

REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for tepraloxydim in Jerusalem artichoke and radishes¹

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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

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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.

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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 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 tepraloxym 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:

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

Belgium proposed to raise the current MRL of tepraloxym 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 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Tepraloxydim is the ISO common name for (5RS)-2-[(E)-1-[(2E)-3-chloroallyloxyimino]propyl]-3-hydroxy-5-perhydrofuran-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 dicotyledonous 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/EC⁶ which entered into force on 01 June 2005 for use as herbicide only. In accordance with Commission Implementing Regulation (EU) No 540/2011⁷ 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 777/2013⁸. 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.

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 tepraloxymid 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 tepraloxymid				
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 Reasoned Opinion on MRLs review (EFSA, 2011)			

The estimated exposure was then compared with the toxicological reference values derived for tepraloxymid (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 tepraloxymid 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 tepraloxymid 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 tepraloxymid 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 tepraloxymid 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 tepraloxymid. For the use on crops under consideration, EFSA concludes that the metabolism of tepraloxymid 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 tepraloxymid residues under frozen conditions in high water content matrices is however requested. Adequate analytical enforcement methods are available to control the residues of tepraloxymid on the commodities under consideration at the validated LOQ of 0.1 mg/kg.

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

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

The occurrence of tepraloxymid 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 tepraloxymid 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 tepraloxymid. 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 tepraloxymid 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 tepraloxymid 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 tepraloxymid				
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 tepraloxymid 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.

REFERENCES

Belgium, 2014. Evaluation report on the modification of MRLs for tepraloxymid in Jerusalem artichoke and radishes prepared by the evaluating Member State Belgium under Article 8 of Regulation (EC) No 396/2005, 03 January 2014, 8 pp.

EC (European Commission), 1996. Appendix G. Livestock Feeding Studies. 7031/VI/95-rev.4.

EC (European Commission), 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev.3.

EC (European Commission), 1997b. Appendix B. General recommendations for the design, preparation and realisation of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev.6.

- EC (European Commission), 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev.2.
- EC (European Commission), 1997d. Appendix E. Processing studies. 7035/VI/95-rev.5.
- EC (European Commission), 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev.3.
- EC (European Commission), 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev.5.
- EC (European Commission), 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95.
- EC (European Commission), 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414). SANCO/3029/99-rev.4.
- EC (European Commission), 2004. Review report for the active substance tepraloxydim. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 3 December 2004 in view of the inclusion of tepraloxydim in Annex I of Council Directive 91/414/EEC. SANCO/10388/2002-rev.4, 30 November 2004.
- EC (European Commission), 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010 Rev. 0, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23-24 March 2010.
- EC (European Commission), 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev.8.1.
- EC (European Commission), 2011. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.9.
- EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers health arising from proposed temporary EU MRLs. Available online: www.efsa.europa.eu
- EFSA (European Food Safety Authority), 2011. Reasoned opinion of EFSA: Review of the existing maximum residue levels (MRLs) for tepraloxydim according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2011;9(10):2423, 56 pp. doi:10.2903/j.efsa.2011.2423
- FAO (Food and Agriculture Organization of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Ed. FAO Plant Production and Protection Paper 197, 264 pp.
- Meier U, 2001. Growth Stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., Federal Biological Research Centre of Agriculture and Forest. Braunschweig, Germany.
- OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL Calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues.
- Spain, 2001. Draft assessment report on the active substance tepraloxydim prepared by the rapporteur Member State Spain in the framework of Council Directive 91/414/EEC, November 2001.

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)

Tepraloxymid			
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)		2nd contributor to MS diet (in % of ADI)		3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
			Commodity / group of commodities		Commodity / group of commodities			
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

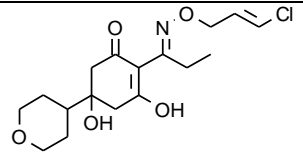
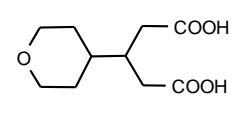
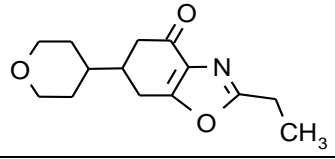
Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Tepraloxymid is unlikely to present a public health concern.

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):		
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	IESTI 1	*)	**) pTMRL/ threshold MRL (mg/kg)	IESTI 2	*)	**) pTMRL/ threshold MRL (mg/kg)	IESTI 1	*)	**) pTMRL/ threshold MRL (mg/kg)	IESTI 2	*)	**) pTMRL/ threshold MRL (mg/kg)
	Highest % of ARfD/ADI	Commodities		Highest % of ARfD/ADI	Commodities		Highest % of ARfD/ADI	Commodities		Highest % of ARfD/ADI	Commodities	
	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-tepraloxdim)	(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-2H-pyran-4-yl)-6,7-dihydro-1,3-benzoxazol-4(5H)-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	rappporteur Member State
SANCO	Directorate-General for Health and Consumers
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake