Review of the existing maximum residue levels for triflumuron 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 triflumuron. To assess the occurrence of triflumuron residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC as well as the 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.

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Keywords: triflumuron, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, benzoylurea insecticide

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Summary

Triflumuron was included in Annex I to Directive 91/414/EEC on 1 April 2011 by Commission Directive 2011/23/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 maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation. To collect the relevant pesticide residues data, EFSA asked Italy, 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 29 August 2016 and finalised on 29 October 2016. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 12 December 2016.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional information provided by the RMS and Member States, EFSA prepared in January 2017 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 23 February 2017 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The primary crop metabolism of triflumuron was investigated in three different crop categories. Triflumuron was the major compound in the studies performed with fruit crops and is therefore the only significant residue expected in fruit crops. However, a different metabolic pathway was observed in root crops and pulses/oilseeds. Therefore, a general residue definition cannot be proposed.

Hydrolysis studies demonstrated that processing by pasteurisation, baking/brewing/boiling is not expected to have a significant impact on the composition of residues; however, sterilisation leads to the formation of significant levels of metabolites M07 and M08. No sterilisation studies were performed with triflumuron labelled on the chlorophenyl ring; however, it cannot be excluded that metabolites M01 and M02 can also be formed following sterilisation.

For fruit crops, the following residue definition for monitoring and risk assessment is proposed: triflumuron. A validated analytical method for enforcement of the proposed residue definition in the four main analytical matrices is available. In addition, since metabolite M07 has a different toxicological profile than the parent compound, a separate risk assessment should be carried out for this compound.

The available data are considered sufficient to derive MRLs proposal as well as risk assessment values for all commodities under evaluation. Considering the data gap regarding the investigation of the nature of residues in processed commodities, all MRLs are considered tentative.

Since all the crops under review are fruit crops (orchards) that usually are not rotated, data on succeeding crops were not required. A specific residue definition for rotational crops is unnecessary.

Studies investigating the magnitude of residues in several processed commodities of apples, peaches and plums are available. Robust processing factors were derived for apples (juice, dry pomace, wet pomace and sauce) and indicative processing factors were derived for apples peel and peeled fruit and peaches canned. In none of these processing studies, sterilisation conditions were applied. Therefore, it was not possible to assess the levels of metabolites in processed commodities. As a consequence, EFSA identified a data gap for additional studies investigating the nature of residues in processed commodities under conditions of sterilisation.

Only the dietary burden calculated for cattle (all diets) was found to exceed the trigger value of 0.1 mg/kg dry matter (DM). The metabolism of triflumuron was investigated in lactating goats and laying hens and triflumuron was found at very low levels. Since the residue levels of metabolites are expected to be well below 0.01 mg/kg when scaled to the calculated dietary burden, the animal residue definition for monitoring and risk assessment should be triflumuron alone. This residue definition is fat soluble. A validated analytical method for the determination of triflumuron in bovine muscle, fat, liver and milk is available. The feeding study performed on dairy cows confirmed that significant levels of triflumuron residues are not expected to occur. Therefore, EFSA proposes to set MRL and risk assessment values for bovine products at the limit of quantification (LOQ). According to the OECD guidance, these values also apply to equine products. MRLs for other livestock were not derived because the crops under review are only fed to ruminants.
Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA Pesticide Residues Intake Model (PRiMo). The highest chronic exposure represented 10.9% of the acceptable daily intake (ADI) (German child). Acute exposure calculations for the parent compound were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance. 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.

A different toxicological reference value was derived for the metabolite M07, therefore, a separate acute consumer risk assessment was performed for metabolite M07 using revision 2 of the EFSA PRiMo. Although the calculations are just indicative, the approach is considered conservative for metabolite M07 as it is assumed that the large portion consumed consists exclusively of sterilised processed products which were produced without peeling. The highest acute exposure was calculated for apples representing 72.9% of the ARfD.
# Table of contents

Abstract .................................................................................................................................................... 1  
Summary .................................................................................................................................................. 3  
Background .............................................................................................................................................. 6  
Terms of Reference ................................................................................................................................... 7  
The active substance and its use pattern .................................................................................................... 7  
Assessment ............................................................................................................................................... 8  
1. Residues in plants ............................................................................................................................ 8  
   1.1. Nature of residues and methods of analysis in plants ...................................................................... 8  
      1.1.1. Nature of residues in primary crops .............................................................................................. 8  
      1.1.2. Nature of residues in rotational crops ........................................................................................... 8  
      1.1.3. Nature of residues in processed commodities ................................................................................ 9  
      1.1.4. Methods of analysis in plants ........................................................................................................ 9  
      1.1.5. Stability of residues in plants ........................................................................................................ 9  
      1.1.6. Proposed residue definitions ......................................................................................................... 9  
   1.2. Magnitude of residues in plants ......................................................................................................... 10  
      1.2.1. Magnitude of residues in primary crops .......................................................................................... 10  
      1.2.2. Magnitude of residues in rotational crops ...................................................................................... 10  
      1.2.3. Magnitude of residues in processed commodities .......................................................................... 10  
      1.2.4. Proposed MRLs ................................................................................................................................ 10  
2. Residues in livestock .......................................................................................................................... 11  
   2.1. Nature of residues and methods of analysis in livestock .................................................................... 11  
   2.2. Magnitude of residues in livestock .................................................................................................... 11  
3. Consumer risk assessment ................................................................................................................ 11  
   3.1. Consumer risk assessment for triflumuron ....................................................................................... 11  
   3.2. Consumer risk assessment for metabolite M07 .............................................................................. 11  
Conclusions ............................................................................................................................................... 12  
Recommendations ..................................................................................................................................... 12  
References ................................................................................................................................................ 13  
Abbreviations ............................................................................................................................................ 15  
Appendix A – Summary of authorised uses considered for the review of MRLs ........................................ 16  
Appendix B – List of end points ................................................................................................................ 20  
Appendix C – Pesticide Residue Intake Model (PRIMo) .......................................................................... 27  
Appendix D – Input values for the exposure calculations .......................................................................... 29  
Appendix E – Decision tree for deriving MRL recommendations ............................................................. 30  
Appendix F – Used compound codes .................................................................................................... 32
Review of the existing MRLs for triflumuron

Background

Regulation (EC) No 396/2005¹ (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/EEC² a reasoned opinion on the review of the existing MRLs for that active substance. In 2009, a decision on the non-inclusion of the active substance was taken by Commission Decision 2009/241/EC³. 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 9 December 2010 (EFSA, 2011), the decision to approve the active substance triflumuron in accordance with the provision of Regulation (EC) 1107/2009, repealing the provisions of Directive 91/414/EEC, was taken. As triflumuron was included in Annex I to Council Directive 91/414/EEC on 1 April 2011 by means of Commission Directive 2011/23/EC,⁴ and has been deemed to be approved under Regulation (EC) No 1107/2009⁵, in accordance with Commission Implementing Regulation (EU) No 540/2011⁶, as amended by Commission Implementing Regulation (EU) No 541/2011⁷, 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.

Italy, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for triflumuron and to prepare a supporting evaluation report (Italy, 2013). The PROFile and the supporting evaluation report were submitted to EFSA on August 2013 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 29 August 2016 and finalised on 29 October 2016. Additional evaluation reports were submitted by Hungary, Italy and the European Reference Laboratories (EURLs) (EURLs 2016; Hungary, 2016; Italy, 2016) and after having considered all the information provided by RMS and Member States, EFSA

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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 2009/241/EC of 16 March 2009 concerning the non-inclusion of triflumuron in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance. OJ L 71, 17.3.2009, p. 59–60.
⁴ Commission Directive 2011/23/EC of 3 March 2011 amending Council Directive 91/414/EEC to include triflumuron as active substance. OJ L 59, 4.3.2011, p. 29–31.
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.
prepared a completeness check report which was made available to all Member States on 12 December 2016. No further clarifications were sought from Member States.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional information provided by the Member States, EFSA prepared in January 2017 a draft reasoned opinion, which was submitted to Member States for commenting via a written procedure. All comments received by 23 February 2017 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Italy, 2013) and the evaluation reports submitted by Member States Hungary, Italy and the EUURLs (EUURL, 2016; Hungary, 2016; Italy, 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) (excel file) and the PROFile are key supporting documents and made publicly available as background documents to this reasoned opinion. Furthermore, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

**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**

Triflumuron is the ISO common name for 1-(2-chlorobenzoyl)-3-(4-trifluoromethoxyphenyl)urea (IUPAC).

Triflumuron is an insecticide belonging to the benzoylurea chemical family. It interferes with chitin synthesis and the moulting cycle, disrupting chitin deposition in the insect cuticle after ingestion. It is used in agriculture on several crops such as fruit trees, cereals, tobacco and cotton. Triflumuron is under assessment for use as a biocide (product-type 18, insecticides, acaricides and products to control other arthropods). The log $P_{OW}$ of 4.9 (at 22°C) indicated that triflumuron is a fat-soluble compound as currently reported in Regulation (EC) No 396/2005. This is in line with the toxicokinetic information although could not be confirmed from the livestock metabolism studies and no residues above the limit of quantification (LOQ) were observed in the cattle feeding study (EFSA, 2011).

The chemical structure of the active substance and its main metabolites are reported in Appendix F. Triflumuron was evaluated in the framework of Directive 91/414/EEC with Italy designated as rapporteur Member State (RMS). Following the peer review, which was carried out by EFSA, a decision on non-inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Decision 20069/241/EC. The applicant made a resubmission application with supplementary information in response to the data gaps identified in the assessment leading to the decision of non-inclusion. Ultimately, based on the EFSA conclusion (EFSA, 2011), triflumuron was included in Annex I of this Directive by Commission Directive 2011/23/EU which entered into force on 1 April 2011 for use as an insecticide with risk mitigation measures for the plant protection product. In accordance with Commission Implementing Regulation (EU) No 540/2011, triflumuron is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC. The representative uses evaluated in the peer review were foliar applications on apples, pears, peaches and nectarines.

The EU MRLs for triflumuron are established in Annexes IIIA of Regulation (EC) No 396/2005 and codex maximum residue limits (CXLs) for the active substance are not available. There are no MRL changes occurred since the entry into force of the Regulation mentioned above.

For the purpose of this MRL review, the critical uses of triflumuron currently authorised within the EU 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. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

Assessment

EFSA has based its assessment on the PROFile submitted by the RMS, the evaluation report accompanying the PROFile (Italy 2013), the draft assessment report (DAR) and its final addendum prepared under Council Directive 91/414/EEC (Italy, 2005, 2008), the additional report to the draft assessment report prepared in the framework of Commission Regulation (EC) No 33/20088 (Italy, 2010), the conclusion on the peer review of the pesticide risk assessment of the active substance triflumuron (EFSA, 2011), the previous reasoned opinion on triflumuron (EFSA, 2014) as well as the evaluation reports submitted during the completeness check (EURLs, 2016; Hungary, 2016; Italy, 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 546/20119 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

The metabolism of triflumuron was investigated in representatives of three different crop categories: fruit crops, root crops and pulses and oilseeds (EFSA, 2011).

After foliar application on tomatoes, triflumuron was the major component of the residue (> 97% of total radioactive residue (TRR)) and no metabolites were identified either in the surface washes or peel of the fruit, thus confirming that the cleavage of the parent compound does not occur in fruit crops.

After foliar application on potatoes, triflumuron was identified in foliage and tubers at 64–99% (at 42 and 7 days after treatment (DAT)) and 42–49% of the TRR (at 42 DAT), respectively. A similar situation was observed after a foliar application on soya bean where total triflumuron accounted for 58% and 99% TRR (at 63 and 0 DAT) in the foliage and pods and for 20–40% TRR (at 77 and 60 DAT) in bean. In mature soybeans (without pods), metabolites M02 and M07 were observed at 31% TRR (0.06 mg eq/kg) and 33% TRR (0.1 mg eq/kg) 60 DAT, respectively. Metabolite M02 was observed at 27% TRR (0.22 mg eq/kg) in tubers 42 DAT.

EFSA considers that for fruit crops the metabolism of triflumuron is sufficiently addressed by the studies available.

1.1.2. Nature of residues in rotational crops

According to the soil degradation studies evaluated in the framework of the peer review, there was no field DT₉₀ reported, but the worst-case DT₅₀ for triflumuron obtained from laboratories studies was 14.6 days, indicating that triflumuron is not persistent (EFSA, 2011). In addition, since orchard crops usually are not rotated, data on succeeding crops were not required. A specific residue definition for rotational crops is unnecessary.

Nevertheless, one confined rotational crop study with triflumuron labelled on the chlorophenyl ring was assessed during the peer review (EFSA, 2011). After two applications on bare soil (0.28 and 0.84 kg a.s/ha), red beet, kale and wheat were planted at three different plant back

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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.
intervals (30, 120 and 270 DAT). The highest total residues in kale, red beet and wheat grown 1 month after the last application were 0.25, 0.66 and 0.53 mg eq/kg, respectively. Nine months after the last treatment (longest plant back interval), the total residues were below 0.01 mg eq/kg in kale, beet tops and beet roots, and were 0.03, 0.07 and 0.08 mg eq/kg in wheat forage, wheat heads and wheat straw, respectively. In all crops and crop parts, triflumuron could be identified (5–11% TRR), although in lower amounts than metabolites M01 and M02. Metabolite M01 was present at 1–20% TRR in different crops, while metabolite M02 was the major component of the total residue (37–64% TRR). It is noted that this study was conducted with an exaggerated rate (ca 3 times the most critical GAP (cGAP)), that the plants were grown partly in a greenhouse and that triflumuron was applied directly to the soil with no target crop present. However, if uses on crops usually rotated are envisaged, further rotational crop studies with a labelling on the trifluoromethoxyphenyl ring will be necessary (EFSA, 2011).

1.1.3. Nature of residues in processed commodities

Studies investigating the nature of residues in processed commodities were assessed in the framework of the peer-review (EFSA, 2011). Studies were conducted with triflumuron radiolabelled in the phenoxy moiety only, simulating representative hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6). Triflumuron was stable under pasteurisation as well as under boiling/brewing/baking. However, the results under conditions simulating sterilisation showed degradation to metabolite M07 (17% of the applied radioactivity (AR)) and metabolite M08 (16% of the AR), while triflumuron was observed at 51% of the AR. No hydrolysis study was available with triflumuron labelled in the chlorophenyl ring, but considering that cleavage of the parent compound does occur though sterilisation, the remaining radioactivity (16% AR) may be due to metabolites M01 and M02 (EFSA, 2011). In order to fully address the metabolic picture in process commodities, an additional hydrolysis study performed with triflumuron labelled on the chlorophenyl ring should be generated (EFSA, 2014).

1.1.4. Methods of analysis in plants

During the peer review, a multiresidue analytical method using high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) was validated for the determination of triflumuron in high water content, high acid content, high oil content and dry commodities with a LOQ of 0.01 mg/kg (EFSA, 2011). Furthermore, the EURL reported validation data for the four main plant matrices, with an LOQ of 0.01 mg/kg (EURL, 2016). Hence, it is concluded that triflumuron can be enforced with a LOQ of 0.01 mg/kg in high water content, high acid content, high oil content and dry commodities.

1.1.5. Stability of residues in plants

In the framework of the peer review, storage stability of triflumuron was demonstrated for a period of 24 months at –18°C in high water content matrices (EFSA, 2011).

1.1.6. Proposed residue definitions

For the uses on fruit crops (only uses under review), EFSA considers that the metabolism of triflumuron is sufficiently addressed. The residue definition for enforcement and risk assessment derived during the peer review (triflumuron only) is still applicable. The parent compound also remains a good marker for enforcement in processed commodities.

It is noted that the triflumuron metabolic pathway is different in roots and pulses and oilseeds. Therefore, if uses other than fruit crops are envisaged in the future, the residue definition for risk assessment proposed for fruit crops will not apply and further consideration on the metabolites M07 and M08 is necessary.

EFSA is of the opinion that the residue definition for risk assessment in processed commodities should also consider the specific degradation observed under sterilisation conditions: cleavage of the parent compound releasing metabolites M07 and M08 (demonstrated from the phenoxy-radiolabelled study) and possibly M01 and M02 (suspected from the chlorophenyl ring moiety). The metabolites M01, M02 and M08 are considered as toxic as the parent compound. However, the metabolite M07 has a different toxicological profile than the parent compound, and thus, a separate risk assessment should be carried out for this compound. To confirm the complete picture of the residues under sterilisation conditions, an additional analytical study should be performed.
conditions, additional studies investigating the nature of triflumuron under sterilisation conditions are needed (see also Section 1.1.3). Meanwhile, it is proposed to consider metabolite M07 separately for risk assessment in processed commodities. This proposal remains tentative.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of triflumuron residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Italy, 2013), including residue trials evaluated in the framework of the peer review (EFSA, 2011) or in the framework of a previous MRL application (EFSA, 2014) and additional data submitted during the completeness check (Hungary, 2016; Italy 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 apricots and plums, the number of residue trials reported is not compliant with the data requirements. Therefore, only tentative MRL and risk assessment values could be derived by EFSA and the following data gaps were identified:

- Apricots and plums: Four additional trials on apricots compliant with the southern outdoor GAP and four additional trials on plums compliant with the southern outdoor GAP are required. For all other crops, appropriate MRL and risk assessment values could be derived by EFSA, taking note of the following considerations.
- Apples and pears: Although appropriate MRL and risk assessment values can be derived from the southern outdoor data, only six trials compliant with the northern GAP are available instead of eight. However, since the northern GAP is clearly less critical than the southern GAP, this will not result in a data gap.

1.2.2. Magnitude of residues in rotational crops

There are no studies investigating the magnitude of residues in rotational crops. However, the metabolism studies provided quantitative information on residues uptake in the different crops investigated (see Section 1.1.2).

1.2.3. Magnitude of residues in processed commodities

Studies investigating the magnitude of residues on apples, peaches and plums were reported in the DAR (Italy, 2005) and in the additional report to the DAR (Italy, 2010). An overview of all available processing studies is available in Appendix B.1.2.3. Robust processing factors were derived for apples (juice, dry pomace, wet pomace and sauce). Indicative processing factors, because the available datasets are limited, were derived for apples peel and peeled fruit and peaches canned. In none of these processing studies, sterilisation conditions were applied. All these processing factors were calculated based on triflumuron levels in raw and processed commodities.

Significant levels of metabolites were identified in the hydrolysis studies in conditions simulating sterilisation (see Section 1.1.3). Therefore, EFSA considers that processing studies under conditions of sterilisation (e.g. fruits canned/preserved) are required. If these processing studies are performed, the levels of metabolites M01 M02, M07 and M08 should be investigated.

1.2.4. Proposed MRLs

Consequently, the available data are considered sufficient to derive MRLs proposal as well as risk assessment values for all commodities under evaluation. Considering the data gap regarding the investigation of the nature of residues in processed commodities, all MRLs are considered tentative.
2. Residues in livestock

Triflumuron is authorised for use on apples that might be fed to livestock. Livestock dietary burdens were therefore calculated for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D. The dietary burdens calculated for cattle were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). Behaviour of residues was therefore assessed in this group of livestock. Exposure to metabolite M07 is not expected to exceed the trigger value of 0.1 mg/kg DM.

2.1. Nature of residues and methods of analysis in livestock

Two metabolism studies on lactating goats and laying hens were assessed in the framework of the peer-review (EFSA, 2011).

After oral administration to goats, the highest total residues of triflumuron were observed in liver (6.12 mg eq/kg), fat (4.82 mg eq/kg) and kidney (1.60 mg eq/kg). Triflumuron was the major residue in all matrices and unchanged triflumuron was predominantly present in fat (96% TRR), milk (60–75% TRR) and muscle (58–80% TRR). Triflumuron was further degraded in liver (15–20% TRR) and kidney (20–27% TRR). Major metabolites in liver were metabolites M01 (0.15 mg eq/kg) and M04 (0.35 mg eq/kg) acid in free and conjugated form (see Appendix F). Major metabolites in kidney were metabolite M03 (see Appendix F) and M04 acid in free and conjugated forms at 0.31 and 0.43 mg eq/kg, respectively. Although liver contained the highest residues, the identification rate was very low, as attempts for further extraction of residues were unsuccessful.

After oral administration to laying hens, triflumuron was the major residue in all hen matrices. Unchanged triflumuron was present in amounts above 90% TRR in muscle, heart, fat and skin, about 85% in liver and eggs and 59% TRR in kidney. Upon analysis only low amounts of metabolites M01 and M02 were identified in hen matrices.

Storage stability of triflumuron was demonstrated for a period of 3 months at –18°C in bovine liver, muscle and milk.

During the peer review, a multiresidue analytical method using HPLC-MS/MS was validated for the determination of triflumuron in bovine liver, fat, bovine muscle and bovine milk with a LOQ of 0.005 mg/kg (EFSA, 2011). During the Member States consultation, the EURLs informed EFSA that an LOQ of 0.01 mg/kg would be more suitable (EFSA, 2017).

Since all the crops under review are fruit crops and the residue levels of metabolites (maximum 0.43 mg eq/kg) are expected to be below 0.01 mg/kg when scaled to the calculated dietary burden (ca 800 times lower than the feeding level of the study), the animal residue definition for monitoring and risk assessment should be triflumuron alone.

2.2. Magnitude of residues in livestock

A feeding study performed on dairy cattle was assessed in the peer-review (EFSA, 2011). In this study, the dose rates were 0.3 and 0.6 triflumuron/kg body weight (bw) per day (feeding levels of 100N and 200N). Residues on milk were below the LOQ of 0.01 mg/kg in all analysed samples. In tissues, residues of triflumuron were below the LOQ of 0.05 mg/kg for liver, kidney and muscle and the LOQ of 0.1 mg/kg for fat. MRLs and risk assessment values for bovine products were derived according to the OECD guidance on this matter which was agreed upon at European level (OECD, 2013). The overview of the study results used to derive the risk assessment values and the MRL proposals are summarised in Appendix B.2.2. According to the OECD guidance, MRLs and risk assessment values derived for bovine also apply to equine products.

3. Consumer risk assessment

3.1. Consumer risk assessment for triflumuron

Chronic exposure calculations for triflumuron 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 E. 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. For the active substance
triflumuron, no acute consumer exposure assessment was performed since no acute reference dose (ARfD) was established.

The exposures calculated were compared with the toxicological reference value for triflumuron derived by EFSA (2011) under Directive 91/414/EEC. The highest chronic exposure was calculated for German child diet representing 10.9% of the acceptable daily intake (ADI). 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.

### 3.2. Consumer risk assessment for metabolite M07

The metabolite M07 is expected in processed products that undergo sterilisation (see Section 1.1.3). Therefore, to take into account the acute toxicity of M07 in processed products after sterilisation, a separate acute risk assessment was performed for M07. In absence of specific studies on the magnitude of residues in sterilised products, the short-term exposure was calculated using the highest residue concentration for triflumuron observed in the raw agricultural commodity (RAC) corrected for the percentage of M07 (17%) formed in the hydrolysis study (see Appendix B.3.1).

Although the calculations are just indicative, the approach is considered conservative for metabolite M07 as it is assumed that the large portion consumed consists exclusively of sterilised processed products which were produced without peeling. However, it is noted that other metabolites that may be formed under conditions of sterilisation were not evaluated in the calculations.

The exposures calculated were compared with the toxicological reference values for metabolite M07, derived by EFSA (2011) under Directive 91/414/EEC. The highest acute exposure was calculated for apples, representing 72.9% of the 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

The primary crop metabolism of triflumuron was investigated in three different crop categories. Triflumuron was the major compound in the studies performed with fruit crops and is therefore the only significant residue expected in fruit crops. However, a different metabolic pathway was observed in root crops and pulses/oilseeds. Therefore, a general residue definition cannot be proposed.

Hydrolysis studies demonstrated that processing by pasteurisation, baking/brewing/boiling is not expected to have a significant impact on the composition of residues, however sterilisation leads to the formation of significant levels of metabolites M07 and M08. No sterilisation studies were performed with triflumuron labelled on the chlorophenyl ring; however, it cannot be excluded that metabolites M01 and M02 can also be formed following sterilisation.

For fruit crops, the following residue definition for monitoring and risk assessment is proposed: triflumuron. A validated analytical method for enforcement of the proposed residue definition in the four main analytical matrices is available. In addition, since metabolite M07 has a different toxicological profile than the parent compound a separate risk assessment should be carried out for this compound.

The available data are considered sufficient to derive MRLs proposal as well as risk assessment values for all commodities under evaluation. Considering the data gap regarding the investigation of the nature of residues in processed commodities, all MRLs are considered tentative.

Since all the crops under review are fruit crops (orchards) that usually are not rotated, data on succeeding crops were not required. A specific residue definition for rotational crops is unnecessary.

Studies investigating the magnitude of residues in several processed commodities of apples, peaches and plums are available. Robust processing factors were derived for apples (juice, dry pomace, wet pomace and sauce) and indicative processing factors were derived for apples peel and peeled fruit and peaches canned. In none of these processing studies, sterilisation conditions were applied. Therefore, it was not possible to assess the levels of metabolites in processed commodities. As a consequence, EFSA identified a data gap for additional studies investigating the nature of residues in processed commodities under conditions of sterilisation.

Only the dietary burden calculated for cattle (all diets) was found to exceed the trigger value of 0.1 mg/kg DM. The metabolism of triflumuron was investigated in lactating goats and laying hens and triflumuron was found at very low levels. Since the residue levels of metabolites are expected to be well below 0.01 mg/kg when scaled to the calculated dietary burden, the animal residue definition for monitoring and risk assessment should be triflumuron alone. This residue definition is fat soluble. A validated analytical method for the determination of triflumuron in bovine muscle, fat, liver and milk is
available. The feeding study performed on dairy cows confirmed that significant levels of triflumuron residues are not expected to occur. Therefore, EFSA proposes to set MRL and risk assessment values for bovine products at the LOQ. According to the OECD guidance, these values also apply to equine products. MRLs for other livestock were not derived because the crops under review are only fed to ruminants.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. The highest chronic exposure represented 10.9% of the ADI (German child). Acute exposure calculations for the parent compound were not carried out because an ARfD was not deemed necessary for this active substance. 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.

A different toxicological reference value was derived for the metabolite M07, therefore a separate acute consumer risk assessment was performed for metabolite M07 using revision 2 of the EFSA PRIMo. Although the calculations are just indicative, the approach is considered conservative for metabolite M07 as it is assumed that the large portion consumed consists exclusively of sterilised processed products which were produced without peeling. The highest acute exposure was calculated for apples, representing 72.9% of the ARfD.

Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see summary table). All MRL values listed in the table are tentative MRLs and need to be confirmed by the following data:

- Studies investigating the magnitude of residues in processed commodities in conditions simulating sterilisation, including a quantitative analysis of metabolites M01, M02, M07 and M08.
- Additional trials on apricots and plums supporting the southern outdoor GAP (Table 1).

**Table 1:** Summary table

| Code number<sup>(a)</sup> | Commodity          | Existing EU MRL (mg/kg) | Outcome of the review | Comment                  |
|-------------------------|--------------------|-------------------------|-----------------------|--------------------------|
|                         |                    |                         | MRL (mg/kg)           |                          |
| Enforcement residue definition (existing): triflumuron<sup>(F)</sup> | Enforcement residue definition (proposed): triflumuron<sup>(F)</sup> |                         | MRL (mg/kg)           |                          |
| 130010                  | Apples             | 0.5                     | 0.5                   | Further consideration needed<sup>(b)</sup> |
| 130020                  | Pears              | 0.5                     | 0.5                   | Further consideration needed<sup>(b)</sup> |
| 140010                  | Apricots           | 1                       | 1                     | Further consideration needed<sup>(b)</sup> |
| 140030                  | Peaches            | 1                       | 0.4                   | Further consideration needed<sup>(b)</sup> |
| 140040                  | Plums              | 1                       | 0.1                   | Further consideration needed<sup>(b)</sup> |
| 1012010                 | Bovine meat        | 0.01*                   | 0.01*                 | Recommended<sup>(c)</sup> |
| 1012020                 | Bovine fat         | 0.01*                   | 0.01*                 | Recommended<sup>(c)</sup> |
| 1012030                 | Bovine liver       | 0.01*                   | 0.01*                 | Recommended<sup>(c)</sup> |
| 1012040                 | Bovine kidney      | 0.01*                   | 0.01*                 | Recommended<sup>(c)</sup> |
| 1015010                 | Equine meat        | 0.01*                   | 0.01*                 | Recommended<sup>(c)</sup> |
| 1015020                 | Equine fat         | 0.01*                   | 0.01*                 | Recommended<sup>(c)</sup> |
| 1015030                 | Equine liver       | 0.01*                   | 0.01*                 | Recommended<sup>(c)</sup> |
| 1015040                 | Equine kidney      | 0.01*                   | 0.01*                 | Recommended<sup>(c)</sup> |
| –                       | Other commodities of plant and/or animal origin | See Reg. (EC) No 839/2008 | – | Further consideration needed<sup>(d)</sup> |

MRL: maximum residue level.

*: 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 (assuming the existing residue definition); no CXL is available (combination E-I in Appendix E).

(c): 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 E).

(d): 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 E).
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Abbreviations

- **a.i.** active ingredient
- **a.s.** active substance
- **ADI** acceptable daily intake
- **AR** applied radioactivity
- **ARfD** acute reference dose
- **BBCH** growth stages of mono- and dicotyledonous plants
- **bw** body weight
- **cGAP** critical GAP
- **CXL** codex maximum residue limit
- **DAR** draft assessment report
- **DAT** days after treatment
- **DB** dietary burden
- **DM** dry matter
- **DT<sub>90</sub>** period required for 90% dissipation (define method of estimation)
- **EMS** evaluating Member State
- **eq** residue expressed as a.s. equivalent
- **EURLs** EU Reference Laboratories (former CRLs)
- **FAO** Food and Agriculture Organization of the United Nations
- **GAP** Good Agricultural Practice
- **HPLC-MS/MS** high-performance liquid chromatography with tandem mass spectrometry
- **HR** highest residue
- **IEDI** international estimated daily intake
- **IESTI** international estimated short-term intake
- **ILV** independent laboratory validation
- **IUPAC** International Union of Pure and Applied Chemistry
- **LOD** limit of detection
- **LOQ** limit of quantification
- **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
- **PF** processing factor
- **PHI** preharvest interval
- **PRIMo** (EFSA) Pesticide Residues Intake Model
- **PROFile** (EFSA) Pesticide Residues Overview File
- **QuEChERS** Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
- **RA** risk assessment
- **RAC** raw agricultural commodity
- **RD** residue definition
- **RMS** rapporteur Member State
- **SANCO** Directorate-General for Health and Consumers
- **SC** suspension concentrate
- **SEU** southern European Union
- **SMILES** simplified molecular-input line-entry system
- **STMR** supervised trials median residue
- **TRR** total radioactive residue
- **UV** ultraviolet (detector)
- **WG** water dispersible granule
- **WHO** World Health Organization
Appendix A – Summary of authorised uses considered for the review of MRLs

| Crop Common name | Scientific name | Region | Outdoor/Indoor | Member state or country | Pest controlled | Formulation Type | Content Conc. | Unit | Method | Growth stage From BBCH | Until BBCH | Number Min. | Max. | Interval (days) Min. | Max. | Rate Min. | Max. | Unit | PHI or waiting period (days) | Comments |
|------------------|-----------------|--------|----------------|------------------------|-----------------|------------------|---------------|------|--------|----------------------|-----------|-------------|-----|---------------------|-----|----------|-----|------|------------------------|----------|
| Apples | Malus domestica | NEU | Outdoor | HU | Cydia pomonella, Grapholita molesta, Cydia pyrivora, Psylla piri, Pandemis cerasana | SC | 480.0 | g/L | Foliar treatment – spraying | 70 | 85 | 1 | 2 | 40 | 40 | 0.012 | kg a.i./ha | 28 |
| Pears | Pyrus communis | NEU | Outdoor | HU | Cydia pomonella, Grapholita molesta, Cydia pyrivora, Psylla piri, Pandemis cerasana | SC | 480.0 | g/L | Foliar treatment – spraying | 70 | 85 | 1 | 2 | 40 | 40 | 0.012 | kg a.i./ha | 28 |
## Critical outdoor GAPs for Southern Europe

| Crop | Scientific name | Region | Outdoor/Indoor | Member state or country | Pest controlled | Formulation | Application | Comments |
|------|----------------|--------|---------------|-------------------------|----------------|-------------|-------------|----------|
| **Apples** | *Malus domesticus* | SEU | Outdoor | IT | Cydia pomonella, Cydia molesta, Leucoptera scitella, Orgya antiqua, Zeuzera pyrina, Psylla piri, Phyllonorycter blancardella, *P. corylifoliella*, Archips podanus, Pandemis cerasana, *P. heparana* | SC 480.0 g/L | Foliar treatment – spraying | 70–85 | 1–2 | 40–40 | 0.18 kg a.i./ha | 28 days |
| **Pears** | *Pyrus communis* | SEU | Outdoor | IT | Cydia pomonella, Cydia molesta, Leucoptera scitella, Orgya antiqua, Zeuzera pyrina, Psylla piri, Phyllonorycter blancardella, *P. corylifoliella*, Archips podanus, Pandemis cerasana, *P. heparana* | SC 480.0 g/L | Foliar treatment – spraying | 70–85 | 1–2 | 40–40 | 0.18 kg a.i./ha | 28 days |

*Review of the existing MRLs for triflumuron*
## Critical outdoor GAPs for Southern Europe

| Crop | Common name | Scientific name | Region | Outdoor/Indoor | Member state or country | Pest controlled | Formulation | Application | PHI or waiting period (days) | Comments |
|------|-------------|-----------------|--------|---------------|------------------------|-----------------|--------------|-------------|-----------------------------|----------|
|      |             |                 |        |               |                        |                 |              |             |                             |          |
| Apricots | Armeniaca vulgaris, syn: Prunus armeniaca | SEU Outdoor IT | Cydia pomonella, Cydia molesta, Leucoptera scitella, Orgya antiqua, Zeuzera pyrina, Psylla piri, Phyllonorycter blandardel, P. corylifoliella, Archips podanus, Pandemis cerasana, P. heparana | SC 480.0 g/L | Foliar treatment – spraying | 70 | 85 | 1 | 2 | 40 | 40 | 0.18 kg a.i./ha | 28 1st application: BBCH 70–75 2nd application: BBCH 80–85 Max application: 0.18 kg a.i./ha per treatment |
| Peaches | Persica vulgaris, syn: Prunus persica | SEU Outdoor IT | Cydia pomonella, Cydia molesta, Leucoptera scitella, Orgya antiqua, Zeuzera pyrina, Psylla piri, Phyllonorycter blandardel, P. corylifoliella, Archips podanus, Pandemis cerasana, P. heparana | SC 480.0 g/L | Foliar treatment – spraying | 70 | 85 | 1 | 2 | 40 | 40 | 0.18 kg a.i./ha | 28 1st application: BBCH 70–75 2nd application: BBCH 80–85 Max application: 0.18 kg a.i./ha per treatment |
## Critical outdoor GAPs for Southern Europe

| Crop | Scientific name | Region | Outdoor/Indoor | Member state or country | Pest controlled | Formulation | Application |
|------|-----------------|--------|----------------|-------------------------|-----------------|-------------|-------------|
|      |                 |        |                |                         |                 | Type        | Content     | Method | Growth stage From BBCH | Until BBCH | Number | Interval (days) Min. | Max. | Min. | Max. | Rate | PHI or waiting period (days) | Comments |
| Plums | Prunus domestica | SEU    | Outdoor        | IT                      | Cydia pomonella, Cydia molesta, Leucoptera scitella, Orgya antiqua, Zeuzera pyrina, Psylla piri, Phyllonorycter blancardella, P. corylifoliella, Archips podanus, Pandemis cerasana, P. heparana | SC 480.0 g/L | Foliar treatment – spraying | 70          | 85  | 1                | 2          | 40        | 40 | 0.18 kg a.i./ha | 28 | 1st application: BBCH 70–75 2nd application: BBCH 80–85 Max application: 0.18 kg a.i./ha per treatment |

GAP: Good Agricultural Practice; BBCH: growth stages of mono- and dicotyledonous plants; PHI: preharvest interval; NEU: northern European Union; SEU: southern European Union; a.i.: active ingredient, SC: suspension concentrate.
Appendix B – List of end points

B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) |
|----------------------------------|-------------|---------|----------------|----------------|
| Fruit crops                      | Tomatoes    | Foliar  | 2 × 0.383 kg a.s./ha, interval 21 days | 7              |
| Root crops                       | Potatoes    | Foliar  | 1 × 1.12 kg a.s./ha                      | 7, 14, 21, 28, 42 |
| Pulses/oilseeds                  | Soybean     | Foliar  | 1 × 1.12 kg a.s./ha                      | 14\(^{(a)}\), 28\(^{(a)}\), 63\(^{(a)}\), 77\(^{(b)}\) |
| Sources: Italy (2005, 2010)      |             |         |                                            |                |
| (a): Beans with pods.            |             |         |                                            |                |
| (b): Beans without pods.         |             |         |                                            |                |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) |
|--------------------------------------|-------------|---------|----------------|-----------|
| Root/tuber crops                     | Red beet    | Bare soil, 1st app: 0.28 kg a.s./ha + 2nd app: 0.84 kg a.s./ha, interval 7 days | 30, 120, 270 |
| Leafy crops                          | Kale        | Bare soil, 1st app: 0.28 kg a.s./ha + 2nd app: 0.84 kg a.s./ha, interval 7 days | 30, 120, 270 |
| Cereals (small grain)                | Wheat       | Bare soil, 1st app: 0.28 kg a.s./ha + 2nd app: 0.84 kg a.s./ha, interval 7 days | 30, 120, 270 |
| Source: Italy (2005)                 |             |         |                                            |            |

| Processed commodities (hydrolysis study) | Conditions | Investigated? |
|------------------------------------------|------------|---------------|
|                                         | Pasteurisation (20 min, 90°C, pH 4) | Yes |
|                                          | Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes |
|                                          | Sterilisation (20 min, 120°C, pH 6) | Yes |
| Source: Italy (2005)                     |            |               |

Can a general residue definition be proposed for primary crops? No
Rotational crop and primary crop metabolism similar? Inconclusive
Residue pattern in processed commodities similar to residue pattern in raw commodities? No (degradation occurs under sterilisation)
Plant residue definition for monitoring (RD-Mo) Triflumuron (for fruit crops only)
Plant residue definition for risk assessment (RD-RA) Triflumuron (for fruit crops only)
Conversion factor (monitoring to risk assessment) Not relevant
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

HPLC-MS/MS (EURL, 2016):
- Method EN 15662:2008 validated in high water and high acid content commodities
- QuEChERS-method (EN 15662:2008) validated in dry commodities
- QuOil method (BVL L 13.04-5:2013-08) validated in high oil content commodities
- LOQ: 0.01 mg/kg

a.s.: active substance; 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; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method).
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category               | Commodity                        | T (°C) | Stability (months) |
|-----------------------------------|------------------------|----------------------------------|--------|-------------------|
|                                   | High water content     | Apple, sauce, pomace and juice.  | –18    | 24 months         |

*Source: Italy (2005)*
## 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 (mg/kg)\(^{(b)}\) | STMR (mg/kg)\(^{(c)}\) |
|----------|--------------------------|-----------------------------------------------------------------------------------------------|---------------------------------------------|-----------------------|-----------------------|-----------------------|
| Apples   | NEU                      | Apples: 0.04; 0.07 Pears: 0.09; 0.13; 0.17; 0.21                                               | Combined data set of overdosed trials on apples and pears performed with 15N rate (Italy, 2005) MRL\(_{OECD} = 0.37\) | 0.4 (tentative)\(^{(d)}\) | 0.21                  | 0.11                  |
|          | SEU                      | Apples: 0.09; 0.09; 0.012; 0.15 Pears: 0.03; 0.07; 0.24; 0.26                                    | Combined data set on apples (4) and pears (4) compliant with GAP (Italy, 2005) MRL\(_{OECD} = 0.46\) | 0.5 (tentative)\(^{(d)}\) | 0.26                  | 0.11                  |
| Apricots | SEU                      | 0.17; 0.27; 0.30; 0.48                                                                        | Trials compliant with GAP (Italy, 2016) MRL\(_{OECD} = 0.92\) | 1 (tentative)\(^{(d),(e)}\) | 0.48                  | 0.29                  |
| Peaches  | SEU                      | 0.02; 0.04; 0.05; 0.06; 0.07; 0.09; 0.09; 0.11; 0.13; 0.14; 0.24                                | Trials compliant with GAP (Italy, 2005) MRL\(_{OECD} = 0.33\) | 0.4 (tentative)\(^{(d)}\) | 0.24                  | 0.09                  |
| Plums    | SEU                      | 0.01; 0.02; 0.03; 0.04                                                                        | Trials compliant with GAP (Italy, 2013a) MRL\(_{OECD} = 0.08\) | 0.1 (tentative)\(^{(d),(e)}\) | 0.04                  | 0.03                  |

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.

\(^{(c)}\): Supervised trials median residue.

\(^{(d)}\): MRL is tentative because studies investigating the nature of residues in processed commodities are missing.

\(^{(e)}\): MRL is tentative because the number of trials compliant with GAP is not sufficient.
B.1.2.2. Residues in succeeding crops

| Study type | Description | Result |
|------------|-------------|--------|
| Confinement rotational crop study (quantitative aspect) | Significant residues occurred in succeeding crops 30 DAT | |
| Field rotational crop study | Not relevant and not required, because orchard crops are usually not rotated | |

B.1.2.3. Processing factors

| Processed commodity | Number of studies(a) | Processing factor (PF) |
|---------------------|----------------------|------------------------|
|                     | Individual values    | Median PF              |
| **Robust processing factors (sufficiently supported by data)** | | |
| Apple/washed fruits  | 5                    | 0.42; 0.46; 0.73; 1.25; 1.50 | 0.73 |
| Apple/dried fruits   | 4                    | 0.10; 0.13; 0.19; 0.38 | 0.16 |
| Apple/apple sauce (pasteurised) | 5 | 0.15; 0.21; 0.31; 0.50; 0.65 | 0.31 |
| Apple/apple juice (pasteurised) | 5 | < 0.04; < 0.04; < 0.05; 0.13; 0.17 | < 0.05 |
| Apple/pomace (wet)   | 3                    | 2.7; 2.7; 2.9 | 2.7 |
| Apple/pomace dried   | 5                    | 7.5; 8.1; 8.3; 8.5; 23.8 | 8.3 |
| **Indicative processing factors (limited data set)** | | |
| Apple/peel           | 2                    | 9.6; 10.5 | 10.1 |
| Apple/poiled fruit   | 2                    | 0.05; 0.12 | 0.09 |
| Peaches/canned (preserve) | 2 | 0.1; 0.1 | 0.1 |
| Plums/dried (prunes) | 2                    | 2.5; 2.5 | 2.5 |

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

B.2. Residues in livestock

| Relevant groups | Dietary burden expressed in mg/kg bw/day | Most critical diet(a) | Most critical commodity(b) | Trigger exceeded (Y/N) |
|----------------|------------------------------------------|-----------------------|---------------------------|------------------------|
|                | Med. | Max. | Med. | Max. | Cattle (beef) | Apple, pomace, wet | Y |
| Cattle (all diets) | 0.0036 | 0.0036 | 0.15 | 0.15 | Cattle (beef) | Apple, pomace, wet | Y |
| Cattle (dairy only) | 0.0029 | 0.0029 | 0.07 | 0.07 | Cattle (dairy) | Apple, pomace, wet | N |
| Sheep (all diets) | 0.0032 | 0.0032 | 0.07 | 0.07 | Sheep (lamb) | Apple, pomace, wet | N |
| Sheep (ewe only) | 0.0025 | 0.0025 | 0.07 | 0.07 | Sheep (ram/ewe) | Apple, pomace, wet | N |
| Swine (all diets) | 0.0000 | 0.0000 | 0.00 | 0.00 | – | – | N |
| Poultry (all diets) | 0.0000 | 0.0000 | 0.00 | 0.00 | – | – | N |
| Poultry (layer only) | 0.0000 | 0.0000 | 0.00 | 0.00 | – | – | N |

bw: body weight; DM: dry matter.
(a): Calculated for the maximum dietary burden.

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 |
|-------------------------------|--------|--------------------------|-----------------|----------------|
| Laying hen | 8.0 | 4 | Not relevant |
| Lactating goat | 3.0 | 3 | 1,000 N/dairy cattle 830 N/meat cattle |

Source: Italy (2005)
| Time needed to reach a plateau concentration in milk and eggs (days) | Plateau not reached during the duration of the study |
|---|---|
| Metabolism in rat and ruminant similar (Yes/No) | Yes |
| Animal residue definition for monitoring (RD-Mo) | triflumuron |
| Animal residue definition for risk assessment (RD-RA) | triflumuron |
| Conversion factor (monitoring to risk assessment) | Not relevant |
| Fat soluble residues (Yes/No) | Yes |
| Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs) | HPLC-MS/MS:  
- Method validated in bovine muscle, bovine liver, bovine fat and bovine milk  
- LOQ: 0.005 mg/kg (EFSA, 2011)  
- LOQ: 0.01 mg/kg (EURL, 2016) |

bw: body weight; HPLC-MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; LOD: limit of detection.

### B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability (months) |
|---|---|---|---|---|
|  | Bovine | Muscle | –18 | 3 months |
|  | Bovine | Liver | –18 | 3 months |
|  | Bovine | Milk | –18 | 3 months |

Source: Italy (2005)

### 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) |
|---|---|---|
|  | Mean | Highest | STMR<sup>(a)</sup> (mg/kg) | HR<sup>(b)</sup> (mg/kg) |
| **Meat ruminants**<sup>(c)</sup> | Closest feeding level (0.3 mg/kg bw; 100 N rate) | | |
| Muscle | < 0.05 | < 0.05 | < 0.01 | < 0.01 | 0.01* |
| Fat | < 0.1 | < 0.1 | < 0.01 | < 0.01 | 0.01* |
| Liver | < 0.05 | < 0.05 | < 0.01 | < 0.01 | 0.01* |
| Kidney | < 0.05 | < 0.05 | < 0.01 | < 0.01 | 0.01* |

**Dairy ruminants**  
MRLs are not required since the intake is not significant

**Poultry**  
MRLs are not required since the intake is not significant

**Pig**  
MRLs are not required since the intake is not significant

MRL: maximum residue level; bw: body weight; STMR: supervised trials median residue; HR: highest residue.

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

(a): Mean residue level, recalculated at the 1N rate for the median dietary burden.

(b): The mean residue level in milk and the highest residue levels in eggs and tissues were recalculated at the 1N rate for the maximum dietary burden.

(c): Closest feeding level and N dose rate related to the maximum dietary burden.
B.3. Consumer risk assessment

B.3.1. Consumer risk assessment for triflumuron

| ADI | 0.014 mg/kg bw per day (EFSA, 2011) |
| --- | ----------------------------------- |
| Highest IEDI, according to EFSA PRIMo | 10.9% ADI (German, child) |
| Assumptions made for the calculations | The calculation is based on the median residue levels in the raw agricultural commodities. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation. |

ARfD | Not necessary |
--- | --- |
Highest IESTI, according to EFSA PRIMo | --- |
Assumptions made for the calculations | --- |

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; MRL: maximum residue level; GAP: Good Agricultural Practice; ARfD: acute reference dose; IESTI: international estimated short-term intake.

B.3.2. Consumer risk assessment for metabolite M07

| ADI | 0.00 mg/kg bw for metabolite M07 (EFSA, 2011) |
| --- | -------------------------------------------- |
| Highest IEDI, according to EFSA PRIMo | 72.9% ARfD (apples) |
| Assumptions made for the calculations | The calculation is based on the highest residue concentration for triflumuron observed in the RAC, corrected for the percentage of M07 formed in the hydrolysis study (17%). The molecular weight between triflumuron and metabolite M07 was not taken into account for the calculation. Although the calculations are just indicative, the approach is sufficiently conservative for metabolite M07 as it is assumed that the large portion consumed consists of sterilised processed products which were produced without peeling. |

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ARfD: acute reference dose; IESTI: international estimated short-term intake; RAC: raw agricultural commodity.

B.4. Proposed MRLs

| Code number(a) | Commodity | Existing EU MRL (mg/kg) | MRL (mg/kg) | Comment |
| --- | --- | --- | --- | --- |
| 130010 | Apples | 0.5 | 0.5 | Further consideration needed(b) |
| 130020 | Pears | 0.5 | 0.5 | Further consideration needed(b) |
| 140010 | Apricots | 1 | 1 | Further consideration needed(b) |
| 140030 | Peaches | 1 | 0.4 | Further consideration needed(b) |
| 140040 | Plums | 1 | 0.1 | Further consideration needed(b) |

Enforcement residue definition (existing): triflumuron(F)
Enforcement residue definition (proposed): triflumuron(F)

www.efs.europa.eu/efsajournal 25 EFSA Journal 2017;15(4):4769
| Code number<sup>(a)</sup> | Commodity                  | Existing EU MRL (mg/kg) | Outcome of the review     | Comment        |
|--------------------------|---------------------------|-------------------------|---------------------------|----------------|
| 1012010                  | Bovine meat               | 0.01*                   | 0.01*                     | Recommended<sup>(c)</sup> |
| 1012020                  | Bovine fat                | 0.01*                   | 0.01*                     | Recommended<sup>(c)</sup> |
| 1012030                  | Bovine liver              | 0.01*                   | 0.01*                     | Recommended<sup>(c)</sup> |
| 1012040                  | Bovine kidney             | 0.01*                   | 0.01*                     | Recommended<sup>(c)</sup> |
| 1015010                  | Equine meat               | 0.01*                   | 0.01*                     | Recommended<sup>(c)</sup> |
| 1015020                  | Equine fat                | 0.01*                   | 0.01*                     | Recommended<sup>(c)</sup> |
| 1015030                  | Equine liver              | 0.01*                   | 0.01*                     | Recommended<sup>(c)</sup> |
| 1015040                  | Equine kidney             | 0.01*                   | 0.01*                     | Recommended<sup>(c)</sup> |
| –                        | Other commodities of plant and/or animal origin | See Reg. (EC) No 839/2008 | –                         | Further consideration needed<sup>(d)</sup> |

**MRL**: maximum residue level.

* 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 (assuming the existing residue definition); no CXL is available (combination E-I in Appendix E).

(c): 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 E).

(d): 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 E).
**Appendix C – Pesticide Residue Intake Model (PRImo)**

### Triflumuron

**Status of the active substance:** Approved  
**Code no.:** Proposed LOQ

| LOQ (mg/kg bw) | Proposed LOQ |
|----------------|-------------|
| ADI (mg/kg bw/day): | 0.014 |
| ARfD (mg/kg bw): | n.n. |
| Source of ADI: | EFSA |
| Source of ARfD: | EFSA |
| Year of evaluation: | 2011 |

### Toxicological end points

| Commodity / group of commodities | pTMRLs at LOQ (in % of ADI) |
|----------------------------------|-----------------------------|
| 10.9  | DE child 9.5 |
| 5.8   | NL child 5.0 |
| 2.5   | FR toddler 2.1 |
| 2.5   | DK child 1.8 |
| 2.3   | FR infant 2.0 |
| 1.9   | IE adult 0.6 |
| 1.9   | PL general population 1.6 |
| 1.7   | UK infant 1.2 |
| 1.7   | WHO Cluster diet B 0.8 |
| 1.6   | LT adult 1.5 |
| 1.6   | UK Toddler 1.3 |
| 1.5   | ES child 0.9 |
| 1.4   | IT kids/toddler 0.7 |
| 1.4   | PT General population 0.8 |
| 1.3   | IT adult 0.6 |
| 1.3   | SE general population 90th percentile 0.8 |
| 1.2   | NL general 0.9 |
| 1.1   | ES adult 0.6 |
| 1.0   | WHO cluster diet E 0.7 |
| 1.0   | WHO regional European diet 0.5 |
| 0.9   | DK adult 0.6 |
| 0.8   | WHO cluster diet D 0.5 |
| 0.7   | WHO Cluster diet F 0.5 |
| 0.7   | FR all population 0.4 |
| 0.6   | UK vegetarian 0.5 |
| 0.4   | UK Adult 0.3 |
| 0.3   | FI adult 0.3 |

### Chronic risk assessment - refined calculations

| No of diets exceeding ADI | TMDI (range) in % of ADI |
|---------------------------|--------------------------|
| 0  | minimum - maximum |
| 11 | --- |

| Commodity / group of commodities | 1st contributor to MS diet (in % of ADI) |
|----------------------------------|----------------------------------------|
| 10.9  | DE child 9.5 |
| 5.8   | NL child 5.0 |
| 2.5   | FR toddler 2.1 |
| 2.5   | DK child 1.8 |
| 2.3   | FR infant 2.0 |
| 1.9   | IE adult 0.6 |
| 1.9   | PL general population 1.6 |
| 1.7   | UK infant 1.2 |
| 1.7   | WHO Cluster diet B 0.8 |
| 1.6   | LT adult 1.5 |
| 1.6   | UK Toddler 1.3 |
| 1.5   | ES child 0.9 |
| 1.4   | IT kids/toddler 0.7 |
| 1.4   | PT General population 0.8 |
| 1.3   | IT adult 0.6 |
| 1.3   | SE general population 90th percentile 0.8 |
| 1.2   | NL general 0.9 |
| 1.1   | ES adult 0.6 |
| 1.0   | WHO cluster diet E 0.7 |
| 1.0   | WHO regional European diet 0.5 |
| 0.9   | DK adult 0.6 |
| 0.8   | WHO cluster diet D 0.5 |
| 0.7   | WHO Cluster diet F 0.5 |
| 0.7   | FR all population 0.4 |
| 0.6   | UK vegetarian 0.5 |
| 0.4   | UK Adult 0.3 |
| 0.3   | FI adult 0.3 |

### Conclusion:

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

Acute risk assessment is not necessary.

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

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

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

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

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

***) pTMRL: provisional temporary MRL.

**No of critical MRLs (IESTI 1):**

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

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### Acute risk assessment / adults / general population - refined calculations

As no ARD was considered necessary, it is concluded that the short-term intake of triflumuron residues is unlikely to present a public health concern.

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

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

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

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

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

***) pTMRL: provisional temporary MRL.

**No of critical MRLs (IESTI 1):**

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

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### Conclusion:

As no ARD was considered necessary, it is concluded that the short-term intake of triflumuron residues is unlikely to present a public health concern.
Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

| Feed commodity   | Median dietary burden | Maximum dietary burden |
|------------------|-----------------------|------------------------|
|                  | Input value (mg/kg)   | Comment                |
| Risk assessment residue definition – triflumuron
| Apple pomace, wet| 0.30                  | STMR × PF (2.7)        |
|                  | 0.30                  | STMR × PF (2.7)        |

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

D.2. Consumer risk assessment for triflumuron

| Commodity     | Chronic risk assessment |
|---------------|-------------------------|
|               | Input value (mg/kg)     | Comment                |
| Risk assessment residue definition – triflumuron
| Apples        | 0.11                    | STMR (tentative)       |
| Pears         | 0.11                    | STMR (tentative)       |
| Apricots      | 0.29                    | STMR (tentative)       |
| Peaches       | 0.09                    | STMR (tentative)       |
| Plums         | 0.03                    | STMR (tentative)       |
| Bovine meat   | 0.01*                   | 0.8 × STMR muscle + 0.2 × STMR fat |
| Bovine fat    | 0.01*                   | STMR                   |
| Bovine liver  | 0.01*                   | STMR                   |
| Bovine kidney | 0.01*                   | STMR                   |
| Equine meat   | 0.01*                   | 0.8 × STMR muscle + 0.2 × STMR fat |
| Equine fat    | 0.01*                   | STMR                   |
| Equine liver  | 0.01*                   | STMR                   |
| Equine kidney | 0.01*                   | STMR                   |

STMR: supervised trials median residue.
*: Indicates that the input value is proposed at the limit of quantification.

D.3. Consumer risk assessment for metabolite M07

| Commodity     | Acute risk assessment |
|---------------|-----------------------|
|               | Input value (mg/kg)   | Comment                |
| Risk assessment residue definition – triflumuron
| Apples        | 0.04                  | HR (tentative) × 0.17(a) |
| Pears         | 0.04                  | HR (tentative) × 0.17(a) |
| Apricots      | 0.08                  | HR (tentative) × 0.17(a) |
| Peaches       | 0.04                  | HR (tentative) × 0.17(a) |
| Plums         | 0.01                  | HR (tentative) × 0.17(a) |

(a): Highest residue concentration for triflumuron observed in the RAC, corrected for the percentage of M07 formed in the hydrolysis study (17%).
Appendix E – Decision tree for deriving MRL recommendations

Evaluation of the GAPs and available residues data at EU level

- GAP or DB > 0.1 mg/kg DM in EU?
  - Yes: MRL derived in Section 3?
    - Yes: MRL fully supported by data?
      - Yes: Tentative median/highest values are included in the RA.
      - No: Current EU MRL is included in the RA.
    - No: Risk identified?
      - Yes: Fall-back MRL available? (Yes/No) 
      - No: Not considered for the RA.
  - No: Specific LOQ or default MRL?
    - Yes: Specific LOQ or default MRL?
      - Yes: No.
      - No: Specific LOQ or default MRL?
        - Yes: Tentative median/highest values are included in the RA.
        - No: Risk identified?
          - Yes: Fall-back MRL available? (Yes/No) 
          - No: Not considered for the RA.

Consumer risk assessment for GAPs evaluated at EU level - EU scenarios

- Current EU MRL is included in the RA. 
  - Risk identified?
    - Yes: Fall-back MRL available? (Yes/No)
    - No: Not considered for the RA.
  - Risk identified?
    - Yes: Tentative median/highest values are included in the RA.
    - No: Risk identified?
      - Yes: Fall-back MRL available? (Yes/No) 
      - No: Not considered for the RA.

Recommendations resulting from EU authorisations and import tolerances

- Specific LOQ or default MRL?
  - Yes: Specific LOQ or default MRL?
    - Yes: No.
    - No: Specific LOQ or default MRL?
      - Yes: Tentative median/highest values are included in the RA.
      - No: Risk identified?
        - Yes: Fall-back MRL available? (Yes/No) 
        - No: Not considered for the RA.

Comparison with CXLs.

(1) Specific LOQ or default MRL?
(2) Maintain current EU MRL?
(3) Specific LOQ or default MRL?
(4) Establish tentative EU MRL?
(5) Specific LOQ or default MRL?
(6) MRL is recommended.
Comparison of the EU recommendation with the existing CXL

- CXL available?
  - Yes: Maintain EU recommendation indicating that no CXL is available.
  - No: RD comparable?
    - Yes: Maintain EU recommendation indicating CXL is not compatible.
    - No: CXL higher?
      - Yes: Maintain EU recommendation indicating that CXL is covered.
      - No: Maintain EU recommendation; higher CXL is not safe for consumer.

Consumer risk assessment with consideration of the existing CXL

- Input values for the RA remain unchanged?
  - Yes: CXL is included in the RA.
  - No: Risk identified?
    - Yes: Consumer risk assessment with consideration of the existing CXL.
    - No: Risk identified?
      - Yes: CXL higher?
        - Yes: Maintain current CXL or EU recommendation?
          - Yes: CXL is recommended; EU recommendation is covered as well.
          - No: Input values for the RA remain unchanged.
        - No: CXL is included in the RA.

Recommendations with consideration of the existing CXL

- EU: Maintain EU recommendation indicating that no CXL is available.
- RD: Maintain EU recommendation indicating CXL is not compatible.
- CXL: Maintain EU recommendation indicating that CXL is covered.
- CXL higher: Maintain current CXL or EU recommendation?
  - Yes: CXL is recommended; EU recommendation is covered as well.
  - No: Input values for the RA remain unchanged.
- Input values for the RA remain unchanged: CXL is included in the RA.
## Appendix F – Used compound codes

| Code/trivial name | Chemical name/SMILES notation | Structural formula |
|-------------------|--------------------------------|--------------------|
| Triflumuron       | 1-(2-chlorobenzoyl)-3-      | ![Structural formula](image) |
|                   | (4-trifluoromethoxyphenyl)urea |                     |
| M01               | 2-chlorobenzamide            | ![Structural formula](image) |
| M02               | 2-chlorobenzoic acid         | ![Structural formula](image) |
|                   | 2-CBA                         |                     |
| M03               | 2-chlorohippuric acid        | ![Structural formula](image) |
| M04               | SIR 8514-3-hydroxy-2-chlorophenyl acid | ![Structural formula](image) |
| M07               | 4-trifluoromethoxyaniline    | ![Structural formula](image) |
| M08               | 4-trifluoromethoxyphenyl urea | ![Structural formula](image) |
|                   | TMPU                          |                     |

SMILES: simplified molecular-input line-entry system.