REASONED OPINION

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Review of the existing maximum residue levels for triflumizole according to Article 12 of Regulation (EC) No 396/2005

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Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance triflumizole. To assess the occurrence of triflumizole 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 (including 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 missing. Hence, the consumer risk assessment is considered indicative only and all MRL proposals derived by EFSA still require further consideration by risk managers.

Keywords: triflumizole, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, azole, fungicide

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Summary

Triflumizole was included in Annex I to Directive 91/414/EEC on 1 July 2010 by Commission Directive 2010/27/EC, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. As the active substance was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, EFSA is required to provide a reasoned opinion on the review of the existing MRLs for that active substance in compliance with Article 12(1) of the aforementioned regulation. To collect the relevant pesticide residues data, EFSA asked the Netherlands, the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report provided by the RMS were made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period, which was initiated by EFSA on 13 July 2016 and finalised on 13 September 2016. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 17 November 2016.

EFSA prepared in January 2017 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission and the additional information provided by the RMS and Member States. Comments received by 16 February 2017 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

During the peer review, the metabolism of triflumizole following foliar application on grape and cucumber was relied upon. Similar residue profiles were obtained from both metabolism studies, where the parent was the main compound (80–87% total radioactive residue (TRR)) and the metabolite FM-6-1 increased slowly up to 11% TRR following treatment. Additional metabolites were identified however remained below 10% of the TRR.

Triflumizole is authorised on crops that can be grown in rotation. However, according to Commission Directive 2010/27/EC, only uses as fungicide in greenhouses on artificial substrates may be authorised. Succeeding crop studies are not provided and are not considered necessary because the current use of triflumizole is for substrate culture only.

Studies investigating the effect of processing on the nature and magnitude of the residue are not available. Bearing in mind that for the considered crops and uses the chronic exposure does not exceed 10% of the acceptable daily intake (ADI) such studies are not needed.

The storage stability data provided show that triflumizole and the metabolites FM-6-1, FD-2-1 and FA-1-1 are stable at −20°C for at least 6 months in high acid and high water commodities.

According to the metabolism studies on cucumber and grapes, a residue definition for monitoring is proposed as the sum of triflumizole and metabolite FM-6-1 ((1*E*)-*N*′-[4-chloro-2-(trifluoromethyl) phenyl]-2-propoxyethanimidamide), expressed as triflumizole. Considering that further metabolites containing the 4-chloro-2-(trifluoromethyl)phenyl group were identified in the metabolism studies, the residue definition for risk assessment is proposed as the sum of triflumizole and metabolites containing the 4-chloro-2-(trifluoromethyl)phenyl group. The proposed residue definitions are limited to fruit crops only. Metabolism studies also allow deriving a worst-case conversion factor from enforcement to risk assessment of 1.5.

A validated method for enforcement of the proposed residue definition in all matrices with a limit of quantification (LOQ) of 0.02 mg/kg is available. Analytical standards for triflumizole and for its FM-6-1 metabolite are commercially available.

Regarding the magnitude of residues, the available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation. However, since residue trials analysing simultaneously for enforcement and risk assessment residue definitions are not available, all derived MRLs should be considered as tentative only.

Triflumizole is not authorised for use on crops that might be fed to livestock in the EU. Therefore, an investigation of residues, as well as the setting of MRLs in commodities of animal origin, is not necessary.

Chronic and acute 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). The highest chronic exposure was calculated for WHO cluster diet B, representing 3% of the ADI, and the highest acute exposure was calculated for tomatoes, representing 68% of the acute reference dose (ARfD). Although major uncertainties remain due to the data gaps identified, EFSA concludes that for all currently

proposed uses of triflumizole, this indicative exposure calculation did not indicate a risk to consumers. The use of triflumizole was previously also assessed by the Joint Meeting on Pesticide residues (JMPR). However, considering that a different residue definition for enforcement was derived by the JMPR, existing codex maximum residue limits (CXLs) could not further be considered by EFSA for consumer risk assessment.

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Background

Regulation (EC) No 396/2005[1] (hereinafter referred to as 'the Regulation') establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide, within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC[2] a reasoned opinion on the review of the existing MRLs for that active substance. In 2008, a decision on the non-inclusion of the active substance was taken by Commission Decision 2008/748/EC.[3] The applicant submitted a new application requesting the accelerated procedure regarding the inclusion of the active substance in Annex I of Directive 91/414/EEC. Based on the EFSA conclusion which was issued on 4 December 2009 (EFSA, 2009), the decision to approve the active substance triflumizole in accordance with the provision of Regulation (EC) 1107/2009, repealing the provisions of Directive 91/414/EEC, was taken. As triflumizole was included in Annex I to Council Directive 91/414/EEC on 1 July 2010 by means of Commission Directive 2010/27/EC,[4] and has been deemed to be approved under Regulation (EC) No 1107/2009[5], in accordance with Commission Implementing Regulation (EU) No 540/2011[6], as amended by Commission Implementing Regulation (EU) No 541/2011[7], EFSA initiated the review of all existing MRLs for that active substance.

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, whereas MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the European Union (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.

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.

The Netherlands, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for triflumizole and to prepare a supporting evaluation report (Netherlands, 2010). The PROFile and the supporting evaluation report were submitted to EFSA on 28 February 2010 and made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period which was initiated by EFSA on 17 July 2016 and finalised on 17 September 2016. Additional evaluation reports were submitted by Belgium, the Netherlands and the EU Reference Laboratories (EURLs) (Belgium, 2016; EURLs, 2016, Netherlands, 2016) and, after having considered all the information provided by

[1] 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.

[2] 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. Repealed by Regulation (EC) No 1107/2009.

[3] Commission Decision 2008/748/EC of 18 September 2008 concerning the concerning the non-inclusion of triflumizole in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance. OJ L 104, 24.4.2010, p. 54–56.

[4] Commission Directive 2010/27/EC of 23 April 2010 amending Council Directive 91/414/EEC to include triflumizole as active substance. OJ L 104, 24.4.2010, p. 54–56.

[5] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

[6] 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.

[7] Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 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. 187–188.

RMS and Member States, EFSA prepared a completeness check report which was made available to all Member States on 17 November 2016. No further clarifications were sought from Member States.

EFSA prepared in January 2017 a draft reasoned opinion, which was submitted to Member States for commenting via a written procedure based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission (codex maximum residue limit; CXLs) and the additional information provided by the Member States and EURLs. All comments received by 16 February 2017 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Netherlands, 2010) and the evaluation reports submitted by Member States (Belgium, 2016; Netherlands, 2016) and the EURLs (2016) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

In addition, key supporting documents to this reasoned opinion are the completeness check report (EFSA, 2016) and the Member States consultation report (EFSA, 2017). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Also, the chronic and acute exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) and the PROFile are key supporting documents and made publicly available.

Considering the importance of the completeness check and consultation report, all documents are considered as background documents to this reasoned opinion and, thus, are made publicly available.

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

The active substance and its use pattern

Triflumizole is the ISO common name for (*E*)-4-chloro-α,α,α-trifluoro-*N*-(1-imidazol-1-yl-2-propoxyethylidene)-*o*-toluidine (IUPAC).

Triflumizole belongs to the group of azole compounds which are used as fungicides. Triflumizole is a fungicide with protective and curative action. It inhibits the biosynthesis of ergosterol by inhibiting the C14-demethylation in sterol. Ergosterol is considered to function as a stabiliser of the cell wall membranes of fungi.

The chemical structure of the active substance and its main metabolites are reported in Appendix E.

Triflumizole was evaluated in the framework of Directive 91/414/EEC with the Netherlands designated as rapporteur Member State (RMS). The representative uses supported for the peer review process comprised indoor foliar spraying against powdery mildew in cucumber, courgette, gherkin, tomato and ornamentals growing on artificial substrate. Following the first decision on non-inclusion of the active substance in Annex I to Directive 91/414/EEC, the applicant submitted a new application requesting the accelerated procedure regarding the inclusion of the active substance in Annex I of Directive 91/414/EEC. Following the peer review, which was carried out by EFSA, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive Commission Directive 2010/27/EC which entered into force on 1 July 2010. According to Regulation (EU) No 540/2011, triflumizole is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to uses as fungicide in greenhouse on artificial substrates only.

The EU MRLs for triflumizole are established in Annex IIIA of Regulation (EC) No 396/2005 and CXLs for triflumizole were also established by the Codex Alimentarius Commission (CAC).

For the purpose of this MRL review, the critical uses of triflumizole 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 Good Agricultural Practices (GAPs) reported by Member States during the completeness check were also considered. The details of the authorised GAPs for active substance are given in Appendix A.

Assessment

EFSA has based its assessment on the PROFile submitted by the RMS, the evaluation report accompanying the PROFile (Netherlands, 2010), the draft assessment report (DAR) (Netherlands, 2006) prepared under Council Directive 91/414/EEC, the additional report to the draft assessment report and the final addendum to the additional report prepared under the framework of resubmission according to Regulation 33/2008[8] (Netherlands, 2009a,b), the conclusion on the peer review of the pesticide risk assessment of the active substance triflumizole (EFSA, 2009) as well as the evaluation reports submitted during the completeness check (Belgium, 2016; EURLs, 2016; Netherlands, 2016). The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011[9] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b, 2016; OECD, 2011, 2013).

More detailed information on the available data and on the conclusions derived by EFSA can be retrieved from the list of end points reported in Appendix B.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

During the peer review, the metabolism of triflumizole following foliar application on grape and cucumber was relied upon. Results from two additional metabolism studies on apples and pears were evaluated but not considered reliable.

In cucumber fruit, the parent represented the major compound during the whole duration of the study (14 days), representing up to 80% of the total radioactive residue (TRR) 3 days after treatment (DAT). The metabolite FM-6-1 is present with 9.1% TRR 3 DAT increasing slowly with increasing DAT. Notably, the concentration of metabolite FM-8-1 increased and represented up to 8.2% TRR 21 DAT and represented the major metabolite 45 DAT (Netherlands, 2009b). Additional metabolites were identified however remained below 3% of the TRR.

A similar profile was observed in the grape metabolism study, where the parent was the main compound (87%, 3 DAT) and the metabolite FM-6-1 increased slowly from 0.2% TRR (3 DAT) to 11.1% TRR (67 DAT). The metabolite FM-8-1 increased to 4.9% TRR 67 DAT and metabolite FD-2-1 to 5.1% TRR. In addition other minor metabolites such as FD-1-1, FD-6-1 and FD-7-1 were observed at 2.47%, 1.73% and 1.2% TRR (Netherlands, 2009b).

1.1.2. Nature of residues in rotational crops

Triflumizole is authorised on crops that can be grown in rotation. However, according to Commission Directive 2010/27/EC only uses as fungicide in greenhouses on artificial substrates may be authorised. Succeeding crop studies are not provided and are not considered necessary because the current use of triflumizole is for substrate culture only. During the peer review, it was further concluded that studies on degradation in soil are not required for uses on artificial substrate.

It has to be noted that in case the intended use would change to non-substrate culture of crops, this issue has to be reconsidered.

1.1.3. Nature of residues in processed commodities

Studies investigating the effect of processing on the nature of the residue are not available. Considering that for the considered crops and uses the chronic exposure does not exceed 10% of the acceptable daily intake (ADI) such studies are not needed.

[8] Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I. OJ L 15, 18.1.2008, p. 5–12.

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

1.1.4. Methods of analysis in plants

In the framework of this review, a high-performance liquid chromatography (HPLC) method with tandem mass spectrometry (MS/MS) detection (HPLC–MS/MS) was considered suitable for monitoring triflumizole and FM-6-1 in high water commodities, with a combined limit of quantification (LOQ) of 0.04 mg/kg. The method was validated by independent laboratory validation (ILV) with a combined LOQ of 0.02 mg/kg for the parent and the metabolite FM-6-1 (Netherlands, 2009a).

According to the information provided by the EU Reference Laboratories (EURLs) during the completeness check, a combined LOQ of 0.02 mg/kg for triflumizole and FM-6-1 (validated in high water, acid, dry and high oil content commodities) is achievable for routine analyses by using the QuEChERS (liquid chromatography with tandem mass spectrometry (LC–MS/MS)) method (EURLs, 2016).

1.1.5. Stability of residues in plants

The storage stability was evaluated during the peer review and a data gap was identified because it was concluded that storage stability period of triflumizole was one and not four months. The RMS provided additional storage stability studies in the evaluation report (Netherlands, 2010). From the provided data, it can be concluded that triflumizole parent, FM-6-1, FD-2-1 and FA-1-1 are stable at −20°C for at least 6 months in high acid and high water commodities.

1.1.6. Proposed residue definitions

According to the metabolism studies on cucumber and grapes outlined in Section 1.1.1, a residue definition for monitoring is proposed as the sum of triflumizole and metabolite FM-6-1 ((1*E*)-*N*′-[4-chloro-2-(trifluoromethyl)phenyl]-2-propoxyethanimidamide), expressed as triflumizole.

Considering that further metabolites containing the 4-chloro-2-(trifluoromethyl)phenyl group were identified in the metabolism studies, the residue definition for risk assessment is proposed as the sum of triflumizole and metabolites containing the 4-chloro-2-(trifluoromethyl)phenyl group.

The proposed residue definitions are limited to fruit crops only. A worst-case conversion factor from enforcement to risk assessment of 1.5 as derived from the metabolism studies is also proposed.

A validated method for enforcement of the proposed residue definition in high water and high acid commodities with an LOQ of 0.02 mg/kg is available. Analytical standards for triflumizole and for its FM-6-1 metabolite are commercially available.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of triflumizole residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Netherlands, 2010), including residue trials evaluated in the framework of the peer review (EFSA, 2009) and additional data submitted during the completeness check (Belgium, 2016; Netherlands, 2016). All residue trial samples considered in this framework were stored in compliance with the demonstrated storage conditions. Decline of residues during storage of the trial samples is therefore not expected.

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 (European Commission, 2016).

For cucumbers, gherkins and courgettes, the number of residue trials reported is not compliant with the data requirements, only tentative MRL and risk assessment values could be derived by EFSA and the following data gaps were identified:

- four additional trials on cucumber compliant with the indoor GAP for cucumber, gherkin and courgettes are required. It is also noted that a different GAP for cucumbers and courgettes is authorised in the Netherlands but not supported by data. Therefore, eight residue trials compliant with the GAP provided by the Netherlands are also still required.

For tomatoes and aubergines, available residue trials are sufficient to derive MRL and risk assessment values, taking note of the following considerations:

- all available trials were performed with three instead of four applications. However, since the first application according to the application conditions reported in the most critical GAP (cGAP), is expected to be done at an early growth stage and therefore not expected to have a significant impact on the final residue level, this is considered as a minor deficiency. It is also noted that a more cGAP for tomatoes is authorised in the Netherlands but not supported by data. Therefore, eight residue trials compliant with the GAPs in the Netherlands are still required.

It has to be noted that the available residue trials were all analysed according to the residue definition for enforcement. Analytical results according to the residue definition for risk assessment are not available and would be required. Therefore, the input values for risk assessment were tentatively calculated by applying a worst-case factor as outlined in Section 1.1.6.

1.2.2. Magnitude of residues in rotational crops

Considering the approval restrictions as reported in Section 1.1.2 for substrate culture only, crop rotation is not expected to occur. Succeeding and rotational crop studies are therefore not considered necessary and were not provided. In case different uses will be granted in the future, this issue may need to be reconsidered.

1.2.3. Magnitude of residues in processed commodities

Studies investigating the effect of processing on the magnitude of the residue are not available. Considering that for the considered crops and uses the chronic exposure does not exceed 10% of the ADI such studies are not needed.

1.2.4. Proposed MRLs

Consequently, the available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation. However, since residue trials analysing simultaneously for enforcement and risk assessment residue definitions are not available, all derived MRLs should be considered as tentative only.

2. Residues in livestock

Triflumizole is not authorised for use on crops that might be fed to livestock. Further investigation of the occurrence of residues in commodities of animal origin is not required and the setting of MRLs in these commodities is not considered necessary.

3. Consumer risk assessment

In the framework of this review, only the uses of triflumizole reported by the RMS in Appendix A were considered; however, the use of triflumizole was previously also assessed by the Joint Meeting on Pesticide residues (JMPR) (FAO, 2013a,b). The codex maximum residue limits (CXLs), resulting from this assessment by the JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. Considering, however, that a different residue definition for enforcement of residues analysed as 4-chloro-2-(trifluoromethyl)aniline expressed as parent triflumizole was derived by the JMPR, existing CXLs could not further be considered by EFSA for consumer risk assessment.

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA PRIMo (EFSA, 2007). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix D. Hence, for those commodities where a tentative MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). All input values included in the exposure calculations are summarised in Appendix C.

The exposures calculated were compared with the toxicological reference values for triflumizole, derived by EFSA under Directive 91/414/EEC. The highest chronic exposure was calculated for WHO cluster diet B, representing 3% of the ADI, and the highest acute exposure was calculated for tomatoes, representing 68% of the acute reference dose (ARfD). Although major uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumers.

Conclusions

During the peer review, the metabolism of triflumizole following foliar application on grape and cucumber was relied upon. Similar residue profiles were obtained from both metabolism studies, where the parent was the main compound (80–87% TRR) and the metabolite FM-6-1 increased slowly up to 11% TRR following treatment. Additional metabolites were identified however remained below 10% of the TRR.

Triflumizole is authorised on crops that can be grown in rotation. However, according to Commission Directive 2010/27/EC only uses as fungicide in greenhouses on artificial substrates may be authorised. Succeeding crop studies are not provided and are not considered necessary because the current use of triflumizole is for substrate culture only.

Studies investigating the effect of processing on the nature and magnitude of the residue are not available. Bearing in mind that for the considered crops and uses the chronic exposure does not exceed 10% of the ADI, such studies are not needed.

The storage stability data provided show that triflumizole and the metabolites FM-6-1, FD-2-1 and FA-1-1 are stable at −20°C for at least 6 months in high acid and high water commodities.

According to the metabolism studies on cucumber and grapes, a residue definition for monitoring is proposed as the sum of triflumizole and metabolite FM-6-1 ((1*E*)-*N*′-[4-chloro-2-(trifluoromethyl) phenyl]-2-propoxyethanimidamide), expressed as triflumizole. Considering that further metabolites containing the 4-chloro-2-(trifluoromethyl)phenyl group were identified in the metabolism studies, the residue definition for risk assessment is proposed as the sum of triflumizole and metabolites containing the 4-chloro-2-(trifluoromethyl)phenyl group. The proposed residue definitions are limited to fruit crops only. Metabolism studies also allow deriving a worst-case conversion factor from enforcement to risk assessment of 1.5.

A validated method for enforcement of the proposed residue definition in all matrices with an LOQ of 0.02 mg/kg is available. Analytical standards for triflumizole and for its FM-6-1 metabolite are commercially available.

Regarding the magnitude of residues, the available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation. However, since residue trials analysing simultaneously for enforcement and risk assessment residue definitions are not available, all derived MRLs should be considered as tentative only.

Triflumizole is not authorised for use on crops that might be fed to livestock in the EU. Therefore, an investigation of residues, as well as the setting of MRLs in commodities of animal origin, is not necessary.

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA PRIMo. The highest chronic exposure was calculated for WHO cluster diet B, representing 3% of the ADI, and the highest acute exposure was calculated for tomatoes, representing 68% of the ARfD. Although major uncertainties remain due to the data gaps identified, EFSA concludes that for all currently proposed uses of triflumizole, this indicative exposure calculation did not indicate a risk to consumers. The use of triflumizole was previously also assessed by the JMPR. However, considering that a different residue definition for enforcement was derived by the JMPR, existing CXLs could not further be considered by EFSA for consumer risk assessment.

Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix D of the reasoned opinion (see Table 1).

None of the MRL values listed in the table are recommended for inclusion in Annex II to the Regulation as they are not sufficiently supported by data (see summary table footnotes for details). In particular, all tentative MRLs need to be confirmed by the following data:

- Complete sets of residue trials supporting the authorisations for all crops under assessment, analysing simultaneously for monitoring and risk assessment residue definitions.

It is highlighted, however, that some of the MRLs derived result from an indoor GAP authorised in Belgium while other GAPs reported by the RMS were not 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:

- eight residue trials compliant with the GAP provided by the Netherlands for cucumbers and courgettes;
- eight residue trials compliant with the GAP provided by the Netherlands for tomatoes.

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.

Table 1: Summary table

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition: triflumizole and metabolite FM-6-1 ((1*E*)-*N*′-[4-chloro-2-(trifluoromethyl) phenyl]-2-propoxyethanimidamide), expressed as triflumizole[(F)]					
0231010	Tomato	1	–	1.5	Further consideration needed[(b)]
0231030	Aubergine/eggplant	0.2	–	1.5	Further consideration needed[(b)]
0232010	Cucumber	0.2	0.5	0.5	Further consideration needed[(c)]
0232020	Gherkin	0.2	–	0.5	Further consideration needed[(b)]
0232030	Courgettes	0.2	–	0.5	Further consideration needed[(b)]
0140020	Cherries	1.5	4	–	Further consideration needed[(d)]
0151010	Table grapes	3	3	–	Further consideration needed[(d)]
0151010	Wine grapes	3	3	–	Further consideration needed[(d)]
0163040	Papaya	0.1*	2	–	Further consideration needed[(d)]
0700000	Hops	0.1*	30	–	Further consideration needed[(d)]
	Other commodities of plant and animal origin	See Reg. 149/2008	–	–	Further consideration needed[(e)]

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(F): Residue is fat soluble.
(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005.
(b): 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).
(c): 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; CXL is not compatible with EU residue definitions (combination E-II in Appendix D).
(d): There are no relevant authorisations or import tolerances reported at EU level; CXL is not compatible with EU residue definitions. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-II in Appendix D).
(e): 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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Abbreviations

a.i.	active ingredient
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CF	conversion factor for enforcement residue definition to risk assessment residue definition
cGAP	critical GAP

CXL	codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
EC	emulsifiable concentrate
EURLs	EU Reference Laboratories (former CRLs)
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
HPLC	high-performance liquid chromatography
HPLC–MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
LC–MS/MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
Mo	monitoring
MRL	maximum residue level
MS	Member States
MS/MS	tandem mass spectrometry detector
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SEU	southern European Union
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
TRR	total radioactive residue
WHO	World Health Organization

Appendix A – Summary of authorised *uses* considered for the review of MRLs

Critical indoor GAPs for Northern and Southern Europe (including post-harvest treatments)																				
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Tomatoes	*Lycopersicon esculentum*	NEU/ SEU	Indoor	BE	Powdery mildew	EC	150	g/L	Foliar treatment – spraying	0	–	1	4	7	7		0.26	kg a.i./ha	3	A more critical GAP was notified by the Netherlands (PHI = 1 day), however not supported by residue trials
Aubergines	*Solanum melongena*	NEU/ SEU	Indoor	BE	Powdery mildew	EC	150	g/L	Foliar treatment – spraying	0	–	1	4	7	7		0.26	kg a.i./ha	3	
Cucumbers	*Cucumis sativus*	NEU/ SEU	Indoor	BE	Powdery mildew	EC	150	g/L	Foliar treatment – spraying	0	–	1	4	7	7		0.38	kg a.i./ha	3	A different GAP is authorised in the Netherlands (6 × 0.225 g a.i./ha; PHI = 1 day), however not supported by residue trials
Gherkins	*Cucumis sativus*	NEU/ SEU	Indoor	BE	Powdery mildew	EC	150	g/L	Foliar treatment – spraying	0	–	1	4	7	7	0.15	0.38	kg a.i./ha	3	
Courgettes	*Cucurbita pepo*, Zucchini Group	NEU/ SEU	Indoor	BE	Powdery mildew	EC	150	g/L	Foliar treatment – spraying	0	–	1	4	7	7	0.15	0.38	kg a.i./ha	3	A different GAP is authorised in the Netherlands (6 × 0.225 g a.i./ha; PHI = 1 day), however not supported by residue trials

GAP: Good Agricultural Practice; BBCH: growth stages of mono- and dicotyledonous plants; EC: emulsifiable concentrate; PHI: pre-harvest interval; NEU: northern European Union; SEU: southern European Union; a.i.: active ingredient.

Appendix B – List of end points

B.1. Residues in plants

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

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

Primary crops (available studies)	**Crop groups**	**Crops**	**Application(s)**	**Sampling (DAT)**
	Fruit crops	Cucumbers	Foliar, 1 × 0.13 or 0.16 mg a.i./leaf	1, 3, 7, 14, 21, 45
			Fruit, 1 × 0.041 mg a.i./fruit	1, 3, 7, 14
		Pear	Foliar, 1 × 1 mg/4 leaves	0, 1, 3, 7, 14, 21, 31, 60, 90
			Fruit, 1 × 0.17 mg/pear	0, 1, 3, 7, 14
		Apple	Foliar, 1 × 127 mg/leaves of a branch	0, 1, 3, 7, 14, 21 31, 60, 90
		Wine grapes	Foliar, 1 × 280 g a.i./ha	3, 7, 14, 31, 67
			Fruit, 1 × 280 g a.i./ha	0, 3, 7, 14, 35
	Source: Netherlands (2006, 2009b)			

Rotational crops (no available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**
	Rotational crop studies are not available and are not required			

Processed commodities (hydrolysis study)	**Conditions**	**Investigated?**
	Pasteurisation (20 min, 90°C, pH 4)	No
	Baking, brewing and boiling (60 min, 100°C, pH 5)	No
	Sterilisation (20 min, 120°C, pH 6)	No
	Not available and not required	

Can a general residue definition be proposed for primary crops?	Yes
Rotational crop and primary crop metabolism similar?	Not available and not required
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not available and not required
Plant residue definition for monitoring (RD-Mo)	Triflumizole and metabolite FM-6-1 ((1*E*)-*N*′-[4-chloro-2-(trifluoromethyl)phenyl]-2-propoxyethanimidamide), expressed as triflumizole (fruits and fruiting vegetables only)
Plant residue definition for risk assessment (RD-RA)	Triflumizole and metabolites containing the 4-chloro-2-(trifluoromethyl)phenyl group triflumizole (fruit crops only)
Conversion factor (monitoring to risk assessment)	1.5
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	High water commodities: • HPLC–MS/MS, LOQ: 0.02 mg/kg for triflumizole and FM-6-1 in cucumber, respectively; ILV available (Netherlands, 2009b) • Confirmatory method LC–MS/MS, LOQ: 0.01 mg/kg for triflumizole and FM-6-1, respectively (Netherlands, 2009b) • LC–MS/MS, LOQ: 0.01 mg/kg for triflumizole and FM-6-1, respectively (EURLs, 2016) High acid, high oil content and dry commodities: • LC–MS/MS, LOQ: 0.01 mg/kg for triflumizole and FM-6-1, respectively (EURLs, 2016)

a.i.: active ingredient; DAT: days after treatment; PBI: plant-back interval; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability (months)**
	High water content	Apples	−20	6
		Cucumber	−20	< 24
	High acid content	Strawberry	−20	24
		Grapes	−20	6
	Source: Netherlands (2010)			

B.1.2. Magnitude of residues in plants

B.1.2.1. Summary of residues data from the supervised residue trials

Crop	Region/ indoor[(a)]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg)[(b)]	$STMR_{Mo}$ (mg/kg)[(c)]	CF[(d)]
Tomatoes Aubergines/ eggplants	EU	**Mo:** 0.78; 0.20; 0.48; 0.48; 0.18; 0.21; 0.34; 0.14	Trials on tomatoes performed with 3 applications instead of 4 acceptable since first of four applications is performed at an early growth stage and not expected to have a significant impact on the final residue level (Netherlands, 2006). Extrapolation to aubergines possible	1.5 (tentative)[(e)]	0.78	0.28	1.5
Cucumbers Gherkins Courgettes	EU	**Mo:** 0.10; 0.11; 0.14; 0.21	Trials on cucumber according to GAP (Netherlands, 2006). Tentative extrapolation to courgettes and gherkins proposed	0.5 (tentative)[(e),(f)]	0.21	0.13	1.5

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue according to the residue definition for monitoring.
(c): Supervised trials median residue according to the residue definition for monitoring.
(d): The conversion factor as derived from the metabolism studies has been tentatively applied for risk assessment.
(e): The derived MRL is only tentative because residue trials were performed according to the monitoring residue definition.
(f): The derived MRL is only tentative considering the limited number of trials.

B.2. Residues in livestock

Relevant groups	Dietary burden expressed in				Most critical diet	Most critical commodity	Trigger exceeded (Y/N)
	mg/kg bw per day		mg/kg DM				
	Med.	Max.	Med.	Max.			
Not applicable because triflumizole is not authorised for use on crops that might be fed to livestock (cattle, sheep, swine, poultry)							

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

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

Livestock (available studies)	Animal	Dose (mg/kg bw per day)	Duration (days)	N rate/comment
	Not available and not required			

Time needed to reach a plateau concentration in milk and eggs (days)	Not applicable
Metabolism in rat and ruminant similar (Yes/No)	Not applicable
Animal residue definition for monitoring (RD-Mo)	Not applicable
Animal residue definition for risk assessment (RD-RA)	Not applicable
Conversion factor (monitoring to risk assessment)	Not applicable
Fat soluble residues (Yes/No)	Not applicable
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Not applicable

B.2.1.2. Stability of residues in livestock

Animal products (available studies)	Animal	Commodity	T (°C)	Stability (months/years)
	Not available and not required			

B.2.2. Magnitude of residues in livestock

B.2.2.1. Summary of the residue data from livestock feeding studies

Animal commodity	Residues at the closest feeding level (mg/kg)		Estimated value at 1N		MRL proposal (mg/kg)	CF
	Mean	Highest	STMR (mg/kg)	HR (mg/kg)		
Not available and not required						

HR: highest residue; STMR: supervised trials median residue; CF: conversion factor

B.3. Consumer risk assessment

B.3.1. Consumer risk assessment

ADI	0.05 mg/kg bw per day (EFSA, 2009)
Highest IEDI, according to EFSA PRIMo	3% ADI (WHO Cluster diet B)
Assumptions made for the calculations	The calculation is based on the median residue levels in the raw agricultural commodities multiplied for the conversion factor (CF) of 1.5 as derived from the metabolism studies. The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation.

ARfD	0.1 mg/kg bw (EFSA, 2009)
Highest IESTI, according to EFSA PRIMo	68% ARfD (tomatoes)
Assumptions made for the calculations	The calculation is based on the highest residue levels in the raw agricultural commodities multiplied for the CF of 1.5 as derived from the metabolism studies.

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; ARfD: acute reference dose; IESTI: international estimated short-term intake.

B.4. Proposed MRLs

Code number[a]	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition: triflumizole and metabolite FM-6-1 ((1*E*)-*N*′-[4-chloro-2-(trifluoromethyl) phenyl]-2-propoxyethanimidamide), expressed as triflumizole[(F)]					
0231010	Tomato	1	–	1.5	Further consideration needed[(b)]
0231030	Aubergine/eggplant	0.2	–	1.5	Further consideration needed[(b)]
0232010	Cucumber	0.2	0.5	0.5	Further consideration needed[(c)]
0232020	Gherkin	0.2	–	0.5	Further consideration needed[(b)]
0232030	Courgettes	0.2	–	0.5	Further consideration needed[(b)]
0140020	Cherries	1.5	4	–	Further consideration needed[(d)]
0151010	Table grapes	3	3	–	Further consideration needed[(d)]
0151010	Wine grapes	3	3	–	Further consideration needed[(d)]
0163040	Papaya	0.1*	2	–	Further consideration needed[(d)]
0700000	Hops	0.1*	30	–	Further consideration needed[(d)]
	Other commodities of plant and animal origin	See Reg. 149/2008	–	–	Further consideration needed[(e)]

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set/proposed at the limit of quantification.
(F): Residue is fat soluble.
(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005.
(b): 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).
(c): 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; CXL is not compatible with EU residue definitions (combination E-II in Appendix D).
(d): There are no relevant authorisations or import tolerances reported at EU level; CXL is not compatible with EU residue definitions. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-II in Appendix D).
(e): 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).

Appendix C – Input values for the exposure calculations

C.1. Livestock dietary burden calculations

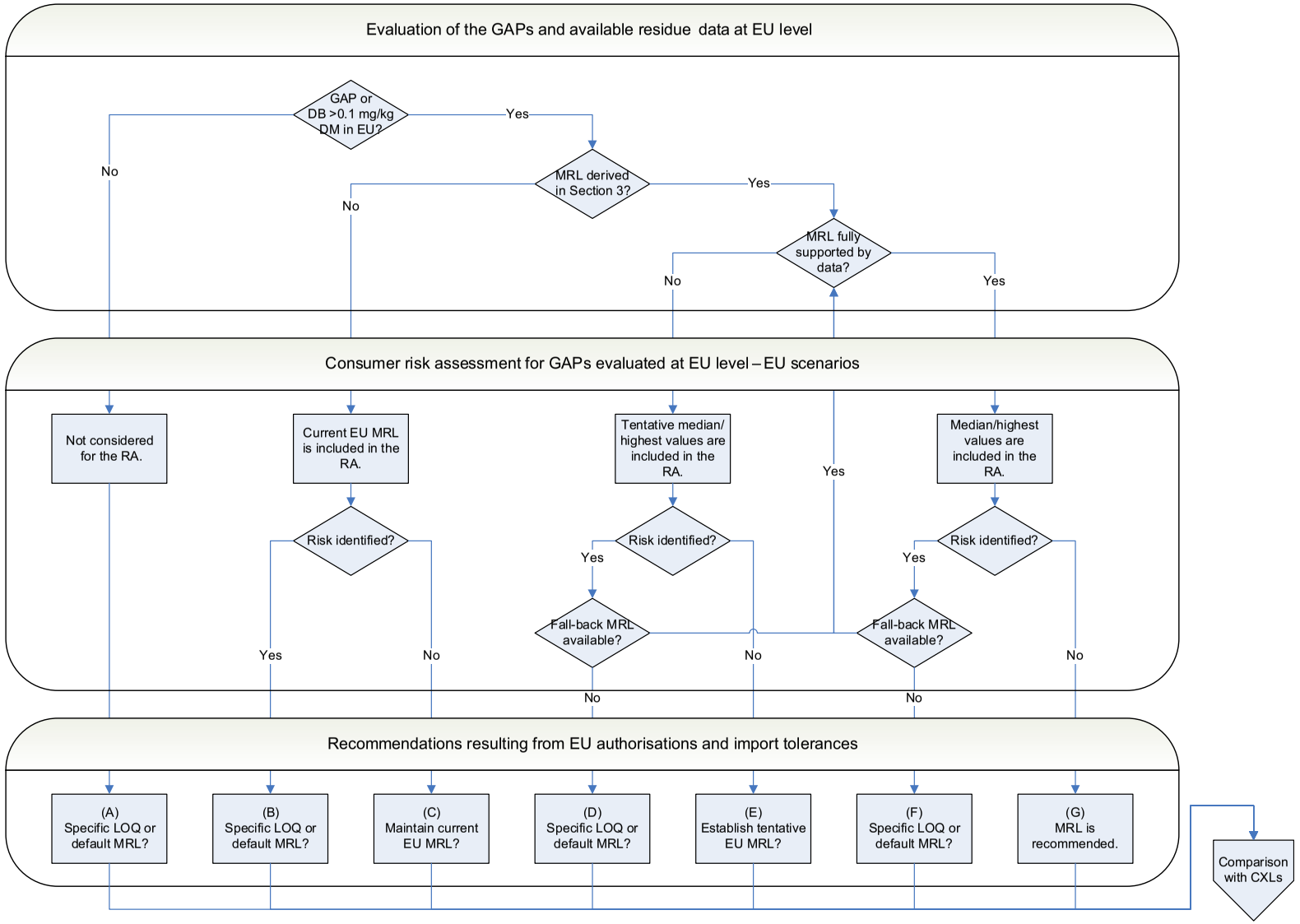
Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition (not applicable see Appendix B.2)				

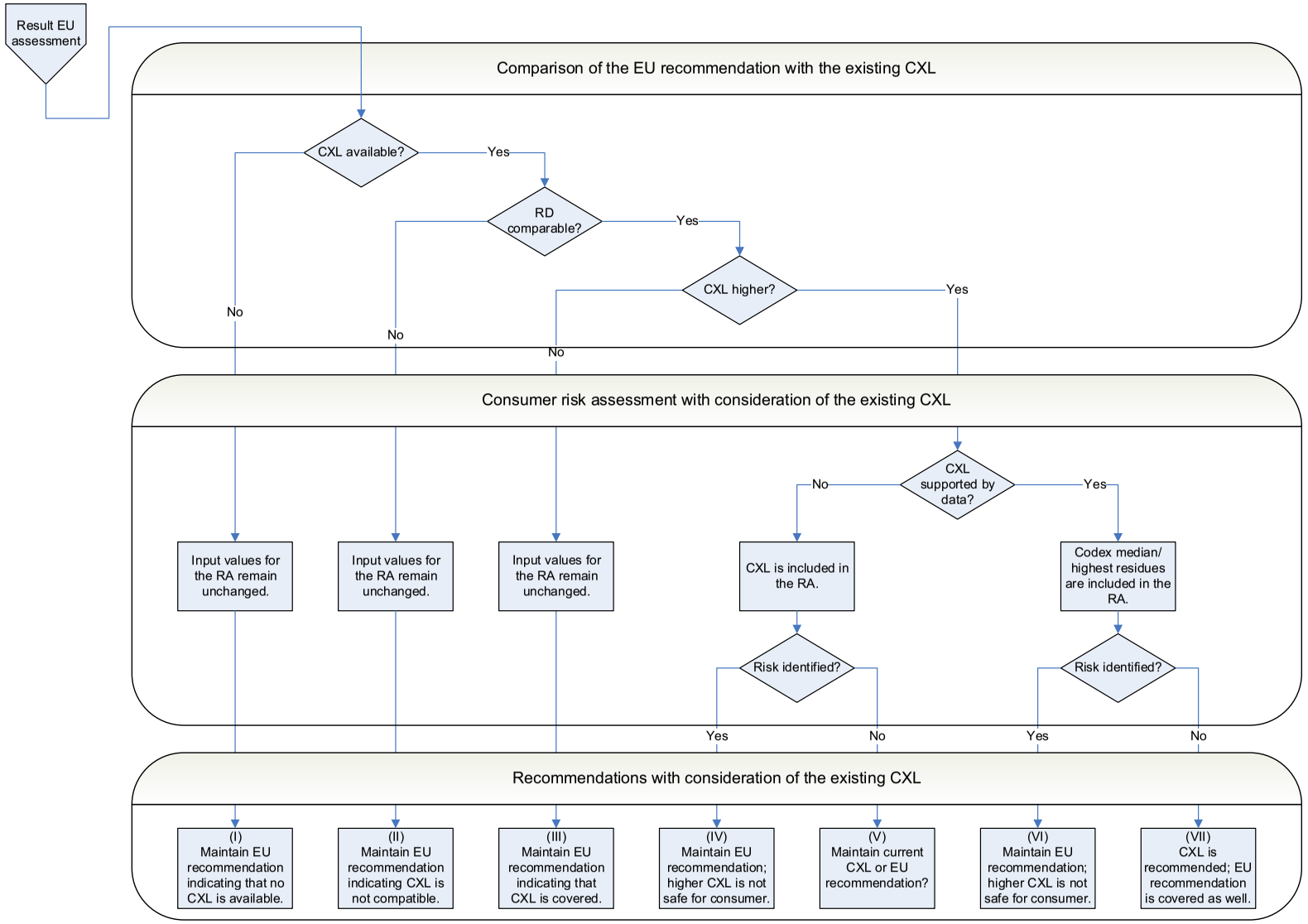
C.2. Consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of triflumizole and all metabolites containing the 4-chloro-2-(trifluoromethyl)phenyl group, expressed as triflumizole				
Tomatoes	0.41	$STMR_{Mo}$ × CF (tentative)	1.17	HR_{Mo} × CF (tentative)
Aubergines/eggplants	0.41	$STMR_{Mo}$ × CF (tentative)	1.17	HR_{Mo} × CF (tentative)
Cucumbers	0.19	$STMR_{Mo}$ × CF (tentative)	0.32	HR_{Mo} × CF (tentative)
Gherkins	0.19	$STMR_{Mo}$ × CF (tentative)	0.32	HR_{Mo} × CF (tentative)
Courgettes	0.19	$STMR_{Mo}$ × CF (tentative)	0.32	HR_{Mo} × CF (tentative)

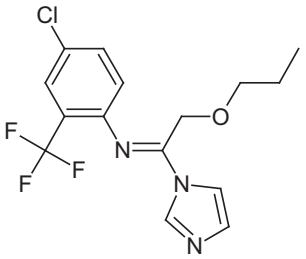
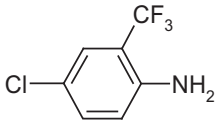
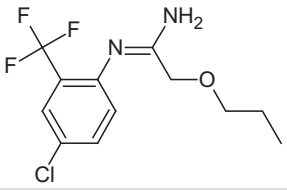
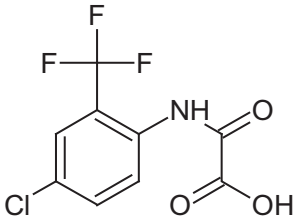
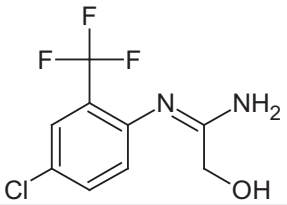
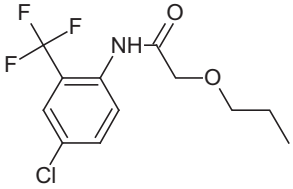
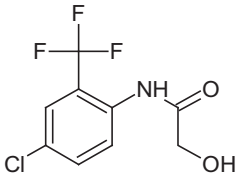
STMR: supervised trials median residue; HR: highest residue; CF: conversion factor.

Appendix D – Decision tree for deriving MRL recommendations




Result EU assessment
Comparison of the EU recommendation with the existing CXL
CXL available?
Yes
No
RD comparable?
Yes
No
CXL higher?
Yes
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 – Used compound codes

Code/trivial name	Chemical name/SMILES notation	Structural formula
Triflumizole	(*E*)-4-Chloro-α,α,α-trifluoro-*N*-(1-imidazol-1-yl-2-propoxyethylidene)-*o*-toluidine	
FA-1-1	4-Chloro-α,α,α-trifluoro-*o*-toluidine	
FM-6-1	(1*E*)-*N*′-[4-Chloro-2-(trifluoromethyl)phenyl]-2-propoxyethanimidamide	
FD-7-1	*N*-(4-Chloro-2-trifluoromethylphenyl)-oxalamic acid or {[4-Chloro-2-(trifluoromethyl)phenyl]amino}(oxo)acetic acid	
FM-8-1	(1*E*)-*N*′-[4-Chloro-2-(trifluoromethyl)phenyl]-2-hydroxyethanimidamide	
FD-1-1	*N*-[4-Chloro-2-(trifluoromethyl)phenyl]-2-propoxyacetamide	
FD-2-1	*N*-[4-Chloro-2-(trifluoromethyl)phenyl]-2-hydroxyacetamide	

SMILES: simplified molecular-input line-entry system.