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Modification of the existing maximum residue level for metaldehyde in leek

European Food Safety Authority (EFSA)

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS), Austria, received an application from De Sangosse SAS to modify the existing maximum residue level (MRL) for the active substance metaldehyde in leek. To accommodate for the intended use of metaldehyde, Austria proposed to raise the existing MRL from the value of 0.5 mg/kg to 1.5 mg/kg. Austria 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 a MRL proposal of 1.5 mg/kg for the proposed use on leek. Adequate analytical enforcement methods are available to control the residues of metaldehyde on the commodity under consideration. Based on the risk assessment results, EFSA concludes that the proposed use of metaldehyde on leek will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

Keywords: metaldehyde, leek, MRL application, consumer risk assessment

Requestor: European Commission

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Amendment: An additional reference 2014a has been included and therefore, the reference 2014 in the previous version has been changed to 2014b throughout the document. In addition, a statement has been included in the tables pages 3 and 12 clarifying that the confirmatory data on standard hydrolysis study requested under MRL review has been addressed. To avoid confusion, the older version has been removed from the EFSA Journal, but is available on request, as is a version showing all the changes made.

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS) Austria, received an application from De Sangosse SAS to modify the existing maximum residue level (MRL) for the active substance metaldehyde in leek. To accommodate for the intended use of metaldehyde, Austria proposed to raise the existing MRL from the value of 0.5 mg/kg to the proposed MRL 1.5 mg/kg. Austria 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 the European Food Safety Authority (EFSA) on 3 October 2016.

EFSA bases its assessment on the evaluation report submitted by the EMS, the draft assessment report (DAR) (and its addendum) prepared under Council Directive 91/414/EEC, the Commission review report on metaldehyde, the conclusion on the peer review of the pesticide risk assessment of the active substance metaldehyde as well as the conclusions from the previous EFSA opinion on the review of the existing MRLs for metaldehyde according to Article 12 of Regulation (EC) No 396/2005.

The toxicological profile of metaldehyde was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.02 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.3 mg/kg bw.

The metabolism of metaldehyde in primary crops was investigated in sugar beet (root vegetables), strawberries (fruits), lettuce (leafy crops), rice and wheat (cereals), and oilseed rape (oilseeds). These data demonstrated that metaldehyde is extensively metabolised with final incorporation of its carbon atoms in natural plant constituents; no metabolites were identified in significant concentrations. From these studies, the peer review concluded to establish the residue definition for enforcement and for risk assessment as metaldehyde. For the uses on leek, EFSA concludes that the metabolism of metaldehyde in primary crops has been sufficiently addressed and that the residue definitions derived are applicable.

EFSA concludes that the submitted residue trials are sufficient to derive MRL proposal of 1.5 mg/kg on leek. Adequate analytical enforcement methods are available to control the residues of metaldehyde in dry matrices and in high water content matrices under consideration which allow in routine enforcement practice a quantification of residues down to the limit of quantification (LOQ) of 0.05 mg/kg.

The occurrence of metaldehyde residues in rotational crops was investigated in the framework of the peer review. Based on the available information on the nature and magnitude of residues, it was concluded that significant residue levels are unlikely to occur in rotational crops, provided that the compound is used according to the proposed good agricultural practice (GAP).

Residues of metaldehyde in commodities of animal origin were not assessed since leek is normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). No acute and chronic consumer intake concerns were identified. The highest chronic intake was calculated to be 9.3% of the ADI (UK toddler). The contribution of residues in leek to the total consumer exposure accounted for a maximum of 0.65% of the ADI (FR toddler). The acute consumer exposure was calculated to be 21.6% of the ARfD for leek.

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

EFSA proposes to amend the existing MRL as reported in the summary table below.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: metaldehyde				
270060	Leek	0.5	1.5	The submitted data are sufficient to derive a MRL proposal. No consumer health risk was identified. The confirmatory data requested under MRL review on standard hydrolysis study is addressed

EU: European Union; MRL: maximum residue level.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

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Background

Regulation (EC) No 396/2005[1] (hereinafter referred to as 'the MRL regulation') establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at the European Union (EU) level. Article 6 of the 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[2], repealed by Regulation (EC) No 1107/2009[3], shall submit to a Member State, when appropriate, an application to modify a MRL in accordance with the provisions of Article 7 of the Regulation.

Austria, hereafter referred to as the evaluating Member State (EMS), received an application from the company De Sangosse SAS[4] to modify the existing MRL for metaldehyde in leek. This application was notified to the European Commission and the European Food Safety Authority (EFSA) and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report was submitted to the European Commission and forwarded to EFSA on 3 October 2016.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2016-00633 and the following subject:

Metaldehyde – MRLs in leek

Austria proposed to raise the existing MRL of metaldehyde in leek from the value of 0.5 mg/kg to 1.5 mg/kg.

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

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

The evaluation report submitted by the EMS (Austria, 2016) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion, and, thus, are made publicly available.

In accordance with Article 11 of the Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months (which may be extended to 6 months if more detailed evaluations need to be carried out) from the date of receipt of the application. If EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

The active substance and its use pattern

Metaldehyde is the ISO common name for r-2,c-4,c-6,c-8-tetramethyl-1,3,5,7-tetroxocane or 2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane (IUPAC). The chemical structure of the active substance is reported in Appendix B.

The details of the intended good agricultural practice (GAP) for metaldehyde in leek triggering the MRL application are given in Appendix A.

Metaldehyde was evaluated in the framework of Directive 91/414/EEC with Austria designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Directive 2011/54/EU[5] which entered into force 1 June 2011; the approval is restricted for the use as molluscicide only. In accordance with Commission Implementing Regulation (EU) No 540/2011[6], metaldehyde is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC.

The representative uses evaluated in the peer review were spreading (manually or with fertiliser spreader) on cereals (rye, oat, wheat, barley and triticale) and oilseed rape to control slugs and snails. The draft assessment report (DAR) has been peer reviewed by EFSA (EFSA, 2010).

[1] 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, 16.3.2005, p. 1–16.
[2] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
[3] 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.
[4] De Sangosse SAS, Bonnel, CS 10005, 47480 Pont du Casse, France.
[5] Commission Implementing Directive 2011/54/EU of 20 April 2011 amending Council Directive 91/414/EEC to include metaldehyde as active substance and amending Commission Decision 2008/934/EC, OJ L 105, 21.4.2011, p. 28–31.
[6] 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, 11.6.2011, p. 1–186.

Following the MRL review under Article 12 of Regulation (EC) No 396/2005, the MRLs for metaldehyde have been set in Annex II of this Regulation.[7]

Assessment

EFSA has based its assessment on the evaluation report submitted by the EMS (Austria, 2016), the DAR (and its addendum) prepared under Directive 91/414/EEC (Austria, 2006, 2009), the Commission review report on metaldehyde (European Commission, 2011b), the conclusion on the peer review of the pesticide risk assessment of the active substance metaldehyde (EFSA, 2010) as well as the conclusions from the previous EFSA opinions on metaldehyde including the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2014a,b). 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[8] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a–g, 2000, 2010a,b, 2015; OECD, 2011).

1. Method of analysis

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

Analytical methods for the determination of metaldehyde residues in plant commodities were assessed during the peer review under Directive 91/414/EEC (EFSA, 2010). The gas chromatography with mass spectrometry (GC–MS) method was proposed as enforcement method for the control of metaldehyde residues in dry matrices and in matrices with high oil, high water and high acid content.

Sufficient validation and independent laboratory validation (ILV) data were submitted to conclude that the analytical method has been adequately validated to enforce metaldehyde residues in high water, high acid and high oil content commodities, and in dry/protein and dry/starch matrices at the limit of quantification (LOQ) of 0.05 mg/kg (EFSA, 2014b).

As the commodity under consideration belongs to high water content commodity groups, EFSA concludes that sufficiently validated analytical methods are available for enforcing the proposed MRLs for metaldehyde in leek.

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 leek is normally not fed to livestock.

2. Mammalian toxicology

The toxicological profile of the active substance metaldehyde was assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2010). The data were sufficient to derive toxicological reference values compiled in Table 1.

Table 1: Overview of the toxicological reference values

	Source	Year	Value	Study	Safety factor
Metaldehyde					
ADI	EFSA	2010	0.02 mg/kg bw per day	Rat, 2-year	100
ARfD	EFSA	2010	0.3 mg/kg bw	52 weeks, dog (acute neurotoxic effects)	100

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

[7] Commission Regulation (EU) No 2015/400 of 25 February 2015 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 bone oil, carbon monoxide, cyprodinil, dodemorph, iprodione, metaldehyde, metazachlor, paraffin oil (CAS 64742-54-7), petroleum oils (CAS 92062-35-6) and propargite in or on certain products. OJ L 171, 14.3.2015, p. 56–113.

[8] 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, 11.6.2011, 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 metaldehyde in primary crops was evaluated by Austria (Austria, 2006, 2009) and reviewed by EFSA (EFSA, 2010) in the framework of the peer review under Directive 91/414/EEC. The overview of the available metabolism studies is presented in Table 2.

Table 2: Summary of available metabolism studies in plants

Crop groups	Crops	Application[(a)]	Sampling (DAT)	Comments
Fruit	Strawberries	F, soil: 1 × 1.5 kg/ha post-planting	1, 7, 14, 28, 42, 70, 84, 98	
Root	Sugar beet	F, soil: 1 × 15.4 kg/ha post-planting	48	
Leafy	Lettuce	F, soil: 1 × 15.4 kg/ha, 38 days post-planting	28	Limited validity since the data on the analytical part of the study are not conclusive
		F, soil: 1 × 3.6 kg/ha, 2 weeks post-planting	4, 6, 8 weeks	Supplementary study to investigate the uptake by lettuce from soil, non-GLP
		F, soil: 1 × 3.6 kg/ha, 5 weeks post-planting	3, 5 weeks	
Cereals/grass	Rice	G, flooding water: 1 × 4.97 kg/ha	114	
	Wheat	Soil: 2 × 3.5 kg/ha post-planting	1, 21, 69	
Pulses/oilseeds	Oilseed rape	Soil: 2 × 3.1 kg/ha	2, 58	

DAT: days after treatment, GLP: good laboratory practice.
(a): Outdoor/field application (F) or glasshouse/protected crops/indoor application (G).

The metabolism studies presented a similar pattern of degradation in all crops. Metaldehyde is extensively metabolised to single carbons units that are incorporated into the plant's carbon pool. No metabolites were identified in significant concentrations. Study results also provide an indication that translocation from soil to crop occurs. In the framework of the peer review and the MRL review, it was concluded that risk assessment and monitoring residue definitions should be metaldehyde only (EFSA, 2010, 2014b).

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 use on leek, EFSA concludes that the metabolism of metaldehyde is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed during the peer review are applicable.

3.1.1.2. Magnitude of residues

Leek *(northern Europe (NEU), southern Europe (SEU), GAP: max. four applications up to 700 g/ha, preharvest interval (PHI) 7 days)*

In support of the MRL application, eight supervised trials were conducted in leek in NEU and four in SEU which reflect the GAP in terms of the total seasonal application rate (700 g/ha). Metaldehyde was applied in three applications of 200, 250 and 250 g/ha, respectively, whereas the proposed GAP defines up to four applications with individual applications at a maximum of 200 g/ha and (max. 700 g/ha). The residue trials, therefore, reflect a slightly more critical GAP, but still within 25% tolerance.

All trials were conducted in 2015 and 2016. Half of the supervised trials (four trials in NEU and two trials in SEU) were residue decline trials.

According to the Mann–Whitney *U*-test, the NEU and SEU trials belong to the same populations ($\alpha = 0.05$). The MRL can therefore be calculated using the combined data.

Based on these data sets, EFSA derived a MRL of 1.5 mg/kg for leek.

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.

The stability of metaldehyde residues in plant matrices under storage conditions prior to analysis was assessed during the peer review under Directive 91/414/EEC (EFSA, 2010). Residues of metaldehyde were found to be stable at $\leq -18°C$ for up to 12 months in high water, high acid and high oil content matrices as well as in dry/starch and dry/protein matrices. As the trial samples were stored for a maximum period of 3 months 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 method used to analyse the residue trial samples has been sufficiently validated and was proven to be fit for the purpose (Austria, 2016).

EFSA concludes that the data are sufficient to derive the following MRL proposals:

- 1.5 mg/kg leek in NEU and SEU (combined data sets)

Table 3: Overview of the available residues trials data

Crop (trial GAP)	Region/ indoor[a]	Residue levels observed in the supervised residue trials[b] (mg/kg)	Recommendations/ comments[c]	MRL proposal (mg/kg)	HR[d] (mg/kg)	STMR[e] (mg/kg)
Leek Total application rate: 700 g/ha per season (split into 3 applications of 200, 250 and 250 g/ha), PHI 7 days)	NEU	2× < 0.05*, 0.1, 0.12, 0.24, 0.29, 0.43, 1.1	MRL_{OECD}: 1.698/2.0	2.0	1.1	**0.18**
	SEU	3× < 0.05*, 0.27	MRL_{OECD}: 0.545/0.6	0.6	0.27	0.05
	NEU + SEU	5× < 0.05*, 0.10, 0.12, 0.24, 0.27, 0.29, 0.43, 1.1	MRL_{OECD}: 1.435/1.5 NEU and SEU data sets similar (U test)	1.5	**1.1**	0.11

MRL: maximum residue level; OECD: Organisation for Economic Co-operation and Development.
The bold indicates that the values are proposed as input values for the consumer dietary exposure assessment.
*: Indicates that the MRL is proposed at the limit of analytical quantification (LOQ).
(a): NEU: Outdoor trials conducted in northern Europe; SEU: Outdoor trials conducted in southern Europe; Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Individual residue levels considered for MRL calculation are reported in ascending order (2× < 0.01, 0.01, 6× 0.02, 0.04, 0.08, 2× 0.10, 0.15, 0.17).
(c): Any information/comment supporting the decision and OECD MRL calculation (unrounded/rounded values).
(d): HR: Highest residue level according to the residue definition for risk assessment.
(e): STMR: Median residue level according to residue definition for risk assessment.

3.1.1.3. Effect of industrial processing and/or household preparation

Standard hydrolysis studies simulating the effect on the *nature* of metaldehyde residues under processing conditions representative of pasteurisation, boiling and sterilisation were assessed in the conclusion of the peer review (EFSA, 2014a), and it was concluded that the compound is hydrolytically stable under the representative conditions. Thus, for processed commodities, the same residue definition as for raw agricultural commodities (RAC) is applicable.

Specific studies to assess the *magnitude* of metaldehyde residues during the processing of leek are not necessary as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the acute daily intake (ADI).

3.1.2. Rotational crops

Leek can be grown in rotation with other plants, and therefore, the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed. The soil degradation studies demonstrated that the degradation rate of metaldehyde is rapid, with a maximum period required for 90% dissipation (DT_{90}) of 22 days (EFSA, 2010), which is below the trigger value of 100 days. Thus, further studies on rotational crops are not required (European Commission, 1997c).

3.2. Nature and magnitude of residues in livestock

As crop under consideration and its by-products are not normally fed to livestock, the nature and magnitude of metaldehyde residues in livestock is not assessed in the framework of this application (European Commission, 1996).

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population[9] (EFSA, 2007).

In the framework of the review of the existing MRLs for metaldehyde according to Article 12 of Regulation (EC) No 396/2005, a comprehensive long-term exposure assessment was performed taking into account the existing uses at the EU level (EFSA, 2014b). EFSA updated this risk assessment with the median residue levels (STMR) derived from the residue trials conducted on the crop under consideration in this MRL application (Table 3). The food commodities, for which no uses were reported in the framework of the Article 12 review, were excluded from the exposure calculation, assuming that there is no use of metaldehyde on these crops. For the commodities of animal origin, the existing MRLs as established in the Regulation (EU) No 2015/400[7] have been used.

The acute exposure assessment was performed only with regard to the commodity under consideration assuming the consumption of a large portion of the food item as reported in the national food surveys and that these items contained residues at the highest residue level (HR) as observed in supervised field trials (Table 3). A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised in Table 4.

[9] The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from Member States (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 are used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

Table 4: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment residue definition: metaldehyde				
Leek	0.18	STMR NEU (Table 3)	1.1	HR (Table 3)
Citrus fruits	0.05*	STMR (EFSA, 2014b)	Acute risk assessment was undertaken only with regard to the crop under consideration	
Tree nuts	0.05*	STMR (EFSA, 2014b)		
Pome fruits	0.05*	STMR (EFSA, 2014b)		
Stone fruits	0.05*	STMR (EFSA, 2014b)		
Table & wine grapes	0.05*	STMR (EFSA, 2014b)		
Cane fruits	0.05*	STMR (EFSA, 2014b)		
Other small fruits & berries	0.05*	STMR (EFSA, 2014b)		
Strawberries	0.05*	STMR (EFSA, 2014b)		
Potatoes	0.03	STMR (EFSA, 2014b)		
Beetroot Turnips	0.05*	STMR (EFSA, 2014b)		
Swedes	0.05*	STMR (EFSA, 2014b)		
Carrots Celeriac Horseradish Jerusalem artichokes Parsnips Parsley root Radishes Salsify	0.02	STMR (EFSA, 2014b)		
Tomatoes Aubergines	0.05*	STMR (EFSA, 2014b)		
Flowering brassica Head brassica	0.05*	STMR (EFSA, 2014b)		
Leafy brassica	0.09	STMR (EFSA, 2014b)		
Kohlrabi	0.05*	STMR (EFSA, 2014b)		
Lettuce and other salad plants including Brassicacea Spinach and similar	0.48	STMR (EFSA, 2014b)		
Fresh herbs	0.48	STMR (EFSA, 2014b)		
Peas & Beans (fresh, with pods)	0.01*	STMR (EFSA, 2014b)		
Peas & Beans (fresh, without pods)	0.01*	STMR (EFSA, 2014b)		
Asparagus	0.01*	STMR (EFSA, 2014b)		
Celery Fennel	0.01*	STMR (EFSA, 2014b)		
Globe artichoke	0.02	STMR (EFSA, 2014b)		
Pulses (dry)	0.01*	STMR (EFSA, 2014b)		
Sunflower seed Sesame seed Soya bean Cotton seed Pumpkin seeds Safflower Borage Gold of pleasure Hempseed	0.05*	STMR (EFSA, 2014b)		

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Rape seed Linseed Poppy seed Mustard seed	0.01*	STMR (EFSA, 2014b)		
Small grain cereals	0.01*	STMR (EFSA, 2014b)		
Maize grain Millet grain Sorghum grain	0.05*	STMR (EFSA, 2014b)		
Sugar beet (root)	0.05*	STMR (EFSA, 2014b)		
Other plant and animal commodities	MRL	MRLs in Regulation (EU) 400/2015		

STMR: supervised trials median residue; HR: highest residue level; NEU: northern Europe; MRL: maximum residue level.
(*): Indicates that the input value is proposed at the limit of analytical quantification (LOQ).

The estimated exposure was then compared with the toxicological reference values derived for metaldehyde (Table 1). The results of the intake calculation using the EFSA PRIMo is a key supporting document and is made publicly available as a background document to this reasoned opinion.

A chronic consumer intake concerns was not identified for any of the European diets incorporated in the EFSA PRIMo. The highest chronic intake was calculated to be 9.3% of the ADI (UK toddler). The contribution of residues in leek to the total consumer exposure accounted for a maximum of 0.65% of the ADI (FR toddler).

An acute consumer risk was not identified in relation to the MRL proposal for crop under consideration. The highest acute consumer exposure was calculated to be 21.6% of the acute reference dose (ARfD) for leek.

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

Conclusions and recommendations

The information submitted was sufficient to propose the MRL summarised in the table below.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: metaldehyde				
270060	Leek	0.5	1.5	The submitted data are sufficient to derive a MRL proposal. No consumer health risk was identified. The confirmatory data requested under MRL review on standard hydrolysis study is addressed

EU: European Union, MRL: maximum residue level.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
DAR	draft assessment report
DAT	days after treatment
DT_{90}	period required for 90% dissipation (define method of estimation)
EMS	evaluating Member State
GAP	good agricultural practice
GC–MS	gas chromatography with mass spectrometry
HR	highest residue
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PAFF	Standing Committee on Plants, Animals, Food and Feed
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RAC	raw agricultural commodity
RB	ready-to-use bait
RMS	rapporteur Member State

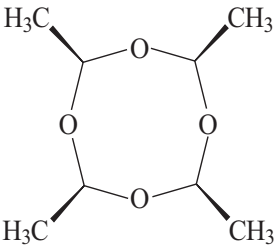
SANCO	Directorate-General for Health and Consumers
SEU	southern Europe
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake

Appendix A – Good Agricultural Practice

Crop	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application	g/hL min–max	Water L/ha min–max	g/ha min–max		
Leek	NEU, SEU (AT, FR)	F	Slugs/snails	RB	40 g/kg	BC	BBCH 00 up to PHI	As required up to total dose 700 g/ha	5 days	–	–	100–200	7	–

NEU: northern Europe; SEU: southern Europe; MS: Member State; BC: broadcast; RB: ready-to-use bait.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.

Appendix B – Used compound codes

Code/trivial name	Chemical name	Structural formula
Metaldehyde	*r*-2,c-4,c-6,c-8-Tetramethyl-1,3,5,7-tetroxocane or 2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane (IUPAC)	

IUPAC: International Union of Pure and Applied Chemistry.