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REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for tepraloxydim in Jerusalem artichoke and radishes[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Belgium, hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRLs for the active substance tepraloxydim in Jerusalem artichoke and radishes. In order to accommodate for the intended uses of tepraloxydim, Belgium proposed to raise the existing MRLs from the limit of quantification of 0.1 mg/kg to 0.4 mg/kg. Belgium drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA. According to EFSA the data are sufficient to derive MRL proposals of 0.4 mg/kg for the proposed uses on Jerusalem artichoke and radishes. Study to confirm the stability of tepraloxydim residues under frozen conditions in high water content matrices is however requested. Adequate analytical enforcement methods are available to control the residues of tepraloxydim on the commodities under consideration. Based on the risk assessment results, EFSA concludes that the proposed uses of tepraloxydim on Jerusalem artichoke and radishes will not result in a consumer exposure exceeding the toxicological reference values and therefore, is unlikely to pose a consumer health risk.

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KEY WORDS

tepraloxydim, Jerusalem artichoke and radishes, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, cyclohexadione-oxime, 3-(tetrahydro-pyran-4-yl)-glutaric and 3-hydroxy-(tetrahydro-pyran-4-yl)-glutaric acid

[1] On request from the European Commission, Question No EFSA-Q-2014-00133, approved on 15 July 2014.

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Belgium, hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRLs for the active substance tepraloxydim in Jerusalem artichoke and radishes. In order to accommodate for the intended uses of tepraloxydim, Belgium proposed to raise the existing MRLs from the limit of quantification of 0.1 mg/kg to 0.4 mg/kg. Belgium drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 27 February 2014.

EFSA bases its assessment on the evaluation report submitted by the EMS, the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC, the Commission Review Report on tepraloxydim, as well as the conclusions from the EFSA Reasoned Opinion on the review of the existing MRLs according Article 12 of Regulation (EC) No 396/2005.

The toxicological profile of tepraloxydim was assessed in the framework of the peer review and the data were sufficient to derive an ADI 0.025 mg/kg bw per day and an ARfD of 0.4 mg/kg bw.

The metabolism of tepraloxydim in primary crops was investigated on root/tuber vegetables and on pulses/oilseeds. Based on these studies the peer review established the residue definition for enforcement and risk assessment as the sum of tepraloxydim and its metabolites that can be hydrolysed either to the 3-(tetrahydro-pyran-4-yl)-glutaric acid moiety or to the 3-hydroxy-(tetrahydro-pyran-4-yl)-glutaric acid moiety, expressed as tepraloxydim. For the use on crops under consideration, EFSA concludes that the metabolism of tepraloxydim in primary crops is sufficiently addressed and the residue definitions are applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to derive MRL proposals of 0.4 mg/kg for the proposed uses on Jerusalem artichoke and radishes. Study to confirm the stability of tepraloxydim residues under frozen conditions in high water content matrices is however requested. Adequate analytical enforcement methods are available to control the residues of tepraloxydim on the commodities under consideration at the validated LOQ of 0.1 mg/kg.

Studies investigating the nature of tepraloxydim residues in processed commodities were assessed in the peer review and showed that tepraloxydim is degraded during pasteurisation, cooking, brewing and sterilisation. During the degradation of tepraloxydim no new metabolites are expected, therefore the residue definitions for enforcement and risk assessment as for raw commodities are applicable.

The occurrence of tepraloxydim residues in rotational crops was investigated during the peer review. Based on the available information, it was concluded that significant residues are unlikely to occur in rotational crops, provided that the active substance is applied according to the GAP (Good Agricultural Practice) proposed on Jerusalem artichoke and radishes.

Residues of tepraloxydim in commodities of animal origin were not assessed in the framework of this application, since the crops under consideration are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). In the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 a comprehensive dietary exposure assessment was performed, taking into account the existing uses of tepraloxydim. The long-term consumer exposure assessment was now updated including the median residue concentration for Jerusalem artichoke and radishes. The total calculated intake accounted for up to 12 % of the ADI (UK toddler). The contribution of residues in Jerusalem artichoke and radishes to the total consumer exposure accounted for lower than 0.1 % of the ADI.

No acute consumer risk was identified in relation to the MRL proposals for crops under consideration. The calculated maximum exposure was 1 % of the ARfD for radishes (UK toddler).

EFSA concludes that the proposed uses of tepraloxydim on Jerusalem artichoke and radishes will not result in a consumer exposure exceeding the toxicological reference values and therefore, is unlikely to pose a consumer health risk.

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

SUMMARY TABLE

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: sum of tepraloxydim and its metabolites that can be hydrolyzed either to the 3-(tetrahydro-pyran-4-yl)-glutaric acid moiety or to the 3-hydroxy-(tetrahydro-pyran-4-yl)-glutaric acid moiety, expressed as tepraloxydim				
0213050	Jerusalem artichoke	0.1*	0.4	The MRL proposals are sufficiently supported by data and no consumer health risk was identified for the intended uses on these crops. Data to confirm the stability of tepraloxydim residues under frozen conditions in high water content matrices are however requested.
0213080	Radishes	0.1*	0.4	

(a): According to Annex I of Regulation (EC) No 396/2005.
(*): Indicates that the MRL is set at the limit of analytical quantification.

TABLE OF CONTENTS

BACKGROUND

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

Belgium, hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRLs for tepraloxydim in Jerusalem artichoke and radishes. This application was notified to the European Commission and EFSA, and was 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 27 February 2014.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2014-00133 and the following subject:

Tepraloxydim - Application to modify the existing MRLs in Jerusalem artichoke and radishes

Belgium proposed to raise the current MRL of tepraloxydim in Jerusalem artichoke and radishes from 0.1 mg/kg to 0.4 mg/kg.

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

TERMS OF REFERENCE

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

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

In this particular case the deadline for providing the reasoned opinion is 27 May 2014.

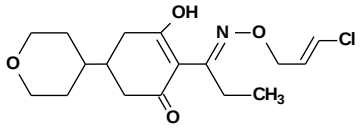
[3] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1-16.

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

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

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Tepraloxydim is the ISO common name for (5RS)-2-{(EZ)-1-[(2E)-3-chloroallyloxyimino]propyl}-3-hydroxy-5-perhydropyran-4-ylcyclohex-2-en-1-one (IUPAC).



Molecular weight: 341.8 g/mol

Tepraloxydim belongs to the group of cyclohexadione-oxime compounds which are used as herbicide. It is absorbed through leaves and translocated to the whole plant where it acts as an acetyl coenzyme A carboxylase (ACCase) inhibitor. Its selectivity spectrum allows for an effective control of many important grass weeds in dicotyledoneous crops and in crops belonging to the *Liliaceae*, following post-emergence application.

Tepraloxydim was evaluated in the framework of Directive 91/414/EEC with Spain being the designated rapporteur Member State (RMS). It was included in Annex I of this Directive by 05/34/EC[6] which entered into force on 01 June 2005 for use as herbicide only. In accordance with Commission Implementing Regulation (EU) No 540/2011[7] tepraloxydim is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC. The representative uses evaluated in the peer review were the outdoor treatment on potato, sugar beet, pea, field bean, oilseed rape and soybean. The Draft Assessment Report (DAR) of tepraloxydim was not peer reviewed by EFSA therefore, no EFSA conclusion is available.

In 2011 EFSA issued a reasoned opinion on the revision of the existing MRLs for tepraloxydim according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011) and the MRL proposals were transposed in the EU legislation by Regulation (EC) No 777/2013[8]. The existing EU MRLs for tepraloxydim on Jerusalem artichoke and radishes are set at the LOQ of 0.1*mg/kg. No CXLs are established for tepraloxydim.

The details of the intended GAP for tepraloxydim are given in Appendix A.

[6] Commission Directive 05/34/EC of 17 May 2005, amending Council Directive 91/414/EEC to include etoxazole and tepraloxydim as active substances OJ L 125, 18.5.2005, p. 5-7.

[7] Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.06.2011, p. 1-186.

[8] Regulation (EU) No 777/2013 of 12 August 2013 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for clodinafop, clomazone, diuron, ethalfluralin, ioxynil, iprovalicarb, maleic hydrazide, mepanipyrim, metconazole, prosulfocarb and tepraloxydim in or on certain products OJ L 221, 17/08/2013, p. 1-48.

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (Belgium, 2014), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (Spain, 2001), the Commission Review Report on tepraloxydim (EC, 2004), as well as the conclusions from previous EFSA opinion on tepraloxydim (EFSA, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[9] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a-g, 2000, 2010a,b, 2011; OECD, 2011).

1. Method of analysis

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

Analytical method based on GC-MSD quantifications was assessed during the peer review under Directive 91/414/EEC and concluded to be sufficiently validated for the determination of tepraloxydim and its metabolites[10] in high water and high oil content matrices. The method was validated for the LOQ of 0.05mg/kg for each moiety group, resulting in an overall LOQ of 0.1 mg/kg in high water and high oil commodities (Spain, 2001).

In addition, QuEChERS method for determination of the parent tepraloxydim in high water content, dry and high acid content commodities at the LOQ of 0.01 mg/kg by HPLC-MS/MS is also applicable (EFSA, 2011).

Since the commodities under consideration belongs to the group of high water content commodities, EFSA concludes that sufficiently validated analytical methods for enforcing the proposed MRLs for tepraloxydim on the Jerusalem artichoke and radishes are available.

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 the crops under consideration are normally not fed to livestock.

2. Mammalian toxicology

The toxicological profile of the active substance tepraloxydim was assessed in the framework of the peer review under Directive 91/414/EEC (EC, 2004). The data were sufficient to derive toxicological reference values for tepraloxydim which are compiled in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
tepraloxydim					
ADI	EC	2004	0.025 mg/kg bw per day	24-months chronic toxicity in rat	200
ARfD	EC	2004	0.4 mg/kg bw	Rat developmental toxicity	100

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

[10] tepraloxydim and its metabolites that can be hydrolysed either to the moiety 3-(tetrahydro-pyran-4-yl)-glutaric acid or to the moiety 3-hydroxy-(tetrahydro-pyran-4-yl)-glutaric acid expressed as tepraloxydim

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Metabolism of tepraloxydim was investigated for foliar application on root and tuber vegetables (sugar beet) and on pulses and oilseeds (summer oilseed rape and soybean) using cyclohexene-4,(6)- ^{14}C-labelled tepraloxydim in the framework of the peer review under Directive 91/414/EEC. The residue definition for enforcement and risk assessment in root/tuber vegetables and pulses/oilseeds crops were defined as the sum of tepraloxydim and its metabolites that can be hydrolysed either to the moiety 3-(tetrahydro-pyran-4-yl)-glutaric acid or to the moiety 3-hydroxy-(tetrahydro-pyran-4-yl)-glutaric acid expressed as tepraloxydim (EFSA, 2011)

The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived in the peer review.

For the uses on Jerusalem artichoke and radishes, EFSA concludes that the metabolism of tepraloxydim is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed in the peer review are applicable.

3.1.1.2. Magnitude of residues

In the support of this application, the EMS refers to the ten NEU outdoor trials performed on carrots and already submitted for the MRLs review under Article 12 (EFSA, 2011). These trials were performed over two seasons according to similar GAPs to those proposed for Jerusalem artichoke and radishes *(1x 0.1 kg/ha; PHI 21 days)*. Residue levels were <0.1 mg/kg in two trials and in the range of 0.1 mg/kg to 0.2 mg/kg in the other one. The number of trials is sufficient to derive an MRL proposal of 0.4 mg/kg on carrot and therefore, to support an extrapolation to Jerusalem artichoke and radishes according to the SANCO 7525/IV/95 guidance document.

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

Storage stability studies in high water content commodities are not available. During the peer review, it was demonstrated that tepraloxydim is stable for a period of 30 months at -20 °C in high oil content and dry commodities only. Tepraloxydim stability in high water content matrices has therefore to be confirmed. However, additional metabolites to those already included in residue definition and taken into account by the common moieties analytical methods are not expected to be formed and provisionally, it can be considered that tepraloxydim residues are stable in high water commodities, pending the submission of the requested data.

According to the EMS, the analytical method used to analyse the supervised residue trial samples has been sufficiently validated and was proven to be fit for the purpose (Belgium, 2014).

EFSA concludes that the data are sufficient to propose a MRL proposal of 0.4 mg/kg for the intended use on Jerusalem artichoke and radishes, in NEU.

Table 3-1: Overview of the available residue trial data

Commodity	Residue region (a)	Outdoor /Indoor	Individual trial results (mg/kg) Enforcement & Risk assessment	STMR (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
Enforcement residue definition: Sum of tepraloxydim and its metabolites that can be hydrolyzed either to the moiety 3-(tetrahydro-pyran-4-yl)-glutaric acid or to the moiety 3-hydroxy-(tetrahydro-pyran-4-yl)-glutaric acid, expressed as tepraloxydim								
carrots → Jerusalem artichoke & radishes	NEU	Outdoor	2x <0.1; 0.10; 0.12; 0.12; 0.13; 0.15; 0.18; 0.19; 0.20	0.13	0.2	0.4	-	R_{ber}= 0.4 R_{max}= 0.3 MRL_{OECD} = 0.4

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e. indoor use) or Import (country code) (EC, 2011).
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residue trial.
(e): Statistical estimation of MRLs according to the EU methodology (R_{ber}, R_{max}; EC, 1997g) and unrounded/rounded values according to the OECD methodology (OECD, 2011).

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of tepraloxydim was investigated during the peer review. A standard hydrolysis study simulating pasteurisation, boiling/brewing/baking and sterilisation conditions was provided. Tepraloxydim is degraded faster at low pH and increasing temperatures. However, since new metabolites compared to those already included in the primary crop residue definition are not expected to be formed, it was concluded that the residue definitions proposed for the raw agricultural commodities (RAC) are applicable to processed commodities.

Specific processing studies on the magnitude of tepraloxydim residues were not provided under current application. However, they are not considered necessary as Jerusalem artichoke and radishes are mostly consumed raw.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Residues in rotational crops were investigated during the peer review under Directive 91/414/EEC, and it was concluded that tepraloxydim residues above 0.01 mg/kg are not expected to be present in rotational crops when the active substance is applied at a maximum dose rate of 100 g/ha. Since the uses on Jerusalem artichoke and radishes refer to a single application at 100 g/ha, EFSA concludes that tepraloxydim residues are unlikely to occur in rotational crops provided that the active substance is applied according to the proposed GAPs.

4. Consumer risk assessment

In the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 a comprehensive dietary exposure assessment was performed, taking into account the existing uses for tepraloxydim (EFSA, 2011). The long-term consumer exposure assessment was now updated including the median residue concentration for Jerusalem artichoke and radishes.

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 [11] (EFSA, 2007).

For the calculation of chronic exposure, EFSA used the median residue values as derived from the residue trials on the crops under consideration (see Table 3-1) and the median residue values reported in the framework of the review of existing MRLs according to Regulation (EC) No 396/2005 of tepraloxydim (EFSA, 2011).

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 the Jerusalem artichoke and radishes assuming the consumption of a large portion of the food items as reported in the national food surveys and that these items contained residues at the highest level as observed in supervised field trials. A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation, when required (EFSA, 2007).

[11] 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).

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: the sum of tepraloxydim and its metabolites that can be hydrolysed either to the moiety 3-(tetrahydro-pyran-4-yl)-glutaric acid or to the moiety 3-hydroxy-(tetrahydro-pyran-4-yl)-glutaric acid, expressed as tepraloxydim				
Jerusalem artichoke	0.13	STMR	0.2	Highest residue
Radish	0.13	STMR	0.2	Highest residue
Other commodities assessed during MRL review	See Table 4-1 in Reasonned Opinion on MRLs review (EFSA, 2011)			

The estimated exposure was then compared with the toxicological reference values derived for tepraloxydim (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 accounted for up to 12 % of the ADI (UK toddler). The contribution of residues in Jerusalem artichoke and radishes to the total consumer exposure accounted for lower than 0.1 % of the ADI.

No acute consumer risk was identified in relation to the MRL proposals for crops under consideration. The calculated maximum exposure in percentage of the ARfD was 1 % for radishes (UK toddler).

EFSA concludes that the intended use of tepraloxydim on Jerusalem artichoke and radishes 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

The toxicological profile of tepraloxydim was assessed in the framework of the peer review and the data were sufficient to derive an ADI 0.025 mg/kg bw per day and an ARfD of 0.4 mg/kg bw.

The metabolism of tepraloxydim in primary crops was investigated on root/tuber vegetables and on pulses/oilseeds. Based on these studies the peer review established the residue definition for enforcement and risk assessment as the sum of tepraloxydim and its metabolites that can be hydrolysed either to the 3-(tetrahydro-pyran-4-yl)-glutaric acid moiety or to the 3-hydroxy-(tetrahydro-pyran-4-yl)-glutaric acid moiety, expressed as tepraloxydim. For the use on crops under consideration, EFSA concludes that the metabolism of tepraloxydim in primary crops is sufficiently addressed and the residue definitions are applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to derive MRL proposals of 0.4 mg/kg for the proposed uses on Jerusalem artichoke and radishes. Study to confirm the stability of tepraloxydim residues under frozen conditions in high water content matrices is however requested. Adequate analytical enforcement methods are available to control the residues of tepraloxydim on the commodities under consideration at the validated LOQ of 0.1 mg/kg.

Studies investigating the nature of tepraloxydim residues in processed commodities were assessed in the peer review and showed that tepraloxydim is degraded during pasteurisation, cooking, brewing and

sterilisation. During the degradation of tepraloxydim no new metabolites are expected, therefore the residue definitions for enforcement and risk assessment as for raw commodities are applicable.

The occurrence of tepraloxydim residues in rotational crops was investigated during the peer review. Based on the available information, it was concluded that significant residues are unlikely to occur in rotational crops, provided that the active substance is applied according to the GAP (Good Agricultural Practice) proposed on Jerusalem artichoke and radishes.

Residues of tepraloxydim in commodities of animal origin were not assessed in the framework of this application, since the crops under consideration are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). In the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 a comprehensive dietary exposure assessment was performed, taking into account the existing uses of tepraloxydim. The long-term consumer exposure assessment was now updated including the median residue concentration for Jerusalem artichoke and radishes. The total calculated intake accounted for up to 12 % of the ADI (UK toddler). The contribution of residues in Jerusalem artichoke and radishes to the total consumer exposure accounted for lower than 0.1 % of the ADI.

No acute consumer risk was identified in relation to the MRL proposals for crops under consideration. The calculated maximum exposure was 1 % of the ARfD for radishes (UK toddler).

EFSA concludes that the proposed uses of tepraloxydim on Jerusalem artichoke and radishes will not result in a consumer exposure exceeding the toxicological reference values and therefore, is unlikely to pose a consumer health risk.

RECOMMENDATIONS

Code number[(a)]	**Commodity**	**Existing EU MRL** (mg/kg)	**Proposed EU MRL** (mg/kg)	**Justification for the proposal**
Enforcement residue definition: sum of tepraloxydim and its metabolites that can be hydrolyzed either to the 3-(tetrahydro-pyran-4-yl)-glutaric acid moiety or to the 3-hydroxy-(tetrahydro-pyran-4-yl)-glutaric acid moiety, expressed as tepraloxydim				
0213050	Jerusalem artichoke	0.1*	0.4	The MRL proposals are sufficiently supported by data and no consumer health risk was identified for the intended uses on these crops. Data to confirm the stability of tepraloxydim residues under frozen conditions in high water content matrices are however requested.
0213080	Radishes	0.1*	0.4	

(a): According to Annex I of Regulation (EC) No 396/2005.
(*): Indicates that the MRL is set at the limit of analytical quantification.

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APPENDICES

Appendix A. GOOD AGRICULTURAL PRACTICE (GAPS)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)
				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	
Jerusalem artichoke	Belgium (NEU)	F	Couch grass	EC	50 g/l	spraying		1				0.1	21
Radishes	Belgium (NEU)	F	Couch grass	EC	50 g/l	spraying		1				0.1	21

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

Appendix B. Pesticide Residue Intake Model (PRIMo)

Tepraloxydim			
Status of the active substance:	Included	Code no.	
LOQ (mg/kg bw):	0.02	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.025	ARfD (mg/kg bw):	0.4
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2004	Year of evaluation:	2004

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum: 1 – 12

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)
12.4	UK Toddler	9.1	Sugar beet (root)	1.4	Potatoes	0.7	Beans	0.0
11.3	WHO Cluster diet F	6.9	Soya bean	1.4	Potatoes	0.5	Swine: Meat	0.3
11.2	WHO Cluster diet B	6.4	Soya bean	1.1	Potatoes	0.4	Poultry: Meat	0.3
11.0	WHO cluster diet E	6.2	Soya bean	1.5	Potatoes	0.5	Rape seed	0.3
8.9	NL child	2.4	Potatoes	2.3	Milk and milk products: Cattle	0.6	Swine: Meat	2.4
8.1	WHO cluster diet D	3.9	Soya bean	1.6	Potatoes	0.4	Milk and milk products: Cattle	0.4
8.0	UK Infant	4.0	Sugar beet (root)	1.3	Potatoes	0.7	Carrots	0.0
6.5	FR infant	2.1	Milk and milk products: Cattle	1.7	Potatoes	1.3	Carrots	2.1
6.2	PT General population	3.2	Soya bean	2.1	Potatoes	0.3	Carrots	0.0
6.0	FR toddler	2.0	Potatoes	1.2	Carrots	0.5	Bovine: Meat	0.1
5.9	WHO regional European diet	1.6	Potatoes	0.8	Soya bean	0.5	Swine: Meat	0.4
5.0	SE general population 90th percentile	1.7	Potatoes	1.0	Milk and milk products: Cattle	0.5	Head cabbage	1.1
4.8	DE child	1.1	Milk and milk products: Cattle	1.0	Potatoes	0.5	Carrots	1.2
4.5	IE adult	0.9	Potatoes	0.3	Parsnips	0.3	Brussels sprouts	0.3
4.5	ES child	1.0	Milk and milk products: Cattle	0.7	Potatoes	0.6	Bovine: Meat	1.0
3.9	NL general	1.1	Potatoes	0.5	Milk and milk products: Cattle	0.4	Swine: Meat	0.5
3.2	UK vegetarian	1.5	Sugar beet (root)	0.5	Potatoes	0.3	Beans	0.0
2.9	UK Adult	1.6	Sugar beet (root)	0.6	Potatoes	0.2	Beans	0.0
2.9	LT adult	1.3	Potatoes	0.4	Swine: Meat	0.3	Head cabbage	0.4
2.5	DK child	1.0	Potatoes	0.7	Carrots	0.3	Birds' eggs	0.1
2.4	ES adult	0.4	Milk and milk products: Cattle	0.4	Potatoes	0.3	Bovine: Meat	0.4
2.3	PL general population	1.4	Potatoes	0.3	Head cabbage	0.2	Carrots	0.0
1.8	FR all population	0.4	Potatoes	0.2	Poultry: Meat	0.2	Milk and milk products: Cattle	0.2
1.5	DK adult	0.6	Potatoes	0.2	Carrots	0.2	Bovine: Meat	0.0
1.1	FI adult	0.5	Potatoes	0.1	Carrots	0.1	Soya bean	0.0
0.8	IT kids/toddler	0.4	Potatoes	0.1	Carrots	0.1	Beans	0.0
0.6	IT adult	0.2	Potatoes	0.1	Carrots	0.1	Beans	0.0

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Tepraloxydim is unlikely to present a public health concern.

Acute risk assessment /children - refined calculations

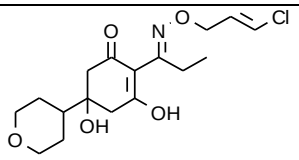
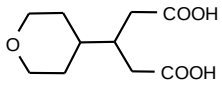
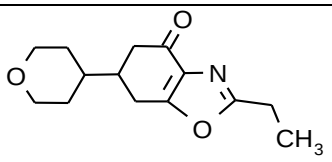
Acute risk assessment / adults / general population - refined calculations

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 variabilty 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)
1.1	Radishes	0.2 / -	0.8	Radishes	0.2 / -	0.6	Radishes	0.2 / -	0.4	Radishes	0.2 / -
						0.3	Jerusalem artichokes	0.2 / -	0.2	Jerusalem artichokes	0.2 / -

Appendix C. LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Code/Trivial name	Chemical name	Structural formula
5-OH-DP (5-hydroxy-tepraloxydim)	(EZ)-(RS)-2-{1-[(2E)-3-chloroallyloxyimino]propyl}-3,5-hydroxy-5-perhydropyran-4-ylcyclohex-2-en-1-one	
GP	3-(tetrahydro-pyran-4-yl)-glutaric acid	
DP-2 (oxazole)	2-ethyl-6-(tetrahydro-2*H*-pyran-4-yl)-6,7-dihydro-1,3-benzoxazol-4(5*H*)-one	

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 to risk assessment residue definition
CXL	Codex Maximum Residue Limit (Codex MRL)
DAR	Draft Assessment Report
DT_{90}	period required for 90 % dissipation (define method of estimation)
EC	European Community
Ec	emulsifiable concentrate
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
GC	gas chromatography
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (former GIFAP)
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
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
MS/MS	tandem mass spectrometry
NEU	northern European Union
MSD	mass spectrometry detector
MW	molecular weight
OECD	Organisation for Economic Co-operation and Development
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
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake