

## REASONED OPINION

### Reasoned opinion on the modification of the existing MRL for triflumuron in peaches, plums, oranges and mandarins<sup>1</sup>

European Food Safety Authority<sup>2</sup>

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#### ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Italy, hereafter referred to as the evaluating Member State (EMS), received an application from Bayer CropScience AG to modify the existing MRLs for the active substance triflumuron in stone fruits and citrus. Italy proposed to lower the existing MRLs from 1 mg/kg to 0.3 mg/kg in peaches and plums. The data were considered as not sufficient to raise the existing MRLs in oranges and mandarins to accommodate for their import from South Africa. According to EFSA the data are sufficient to derive MRL proposals of 0.4 mg/kg and 0.08 mg/kg for the proposed use on peaches and plums, respectively. EFSA confirms the conclusion of the EMS that the import tolerance request for oranges and mandarins is not sufficiently supported by data. An adequate analytical enforcement method is available to control the residues of triflumuron in the commodities under consideration. Based on a preliminary risk assessment, EFSA concludes that the proposed use of triflumuron on peaches and plums will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

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#### KEY WORDS

triflumuron, citrus and stone fruits, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, benzoylurea insecticide, 4-trifluoro-methoxyaniline (M07)

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## SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Italy, hereafter referred to as the evaluating Member State (EMS), received an application from Bayer CropScience AG to modify the existing MRLs for the active substance triflumuron in stone fruits and citrus. Italy proposed to lower the existing MRLs from 1 mg/kg to 0.3 mg/kg in peaches and plums. The data were considered as not sufficient to raise the existing MRLs from 1 mg/kg to 2 mg/kg in oranges and mandarins to accommodate for their import from South Africa. Italy drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 4 December 2013.

EFSA bases its assessment on the evaluation report, the Draft Assessment Report (DAR), its addendum and the Additional Report (AR) prepared under Council Directive 91/414/EEC, the Commission review report on triflumuron and the conclusion on the peer review of the pesticide risk assessment of the active substance triflumuron.

The toxicological profile of triflumuron was assessed in the framework of the peer review under Council Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.014 mg/kg bw per day. No ARfD was deemed necessary for triflumuron. An ARfD of 0.005 mg/kg bw was derived for the metabolite M07 which was observed in metabolism studies in soya bean and potato and which is expected to be formed during food processing (sterilisation).

The metabolism of triflumuron in primary crops was investigated after foliar applications on three different crop groups: fruit and fruiting vegetables (apples, tomatoes), root/tuber vegetables (potatoes) and pulses/oilseeds (soya bean) in the framework of the peer review under Council Directive 91/414/EEC. For the uses on the crops under consideration (fruit and fruiting vegetables group), EFSA concludes that the metabolism of triflumuron is sufficiently addressed and the residue definition for enforcement and risk assessment as triflumuron agreed in the peer review is applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to derive MRL proposals of 0.4 mg/kg and 0.08 mg/kg for the proposed use on peaches and plums, respectively. The import tolerance request for oranges and mandarins is not sufficiently supported by data and no amendment of the existing MRL is proposed. An adequate analytical enforcement method is available to control the residues of triflumuron in the commodities under consideration at the validated LOQ of 0.01 mg/kg.

The effect of processing on the nature of triflumuron residues was assessed in the framework of the peer review. Although hydrolysis of triflumuron was observed under sterilization conditions, with formation of degradation products M07 and M08 in relevant amounts, the parent compound still represented a significant part of the radioactivity. Thus, the same enforcement residue definition as for raw agricultural commodities (RAC) was proposed for processed products. EFSA does not recommend the inclusion of the processing factors derived for peach and plum preserve during the peer review in Annex VI of Regulation (EC) No 396/2005 as not sufficiently robust.

Investigations of residues in rotational crops are not required since the proposed use of triflumuron is on permanent crops.

Residues of triflumuron in commodities of animal origin were not assessed in the framework of this application, since stone fruits are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). For the calculation of the chronic exposure EFSA used the median residue values as derived from the residue trials on peaches and plums and the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005. No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMO. The total calculated intake accounted for

28 % of the ADI. The contribution of residues to the total consumer exposure accounted for a maximum of 0.37 % of the ADI for peaches and 0.07 % of the ADI for plums.

For the active substance triflururon no acute consumer exposure assessment was performed since no ARfD was established. However, to take into account the acute toxicity of M07 in processed peach and plum products after sterilisation, a separate acute risk assessment was performed for M07. The short-term exposure was calculated using the highest residue concentration for triflururon observed in the RAC, corrected for the percentage of M07 formed in the hydrolysis study. Although the calculations are just indicative, the approach is sufficiently conservative as it is assumed that the large portion consumed consists of sterilised processed products which were produced without peeling. No acute consumer risk was identified in relation to the potential exposure to the metabolite M07 from processed products undergoing a sterilisation process. The calculated maximum exposure in percentage of the ARfD was 81 % for processed peaches and 9 % for processed plums.

It should be noted that the short and long-term exposure assessments are preliminary and affected by uncertainty resulting from the lack of appropriate information on the magnitude of M07 and M08 in crops different than the fruits and fruiting vegetable and in processed products (sterilised). A more realistic risk assessment will be performed in the framework of Article 12 of Regulation (EC) No 396/2005 when full information on authorised uses of triflururon and additional data will be available to EFSA.

EFSA concludes that the proposed use of triflururon on peaches and plums will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

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

#### SUMMARY TABLE

Code number <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
<b>Enforcement residue definition: Triflururon (F)</b>				
140030	Peaches	1	0.4	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended use on these fruits. Before lowering the MRLs, it has to be clarified if a more critical GAP than that reported by the EMS is still authorised, which requires maintaining the existing MRLs on peaches and plums. It is noted that the existing MRLs do not pose a consumer health risk.
140040	Plums	1	0.08	
110020	Oranges	1	No new proposal	The import tolerance request to accommodate for import of citrus fruits from South Africa is not sufficiently supported by data. It is noted that the MRL established in South Africa is lower than the existing MRL in the EU (0.5 mg/kg).
110050	Mandarins	1	No new proposal	

(a): According to Annex I of Regulation (EC) No 396/2005.

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

(F): Fat-soluble.

## TABLE OF CONTENTS

Abstract .....	1
Summary .....	2
Table of contents .....	4
Background .....	5
Terms of reference.....	5
The active substance and its use pattern.....	6
Assessment .....	7
1. Method of analysis.....	7
1.1. Methods for enforcement of residues in food of plant origin .....	7
1.2. Methods for enforcement of residues in food of animal origin .....	7
2. Mammalian toxicology .....	7
3. Residues.....	8
3.1. Nature and magnitude of residues in plant.....	8
3.1.1. Primary crops.....	8
3.1.2. Rotational crops .....	11
3.2. Nature and magnitude of residues in livestock .....	11
4. Consumer risk assessment .....	12
Conclusions and recommendations .....	13
References .....	15
Appendices .....	17
Appendix A. Good Agricultural Practice (GAPs) .....	17
Appendix B. Pesticide Residue Intake Model (PRIMo).....	18
Appendix C. Existing EU maximum residue levels (MRLs) .....	20
Abbreviations .....	23

## BACKGROUND

Regulation (EC) No 396/2005<sup>3</sup> establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC<sup>4</sup>, repealed by Regulation (EC) No 1107/2009<sup>5</sup>, shall submit to a Member State, when appropriate, an application to modify a MRL or an import tolerance in accordance with the provisions of Article 7 of that Regulation.

Italy, hereafter referred to as the evaluating Member State (EMS), received an application from the company Bayer CropScience AG<sup>6</sup> to modify the existing MRLs for the active substance triflumuron in peaches, plums, oranges and mandarins. This application was notified to the European Commission and EFSA and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 4 December 2013.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2013-00979 and the following subject:

*Triflumuron - Application to modify the existing MRLs in peaches (nectarines), plums, oranges and mandarins.*

Italy proposed to lower the existing MRLs of triflumuron in peaches and plums from the value of 1 mg/kg to 0.3 mg/kg, whereas the data were considered as not sufficient to raise the existing MRLs from 1 mg/kg to 2 mg/kg in oranges and mandarins to accommodate the import from South Africa as requested by the applicant.

EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

## TERMS OF REFERENCE

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the deadline for providing the reasoned opinion is 4 March 2014.

<sup>3</sup> Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1-16.

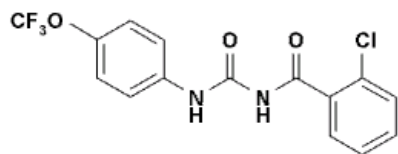
<sup>4</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1-32.

<sup>5</sup> 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.

<sup>6</sup> Bayer CropScience AG, Alfred-Nobel-Str. 50, 40789 Monheim am Rhein, Germany.

## THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Triflumuron is the ISO common name for 1-(2-chlorobenzoyl)-3-[4-trifluoromethoxyphenyl]urea (IUPAC). The chemical structure of the compound is reported below.



Molecular weight: 358.7 g/mol

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 LOQ were observed in the cattle feeding study (EFSA, 2011).

Triflumuron was evaluated in the framework of Council Directive 91/414/EEC with Italy designated as rapporteur Member State (RMS). Following the peer review (EFSA, 2008) a decision not to include that active substance in Annex I of Council Directive 91/414/EEC (Commission Decision 2009/241/EC)<sup>7</sup> was taken. 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<sup>8</sup> which entered into force on 1 April 2011 for use as insecticide with risk mitigation measures for the plant protection product. In accordance with Commission Implementing Regulation (EU) No 540/2011<sup>9</sup> 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 Draft Assessment Report (DAR) of triflumuron and its Additional Report (AR) have been peer reviewed by EFSA (EFSA, 2008, 2011).

The EU MRLs for triflumuron are established in Annex IIIA of Regulation (EC) No 396/2005 (Appendix C). The review of the existing MRL according to Article 12 of Regulation (EC) No 396/2005 is at an early stage. The existing EU MRLs for triflumuron in the crops under consideration are set at 1 mg/kg. Codex Alimentarius has not established CXLs for triflumuron. According to the information publicly available the MRL established for triflumuron in citrus fruit in South Africa is 0.5 mg/kg.<sup>10</sup>

The details of the intended GAP for triflumuron on peaches and plums and the reported South African GAP on oranges and mandarins are given in Appendix A.

<sup>7</sup> Commission Decision 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, 17.03.2009, p. 59-60.

<sup>8</sup> Commission Directive 2011/23/EU of 3 March 2011 amending Council Directive 91/414/EEC to include triflumuron as active substance. OJ L 59, 04.03.2011, p. 29-31.

<sup>9</sup> Commission Implementing Regulation (EU) No 540/2011 of 23 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, 11.06.2011, p. 1-186.

<sup>10</sup> South Africa. Regulations governing the maximum limits for pesticide residues that may be present in foodstuffs. GNR No 246 of 1994 and amendments. Full text available online: [saf73495.pdf](http://www.saf73495.pdf)

## ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (Italy, 2013), the Draft Assessment Report (DAR), its addendum and the Additional Report (AR) prepared under Council Directive 91/414/EEC (Italy, 2005, 2008, 2010), the Commission review report on triflumuron (EC, 2011a) and the conclusion on the peer review of the pesticide risk assessment of the active substance triflumuron (EFSA, 2008, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011<sup>11</sup> and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a-g, 2000, 2010a,, 2011b; OECD, 2011).

### 1. Method of analysis

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

Analytical methods for the determination of triflumuron residues in plant commodities were assessed during the peer review under Council Directive 91/414/EEC (Italy, 2008; EFSA, 2011). The liquid chromatography coupled with tandem mass spectrometry detection (LC-MS/MS), was adequately validated in high water (tomatoes) and high acid (oranges) content commodities and in dry commodities (wheat grains) at the LOQ of 0.01 mg/kg (EFSA, 2011).

Since the commodities under consideration belong to the group of high water and high acid content commodities, EFSA concludes that a sufficiently validated analytical method is available to control the residues of triflumuron in stone and citrus fruits.

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

Since the setting of MRLs for triflumuron in commodities of animal origin is not proposed in the framework of the current MRL application (see Section 3.2), the assessment of analytical methods for the determination of residues in food of animal origin is not required.

### 2. Mammalian toxicology

The toxicological profile of the active substance triflumuron was assessed in the framework of the peer review under Council Directive 91/414/EEC (EC, 2011a; EFSA, 2011). The data were sufficient to derive toxicological reference values which are compiled in Table 2-1.

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

	Source	Year	Value	Study relied upon	Safety factor
Triflumuron					
ADI	EC	2011	0.014 mg/kg bw per day	1-yr dog supported by 2-yr rat	100
ARfD	EC	2011	Not necessary.		

<sup>11</sup> Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127-175.



	Source	Year	Value	Study relied upon	Safety factor
4-trifluoro-methoxyaniline (M07) <sup>12</sup>					
ADI	EC	2011	A separate ADI not established as not necessary.		
ARfD	EC	2011	0.005 mg/kg	6-d single dose toxicity rat	100

In Table 2-1, EFSA also reported the ARfD derived for the 4-trifluoro-methoxyaniline (M07), a metabolite that was found in significant concentrations in soya beans and potatoes and which was identified as a degradation product after processing (sterilisation). The metabolite M07 and a second metabolite (M08<sup>13</sup>) have been provisionally included in the residue definition for risk assessment of oilseeds/pulses and root/tuber crops (EFSA, 2011). M07 was shown to be more acutely toxic than the parent compound, for which an acute reference dose was not considered needed. An ARfD was established for M07, whereas its chronic toxicity is covered by the toxicity of the parent triflumuron. M08 was considered as toxic as the parent compound and the toxicological reference values of the parent compound are applicable to M08 (EFSA, 2011).

### 3. Residues

#### 3.1. Nature and magnitude of residues in plant

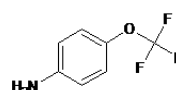
##### 3.1.1. Primary crops

##### 3.1.1.1. Nature of residues

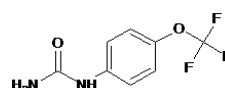
In the framework of the peer review under Council Directive 91/414/EEC the metabolism of triflumuron in primary crops was investigated after foliar applications on three different crop groups: fruit and fruiting vegetables (apples, tomatoes), root/tuber vegetables (potatoes) and pulses/oilseeds (soya bean) (EFSA, 2011). The design and results of the metabolism studies are discussed in detail in the DAR and the AR (Italy, 2005, 2010). Based on the results of the plant metabolism studies, the peer review established the residue definition for monitoring as triflumuron (EFSA, 2011). The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived during the peer review. Since no metabolites were detected in significant levels in the metabolism studies conducted on apples and tomatoes, for fruit and fruiting vegetables the residue definition for risk assessment was restricted to the parent triflumuron.

Metabolites M07 and M08 were found in significant proportions in both the soya and potato metabolism studies (M07: up to about 30 % of the TRR in soya beans; M08 up to 14 % TRR in potato tuber). Therefore the peer review provisionally included M07 and M08 in the residue definition for risk assessment for the oilseeds/pulses and root/tuber crops (sum of triflumuron and metabolites M07 and M08, expressed as triflumuron). Bearing in mind the different toxicological properties of M07 (see Table 2-1), the need for setting a separate residue definition for risk assessment should be considered in the future. It is noted that M08 is also a plant metabolite of the active substance indoxacarb (EFSA, 2011). No metabolism studies are available to define the appropriate residue definition for risk assessment in cereals and leafy crops.

<sup>12</sup> M07: 4-trifluoro-methoxyaniline .



<sup>13</sup> M08: 1-[4-(trifluoromethoxy)phenyl]urea





For the uses on the crops under consideration (fruit and fruiting vegetables group), EFSA concludes that the metabolism of triflumuron in primary crops is sufficiently addressed and the residue definitions for enforcement and risk assessment as triflumuron agreed in the peer review are applicable.

#### 3.1.1.2. Magnitude of residues

In support of the MRL/import tolerance application the results from residue trials on the crops under consideration were provided. Part of the trials was designed as decline studies.

##### a. Peaches

The twelve residue trials previously assessed during the peer review support the intended use on peaches which corresponds to the representative use (EFSA, 2011). According to the OECD methodology a MRL proposal of 0.4 mg/kg is derived for the intended use in Italy.

##### b. Plums

Four GAP-compliant residue trials conducted on plums in Southern France and Italy over two seasons are available. According to the EU guidance document (EC, 2011b) plums were still classified as a minor crop at the time of the submission of the MRL application (15 February 2013). The data are sufficient to derive a MRL proposal of 0.08 mg/kg for the intended use in Italy.

##### c. Oranges, mandarins (import tolerance)

Three residue trials conducted on oranges and four on mandarins are GAP-compliant (within the acceptable deviation of  $\pm 25\%$  for application rate). The data are not sufficient to derive MRLs for oranges and mandarins, which are both classified as major crops worldwide. According to the guidance document at least eight residue trials on each crop are required to derive a MRL proposal (EC, 2011b).

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Table 3-1.

Based on the results of a storage stability study on apples, the peer review concluded that residues of triflumuron are stable at about  $\leq -18^\circ\text{C}$  for up to 24 months in high water content matrices (EFSA, 2011). As the samples of the supervised residue trials on peaches and plums were stored (9 months peaches and 12 months plums) under conditions for which integrity of the samples was demonstrated (Italy, 2010; Italy, 2013), EFSA concludes that the residue data on stone fruits are valid with regard to storage stability. The storage stability in high acid content commodities has not been investigated, therefore the validity of the results from the submitted residue trials on oranges and mandarins can not be confirmed.

According to the EMS, the analytical method used to analyse the supervised residue trial samples on pome fruits has been sufficiently validated and was proven to be fit for the purpose (Italy, 2013).

EFSA concludes that the data are sufficient to derive a MRL proposal of 0.4 mg/kg and 0.08 mg/kg<sup>14</sup> for the intended use on peaches and plums in Italy. The import tolerance request for oranges and mandarins is not sufficiently supported by data.

<sup>14</sup> Italy proposed the group MRL of 0.3 mg/kg for the stone fruits peach and plum based on the same set of studies. The difference in the MRL value is a consequence of the calculation methodology applied.

**Table 3-1:** Overview of the available residues trials data

Commodity	Residue region  (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF  (d)	Comments  (e)
			Enforcement (triflumuron)	Risk assessment (triflumuron)					
Enforcement residue definition: Triflumuron Risk assessment residue definition: Triflumuron (fruits and fruiting vegetables)									
Peaches	SEU	Outdoor	0.02; 0.04 <sup>(f)</sup> ; 0.05 <sup>(f)</sup> ; 0.06; 0.07; 2 x 0.09; 0.11; 2 x 0.13; 0.14; 0.24 <sup>(g)</sup>	0.02; 0.04 <sup>(f)</sup> ; 0.05 <sup>(f)</sup> ; 0.06; 0.07; 2 x 0.09; 0.11; 2 x 0.13; 0.14; 0.24 <sup>(g)</sup>	0.09	0.24	0.4	1	Refer to EFSA, 2011. R <sub>ber</sub> = 0.26 R <sub>max</sub> = 0.26 MRL <sub>OECD</sub> = 0.33/0.4
Plums	SEU	Outdoor	0.01; 0.02; 0.03; 0.04	0.01; 0.02; 0.03; 0.04	0.03	0.04	0.08	1	R <sub>ber</sub> = 0.08 R <sub>max</sub> = 0.09 MRL <sub>OECD</sub> = 0.077/0.08
Oranges	Import (ZA)	Outdoor	0.31; 0.42; 0.63	0.31; 0.42; 0.63	The data are not sufficient to derive a MRL proposal.				
Mandarins			0.58; 0.61; 0.64; 0.82	0.58; 0.61; 0.64; 0.82	The data are not sufficient to derive a MRL proposal.				

No separate chronic risk assessment was not performed for M07... indoor use) or Import (country code) (EC, 2011).

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residue trial.

(e): Statistical estimation of MRLs according to the EU methodology (R<sub>ber</sub>, R<sub>max</sub>; EC, 1997g) and unrounded/rounded values according to the OECD methodology (OECD, 2011).

(f): Highest values measured in the decline studies at a longer PHI (21 days) than the PHI of the intended GAP (14 days).

(g): Detected as potential outlier (Dixon's Q-test, FAO, 2009). Since no justification for the high residue concentration was reported, data point was not excluded from the data set used to derive the MRL proposal.

### 3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of triflumuron was investigated in studies performed at three test conditions representing pasteurisation, baking/brewing/boiling and sterilisation (20 minutes at 90°C, pH 4; 60 minutes at 100°C pH 5; 20 minutes at 120°C, pH 6). The study was performed with the compound radiolabelled in the phenoxy moiety and is reported in the DAR and in the conclusion on the peer review (Italy, 2005, 2010; EFSA, 2011). Triflumuron showed to be stable under hydrolysis condition except under conditions simulating sterilisation, where triflumuron partially degraded to the compounds M07 (17 % of the AR) and M08 (16 % of the AR). No hydrolysis study is available with the active substance labelled in the chlorophenyl ring.

Considering that free triflumuron represented a significant part of the radioactivity in processed commodities, the peer review proposed the same residue definition for processed products as for the raw agricultural commodities (RAC) for monitoring purposes (EFSA, 2011). EFSA is of the opinion that the residue definition for risk assessment of processed commodities should be reconsidered taking into account M07 and M08, degradation products produced under sterilisation conditions. A separate residue definition for the degradation product M07 would be appropriate, considering its different toxicological profile (see Table 2-1). Degradation products formed from the chlorophenyl ring moiety should be investigated.

The magnitude of triflumuron residues in processed products was assessed in three studies on apples, one study on peaches and one on plums during the peer review (Italy, 2005; 2010). No new information was submitted in the framework of this MRL application. A reduction of triflumuron residues was observed in peach and plum preserve (prepared from peeled fruit and subject to pasteurisation) and in apple juice (pasteurised) and sauce (pasteurised). In the peel of peaches and apple, in apple pomace and in dried prunes the residue concentrations were higher than in the unprocessed RAC (EFSA, 2011). Data were provided, which demonstrated that the metabolites M07 and M08 were not detected above the LOQ (<0.005 mg/kg) in apple processing fractions (Italy, 2010; EFSA, 2011). In none of the processing studies sterilisation conditions were applied. Thus, information on the residue level of M07 and M08 in sterilised processed products (i.e. canned stone fruits) should be provided. If their presence is confirmed in processed fruit products, the dietary exposure assessment should take into account these degradation products.

Since for peaches and prunes no robust processing factor could be derived, EFSA does not recommend the inclusion of the processing factors reported in the EFSA conclusion (EFSA, 2011) in Annex VI of Regulation (EC) No 396/2005.

### 3.1.2. Rotational crops

Investigations of residues in rotational crops are not required since the proposed use of triflumuron is on permanent crops.

## 3.2. Nature and magnitude of residues in livestock

Residues of triflumuron in commodities of animal origin were not assessed in the framework of this application, since stone fruits are normally not fed to livestock.

#### 4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population<sup>15</sup> (EFSA, 2007).

For the calculation of the chronic exposure, EFSA used the median residue values as derived from the residue trials on peaches and plums (see Table 3-1). For the remaining commodities of plant and animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values. EFSA notes that for the oilseeds, cereals and for head cabbages, for which the existing MRL is above the LOQ, no information is available to estimate the concentration of metabolites M07 and M08 in the treated crops and to derive conversion factors for the risk assessment.

The model assumptions for the long-term exposure assessment are considered to be sufficiently conservative for a first tier exposure assessment, assuming that all food items consumed have been treated with the active substance under consideration. In reality, it is not likely that all food consumed will contain residues at the MRL or at levels of the median residue values identified in supervised field trials. However, if this first tier exposure assessment does not exceed the toxicological reference value for long-term exposure (i.e. the ADI), a consumer health risk can be excluded with a high probability.

For the active substance triflumuron no acute consumer exposure assessment was performed since no ARfD was established. However, to take into account the acute toxicity of M07 in processed peach and plum 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 RAC (see Table 3-2), corrected for the percentage of M07 formed in the hydrolysis study<sup>16</sup> (see Section 3.1.1.3). Although the calculations are just indicative, the approach is sufficiently conservative as it is assumed that the large portion consumed consists of sterilised processed products which were produced without peeling.

The input values used for the chronic (triflumuron) and acute (M07) dietary exposure calculation are summarised in Table 4-1 and Table 4-2, respectively.

**Table 4-1:** Input values for the consumer dietary exposure assessment for parent triflumuron

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<b>Risk assessment residue definition:</b> Triflumuron (fruits and fruiting vegetables) Sum triflumuron, M07 and M08 expressed as triflumuron (provisional) (oilseeds/pulses, root/tuber vegetables)				
Peaches	0.09	Median residue (see Table 3-1)	The acute risk assessment was not performed since no ARfD is established for triflumuron.	
Plums	0.03	Median residue (see Table 3-1)		
Other commodities of plant and animal origin	MRL	See Appendix C		

<sup>15</sup> The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMO is given in its reference section (EFSA, 2007).

<sup>16</sup> The difference in molecular weight between triflumuron and M07 was not taken into account for the calculation.

**Table 4-2:** Input values for the acute dietary exposure assessment for M07 (processed products)

Commodity	Acute exposure assessment <sup>(a)</sup>	
	Input value (mg/kg)	Comment
<b>Provisional risk assessment residue definition for processed products: M07 (sterilisation conditions)</b>		
Peaches	0.07 (0.4*0.17)	Highest residue
Plums	0.01 (0.08*0.17)	Highest residue

(a) No separate chronic risk assessment was performed since no separate ADI is established for M07.

The estimated exposure was then compared with the toxicological reference values derived for triflumuron and M07 (see Table 2-1). The results of the intake calculations are presented in Appendix B to this reasoned opinion.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for 28 % of the ADI (German child diet). The contribution of residues to the total consumer exposure accounted for a maximum of 0.37 % of the ADI for peaches and 0.07 % of the ADI for plums (Irish adult diet).

No acute consumer risk was identified in relation to the potential exposure to the metabolite M07 from processed products undergoing a sterilisation process. The calculated maximum exposure in percentage of the ARfD was 81 % for processed peaches and 9 % for processed plums.

It should be noted that the short and long-term exposure assessments are preliminary and affected by uncertainty resulting from the lack of appropriate information on the magnitude of M07 and M08 in crops different than the fruits and fruiting vegetable and in processed products (sterilised). A more realistic risk assessment will be performed in the framework of Article 12 of Regulation (EC) No 396/2005 when full information on authorised uses of triflumuron and additional data will be available to EFSA.

EFSA concludes that the intended use of triflumuron on peaches and plums will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

## CONCLUSIONS AND RECOMMENDATIONS

### CONCLUSIONS

The toxicological profile of triflumuron was assessed in the framework of the peer review under Council Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.014 mg/kg bw per day. No ARfD was deemed necessary for triflumuron. An ARfD of 0.005 mg/kg bw was derived for the metabolite M07 which was observed in metabolism studies in soya bean and potato and which is expected to be formed during food processing (sterilisation).

The metabolism of triflumuron in primary crops was investigated after foliar applications on three different crop groups: fruit and fruiting vegetables (apples, tomatoes), root/tuber vegetables (potatoes) and pulses/oilseeds (soya bean) in the framework of the peer review under Council Directive 91/414/EEC. For the uses on the crops under consideration (fruit and fruiting vegetables group), EFSA concludes that the metabolism of triflumuron is sufficiently addressed and the residue definition for enforcement and risk assessment as triflumuron agreed in the peer review is applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to derive MRL proposals of 0.4 mg/kg and 0.08 mg/kg for the proposed use on peaches and plums, respectively. The import tolerance request for oranges and mandarins is not sufficiently supported by data and no amendment of the existing MRL is proposed. An adequate analytical enforcement method is available to control the residues of triflumuron in the commodities under consideration at the validated LOQ of 0.01 mg/kg.

The effect of processing on the nature of triflumuron residues was assessed in the framework of the peer review. Although hydrolysis of triflumuron was observed under sterilization conditions, with formation of degradation products M07 and M08 in relevant amounts, the parent compound still represented a significant part of the radioactivity. Thus, the same enforcement residue definition as for raw agricultural commodities (RAC) was proposed for processed products. EFSA does not recommend the inclusion of the processing factors derived for peach and plum preserve during the peer review in Annex VI of Regulation (EC) No 396/2005 as not sufficiently robust.

Investigations of residues in rotational crops are not required since the proposed use of triflumuron is on permanent crops.

Residues of triflumuron in commodities of animal origin were not assessed in the framework of this application, since stone fruits are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). For the calculation of the chronic exposure EFSA used the median residue values as derived from the residue trials on peaches and plums and the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005. No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for 28 % of the ADI. The contribution of residues to the total consumer exposure accounted for a maximum of 0.37 % of the ADI for peaches and 0.07 % of the ADI for plums.

For the active substance triflumuron no acute consumer exposure assessment was performed since no ARfD was established. However, to take into account the acute toxicity of M07 in processed peach and plum products after sterilisation, a separate acute risk assessment was performed for M07. The short-term exposure was calculated using the highest residue concentration for triflumuron observed in the RAC, corrected for the percentage of M07 formed in the hydrolysis study. Although the calculations are just indicative, the approach is sufficiently conservative as it is assumed that the large portion consumed consists of sterilised processed products which were produced without peeling. No acute consumer risk was identified in relation to the potential exposure to the metabolite M07 from processed products undergoing a sterilisation process. The calculated maximum exposure in percentage of the ARfD was 81 % for processed peaches and 9 % for processed plums.

It should be noted that the short and long-term exposure assessments are preliminary and affected by uncertainty resulting from the lack of appropriate information on the magnitude of M07 and M08 in crops different than the fruits and fruiting vegetable and in processed products (sterilised). A more realistic risk assessment will be performed in the framework of Article 12 of Regulation (EC) No 396/2005 when full information on authorised uses of triflumuron and additional data will be available to EFSA.

EFSA concludes that the proposed use of triflumuron on peaches and plums will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.



## RECOMMENDATIONS

Code number <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
<b>Enforcement residue definition:</b> Triflumuron (F)				
140030	Peaches	1	0.4	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended use on these fruits. Before lowering the MRLs, it has to be clarified if a more critical GAP than that reported by the EMS is still authorised, which requires maintaining the existing MRLs on peaches and plums. It is noted that the existing MRLs do not pose a consumer health risk.
140040	Plums	1	0.08	
110020	Oranges	1	No new proposal	The import tolerance request to accommodate for import of citrus fruits from South Africa is not sufficiently supported by data. It is noted that the MRL established in South Africa is lower than the existing MRL in the EU (0.5 mg/kg).
110050	Mandarins	1	No new proposal	

(a): According to Annex I of Regulation (EC) No 396/2005.

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

(F): Fat-soluble.

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## APPENDICES

### Appendix A. Good Agricultural Practice (GAPs)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d - f)	conc. of a.s. (i)	method kind (f - h)	growth stage & season (j)	number min max (k)	interval min max	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
Peaches, Plums	IT	F	Insects	SC	480 g/L	spray	BBCH 70-75 (1st appl.) BBCH 80-85 (2nd appl.)	1-2	40 days	0.06	500-1500	0.18	14	
Oranges, Mandarins	South Africa	F	Insects	SC	480 g/L	spray		1	-			0.96	30	

- Remarks:
- (a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
  - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
  - (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
  - (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
  - (e) GCPF Technical Monograph No 2, 4<sup>th</sup> Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used
  - (f) All abbreviations used must be explained
  - (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
  - (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
  - (i) g/kg or g/l
  - (j) Growth stage at last treatment (Growth stages of mono- and dicotyledonous plants. BBCH Monograph, 2<sup>nd</sup> Ed., 2001), including where relevant, information on season at time of application
  - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
  - (l) PHI - minimum pre-harvest interval
  - (m) Remarks may include: Extent of use/economic importance/restrictions (i.e. feeding, grazing)

## Appendix B. Pesticide Residue Intake Model (PRIMO)

<div> <div>Triflumuron</div> <div> <div>Status of the active substance: approved</div> <div>Code no.</div> </div> <div> <div>LOQ (mg/kg bw): 0.05</div> <div>proposed LOQ:</div> </div> <div>Toxicological end points</div> <div> <div>ADI (mg/kg bw/day): 0.014</div> <div>ARfD (mg/kg bw): n.n.</div> </div> <div> <div>Source of ADI: EC</div> <div>Source of ARfD: EC</div> </div> <div> <div>Year of evaluation: 2011</div> <div>Year of evaluation: 2011</div> </div> </div>									
Chronic risk assessment - refined calculations									
				TMDI (range) in % of ADI minimum - maximum					
				4 28					
				No of diets exceeding ADI: ---					
	Highest calculated TMDI values in % of ADI	MS Diet		Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	pTMDRs at LOQ (in % of ADI)
	28.1	DE child		4.4	Pears	4.3	Apples	2.6	Apricots
	25.4	IE adult		5.0	Grapefruit	4.8	Pears	1.8	Wine grapes
	23.5	WHO Cluster diet B		3.0	Wheat	2.7	Pears	2.6	Wine grapes
	21.9	NL child		3.0	Pears	2.4	Bananas	2.3	Apples
	19.3	UK Toddler		8.2	Sugar beet (root)	1.5	Bananas	1.5	Milk and cream,
	17.6	UK Infant		3.6	Sugar beet (root)	2.8	Milk and cream,	2.1	Bananas
	15.9	FR toddler		2.8	Milk and cream,	1.8	Bananas	1.8	Pears
	15.6	WHO cluster diet E		2.3	Wine grapes	1.4	Wheat	1.4	Potatoes
	15.5	DK child		4.8	Pears	2.0	Wheat	1.6	Bananas
	14.4	PT General population		3.6	Wine grapes	2.4	Pears	1.9	Potatoes
	13.3	SE general population 90th percentile		2.6	Bananas	2.5	Pears	1.5	Potatoes
	12.7	ES child		3.2	Pears	1.6	Wheat	1.4	Bananas
	12.6	FR all population		5.7	Wine grapes	1.2	Wheat	0.9	Pears
	12.1	WHO cluster diet D		2.3	Wheat	1.5	Potatoes	0.9	Limes
	11.1	FR infant		2.3	Pears	1.8	Milk and cream,	1.5	Potatoes
	10.7	WHO regional European diet		1.4	Potatoes	1.3	Pears	1.1	Wheat
	10.6	WHO Cluster diet F		1.3	Wheat	1.2	Potatoes	0.9	Soya bean
	10.4	IT kids/toddler		2.5	Pears	2.4	Wheat	0.8	Bananas
	9.5	NL general		1.2	Pears	1.0	Potatoes	0.9	Wine grapes
	8.8	ES adult		2.3	Pears	0.8	Wheat	0.6	Wine grapes
	8.2	UK vegetarian		1.3	Sugar beet (root)	1.2	Wine grapes	0.8	Grapefruit
	7.6	IT adult		1.7	Pears	1.5	Wheat	0.8	Apricots
	7.4	DK adult		2.0	Wine grapes	1.5	Pears	0.7	Wheat
	7.3	UK Adult		1.5	Wine grapes	1.4	Sugar beet (root)	0.6	Wheat
	6.6	PL general population		2.0	Pears	1.2	Potatoes	0.7	Apples
	5.6	LT adult		1.1	Potatoes	1.1	Pears	0.7	Apples
	4.2	FI adult		0.4	Potatoes	0.4	Wine grapes	0.4	Milk and cream,
<b>Conclusion:</b> The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMDRs were below the ADI. A long-term intake of residues of Triflumuron is unlikely to present a public health concern.									

<div>Metabolite M07 of triflumuron</div> <div><div>Status of the active substance:</div><div>Code no.</div></div> <div><div>LOQ (mg/kg bw):</div><div>proposed LOQ:</div></div> <div>Toxicological end points</div> <div><div>ADI (mg/kg bw/day):</div><div>n.n.</div><div>ARfD (mg/kg bw):</div><div>0.005</div></div> <div><div>Source of ADI:</div><div>EC</div><div>Source of ARfD:</div><div>EC</div></div> <div><div>Year of evaluation:</div><div>2011</div><div>Year of evaluation:</div><div>2011</div></div>												
Indicative risk assessment assuming that the large portion consumed consists of sterilised processed products which were produced without peeling.												
Acute risk assessment /children						Acute risk assessment / adults / general population						
The acute risk assessment is based on the ARfD.												
For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.												
In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.												
In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.												
Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.												
Processed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):			No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):		
	IESTI 1 *)			IESTI 2 *)			IESTI 1 *)			IESTI 2 *)		
	Highest % of ARfD/ADI			Highest % of ARfD/ADI			Highest % of ARfD/ADI			Highest % of ARfD/ADI		
	Commodities			Commodities			Commodities			Commodities		
	pTMRL/ threshold MRL (mg/kg)			pTMRL/ threshold MRL (mg/kg)			pTMRL/ threshold MRL (mg/kg)			pTMRL/ threshold MRL (mg/kg)		
	80.7			59.2			23.8			18.4		
	Peach,processed			Peach,processed			Peaches			Peaches		
	0.068 / -			0.068 / -			0.068 / -			0.068 / -		
	9.0			7.3			2.6			2.1		
	Plum, processed			Plum, processed			Plums			Plums		
0.0136 / -			0.0136 / -			0.0136 / -			0.0136 / -			
No of critical MRLs (IESTI 1)			No of critical MRLs (IESTI 2)			No of critical MRLs (IESTI 1)			No of critical MRLs (IESTI 2)			
*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.												
**) pTMRL: provisional temporary MRL												
***) pTMRL: provisional temporary MRL for unprocessed commodity												
Conclusion:												
For Metabolite M07 of triflumuron IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.												
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.												
For processed commodities, no exceedance of the ARfD/ADI was identified.												

## Appendix C. Existing EU maximum residue levels (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 25/03/2014 08:59))

Code number	Groups and examples of individual products to which the MRLs apply	Triflumuron (F)
100000	1. FRUIT FRESH OR FROZEN NUTS	
110000	(i) Citrus fruit	
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), ugli and other hybrids)	1
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	1
110030	Lemons (Citron, lemon, Buddha's hand (Citrus medica var. sarcodactylis))	0,05*
110040	Limes	0,05*
110050	Mandarins (Clementine, tangerine, mineola and other hybrids tangor (Citrus reticulata x sinensis))	1
110990	Others	0,05*
120000	(ii) Tree nuts	0,05*
120010	Almonds	0,05*
120020	Brazil nuts	0,05*
120030	Cashew nuts	0,05*
120040	Chestnuts	0,05*
120050	Coconuts	0,05*
120060	Hazelnuts (Filbert)	0,05*
120070	Macadamia	0,05*
120080	Pecans	0,05*
120090	Pine nuts	0,05*
120100	Pistachios	0,05*
120110	Walnuts	0,05*
120990	Others	0,05*
130000	(iii) Pome fruit	
130010	Apples (Crab apple)	0,5
130020	Pears (Oriental pear)	0,5
130030	Quinces	1
130040	Medlar	1
130050	Loquat	1
130990	Others	1
140000	(iv) Stone fruit	1
140010	Apricots	1
140020	Cherries (Sweet cherries, sour cherries)	1
140030	Peaches (Nectarines and similar hybrids)	1

Code number	Groups and examples of individual products to which the MRLs apply	Triflumuron (F)
140040	Plums (Damson, greengage, mirabelle, sloe, red date/Chinese date/Chinese jujube (Ziziphus zizyphus))	1
140990	Others	1
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	0,2
151010	Table grapes	0,2
151020	Wine grapes	0,2
152000	(b) Strawberries	0,05*
153000	(c) Cane fruit	0,05*
153010	Blackberries	0,05*
153020	Dewberries (Loganberries, tayberries, boysenberries, cloudberry and other Rubus hybrids)	0,05*
153030	Raspberries (Wineberries, arctic bramble/raspberry, (Rubus arcticus), nectar raspberries (Rubus arcticus x Rubus idaeus))	0,05*
153990	Others	0,05*
154000	(d) Other small fruit & berries	0,05*
154010	Blueberries (Bilberries)	0,05*
154020	Cranberries (Cowberries/red bilberries (V. vitis-idaea))	0,05*
154030	Currants (red, black and white)	0,05*
154040	Gooseberries (Including hybrids with other Ribes species)	0,05*
154050	Rose hips	0,05*
154060	Mulberries (Arbutus berry)	0,05*
154070	Azarole (mediterranean medlar) (Kiwiberly (Actinidia arguta))	0,05*
154080	Elderberries (Black chokeberry/appleberry, mountain ash, buckthorn/sea sawallowthorn, hawthorn, serviceberries, and other treeberries)	0,05*
154990	Others	0,05*
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	
161010	Dates	2
161020	Figs	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Triflumuron (F)
161030	Table olives	0,05*
161040	Kumquats (Marumi kumquats, nagami kumquats, limequats (Citrus aurantifolia x Fortunella spp.))	0,05*
161050	Carambola (Bilimbi)	0,05*
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple/water apple, pomerac, rose apple, Brazilian cherry, Surinam cherry/grumichama (Eugenia uniflora))	0,05*
161990	Others	0,05*
162000	(b) Inedible peel, small	0,05*
162010	Kiwi	0,05*
162020	Lychee (Litchi) (Pulasan, rambutan/hairy litchi, longan, mangosteen, langsat, salak)	0,05*
162030	Passion fruit	0,05*
162040	Prickly pear (cactus fruit)	0,05*
162050	Star apple	0,05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel/yellow sapote, mamey sapote)	0,05*
162990	Others	0,05*
163000	(c) Inedible peel, large	
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05*
163030	Mangoes	0,2
163040	Papaya	0,05*
163050	Pomegranate	0,05*
163060	Cherimoya (Custard apple, sugar apple/sweetsop, ilama (Annona diversifolia) and other medium sized Annonaceae fruits)	0,05*
163070	Guava (Red pitaya/dragon fruit (Hylocereus undatus))	0,05*
163080	Pineapples	0,05*
163090	Bread fruit (Jackfruit)	0,05*
163100	Durian	0,05*
163110	Soursop (guanabana)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Triflumuron (F)
163990	Others	0,05*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	0,05*
211000	(a) Potatoes	0,05*
212000	(b) Tropical root and tuber vegetables	0,05*
212010	Cassava (Dasheen, eddoe/Japanese taro, tannia)	0,05*
212020	Sweet potatoes	0,05*
212030	Yams (Potato bean/yam bean, Mexican yam bean)	0,05*
212040	Arrowroot	0,05*
212990	Others	0,05*
213000	(c) Other root and tuber vegetables except sugar beet	0,05*
213010	Beetroot	0,05*
213020	Carrots	0,05*
213030	Celeriac	0,05*
213040	Horseradish (Angelica roots, lovage roots, gentiana roots)	0,05*
213050	Jerusalem artichokes (Crosne)	0,05*
213060	Parsnips	0,05*
213070	Parsley root	0,05*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties, tiger nut (Cyperus esculentus))	0,05*
213090	Salsify (Scorzoneria, Spanish salsify/Spanish oysterplant, edible burdock)	0,05*
213100	Swedes	0,05*
213110	Turnips	0,05*
213990	Others	0,05*
220000	(ii) Bulb vegetables	0,05*
220010	Garlic	0,05*
220020	Onions (Other bulb onions, silverskin onions)	0,05*
220030	Shallots	0,05*
220040	Spring onions and welsh onions (Other green onions and similar varieties)	0,05*
220990	Others	0,05*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Triflurumuron (F)
231010	Tomatoes (Cherry tomatoes, Physalis spp., goji berry, wolfberry (Lycium barbarum and L. chinense), tree tomato)	0,05*
231020	Peppers (Chilli peppers)	0,05*
231030	Aubergines (egg plants) (Pepino, antroewa/white eggplant (S. macrocarpon))	0,05*
231040	Okra (lady's fingers)	0,05*
231990	Others	0,05*
232000	(b) Cucurbits — edible peel	0,05*
232010	Cucumbers	0,05*
232020	Gherkins	0,05*
232030	Courgettes (Summer squash, marrow (patisson), lauki (Lagenaria siceraria), chayote, sopropo/bitter melon, snake gourd, angled luffa/teroi)	0,05*
232990	Others	0,05*
233000	(c) Cucurbits-inedible peel	0,05*
233010	Melons (Kiwano)	0,05*
233020	Pumpkins (Winter squash, marrow (late variety))	0,05*
233030	Watermelons	0,05*
233990	Others	0,05*
234000	(d) Sweet corn (Baby corn)	0,2
239000	(e) Other fruiting vegetables	0,05*
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	0,05*
241010	Broccoli (Calabrese, Broccoli raab, Chinese broccoli)	0,05*
241020	Cauliflower	0,05*
241990	Others	0,05*
242000	(b) Head brassica	
242010	Brussels sprouts	0,05*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,2
242990	Others	0,05*
243000	(c) Leafy brassica	0,05*
243010	Chinese cabbage (Indian or Chinese) mustard, pak choi, Chinese flat cabbage/ai goo choi, choy sum, Peking cabbage/pe-tsai)	0,05*
243020	Kale (Borecole/curly kale, collards, Portuguese Kale, Portuguese cabbage, cow cabbage)	0,05*
243990	Others	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Triflurumuron (F)
244000	(d) Kohlrabi	0,05*
250000	(v) Leaf vegetables & fresh herbs	0,05*
251000	(a) Lettuce and other salad plants including Brassicaceae	0,05*
251010	Lamb's lettuce (Italian corn salad)	0,05*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,05*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curly leaf endive, sugar loaf (C. endivia var. crispum/C. intybus var. foliosum), dandelion greens)	0,05*
251040	Cress (Mung bean sprouts, alfalfa sprouts)	0,05*
251050	Land cress	0,05*
251060	Rocket, Rucola (Wild rocket (Diplomatix spp.))	0,05*
251070	Red mustard	0,05*
251080	Leaves and sprouts of Brassica spp. including turnip greens (Mizuna, leaves of peas and radish and other baby leaf crops, including brassica crops (crops harvested up to 8 true leaf stage), kohlrabi leaves)	0,05*
251990	Others	0,05*
252000	(b) Spinach & similar (leaves)	0,05*
252010	Spinach (New Zealand spinach, amaranthus spinach (pak-khom, tampara), tajar leaves, bitterblad/bitawin)	0,05*
252020	Purslane (Winter purslane/miner's lettuce, garden purslane, common purslane, sorrel, glasswort, agretti (Salsola soda))	0,05*
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*
252990	Others	0,05*
253000	(c) Vine leaves (grape leaves) (Malabar nightshade, banana leaves, climbing wattle (Acacia pennata))	0,05*
254000	(d) Water cress (Morning glory/Chinese convolvulus/water convolvulus/water	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Triflurumuron (F)
	spinach/kangkung (Ipomea aquatica), water clover, water mimosa)	
255000	(e) Witloof	0,05*
256000	(f) Herbs	0,05*
256010	Chervil	0,05*
256020	Chives	0,05*
256030	Celery leaves (Fennel leaves, coriander leaves, dill leaves, caraway leaves, lovage, angelica, sweet cicely and other Apiaceae leaves, culantro/stinking/long coriander/stink weed (Eryngium foetidum))	0,05*
256040	Parsley (leaves of root parsley)	0,05*
256050	Sage (Winter savory, summer savory, Borago officinalis leaves)	0,05*
256060	Rosemary	0,05*
256070	Thyme (Marjoram, oregano)	0,05*
256080	Basil (Balm leaves, mint, peppermint, holy basil, sweet basil, hairy basil, edible flowers (marigold flower and others), pennywort, wild betel leaf, curry leaves)	0,05*
256090	Bay leaves (laurel) (Lemon grass)	0,05*
256100	Tarragon (Hyssop)	0,05*
256990	Others	0,05*
260000	(vi) Legume vegetables (fresh)	0,05*
260010	Beans (with pods) (Green bean/French beans/snap beans, scarlet runner bean, slicing bean, yard long beans, guar beans, soya beans)	0,05*
260020	Beans (without pods) (Broad beans, flageolets, jack bean, lima bean, cowpea)	0,05*
260030	Peas (with pods) (Mangetout/sugar peas/snow peas)	0,05*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,05*
260050	Lentils	0,05*
260990	Others	0,05*
270000	(vii) Stem vegetables (fresh)	0,05*
270010	Asparagus	0,05*
270020	Cardoons (Borago officinalis stems)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Triflurumuron (F)
270030	Celery	0,05*
270040	Fennel	0,05*
270050	Globe artichokes (Banana flower)	0,05*
270060	Leek	0,05*
270070	Rhubarb	0,05*
270080	Bamboo shoots	0,05*
270090	Palm hearts	0,05*
270990	Others	0,05*
280000	(viii) Fungi	0,05*
280010	Cultivated fungi (Common mushroom, oyster mushroom, shiitake, fungus mycelium (vegetative parts))	0,05*
280020	Wild fungi (Chanterelle, truffle, morel, cep)	0,05*
280990	Others	0,05*
290000	(ix) Sea weeds	0,05*
300000	3. PULSES, DRY	0,05*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,05*
300020	Lentils	0,05*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,05*
300040	Lupins	0,05*
300990	Others	0,05*
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	0,2
401010	Linseed	0,2
401020	Peanuts	0,2
401030	Poppy seed	0,2
401040	Sesame seed	0,2
401050	Sunflower seed	0,2
401060	Rape seed (Bird rapeseed, turnip rape)	0,2
401070	Soya bean	0,2
401080	Mustard seed	0,2
401090	Cotton seed	0,2
401100	Pumpkin seeds (Other seeds of Cucurbitaceae)	0,2
401110	Safflower	0,2
401120	Borage (Purple viper's bugloss/Canary flower (Echium plantagineum), Com Gromwell (Buglossoides arvensis))	0,2
401130	Gold of pleasure	0,2

Code number	Groups and examples of individual products to which the MRLs apply	Triflururon (F)
401140	Hempseed	0,2
401150	Castor bean	0,2
401990	Others	0,2
402000	(i) Oilfruits	0,05*
402010	Olives for oil production	0,05*
402020	Palm nuts (palm oil kernels)	0,05*
402030	Palmfruit	0,05*
402040	Kapok	0,05*
402990	Others	0,05*
500000	5. CEREALS	
500010	Barley	0,05*
500020	Buckwheat (Amaranthus, quinoa)	0,05*
500030	Maize	0,2
500040	Millet (Foxtail millet, teff, finger millet, pearl millet)	0,05*
500050	Oats	0,05*
500060	Rice (Indian/wild rice (Zizania aquatica))	0,05*
500070	Rye	0,05*
500080	Sorghum	0,05*
500090	Wheat (Spelt, triticale)	0,05*
500990	Others (Canary grass seeds (Phalaris canariensis))	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	
610000	(i) Tea	0,05*
620000	(ii) Coffee beans	0,05*
630000	(iii) Herbal infusions (dried)	0,05*
631000	(a) Flowers	0,05*
631010	Camomille flowers	0,05*
631020	Hybiscus flowers	0,05*
631030	Rose petals	0,05*
631040	Jasmine flowers (Elderflowers (Sambucus nigra))	0,05*
631050	Lime (linden)	0,05*
631990	Others	0,05*
632000	b) Leaves	0,05*
632010	Strawberry leaves	0,05*
632020	Rooibos leaves (Ginkgo leaves)	0,05*
632030	Maté	0,05*
632990	Others	0,05*
633000	(c) Roots	0,05*
633010	Valerian root	0,05*
633020	Ginseng root	0,05*
633990	Others	0,05*
639000	(d) Other herbal infusions	0,05*
640000	(iv) Cocoa beans (fermented or dried)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Triflururon (F)
650000	(v) Carob (st johns bread)	0,05*
700000	7. HOPS (dried)	0,05*
800000	8. SPICES	0,05*
810000	(i) Seeds	0,05*
810010	Anise	0,05*
810020	Black caraway	0,05*
810030	Celery seed (Lovage seed)	0,05*
810040	Coriander seed	0,05*
810050	Cumin seed	0,05*
810060	Dill seed	0,05*
810070	Fennel seed	0,05*
810080	Fenugreek	0,05*
810090	Nutmeg	0,05*
810990	Others	0,05*
820000	(ii) Fruits and berries	0,05*
820010	Allspice	0,05*
820020	Sichuan pepper (Anise pepper, Japan pepper)	0,05*
820030	Caraway	0,05*
820040	Cardamom	0,05*
820050	Juniper berries	0,05*
820060	Pepper, black, green and white (Long pepper, pink pepper)	0,05*
820070	Vanilla pods	0,05*
820080	Tamarind	0,05*
820990	Others	0,05*
830000	(iii) Bark	0,05*
830010	Cinnamon (Cassia)	0,05*
830990	Others	0,05*
840000	(iv) Roots or rhizome	0,05*
840010	Liquorice	0,05*
840020	Ginger	0,05*
840030	Turmeric (Curcuma)	0,05*
840040	Horseradish	0,05*
840990	Others	0,05*
850000	(v) Buds	0,05*
850010	Cloves	0,05*
850020	Capers	0,05*
850990	Others	0,05*
860000	(vi) Flower stigma	0,05*
860010	Saffron	0,05*
860990	Others	0,05*
870000	(vii) Aril	0,05*
870010	Mace	0,05*
870990	Others	0,05*
900000	9. SUGAR PLANTS	0,05*
900010	Sugar beet (root)	0,05*
900020	Sugar cane	0,05*
900030	Chicory roots	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Triflururon (F)
900990	Others	0,05*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	0,01*
1010000	(i) Tissue	0,01*
1011000	(a) Swine	0,01*
1011010	Muscle	0,01*
1011020	Fat	0,01*
1011030	Liver	0,01*
1011040	Kidney	0,01*
1011050	Edible offal	0,01*
1011990	Others	0,01*
1012000	(b) Bovine	0,01*
1012010	Muscle	0,01*
1012020	Fat	0,01*
1012030	Liver	0,01*
1012040	Kidney	0,01*
1012050	Edible offal	0,01*
1012990	Others	0,01*
1013000	(c) Sheep	0,01*
1013010	Muscle	0,01*
1013020	Fat	0,01*
1013030	Liver	0,01*
1013040	Kidney	0,01*
1013050	Edible offal	0,01*
1013990	Others	0,01*
1014000	(d) Goat	0,01*
1014010	Muscle	0,01*
1014020	Fat	0,01*
1014030	Liver	0,01*
1014040	Kidney	0,01*
1014050	Edible offal	0,01*
1014990	Others	0,01*
1015000	(e) Horses, asses, mules or hinnies	0,01*
1015010	Muscle	0,01*
1015020	Fat	0,01*
1015030	Liver	0,01*
1015040	Kidney	0,01*
1015050	Edible offal	0,01*
1015990	Others	0,01*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,01*
1016010	Muscle	0,01*
1016020	Fat	0,01*
1016030	Liver	0,01*
1016040	Kidney	0,01*
1016050	Edible offal	0,01*
1016990	Others	0,01*

Code number	Groups and examples of individual products to which the MRLs apply	Triflururon (F)
1017000	(g) Other farm animals (Rabbit, kangaroo, deer)	0,01*
1017010	Muscle	0,01*
1017020	Fat	0,01*
1017030	Liver	0,01*
1017040	Kidney	0,01*
1017050	Edible offal	0,01*
1017990	Others	0,01*
1020000	(ii) Milk	0,01*
1020010	Cattle	0,01*
1020020	Sheep	0,01*
1020030	Goat	0,01*
1020040	Horse	0,01*
1020990	Others	0,01*
1030000	(iii) Bird eggs	0,01*
1030010	Chicken	0,01*
1030020	Duck	0,01*
1030030	Goose	0,01*
1030040	Quail	0,01*
1030990	Others	0,01*
1040000	(iv) Honey (Royal jelly, pollen, honey comb with honey (comb honey))	0,01*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,01*
1060000	(vi) Snails	0,01*
1070000	(vii) Other terrestrial animal products (Wild game)	0,01*

(\*) Indicates lower limit of analytical determination



## ABBREVIATIONS

ADI	acceptable daily intake
AR	Additional Report
AR	applied radioactivity
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DAR	Draft Assessment Report
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (former GIFAP)
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
i.e.	that is (id est, <i>Latin</i> )
ISO	International Organization for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
L	litre
LOQ	limit of quantification
MRL	maximum residue level
MS/MS	tandem mass spectrometry
OECD	Organization for Economic Co-operation and Development
PHI	pre-harvest interval
P <sub>ow</sub>	partition coefficient between n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model

R <sub>ber</sub>	statistical calculation of the MRL by using a non-parametric method
R <sub>max</sub>	statistical calculation of the MRL by using a parametric method
RAC	raw agricultural commodity
RMS	rapporteur Member State
SEU	Southern European Union
SC	suspension concentrate
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WHO	World Health Organization
yr	year
ZA	South Africa