

## REASONED OPINION

### Reasoned opinion on the modification of the existing MRLs for teflubenzuron in various fruiting vegetables<sup>1</sup>

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

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#### SUMMARY

According to Article 6 of the Regulation (EC) No 396/2005, the Netherlands, herewith referred to as the Evaluating Member State (EMS), received an application from the company Exponent International Ltd. to modify the existing MRLs for the active substance teflubenzuron in tomatoes, peppers, aubergines, okra, cucumbers, gherkins and courgettes. In order to accommodate for the intended indoor use of teflubenzuron on these crops in the Netherlands, the EMS proposes to raise the existing MRLs in these crops and to delete the MRL in pome fruit, taking into account the restrictions on the use of teflubenzuron according to Commission Directive 2009/37/EC (only uses in glasshouses on artificial substrate or closed hydroponic systems can be authorized). The EMS Netherlands drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 13 September 2011.

EFSA derives the following conclusions based on the submitted evaluation report prepared by the EMS Netherlands, the Draft Assessment Report (DAR) prepared by the rapporteur Member State (RMS) United Kingdom under Directive 91/414/EEC and the EFSA conclusion on the peer review of teflubenzuron.

The toxicological profile of teflubenzuron was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI value of 0.01 mg/kg bw/day. Due to the low acute toxicity of the active substance the setting of an ARfD was considered not necessary.

The metabolism of teflubenzuron in primary crops was investigated in fruit crops and root and tuber vegetables. Based on the results of the metabolism studies the peer review concluded on a provisional residue definition for fruit and root crops for monitoring and risk assessment as teflubenzuron only. Residue definition according to Regulation (EC) No 396/2005 is established as parent teflubenzuron. For the uses on the crops under consideration, which belong to the group of fruits and fruiting vegetables, EFSA concludes that the metabolism of teflubenzuron is sufficiently elucidated and the provisional residue definitions agreed in the peer review are applicable. Adequate analytical enforcement methods are available to control teflubenzuron residues in the crops under consideration.

The submitted residue data are sufficient to derive the following MRL proposals in support of the intended indoor use in the Netherlands: 1.5 mg/kg in the whole group of *Solanaceae*, 0.5 mg/kg in

<sup>1</sup> On request from the European Commission, Question No EFSA-Q-2011-01027, approved on 21 March 2012.

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courgettes and 1.5 mg/kg in gherkins. For cucumbers there is no need to modify the existing MRL of 0.5 mg/kg. The existing EU MRL of 1 mg/kg for pome fruit which is proposed for the deletion is identical to the CXL for pome fruit, established by the JMPR in 1996 in support of the southern European uses. According to the JMPR, the use of teflubenzuron is authorized also in Jordan, The United Arab Emirates (apples and pears) and in Argentina (apples only). The deletion of the CXL/EU MRL for teflubenzuron in pome fruits might affect the international trade.

The effect of processing on the nature of teflubenzuron residues has not been investigated in standard hydrolysis studies. Instead, the studies submitted for the peer review investigating the effects of processing on the magnitude of residues in heated apple pomace and canned sterilized tomatoes were considered sufficient by the peer review to demonstrate the stability of teflubenzuron under processing conditions. The effects of processing on the magnitude of teflubenzuron residues in processed tomatoes were assessed in the framework of the peer review and the relevant processing factors were derived which are now proposed for the enforcement purposes:

- Tomatoes, juice: 0.17
- Tomatoes, puree: 0.45
- Tomatoes, canned tomatoes: 0.07

Processing studies with other crops under consideration have not been performed and are not necessary given the low contribution of these commodities to the total dietary intake.

Since the proposed use of teflubenzuron is on artificial soil/hydroponic systems in glasshouse, investigations of residues in rotational crops are not relevant. The crops under consideration are not fed to livestock and therefore the nature and magnitude of teflubenzuron residues in livestock was not assessed in the framework of this application.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the calculation of the chronic exposure, EFSA used the median residue values as derived from the residue trials on peppers, tomatoes, cucumbers and gherkins. The median residue value for tomatoes was used also as an input value for aubergines and okra, whereas the median residue value for cucumbers was used as an input value for courgettes. For pome fruit the median residue value was available to refine the intake calculations. 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. Acute exposure calculations were not undertaken due to the low acute toxicity of the active substance. The estimated chronic exposure was then compared with the toxicological reference value derived for teflubenzuron.

Chronic consumer intake concerns were identified for one diet incorporated in the EFSA PRIMo. The total calculated exposure accounted for up to **116%** of the ADI for German child diet. The main contributor to the total exposure was apple, accounting for 58% (scenario 1).

According to Directive 2009/37/EC, the use of teflubenzuron on apples cannot anymore be authorized in the EU and therefore the MRL for teflubenzuron in apples should be deleted, e.g. set at the LOQ. EFSA thus performed a second consumer exposure calculation (scenario 2), using the LOQ of 0.01 mg/kg as an input value for apple. In this case, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values ranged from **14 to 76 %** of the ADI (maximum for WHO Cluster diet B). The contribution of residues in the crops under consideration to the total consumer exposure (in the percentage of the ADI) accounted for a maximum of 10.2% for tomatoes (WHO Cluster diet B), 2.3% for peppers (WHO Cluster diet B), 1.6% for cucumbers (DK child diet) and below 1% for aubergines, okra, gherkins and courgettes. Further lowering of the chronic consumer exposure is expected when all uses not supported according to Commission Directive 2009/37/EC are withdrawn.

Provided that the existing MRL for apple is deleted, EFSA concludes that the intended use of teflubenzuron on the crops under consideration will not result in a consumer exposure exceeding the toxicological reference values and therefore will not pose a public health concern.

EFSA notes that the existing MRLs for crops which cannot be grown in glasshouses (on artificial substrate or closed hydroponic systems) and for which the existing EU MRL is above the LOQ, could be considered for deletion, taking into account the restrictions of the approval for teflubenzuron. However, the need to keep certain MRLs to accommodate for the international trade (e.g. CXLs) has to be taken into account.

The recommendations of EFSA are compiled in the table below:

Code number <sup>a</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
<b>Enforcement residue definition: Teflubenzuron</b>				
0231010	Tomatoes	1	1.5	Provided that the existing MRL for apple is deleted, no risk for consumers was identified for the intended indoor uses. The MRL proposals are sufficiently supported by data.
0231020	Peppers	0.5	1.5	
0231030	Aubergines (egg plants)	0.5	1.5	
0231040	Okra, lady`s fingers	0.5	1.5	
0232010	Cucumbers	0.5	0.5 (no new proposal)	
0232020	Gherkins	0.5	1.5	
0232030	Courgettes	0.2	0.5	
0130010	Apples	1	0.01* (LOQ)	The use of teflubenzuron on apples is not anymore supported in the EU according to Directive 2009/37/EC and therefore the deletion of EU MRL is proposed. However, since the CXL is identical with the existing EU MRL, this deletion might have an effect on the international trade.

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

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

## KEY WORDS

Teflubenzuron, Solanaceae, cucurbits with edible peel, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, benzoylurea insecticide

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## BACKGROUND

Commission Regulation (EC) No 396/2005<sup>3</sup> establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that a party 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 set or modify an MRL in accordance with the provisions of Article 7 of that regulation.

The Netherlands, hereafter referred to as the evaluating Member State (EMS), received an application from the company Exponent International Ltd.<sup>6</sup> to modify the existing MRLs for the active substance teflubenzuron in *Solanaceae* (tomato, pepper, aubergine, okra) and cucurbits with edible peel and to delete the MRLs for pome fruit. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 13 September 2011. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2011-01027 and the following subject:

*Teflubenzuron - Application to modify the existing MRLs in Solanaceae and cucurbits (edible peel) and to delete the MRLs for pome fruit.*

The EMS proposed the following MRLs: 0.05\* (LOQ) in pome fruit and 1 mg/kg in the whole group of *Solanaceae* and cucurbits with edible peel.

EFSA then proceeded with the assessment of the application 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 calculated deadline for providing the reasoned opinion is 13 December 2011.

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<sup>3</sup> Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005. OJ L 70, 16.3.2005, p. 1-16.

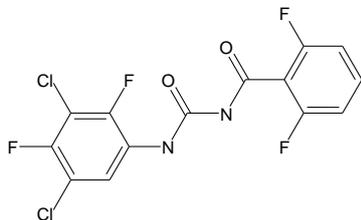
<sup>4</sup> Council Directive 91/414/EEC of 15 July 1991, OJ L 230, 19.8.1991, p. 1-32.

<sup>5</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009. OJ L 309, 24.11.2009, p. 1-50.

<sup>6</sup> Exponent International Ltd., Hornbeam Park, The Lenz, HG2 8RE, Harrogate, The United Kingdom

## THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Teflubenzuron is the ISO common name for 1-(3,5-dichloro-2,4-difluorophenyl)-3-(2,6-difluorobenzoyl)urea (IUPAC).



Teflubenzuron belongs to the class of benzoylurea insecticides. It acts by inhibition of chitin synthesis and moulting, disrupting chitin deposition in the insect cuticle after ingestion. It may affect fertility of female insects after contact or ingestion. Teflubenzuron is used in agriculture to control codling moth, leaf miners, whiteflies and caterpillars in fruit trees, vines, vegetables, potatoes, soybean, tobacco, cotton. Teflubenzuron is fat soluble.

Teflubenzuron was assessed as a stage three active substance according to Directive 91/414/EEC with the United Kingdom being the designated rapporteur Member State (RMS). The representative uses assessed for the peer review were foliar application on apples and tomatoes (indoor) for the control of codling moth, leaf miners, whiteflies and caterpillars. EFSA was involved in the peer review and therefore an EFSA conclusion is available (EFSA, 2008a). The active substance was included in Annex I of Directive 91/414/EEC by means of Commission Directive 2009/37/EC<sup>7</sup> for uses as an insecticide only in glasshouses (on artificial substrate or closed hydroponic systems). The Member States had to withdraw the existing authorisations for plant protection products containing teflubenzuron by 31 May 2010.

The EU MRLs for teflubenzuron are established in the framework of the setting of temporary MRLs (EFSA, 2007b) in Annex IIIA of Regulation (EC) No 396/2005 (Appendix C). The existing EU MRLs for teflubenzuron are set at 1 mg/kg in pome fruit and tomatoes, at 0.5 mg/kg in peppers, aubergines, okra, cucumbers, gherkins and at 0.2 mg/kg in courgettes. In 2008 EFSA issued a reasoned opinion on the modification of the existing MRL for teflubenzuron on peppers but no MRL proposal was derived due to chronic consumer intake concerns identified, mainly driven by the existing EU MRL in apples (EFSA, 2008b). The Codex Alimentarius Commission has established CXLs for teflubenzuron in several crops: 1 mg/kg in pome fruit, 0.5 mg/kg in Brussels sprouts, 0.2 mg/kg in head cabbage, 0.1 mg/kg in plums (including prunes) and 0.05\* mg/kg in potatoes (see Appendix D).

The intended GAP in the Netherlands for which a modification of the existing MRLs is requested refers to an indoor foliar application of teflubenzuron on the crops grown in artificial soil/hydroponic systems. The intended application rate is 0.075-0.225 kg a.s./ha. The PHI is 3 days. The details of the GAP are given in Appendix A.

In addition, the Netherlands propose the deletion of the MRL for the whole group of pome fruit, taking into account the Annex I inclusion restrictions for teflubenzuron as referred to in Commission Directive 2009/37/EC, i.e., only uses in glasshouses on artificial substrate or closed hydroponic systems can be authorized in the EU.

<sup>7</sup> Commission Directive 2009/37/EC of 23 April 2009, OJ L 104, 24.4.2009., 23-32 pp.

## ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (The Netherlands, 2011), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (The United Kingdom, 2007), the conclusions on the peer review of the pesticide risk assessment of the active substance teflubenzuron (EFSA, 2008a) as well as a previous EFSA opinion on teflubenzuron (EFSA, 2008b). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation of the Authorization of Plant Protection Products set out in Regulation (EU) No 546/2011<sup>8</sup> and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2004, 2008, 2010, 2011; OECD, 2011a, 2011b).

### 1. Methods of analysis

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

Analytical methods for the determination of teflubenzuron residues in plant commodities were assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2008a). The experts concluded that residues of teflubenzuron in high water content plant matrices can be monitored by HPLC-UV at an LOQ of 0.05 mg/kg. However, a data gap was set by the peer review experts regarding the independent laboratory validation (ILV) for the enforcement method for tomatoes. The multi-residue method DFG S 19 with GC-ECD can be used to determine the residues of teflubenzuron in apple with an LOQ of 0.01 mg/kg, but further validation data were required for accuracy and precision (EFSA, 2008a). The applicant has not provided additional validation data for the determination of teflubenzuron in matrices with high water content.

The multi-residue QuEChERS method described in the European Standard EN 15662:2008 is also applicable for the determination of teflubenzuron residues in high water content matrices at the validated LOQ of 0.01 mg/kg (CEN, 2008).

EFSA therefore concludes that sufficiently validated analytical methods are available to monitor teflubenzuron residues in the crops under consideration.

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

Analytical methods for the determination of teflubenzuron residues in food of animal origin were not assessed, since no MRLs are proposed for food commodities of animal origin in the framework of this application.

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<sup>8</sup> Commission Regulation (EU) No 546/2011 of 10 June 2011, OJ L 155, 11.6.2011, p.127-174

## 2. Mammalian toxicology

The toxicological profile of the active substance teflubenzuron was assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2008a). The data were sufficient to derive toxicological reference values for which are compiled in Table 2-1.

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

	Source	Year	Value	Study relied upon	Safety factor
Teflubenzuron					
ADI	EFSA	2008	0.01 mg/kg bw/d	Mouse carcinogenicity	200*
ARfD	EFSA	2008	Not allocated		

(\*): Based on an LOAEL

## 3. Residues

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

#### 3.1.1. Primary crops

##### 3.1.1.1. Nature of residues

The metabolism of teflubenzuron in primary crops was evaluated in the framework of the peer review under Directive 91/414/EEC (EFSA, 2008a). The overview of the metabolism study designs is presented in the table below.

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

Group	Crop	Label position	Application details				Remarks
			Method, F, G or P <sup>(a)</sup>	Rate	No/ Interval	Sampling	
Fruits and fruiting vegetable	Apples	Aniline ring <sup>14</sup> C	Foliar/F	0.02 kg a.s./hL (total rate 0.8 mL /apple)	3/3 weeks	After 1 <sup>st</sup> , 2 <sup>nd</sup> and 3 <sup>rd</sup> treatment and at maturity	
Leafy vegetables	Spinach	Aniline ring <sup>14</sup> C	Foliar/G	0.06 kg a.s./ha	1 (run-off)/ 21 days after sowing	0, 8 and 15 DAT	**
Root and tuber vegetables	Potatoes	Aniline ring <sup>14</sup> C	1) Foliar /G 2) Soil treatment/ G	0.09 kg a.s./ha	4/ 2 weeks	63 DAT (maturity)	

(a): Outdoor/field use (F) or glasshouse/ /indoor application (G) or protected (P)

\*\*): During the EFSA evaluation, the study on spinach was regarded as non-acceptable, requesting further metabolism studies to be submitted (EFSA, 2008a).

The peer review experts meeting discussed the acceptability of the metabolism studies in primary crops. The main issues of concern were 23% non characterised radioactive residues in one spinach sample and the fact that in all metabolism studies on primary crops only aniline ring labelled teflubenzuron was used. The peer review concluded that due to the high proportion of teflubenzuron found in apples and tomatoes (98%), studies with labels in both rings are not required for the supported uses. However, further investigation of leaf metabolism with labelling in both rings is required in case of future uses on leafy crops. If cleavage of the teflubenzuron molecule is detected in these new metabolism studies and taking into account the toxicity of the found metabolites it may be necessary to perform metabolism studies in other crops.

On the basis of the results of the metabolism studies on primary crops the peer review concluded on a provisional residue definition for fruit and root crops for monitoring and risk assessment as teflubenzuron only. For the uses on the crops under consideration, which belong to the group of fruits and fruiting vegetables, EFSA concludes that the metabolism of teflubenzuron is sufficiently elucidated and the provisional residue definitions agreed in the peer review are applicable.

The existing enforcement residue definition according to Regulation (EC) No 396/2005 is established as parent teflubenzuron.

#### 3.1.1.2. Magnitude of residues

##### *a) Peppers*

The intended use on peppers is the same for which an authorisation was required according to the previously issued EFSA reasoned opinion (EFSA, 2008b) and therefore the EMS resubmitted the same four residue trials on peppers. All trials have been performed according to the intended GAP. Peppers, according to the EU guidance document, until 1 April 2013 are still considered as minor crop in the NEU (EC, 2011) and therefore the submitted 4 residue trials are sufficient to support the intended indoor use on peppers in the Netherlands.

##### *b) Tomatoes*

The intended use on tomatoes is the same which was assessed in the framework of the peer review (EFSA, 2008a) and therefore the EMS referred to residue trials on tomatoes submitted in support of this use and as reported in the EFSA conclusion. All residue trials, according to the peer review, were compliant with the intended GAP. In addition, 4 GAP compliant residue trials on cherry tomatoes were submitted in the framework of the current application. Trials were performed in 2009 in Italy, Spain and northern and southern France. The available residue trials on tomatoes and cherry tomatoes were combined. The number of trials is sufficient according to the EU guidance document (EC, 2011) to support the intended indoor use on tomatoes in the Netherlands.

##### *c) Aubergine, okra*

No residue trials have been submitted on aubergines and okra. The EMS proposes to combine the residue data on tomatoes and peppers and to extrapolate them to aubergines and okra. According to EU guidance documents, it is acceptable to extrapolate the residue data from tomatoes to aubergines and sufficient residue trials are available to support this extrapolation (EC, 2011). No specific extrapolation rules are given in the EU guidance document regarding okra. Considering that this is a minor crop, EFSA used the residue trial data on tomatoes to support the intended use on okra.

d) *Cucumbers*

The applicant submitted 8 indoor residue trials on cucumbers which were performed in the Netherlands (5), northern France (1), southern France (1) and Greece (1) in 2000 or 2009. Two of these residue trials were designed as residue decline trials. Five residue trials from the Netherlands were performed with 2 instead of 3 applications; at the same time, the application rate was slightly higher, but within the acceptable deviation of 25%. The EMS is of the opinion that the higher application rate will compensate for the lower number of applications. The residues in all underdosed trial samples were within the same range as in the GAP compliant trials on cucumbers and therefore, considering also the arguments of the EMS, EFSA accepted the submitted residue trials data.

The applicant proposes to extrapolate the residue data from cucumbers to courgettes. Such an extrapolation is acceptable according to EU guidance document and a sufficient number of trials has been submitted to support this extrapolation (EC, 2011).

e) *Gherkins*

The applicant also submitted 4 GAP compliant indoor residue trials on gherkins. Trials were performed in 2009 in Spain and Poland and were designed as residue decline studies.

f) *Pome fruit*

The EMS proposes to delete the MRL for pome fruit, taking into account the Annex I inclusion restrictions for teflubenzuron as referred to in Commission Directive 2009/37/EC. The existing EU MRL for teflubenzuron in pome fruit is set at 1 mg/kg and is identical to the CXL set for pome fruit, which is based on the southern European uses evaluated by the JMPR in 1996 (FAO, 1996). According to the JMPR, the use of teflubenzuron is authorized also in Jordan, The United Arab Emirates on apples and pears and in Argentina (apples only) (FAO, 1996). The deletion of the CXL/EU MRL for teflubenzuron in pome fruits might affect the international trade.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarized in Table 3-2.

In the framework of the peer review of teflubenzuron several storage stability studies were submitted. Storage stability studies were carried out in tomato, apple, pear, potato and cabbage. Storage stability studies demonstrate that teflubenzuron is stable in apple, pear, potato and cabbage for 36 months and in tomatoes for 18 months when stored under deep frozen conditions (EFSA, 2008a). Prior to analysis, pepper samples were stored frozen for a maximum of 15 months, cherry tomato samples for a maximum of ca. 8 months, cucumber samples for 15 months and gherkin samples for ca. 7 months. As the supervised residue trial samples were stored under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability.

According to the EMS, the analytical methods used to analyse supervised residue trial samples have been sufficiently validated and were proven to be fit for purpose (The Netherlands, 2011).

EFSA considers that the data are sufficient to derive the following MRL proposals in support of the intended indoor use in the Netherlands: 1.5 mg/kg in the whole group of *Solanaceae*, 0.5 mg/kg in courgettes and 1.5 mg/kg in gherkins. For cucumbers there is no need to modify the existing MRL of 0.5 mg/kg.

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

Commodity	Region <sup>(a)</sup>	Outdoor/Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) <sup>(b)</sup>	Highest residue (mg/kg) <sup>(c)</sup>	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement (Teflubenzuron)	Risk assessment (Teflubenzuron)					
Sweet pepper	EU	Indoor	0.41; 0.46; 0.46; 0.61	0.41; 0.46; 0.46; 0.61	0.46	0.61	1.5	1.0	R <sub>ber</sub> =1.45 R <sub>max</sub> =0.93 OECD MRL <sup>e</sup> =1.5
Tomatoes (incl. cherry tomatoes) → aubergines, okra	EU	Indoor	3 x 0.07; 0.09; <u>0.26</u> ; 0.32; 0.33; 0.35; <u>0.42</u> ; 0.49; <u>0.58</u> ; <u>0.88</u>	3 x 0.07; 0.09; <u>0.26</u> ; 0.32; 0.33; 0.35; <u>0.42</u> ; 0.49; <u>0.58</u> ; <u>0.88</u>	0.33	0.88	1.5	1.0	The underlined values refer to residue trials on cherry tomatoes R <sub>ber</sub> =0.95 R <sub>max</sub> =0.99 OECD MRL <sup>e</sup> =1.5 (rounded) and 1.3 (unrounded)
Cucumbers → courgettes	EU	Indoor	<u>0.05</u> ; 0.05; 0.06; <u>0.1</u> ; <u>0.1</u> ; <u>0.12</u> ; <u>0.16</u> ; 0.33	<u>0.05</u> ; 0.05; 0.06; <u>0.1</u> ; <u>0.1</u> ; <u>0.12</u> ; <u>0.16</u> ; 0.33	0.1	0.33	0.5	1.0	The underlined values refer to underdosed residue trials. R <sub>ber</sub> =0.3 R <sub>max</sub> =0.42 OECD MRL <sup>e</sup> =0.5
Gherkins	EU	Indoor	0.08; 0.23 <sup>f</sup> ; 0.42; 0.55	0.08; 0.23 <sup>f</sup> ; 0.42; 0.55	0.33	0.55	1.5	1.0	R <sub>ber</sub> =1.38 R <sub>max</sub> =1.04 OECD MRL <sup>e</sup> =1.5 (rounded) and 1.15 (unrounded value)
Apples → pome fruit	SEU	Outdoor	0.23; 0.27; 0.43; 0.45; 0.51; 0.6; 0.65; 0.71	0.23; 0.27; 0.43; 0.45; 0.51; 0.6; 0.65; 0.71	0.48	0.71	1 (=existing EU MRL proposed for deletion)	1.0	The EMS proposes to delete the existing EU MRL which is identical with the CXL and is based on the SEU use (FAO, 1996).

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.

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

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

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

(e) : The MRL calculated using the OECD MRL calculator (OECD, 2011b)

(f) : Residue value within a trial higher at a longer PHI of 6 days.

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

The effect of processing on the nature of teflubenzuron has not been investigated under standard hydrolysis studies. The peer review concluded on the basis of studies investigating effects of processing on the magnitude of residues that teflubenzuron remains stable when apple pomace is heated in an oven at 90°C for several hours. Teflubenzuron was shown also to be stable in peeled and canned tomatoes during sterilisation. The EFSA evaluation considered these results sufficient to demonstrate stability of teflubenzuron under processing conditions (EFSA, 2008a).

The effects of processing on the magnitude of teflubenzuron residues in processed tomatoes were assessed in the framework of the peer review and the relevant processing factors were derived (EFSA, 2008a) which are now proposed for the enforcement purposes:

- Tomatoes, juice: 0.17
- Tomatoes, puree: 0.45
- Tomatoes, canned tomatoes: 0.07

Processing studies with other crops under consideration have not been performed and are not necessary given the low contribution of these crops to the total dietary intake.

### 3.1.2. Rotational crops

Since the proposed use of teflubenzuron is on artificial soil/hydroponic systems in glasshouses, the investigation of residues in rotational crops is not relevant.

## 3.2. Nature and magnitude of residues in livestock

Since the crops under consideration are not fed to livestock, the nature and magnitude of teflubenzuron residues in livestock was not assessed in the framework of this application.

## 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>9</sup> (EFSA, 2007a).

For the calculation of the chronic exposure, EFSA used the median residue values as derived from the residue trials on peppers, tomatoes, cucumbers and gherkins (see Table 3-2). The median residue value for tomatoes was used also as an input value for aubergines and okra whereas the median residue value for cucumbers was used as an input value for courgettes. For pome fruit the median residue value supporting the existing MRL was used as an input value to refine the intake calculations (FAO, 1996). 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. The model assumptions for the long-term exposure assessment are considered to be rather conservative, assuming that all food items consumed have been treated with the active substance under consideration. In

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<sup>9</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, 2007a).

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.

Acute consumer exposure was not performed due to the low acute toxicity of the active substance.

The input values used for the dietary exposure calculation are summarized in Table 4-1.

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

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<b>Risk assessment residue definition: Teflubenzuron</b>				
Peppers	0.46	Median residue (Table 3-2)	Acute exposure calculation was not performed due to the low acute toxicity of the active substance.	
Tomatoes	0.33	Median residue (Table 3-2)		
Aubergines, okra	0.33	Median residue (tomatoes) (Table 3-2)		
Cucumbers, courgettes	0.1	Median residue (Table 3-2)		
Gherkins	0.33	Median residue (Table 3-2)		
Apples	0.48 <sup>a</sup> /0.01 <sup>b</sup>	Median residue <sup>a</sup> (FAO, 1996)/LOQ <sup>b</sup>		
Pears, quinces, medlar, loquat	0.48	Median residue (FAO, 1996)		
Other commodities of food and animal origin	MRL	See Appendix C		

(a): Input value in scenario 1

(b): Input value in scenario 2

The estimated chronic exposure was then compared with the toxicological reference value derived for teflubenzuron (see Table 2-1). The results of the intake calculation are presented in Appendix B to this reasoned opinion.

Chronic consumer intake concerns were identified for one diet incorporated in the EFSA PRIMo. The total calculated exposure accounted for up to 116% of the ADI for German child diet. The main contributor to the total exposure was apple, accounting for 58% (see **scenario 1** in Appendix B).

According to Directive 2009/37/EC, the use of teflubenzuron on apples cannot anymore be authorized in the EU and therefore the MRL for teflubenzuron in apples should be deleted, e.g. set at the LOQ. EFSA thus performed a second consumer exposure calculation (**scenario 2**), using the LOQ of 0.01 mg/kg as an input value for apple. In this case, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values ranged from 14 to 76 % of the ADI (maximum for WHO Cluster diet B). The contribution of residues in the crops under consideration to the total consumer exposure (in the percentage of the ADI) accounted for a maximum of 10.2% for tomatoes (WHO Cluster diet B), 2.3% for peppers (WHO Cluster diet B), 1.6% for cucumbers (DK child diet) and below 1% for aubergines, okra, gherkins and courgettes.

Further lowering of the chronic consumer exposure is expected when all uses not supported according to Commission Directive 2009/37/EC are withdrawn. However, the need to keep certain MRLs to accommodate for the international trade (e.g. CXLs) has to be taken into account.

Provided that the existing MRL for apple is deleted, EFSA concludes that the intended use of teflubenzuron on the crops under consideration will not result in a consumer exposure exceeding the toxicological reference values and therefore will not pose a public health concern.

## CONCLUSIONS AND RECOMMENDATIONS

### CONCLUSIONS

The toxicological profile of teflubenzuron was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI value of 0.01 mg/kg bw/day. Due to the low acute toxicity of the active substance the setting of an ARfD was considered not necessary.

The metabolism of teflubenzuron in primary crops was investigated in fruit crops and root and tuber vegetables. Based on the results of the metabolism studies the peer review concluded on a provisional residue definition for fruit and root crops for monitoring and risk assessment as teflubenzuron only. Residue definition according to Regulation (EC) No 396/2005 is established as parent teflubenzuron. For the uses on the crops under consideration, which belong to the group of fruits and fruiting vegetables, EFSA concludes that the metabolism of teflubenzuron is sufficiently elucidated and the provisional residue definitions agreed in the peer review are applicable. Adequate analytical enforcement methods are available to control teflubenzuron residues in the crops under consideration.

The submitted residue data are sufficient to derive the following MRL proposals in support of the intended indoor use in the Netherlands: 1.5 mg/kg in the whole group of *Solanaceae*, 0.5 mg/kg in courgettes and 1.5 mg/kg in gherkins. For cucumbers there is no need to modify the existing MRL of 0.5 mg/kg. The existing EU MRL of 1 mg/kg for pome fruit which is proposed for the deletion is identical to the CXL for pome fruit, established by the JMPR in 1996 in support of the southern European uses. According to the JMPR, the use of teflubenzuron is authorized also in Jordan, The United Arab Emirates (apples and pears) and in Argentina (apples only). The deletion of the CXL/EU MRL for teflubenzuron in pome fruits might affect the international trade.

The effect of processing on the nature of teflubenzuron residues has not been investigated in standard hydrolysis studies. Instead, the studies submitted for the peer review investigating the effects of processing on the magnitude of residues in heated apple pomace and canned sterilized tomatoes were considered sufficient by the peer review to demonstrate the stability of teflubenzuron under processing conditions. The effects of processing on the magnitude of teflubenzuron residues in processed tomatoes were assessed in the framework of the peer review and the relevant processing factors were derived which are now proposed for the enforcement purposes:

- Tomatoes, juice: 0.17
- Tomatoes, puree: 0.45
- Tomatoes, canned tomatoes: 0.07

Processing studies with other crops under consideration have not been performed and are not necessary given the low contribution of these commodities to the total dietary intake.

Since the proposed use of teflubenzuron is on artificial soil/hydroponic systems in glasshouse, investigations of residues in rotational crops are not relevant. The crops under consideration are not fed to livestock and therefore the nature and magnitude of teflubenzuron residues in livestock was not assessed in the framework of this application.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the calculation of the chronic exposure, EFSA used the median residue values as derived from the residue trials on peppers, tomatoes, cucumbers and gherkins. The median residue value for tomatoes was used also as an input value for aubergines and okra, whereas the median residue value for cucumbers was used as

an input value for courgettes. For pome fruit the median residue value was available to refine the intake calculations. 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. Acute exposure calculations were not undertaken due to the low acute toxicity of the active substance. The estimated chronic exposure was then compared with the toxicological reference value derived for teflubenzuron.

Chronic consumer intake concerns were identified for one diet incorporated in the EFSA PRIMo. The total calculated exposure accounted for up to **116%** of the ADI for German child diet. The main contributor to the total exposure was apple, accounting for 58% (scenario 1).

According to Directive 2009/37/EC, the use of teflubenzuron on apples cannot anymore be authorized in the EU and therefore the MRL for teflubenzuron in apples should be deleted, e.g. set at the LOQ. EFSA thus performed a second consumer exposure calculation (scenario 2), using the LOQ of 0.01 mg/kg as an input value for apple. In this case, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values ranged from **14 to 76 %** of the ADI (maximum for WHO Cluster diet B). The contribution of residues in the crops under consideration to the total consumer exposure (in the percentage of the ADI) accounted for a maximum of 10.2% for tomatoes (WHO Cluster diet B), 2.3% for peppers (WHO Cluster diet B), 1.6% for cucumbers (DK child diet) and below 1% for aubergines, okra, gherkins and courgettes. Further lowering of the chronic consumer exposure is expected when all uses not supported according to Commission Directive 2009/37/EC are withdrawn.

Provided that the existing MRL for apple is deleted, EFSA concludes that the intended use of teflubenzuron on the crops under consideration will not result in a consumer exposure exceeding the toxicological reference values and therefore will not pose a public health concern.

EFSA notes that the existing MRLs for crops which cannot be grown in glasshouses (on artificial substrate or closed hydroponic systems) and for which the existing EU MRL is above the LOQ, could be considered for deletion, taking into account the restrictions of the approval for teflubenzuron. However, the need to keep certain MRLs to accommodate for the international trade (e.g. CXLs) has to be taken into account.

## 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: Teflubenzuron</b>				
0231010	Tomatoes	1	1.5	Provided that the existing MRL for apple is deleted, no risk for consumers was identified for the intended indoor uses. The MRL proposals are sufficiently supported by data.
0231020	Peppers	0.5	1.5	
0231030	Aubergines (egg plants)	0.5	1.5	
0231040	Okra, lady`s fingers	0.5	1.5	
0232010	Cucumbers	0.5	0.5 (no new proposal)	
0232020	Gherkins	0.5	1.5	
0232030	Courgettes	0.2	0.5	

Code number <sup>a</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
0130010	Apples	1	0.01* (LOQ)	The use of teflubenzuron on apples is not anymore supported in the EU according to Directive 2009/37/EC and therefore the deletion of EU MRL is proposed. However, since the CXL is identical with the existing EU MRL, this deletion might have an effect on the international trade.

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

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

## REFERENCES

- Anastassiades M, Lehotay SJ, Stajnbaher D, Schenck FJ, 2003. Fast and Easy Multiresidue Method Employing Acetonitrile Extraction/Partitioning and Dispersive Solid-Phase Extraction for the Determination of Pesticide Residues in Produce. *Journal of AOAC International*, 86, 22, 412-431.
- CEN (European Committee for Standardization), 2008. Foods of plant origin - Determination of pesticide residues using GC-MS and/or LC-MS/MS following acetonitrile extraction/partitioning and clean-up by dispersive SPE. QuEChERS-method. EN EN 15662.2008. November 2008.
- EC (European Commission), 1996. Appendix G. Livestock Feeding Studies. 7031/VI/95 rev.4. Available from: [http://ec.europa.eu/food/plant/protection/resources/publications\\_en.htm](http://ec.europa.eu/food/plant/protection/resources/publications_en.htm).
- EC (European Commission), 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev.3. Available from: [http://ec.europa.eu/food/plant/protection/resources/publications\\_en.htm](http://ec.europa.eu/food/plant/protection/resources/publications_en.htm)
- EC (European Commission), 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev.6. Available from: [http://ec.europa.eu/food/plant/protection/resources/publications\\_en.htm](http://ec.europa.eu/food/plant/protection/resources/publications_en.htm)
- EC (European Commission), 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev.2. Available from: [http://ec.europa.eu/food/plant/protection/resources/publications\\_en.htm](http://ec.europa.eu/food/plant/protection/resources/publications_en.htm)
- EC (European Commission), 1997d. Appendix E. Processing studies. 7035/VI/95-rev.5. Available from: [http://ec.europa.eu/food/plant/protection/resources/publications\\_en.htm](http://ec.europa.eu/food/plant/protection/resources/publications_en.htm)
- EC (European Commission), 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3. Available from: [http://ec.europa.eu/food/plant/protection/resources/publications\\_en.htm](http://ec.europa.eu/food/plant/protection/resources/publications_en.htm)
- EC (European Commission), 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev.5. Available from: [http://ec.europa.eu/food/plant/protection/resources/publications\\_en.htm](http://ec.europa.eu/food/plant/protection/resources/publications_en.htm)
- EC (European Commission), 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010. Available from: [http://ec.europa.eu/food/plant/protection/resources/publications\\_en.htm](http://ec.europa.eu/food/plant/protection/resources/publications_en.htm)
- EC (European Commission), 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414. SANCO/3029/99-rev.4. Available from: [http://ec.europa.eu/food/plant/protection/resources/publications\\_en.htm](http://ec.europa.eu/food/plant/protection/resources/publications_en.htm)
- EC (European Commission), 2004. Residue analytical methods. For post-registration control. SANCO/825/00-rev.7. Available from: [http://ec.europa.eu/food/plant/protection/resources/publications\\_en.htm](http://ec.europa.eu/food/plant/protection/resources/publications_en.htm)

- EC (European Commission), 2008. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.8. Available from: [http://ec.europa.eu/food/plant/protection/resources/publications\\_en.htm](http://ec.europa.eu/food/plant/protection/resources/publications_en.htm)
- EC (European Commission), 2010. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010 Rev. 0, finalized in the Standing Committee on the Food Chain and Animal Health at its meeting of 23-24 March 2010.
- EC (European Commission), 2011. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.9. Available from: [http://ec.europa.eu/food/plant/protection/resources/publications\\_en.htm](http://ec.europa.eu/food/plant/protection/resources/publications_en.htm)
- EFSA (European Food Safety Authority), 2007a. Pesticide Residues Intake Model for assessment of acute and chronic consumer exposure to pesticide residues-rev.2. Available from <http://www.efsa.europa.eu/en/mrls/mrlteam.htm>
- EFSA (European Food Safety Authority), 2007b. Reasoned opinion on the potential chronic and acute risk to consumers` health arising from proposed temporary EU MRLs. 15 March 2007.
- EFSA (European Food Safety Authority), 2008a. Conclusion on the peer review of the pesticide risk assessment of the active substance teflubenzuron. EFSA Scientific Report (2008) 184, 1-106 pp.
- EFSA (European Food Safety Authority), 2008b. Reasoned opinion on the modification of the existing MRL for teflubenzuron in peppers prepared by EFSA Pesticide Risk Assessment Peer Review (PRAPeR) Unit. EFSA Scientific Report (2008), 208, 1-26 pp.
- FAO (Food and Agriculture Organization of the United Nations), 1996 . Teflubenzuron In: Pesticide residues in food—1996. Evaluations. Part I. Residues. FAO Plant Production and Protection Paper 142, 443-523 pp.
- Meier U, 2001. Growth Stages of mono- and dicotyledonous plants. BBCH Monograph, 2<sup>nd</sup> Ed., Federal Biological Research Centre of Agriculture and Forest. Braunschweig, Germany. Available from: [http://www.jki.bund.de/fileadmin/dam\\_uploads/\\_veroeff/bbch/BBCH-Skala\\_englisch.pdf](http://www.jki.bund.de/fileadmin/dam_uploads/_veroeff/bbch/BBCH-Skala_englisch.pdf)
- OECD (Organization for Economic Co-operation and Development), 2011a. OECD MRL Calculator: User Guide. Series of pesticides No. 56, ENV/JM/MONO(2011)2, 1 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available from: <http://www.oecd.org/env/pesticides>
- OECD (Organization for Economic Co-operation and Development), 2011b. OECD MRL Calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available from: <http://www.oecd.org/env/pesticides>
- The Netherlands, 2011. Evaluation report on the modification of MRLs for teflubenzuron in *Solanaceae* and cucurbits with edible peel, and deletion of the MRL for pome fruit prepared by the evaluating Member State Netherlands under Article 8 of Regulation (EC) No 396/2005, 11 July 2011, 28 pp.
- The United Kingdom, 2007. Draft assessment report on the active substance teflubenzuron prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, July, 2007.

**Appendix A. GOOD AGRICULTURAL PRACTICES (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		
<i>Solanaceae</i> (peppers, tomatoes, aubergines, okra), Cucurbits with edible peel (cucumbers, gherkins, courgettes)	NL	G	a)Caterpillars ( <i>Spodoptera exigua</i> ) b)Whitefly (larvae) ( <i>Trialeurodes vaporariorum</i> , <i>Bemisia tabaci</i> ) c)Californian trips	SC	150 g/L	Spray	Application is pest related (at 1 <sup>st</sup> flight of adults)	3	7	0.1% 0.015 g a.s./hL	500-1500	0.075-0.225	3	

- 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 suckling 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 RESIDUES INTAKE MODEL (PRIMO)

### Scenario 1

		<b>Teflubenzuron</b>				<b>Prepare workbook for refined calculations</b>		
Status of the active substance:		<b>Included</b>	Code no.			<b>Undo refined calculations</b>		
LOQ (mg/kg bw):			proposed LOQ:					
<b>Toxicological end points</b>								
ADI (mg/kg bw/day):		<b>0.01</b>	ARID (mg/kg bw):	<b>n.n.</b>				
Source of ADI:		<b>EFSA</b>	Source of ARID:	<b>EFSA</b>				
Year of evaluation:		<b>2008</b>	Year of evaluation:	<b>2008</b>				
<b>Chronic risk assessment - refined calculations</b>								
		TMDI (range) in % of ADI minimum - maximum						
		16 - 116						
		<b>No of diets exceeding ADI:</b>		1				
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRs at LOQ (in % of ADI)
116.2	DE child	57.9	Apples	12.7	Table grapes	7.1	Milk and cream,	
89.4	NL child	30.4	Apples	14.7	Milk and cream,	7.6	Table grapes	
80.6	WHO Cluster diet B	17.9	Wine grapes	10.2	Tomatoes	8.5	Wheat	
73.5	IE adult	12.5	Wine grapes	7.3	Dates	5.7	Peaches	
60.0	FR toddler	19.8	Milk and cream,	12.6	Apples	5.1	Potatoes	
58.5	FR all population	40.0	Wine grapes	3.3	Wheat	2.3	Apples	
55.3	PT General population	24.9	Wine grapes	5.3	Potatoes	5.0	Apples	
52.3	UK Infant	19.4	Milk and cream,	7.5	Apples	5.0	Sugar beet (root)	
51.7	WHO cluster diet E	16.1	Wine grapes	4.1	Apples	3.9	Wheat	
51.5	UK Toddler	11.4	Sugar beet (root)	10.3	Milk and cream,	8.2	Apples	
47.7	DK child	11.1	Apples	6.3	Milk and cream,	5.5	Wheat	
43.6	WHO cluster diet D	6.5	Wheat	4.1	Potatoes	3.6	Wine grapes	
41.8	FR infant	12.9	Milk and cream,	12.0	Apples	4.1	Potatoes	
38.4	SE general population 90th percentile	6.2	Milk and cream,	5.0	Apples	4.2	Potatoes	
37.3	WHO regional European diet	4.0	Potatoes	3.6	Tomatoes	3.2	Apples	
35.8	ES child	6.3	Milk and cream,	5.5	Apples	4.4	Wheat	
34.8	NL general	6.3	Wine grapes	5.7	Apples	3.3	Milk and cream,	
34.1	WHO Cluster diet F	6.0	Wine grapes	3.6	Wheat	3.4	Potatoes	
32.9	DK adult	13.9	Wine grapes	3.8	Apples	2.7	Milk and cream,	
30.2	IT kids/toddler	6.6	Wheat	4.7	Tomatoes	4.3	Apples	
28.1	ES adult	4.2	Wine grapes	3.7	Apples	2.6	Tomatoes	
28.1	PL general population	9.8	Apples	3.4	Potatoes	3.2	Table grapes	
27.2	UK vegetarian	8.1	Wine grapes	2.8	Apples	2.1	Tomatoes	
26.0	UK Adult	10.8	Wine grapes	2.0	Sugar beet (root)	2.0	Apples	
25.9	IT adult	4.1	Wheat	3.8	Tomatoes	3.8	Apples	
24.2	LT adult	9.0	Apples	3.2	Potatoes	2.0	Tomatoes	
16.3	FI adult	3.1	Wine grapes	2.8	Milk and cream,	1.9	Apples	
<b>Conclusion:</b>								
The estimated Theoretical Maximum Daily Intakes based on MS and WHO diets and pTMRs were in the range of 16.3% to 116% of the ADI. For 1 diets the ADI is exceeded. Further refinements of the dietary intake estimates have not been performed. A public health risk can not be excluded at the moment.								

## Scenario 2

Teflubenzuron									
Status of the active substance:		Included		Code no.		Prepare workbook for refined calculations			
LOQ (mg/kg bw):				proposed LOQ:					
Toxicological end points									
ADI (mg/kg bw/day):		0.01		ARfD (mg/kg bw):		n.n.			
Source of ADI:		EFSA		Source of ARfD:		EFSA			
Year of evaluation:		2008		Year of evaluation:		2008			
Chronic risk assessment - refined calculations									
TMDI (range) in % of ADI minimum - maximum									
14                      76									
No of diets exceeding ADI:                      ---									
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)	
75.9	WHO Cluster diet B	17.9	Wine grapes	10.2	Tomatoes	8.5	Wheat		
69.6	IE adult	12.5	Wine grapes	7.3	Dates	5.7	Peaches		
59.7	NL child	14.7	Milk and cream,	7.6	Table grapes	5.9	Potatoes		
59.5	DE child	12.7	Table grapes	7.1	Milk and cream,	4.1	Wheat		
56.3	FR all population	40.0	Wine grapes	3.3	Wheat	1.4	Tomatoes		
50.4	PT General population	24.9	Wine grapes	5.3	Potatoes	3.9	Wheat		
47.8	WHO cluster diet E	16.1	Wine grapes	3.9	Wheat	3.8	Potatoes		
47.7	FR toddler	19.8	Milk and cream,	5.1	Potatoes	2.6	Wheat		
44.9	UK Infant	19.4	Milk and cream,	5.0	Sugar beet (root)	3.3	Potatoes		
43.5	UK Toddler	11.4	Sugar beet (root)	10.3	Milk and cream,	3.9	Wheat		
40.5	WHO cluster diet D	6.5	Wheat	4.1	Potatoes	3.6	Wine grapes		
36.8	DK child	6.3	Milk and cream,	5.5	Wheat	4.4	Rye		
34.1	WHO regional European diet	4.0	Potatoes	3.6	Tomatoes	3.0	Wheat		
33.5	SE general population 90th percentile	6.2	Milk and cream,	4.2	Potatoes	3.2	Wheat		
31.1	WHO Cluster diet F	6.0	Wine grapes	3.6	Wheat	3.4	Potatoes		
30.4	ES child	6.3	Milk and cream,	4.4	Wheat	3.2	Tomatoes		
30.0	FR infant	12.9	Milk and cream,	4.1	Potatoes	1.5	Pears		
29.2	DK adult	13.9	Wine grapes	2.7	Milk and cream,	2.0	Wheat		
29.2	NL general	6.3	Wine grapes	3.3	Milk and cream,	2.7	Potatoes		
26.0	IT kids/toddler	6.6	Wheat	4.7	Tomatoes	3.5	Peaches		
24.5	ES adult	4.2	Wine grapes	2.6	Tomatoes	2.5	Milk and cream,		
24.5	UK vegetarian	8.1	Wine grapes	2.1	Tomatoes	2.0	Wheat		
24.1	UK Adult	10.8	Wine grapes	2.0	Sugar beet (root)	1.7	Wheat		
22.2	IT adult	4.1	Wheat	3.8	Tomatoes	3.8	Peaches		
18.5	PL general population	3.4	Potatoes	3.2	Table grapes	2.9	Tomatoes		
15.4	LT adult	3.2	Potatoes	2.0	Tomatoes	2.0	Head cabbage		
14.4	FI adult	3.1	Wine grapes	2.8	Milk and cream,	1.4	Tomatoes		
<p><b>Conclusion:</b> The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Teflubenzuron is unlikely to present a public health concern.</p>									

## Appendix C. EXISTING EU MAXIMUM RESIDUE LIMITS (MRLs)

(Pesticides - Web Version - EU MRLs  
(File created on 16/02/2012 17:19))

Code number	Groups and examples of individual products to which the MRLs apply (a)	Teflubenzuron
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,05*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), uglı and other hybrids)	0,05*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,05*
110030	Lemons (Citron, lemon)	0,05*
110040	Limes	0,05*
110050	Mandarins (Clementine, tangerine, mineola and other hybrids)	0,05*
110990	Others	0,05*
120000	(ii) Tree nuts (shelled or unshelled)	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	1
130010	Apples (Crab apple)	1
130020	Pears (Oriental pear)	1
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
140040	Plums (Damson, greengage, mirabelle, sloe)	1
140990	Others	1
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	1
151010	Table grapes	1
151020	Wine grapes	1
152000	(b) Strawberries	0,2
153000	(c) Cane fruit	0,2
153010	Blackberries	0,2
153020	Dewberries (Loganberries, boysenberries, and cloudberrries)	0,2
153030	Raspberries (Wineberries, arctic bramble/raspberry, (Rubus arcticus), nectar raspberries (Rubus arcticus x idaeus))	0,2
153990	Others	0,2
154000	(d) Other small fruit & berries	0,2
154010	Blueberries (Bilberries)	0,2
154020	Cranberries (Cowberries (red bilberries))	0,2
154030	Currants (red, black and white)	0,2
154040	Gooseberries (Including hybrids with other ribes species)	0,2
154050	Rose hips	0,2
154060	Mulberries (Including arbutus berry)	0,2
154070	Azarole (mediterranean medlar) (Kiwiberry (Actinidia arguta))	0,2
154080	Elderberries (Black chokeberry (appleberry), mountain ash, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,2
154990	Others	0,2
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	

161010	Dates	2
161020	Figs	0,05*
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), mangosteen)	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), and mammy sapote)	0,05*
162990	Others	0,05*
163000	(c) Inedible peel, large	0,05*
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05*
163030	Mangoes	0,05*
163040	Papaya	0,05*
163050	Pomegranate	0,05*
163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0,05*
163070	Guava (Red pitaya or 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*
163990	Others	0,05*
200000	2. VEGETABLES FRESH OR FROZEN	

210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	0,1
212000	(b) Tropical root and tuber vegetables	
212010	Cassava (Dasheen, eddöe (Japanese taro), tannia)	0,05*
212020	Sweet potatoes	0,1
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	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))	0,05*
213100	Swedes	0,05*
213110	Tumips	0,05*
213990	Others	0,05*
220000	(ii) Bulb vegetables	0,05*
220010	Garlic	0,05*
220020	Onions (Silverskin onions)	0,05*
220030	Shallots	0,05*
220040	Spring onions (Welsh onion and similar varieties)	0,05*
220990	Others	0,05*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes, tree tomato, Physalis, gojiberry, wolfberry (Lycium barbarum and L. chinense))	1
231020	Peppers (Chilli peppers)	0,5
231030	Aubergines (egg plants) (Pepino)	0,5
231040	Okra, lady's fingers	0,5
231990	Others	0,5

232000	(b) Cucurbits - edible peel	
232010	Cucumbers	0,5
232020	Gherkins	0,5
232030	Courgettes (Summer squash, marrow (patisson))	0,2
232990	Others	0,2
233000	(c) Cucurbits-inedible peel	
233010	Melons (Kiwano )	0,2
233020	Pumpkins (Winter squash)	0,05*
233030	Watermelons	0,05*
233990	Others	0,05*
234000	(d) Sweet com	0,2
239000	(e) Other fruiting vegetables	0,05*
240000	(iv) Brassica vegetables	0,5
241000	(a) Flowering brassica	0,5
241010	Broccoli (Calabrese, Chinese broccoli, broccoli raab )	0,5
241020	Cauliflower	0,5
241990	Others	0,5
242000	(b) Head brassica	0,5
242010	Brussels sprouts	0,5
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,5
242990	Others	0,5
243000	(c) Leafy brassica	0,5
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), choi sum, peking cabbage (pe-tsai, )	0,5
243020	Kale (Borecole (curly kale), collards, Portuguese Kale, Portuguese cabbage, cow cabbage)	0,5
243990	Others	0,5
244000	(d) Kohlrabi	0,5
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	0,05*
251010	Lamb's lettuce (Italian comsalad)	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, curd leaf endive, sugar loaf)	0,05*
251040	Cress	0,05*

251050	Land cress	0,05*
251060	Rocket, Rucola (Wild rocket)	0,05*
251070	Red mustard	0,05*
251080	Leaves and sprouts of Brassica spp (Mizuna, leaves of peas and radish and other babyleaf brassica crops (crops harvested up to 8 true leaf stage))	0,05*
251990	Others	0,05*
252000	(b) Spinach & similar (leaves)	0,05*
252010	Spinach (New Zealand spinach, amaranthus spinach)	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)	0,05*
254000	(d) Water cress	0,05*
255000	(e) Witloof	0,05*
256000	(f) Herbs	2
256010	Chervil	2
256020	Chives	2
256030	Celery leaves (Fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea leaves)	2
256040	Parsley	2
256050	Sage (Winter savory, summer savory, )	2
256060	Rosemary	2
256070	Thyme (Marjoram, oregano)	2
256080	Basil (Balm leaves, mint, peppermint)	2
256090	Bay leaves (laurel)	2
256100	Tarragon (Hyssop)	2
256990	Others (Edible flowers )	2
260000	(vi) Legume vegetables (fresh)	0,05*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong 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) Stern vegetables (fresh)	
270010	Asparagus	0,05*
270020	Cardoons	0,05*
270030	Celery	0,5
270040	Fennel	0,05*
270050	Globe artichokes	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	
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*
280020	Wild (Chanterelle, Truffle, Morel, Cep)	0,2
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	0,05*
401000	(i) Oilseeds	0,05*
401010	Linseed	0,05*
401020	Peanuts	0,05*
401030	Poppy seed	0,05*
401040	Sesame seed	0,05*
401050	Sunflower seed	0,05*
401060	Rape seed (Bird rapeseed, tumip rape)	0,05*
401070	Soya bean	0,05*
401080	Mustard seed	0,05*
401090	Cotton seed	0,05*
401100	Pumpkin seeds (Other seeds of cucurbitacea)	0,05*
401110	Safflower	0,05*
401120	Borage	0,05*

401130	Gold of pleasure	0,05*
401140	Hempseed	0,05*
401150	Castor bean	0,05*
401990	Others	0,05*
402000	(ii) Oilfruits	0,05*
402010	Olives for oil production	0,05*
402020	Palm nuts (palmoil kernels)	0,05*
402030	Palmfruit	0,05*
402040	Kapok	0,05*
402990	Others	0,05*
500000	5. CEREALS	
500010	Barley	0,1
500020	Buckwheat (Amaranthus, quinoa)	0,05*
500030	Maize	0,1
500040	Millet (Foxtail millet, teff)	0,05*
500050	Oats	0,1
500060	Rice	0,05*
500070	Rye	0,1
500080	Sorghum	0,05*
500090	Wheat (Spelt, triticale )	0,1
500990	Others	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,05*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,05*
620000	(ii) Coffee beans	0,05*
630000	(iii) Herbal infusions (dried)	0,05*
631000	(a) Flowers	0,05*
631010	Camomille flowers	0,05*
631020	Hybiscus flowers	0,05*
631030	Rose petals	0,05*
631040	Jasmine flowers (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 (fermented beans)	0,05*
650000	(v) Carob (st johns bread)	0,05*

70000	7. HOPS (dried) , including hop pellets and unconcentrated powder	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	Anise pepper (Japan pepper)	0,05*
820030	Caraway	0,05*
820040	Cardamom	0,05*
820050	Juniper berries	0,05*
820060	Pepper, black and white (Long pepper, pink pepper)	0,05*
820070	Vanilla pods	0,05*
820080	Tamarind	0,05*
820990	Others	0,05*
830000	(iii) Bark	0,05*
830010	Cinnamon (Cassia )	0,05*
830990	Others	0,05*
840000	(iv) Roots or rhizome	0,05*
840010	Liquorice	0,05*
840020	Ginger	0,05*
840030	Turmeric (Curcuma)	0,05*
840040	Horseradish	0,05*
840990	Others	0,05*
850000	(v) Buds	0,05*
850010	Cloves	0,05*
850020	Capers	0,05*

850990	Others	0,05*
860000	(vi) Flower stigma	0,05*
860010	Saffron	0,05*
860990	Others	0,05*
870000	(vii) Aril	0,05*
870010	Mace	0,05*
870990	Others	0,05*
900000	9. SUGAR PLANTS	0,05*
900010	Sugar beet (root)	0,05*
900020	Sugar cane	0,05*
900030	Chicory roots	0,05*
900990	Others	0,05*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	0,05*
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,05*
1011000	(a) Swine	0,05*
1011010	Meat	0,05*
1011020	Fat free of lean meat	0,05*
1011030	Liver	0,05*
1011040	Kidney	0,05*
1011050	Edible offal	0,05*
1011990	Others	0,05*
1012000	(b) Bovine	0,05*
1012010	Meat	0,05*
1012020	Fat	0,05*
1012030	Liver	0,05*
1012040	Kidney	0,05*
1012050	Edible offal	0,05*
1012990	Others	0,05*
1013000	(c) Sheep	0,05*
1013010	Meat	0,05*

1013020	Fat	0,05*
1013030	Liver	0,05*
1013040	Kidney	0,05*
1013050	Edible offal	0,05*
1013990	Others	0,05*
1014000	(d) Goat	0,05*
1014010	Meat	0,05*
1014020	Fat	0,05*
1014030	Liver	0,05*
1014040	Kidney	0,05*
1014050	Edible offal	0,05*
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	0,05*
1015010	Meat	0,05*
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
1015050	Edible offal	0,05*
1015990	Others	0,05*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*
1016010	Meat	0,05*
1016020	Fat	0,05*
1016030	Liver	0,05*
1016040	Kidney	0,05*
1016050	Edible offal	0,05*
1016990	Others	0,05*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,05*
1017010	Meat	0,05*
1017020	Fat	0,05*
1017030	Liver	0,05*
1017040	Kidney	0,05*
1017050	Edible offal	0,05*
1017990	Others	0,05*

1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,05*
1020010	Cattle	0,05*
1020020	Sheep	0,05*
1020030	Goat	0,05*
1020040	Horse	0,05*
1020990	Others	0,05*
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,05*
1030010	Chicken	0,05*
1030020	Duck	0,05*
1030030	Goose	0,05*
1030040	Quail	0,05*
1030990	Others	0,05*
1040000	(iv) Honey (Royal jelly, pollen)	0,05*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,05*
1060000	(vi) Snails	0,05*
1070000	(vii) Other terrestrial animal products	0,05*

(\* ) Indicates lower limit of analytical determination

## Appendix D. CXLS TEFLUBENZURON

### PESTICIDE DETAILS

#### 190 Teflubenzuron

##### Functional Class

Insect growth regulator

##### Maximum Residue Limits for Teflubenzuron

Commodity	MRL	Year of Adoption	of Symbols	Note
 Brussels sprouts	0.5 mg/Kg	1999		
 Cabbages, Head	0.2 mg/Kg	1999		
 Plums (including prunes)	0.1 mg/Kg	1999		
 Pome fruits	1 mg/Kg	1999		
 Potato	0.05 mg/Kg	1999	(*)	

(\*)At or about the limit of determination.

Other information

##### JMPR-related information

ADI/PTDI 0.01 mg/kg body weight -1994

Residue definition: Teflubenzuron (fat-soluble)

## ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
ca.	circa, approximately
CAC	Codex Alimentarius Commission
CEN	European Committee for Standardization (Comité Européen de Normalisation, <i>French</i> )
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DE	Germany
DK	Denmark
dw	dry weight
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
EURLs	EU Reference Laboratories (former CRLs)
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC	gas chromatography
GC-ECD	gas chromatography with electron capture detector
GS	growth stage
ha	hectare
hL	hectolitre
HPLC-UV	high performance liquid chromatography with ultra-violet detection
i.e.	that is (id est, <i>Latin</i> )
ILV	independent laboratory validation
ISO	International Organization for Standardization

IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
L	litre
LC	liquid chromatography
LOAEL	lowest observed adverse effect level
LOQ	limit of quantification (determination)
MRL	maximum residue limit
MS	Member States
NEU	northern European Union
NL	The Netherlands
OECD	Organization for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (method)
$R_{ber}$	statistical calculation of the MRL by using a non-parametric method
$R_{max}$	statistical calculation of the MRL by using a parametric method
RD	residue definition
RMS	rappporteur Member State
SC	suspension concentrate
SEU	Southern European Union
TMDI	theoretical maximum daily intake
WHO	World Health Organisation
wk	week
yr	year