean (mg/kg) | Max. (mg/kg) | Mean (mg/kg) | Max. (mg/kg) | | | | |
| Milk | 0.14 | 0.27 | 0.64 | 3 | <0.02 [(d)] | - [(e)] | <0.02 [(d)] | - [(e)] | 0.02 | 0.02 | 0.02 (tentative) | 1.00 |
| **Enforcement residue definition:** sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin.<br>**Risk assessment residue definition:** sum of trifloxystrobin, CGA321113 and its conjugates, expressed as trifloxystrobin. | | | | | | | | | | | | |
| Ruminant liver | 0.19 | 0.38 | 0.06 | 3 | <0.04 | <0.04 | <0.04 | <0.04 | 0.04 | 0.07 | 0.07 (tentative) | 3.30 |
| | | | 0.19 | 3 | <0.04 | <0.04 | <0.04 | <0.04 | | | | |
| | | | 0.64 | 3 | 0.08 | 0.11 | 0.08 | 0.11 | | | | |
| Ruminant kidney | 0.19 | 0.38 | 0.06 | 3 | <0.04 | <0.04 | <0.04 | <0.04 | 0.04 | 0.04 | 0.04 (tentative) | 1.30 |
| | | | 0.19 | 3 | <0.04 | <0.04 | <0.04 | <0.04 | | | | |
| | | | 0.64 | 3 | 0.04 | 0.04 | 0.04 | 0.04 | | | | |

n.a.: Not analysed.
n.r.: Not reported.
(a): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).
(b): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).
(c): The median conversion factor for enforcement to risk assessment.
(d): Mean residue level from day 1 until day 28 (3 cows, 28 sampling days).
(e): Only the mean values are considered for calculating MRLs in milk.

## 4. Consumer risk assessment

In the framework of this review, only the uses of trifloxystrobin reported by the RMS in Appendix A were considered, however the use of trifloxystrobin was previously also assessed by the JMPR (FAO, 2004). The CXLs, resulting from this assessment by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. In order to facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs (see Appendix C.2).

### 4.1. Consumer risk assessment without consideration of the existing CXLs

Chronic exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo) (EFSA, 2007). Input values for the exposure calculations were derived in compliance with Appendix D and are summarised in Table 4-1. The (tentative) median residue values selected for chronic intake calculations are based on the residue levels in the raw agricultural commodities reported in section 3, multiplied by the conversion factor derived for the corresponding crops. When CGA321113 levels were always below the LOQ, the most occurring conversion factor for the other crops belonging to the same crop group (CF of 1.2 for fruits and fruiting vegetables; CF of 1 for leafy and stem vegetables and for sugar beet leaves; CF of 2 for root and tuber vegetables) was applied for an indicative calculation. When data on CGA321113 levels was not available or not sufficient to derive a reliable conversion factor, EFSA considered the highest conversion factor of 2. For those commodities where data were insufficient to derive an MRL in section 3, EFSA considered the existing EU MRL multiplied by the highest conversion factor of 2. This approach leads to an overestimation of the consumer exposure but it is considered acceptable for the time being as it does not lead to an exceedance of the ADI (see below). The contributions of other commodities, for which no GAP was reported in the framework of this review, were not included in the calculation. Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

**Table 4-1:** Input values for the consumer risk assessment (without consideration of CXLs)

| Commodity | Chronic risk assessment | |
|---|---|---|
| | Input value (mg/kg) | Comment |
| **Risk assessment residue definition:** sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | | |
| Apples, Pears | 0.20 | Median residue x CF [(a)] |
| Other pome fruits | 0.08 | Median residue x CF [(a)] |
| Apricots, Peaches | 0.44 | Median residue x CF (tentative) [(b)] |
| Cherries | 0.13 | Median residue x CF (tentative) [(b)] |
| Plums | 0.07 | Median residue x CF [(a)] |
| Table and wine grapes | 0.16 | Median residue x CF [(a)] |
| Strawberries | 0.11 | Median residue x CF [(a)] |
| Blackberries, Raspberries | 0.04 | EU MRL x 2 [(c)] |
| Blueberries | 0.60 | Median residue x CF [(a)] |
| Currants (red, black and white), Gooseberries | 0.35 | Median residue x CF (tentative) [(b)] |
| Table olives | 0.06 | Median residue x CF [(a)] |

| Commodity | Chronic risk assessment | |
|---|---|---|
| | Input value (mg/kg) | Comment |
| Passion fruit | 0.86 | Median residue x CF (tentative) [(b)] |
| Bananas | 0.01 | Median residue x CF [(a)] |
| Beetroot | 0.02 | Median residue x CF [(a)] |
| Carrots, Parsnips, Salsify, Swedes, Turnips | 0.04 | Median residue x CF [(a)] |
| Celeriac | 0.02 | Median residue x CF [(a)] |
| Horseradish, Parsley root | 0.05 | Median residue x CF [(a)] |
| Garlic, Onion | 0.01 | Median residue x CF [(a)] |
| Tomatoes | 0.10 | Median residue x CF [(a)] |
| Peppers | 0.10 | Median residue x CF (tentative) [(b)] |
| Aubergines (egg plants) | 0.09 | Median residue x CF [(a)] |
| Cucumbers, Gherkins | 0.07 | Median residue x CF (tentative) [(b)] |
| Courgettes | 0.08 | Median residue x CF (tentative) [(b)] |
| Melons | 0.08 | Median residue x CF [(a)] |
| Pumpkins | 0.40 | EU MRL x 2 [(c)] |
| Watermelons | 0.05 | Median residue x CF [(a)] |
| Broccoli, Cauliflower | 0.04 | Median residue x CF [(a)] |
| Brussels sprouts | 0.15 | Median residue x CF [(a)] |
| Head cabbage | 0.05 | Median residue x CF [(a)] |
| Chinese cabbage, Kale | 1.32 | Median residue x CF (tentative) [(b)] |
| Lettuce | 5.53 | Median residue x CF [(a)] |
| Scarole (broad-leaf endive), Herbs | 5.53 | Median residue x CF (tentative) [(b)] |
| Witloof | 0.04 | EU MRL x 2 [(c)] |
| Beans (fresh, with pods) | 0.39 | Median residue x CF (tentative) [(b)] |
| Peas (fresh, with pods) | 0.04 | EU MRL x 2 [(c)] |
| Celery | 0.08 | Median residue x CF [(a)] |
| Globe artichokes | 0.07 | Median residue x CF [(a)] |
| Leek | 0.07 | Median residue x CF (tentative) [(b)] |
| Olives for oil production | 0.6 | EU MRL x 2 [(c)] |
| Barley grain | 0.06 | Median residue x CF (tentative) [(b)] |
| Oats grain | 0.05 | Median residue x CF (tentative) [(b)] |
| Wheat and rye grain | 0.03 | Median residue x CF [(a)] |
| Hops (dried), including hop pellets and unconcentrated powder | 11.2 | Median residue x CF [(a)] |
| Sugar beet (root) | 0.02 | Median residue x CF [(a)] |
| Chicory root | 0.04 | EU MRL x 2 [(c)] |

| Commodity | Chronic risk assessment | |
|---|---|---|
| | Input value (mg/kg) | Comment |
| Swine meat | 0.04 | Median residue (tentative) (d) |
| Swine fat (free of lean meat) | 0.04 | Median residue (tentative) (d) |
| Swine liver | 0.04 | Median residue (tentative) (d) |
| Swine kidney | 0.04 | Median residue (tentative) (d) |
| Ruminant meat | 0.04 | Median residue (tentative) (d) |
| Ruminant fat | 0.04 | Median residue (tentative) (d) |
| Poultry meat | 0.04 | Median residue (tentative) (d) |
| Poultry fat | 0.04 | Median residue (tentative) (d) |
| Poultry liver | 0.04 | Median residue (tentative) (d) |
| Ruminant milk | 0.02 | Median residue (tentative) (d) |
| Birds' eggs | 0.04 | Median residue (tentative) (d) |
| **Risk assessment residue definition:** trifloxystrobin, CGA321123 and its conjugates, expressed as trifloxystrobin | | |
| Ruminant liver | 0.13 | Median residue (tentative) x CF (d) |
| Ruminant kidney | 0.05 | Median residue (tentative) x CF (d) |

(*): Indicates that the input value is proposed at the limit of analytical quantification.
(a): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment value derived in section 3 are used for the exposure calculations.
(b): Use reported by the RMS is not fully supported by data but the risk assessment values derived in section 3 are used for indicative exposure calculations.
(c): Use reported by the RMS is not supported by data; the existing EU MRL multiplied by a conversion factor for risk assessment is used for indicative exposure calculations.
(d): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS, is not fully supported by data; the risk assessment values derived in section 3 are used for indicative exposure calculations.

The calculated exposures were compared with the toxicological reference value derived for trifloxystrobin (see Table 2-1); detailed results of the calculations are presented as the EU scenario in Appendix B.1. The highest chronic exposure was calculated for WHO Cluster diet B, representing 5.9 % of the ADI.

Based on the above calculations, EFSA concludes that the use of trifloxystrobin on crops fully supported by data (footnote (a) in Table 4-1), is acceptable with regard to consumer exposure. For the other crops, major uncertainties remain due to the data gaps identified in section 3, but considering tentative MRLs or the existing EU MRLs in the exposure calculation did not indicate a risk to consumers.

### 4.2. Consumer risk assessment with consideration of the existing CXLs

In order to include the CXLs in the calculations of the consumer exposure, all data relevant to the consumer exposure assessment have been collected from JMPR evaluations and reported in Appendix C.2 to this document. These CXLs were compared with the EU MRL proposals in compliance with Appendix D and input values resulting from this comparison are summarised in Table 4-2.

For commodities of animal origin, although MRLs derived by JMPR are slightly higher than those derived at EU level, the median and highest residue values derived by JMPR are below the MRLs

derived at EU level. The CXLs for commodities of animal origin are therefore considered to be covered by the EU MRL proposals and therefore not further considered.

**Table 4-2:** Input values for the consumer risk assessment (with consideration of CXLs)

| Commodity | Chronic risk assessment | |
|---|---|---|
| | Input value (mg/kg) | Comment |
| **Risk assessment residue definition:** sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | | |
| Citrus fruits | 0.10 | Median residue (CXL) [(a)] |
| Tree nuts | 0.02 | Median residue (CXL) [(a)] |
| Pome fruits | 0.11 | Median residue (CXL) [(a)] |
| Stone fruits | 0.36 | Median residue (CXL) [(a)] |
| Table and wine grapes | 0.13 | Median residue (CXL) [(a)] |
| Strawberries | 0.32 | Median residue (CXL) [(a)] |
| Blackberries, Raspberries | 0.04 | EU MRL x 2 [(b)] |
| Blueberries | 0.60 | Median residue x CF [(c)] |
| Currants (red, black and white), Gooseberries | 0.35 | Median residue x CF (tentative) [(d)] |
| Table olives | 0.09 | Median residue (CXL) [(a)] |
| Passion fruit | 0.86 | Median residue x CF (tentative) [(d)] |
| Bananas | 0.02 | Median residue (CXL) [(a)] |
| Papaya | 0.19 | Median residue (CXL) [(a)] |
| Potatoes | 0.02 | Median residue (CXL) [(a)] |
| Beetroot | 0.02 | Median residue x CF [(c)] |
| Carrots | 0.05 | Median x CF (CXL) [(a)] |
| Celeriac | 0.02 | Median residue x CF [(c)] |
| Horseradish, Parsley root | 0.05 | Median residue x CF [(c)] |
| Parsnips, Salsify, Swedes, Turnips | 0.04 | Median residue x CF [(c)] |
| Radishes | 0.06 | Median x CF (CXL) [(a)] |
| Garlic, Onion | 0.01 | Median residue x CF [(c)] |
| Tomatoes | 0.08 | Median residue (CXL) [(a)] |
| Peppers | 0.10 | Median residue x CF (tentative) [(d)] |
| Aubergines (egg plants) | 0.08 | Median residue (CXL) [(a)] |
| Cucumbers, Gherkins | 0.07 | Median residue x CF (tentative) [(d)] |
| Courgettes | 0.09 | Median x CF (CXL) [(a)] |
| Melons, Pumpkins, Watermelons | 0.09 | Median x CF (CXL) [(a)] |
| Broccoli, Cauliflower | 0.20 | Median x CF (CXL) [(a)] |
| Brussels sprouts | 0.15 | Median residue x CF [(c)] |
| Head cabbage | 0.20 | Median x CF (CXL) [(a)] |
| Chinese cabbage, Kale | 1.32 | Median residue x CF (tentative) [(d)] |

| Commodity | Chronic risk assessment | |
|---|---|---|
| | Input value (mg/kg) | Comment |
| Lettuce | 5.53 | Median residue x CF [(c)] |
| Scarole (broad-leaf endive), Herbs | 5.53 | Median residue x CF (tentative) [(d)] |
| Leaves and sprouts of Brassica spp | 1.56 | Median x CF (CXL) [(a)] |
| Witloof | 0.04 | EU MRL x 2 [(b)] |
| Beans (fresh, with pods) | 0.39 | Median residue x CF (tentative) [(d)] |
| Peas (fresh, with pods) | 0.04 | EU MRL x 2 [(b)] |
| Asparagus | 0.05 | Median residue (CXL) [(a)] |
| Celery | 0.18 | Median residue (CXL) [(a)] |
| Globe artichokes | 0.07 | Median residue x CF [(c)] |
| Leek | 0.25 | Median x CF (CXL) [(a)] |
| Peanuts | 0.02 | Median residue (CXL) [(a)] |
| Olives for oil production | 0.60 | EU MRL x 2 [(b)] |
| Barley grain | 0.06 | Median x CF (CXL) [(a)] |
| Maize grain | 0.02 | Median x CF (CXL) [(a)] |
| Oats grain | 0.05 | Median residue x CF (tentative) [(d)] |
| Rice grain | 0.17 | Median x CF (CXL) [(a)] |
| Wheat, rye grain | 0.03 | Median residue x CF [(c)] |
| Hops (dried), including hop pellets and unconcentrated powder | 11.2 | Median residue x CF [(c)] |
| Sugar beet (root) | 0.02 | Median residue (CXL) [(a)] |
| Chicory root | 0.04 | EU MRL x 2 [(b)] |
| Swine meat | 0.02 | Median residue (tentative) [(e)] |
| Swine fat (free of lean meat) | 0.02 | Median residue (tentative) [(e)] |
| Swine liver | 0.02 | Median residue (tentative) [(e)] |
| Swine kidney | 0.02 | Median residue (tentative) [(e)] |
| Ruminant meat | 0.04 | Median residue (tentative) [(e)] |
| Ruminant fat | 0.04 | Median residue (tentative) [(e)] |
| Poultry meat | 0.04 | Median residue (tentative) [(e)] |
| Poultry fat | 0.04 | Median residue (tentative) [(e)] |
| Poultry liver | 0.04 | Median residue (tentative) [(e)] |
| Ruminant milk | 0.02 | Median residue (tentative) [(e)] |
| Birds' eggs | 0.04 | Median residue (tentative) [(e)] |
| **Risk assessment residue definition:** trifloxystrobin, CGA321123 and its conjugates, expressed as trifloxystrobin | | |
| Ruminant liver | 0.13 | Median residue (tentative) [(e)] |
| Ruminant kidney | 0.05 | Median residue (tentative) [(e)] |

(*): Indicates that the the input value is proposed at the limit of analytical quantification.

(a): CXL is supported by data; the corresponding risk assessment value are used for the exposure calculations.
(b): Use reported by the RMS is not supported by data; the existing EU MRL multiplied by a conversion factor for risk assessment is used for indicative exposure calculations.
(c): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment value derived in section 3 is used for the exposure calculations.
(d): Use reported by the RMS is not fully supported by data but the risk assessment value derived in section 3 is used for indicative exposure calculations.
(e): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS, is not fully supported by data; the risk assessment values derived in section 3 are used for indicative exposure calculations.

Chronic and acute exposure calculations were also performed using revision 2 of the EFSA PRIMo and calculated exposures were compared with the toxicological reference value derived for trifloxystrobin (see Table 2-1); detailed results of the calculations are presented as the EU/Codex scenario in Appendix B.2. The highest chronic exposure was calculated for WHO Cluster diet B, representing 6.1 % of the ADI.

Based on the above calculations, EFSA concludes that the CXLs are adequately supported by data and that they are not expected to be of concern for European consumers.

## CONCLUSIONS AND RECOMMENDATIONS

### CONCLUSIONS

The toxicological profile of trifloxystrobin was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI being established at 0.1 mg/kg bw per d. An ARfD was not deemed necessary.

Primary crop metabolism of trifloxystrobin was investigated in three different crop groups following foliar applications. Based on these studies, EFSA proposes to define the residue for enforcement in all plant commodities as parent trifloxystrobin while for risk assessment the relevant residue is defined as the sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin. Validated analytical methods for enforcement of this residue definition are available with an LOQ of 0.01 mg/kg.

Regarding the magnitude of residues in primary crops, at least one GAP is fully supported by data for most of the crops reported and the available residue data were considered acceptable to derive MRL proposals as well as risk assessment, except for cherry, apricot, peach, currants, gooseberries, passion fruit, pepper, cucurbits with edible peel, leafy brassica, scarole, herbs, beans (fresh, with pods), leek, barley and oats where additional data are required (residue trials compliant with GAP) and only tentative MRLs are derived. For blackberries, raspberries, pumpkins, witloof, peas (fresh, with pods), olives for oil production and chicory roots, the available data were insufficient to derive tentative MRLs.

The hydrolysis studies demonstrated that under pasteurisation, baking/boiling/brewing and sterilisation conditions, trifloxystrobin remained stable in processed commodities. Consequently, the residue definitions proposed for enforcement and risk assessment of raw commodities also apply to processed commodities. Studies investigating the magnitude of residues in processed commodities of apple and wines were also reported. As data on trifloxystrobin and CGA 321113 residue levels in raw and processed commodities were not reported, it was not possible to derive processing factors according to the proposed residue definitions.

The potential incorporation of soil residues into succeeding and rotational crops was investigated in lettuce, radish and wheat during the peer review and the residue definition set for the primary crops also applies to the rotational crops. Trifloxystrobin residue levels are also not expected to exceed 0.01 mg/kg in rotational commodities, provided that trifloxystrobin is applied in compliance with the GAPs reported in Appendix A.

Based on the uses reported by the RMS, significant intakes were calculated for ruminants, poultry and pigs. Metabolism in lactating ruminants and poultry was sufficiently investigated and findings in ruminants can be extrapolated to pigs. The relevant residue definition for enforcement in all commodities of animal origin was defined as sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin. For risk assessment, the residue definition is the same, except in ruminant liver and kidney, where EFSA proposes to define the residue as the sum of trifloxystrobin, CGA321113 and its conjugates, expressed as trifloxystrobin. Fully validated analytical methods for enforcement of the residue definition are not available and they are therefore still required. Feeding studies also allowed to derive MRLs in ruminants and pigs. Considering however that no fully validated analytical method is available, these MRLs are tentative.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure represented 5.9 % of the ADI (WHO Cluster diet B). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for trifloxystrobin. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out. The highest chronic exposure represented 6.1 % of the ADI (WHO Cluster diet B).

## RECOMMENDATIONS

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D of the reasoned opinion (see summary table). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see summary table footnotes for details). In particular, some tentative MRLs and existing EU MRLs need to be confirmed by the following data:

- an analytical method fully validated and its ILV for the determination of trifloxystrobin and its metabolite CGA 321113 in animal commodities;
- 4 residue trials on raspberry complying with the northern GAP on blackberry and raspberry;
- 6 residue trials on currants complying with the northern GAP on currants and gooseberries and including results in accordance with the residue definition for risk assessment;
- 4 residue trials complying with the import tolerance on passion fruit;
- 8 trials complying with the southern GAP and 3 additional trials complying with the indoor GAP on pepper;
- 8 residue trials on cucumbers complying with the northern GAP on cucurbits with edible peel and 8 residue trials complying with the indoor GAP on cucumber;
- 2 additional trials on kale complying with the northern GAP on leafy brassica, including residue data in accordance with the residue definition for risk assessment;
- 4 trials on lettuce (open leaves variety) complying with the indoor GAP and 4 trials on lettuce (open leaves variety) complying with the northern GAP on scarole and herbs;
- 4 residue trials complying with the northern GAP on witloof;
- 8 trials complying with the indoor GAP and 6 additional trials complying with the northern GAP on beans (fresh, with pods) (including residue data in accordance with the residue definition for risk assessment);
- 8 residue trials complying with the indoor GAP on peas (fresh, with pods);
- 8 residue trials complying with the southern GAP on olives for oil production;
- 8 residue trials complying with the northern GAP on oats;

- 4 residue trials complying with the northern GAP on chicory roots.

It is highlighted, however, that some of the MRLs derived result from a CXL or from a GAP in one climatic zone only, while other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gaps which are not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- 7 additional residue trials (with a minimum of 4 trials on apricots) complying with the northern outdoor GAP on apricot and peaches and 8 residue trials (with a minimum of 4 trials on apricots) complying with the southern outdoor GAP on apricot and peaches;
- 8 residue trials on cherries complying with the northern GAP, 1 additional trial on cherries complying with the southern GAP and 4 residue trials on cherries complying with the indoor GAP;
- 8 residue trials on grapes complying with the indoor GAP;
- 6 additional residue trials on strawberries complying with the northern GAP and 8 trials complying with the southern GAP;
- 8 residue trials complying with the southern GAP on tomato;
- 4 additional residue trials complying with the southern GAP on courgettes;
- 8 residue trials complying with the northern GAP on melons;
- 4 residue trials complying with the northern GAP and 4 residue trials complying with the indoor GAP on pumpkin;
- 2 additional residue trials complying with the southern GAP on watermelon;
- 8 residue trials complying with the northern GAP and 6 additional residue trials complying with the southern GAP on leek (including residue data in accordance with the residue definition for risk assessment);
- 2 additional residue trials on wheat complying with the southern GAP on wheat and rye;
- 2 additional residue trials complying with the southern GAP on barley;
- 4 residue trials complying with the northern GAP on grass.

If the above reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

Minor deficiencies were also identified in the assessment but these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data are therefore considered desirable but not essential:

- data on the toxicological relevance and magnitude of the compound SA04271 in cereal grain;
- a detailed evaluation report of the latest storage stability studies as well as the storage conditions of the residues trials samples for which storage conditions were not yet reported;
- 1 additional residue trial on plum complying with the northern GAP;
- 1 additional residue trial on melon complying with the southern GAP;
- 1 additional residue trial on barley supporting the northern GAP;
- 1 additional residue trial on wheat complying with the northern GAP on wheat and rye;
- information on the storage conditions of the samples from livestock feeding studies.

## SUMMARY TABLE

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | |
|---|---|---|---|---|---|
| | | | | MRL (mg/kg) | Comment |
| **Enforcement residue definition :** trifloxystrobin | | | | | |
| 110000 | Citrus fruit | 0.3 | 0.5 | 0.5 | Recommended [(a)] |
| 120000 | Tree nuts | 0.02* | 0.02* | 0.02 | Recommended [(a)] |
| 130000 | Pome fruit | 0.5 | 0.7 | 0.7 | Recommended [(b)] |
| 140010 | Apricots | 1 | 3 | 3 | Recommended [(c)] |
| 140020 | Cherries | 1 | 3 | 3 | Recommended [(c)] |
| 140030 | Peaches | 1 | 3 | 3 | Recommended [(c)] |
| 140040 | Plums | 0.2 | 3 | 3 | Recommended [(b)] |
| 151000 | Table and wine grapes | 5 | 3 | 3 | Recommended [(b)] |
| 152000 | Strawberries | 0.5 | 1 | 1 | Recommended [(b)] |
| 153010 | Blackberries | 0.02* | - | 0.02 | Further consideration needed [(d)] |
| 153030 | Raspberries | 0.02* | - | 0.02 | Further consideration needed [(d)] |
| 154010 | Blueberries | 2 | - | 2 | Recommended [(e)] |
| 154030 | Currants (red, black and white) | 1 | - | 1.5 | Further consideration needed [(f)] |
| 154040 | Gooseberries | 1 | - | 1.5 | Further consideration needed [(f)] |
| 1610030 | Table olives | 0.3 | 0.3 | 0.3 | Recommended [(b)] |
| 162030 | Passion fruit | 4 | - | 4 | Further consideration needed [(f)] |
| 163020 | Bananas | 0.05 | 0.05 | 0.05 | Recommended [(b)] |
| 162030 | Papaya | 1 | 0.6 | 0.6 | Recommended [(a)] |
| 211000 | Potatoes | 0.02* | 0.02* | 0.02 | Recommended [(a)] |
| 213010 | Beetroot | 0.02* | - | 0.02 | Recommended [(e)] |
| 213020 | Carrots | 0.05 | 0.1 | 0.1 | Recommended [(b)] |
| 213030 | Celeriac | 0.02* | - | 0.02 | Recommended [(e)] |
| 213040 | Horseradish | 0.02* | - | 0.08 | Recommended [(e)] |
| 213060 | Parsnips | 0.04 | - | 0.04 | Recommended [(e)] |
| 213070 | Parsley root | 0.04 | - | 0.08 | Recommended [(e)] |
| 213080 | Radishes | 0.02* | 0.08 | 0.08 | Recommended [(a)] |
| 213090 | Salsify | 0.04 | - | 0.04 | Recommended [(e)] |
| 213100 | Swedes | 0.04 | - | 0.04 | Recommended [(e)] |
| 213110 | Turnips | 0.04 | - | 0.04 | Recommended [(e)] |
| 220010 | Garlic | 0.02* | - | 0.01* | Recommended [(e)] |
| 220020 | Onions | 0.02* | - | 0.01* | Recommended [(e)] |
| 231010 | Tomatoes | 0.5 | 0.7 | 0.7 | Recommended [(b)] |
| 231020 | Peppers | 0.3 | 0.3 | 0.4 | Further consideration needed [(g)] |

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | |
|---|---|---|---|---|---|
| | | | | MRL (mg/kg) | Comment |
| 231030 | Aubergines (egg plants) | 0.3 | 0.7 | 0.7 | Recommended [b] |
| 232010 | Cucumbers | 0.2 | 0.3 | 0.3 | Further consideration needed [g] |
| 232020 | Gherkins | 0.2 | 0.3 | 0.3 | Further consideration needed [g] |
| 232030 | Courgettes | 0.2 | 0.3 | 0.3 | Recommended [c] |
| 233010 | Melons | 0.3 | 0.3 | 0.3 | Recommended [b] |
| 233020 | Pumpkins | 0.2 | 0.3 | 0.3 | Recommended [h] |
| 233030 | Watermelons | 0.2 | 0.3 | 0.3 | Recommended [b] |
| 241000 | Flowering brassica | 0.05 | 0.5 | 0.5 | Recommended [b] |
| 242010 | Brussels sprouts | 0.5 | 0.1 | 0.6 | Recommended [i] |
| 242020 | Head cabbage | 0.3 | 0.5 | 0.5 | Recommended [b] |
| 243000 | Leafy brassica | 3 | - | 3 | Further consideration needed [f] |
| 251020 | Lettuce | 10 | - | 15 | Recommended [e] |
| 251030 | Scarole (broad-leaf endive) | 10 | - | 15 | Further consideration needed [f] |
| 251080 | Leaves and sprouts of Brassica spp | 0.02* | 15 | 15 | Recommended [a] |
| 255000 | Witloof | 0.02* | - | 0.02 | Further consideration needed [d] |
| 256000 | Herbs | 10 | - | 15 | Further consideration needed [f] |
| 260010 | Beans (fresh, with pods) | 0.5 | - | 1 | Further consideration needed [f] |
| 260030 | Peas (fresh, with pods) | 0.02* | - | 0.02 | Further consideration needed [d] |
| 270010 | Asparagus | 0.02* | 0.05* | 0.05 | Recommended [a] |
| 270030 | Celery | 1 | 1 | 1 | Recommended [b] |
| 270050 | Globe artichokes | 0.2 | - | 0.3 | Recommended [e] |
| 270060 | Leek | 0.2 | 0.7 | 0.7 | Recommended [c] |
| 401020 | Peanuts | 0.05* | 0.02* | 0.02 | Recommended [a] |
| 402010 | Olives for oil production | 0.3 | - | 0.3 | Further consideration needed [d] |
| 500010 | Barley grain | 0.3 | 0.5 | 0.5 | Recommended [c] |
| 500030 | Maize grain | 0.02* | 0.02* | 0.02 | Recommended [a] |
| 500050 | Oats grain | 0.02* | - | 0.4 | Further consideration needed [f] |
| 500060 | Rice grain | 0.02* | 5 | 5 | Recommended [a] |
| 500070 | Rye grain | 0.05 | - | 0.3 | Recommended [e] |
| 500090 | Wheat grain | 0.05 | 0.2 | 0.3 | Recommended [i] |
| 700000 | Hops (dried), including hop pellets and unconcentrated powder | 30 | 40 | 40 | Recommended [i] |
| 900010 | Sugar beet (root) | 0.05 | - | 0.02 | Recommended [e] |
| 900030 | Chicory roots | 0.02* | - | 0.02 | Further consideration needed [d] |
| - | Other products of plant | See App. | - | - | Further consideration needed [j] |

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | |
|---|---|---|---|---|---|
| | | | | MRL (mg/kg) | Comment |
| | origin | C.1 | | | |
| **Enforcement residue definition:** sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin. | | | | | |
| 1011010 | Swine muscle | 0.04* | 0.05 | 0.04 | Further consideration needed [g] |
| 1011020 | Swine fat (free of lean meat) | 0.04* | 0.05 | 0.04 | Further consideration needed [g] |
| 1011030 | Swine liver | 0.04* | 0.05 | 0.04 | Further consideration needed [g] |
| 1011040 | Swine kidney | 0.04* | 0.04* | 0.04 | Further consideration needed [g] |
| 1012010 | Bovine muscle | 0.04* | 0.05 | 0.04 | Further consideration needed [g] |
| 1012020 | Bovine fat | 0.04* | 0.05 | 0.06 | Further consideration needed [g] |
| 1012030 | Bovine liver | 0.04* | 0.05 | 0.07 | Further consideration needed [g] |
| 1012040 | Bovine kidney | 0.04* | 0.04* | 0.04 | Further consideration needed [g] |
| 1013010 | Sheep muscle | 0.04* | 0.05 | 0.04 | Further consideration needed [g] |
| 1013020 | Sheep fat | 0.04* | 0.05 | 0.06 | Further consideration needed [g] |
| 1013030 | Sheep liver | 0.04* | 0.05 | 0.07 | Further consideration needed [g] |
| 1013040 | Sheep kidney | 0.04* | 0.04* | 0.04 | Further consideration needed [g] |
| 1014010 | Goat muscle | 0.04* | 0.05 | 0.04 | Further consideration needed [g] |
| 1014020 | Goat fat | 0.04* | 0.05 | 0.06 | Further consideration needed [g] |
| 1014030 | Goat liver | 0.04* | 0.05 | 0.07 | Further consideration needed [g] |
| 1014040 | Goat kidney | 0.04* | 0.04* | 0.04 | Further consideration needed [g] |
| 1016010 | Poultry muscle | 0.04* | 0.04* | 0.04 | Further consideration needed [g] |
| 1016020 | Poultry fat | 0.04* | 0.05 | 0.04 | Further consideration needed [g] |
| 1016030 | Poultry liver | 0.04* | 0.04* | 0.04 | Further consideration needed [g] |
| 1020010 | Cattle milk | 0.02* | 0.02* | 0.02 | Further consideration needed [g] |
| 1020020 | Sheep milk | 0.02* | 0.02* | 0.02 | Further consideration needed [g] |
| 1020030 | Goat milk | 0.02* | 0.02* | 0.02 | Further consideration needed [g] |
| 1030000 | Birds' eggs | 0.04* | 0.04* | 0.04 | Further consideration needed [g] |
| - | Other product of animal origin | See App. C.1 | - | - | Further consideration needed [j] |

(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix D).
(b): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination G-VII in Appendix D).
(c): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower tentative MRL (combination E-VII in Appendix D).
(d): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL; no CXL is available (combination C-I in Appendix D).
(e): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).
(f): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available (combination E-I in Appendix D).

(g): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; existing CXL is covered by the tentative MRL (combination E-III in Appendix D).
(h): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level is not supported by data but the existing EU MRL is lower than the existing CXL (combination C-VII in Appendix D).
(i): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination G-III in Appendix D).
(j): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).

## DOCUMENTATION PROVIDED TO EFSA

1. Pesticide Residues Overview File (PROFile) on trifloxystrobin prepared by the rapporteur Member State United Kingdom in the framework of Article 12 of Regulation (EC) No 396/2005. Submitted to EFSA on 21 July 2011. Last updated on 02 November 2012.

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# APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

| Critical Outdoor GAPs for Northern Europe | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Crop | | Region | Outdoor/ Indoor | Member state or Country | Pests controlled | Formulation | | | Application | | | | | | | | Application rate | | | PHI or wiaiting period (days) | Comments (max. 250 charachters) |
| | | | | | | | Content | | | Growth stage | | Number | | Interval (days) | | | | | | | |
| Common name | Scientific name | | | | | Type | Conc. | Unit | Method | From BBCH | Until BBCH | Min. | Max. | Min. | Max. | Min. rate | Max. rate | Rate Unit | | |
| Apples | *Malus domesticus* | NEU | Outdoor | DE | Fungal storage rots | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 4 | 4 | 10 | 14 | 0.03 | 0.08 | kg a.i./ha | 7 | Note: Application rate for standard tree of 3 m height equivalent to 0.075 kg a.i./ha and 1500 l water/ha. The applicant has noted no more than 4 applications/crop/year. |
| Pears | *Pyrus communis* | NEU | Outdoor | DE | Fungal storage rots | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 4 | 4 | 10 | 14 | 0.03 | 0.08 | kg a.i./ha | 7 | Note: Application rate for standard tree of 3 m height equivalent to 0.075 kg a.i./ha and 1500 l water/ha. The applicant has noted no more than 4 applications/crop/year. |
| Quinces | *Cydonia oblonga* | NEU | Outdoor | DE | Fungal storage rots | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 4 | 4 | 10 | 14 | 0.03 | 0.08 | kg a.i./ha | 7 | Note: Application rate for standard tree of 3 m height equivalent to 0.075 kg a.i./ha and 1500 l water/ha. The applicant has noted no more than 4 applications/crop/year. |
| Medlar | *Mespilus germanica* | NEU | Outdoor | DE | Fungal storage rots | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 4 | 4 | 10 | 14 | 0.03 | 0.08 | kg a.i./ha | 7 | Note: Application rate for standard tree of 3 m height equivalent to 0.075 kg a.i./ha and 1500 l water/ha. The applicant has noted no more than 4 applications/crop/year. |
| Loquat | *Eriobotrya japonica* | NEU | Outdoor | DE | Fungal storage rots | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 4 | 4 | 10 | 14 | 0.03 | 0.08 | kg a.i./ha | 7 | Note: Application rate for standard tree of 3 m height equivalent to 0.075 kg a.i./ha and 1500 l water/ha. The applicant has noted no more than 4 applications/crop/year. |
| Apricots | *Prunus armeniaca* | NEU | Outdoor | DE | Erysiphe cichoriacearum | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 2 | 2 | 7 | 10 | 0.08 | 0.25 | kg a.i./ha | 7 | Note: Application rate for standard tree of 3 m height equivalent to 0.252 kg a.i./ha and 1500 l water/ha. The applicant has noted no more than 2 applications/crop/year. |
| Cherries | *Prunus cerasus, Prunus avium* | NEU | Outdoor | DE | Gnomonia erythrostoma | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 1 | 1 | | | 0.08 | 0.25 | kg a.i./ha | 7 | Note: Application rate for standard tree of 3 m height equivalent to 0.252 kg a.i./ha and 1500 l water/ha. The applicant has noted no more than 1 applications/crop/year. |
| Peaches | *Prunus persica* | NEU | Outdoor | DE | Erysiphe cichoriacearum | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 2 | 2 | 7 | 10 | 0.08 | 0.25 | kg a.i./ha | 7 | Note: Application rate for standard tree of 3 m height equivalent to 0.252 kg a.i./ha and 1500 l water/ha. The applicant has noted no more than 2 applications/crop/year. |
| Plums | *Prunus domestica* | NEU | Outdoor | DE | Tranzschelia pruni-spinosae Monilinia laxa Stigmina carophila Polystigma rubrum | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 2 | 2 | 10 | 14 | 0.09 | 0.25 | kg a.i./ha | 7 | Note: Application rate for standard tree of 3 m height equivalent to 0.252 kg a.i./ha and 1500 l water/ha |
| Table grapes | *Vitis euvitis* | NEU | Outdoor | NL | Powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 3 | 14 | 21 | 0.13 | 0.13 | kg a.i./ha | 35 | |
| Wine grapes | *Vitis euvitis* | NEU | Outdoor | NL | Powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 3 | 14 | 21 | 0.13 | 0.13 | kg a.i./ha | 35 | |
| Strawberries | *Fragaria x ananassa* | NEU | Outdoor | DE | Sphaerotheca macularis Diplocarpon earliana Mycosphaerella fragariare | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 3 | 7 | 10 | 0.15 | 0.15 | kg a.i./ha | 3 | Note: No more than 3 applications/crop/year |
| Blackberries | *Rubus fruticosus* | NEU | Outdoor | DE | Phragmidium violaceum Rhabdospora ruborum | WG | 500.0 | g/kg | Foliar treatment - spraying | 0 | 60 | 3 | 3 | | | 0.10 | 0.10 | kg a.i./ha | n.a. | Note: No more than 3 applications/crop/year |
| Raspberries | *Rubus idaeus* | NEU | Outdoor | DE | Didymella applanata, Phragmidium rubi-idaei | WG | 500.0 | g/kg | Foliar treatment - spraying | 0 | 60 | 3 | 3 | | | 0.10 | 0.10 | kg a.i./ha | n.a. | Note: No more than 3 applications/crop/year |
| Blueberries | *Vaccinium corymbosum* | NEU | Outdoor | NL | Anthracnose, Botrytis | WG | 500.0 | g/kg | Foliar treatment - spraying | 19 | 91 | 3 | 3 | 7 | 10 | 0.20 | 0.20 | kg a.i./ha | 7 | |
| Cranberries | *Vaccinium macrocarpon* | NEU | Outdoor | BE | Powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | | | 1 | 3 | 7 | | | 0.11 | kg a.i./ha | 7 | 0.055 kg a.i./ha leaf wall area (conversion rate of 2) |
| Currants (red, black and white) | *Ribes nigrum, rubrum* | NEU | Outdoor | DE | Sphaerotheca mors-uvae | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 3 | | | 0.10 | 0.10 | kg a.i./ha | 14 | Note: No more than 3 applications/crop/year |

| Critical Outdoor GAPs for Northern Europe | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Crop | | Region | Outdoor/ Indoor | Member state or Country | Pests controlled | Formulation | | | Application | | | | | | | Application rate | | | PHI or wiaiting period (days) | Comments (max. 250 charachters) |
| Common name | Scientific name | | | | | Type | Content | | Method | Growth stage | | Number | | Interval (days) | | Min. rate | Max. rate | Rate Unit | | |
| | | | | | | | Conc. | Unit | | From BBCH | Until BBCH | Min. | Max. | Min. | Max. | | | | | |
| Gooseberries | *Ribes uva-crispa* | NEU | Outdoor | DE | Sphaerotheca mors-uvae | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 3 | | | 0.10 | 0.10 | kg a.i./ha | 14 | Note: No more than 3 applications/crop/year |
| Rose hips | *Rosa canina* | NEU | Outdoor | DE | Sphaerotheca mors-uvae | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 3 | | | 0.10 | 0.10 | kg a.i./ha | n.a. | Trials performed on currants with a PHI of 14 days used for deriving a tentative MRL. Notifier should confirm PHI. |
| Mulberries | *Morus spp;* | NEU | Outdoor | DE | Sphaerotheca mors-uvae | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 3 | | | 0.10 | 0.10 | kg a.i./ha | n.a. | Trials performed on currants with a PHI of 14 days used for deriving a tentative MRL. Notifier should confirm PHI. |
| Azarole (mediteranean medlar) | *Crataegus azarolus* | NEU | Outdoor | DE | Sphaerotheca mors-uvae | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 3 | | | 0.10 | 0.10 | kg a.i./ha | n.a. | Trials performed on currants with a PHI of 14 days used for deriving a tentative MRL. Notifier should confirm PHI. |
| Elderberries | *Sambucus nigra* | NEU | Outdoor | DE | Sphaerotheca mors-uvae | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 3 | | | 0.10 | 0.10 | kg a.i./ha | n.a. | Trials performed on currants with a PHI of 14 days used for deriving a tentative MRL. Notifier should confirm PHI. |
| Carrots | *Daucus carota* | NEU | Outdoor | NL | Alternaria dauci | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 3 | | | 0.13 | 0.20 | kg a.i./ha | 14 | |
| Celeriac | *Apium graveolens var. rapaceum* | NEU | Outdoor | NL | Septoria apicola | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 3 | | | 0.13 | 0.13 | kg a.i./ha | 14 | |
| Parsnips | *Pastinaca sativa* | NEU | Outdoor | BE | leaf blight, powdery mildew | WG | | | Foliar treatment - spraying | | | 1 | 2 | | | | 0.08 | kg a.i./ha | 21 | |
| Parsley root | *Petroselinum crispum* | NEU | Outdoor | BE | leaf blight, powdery mildew | WG | | | Foliar treatment - spraying | | | 1 | 2 | | | | 0.08 | kg a.i./ha | 21 | |
| Salsify | *Tragopogon porrifolius* | NEU | Outdoor | BE | leaf blight, powdery mildew | WG | | | Foliar treatment - spraying | | | 1 | 2 | | | | 0.10 | kg a.i./ha | 21 | |
| Swedes | *Brassica napus var. napobrassica* | NEU | Outdoor | BE | leaf blight, powdery mildew | WG | | | Foliar treatment - spraying | | | 1 | 2 | | | | 0.10 | kg a.i./ha | 21 | |
| Turnips | *Brassica rapa* | NEU | Outdoor | BE | leaf blight, powdery mildew | WG | | | Foliar treatment - spraying | | | 1 | 2 | | | | 0.10 | kg a.i./ha | 21 | |
| Spring onions | *Allium cepa* | NEU | Outdoor | BE | Rust | WG | | | Foliar treatment - spraying | | | 1 | 2 | | | | 0.10 | kg a.i./ha | 21 | |
| Cucumbers | *Cucumis sativus* | NEU | Outdoor | DE | Erysiphe cichoracearum Sphaerotheca fuliginea Didymella bryoniae | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 1 | 1 | | | 0.25 | 0.25 | kg a.i./ha | 3 | Note: No more than 1 application/crop/year |
| Gherkins | *Cucumis sativus* | NEU | Outdoor | DE | Erysiphe cichoracearum Sphaerotheca fuliginea Didymella bryoniae | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 1 | 1 | | | 0.25 | 0.25 | kg a.i./ha | 3 | Note: No more than 1 application/crop/year |
| Courgettes | *Cucurbita pepo var. melopepo* | NEU | Outdoor | DE | Erysiphe cichoracearum Sphaerotheca fuliginea Didymella bryoniae | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 1 | 1 | | | 0.25 | 0.25 | kg a.i./ha | 3 | Note: No more than 1 application/crop/year |
| Broccoli | *Brassica oleracea var. italica* | NEU | Outdoor | NL | Albugo candida | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 3 | 7 | 10 | 0.20 | 0.20 | kg a.i./ha | 3 | |
| Cauliflower | *Brassica oleracea var. botrytis* | NEU | Outdoor | NL | Albugo candida | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 3 | 7 | 10 | 0.20 | 0.20 | kg a.i./ha | 3 | |
| Brussels sprouts | *Brassica oleracea var. gemmifera* | NEU | Outdoor | NL | Albugo candida | WG | 500.0 | g/kg | Foliar treatment - spraying | 41 | 79 | 3 | 3 | | | 0.20 | 0.20 | kg a.i./ha | 14 | |
| Head cabbage | *Brassica oleracea convar capitata* | NEU | Outdoor | NL | Albugo candida | WG | 500.0 | g/kg | Foliar treatment - spraying | 41 | 79 | 3 | 3 | | | 0.20 | 0.20 | kg a.i./ha | 14 | |
| Chinese cabbage | *Brassica pekinensis* | NEU | Outdoor | DE | Erysiphe cruciferarum Fungal leaf sport diseas | WG | 500.0 | g/kg | Foliar treatment - spraying | 16 | 45 | 1 | 1 | | | 0.20 | 0.20 | kg a.i./ha | 14 | Note: No more than 1 application/crop/year |
| Kale | *Brassica oleracea convar. Acephalea* | NEU | Outdoor | DE | Erysiphe cruciferarum Fungal leaf sport diseas | WG | 500.0 | g/kg | Foliar treatment - spraying | 16 | 45 | 1 | 1 | | | 0.20 | 0.20 | kg a.i./ha | 14 | Note: No more than 1 application/crop/year |
| Scarole (broad-leaf endive) | *Cichorium endiva* | NEU | Outdoor | NL | Botrytis Sclerotinia | WG | 500.0 | g/kg | Foliar treatment - spraying | 19 | 49 | 3 | 3 | 7 | 10 | 0.20 | 0.20 | kg a.i./ha | 7 | |
| Witloof | *Cichorium intybus. var. Foliosum* | NEU | Outdoor | NL | powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 3 | | | 0.13 | 0.13 | kg a.i./ha | n.a. | Application made at first infestation. Interval of 14 days. PHI or BBCH at last application not reported. |
| Chervil | *Anthriscus cerefolium* | NEU | Outdoor | NL | Downey mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | 20 | 49 | | 3 | | | | 0.20 | kg a.i./ha | 7 | |
| Chives | *Allium schoenoprasum* | NEU | Outdoor | NL | Downey mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | 20 | 49 | | 3 | | | | 0.20 | kg a.i./ha | 7 | |
| Celery leaves | *Apium graveolens var. seccalinum* | NEU | Outdoor | NL | Downey mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | 20 | 49 | | 3 | | | | 0.20 | kg a.i./ha | 7 | |
| Parsley | *Petroselinum crispum* | NEU | Outdoor | NL | Downey mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | 20 | 49 | | 3 | | | | 0.20 | kg a.i./ha | 7 | |

| Critical Outdoor GAPs for Northern Europe | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Crop | | Region | Outdoor/ Indoor | Member state or Country | Pests controlled | Formulation | | | Application | | | | | | | Application rate | | | PHI or wiaiting period (days) | Comments (max. 250 charachters) |
| Common name | Scientific name | | | | | Type | Content | | Method | Growth stage | | Number | | Interval (days) | | Min. rate | Max. rate | Rate Unit | | |
| | | | | | | | Conc. | Unit | | From BBCH | Until BBCH | Min. | Max. | Min. | Max. | | | | | |
| Sage | *Salvia officinalis* | NEU | Outdoor | NL | Downey mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | 20 | 49 | | 3 | | | | 0.20 | kg a.i./ha | 7 | |
| Rosemary | *Rosmarinus officinalis* | NEU | Outdoor | NL | Downey mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | 20 | 49 | | 3 | | | | 0.20 | kg a.i./ha | 7 | |
| Thyme | *Thymus spp.* | NEU | Outdoor | NL | Downey mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | 20 | 49 | | 3 | | | | 0.20 | kg a.i./ha | 7 | |
| Basil | *Ocimum basilicum* | NEU | Outdoor | NL | Downey mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | 20 | 49 | | 3 | | | | 0.20 | kg a.i./ha | 7 | |
| Bay leaves (laurel) | *Laurus nobilis* | NEU | Outdoor | NL | Downey mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | 20 | 49 | | 3 | | | | 0.20 | kg a.i./ha | 7 | |
| Tarragon | *Artemisia dracunculus* | NEU | Outdoor | NL | Downey mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | 20 | 49 | | 3 | | | | 0.20 | kg a.i./ha | 7 | |
| Celery | *Apium graveolens var. dulce* | NEU | Outdoor | NL | Septoria apicola | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 3 | | | 0.13 | 0.13 | kg a.i./ha | 14 | |
| Leek | *Allium porrum* | NEU | Outdoor | NL | Altermaria porri and Puccinia spp,. | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 3 | | | 0.20 | 0.20 | kg a.i./ha | 14 | |
| Barley | *Hordeum spp.* | NEU | Outdoor | UK, IE | Fungicide | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | 71 | 2 | 2 | | | 0.25 | 0.25 | kg a.i./ha | 35 | |
| Oats | *Avena fatua* | NEU | Outdoor | FI | Mildew, rust, oat leaf sport | EC | 250.0 | g/l | Foliar treatment - spraying | n.a. | n.a. | 1 | 1 | | | 0.13 | 0.13 | kg a.i./ha | 35 | |
| Wheat | *Triticum aestivum* | NEU | Outdoor | UK, IE | Fungicide | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | 71 | 2 | 2 | | | 0.25 | 0.25 | kg a.i./ha | n.a. | |
| Hops | *Humulus lupulus* | NEU | Outdoor | DE | Sphaerotheca macularis | WG | 500.0 | g/kg | Foliar treatment - spraying | 31 | 55 | 2 | 2 | 10 | 14 | 0.28 | 0.63 | kg a.i./ha | 14 | Note: No more than 2 application/crop/year |
| Sugar beet | *Beta vulgaris* | NEU | Outdoor | LV | Leaf spot, rust and mildew | SC | | g/l | Foliar treatment - spraying | n.a. | n.a. | 2 | 2 | | | 0.14 | 0.14 | kg a.i./ha | 21 | |
| Grass | *not specified* | NEU | Outdoor | NL | Rust | SC | 375.0 | g/l | Foliar treatment - spraying | n.a. | n.a. | 1 | 1 | | | 0.19 | 0.19 | kg a.i./ha | 49 | |

| Critical Outdoor GAPs for Southern Europe | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Crop | | Region | Outdoor/ Indoor | Member state or Country | Pests controlled | Formulation | | | Application | | | | | | | | Application rate | | | PHI or wiaiting period (days) | Comments (max. 250 charachters) |
| | | | | | | | Content | | | Growth stage | | Number | | Interval (days) | | | | | | | |
| Common name | Scientific name | | | | | Type | Conc. | Unit | Method | From BBCH | Until BBCH | Min. | Max. | Min. | Max. | Min. rate | Max. rate | Rate Unit | | |
| Apples | *Malus domesticus* | SEU | Outdoor | IT | Apple scab (Venturia inaequalis) and apple powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | 61 | 85 | 3 | 3 | 10 | 10 | 0.08 | 0.11 | kg a.i./ha | 14 | |
| Pears | *Pyrus communis* | SEU | Outdoor | IT | Apple scab (Venturia inaequalis) and apple powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | 61 | 85 | 3 | 3 | 10 | 10 | 0.08 | 0.11 | kg a.i./ha | 14 | |
| Apricots | *Prunus armeniaca* | SEU | Outdoor | ES | Oidium | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 4 | 4 | | | 0.01 | 0.01 | kg a.i./hL | 7 | |
| Peaches | *Prunus persica* | SEU | Outdoor | ES | Oidium | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 4 | 4 | | | 0.01 | 0.01 | kg a.i./hL | 7 | |
| Table grapes | *Vitis euvitis* | SEU | Outdoor | IT | Powdery mildew, black rot | WG | 500.0 | g/kg | Foliar treatment - spraying | 55 | 69 | 3 | 3 | 10 | 14 | 0.06 | 0.13 | kg a.i./ha | 35 | |
| Wine grapes | *Vitis euvitis* | SEU | Outdoor | IT | Powdery mildew, black rot | WG | 500.0 | g/kg | Foliar treatment - spraying | 55 | 69 | 3 | 3 | 10 | 14 | 0.06 | 0.13 | kg a.i./ha | 35 | |
| Strawberries | *Fragaria x ananassa* | SEU | Outdoor | ES | Oidium | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 3 | | | 0.15 | 0.15 | kg a.i./ha | 1 | |
| Bananas | *Musa x paradisica* | SEU | Outdoor | FR | | | | | Foliar treatment - spraying | | | 4 | 4 | | | 0.08 | 0.08 | kg a.i./ha | 3 | |
| Tomatoes | *Lycopersicum esculentum* | SEU | Outdoor | ES | Oidium | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 7 | | | 0.19 | 0.19 | kg a.i./ha | 1 | |
| Peppers | *Capsicum annuum, var grossum and var. longum* | SEU | Outdoor | ES | Oidium | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 7 | | | 0.10 | 0.10 | kg a.i./ha | 1 | |
| Cucumbers | *Cucumis sativus* | SEU | Outdoor | IT | Oidium | WG | 500.0 | g/kg | Foliar treatment - spraying | 55 | 85 | 3 | 3 | 7 | 10 | 0.08 | 0.13 | kg a.i./ha | 3 | |
| Melons | *Cucumis melo* | SEU | Outdoor | ES | Oidium | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 4 | 4 | | | 0.13 | 0.13 | kg a.i./ha | 3 | |
| Watermelons | *Citrullus lanatus* | SEU | Outdoor | IT | Powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 3 | | | 0.08 | 0.13 | kg a.i./ha | 3 | |
| Globe artichokes | *Cynara scolymus* | SEU | Outdoor | IT | Leveillula taurica | WG | 250.0 | g/kg | Foliar treatment - spraying | 19 | 83 | 1 | 3 | | | | 0.08 | kg a.i./ha | 7 | |
| Olives for oil production | *Olea europaea* | SEU | Outdoor | ES | Repilo | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 1 | 2 | | | 0.05 | 0.05 | kg a.i./hL | 14 | |
| Barley | *Hordeum spp.* | SEU | Outdoor | IT | Puccinia spp., Erisiphe graminis and Fusarium spp. | EC | 187.5 | g/l | Foliar treatment - spraying | | 65 | 1 | 1 | | | 0.11 | 0.19 | kg a.i./ha | 42 | |
| Wheat | *Triticum aestivum* | SEU | Outdoor | IT | Puccinia spp., Erisiphe graminis and Fusarium spp. | EC | 187.5 | g/l | Foliar treatment - spraying | | 65 | 1 | 1 | | | 0.11 | 0.19 | kg a.i./ha | 42 | |
| Sugar beet | *Beta vulgaris* | SEU | Outdoor | IT | Cercospora beticola and Erysiphe betae | EC | 187.5 | g/l | Foliar treatment - spraying | | 49 | 3 | 3 | 18 | 21 | 0.11 | 0.15 | kg a.i./ha | 21 | |

| Critical Indoor GAPs for Northern and Southern Europe (incl. post-harvest treatments) | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Crop | | Region | Outdoor/ Indoor | Member state or Country | Pests controlled | Formulation | | | Application | | | | | | | | Application rate | | | PHI or wiaiting period (days) | Comments (max. 250 charachters) |
| | | | | | | | Content | | | Growth stage | | Number | | Interval (days) | | | | | | | |
| Common name | Scientific name | | | | | Type | Conc. | Unit | Method | From BBCH | Until BBCH | Min. | Max. | Min. | Max. | Min. rate | Max. rate | Rate Unit | | |
| Strawberries | *Fragaria x ananassa* | NEU/SEU | Indoor | DE | Sphaerotheca macularis Mycospharella fragariae Diplocarpon earliana | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 3 | 7 | 10 | 0.15 | 0.15 | kg a.i./ha | 3 | Note: No more than 3 applications/crop/year |
| Gooseberries | *Ribes uva-crispa* | NEU/SEU | Indoor | BE | | | | | | n.a. | n.a. | 1 | 2 | | | 0.09 | 0.09 | kg a.i./ha | 7 | |
| Tomatoes | *Lycopersicum esculentum* | NEU/SEU | Indoor | NL | Powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 3 | 7 | 10 | 0.03 | 0.09 | kg a.i./ha | 1 | |
| Peppers | *Capsicum annuum, var grossum and var. longum* | NEU/SEU | Indoor | NL | Powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 3 | 7 | 10 | 0.03 | 0.09 | kg a.i./ha | 1 | |
| Aubergines (egg plants) | *Solanum melongena* | NEU/SEU | Indoor | BE | Powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | | | 1 | 3 | 7 | 10 | | 0.16 | kg a.i./ha | 1 | Note:3 applications of one 2.5 g tablet disoolved in 1250 mL of water. |
| Cucumbers | *Cucumis sativus* | NEU/SEU | Indoor | DE | Erysiphe cichoracearum Sphaerotheca fuliginea Didymella bryoniae | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 2 | 2 | 7 | 14 | 0.13 | 0.25 | kg a.i./ha | 3 | |
| Gherkins | *Cucumis sativus* | NEU/SEU | Indoor | DE | Erysiphe cichoracearum Sphaerotheca fuliginea Didymella bryoniae | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 2 | 2 | 7 | 14 | 0.13 | 0.25 | kg a.i./ha | 3 | |
| Courgettes | *Cucurbita pepo var. melopepo* | NEU/SEU | Indoor | NL | Powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 3 | 7 | 10 | 0.03 | 0.06 | kg a.i./ha | 3 | |
| Melons | *Cucumis melo* | NEU/SEU | Indoor | NL | Powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 3 | 7 | 10 | 0.03 | 0.09 | kg a.i./ha | 1 | |
| Pumpkins | *Cucurbita maxima* | NEU/SEU | Indoor | NL | Powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | n.a. | n.a. | 3 | 3 | 7 | 10 | 0.03 | 0.09 | kg a.i./ha | 1 | |
| Watermelons | *Citrullus lanatus* | NEU/SEU | Indoor | IT | Powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | 55 | 85 | 3 | 3 | 10 | 14 | 0.08 | 0.13 | kg a.i./ha | 3 | |
| Lettuce | *Lactuca sativa* | NEU/SEU | Indoor | NL | Botrytis Sclerotinia | WG | 500.0 | g/kg | Foliar treatment - spraying | | | 3 | 3 | 7 | 10 | 0.20 | 0.20 | kg a.i./ha | 7 | |
| Scarole (broad-leaf endive) | *Cichorium endiva* | NEU/SEU | Indoor | NL | Botrytis Sclerotinia | WG | 500.0 | g/kg | Foliar treatment - spraying | | | 3 | 3 | 7 | 10 | 0.20 | 0.20 | kg a.i./ha | 7 | |
| Chervil | *Anthriscus cerefolium* | NEU/SEU | Indoor | NL | Powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | | | 3 | 3 | 7 | 10 | 0.20 | 0.20 | kg a.i./ha | 7 | |
| Chives | *Allium schoenoprasum* | NEU/SEU | Indoor | NL | Powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | | | 3 | 3 | 7 | 10 | 0.20 | 0.20 | kg a.i./ha | 7 | |
| Celery leaves | *Apium graveolens var. seccalinum* | NEU/SEU | Indoor | NL | Powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | | | 3 | 3 | 7 | 10 | 0.20 | 0.20 | kg a.i./ha | 7 | |
| Parsley | *Petroselinum crispum* | NEU/SEU | Indoor | NL | Powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | | | 3 | 3 | 7 | 10 | 0.20 | 0.20 | kg a.i./ha | 7 | |
| Sage | *Salvia officinalis* | NEU/SEU | Indoor | NL | Powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | | | 3 | 3 | 7 | 10 | 0.20 | 0.20 | kg a.i./ha | 7 | |
| Rosemary | *Rosmarinus officinalis* | NEU/SEU | Indoor | NL | Powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | | | 3 | 3 | 7 | 10 | 0.20 | 0.20 | kg a.i./ha | 7 | |
| Thyme | *Thymus spp.* | NEU/SEU | Indoor | NL | Powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | | | 3 | 3 | 7 | 10 | 0.20 | 0.20 | kg a.i./ha | 7 | |
| Basil | *Ocimum basilicum* | NEU/SEU | Indoor | NL | Powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | | | 3 | 3 | 7 | 10 | 0.20 | 0.20 | kg a.i./ha | 7 | |
| Bay leaves (laurel) | *Laurus nobilis* | NEU/SEU | Indoor | NL | Powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | | | 3 | 3 | 7 | 10 | 0.20 | 0.20 | kg a.i./ha | 7 | |
| Tarragon | *Artemisia dracunculus* | NEU/SEU | Indoor | NL | Powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | | | 3 | 3 | 7 | 10 | 0.20 | 0.20 | kg a.i./ha | 7 | |
| Beans (with pods) | *Phaseolus vulgaris,* | NEU/SEU | Indoor | NL | Powdery mildew | WG | 500.0 | g/kg | Foliar treatment - spraying | | | 3 | 3 | 7 | 10 | 0.03 | 0.06 | kg a.i./ha | 1 | |
| Peas (with pods) | *Pisum sativum* | NEU/SEU | Indoor | DE | Uromyces appendiculatus Colletotrichum lindemuthianum | WG | 500.0 | g/kg | Foliar treatment - spraying | | | 1 | 1 | | | 0.13 | 0.25 | kg a.i./ha | 3 | |

| Critical GAPs for Import Tolerances (non-European indoor, outdoor or post-harvest treatments) | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Crop | | Region | Outdoor/ Indoor | Member state or Country | Pests controlled | Formulation | | | Application | | | | | | | | Application rate | | | PHI or wiaiting period (days) | Comments (max. 250 charachters) |
| | | | | | | | Content | | | Growth stage | | Number | | Interval (days) | | | | | | |
| Common name | Scientific name | | | | | Type | Conc. | Unit | Method | From BBCH | Until BBCH | Min. | Max. | Min. | Max. | Min. rate | Max. rate | Rate Unit | | |
| Passion fruit | *Passiflora edulis* | non-EU | Outdoor | Kenya | Alternaria septoria and cladosporium | WG | 500.0 | g/kg | Foliar treatment - spraying | | | | 2 | | | | 0.40 | kg a.i./ha | 3 | 7 days between applications |

## APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Appendix B.1 – EU scenario including all EU MRL proposals resulting from the GAPs reported by the RMS

Appendix B.2 – EU/Codex scenario including demonstrated safe EU MRL proposals and all CXLs

## APPENDIX B.1 – EU SCENARIO INCLUDING ALL EU MRL PROPOSALS RESULTING FROM THE GAPS REPORTED BY THE RMS

| Trifloxystrobin | | | |
|---|---|---|---|
| Status of the active substance: | **Approved** | Code no. | |
| LOQ (mg/kg bw): | | proposed LOQ: | |
| **Toxicological end points** | | | |
| ADI (mg/kg bw/day): | **0,1** | ARfD (mg/kg bw): | **n.n.** |
| Source of ADI: | **COM** | Source of ARfD: | **COM** |
| Year of evaluation: | **2003** | Year of evaluation: | **2003** |

**Chronic risk assessment - refined calculations**

| | TMDI (range) in % of ADI minimum - maximum |
|---|---|
| **No of diets exceeding ADI:** | 1 --- 6 |

| Highest calculated TMDI values in % of ADI | MS Diet | Highest contributor to MS diet (in % of ADI) | Commodity / group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity / group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity / group of commodities | pTMRLs at LOQ (in % of ADI) |
|---|---|---|---|---|---|---|---|---|
| 5,9 | WHO Cluster diet B | 2,0 | Lettuce | 1,2 | Olives for oil production | 0,3 | Tomatoes | |
| 5,0 | NL child | 1,3 | Apples | 1,1 | Scarole (broad-leaf endive) | 0,6 | Milk and cream, | |
| 4,9 | DE child | 2,4 | Apples | 0,3 | Lettuce | 0,3 | Milk and cream, | |
| 4,2 | ES adult | 3,0 | Lettuce | 0,3 | Olives for oil production | 0,2 | Apples | |
| 4,0 | ES child | 2,3 | Lettuce | 0,4 | Olives for oil production | 0,3 | Milk and cream, | |
| 3,8 | WHO regional European diet | 2,1 | Lettuce | 0,2 | Scarole (broad-leaf endive) | 0,2 | Scarole (broad-leaf endive) | |
| 3,2 | IT adult | 2,1 | Lettuce | 0,2 | Peaches | 0,2 | Apples | |
| 2,8 | IE adult | 0,5 | Lettuce | 0,3 | Other leafy brassica | 0,2 | Peaches | |
| 2,8 | FR toddler | 0,8 | Milk and cream, | 0,5 | Apples | 0,4 | Beans (with pods) | |
| 2,7 | IT kids/toddler | 1,6 | Lettuce | 0,2 | Wheat | 0,2 | Apples | |
| 2,7 | WHO Cluster diet F | 1,7 | Lettuce | 0,1 | Apples | 0,1 | Wheat | |
| 2,5 | NL general | 0,7 | Lettuce | 0,6 | Scarole (broad-leaf endive) | 0,2 | Apples | |
| 2,5 | WHO cluster diet E | 0,5 | Lettuce | 0,3 | Scarole (broad-leaf endive) | 0,3 | Herbs | |
| 2,4 | DK child | 0,8 | Lettuce | 0,5 | Apples | 0,3 | Milk and cream, | |
| 2,1 | FR all population | 0,6 | Wine grapes | 0,5 | Lettuce | 0,2 | Scarole (broad-leaf endive) | |
| 2,0 | WHO cluster diet D | 0,4 | Herbs | 0,2 | Chinese cabbage | 0,2 | Wheat | |
| 1,9 | FR infant | 0,5 | Milk and cream, | 0,5 | Apples | 0,3 | Beans (with pods) | |
| 1,8 | UK Toddler | 0,5 | Sugar beet (root) | 0,4 | Milk and cream, | 0,3 | Apples | |
| 1,8 | UK Infant | 0,8 | Milk and cream, | 0,3 | Apples | 0,2 | Sugar beet (root) | |
| 1,6 | SE general population 90th percentile | 0,3 | Chinese cabbage | 0,2 | Milk and cream, | 0,2 | Apples | |
| 1,5 | UK vegetarian | 0,8 | Lettuce | 0,1 | Wine grapes | 0,1 | Apples | |
| 1,3 | PT General population | 0,4 | Wine grapes | 0,2 | Apples | 0,2 | Peaches | |
| 1,3 | UK Adult | 0,6 | Lettuce | 0,2 | Wine grapes | 0,1 | Apples | |
| 1,1 | LT adult | 0,4 | Apples | 0,4 | Lettuce | 0,1 | Milk and cream, | |
| 1,0 | FI adult | 0,4 | Lettuce | 0,1 | Milk and cream, | 0,1 | Apples | |
| 0,9 | PL general population | 0,4 | Apples | 0,1 | Tomatoes | 0,1 | Lettuce | |
| 0,9 | DK adult | 0,2 | Wine grapes | 0,2 | Apples | 0,1 | Milk and cream, | |

**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.

## APPENDIX B.2 – EU/CODEX SCENARIO INCLUDING DEMONSTRATED SAFE EU MRL PROPOSALS AND ALL CXLS

| Trifloxystrobin | | | |
|---|---|---|---|
| Status of the active substance: | **Approved** | Code no. | |
| LOQ (mg/kg bw): | | proposed LOQ: | |
| **Toxicological end points** | | | |
| ADI (mg/kg bw/day): | **0,1** | ARfD (mg/kg bw): | **n.n.** |
| Source of ADI: | **COM** | Source of ARfD: | **COM** |
| Year of evaluation: | **2003** | Year of evaluation: | **2003** |

**Chronic risk assessment - refined calculations**

| TMDI (range) in % of ADI minimum - maximum | |
|---|---|
| 1 | 6 |
| **No of diets exceeding ADI:** | --- |

| Highest calculated TMDI values in % of ADI | MS Diet | Highest contributor to MS diet (in % of ADI) | Commodity / group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity / group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity / group of commodities | pTMRLs at LOQ (in % of ADI) |
|---|---|---|---|---|---|---|---|---|
| 6,1 | WHO Cluster diet B | 2,0 | Lettuce | 1,2 | Olives for oil production | 0,3 | Herbs | |
| 5,3 | NL child | 1,1 | Scarole (broad-leaf endive) | 0,7 | Apples | 0,6 | Milk and cream, | |
| 4,4 | DE child | 1,3 | Apples | 0,4 | Oranges | 0,3 | Lettuce | |
| 4,3 | ES adult | 3,0 | Lettuce | 0,3 | Olives for oil production | 0,1 | Oranges | |
| 4,3 | ES child | 2,3 | Lettuce | 0,4 | Olives for oil production | 0,3 | Milk and cream, | |
| 4,0 | WHO regional European diet | 2,1 | Lettuce | 0,2 | Scarole (broad-leaf endive) | 0,2 | Scarole (broad-leaf endive) | |
| 3,3 | FR toddler | 0,8 | Milk and cream, | 0,4 | Beans (with pods) | 0,3 | Scarole (broad-leaf endive) | |
| 3,2 | IE adult | 0,5 | Lettuce | 0,3 | Other leafy brassica | 0,2 | Herbs | |
| 3,2 | IT adult | 2,1 | Lettuce | 0,1 | Herbs | 0,1 | Peaches | |
| 3,0 | WHO Cluster diet F | 1,7 | Lettuce | 0,1 | Wheat | 0,1 | Chinese cabbage | |
| 2,8 | IT kids/toddler | 1,6 | Lettuce | 0,2 | Wheat | 0,1 | Peaches | |
| 2,8 | NL general | 0,7 | Lettuce | 0,6 | Scarole (broad-leaf endive) | 0,1 | Oranges | |
| 2,7 | WHO cluster diet E | 0,5 | Lettuce | 0,3 | Scarole (broad-leaf endive) | 0,3 | Herbs | |
| 2,3 | DK child | 0,8 | Lettuce | 0,3 | Milk and cream, | 0,2 | Apples | |
| 2,2 | WHO cluster diet D | 0,4 | Herbs | 0,2 | Chinese cabbage | 0,2 | Wheat | |
| 2,1 | UK Toddler | 0,5 | Sugar beet (root) | 0,4 | Milk and cream, | 0,2 | Oranges | |
| 2,1 | UK Infant | 0,8 | Milk and cream, | 0,2 | Sugar beet (root) | 0,2 | Apples | |
| 2,1 | FR all population | 0,5 | Wine grapes | 0,5 | Lettuce | 0,2 | Scarole (broad-leaf endive) | |
| 2,1 | FR infant | 0,5 | Milk and cream, | 0,3 | Beans (with pods) | 0,3 | Apples | |
| 1,9 | SE general population 90th percentile | 0,3 | Chinese cabbage | 0,2 | Milk and cream, | 0,1 | Head cabbage | |
| 1,7 | UK vegetarian | 0,8 | Lettuce | 0,1 | Wine grapes | 0,1 | Oranges | |
| 1,5 | UK Adult | 0,6 | Lettuce | 0,1 | Wine grapes | 0,1 | Sugar beet (root) | |
| 1,4 | PT General population | 0,3 | Wine grapes | 0,2 | Olives for oil production | 0,1 | Rice | |
| 1,1 | LT adult | 0,4 | Lettuce | 0,2 | Apples | 0,1 | Milk and cream, | |
| 1,1 | FI adult | 0,4 | Lettuce | 0,1 | Milk and cream, | 0,1 | Oranges | |
| 0,9 | PL general population | 0,2 | Apples | 0,1 | Lettuce | 0,1 | Head cabbage | |
| 0,8 | DK adult | 0,2 | Wine grapes | 0,1 | Milk and cream, | 0,1 | Apples | |

**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.

# APPENDIX C – EXISTING EU MAXIMUM RESIDUE LIMITS (MRLS) AND CODEX LIMITS (CXLS)

Appendix C.1 – Existing EU MRLs

Appendix C.2 – Existing CXLs

## APPENDIX C.1 – EXISTING EU MRLS

(Pesticides - Web Version - EU MRLs - File created on 20/12/2013 13:37)

| Code number | Groups and examples of individual products to which the MRLs apply [(a)] | Trifloxystrobin (F) (R) |
|---|---|---|
| 100000 | 1. FRUIT FRESH OR FROZEN; NUTS | |
| 110000 | (i) Citrus fruit | 0.3 |
| 110010 | Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids) | 0.3 |
| 110020 | Oranges (Bergamot, bitter orange, chinotto and other hybrids) | 0.3 |
| 110030 | Lemons (Citron, lemon ) | 0.3 |
| 110040 | Limes | 0.3 |
| 110050 | Mandarins (Clementine, tangerine and other hybrids) | 0.3 |
| 110990 | Others | 0.3 |
| 120000 | (ii) Tree nuts (shelled or unshelled) | 0.02* |
| 120010 | Almonds | 0.02* |
| 120020 | Brazil nuts | 0.02* |
| 120030 | Cashew nuts | 0.02* |
| 120040 | Chestnuts | 0.02* |
| 120050 | Coconuts | 0.02* |
| 120060 | Hazelnuts (Filbert) | 0.02* |
| 120070 | Macadamia | 0.02* |
| 120080 | Pecans | 0.02* |
| 120090 | Pine nuts | 0.02* |
| 120100 | Pistachios | 0.02* |
| 120110 | Walnuts | 0.02* |
| 120990 | Others | 0.02* |
| 130000 | (iii) Pome fruit | 0.5 |
| 130010 | Apples (Crab apple) | 0.5 |
| 130020 | Pears (Oriental pear) | 0.5 |
| 130030 | Quinces | 0.5 |
| 130040 | Medlar | 0.5 |
| 130050 | Loquat | 0.5 |
| 130990 | Others | 0.5 |
| 140000 | (iv) Stone fruit | |
| 140010 | Apricots | 1 |
| 140020 | Cherries (sweet cherries, sour cherries) | 1 |
| 140030 | Peaches (Nectarines and similar hybrids) | 1 |

| Code number | Groups and examples of individual products to which the MRLs apply [(a)] | Trifloxystrobin (F) (R) |
|---|---|---|
| 140040 | Plums (Damson, greengage, mirabelle) | 0.2 |
| 140990 | Others | 0.02* |
| 150000 | (v) Berries & small fruit | |
| 151000 | (a) Table and wine grapes | 5 |
| 151010 | Table grapes | 5 |
| 151020 | Wine grapes | 5 |
| 152000 | (b) Strawberries | 0.5 |
| 153000 | (c) Cane fruit | 0.02* |
| 153010 | Blackberries | 0.02* |
| 153020 | Dewberries (Loganberries, Boysenberries, and cloudberries) | 0.02* |
| 153030 | Raspberries (Wineberries ) | 0.02* |
| 153990 | Others | 0.02* |
| 154000 | (d) Other small fruit & berries | |
| 154010 | Blueberries (Bilberries cowberries (red bilberries)) | 2 |
| 154020 | Cranberries | 0.02* |
| 154030 | Currants (red, black and white) | 1 |
| 154040 | Gooseberries (Including hybrids with other ribes species) | 1 |
| 154050 | Rose hips | 0.02* |
| 154060 | Mulberries (arbutus berry) | 0.02* |
| 154070 | Azarole (mediteranean medlar) | 0.02* |
| 154080 | Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries) | 2 |
| 154990 | Others | 0.02* |
| 160000 | (vi) Miscellaneous fruit | |

| Code number | Groups and examples of individual products to which the MRLs apply [(a)] | Trifloxystrobin (F) (R) |
|---|---|---|
| 161000 | (a) Edible peel | |
| 161010 | Dates | 0.02* |
| 161020 | Figs | 0.02* |
| 161030 | Table olives | 0.3 |
| 161040 | Kumquats (Marumi kumquats, nagami kumquats) | 0.02* |
| 161050 | Carambola (Bilimbi) | 0.02* |
| 161060 | Persimmon | 0.02* |
| 161070 | Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry) | 0.02* |
| 161990 | Others | 0.02* |
| 162000 | (b) Inedible peel, small | |
| 162010 | Kiwi | 0.02* |
| 162020 | Lychee (Litchi) (Pulasan, rambutan (hairy litchi)) | 0.02* |
| 162030 | Passion fruit | 4 |
| 162040 | Prickly pear (cactus fruit) | 0.02* |
| 162050 | Star apple | 0.02* |
| 162060 | American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote) | 0.02* |
| 162990 | Others | 0.02* |
| 163000 | (c) Inedible peel, large | |
| 163010 | Avocados | 0.02* |
| 163020 | Bananas (Dwarf banana, plantain, apple banana) | 0.05 |
| 163030 | Mangoes | 0.5 |
| 163040 | Papaya | 1 |
| 163050 | Pomegranate | 0.02* |
| 163060 | Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized | 0.02* |

| Code number | Groups and examples of individual products to which the MRLs apply [(a)] | Trifloxystrobin (F) (R) |
|---|---|---|
| | Annonaceae) | |
| 163070 | Guava | 0.02* |
| 163080 | Pineapples | 0.02* |
| 163090 | Bread fruit (Jackfruit) | 0.02* |
| 163100 | Durian | 0.02* |
| 163110 | Soursop (guanabana) | 0.02* |
| 163990 | Others | 0.02* |
| 200000 | 2. VEGETABLES FRESH OR FROZEN | |
| 210000 | (i) Root and tuber vegetables | |
| 211000 | (a) Potatoes | 0.02* |
| 212000 | (b) Tropical root and tuber vegetables | 0.02* |
| 212010 | Cassava (Dasheen, eddoe (Japanese taro), tannia) | 0.02* |
| 212020 | Sweet potatoes | 0.02* |
| 212030 | Yams (Potato bean (yam bean), Mexican yam bean) | 0.02* |
| 212040 | Arrowroot | 0.02* |
| 212990 | Others | 0.02* |
| 213000 | (c) Other root and tuber vegetables except sugar beet | |
| 213010 | Beetroot | 0.02* |
| 213020 | Carrots | 0.05 |
| 213030 | Celeriac | 0.02* |
| 213040 | Horseradish | 0.02* |
| 213050 | Jerusalem artichokes | 0.02* |
| 213060 | Parsnips | 0.04 |
| 213070 | Parsley root | 0.04 |
| 213080 | Radishes (Black radish, Japanese radish, small radish and similar varieties) | 0.02* |
| 213090 | Salsify (Scorzonera, Spanish salsify (Spanish oysterplant)) | 0.04 |
| 213100 | Swedes | 0.04 |
| 213110 | Turnips | 0.04 |
| 213990 | Others | 0.02* |
| 220000 | (ii) Bulb vegetables | |

| Code number | Groups and examples of individual products to which the MRLs apply [(a)] | Trifloxystrobin (F) (R) |
|---|---|---|
| 220010 | Garlic | 0.02* |
| 220020 | Onions (Silverskin onions) | 0.02* |
| 220030 | Shallots | 0.02* |
| 220040 | Spring onions (Welsh onion and similar varieties) | 0.1 |
| 220990 | Others | 0.02* |
| 230000 | (iii) Fruiting vegetables | |
| 231000 | (a) Solanacea | |
| 231010 | Tomatoes (Cherry tomatoes, ) | 0.5 |
| 231020 | Peppers (Chilli peppers) | 0.3 |
| 231030 | Aubergines (egg plants) (Pepino) | 0.3 |
| 231040 | Okra, lady's fingers | 0.02* |
| 231990 | Others | 0.02* |
| 232000 | (b) Cucurbits - edible peel | 0.2 |
| 232010 | Cucumbers | 0.2 |
| 232020 | Gherkins | 0.2 |
| 232030 | Courgettes (Summer squash, marrow (patisson)) | 0.2 |
| 232990 | Others | 0.2 |
| 233000 | (c) Cucurbits-inedible peel | |
| 233010 | Melons (Kiwano ) | 0.3 |
| 233020 | Pumpkins (Winter squash) | 0.2 |
| 233030 | Watermelons | 0.2 |
| 233990 | Others | 0.02* |
| 234000 | (d) Sweet corn | 0.02* |
| 239000 | (e) Other fruiting vegetables | 0.02* |
| 240000 | (iv) Brassica vegetables | |
| 241000 | (a) Flowering brassica | |
| 241010 | Broccoli (Calabrese, Chinese broccoli, Broccoli raab) | 0.05 |
| 241020 | Cauliflower | 0.05 |
| 241990 | Others | 0.02* |
| 242000 | (b) Head brassica | |
| 242010 | Brussels sprouts | 0.5 |
| 242020 | Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage) | 0.3 |
| 242990 | Others | 0.02* |
| 243000 | (c) Leafy brassica | 3 |
| 243010 | Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage) | 3 |
| 243020 | Kale (Borecole (curly kale), collards) | 3 |
| 243990 | Others | 3 |
| 244000 | (d) Kohlrabi | 0.5 |
| 250000 | (v) Leaf vegetables & fresh herbs | |
| 251000 | (a) Lettuce and other salad plants including Brassicacea | |
| 251010 | Lamb´s lettuce (Italian cornsalad) | 0.02* |
| 251020 | Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce) | 10 |
| 251030 | Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf) | 10 |
| 251040 | Cress | 0.02* |
| 251050 | Land cress | 0.02* |
| 251060 | Rocket, Rucola (Wild rocket) | 0.02* |
| 251070 | Red mustard | 0.02* |
| 251080 | Leaves and sprouts of Brassica spp (Mizuna) | 0.02* |
| 251990 | Others | 0.02* |
| 252000 | (b) Spinach & similar (leaves) | 0.02* |
| 252010 | Spinach (New Zealand spinach, turnip greens (turnip tops)) | 0.02* |
| 252020 | Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth) | 0.02* |
| 252030 | Beet leaves (chard) (Leaves of beetroot) | 0.02* |
| 252990 | Others | 0.02* |
| 253000 | (c) Vine leaves (grape leaves) | 0.02* |
| 254000 | (d) Water cress | 0.02* |
| 255000 | (e) Witloof | 0.02* |
| 256000 | (f) Herbs | 10 |
| 256010 | Chervil | 10 |
| 256020 | Chives | 10 |
| 256030 | Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea) | 10 |
| 256040 | Parsley | 10 |
| 256050 | Sage (Winter savory, summer savory, ) | 10 |
| 256060 | Rosemary | 10 |
| 256070 | Thyme ( marjoram, oregano) | 10 |
| 256080 | Basil (Balm leaves, mint, peppermint) | 10 |
| 256090 | Bay leaves (laurel) | 10 |
| 256100 | Tarragon (Hyssop) | 10 |
| 256990 | Others | 10 |
| 260000 | (vi) Legume vegetables (fresh) | |
| 260010 | Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans) | 1 |
| 260020 | Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea) | 0.02* |
| 260030 | Peas (with pods) (Mangetout (sugar peas)) | 0.02* |
| 260040 | Peas (without pods) (Garden pea, green pea, chickpea) | 0.02* |
| 260050 | Lentils | 0.02* |
| 260990 | Others | 0.02* |
| 270000 | (vii) Stem vegetables (fresh) | |
| 270010 | Asparagus | 0.02* |
| 270020 | Cardoons | 0.02* |
| 270030 | Celery | 1 |
| 270040 | Fennel | 0.02* |
| 270050 | Globe artichokes | 0.2 |
| 270060 | Leek | 0.2 |
| 270070 | Rhubarb | 0.02* |
| 270080 | Bamboo shoots | 0.02* |
| 270090 | Palm hearts | 0.02* |
| 270990 | Others | 0.02* |
| 280000 | (viii) Fungi | 0.02* |
| 280010 | Cultivated (Common mushroom, Oyster mushroom, Shi-take) | 0.02* |
| 280020 | Wild (Chanterelle, Truffle, Morel ,) | 0.02* |
| 280990 | Others | 0.02* |
| 290000 | (ix) Sea weeds | 0.02* |
| 300000 | 3. PULSES, DRY | 0.02* |
| 300010 | Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas) | 0.02* |
| 300020 | Lentils | 0.02* |
| 300030 | Peas (Chickpeas, field peas, chickling vetch) | 0.02* |
| 300040 | Lupins | 0.02* |
| 300990 | Others | 0.02* |
| 400000 | 4. OILSEEDS AND OILFRUITS | |
| 401000 | (i) Oilseeds | 0.05* |
| 401010 | Linseed | 0.05* |
| 401020 | Peanuts | 0.05* |
| 401030 | Poppy seed | 0.05* |
| 401040 | Sesame seed | 0.05* |
| 401050 | Sunflower seed | 0.05* |
| 401060 | Rape seed (Bird rapeseed, turnip rape) | 0.05* |
| 401070 | Soya bean | 0.05* |
| 401080 | Mustard seed | 0.05* |
| 401090 | Cotton seed | 0.05* |
| 401100 | Pumpkin seeds | 0.05* |
| 401110 | Safflower | 0.05* |
| 401120 | Borage | 0.05* |
| 401130 | Gold of pleasure | 0.05* |
| 401140 | Hempseed | 0.05* |
| 401150 | Castor bean | 0.05* |
| 401990 | Others | 0.05* |
| 402000 | (ii) Oilfruits | |
| 402010 | Olives for oil production | 0.3 |
| 402020 | Palm nuts (palmoil | 0.05* |

| Code number | Groups and examples of individual products to which the MRLs apply [(a)] | Trifloxystrobin (F) (R) |
|---|---|---|
| | kernels) | |
| 402030 | Palmfruit | 0.05* |
| 402040 | Kapok | 0.05* |
| 402990 | Others | 0.05* |
| 500000 | 5. CEREALS | |
| 500010 | Barley | 0.3 |
| 500020 | Buckwheat | 0.02* |
| 500030 | Maize | 0.02* |
| 500040 | Millet (Foxtail millet, teff) | 0.02* |
| 500050 | Oats | 0.02* |
| 500060 | Rice | 0.02* |
| 500070 | Rye | 0.05 |
| 500080 | Sorghum | 0.02* |
| 500090 | Wheat (Spelt Triticale) | 0.05 |
| 500990 | Others | 0.02* |
| 600000 | 6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA | 0.05* |
| 610000 | (i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis) | 0.05* |
| 620000 | (ii) Coffee beans | 0.05* |
| 630000 | (iii) Herbal infusions (dried) | 0.05* |
| 631000 | (a) Flowers | 0.05* |
| 631010 | Camomille flowers | 0.05* |
| 631020 | Hybiscus flowers | 0.05* |
| 631030 | Rose petals | 0.05* |
| 631040 | Jasmine flowers | 0.05* |
| 631050 | Lime (linden) | 0.05* |
| 631990 | Others | 0.05* |
| 632000 | (b) Leaves | 0.05* |
| 632010 | Strawberry leaves | 0.05* |
| 632020 | Rooibos leaves | 0.05* |
| 632030 | Maté | 0.05* |
| 632990 | Others | 0.05* |
| 633000 | (c) Roots | 0.05* |
| 633010 | Valerian root | 0.05* |
| 633020 | Ginseng root | 0.05* |
| 633990 | Others | 0.05* |
| 639000 | (d) Other herbal infusions | 0.05* |
| 640000 | (iv) Cocoa (fermented beans) | 0.05* |
| 650000 | (v) Carob (st johns bread) | 0.05* |
| 700000 | 7. HOPS (dried) , | 30 |

| Code number | Groups and examples of individual products to which the MRLs apply [(a)] | Trifloxystrobin (F) (R) |
|---|---|---|
| | including hop pellets and unconcentrated powder | |
| 800000 | 8. SPICES | 0.05* |
| 810000 | (i) Seeds | 0.05* |
| 810010 | Anise | 0.05* |
| 810020 | Black caraway | 0.05* |
| 810030 | Celery seed (Lovage seed) | 0.05* |
| 810040 | Coriander seed | 0.05* |
| 810050 | Cumin seed | 0.05* |
| 810060 | Dill seed | 0.05* |
| 810070 | Fennel seed | 0.05* |
| 810080 | Fenugreek | 0.05* |
| 810090 | Nutmeg | 0.05* |
| 810990 | Others | 0.05* |
| 820000 | (ii) Fruits and berries | 0.05* |
| 820010 | Allspice | 0.05* |
| 820020 | Anise pepper (Japan pepper) | 0.05* |
| 820030 | Caraway | 0.05* |
| 820040 | Cardamom | 0.05* |
| 820050 | Juniper berries | 0.05* |
| 820060 | Pepper, black and white (Long pepper, pink pepper) | 0.05* |
| 820070 | Vanilla pods | 0.05* |
| 820080 | Tamarind | 0.05* |
| 820990 | Others | 0.05* |
| 830000 | (iii) Bark | 0.05* |
| 830010 | Cinnamon (Cassia ) | 0.05* |
| 830990 | Others | 0.05* |
| 840000 | (iv) Roots or rhizome | 0.05* |
| 840010 | Liquorice | 0.05* |
| 840020 | Ginger | 0.05* |
| 840030 | Turmeric (Curcuma) | 0.05* |
| 840040 | Horseradish | 0.05* |
| 840990 | Others | 0.05* |
| 850000 | (v) Buds | 0.05* |
| 850010 | Cloves | 0.05* |
| 850020 | Capers | 0.05* |
| 850990 | Others | 0.05* |
| 860000 | (vi) Flower stigma | 0.05* |
| 860010 | Saffron | 0.05* |
| 860990 | Others | 0.05* |
| 870000 | (vii) Aril | 0.05* |
| 870010 | Mace | 0.05* |
| 870990 | Others | 0.05* |
| 900000 | 9. SUGAR PLANTS | |

| Code number | Groups and examples of individual products to which the MRLs apply [(a)] | Trifloxystrobin (F) (R) |
|---|---|---|
| 900010 | Sugar beet (root) | 0.05 |
| 900020 | Sugar cane | 0.02* |
| 900030 | Chicory roots | 0.02* |
| 900990 | Others | 0.02* |
| 1000000 | 10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS | |
| 1010000 | (i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these | 0.04* |
| 1011000 | (a) Swine | 0.04* |
| 1011010 | Meat | 0.04* |
| 1011020 | Fat free of lean meat | 0.04* |
| 1011030 | Liver | 0.04* |
| 1011040 | Kidney | 0.04* |
| 1011050 | Edible offal | 0.04* |
| 1011990 | Others | 0.04* |
| 1012000 | (b) Bovine | 0.04* |
| 1012010 | Meat | 0.04* |
| 1012020 | Fat | 0.04* |
| 1012030 | Liver | 0.04* |
| 1012040 | Kidney | 0.04* |
| 1012050 | Edible offal | 0.04* |
| 1012990 | Others | 0.04* |
| 1013000 | (c) Sheep | 0.04* |
| 1013010 | Meat | 0.04* |
| 1013020 | Fat | 0.04* |
| 1013030 | Liver | 0.04* |
| 1013040 | Kidney | 0.04* |
| 1013050 | Edible offal | 0.04* |
| 1013990 | Others | 0.04* |
| 1014000 | (d) Goat | 0.04* |
| 1014010 | Meat | 0.04* |
| 1014020 | Fat | 0.04* |
| 1014030 | Liver | 0.04* |
| 1014040 | Kidney | 0.04* |
| 1014050 | Edible offal | 0.04* |
| 1014990 | Others | 0.04* |
| 1015000 | (e) Horses, asses, mules or hinnies | 0.04* |

| Code number | Groups and examples of individual products to which the MRLs apply [(a)] | Trifloxystrobin (F) (R) |
|---|---|---|
| 1015010 | Meat | 0.04* |
| 1015020 | Fat | 0.04* |
| 1015030 | Liver | 0.04* |
| 1015040 | Kidney | 0.04* |
| 1015050 | Edible offal | 0.04* |
| 1015990 | Others | 0.04* |
| 1016000 | (f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon | 0.04* |
| 1016010 | Meat | 0.04* |
| 1016020 | Fat | 0.04* |
| 1016030 | Liver | 0.04* |
| 1016040 | Kidney | 0.04* |
| 1016050 | Edible offal | 0.04* |
| 1016990 | Others | 0.04* |
| 1017000 | (g) Other farm animals (Rabbit, Kangaroo) | 0.04* |
| 1017010 | Meat | 0.04* |
| 1017020 | Fat | 0.04* |
| 1017030 | Liver | 0.04* |
| 1017040 | Kidney | 0.04* |
| 1017050 | Edible offal | 0.04* |
| 1017990 | Others | 0.04* |
| 1020000 | (ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd | 0.02* |
| 1020010 | Cattle | 0.02* |
| 1020020 | Sheep | 0.02* |
| 1020030 | Goat | 0.02* |
| 1020040 | Horse | 0.02* |
| 1020990 | Others | 0.02* |
| 1030000 | (iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter | 0.04* |
| 1030010 | Chicken | 0.04* |
| 1030020 | Duck | 0.04* |

| Code number | Groups and examples of individual products to which the MRLs apply [(a)] | Trifloxystrobin (F) (R) |
|---|---|---|
| 1030030 | Goose | 0.04* |
| 1030040 | Quail | 0.04* |
| 1030990 | Others | 0.04* |
| 1040000 | (iv) Honey (Royal jelly, pollen) | 0.04* |
| 1050000 | (v) Amphibians and reptiles (Frog legs, crocodiles) | 0.04* |
| 1060000 | (vi) Snails | 0.04* |
| 1070000 | (vii) Other terrestrial animal products | 0.04* |

(*) Indicates lower limit of analytical determination

# APPENDIX C.2 – EXISTING CXLS

| Summary of CXLs for trifloxystrobin in plant commodities | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Commodity code | Commodity name | Values adopted by the CCPR | | Critical values of the JMPR evaluation | | | | | Risk assessment values as calculated by EFSA | | | | Comments on the JMPR evaluation | | |
| | | Residue definition | CXL (mg/kg) | Residue definition | STMR (-P) (mg/kg) | HR (-P) (mg/kg) | Default variability factor | Reduced variability factor | STMR (mg/kg) | HR (mg/kg) | Median peeling factor | Median conversion factor | Year | Based on EU GAP only? | Other comments |
| 110010 | Grapefruit | Trifloxystrobin | 0.5 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.095 | n.c. | 1 | n.c. | 0.095 | 0.23 | n.k. | 1 | 2004 | No | All GAP-compliant trials were conducted in the USA. Data for orange, grapefruit and lemon were combined to derive an MRL for citrus. No differences in residues between the definitions were observed, therefore no conversion factor is required. |
| 110020 | Oranges | Trifloxystrobin | 0.5 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.095 | n.c. | 1 | n.c. | 0.095 | 0.23 | n.k. | 1 | 2004 | No | |
| 110030 | Lemons | Trifloxystrobin | 0.5 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.095 | n.c. | 1 | n.c. | 0.095 | 0.23 | n.k. | 1 | 2004 | No | |
| 110040 | Limes | Trifloxystrobin | 0.5 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.095 | n.c. | 1 | n.c. | 0.095 | 0.23 | n.k. | 1 | 2004 | No | |
| 110050 | Mandarins | Trifloxystrobin | 0.5 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.095 | n.c. | 1 | n.c. | 0.095 | 0.23 | n.k. | 1 | 2004 | No | |
| 120010 | Almonds | Trifloxystrobin | 0.02 * | Sum of trifloxystrobin and CGA321113, expressed as | 0 | n.c. | 1 | n.c. | 0.02 | 0.02 | n.a. | 1 | 2004 | No | All GAP-compliant trials were conducted in the USA. Data for almonds and pecans were combined to derive an MRL for tree nuts. All residues were <0.02 therefore no conversion factor is required. |
| 120020 | Brazil nuts | Trifloxystrobin | 0.02 * | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0 | n.c. | 1 | n.c. | 0.02 | 0.02 | n.a. | 1 | 2004 | No | |
| 120030 | Cashew nuts | Trifloxystrobin | 0.02 * | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0 | n.c. | 1 | n.c. | 0.02 | 0.02 | n.a. | 1 | 2004 | No | |
| 120040 | Chestnuts | Trifloxystrobin | 0.02 * | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0 | n.c. | 1 | n.c. | 0.02 | 0.02 | n.a. | 1 | 2004 | No | |
| 120050 | Coconuts | Trifloxystrobin | 0.02 * | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0 | n.c. | 1 | n.c. | 0.02 | 0.02 | n.a. | 1 | 2004 | No | |
| 120060 | Hazelnuts | Trifloxystrobin | 0.02 * | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0 | n.c. | 1 | n.c. | 0.02 | 0.02 | n.a. | 1 | 2004 | No | |
| 120070 | Macadamia | Trifloxystrobin | 0.02 * | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0 | n.c. | 1 | n.c. | 0.02 | 0.02 | n.a. | 1 | 2004 | No | |
| 120080 | Pecans | Trifloxystrobin | 0.02 * | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0 | n.c. | 1 | n.c. | 0.02 | 0.02 | n.a. | 1 | 2004 | No | |
| 120090 | Pine nuts | Trifloxystrobin | 0.02 * | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0 | n.c. | 1 | n.c. | 0.02 | 0.02 | n.a. | 1 | 2004 | No | |
| 120100 | Pistachios | Trifloxystrobin | 0.02 * | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0 | n.c. | 1 | n.c. | 0.02 | 0.02 | n.a. | 1 | 2004 | No | |
| 120110 | Walnuts | Trifloxystrobin | 0.02 * | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0 | n.c. | 1 | n.c. | 0.02 | 0.02 | n.a. | 1 | 2004 | No | |
| 130010 | Apples | Trifloxystrobin | 0.7 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.11 | n.c. | 1 | n.c. | 0.105 | 0.44 | n.a. | 1 | 2004 | No | Trials were conducted in both EU and non-EU countries according to appropriate GAP. Data on apple and pear were combined to derive an MRL for pome fruit. The HR and STMR for each definition are so similar that no conversion factor has been determined. |
| 130020 | Pears | Trifloxystrobin | 0.7 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.11 | n.c. | 1 | n.c. | 0.105 | 0.44 | n.a. | 1 | 2004 | No | |
| 130030 | Quinces | Trifloxystrobin | 0.7 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.11 | n.c. | 1 | n.c. | 0.105 | 0.44 | n.a. | 1 | 2004 | No | |
| 130040 | Medlar | Trifloxystrobin | 0.7 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.11 | n.c. | 1 | n.c. | 0.105 | 0.44 | n.a. | 1 | 2004 | No | |
| 130050 | Loquat | Trifloxystrobin | 0.7 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.11 | n.c. | 1 | n.c. | 0.105 | 0.44 | n.a. | 1 | 2004 | No | |
| 140010 | Apricots | Trifloxystrobin | 3 | Sum of trifloxystrobin and CGA321113, expressed as | 0.38 | n.c. | 1 | n.c. | 0.355 | 1.9 | n.a. | 1 | 2004 | No | Trials were conducted in both EU and non-EU countries according to appropriate GAP. Data on cherry, apricot, peach and plum were combined to derive an MRL for stone fruit. The HR and STMR for each definition are so similar that no conversion factor has been determined. |
| 140020 | Cherries | Trifloxystrobin | 3 | Sum of trifloxystrobin and CGA321113, expressed as | 0.38 | n.c. | 1 | n.c. | 0.355 | 1.9 | n.a. | 1 | 2004 | No | |
| 140030 | Peaches | Trifloxystrobin | 3 | Sum of trifloxystrobin and CGA321113, expressed as | 0.38 | n.c. | 1 | n.c. | 0.355 | 1.9 | n.a. | 1 | 2004 | No | |
| 140040 | Plums | Trifloxystrobin | 3 | Sum of trifloxystrobin and CGA321113, expressed as | 0.38 | n.c. | 1 | n.c. | 0.355 | 1.9 | n.a. | 1 | 2004 | No | |

| Summary of CXLs for trifloxystrobin in plant commodities | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Commodity code | Commodity name | Values adopted by the CCPR | | Critical values of the JMPR evaluation | | | | | Risk assessment values as calculated by EFSA | | | | Comments on the JMPR evaluation | | |
| | | Residue definition | CXL (mg/kg) | Residue definition | STMR (-P) (mg/kg) | HR (-P) (mg/kg) | Default variability factor | Reduced variability factor | STMR (mg/kg) | HR (mg/kg) | Median peeling factor | Median conversion factor | Year | Based on EU GAP only? | Other comments |
| 151010 | Table grapes | Trifloxystrobin | 3 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.15 | n.c. | 1 | n.c. | 0.13 | 2.2 | n.a. | 1 | 2004 | No | Trials were conducted in both EU and non-EU countries according to appropriate GAP. Data on cherry, apricot, peach and plum were combined to derive an MRL for stone fruit. The HR and STMR for each definition are so similar that no conversion factor has been determined. |
| 151020 | Wine grapes | Trifloxystrobin | 3 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.15 | n.c. | 1 | n.c. | 0.13 | 2.2 | n.a. | 1 | 2004 | No | |
| 152000 | Strawberries | Trifloxystrobin | 1 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.335 | n.c. | 1 | n.c. | 0.29 | 0.5 | n.a. | 1.1 | 2012 | No | Trials were conducted in the US according to GAP. |
| 161030 | Table olives | Trifloxystrobin | 0.3 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.085 | n.c. | 1 | n.c. | 0.09 | 0.13 | n.a. | 1 | 2012 | Yes | Trials were conducted in SEU MS according to the GAP of Spain. |
| 163020 | Bananas | Trifloxystrobin | 0.05 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.02 | n.c. | 1 | n.c. | 0.02 | 0.03 | 1 | 1 | 2004 | No | All GAP-compliant trials were conducted outside of the EU. All residues were around the LOQ on a whole fruit basis and therefore the conversion and peeling factors have been estimated as 1. |
| 163040 | Papaya | Trifloxystrobin | 0.6 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.2 | n.c. | 1 | n.c. | 0.19 | 0.27 | n.k. | 1 | 2012 | No | Trials were conducted in the US according to GAP. Data were for the whole fruit only. |
| 211000 | Potatoes | Trifloxystrobin | 0.02 * | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.02 | n.c. | 1 | n.c. | 0.02 | 0.02 | n.a. | 1 | 2004 | No | All GAP-compliant trials were conducted in the USA. All residues were <LOQ therefore no conversion factor is required. |
| 213020 | Carrots | Trifloxystrobin | 0.1 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.035 | n.c. | 1 | n.c. | 0.025 | 0.04 | n.a. | 2 | 2004 | No | GAP-compliant trials were conducted in the EU and Switzerland. |
| 213080 | Radishes | Trifloxystrobin | 0.08 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.065 | n.c. | 1 | n.c. | 0.03 | 0.05 | n.a. | 2 | 2012 | No | Trials were conducetd in the US according to GAP. |
| 231010 | Tomatoes | Trifloxystrobin | 0.7 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.08 | n.c. | 1 | n.c. | 0.08 | 0.49 | n.a. | 1 | 2004 | No | All trials were conducted in the USA according to GAP. Parent and total residues were combined into a single data set. No conversion factor is required. |
| 231020 | Peppers | Trifloxystrobin | 0.3 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.1 | n.c. | 1 | n.c. | 0.1 | 0.16 | n.a. | 1 | 2004 | No | All trials were conducted in the USA according to GAP. Parent and total residues were combined into a single data set. No conversion factor is required. |
| 231030 | Aubergines (egg plants) | Trifloxystrobin | 0.7 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.08 | n.c. | 1 | n.c. | 0.08 | 0.49 | n.a. | 1 | 2004 and 2012 | No | Extrapolated from tomato. |
| 232010 | Cucumbers | Trifloxystrobin | 0.3 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.095 | n.c. | 1 | n.c. | 0.07 | 0.24 | n.a. | 1.29 | 2004 | No | Trials were conducted in both EU and non-EU countries according to appropriate GAP. Data on cucumber, melon and courgette were combined to derive an MRL for cucurbits. The HR and STMR are so similar that no conversion factor has been determined. All data relate to the whole fruit therefore no MPF could be derived. |
| 232020 | Gherkins | Trifloxystrobin | 0.3 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.095 | n.c. | 1 | n.c. | 0.07 | 0.24 | n.a. | 1.29 | 2004 | No | |
| 232030 | Courgettes | Trifloxystrobin | 0.3 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.095 | n.c. | 1 | n.c. | 0.07 | 0.24 | n.a. | 1.29 | 2004 | No | |
| 233010 | Melons | Trifloxystrobin | 0.3 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.095 | n.c. | 1 | n.c. | 0.07 | 0.24 | n.a. | 1.29 | 2004 | No | |
| 233020 | Pumpkins | Trifloxystrobin | 0.3 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.095 | n.c. | 1 | n.c. | 0.07 | 0.24 | n.k. | 1.29 | 2004 | No | |
| 233030 | Watermelons | Trifloxystrobin | 0.3 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.095 | n.c. | 1 | n.c. | 0.07 | 0.24 | n.k. | 1.29 | 2004 | No | |

| Summary of CXLs for trifloxystrobin in plant commodities | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Commodity code | Commodity name | Values adopted by the CCPR | | Critical values of the JMPR evaluation | | | | | Risk assessment values as calculated by EFSA | | | | Comments on the JMPR evaluation | | |
| | | Residue definition | CXL (mg/kg) | Residue definition | STMR (-P) (mg/kg) | HR (-P) (mg/kg) | Default variability factor | Reduced variability factor | STMR (mg/kg) | HR (mg/kg) | Median peeling factor | Median conversion factor | Year | Based on EU GAP only? | Other comments |
| 241010 | Broccoli | Trifloxystrobin | 0.5 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.17 | n.c. | 1 | n.c. | 0.13 | 0.35 | n.a. | 1.51 | 2004 | No | GAP-compliant trials were conducted in the EU and Switzerland. Data for head cabbage, Brussels sprout, cauliflower and broccoli were combined into a single data set to derive an MRL for flowering and head brassica. |
| 241020 | Cauliflower | Trifloxystrobin | 0.5 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.17 | n.c. | 1 | n.c. | 0.13 | 0.35 | n.a. | 1.51 | 2004 | No | |
| 242010 | Brussels sprouts | Trifloxystrobin | 0.1 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.17 | n.c. | 1 | n.c. | 0.13 | 0.35 | n.a. | 1.51 | 2004 | No | |
| 242020 | Head cabbage | Trifloxystrobin | 0.5 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.17 | n.c. | 1 | n.c. | 0.13 | 0.35 | n.a. | 1.51 | 2004 | No | |
| 251020 | Lettuce | Trifloxystrobin | 15 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 5.55 | n.c. | 1 | n.c. | 5.5 | 7.2 | n.a. | 1 | 2012 | Yes | Trials were conducted indoors in the EU. |
| 251080 | Leaves and sprouts of Brassica spp | Trifloxystrobin | 15 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 1.4 | n.c. | 1 | n.c. | 1.3 | 6.8 | n.a. | 1.2 | 2012 | No | Trials were conducted in the US according to GAP. |
| 270010 | Asparagus | Trifloxystrobin | 0.05 * | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0 | n.c. | 1 | n.c. | 0.05 | 0.05 | n.a. | 1 | 2012 | No | Trials were conducted in the US according to GAP. |
| 270030 | Celery | Trifloxystrobin | 1 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.18 | n.c. | 1 | n.c. | 0.18 | 0.21 | n.a. | 1 | 2004 | No | All trials were conducted in Switzerland according to GAP. No residues of the metabolite were, therefore no conversion factor is required. |
| 270060 | Leek | Trifloxystrobin | 0.7 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.31 | n.c. | 1 | n.c. | 0.15 | 0.4 | n.a. | 1.63 | 2004 | No | GAP-compliant trials were conducted in the EU and Switzerland. |
| 401020 | Peanuts | Trifloxystrobin | 0.02 * | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0 | n.c. | 1 | n.c. | 0.02 | 0.02 | n.a. | 1 | 2004 | No | All GAP-compliant trials were conducted in Brazil. All residues were <0.02 therefore no conversion factor is required. JMPR states the STMR as 0. |
| 402010 | Olives for oil production | Trifloxystrobin | 0.3 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.085 | n.c. | 1 | n.c. | 0.09 | 0.13 | n.a. | 1 | 2012 | Yes | Trials were conducted in SEU MS according to the GAP of Spain. |
| 500010 | Barley grain | Trifloxystrobin | 0.5 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.04 | n.c. | 1 | n.c. | 0.04 | 0.4 | n.a. | 1.5 | 2004 | Yes | All trials conducted in the EU according to GAP. |
| 500030 | Maize grain | Trifloxystrobin | 0.02 * | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.02 | n.c. | 1 | n.c. | 0.02 | 0.02 | n.a. | 1 | 2004 | No | All trials conducted outside of the EU according to GAP. A conversion factor has not been derived as the majority of residues are <LOQ. |
| 500060 | Rice grain | Trifloxystrobin | 5 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.16 | n.c. | 1 | n.c. | 0.11 | 3.4 | n.a. | 1.5 | 2004 | No | All trials conducted outside of the EU according to GAP. |
| 500090 | Wheat grain | Trifloxystrobin | 0.2 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.02 | n.c. | 1 | n.c. | 0.02 | 0.14 | n.a. | 2 | 2004 | No | Based on trials conducted in the EU and USA according to appropriate GAP. |
| 700000 | Hops (dried), including hop pellets and unconcentrated powder | Trifloxystrobin | 40 | Sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin | 9.95 | n.c. | 1 | n.c. | 9.05 | 26 | n.a. | 1.115 | 2004 | No | Trials were conducted in Germany and the USA according to GAP. |

(*) Indicates the lower limit of analytical quantification.

n.a.: not applicable

n.c.: not considered

n.k.: not known

| Summary of CXLs for trifloxystrobin in livestock commodities | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Commodity code | Commodity name | Values adopted by the CCPR | | | Critical values of the JMPR evaluation | | | Comment on the JMPR evaluation | | |
| | | Residue definition | Fat soluble? | CXL (mg/kg) | Residue definition | STMR (mg/kg) | HR (mg/kg) | Year | Based on EU GAP only? | Other comments |
| 1011010 | Swine meat | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | yes | 0.02 | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.0012 | 0.014 | 2004 | no | Based on an estimated dietary burden for MRLs and STMRs of 6.3 and 2.1 mg/kg for beef cattle and 5.2 and 1.4 mg/kg for dairy cattle. The CXL for meat is 0.05 mg/kg, set on the basis of a HR of 0.024 mg/kg in fat. The STMR and HR for muscle are 0 and 0.012 mg/kg. |
| 1011020 | Swine fat (free of lean meat) | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | yes | 0.05 | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.006 | 0.024 | 2004 | no | |
| 1011030 | Swine liver | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | n.a. | 0.05 | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.008 | 0.033 | 2004 | no | |
| 1011040 | Swine kidney | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | n.a. | 0.04 * | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.004 | 0.012 | 2004 | no | |
| 1012010 | Bovine meat | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | yes | 0.02 | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.0012 | 0.014 | 2004 | no | Based on an estimated dietary burden for MRLs and STMRs of 6.3 and 2.1 mg/kg for beef cattle and 5.2 and 1.4 mg/kg for dairy cattle. The CXL for meat is 0.05 mg/kg, set on the basis of a HR of 0.024 mg/kg in fat. The STMR and HR for muscle are 0 and 0.012 mg/kg. |
| 1012020 | Bovine fat | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | yes | 0.05 | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.006 | 0.024 | 2004 | no | |
| 1012030 | Bovine liver | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | n.a. | 0.05 | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.008 | 0.033 | 2004 | no | |
| 1012040 | Bovine kidney | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | n.a. | 0.04 * | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.004 | 0.012 | 2004 | no | |
| 1013010 | Sheep meat | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | yes | 0.02 | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.0012 | 0.014 | 2004 | no | Based on an estimated dietary burden for MRLs and STMRs of 6.3 and 2.1 mg/kg for beef cattle and 5.2 and 1.4 mg/kg for dairy cattle. The CXL for meat is 0.05 mg/kg, set on the basis of a HR of 0.024 mg/kg in fat. The STMR and HR for muscle are 0 and 0.012 mg/kg. |
| 1013020 | Sheep fat | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | yes | 0.05 | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.006 | 0.024 | 2004 | no | |
| 1013030 | Sheep liver | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | n.a. | 0.05 | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.008 | 0.033 | 2004 | no | |
| 1013040 | Sheep kidney | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | n.a. | 0.04 * | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.004 | 0.012 | 2004 | no | |
| 1014010 | Goat meat | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | yes | 0.02 | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.0012 | 0.014 | 2004 | no | Based on an estimated dietary burden for MRLs and STMRs of 6.3 and 2.1 mg/kg for beef cattle and 5.2 and 1.4 mg/kg for dairy cattle. The CXL for meat is 0.05 mg/kg, set on the basis of a HR of 0.024 mg/kg in fat. The STMR and HR for muscle are 0 and 0.012 mg/kg. |
| 1014020 | Goat fat | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | yes | 0.05 | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.006 | 0.024 | 2004 | no | |
| 1014030 | Goat liver | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | n.a. | 0.05 | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.008 | 0.033 | 2004 | no | |
| 1014040 | Goat kidney | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | n.a. | 0.04 * | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.004 | 0.012 | 2004 | no | |
| 1015010 | Horses, asses, mules or hinnies meat | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | yes | 0.02 | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | #REF! | 0.014 | 2004 | no | See comment above. |
| 1016010 | Poultry meat | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | yes | 0.04 * | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0 | 0.04 | 2004 | no | The max dietary burden for poultry was estimated as 2.5 mg/kg. No residues (<0.04 mg/kg) were found in tissues or eggs at a feed level of 15 mg/kg. No change to the CXL, STMR or HR from reporting on a fat basis. |
| 1016020 | Poultry fat | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | yes | 0.04 * | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0 | 0.04 | 2004 | no | |
| 1016030 | Poultry liver | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | n.a. | 0.04 * | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0 | 0.04 | 2004 | no | |
| 1016040 | Poultry kidney | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | n.a. | 0.04 * | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0 | 0.04 | 2004 | no | |
| 1016050 | Poultry edible offal | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | n.a. | 0.04 * | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0 | 0.04 | 2004 | no | |
| 1017010 | Other farm animals meat | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | yes | 0.02 | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.0012 | 0.014 | 2004 | no | Based on an estimated dietary burden for MRLs and STMRs of 6.3 and 2.1 mg/kg for beef cattle and 5.2 and 1.4 mg/kg for dairy cattle. The CXL for meat is 0.05 mg/kg, set on the basis of a HR of 0.024 mg/kg in fat. The STMR and HR for muscle are 0 and 0.012 mg/kg. |
| 1017020 | Other farm animals fat | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | yes | 0.05 | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0.006 | 0.024 | 2004 | no | |
| 1020010 | Cattle milk | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | no | 0.02 * | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0 | 0.005 | 2004 | no | Based on an estimated dietary burden for MRLs and STMRs of 6.3 and 2.1 mg/kg for beef cattle and 5.2 and 1.4 mg/kg for dairy cattle. |
| 1020020 | Sheep milk | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | no | 0.02 * | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0 | 0.005 | 2004 | no | |
| 1020030 | Goat milk | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | no | 0.02 * | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0 | 0.005 | 2004 | no | |
| 1020040 | Horse milk | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | no | 0.02 * | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0 | 0.005 | 2004 | no | |
| 1030000 | Birds' eggs | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | n.a. | 0.04 * | Trifloxystrobin and CGA321113, expressed as trifloxystrobin | 0 | 0.04 | 2004 | no | The max dietary burden for poultry was estimated as 2.5 mg/kg. No residues (<0.04 mg/kg) were found in tissues or eggs at a feed level of 15 mg/kg. |

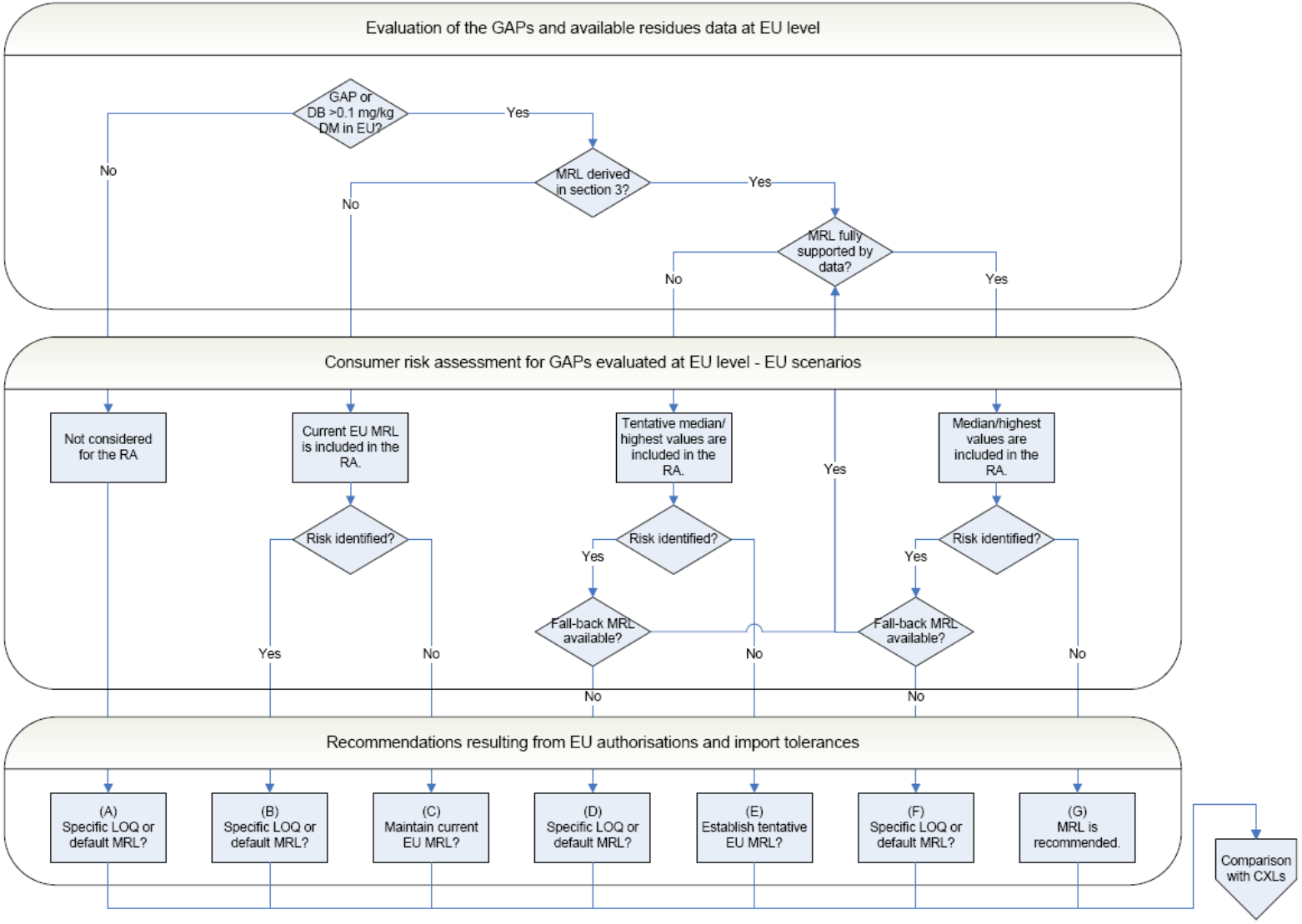
(*) Indicates the lower limit of analytical quantification.

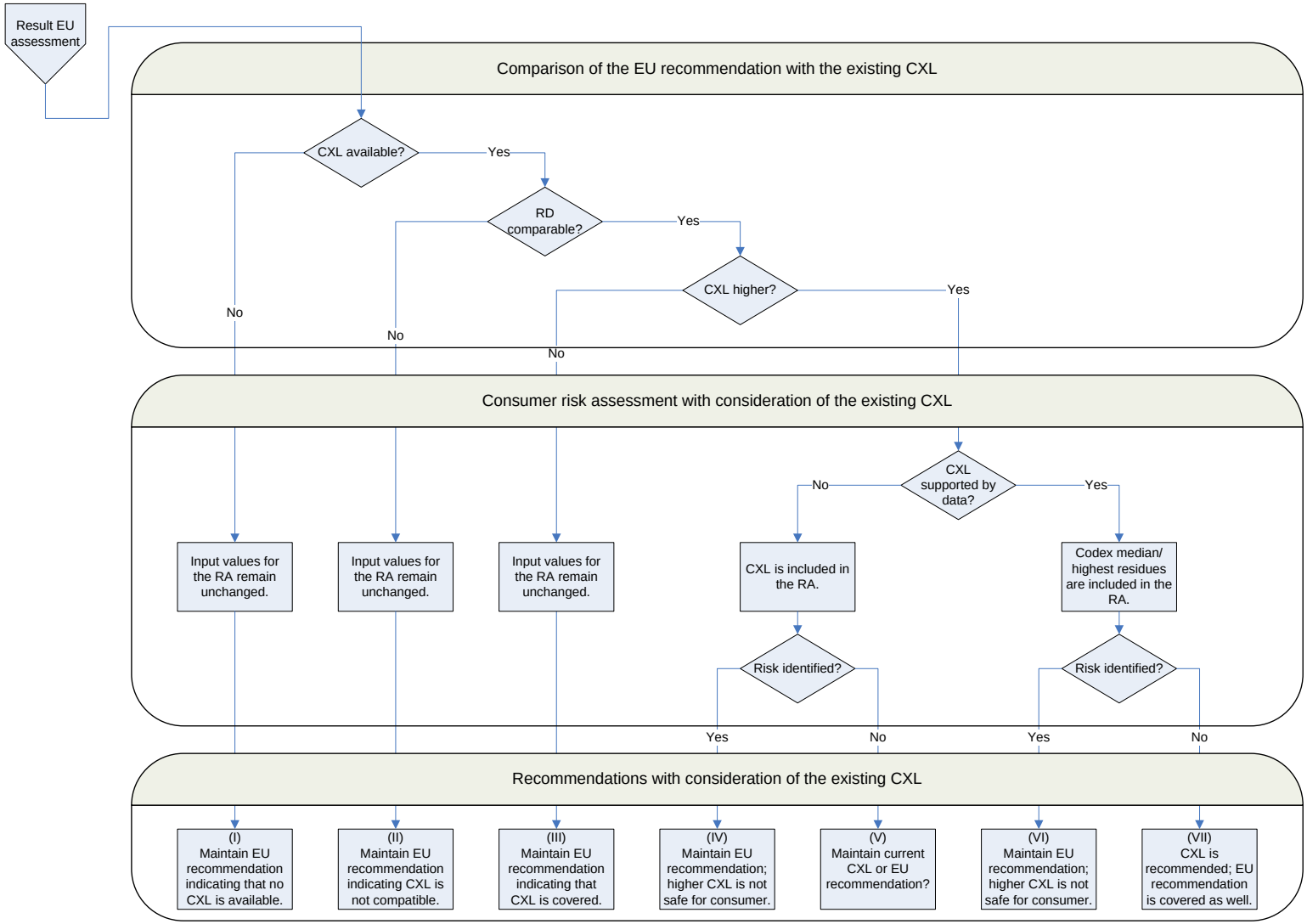
n.a.: not applicable

n.c.: not considered

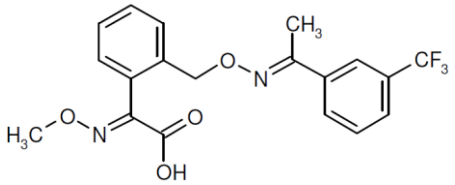
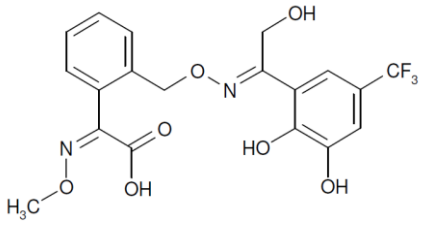
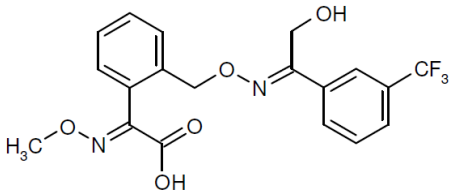
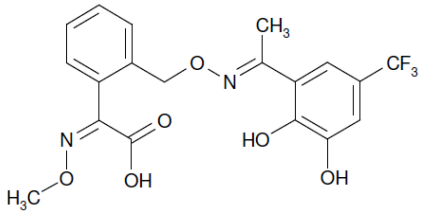
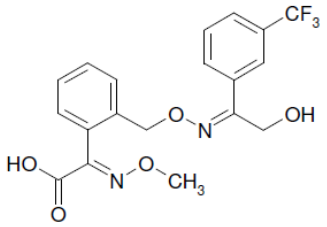
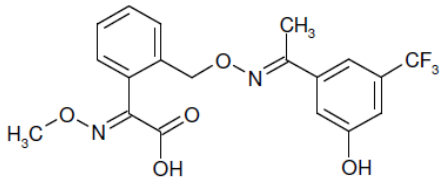
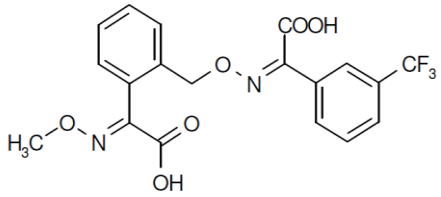
n.k.: not known

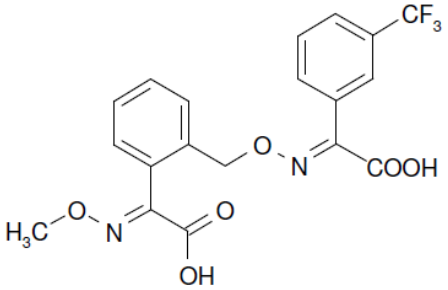
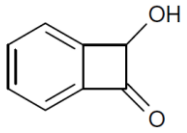
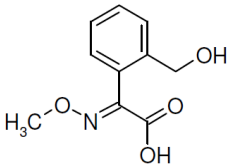
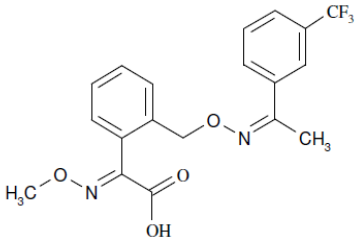
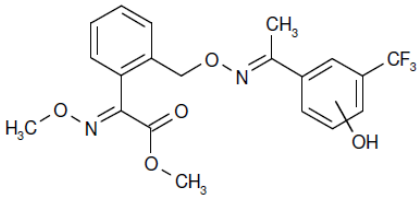
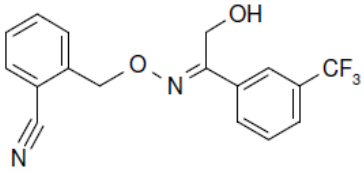
## APPENDIX D – DECISION TREE FOR DERIVING MRL RECOMMENDATIONS




Result EU assessment
Comparison of the EU recommendation with the existing CXL
CXL available?
Yes
RD comparable?
Yes
CXL higher?
Yes
No
No
No
Consumer risk assessment with consideration of the existing CXL
CXL supported by data?
No
Yes
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
CXL is included in the RA.
Codex median/ highest residues are included in the RA.
Risk identified?
Risk identified?
Yes
No
Yes
No
Recommendations with consideration of the existing CXL
(I) Maintain EU recommendation indicating that no CXL is available.
(II) Maintain EU recommendation indicating CXL is not compatible.
(III) Maintain EU recommendation indicating that CXL is covered.
(IV) Maintain EU recommendation; higher CXL is not safe for consumer.
(V) Maintain current CXL or EU recommendation?
(VI) Maintain EU recommendation; higher CXL is not safe for consumer.
(VII) CXL is recommended; EU recommendation is covered as well.

## APPENDIX E – LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

| Common name | IUPAC name | Structural formula |
|---|---|---|
| CGA 321113 | (E, E)-methoxyimino- {2-[1-(3-trifluoromethyl-phenyl)-ethylideneamino-oxymethyl]-phenyl}-acetic acid. |  |
| $II_{19a}$ | {2-[1-(2,3-dihydroxy-5-methyl-phenyl)-2-hydroxy-ethylideneamino-oxymethyl]-phenyl}-methoxy-imino-acetic acid |  |
| NOA443152 | 2-[2-hydroxy-1-(3-trifluoromethyl-phenyl)-ethylideneaminooxy-methyl]-phenyl}-methoxyimino-acetic acid |  |
| $II_{21a}$ | 2-[[[[(1E)-1-[2,3-dihydroxy-5-(trifluoromethyl)phenyl]ethylidene]amino]oxy]-methyl]-a-(methoxyimino)- benzeneacetic acid |  |
| BO172741 | (2-[2-hydroxy-1-(3-trifluoromethyl-phenyl)-ethylideneaminooxy-methyl]-phenyl}-methoxyimino-acetic acid<br>(E,E isomer of NOA443152) |  |
| NOA414412 | 2-[1-(3-hydroxy-5-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-phenyl}-methoxyimino-acetic acid |  |
| NOA413161 | (E,Z)-{2-[carboxy-(3-trifluoromethyl-phenyl)-methyleneaminooxy-methyl]-phenyl}-methoxyiminoacetic acid |  |

| Common name | IUPAC name | Structural formula |
|---|---|---|
| NOA413163 | (E,E)-{2-[carboxy-(3-trifluoromethyl-phenyl)-methyleneaminooxy-methyl]-phenyl}-methoxyiminoacetic acid |  |
| SA04271 | 8-hydroxybicyclo[4.2.0]octa-1,3,5-trien-7-one |  |
| CGA347242 | (2-hydroxyethyl-phenyl)-methoxyimino-acetic acid |  |
| CGA 373466 | (Z, E)-methoxyimino-{2-[1-(3-trifluoro methyl-phenyl)-ethylideneaminooxymethyl]-phenyl}-acetic acid |  |
| L13b | {2-[1-(hydroxy-5-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-phenyl}-methoxyimino-acetic acid methyl ester |  |
| BO172631 | 2-[2-hydroxy-1-(3-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-benzonitrile |  |

## ABBREVIATIONS

| | |
|---|---|
| a.s. | active substance |
| ADI | acceptable daily intake |
| AR | applied radioactivity |
| ARfD | acute reference dose |
| bw | body weight |
| CAC | Codex Alimentarius Commission |
| CEN | European Committee for Standardization (Comité Européen de Normalisation) |
| CF | conversion factor for enforcement residue definition to risk assessment residue definition |
| CXL | codex maximum residue limit |
| d | day |
| DAR | Draft Assessment Report (prepared under Council Directive 91/414/EEC) |
| DAT | days after treatment |
| DM | dry matter |
| $DT_{90}$ | period required for 90 percent dissipation (define method of estimation) |
| EC | European Commission |
| EC | emulsifiable concentrate |
| EFSA | European Food Safety Authority |
| eq | residue expressed as a.s. equivalent |
| EU | European Union |
| EURL | EU Reference Laboratories (former CRLs) |
| FAO | Food and Agriculture Organization of the United Nations |
| GAP | good agricultural practice |
| GC-ECD | gas chromatography with electron capture detector |
| ha | hectare |
| HPLC-MS/MS | high performance liquid chromatography with tandem mass spectrometry |

| | |
|---|---|
| HPLC-UVD | high performance liquid chromatography with ultra-violet detector |
| ILV | independent laboratory validation |
| ISO | International Organisation for Standardization |
| IUPAC | International Union of Pure and Applied Chemistry |
| JMPR | Joint FAO/WHO Meeting on Pesticide Residues |
| LOQ | limit of quantification |
| MRL | maximum residue limit |
| MS | Member States |
| NEU | northern European Union |
| OECD | Organisation for Economic Co-operation and Development |
| PHI | pre-harvest interval |
| $P_{o/w}$ | partition coefficient n-octanol/water |
| PRIMo | (EFSA) Pesticide Residues Intake Model |
| PROFile | (EFSA) Pesticide Residues Overview File |
| $R_{ber}$ | statistical calculation of the MRL by using a non-parametric method |
| $R_{max}$ | statistical calculation of the MRL by using a parametric method |
| RA | risk assessment |
| RAC | raw agricultural commodity |
| RMS | rapporteur Member State |
| RSD | relative standard deviation |
| SC | suspension concentrate |
| SEU | Southern European Union |
| TRR | total radioactive residue |
| WG | water dispersible granule |
| WHO | World Health Organization |