

REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for tebufenpyrad in cucumbers and courgettes¹

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Germany, herewith referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRLs for tebufenpyrad in cucumbers and courgettes. In order to accommodate for the intended indoor and outdoor use of tebufenpyrad in southern and northern Europe, the EMS proposed to raise the existing MRLs in cucumbers and courgettes from 0.1 mg/kg to 0.3 mg/kg. The EMS 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. According to EFSA the data are sufficient to derive a MRL proposal of 0.3 mg/kg for the proposed indoor and SEU outdoor uses on cucumbers and courgettes. The intended outdoor NEU use is not sufficiently supported by residue data. Based on the risk assessment results, EFSA concludes that the intended indoor use of tebufenpyrad on cucumbers and courgettes will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

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KEY WORDS

Tebufenpyrad, cucumbers, courgettes, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, pyrazole insecticide and acaricide

¹ On request from European Commission, Question No EFSA-Q-2009-00364, approved on 25 June 2012.

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Germany, herewith referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRLs for tebufenpyrad in cucumbers and courgettes. In order to accommodate for the intended indoor and outdoor use of tebufenpyrad in southern and northern Europe, the EMS proposed to raise the existing MRLs in cucumbers and courgettes from 0.1 mg/kg to 0.3 mg/kg. The EMS 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 30 January 2009. On 23 April 2009 some data requirements were identified, which prevented EFSA to conclude on the consumer risk assessment. An updated evaluation report, addressing those data requirements, was submitted by the EMS on 27 March 2012 and taken into consideration by EFSA for finalization of this reasoned opinion

EFSA bases its assessment on the updated evaluation report submitted by the EMS, the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC, the conclusion on the peer review of the pesticide risk assessment of the active substance tebufenpyrad and the conclusions of the previously issued EFSA reasoned opinion on the modification of the existing MRLs for tebufenpyrad.

The toxicological profile of tebufenpyrad was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.01 mg/kg bw per day and an ARfD of 0.02 mg/kg bw.

The metabolism of tebufenpyrad in primary crops was investigated in apples only, representing the crop group of fruits and fruiting vegetables. From these studies the peer review concluded to establish the residue definition for enforcement and risk assessment as parent tebufenpyrad. For the use on the crops under consideration EFSA concludes that the metabolism of tebufenpyrad is sufficiently addressed and that the derived residue definitions are applicable. Adequate analytical enforcement methods are available to control the residues of tebufenpyrad in the crops under consideration.

EFSA considers that the submitted supervised residue trials are sufficient to derive a MRL proposal of 0.3 mg/kg for the proposed indoor and SEU outdoor uses on cucumbers and courgettes. The intended outdoor NEU use is not sufficiently supported by residue data.

Studies investigating the nature of tebufenpyrad residues in processed commodities were assessed in the framework of the peer review and showed that the compound is hydrolytically stable. Therefore for processed commodities the same residue definition as for raw agricultural commodities is applicable. Studies investigating the magnitude of tebufenpyrad residues in processed cucumbers and courgettes are not available. Considering the high calculated consumer exposure to tebufenpyrad residues, processing studies would be desirable with the crops that contribute significantly to the total dietary exposure (apples, oranges).

Cucumbers and courgettes can be grown in a crop rotation. The studies demonstrated that the soil degradation rate of tebufenpyrad and its metabolite CL 810 721 exceeds the DT₉₀ trigger value of 100 days. Metabolite CL 810 721 has been observed also in rat metabolism and some toxicological studies that have been performed in the framework of the peer review indicate that the metabolite is of the same or lower toxicity than parent tebufenpyrad. Lacking studies on the nature and magnitude of tebufenpyrad related residues in rotational/succeeding crops EFSA can not estimate if and in which concentration residues resulting from the use of tebufenpyrad on primary crops occur in rotational crops. Consequently, the risk assessment for rotational crops cannot be finalised. EFSA therefore recommends that Member States granting new authorisations for tebufenpyrad define appropriate restrictions in order to avoid contamination of rotational crops.

Residues of tebufenpyrad in commodities of animal origin were not assessed in the framework of this application, since cucumbers and courgettes are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticides Residues Intake Model (PRIMo). It is noted that in this risk assessment the possible occurrence of residues in rotational/succeeding crops resulting from the use of tebufenpyrad on primary crops could not be considered since the relevant studies are not available at the moment. For the calculation of the chronic exposure, EFSA used the median residue value as derived from the outdoor residue trials on cucumbers; the same value was used as an input value for courgettes. 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 acute exposure assessment was performed only with regard to cucumbers and courgettes, assuming the consumption of a large portion of the food items as reported in the national food surveys containing residues at the highest level as observed in supervised field trials.

The estimated exposure was then compared with the toxicological reference values derived for tebufenpyrad.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values accounted for up to 87.9% of the ADI (maximum for DE child diet). The contribution of residues in the crops under consideration to the total consumer exposure (in percentage of the ADI) accounted for a maximum of 1.31% for cucumbers (DK child diet) and 0.54 % for courgettes (FR infant diet).

No acute consumer risk was identified in relation to the MRL proposals for the crops under consideration. The calculated maximum exposure in percentage of the ARfD was 55% for cucumbers and 44% for courgettes.

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

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

Summary table

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Tebufenpyrad (F)				
0232010	Cucumbers	0.1	0.3	The MRL proposals are supported by data and no risk for consumers was identified. The MRL proposals reflect the indoor use and the SEU outdoor use. Due to the lack of studies on the nature and magnitude of tebufenpyrad related residues in rotational/succeeding crops, the risk assessment for rotational crops could not be finalised. Member States granting authorisations for the crops under consideration have to define appropriate restrictions to avoid contamination of rotational crops (<i>e.g.</i> restriction of the GAP to uses under glass on artificial substrates and/or hydroponic systems).
0232030	Courgettes	0.1	0.3 ^b	

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

(b): The applicant has to confirm the use on courgettes.

(F): Fat-soluble pesticide.

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BACKGROUND

Regulation (EC) No 396/2005³ 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/EEC⁴, repealed by Regulation (EC) No 1107/2009⁵, shall submit to a Member State, when appropriate, an application to set or to modify an MRL in accordance with the provisions of Article 7 of that Regulation.

Germany⁶ hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRLs for tebufenpyrad in cucumbers and courgettes. This application was notified to the European Commission and EFSA and subsequently evaluated 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 30 January 2009.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2009-00364 and the following subject:

Tebufenpyrad - Application to modify the existing MRL for tebufenpyrad in cucumbers from 0.1 mg/kg to 0.2 mg/kg and in courgettes from 0.1 mg/kg to 0.2 mg/kg.

The EMS Germany proposed to raise the existing MRL of tebufenpyrad in the crops under consideration from 0.1 mg/kg to 0.3 mg/kg.

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

On 23 April 2009 some data requirements were identified, which prevented EFSA to conclude on the consumer risk assessment. An updated evaluation report, addressing those data requirements, was submitted by the EMS on 27 March 2012 and taken into consideration by EFSA for finalization of this reasoned opinion.

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 consumers 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 3 April 2012.

³ Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005. OJ L 70, 16.03.2005, p. 1-16.

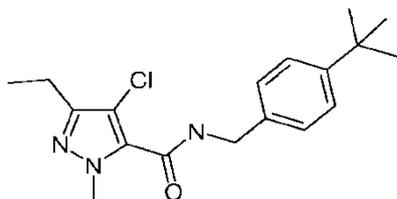
⁴ Council Directive 91/414/EEC of 15 July 1991. OJ L 230, 19.08.1991, p. 1-32.

⁵ 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

⁶ Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Tebufenpyrad is the ISO common name for N-(4-tert-butylbenzyl)-4-chloro-3-ethyl-1-methylpyrazole-5-carboxamide (IUPAC). The chemical structure of tebufenpyrad is the following:



Molecular weight (MW): 333.8 g/mol

Tebufenpyrad belongs to the group of pyrazole insecticides and acaricides. It is a non-systemic substance, active by contact and ingestion routes. Tebufenpyrad has a broad spectrum of activity on a wide variety of mite pests and on all developmental stages of mites (eggs, larvae, nymph and adults). Tebufenpyrad acts by inhibiting mitochondrial respiration. It is used to control all stages of *Tetranychus*, *Panonychus*, *Oligonychus*, *Eotetranychus spp.* on fruit, vines, citrus, vegetables, hops, ornamentals, melons and cotton.

Tebufenpyrad was peer reviewed under Directive 91/414/EEC with Germany being the designated rapporteur Member State (RMS). It is included in Annex I of this Directive by Directive 2009/11/EC⁷ for the uses as insecticide and acaricide only. The representative use supported in the peer review refers to the outdoor foliar application of tebufenpyrad on pome fruit. The EFSA conclusion on the peer review of tebufenpyrad is available (EFSA, 2008).

In the European Union currently temporary MRLs for tebufenpyrad are established in Annex IIIA of Regulation (EC) No 396/2005 (Appendix B). The current MRL for cucumbers and courgettes is set at 0.1 mg/kg. Codex Alimentarius has not established maximum limits for tebufenpyrad.

The applicant has submitted intended GAPs for the indoor use and outdoor SEU and NEU uses of tebufenpyrad on cucumbers (see Appendix A). The use on courgettes is not reported in the submitted GAP tables, but, as the MRL request was made also for courgettes, EFSA assumes that the GAPs are applicable to courgettes as well. The applicant, however, has to confirm this. The details of the intended GAPs for tebufenpyrad are given in Appendix A.

⁷ Commission Directive 2009/11/EC of 18 February. OJ L 48, 19.2.2009, p. 5-12

ASSESSMENT

EFSA bases its assessment on the updated evaluation report submitted by the EMS (Germany, 2012), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (Germany, 2007), the conclusion on the peer review of the pesticide risk assessment of the active substance tebufenpyrad (EFSA, 2008) and the conclusions of the previously issued EFSA reasoned opinion on the modification of the existing MRLs for tebufenpyrad (EFSA, 2009). 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 546/2011⁸ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011; OECD, 2011).

1. Method of analysis

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

Analytical methods for the determination of tebufenpyrad residues in plant commodities were assessed during the peer review under Directive 91/414/EEC (Germany, 2007). A multi residue method (DFG S19) using GC-MS detection was considered sufficiently validated for the determination of tebufenpyrad residues in high water and high acid content matrices at the LOQ of 0.01 mg/kg and in high oil content matrices at the LOQ of 0.05 mg/kg (EFSA, 2008).

EFSA concludes that sufficiently validated analytical methods are available to control tebufenpyrad residues in the crops under consideration.

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

Analytical methods for the determination of residues in food of animal origin are not assessed in the current application, since cucumbers and courgettes are normally not fed to livestock.

2. Mammalian toxicology

The toxicological profile of the active substance tebufenpyrad was assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2008). 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
Tebufenpyrad					
ADI	EFSA	2008	0.01 mg/kg bw per day	2 yr and 90-day rat (overall assessment rounded)	100
ARfD	EFSA	2008	0.02 mg/kg bw	Acute clinical signs in dog studies (overall assessment)	100

⁸ Commission Regulation (EU) No 546/2011 of 10 June 2011. OJ L 155, 11.06.2011, p. 127-175.

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 tebufenpyrad in apples was investigated in the framework of the peer review under Directive 91/414/EEC (EFSA, 2008). The overview of the metabolism study design is presented in the table below.

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

Group	Crop	Label position	Application details				
			Method, F or G ^(a)	Rate (kg a.s./ha)	No/ Interval	Sampling	Remarks
Fruits and fruiting vegetable	Apples	[phenyl-U- ¹⁴ C]- and [pyrazole-3- ¹⁴ C]-tebufenpyrad	Foliar/F	0.74	3/30-33	14 DALA	

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

Tebufenpyrad was only slightly metabolised and made up circa 63% (0.18 mg eq./kg) of the TRR. Some minor metabolites were identified but they were only present at or below 0.01 mg/kg (0.2-1.8% TRR). Therefore the peer review concluded that residue for enforcement and risk assessment should be defined as parent tebufenpyrad.

For the uses on the fruiting crops under consideration, EFSA concludes that the metabolism of tebufenpyrad is sufficiently addressed and the residue definitions agreed in the peer review are applicable.

3.1.1.2. Magnitude of residues

In support of the intended **outdoor** GAP in the SEU the applicant submitted in total 7 residue trials on cucumbers and 1 residue trial on courgettes. Trials have been performed in Spain and Italy (1991-2007). Two residue trials on cucumbers were disregarded as samples were not analysed for the 3 day PHI (only 0, and 7, 14, 21 day PHI). Thus, in total 5 GAP compliant residue trials on cucumbers and 1 GAP compliant residue trial on courgettes are available. The applicant proposes to extrapolate residue data to courgettes. According to the currently applicable EC guidance document, cucumbers and courgettes⁹ are considered as minor crops in southern Europe (EC, 2011). The number of submitted trials is sufficient to support the intended use on cucumbers. The extrapolation rules in the EU guidance document do not explicitly mention the extrapolation to courgettes alone (only the group extrapolation), but, considering the morphological similarities of cucumbers and courgettes, EFSA considers that such an extrapolation can be supported. The residue data on cucumbers and courgettes were therefore pooled to derive a MRL proposal. Residue data indicate that a MRL of 0.3 mg/kg is required to support the intended outdoor SEU use on cucumbers and courgettes.

No residue trials have been submitted to support the intended **outdoor** GAP in the NEU.

In support of the intended **indoor** GAP, the applicant submitted 8 GAP compliant indoor residue trials on cucumbers, which have been performed in Spain and Italy (1993-2007). Sufficient number of trials is submitted to support the intended indoor use on cucumbers. The applicant proposes residue

⁹ As from 1 April 2013 courgettes will be considered as a major crop in the SEU (EC, 2011)

extrapolation to courgettes. The extrapolation rules in the EU guidance document do not explicitly mention the extrapolation to courgettes alone (only the group extrapolation), but, considering the morphological similarities of cucumbers and courgettes, EFSA considers that such an extrapolation can be supported. A MRL proposal of 0.3 mg/kg is thus derived for cucumbers and courgettes.

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

The storage stability of tebufenpyrad in primary crops was investigated in the framework of the peer review (EFSA, 2008). Residues of tebufenpyrad were found to be stable at $\leq -18^{\circ}\text{C}$ for up to 24 months in matrices with high water content. 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 the supervised residue trial samples have been sufficiently validated and were proven to be fit for purpose (Germany, 2012).

Table 3-2: 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 (Tebufenpyrad)	Risk assessment (Tebufenpyrad)					
Cucumbers → courgettes	SEU	Outdoor	0.03; 0.048; 0.067; 0.093 ^f ; 0.095; 0.112;	0.03; 0.048; 0.067; 0.093 ^f ; 0.095; 0.112;	0.08	0.112	0.3	1	R _{ber} = 0.2 R _{max} = 0.19 MRL _{OECD} = 0.22/0.3
Cucumbers → courgettes	EU	Indoor	0.034; <0.05; 0.047; 0.049; 0.056; 0.077; 0.088; 0.189	0.034; <0.05; 0.047; 0.049; 0.056; 0.077; 0.088; 0.189	0.053	0.189	0.3	1	R _{ber} =0.17 R _{max} =0.23 MRL _{OECD} = 0.27/0.3
Cucumbers, courgettes	NEU	Outdoor	-	-	No residue data submitted to support the intended outdoor GAP in the NEU.				

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (*i.e.* outdoor use) or Import (country code) (EC, 2011).

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

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

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

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

(f): Residue trial on courgettes.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of tebufenpyrad residues was investigated in a simulated hydrolysis study in the framework of the peer review (Germany, 2007). Tebufenpyrad was found to be stable under all 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). Thus, for processed commodities the same residue definition as for raw agricultural commodities (RAC) is applicable (EFSA, 2008).

Studies investigating the magnitude of tebufenpyrad residues in processed cucumbers and courgettes are not available. Considering the high calculated consumer exposure to tebufenpyrad residues (see section 4), processing studies would be desirable with the crops that contribute significantly to the total dietary exposure (apples, oranges).

3.1.2. Rotational crops

Cucumbers and courgettes can be grown in a crop rotation. The soil degradation studies demonstrated that the degradation rate of tebufenpyrad in soil is moderate; the maximum DT_{90field} value is ranging from 3 to 360 days, (EFSA, 2008). Under laboratory conditions the parent compound degrades slowly with a maximum DT_{90lab} value of 575 days. The degradation of tebufenpyrad in soil forms two soil metabolites - CL 810 721¹⁰ and CL 810 728¹¹ - of which metabolite CL 810 721, according to laboratory studies, has a maximum DT_{90lab} of 180.5 days. Metabolite CL 810 728 was found to be of low persistence. Metabolite CL 810 721 has been observed also in rat metabolism and some toxicological studies have been performed in the framework of the peer review (EFSA, 2008). Study results indicate that the metabolite is of the same or lower toxicity than parent tebufenpyrad.

Since the representative use for the peer review was on a perennial crop, the nature and magnitude of tebufenpyrad residues in rotation/succeeding crops was not further investigated.

Lacking studies on the nature and magnitude of tebufenpyrad related residues in rotational/succeeding crops EFSA cannot estimate if and in which concentration residues resulting from the use of tebufenpyrad on primary crops occur in rotational crops. Consequently, the risk assessment for rotational crops cannot be finalised. EFSA therefore recommends that Member States granting new authorisations for tebufenpyrad define appropriate restrictions in order to avoid contamination of rotational crops. A possible risk management option is the restriction of the use of tebufenpyrad in glasshouses on artificial substrate or on closed hydroponic systems.

EFSA notes that the open points regarding nature and magnitude of tebufenpyrad residues (and metabolites) in rotational crops has to be addressed in the review of the existing MRLs for tebufenpyrad under the Article 12 of Regulation (EC) No 396/2005.

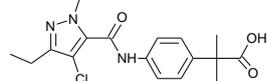
3.2. Nature and magnitude of residues in livestock

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

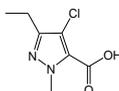
4. Consumer risk assessment

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

¹⁰ 2-(4-((4-chloro-3-ethyl-1-methyl-1H-pyrazol-5-yl)carbonyl)amino)phenyl)-2-methylpropanoic acid



¹¹ 4-chloro-3-ethyl-1-methyl-5-pyrazolecarboxylic acid



data for different sub-groups of the EU population¹² (EFSA, 2007). It is noted that in this risk assessment the possible occurrence of residues in rotational/succeeding crops resulting from the use of tebufenpyrad on primary crops could not be considered since the relevant studies are not available at the moment (see section 3.1.2).

For the calculation of the chronic exposure, EFSA used the median residue value as derived from the outdoor residue trials on cucumbers (see Table 3-2); the same value was used as an input value for courgettes. 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 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.

The acute exposure assessment was performed only with regard to cucumbers and courgettes, assuming the consumption of a large portion of the food items as reported in the national food surveys containing residues at the highest level as observed in supervised field trials on cucumbers. A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation, when required (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised 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
Risk assessment residue definition: Tebufenpyrad				
Cucumbers	0.08	Median residue (SEU outdoor use) (Table 3-2)	0.189	Highest residue (indoor use) (Table 3-2)
Courgettes	0.08	Median residue (SEU outdoor use on cucumbers) (Table 3-2)	0.189	Highest residue (indoor use on cucumbers) (Table 3-2)
Other food commodities of plant and animal origin	MRL	See Appendix C	Acute risk assessment was undertaken only with regard to the crops under consideration.	

The estimated exposure was then compared with the toxicological reference values derived for tebufenpyrad (see Table 2-1). The results of the intake calculation 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 values accounted for up to 87.9% of the ADI (maximum for DE child diet). The contribution of residues in the crops under consideration to the total consumer

¹² 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).

exposure (in percentage of the ADI) accounted for a maximum of 1.31% for cucumbers (DK child diet) and 0.54 % for courgettes (FR infant diet).

No acute consumer risk was identified in relation to the MRL proposals for the crops under consideration. The calculated maximum exposure in percentage of the ARfD was 55% for cucumbers and 44% for courgettes.

EFSA concludes that the intended use of tebufenpyrad on cucumbers and courgettes 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 tebufenpyrad was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.01 mg/kg bw per day and an ARfD of 0.02 mg/kg bw.

The metabolism of tebufenpyrad in primary crops was investigated in apples only, representing the crop group of fruits and fruiting vegetables. From these studies the peer review concluded to establish the residue definition for enforcement and risk assessment as parent tebufenpyrad. For the use on the crops under consideration EFSA concludes that the metabolism of tebufenpyrad is sufficiently addressed and that the derived residue definitions are applicable. Adequate analytical enforcement methods are available to control the residues of tebufenpyrad in the crops under consideration.

EFSA considers that the submitted supervised residue trials are sufficient to derive a MRL proposal of 0.3 mg/kg for the proposed indoor and SEU outdoor uses on cucumbers and courgettes. The intended outdoor NEU use is not sufficiently supported by residue data.

Studies investigating the nature of tebufenpyrad residues in processed commodities were assessed in the framework of the peer review and showed that the compound is hydrolytically stable. Therefore for processed commodities the same residue definition as for raw agricultural commodities is applicable. Studies investigating the magnitude of tebufenpyrad residues in processed cucumbers and courgettes are not available. Considering the high calculated consumer exposure to tebufenpyrad residues, processing studies would be desirable with the crops that contribute significantly to the total dietary exposure (apples, oranges).

Cucumbers and courgettes can be grown in a crop rotation. The studies demonstrated that the soil degradation rate of tebufenpyrad and its metabolite CL 810 721 exceeds the DT_{90} trigger value of 100 days. Metabolite CL 810 721 has been observed also in rat metabolism and some toxicological studies that have been performed in the framework of the peer review indicate that the metabolite is of the same or lower toxicity than parent tebufenpyrad. Lacking studies on the nature and magnitude of tebufenpyrad related residues in rotational/succeeding crops EFSA can not estimate if and in which concentration residues resulting from the use of tebufenpyrad on primary crops occur in rotational crops. Consequently, the risk assessment for rotational crops cannot be finalised. EFSA therefore recommends that Member States granting new authorisations for tebufenpyrad define appropriate restrictions in order to avoid contamination of rotational crops.

Residues of tebufenpyrad in commodities of animal origin were not assessed in the framework of this application, since cucumbers and courgettes are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticides Residues Intake Model (PRIMo). It is noted that in this risk assessment the possible occurrence of residues in rotational/succeeding crops resulting from the use of tebufenpyrad on primary crops could not be considered since the relevant studies are not available at the moment. For the calculation of the chronic exposure, EFSA used the median residue value as derived from the outdoor residue trials on cucumbers; the same value was used as an input value for courgettes. 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 acute exposure assessment was performed only with regard to cucumbers and courgettes, assuming the consumption of a large portion of the food items as reported in the national food surveys containing residues at the highest level as observed in supervised field trials.

The estimated exposure was then compared with the toxicological reference values derived for tebufenpyrad.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values accounted for up to 87.9% of the ADI (maximum for DE child diet). The contribution of residues in the crops under consideration to the total consumer exposure (in percentage of the ADI) accounted for a maximum of 1.31% for cucumbers (DK child diet) and 0.54 % for courgettes (FR infant diet).

No acute consumer risk was identified in relation to the MRL proposals for the crops under consideration. The calculated maximum exposure in percentage of the ARfD was 55% for cucumbers and 44% for courgettes.

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

RECOMMENDATIONS

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Tebufenpyrad (F)				
0232010	Cucumbers	0.1	0.3	The MRL proposals are supported by data and no risk for consumers was identified. The MRL proposals reflect the indoor use and the SEU outdoor use. Due to the lack of studies on the nature and magnitude of tebufenpyrad related residues in rotational/succeeding crops, the risk assessment for rotational crops could not be finalised. Member States granting authorisations for the crops under consideration have to define appropriate restrictions to avoid contamination of rotational crops (<i>e.g.</i> restriction of the GAP to uses under glass on artificial substrates and/or hydroponic systems).
0232030	Courgettes	0.1	0.3b	

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

(b): The applicant has to confirm the use on courgettes.

(F): Fat-soluble pesticide.

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APPENDICES

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		
Cucumbers	ES	F	Spider mites	SC	310 g/L	spray	At infestation	1	-	0.02	1000	0.2	3	Critical SEU outdoor GAP
	ES	G	Spider mites	SC	310 g/L	spray	At infestation	1	-	0.02	1000	0.2	3	Critical EU indoor GAP
Cucumbers	LUX, BE	F	Spider mites	WP	200 g/L	spray	At infestation	1	-	0.01	1000	0.1	3	Critical NEU outdoor GAP
	LUX, BE	G	Spider mites	WP	200 g/L	spray	At infestation	1	-	0.01	1000	0.1	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 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, 4th 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, 2nd 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)

B. PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Tebufenpyrad													
Status of the active substance:		included		Code no.		Prepare workbook for refined calculations							
LOQ (mg/kg bw):		0.05		proposed LOQ:									
Toxicological end points													
ADI (mg/kg bw/day):		0.01		ARfD (mg/kg bw):		Undo refined calculations							
Source of ADI:		EFSA		Source of ARfD:						EFSA			
Year of evaluation:		2008		Year of evaluation:									
Chronic risk assessment - refined calculations													
TMDI (range) in % of ADI minimum - maximum													
15 88													
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	pTMRs at LOQ (in % of ADI)					
87.9	DE child	24.1	Apples	19.0	Oranges	7.1	Milk and cream,	15.2					
80.2	NL child	15.6	Oranges	14.7	Milk and cream,	12.7	Apples	26.1					
73.7	WHO Cluster diet B	15.4	Tomatoes	9.0	Wine grapes	4.3	Wheat	16.8					
66.7	FR toddler	19.8	Milk and cream,	11.0	Beans (with pods)	10.0	Oranges	29.5					
56.1	IE adult	6.3	Wine grapes	5.2	Oranges	4.1	Melons	14.1					
52.0	UK Toddler	11.4	Sugar beet (root)	10.3	Milk and cream,	9.9	Oranges	28.5					
47.9	UK Infant	19.4	Milk and cream,	6.5	Oranges	5.0	Sugar beet (root)	31.8					
42.9	FR infant	12.9	Milk and cream,	8.4	Beans (with pods)	5.0	Apples	19.1					
41.4	ES child	10.8	Oranges	6.3	Milk and cream,	4.9	Tomatoes	14.2					
37.7	WHO cluster diet E	8.0	Wine grapes	2.8	Beans (with pods)	2.6	Tomatoes	11.5					
37.6	FR all population	20.0	Wine grapes	2.2	Tomatoes	1.6	Wheat	5.8					
35.1	PT General population	12.4	Wine grapes	4.5	Tomatoes	3.1	Oranges	7.0					
33.5	DK child	6.3	Milk and cream,	4.6	Apples	2.8	Wheat	17.0					
33.3	SE general population 90th percentile	6.2	Milk and cream,	3.8	Tomatoes	3.7	Oranges	13.7					
32.2	NL general	7.4	Oranges	3.3	Milk and cream,	3.1	Wine grapes	8.4					
32.0	WHO regional European diet	5.5	Tomatoes	2.5	Oranges	2.4	Milk and cream,	11.0					
31.6	WHO cluster diet D	5.1	Tomatoes	3.3	Wheat	2.5	Milk and cream,	11.7					
29.5	ES adult	6.5	Oranges	3.9	Tomatoes	2.5	Milk and cream,	7.4					
28.5	WHO Cluster diet F	4.4	Oranges	3.4	Tomatoes	3.0	Wine grapes	10.3					
25.3	IT kids/toddler	7.1	Tomatoes	3.3	Wheat	2.4	Oranges	5.8					
23.8	UK vegetarian	4.3	Oranges	4.1	Wine grapes	3.1	Tomatoes	6.9					
22.0	IT adult	5.8	Tomatoes	2.1	Wheat	1.9	Oranges	3.9					
21.6	DK adult	7.0	Wine grapes	2.7	Milk and cream,	2.1	Tomatoes	6.7					
20.6	UK Adult	5.4	Wine grapes	2.8	Oranges	2.2	Tomatoes	6.5					
19.2	FI adult	4.8	Oranges	2.8	Milk and cream,	2.1	Tomatoes	5.5					
16.7	PL general population	4.4	Tomatoes	4.1	Apples	1.7	Potatoes	2.7					
15.4	LT adult	3.7	Apples	3.1	Tomatoes	2.0	Milk and cream,	6.4					
Conclusion:													
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI. A long-term intake of residues of Tebufenpyrad is unlikely to present a public health concern.													

Acute risk assessment /children - refined calculations						Acute risk assessment / adults / general population - refined calculations									
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.															
Unprocessed 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	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)			
	55.3	Cucumbers	0.189 / -	55.3	Cucumbers	0.189 / -	25.5	Courgettes	0.189 / -	19.2	Courgettes	0.189 / -			
	43.9	Courgettes	0.189 / -	31.4	Courgettes	0.189 / -	18.6	Cucumbers	0.189 / -	18.6	Cucumbers	0.189 / -			
No of critical MRLs (IESTI 1)				---				No of critical MRLs (IESTI 2)				---			
Processed commodities	No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:					
	---			---			---			---					
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
			***)			***)			***)			***)			
*) 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 Tebufenpyrad 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.															

C. EXISTING EU MAXIMUM RESIDUE LEVELS (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 07/06/2012 17:36))

Code number	Groups and examples of individual products to which the MRLs apply	Tebufenpyrad (F)	Code number	Groups and examples of individual products to which the MRLs apply	Tebufenpyrad (F)	Code number	Groups and examples of individual products to which the MRLs apply	Tebufenpyrad (F)	Code number	Groups and examples of individual products to which the MRLs apply	Tebufenpyrad (F)
100000	1. FRUIT FRESH OR FROZEN; NUTS		151000	(a) Table and wine grapes	0,5		rambutan (hairy litchi))		213040	Horseradish	0,05*
110000	(i) Citrus fruit	0,5	151010	Table grapes	0,5	162030	Passion fruit	0,05*	213050	Jerusalem artichokes	0,05*
110010	Grapefruit (Shaddock, pomelos, sweeties, tangelo, ugli and other hybrids)	0,5	151020	Wine grapes	0,5	162040	Prickly pear (cactus fruit)	0,05*	213060	Parsnips	0,05*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,5	152000	(b) Strawberries	0,5	162050	Star apple	0,05*	213070	Parsley root	0,05*
110030	Lemons (Citron, lemon)	0,5	153000	(c) Cane fruit	0,05*	162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, caristel (yellow sapote), and mammy sapote)	0,05*	213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,05*
110040	Limes	0,5	153010	Blackberries	0,05*	162990	Others	0,05*	213100	Swedes	0,05*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,5	153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,05*	163000	(c) Inedible peel, large	0,05*	213110	Turnips	0,05*
110990	Others	0,5	153030	Raspberries (Wineberries)	0,05*	163010	Avocados	0,05*	213990	Others	0,05*
120000	(ii) Tree nuts (shelled or unshelled)	0,05*	153990	Others	0,05*	163020	Bananas (Dwarf banana, plantain, apple banana)	0,05*	220000	(ii) Bulb vegetables	0,05*
120010	Almonds	0,05*	154000	(d) Other small fruit & berries	1	163030	Mangoes	0,05*	220010	Garlic	0,05*
120020	Brazil nuts	0,05*	154010	Blueberries (Bilberries, cowberries (red bilberries))	1	163040	Papaya	0,05*	220020	Onions (Silverskin onions)	0,05*
120030	Cashew nuts	0,05*	154020	Cranberries	1	163050	Pomegranate	0,05*	220030	Shallots	0,05*
120040	Chestnuts	0,05*	154030	Currants (red, black and white)	1	163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0,05*	220040	Spring onions (Welsh onion and similar varieties)	0,05*
120050	Coconuts	0,05*	154040	Gooseberries (Including hybrids with other ribes species)	1	163070	Guava	0,05*	220990	Others	0,05*
120060	Hazelnuts (Filbert)	0,05*	154050	Rose hips	1	163080	Pineapples	0,05*	230000	(iii) Fruiting vegetables	
120070	Macadamia	0,05*	154060	Mulberries (arbutus berry)	1	163090	Bread fruit (Jackfruit)	0,05*	231000	(a) Solanacea	
120080	Pecans	0,05*	154070	Azazole (mediterranean medlar)	1	163100	Durian	0,05*	231010	Tomatoes (Cherry tomatoes,)	0,5
120090	Pine nuts	0,05*	154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea allowthorn), hawthorn, service berries, and other treeberries)	1	163110	Soursop (guanabana)	0,05*	231020	Peppers (Chilli peppers)	0,5
120100	Pistachios	0,05*	154990	Others	1	163990	Others	0,05*	231030	Aubergines (egg plants) (Pepino)	0,5
120110	Walnuts	0,05*	160000	(vi) Miscellaneous fruit	0,05*	200000	2. VEGETABLES FRESH OR FROZEN		231040	Okra, lady's fingers	0,05*
120990	Others	0,05*	161000	(a) Edible peel	0,05*	210000	(i) Root and tuber vegetables	0,05*	231990	Others	0,05*
130000	(iii) Pome fruit	0,2	161010	Dates	0,05*	211000	(a) Potatoes	0,05*	232000	(b) Cucurbits - edible peel	
130010	Apples (Crab apple)	0,2	161020	Figs	0,05*	212000	(b) Tropical root and tuber vegetables	0,05*	232010	Cucumbers	0,1
130020	Pears (Oriental pear)	0,2	161030	Table olives	0,05*	212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*	232020	Gherkins	0,5
130030	Quinces	0,2	161040	Kumquats (Marumi kumquats, nagami kumquats)	0,05*	212020	Sweet potatoes	0,05*	232030	Courgettes (Summer squash, marrow (patisson))	0,1
130040	Medlar	0,2	161050	Carambola (Bilimbi)	0,05*	212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,05*	232990	Others	0,1
130050	Loquat	0,2	161060	Persimmon	0,05*	212040	Arrowroot	0,05*	233000	(c) Cucurbits-inedible peel	
130990	Others	0,2	161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,05*	212990	Others	0,05*	233010	Melons (Kiwano)	0,5
140000	(iv) Stone fruit		161990	Others	0,05*	213000	(c) Other root and tuber vegetables except sugar beet	0,05*	233020	Pumpkins (Winter squash)	0,05*
140010	Apricots	0,5	162000	(b) Inedible peel, small	0,05*	213010	Beetroot	0,05*	233030	Watermelons	0,5
140020	Cherries (sweet cherries, sour cherries)	0,5	162010	Kiwi	0,05*	213020	Carrots	0,05*	233990	Others	0,05*
140030	Peaches (Nectarines and similar hybrids)	0,3	162020	Lychee (Litchi) (Pulasan,	0,05*	213030	Celeriac	0,05*	234000	(d) Sweet corn	0,05*
140040	Plums (Damson, greengage, mirabelle)	0,5							239000	(e) Other fruiting vegetables	0,05*
140990	Others	0,5							240000	(iv) Brassica vegetables	0,05*
150000	(v) Berries & small fruit								241000	(a) Flowering brassica	0,05*
									241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,05*
									241020	Cauliflower	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Tebufenpyrad (F)
241990	Others	0,05*
242000	(b) Head brassica	0,05*
242010	Brussels sprouts	0,05*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,05*
242990	Others	0,05*
243000	(c) Leafy brassica	0,05*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,05*
243020	Kale (Borecole (curly kale), collards)	0,05*
243990	Others	0,05*
244000	(d) Kohlrabi	0,05*
250000	(v) Leaf vegetables & fresh herbs	0,05*
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)	0,05*
251990	Others	0,05*
252000	(b) Spinach & similar (leaves)	0,05*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,05*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sonel, glasswort)	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*

Code number	Groups and examples of individual products to which the MRLs apply	Tebufenpyrad (F)
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 Apiacea)	0,05*
256040	Parsley	0,05*
256050	Sage (Winter savory, summer savory,)	0,05*
256060	Rosemary	0,05*
256070	Thyme (marjoram, oregano)	0,05*
256080	Basil (Balm leaves, mint, peppermint)	0,05*
256090	Bay leaves (laurel)	0,05*
256100	Tamagon (Hyssop)	0,05*
256990	Others	0,05*
260000	(vi) Legume vegetables (fresh)	
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	1
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,05*
260030	Peas (with pods) (Mangetout (sugar 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	0,05*
270030	Celery	0,05*
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	0,05*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*
280020	Wild (Chanterelle, Truffle, Morel,)	0,05*
280990	Others	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Tebufenpyrad (F)
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, turnip rape)	0,05*
401070	Soya bean	0,05*
401080	Mustard seed	0,05*
401090	Cotton seed	0,05*
401100	Pumpkin seeds	0,05*
401110	Safflower	0,05*
401120	Borage	0,05*
401130	Gold of pleasure	0,05*
401140	Hempseed	0,05*
401150	Castor bean	0,05*
401990	Others	0,05*
402000	(ii) Oilfruits	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	0,05*
500010	Barley	0,05*
500020	Buckwheat	0,05*
500030	Maize	0,05*
500040	Millet (Foxtail millet, teff)	0,05*
500050	Oats	0,05*
500060	Rice	0,05*
500070	Rye	0,05*
500080	Sorghum	0,05*
500090	Wheat (Spelt Triticale)	0,05*
500990	Others	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,1

Code number	Groups and examples of individual products to which the MRLs apply	Tebufenpyrad (F)
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1
620000	(ii) Coffee beans	0,1
630000	(iii) Herbal infusions (dried)	0,1
631000	(a) Flowers	0,1
631010	Camomille flowers	0,1
631020	Hybiscus flowers	0,1
631030	Rose petals	0,1
631040	Jasmine flowers	0,1
631050	Lime (linden)	0,1
631990	Others	0,1
632000	(b) Leaves	0,1
632010	Strawberry leaves	0,1
632020	Rooibos leaves	0,1
632030	Maté	0,1
632990	Others	0,1
633000	(c) Roots	0,1
633010	Valerian root	0,1
633020	Ginseng root	0,1
633990	Others	0,1
639000	(d) Other herbal infusions	0,1
640000	(iv) Cocoa (fermented beans)	0,1
650000	(v) Carob (st johns bread)	0,1
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	0,5
800000	8. SPICES	0,1
810000	(i) Seeds	0,1
810010	Anise	0,1
810020	Black caraway	0,1
810030	Celery seed (Lovage seed)	0,1
810040	Coriander seed	0,1
810050	Cumin seed	0,1
810060	Dill seed	0,1
810070	Fennel seed	0,1
810080	Fenugreek	0,1
810090	Nutmeg	0,1
810990	Others	0,1
820000	(ii) Fruits and berries	0,1
820010	Allspice	0,1
820020	Anise pepper (Japan pepper)	0,1
820030	Caraway	0,1
820040	Cardamom	0,1
820050	Juniper berries	0,1
820060	Pepper, black and white (Long pepper, pink pepper)	0,1
820070	Vanilla pods	0,1
820080	Tamarind	0,1
820990	Others	0,1

Code number	Groups and examples of individual products to which the MRLs apply	Tebufenpyrad (F)
830000	(iii) Bark	0,1
830010	Cinnamon (Cassia)	0,1
830990	Others	0,1
840000	(iv) Roots or rhizome	0,1
840010	Liquorice	0,1
840020	Ginger	0,1
840030	Turmeric (Curcuma)	0,1
840040	Horseradish	0,1
840990	Others	0,1
850000	(v) Buds	0,1
850010	Cloves	0,1
850020	Capers	0,1
850990	Others	0,1
860000	(vi) Flower stigma	0,1
860010	Saffron	0,1
860990	Others	0,1
870000	(vii) Aril	0,1
870010	Mace	0,1
870990	Others	0,1
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	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Tebufenpyrad (F)
	processed as flours or meals other processed products such as sausages and food preparations based on these	
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*

Code number	Groups and examples of individual products to which the MRLs apply	Tebufenpyrad (F)
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	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Tebufenpyrad (F)
	curd	
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
(F): 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
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council
d	day
DALA	days after last application
DAR	Draft Assessment Report
DT ₉₀	period required for 90 % dissipation
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EU	European Union
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (former GIFAP)
GLP	Good Laboratory Practice
ha	hectare
hL	hectolitre
IPCS	International Programme of Chemical Safety
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
L	litre
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
NEU	northern European Union
MW	molecular weight
OECD	Organisation for Economic Co-operation and Development
PHI	pre-harvest interval

PRIMo	(EFSA) Pesticide Residues Intake Model
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
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SC	suspension concentrate
SEU	Southern European Union
WHO	World Health Organisation
WP	wettable powder
wk	week
yr	year