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Modification of the existing maximum residue level for kresoxim-methyl in leeks

European Food Safety Authority (EFSA)

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS), the Netherlands, received an application from BASF SE to modify the existing maximum residue level (MRL) for the active substance kresoxim-methyl in leeks. In order to accommodate for the intended use of kresoxim-methyl, the Netherlands proposed to raise the value of existing MRL to 9 mg/kg. The Netherlands 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 10 mg/kg for the proposed use on leeks. An adequate analytical enforcement method is available to control the residues of kresoxim-methyl on the commodity under consideration. Based on the risk assessment results, EFSA concludes that the proposed use of kresoxim-methyl on leeks will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk.

Keywords: kresoxim-methyl, leeks, MRL application, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the Netherlands received an application from BASF SE to modify the existing maximum residue level (MRL) for the active substance kresoxim-methyl in leeks. In order to accommodate for the intended use of kresoxim-methyl, the Netherlands proposed to raise the existing MRL to 9 mg/kg. The Netherlands 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 24 April 2015.

EFSA bases its assessment on the evaluation report, the assessment report and its final addendum prepared for the renewal of the inclusion of kresoxim-methyl in Annex I to Directive 91/414/EEC, the Commission review reports on kresoxim-methyl, the JMPR evaluation report, the conclusion on the peer review of the pesticide risk assessment of the active substance kresoxim-methyl as well as the conclusions from previous EFSA opinions on kresoxim-methyl.

The toxicological profile of kresoxim-methyl 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 0.4 mg/kg bw per day. No acute reference dose (ARfD) was deemed necessary.

The metabolism of kresoxim-methyl in primary crops was investigated in three crop groups following foliar applications. The review of the existing MRLs for kresoxim-methyl performed under Article 12 of Regulation (EC) No 396/2005 confirmed the conclusion of the peer review that the relevant residue definition for enforcement is kresoxim-methyl. For risk assessment, the residue definition is the sum of kresoxim-methyl and the metabolites BF 490-2 and BF 490-9, free and conjugated, expressed as parent compound. For the use on leeks, EFSA concludes that the metabolism of kresoxim-methyl in primary crops has been sufficiently addressed and that the residue definitions derived are applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 10 mg/kg on leeks. An adequate analytical enforcement method is available to monitor the residues of kresoxim-methyl on the commodity under consideration at the validated LOQ of 0.05 mg/kg.

Since kresoxim-methyl was almost totally degraded to the acid metabolite BF 490-1 under sterilisation conditions, this metabolite was added to the residue definition for enforcement and risk assessment set in primary crops. Studies investigating the magnitude of kresoxim-methyl residues in processed leek products were not provided and are not required.

The occurrence of kresoxim-methyl residues in rotational crops was investigated in the framework of the peer review and the same residue definition as for primary crops was established for rotational crops. The conclusion of the Article 12 MRL review that sufficient information is not available to confirm that the use of the active substance on leeks as primary crop will not result in the presence of significant residues in rotational crops is still valid. Under the Article 12 MRL review, EFSA identified a data gap for field crop rotational trials which is also relevant for the current application. Meanwhile, Member States should consider this point when granting authorisations and, where relevant, take appropriate risk mitigation measures in order to avoid the presence of kresoxim-methyl residues in rotational crops.

Residues of kresoxim-methyl in commodities of animal origin were not assessed, since leeks are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). EFSA updated the chronic consumer risk assessment conducted under the Article 12 MRL review taking into account the median residue level (STMR) derived from the residue trials on leeks assessed in this 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 1.1 % of the ADI. No acute consumer exposure assessment was performed, since the setting of an ARfD was not necessary for kresoxim-methyl.

EFSA concludes that the proposed use of kresoxim-methyl on leeks will not result in a consumer exposure exceeding the toxicological reference value 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: kresoxim-methyl (R)				
0270060	Leeks	6	10	NEU use supported

(a): Commodity code number according to Annex I of Regulation (EC) 396/2005.
(R): The residue definition differs for the following combinations pesticide-code number:
Kresoxim-methyl — code 1000000 except 1040000: kresoxim methyl (BF 490-9, expressed as parent)
Metabolite BF 490-9 = 2-[2-(4-hydroxy-2-methylphenoxymethyl)phenyl]-2-methoxy-iminoacetic acid.

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Background

Regulation (EC) No 396/2005[1] establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at 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 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.

The Netherlands, hereafter referred to as the evaluating Member State (EMS), received an application from the company BASF SE[4] to modify the existing MRL for the active substance kresoxim-methyl in leeks. 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 to EFSA on 24 April 2015.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2015-00284 and the following subject:

Kresoxim-methyl - Modification of existing MRLs in leek.

The Netherlands proposed to raise the existing MRL of kresoxim-methyl in leeks from the value of 5 mg/kg to 9 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.

In accordance with Article 11 of the 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 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

Kresoxim-methyl is the ISO common name for (*E*)-methoxyimino[*α*-(*o*-tolyloxy)-*o*-tolyl]acetate (IUPAC).

The chemical structures of the active substance and its main metabolites are reported in Appendix C. Kresoxim-methyl has been approved for use as a fungicide.

Kresoxim-methyl was evaluated in the framework of Directive 91/414/EEC with Belgium designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Directive 1999/1/EC[5] which entered into force on 01 February 1999 for use as fungicide only. The Draft Assessment Report (DAR) of kresoxim-methyl prepared for the Annex I inclusion was not peer reviewed by EFSA.

The renewal of the Annex I inclusion of the active substance, expiring in December 2011, was performed with Belgium and Lithuania being the designated RMS and co-RMS, respectively. Kresoxim-methyl was then approved under Regulation (EC) No 1107/2009, which in the meantime repealed

[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, 16.03.2005, 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, 19.08.1991, 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] BASF SE, Speyerer Strasse 2, 67117, Limburgerhof, Germany.
[5] Commission Directive 1999/1/EC of 21 January 1999 including an active substance (kresoxim-methyl) in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market. OJ L 21, 28.01.1999, p. 21-23.

Directive 91/414/EEC, by Commission Implementing Regulation (EU) No 810/2011[6], which also amended Commission Implementing Regulation (EU) No 540/2011[7] accordingly. The representative uses supported in the Annex I renewal (AIR) refer to foliar applications of kresoxim-methyl on cereals, apples, pears and grapes. The Renewal Assessment Report has been peer reviewed by EFSA (EFSA, 2010a).

The EU MRLs for kresoxim-methyl are established in Annex II of Regulation (EC) No 396/2005. Since the entry into force of this Regulation, EFSA has issued a number of reasoned opinions on the modification of MRLs for kresoxim-methyl, including the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005. The proposals from these reasoned opinions have been considered in the preparation of the EU legislation. The MRL changes that were reported in the EU legislation since the entry into force of the abovementioned Regulation are summarised in Table 1.

Table 1: Overview of the MRL changes since the entry into force of Regulation (EC) No 396/2005

Procedure[(a)]	Considered by Regulation	Remarks
Art. 10 (EFSA, 2010b)	(EU) No 813/2011	blueberries, cranberries
AIR peer review (EFSA, 2010a)	(EU) No 251/2013	barley, rye, wheat
Art. 10 (EFSA, 2013)	(EU) No 364/2014	azaroles
Art. 12 (EFSA, 2014)	(EU) No 1200/2015	various commodity, including leek; change in the residue definition[(b)]

(a): Art. 10: Assessment of MRL application according to Article 6 to 10 of Regulation (EC) No 396/2005.
Art. 12: Review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005.
(b): The raising of the MRL on leeks from 5 to 6 mg/kg, the changes of other MRLs and in residue definition enter into force the 12th of August 2015.

Codex Alimentarius has set Codex maximum residue limits (CXLs) for a wide range of commodities, which have been considered for adoption in the EU legislation as well (EFSA, 2014). However, no CXL has been established for leek.

The details of the intended GAP for kresoxim-methyl in northern Europe (NEU) is given in Appendix A.

Assessment

EFSA bases its assessment on the evaluation report submitted by the EMS (Netherlands, 2015), the Assessment Report and its final addendum prepared for the renewal of the inclusion of kresoxim-methyl in Annex I to Directive 91/414/EEC (Belgium, 2010a, b), the Commission review reports on kresoxim-methyl (European Commission, 1998, 2011a, 2014), the JMPR evaluation report (FAO, 2001), the conclusion on the peer review of the pesticide risk assessment of the active substance kresoxim-methyl (EFSA, 2010a) as well as the conclusions from previous EFSA opinions on kresoxim-methyl, including the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2010b, 2013, 2014). 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, 2011b; OECD, 2011).

[6] Commission Implementing Regulation (EU) No 810/2011 of 11 August 2011 approving the active substance kresoxim-methyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 207, 12.08.2011, p. 7–11.
[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] 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.

1. Method of analysis

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

The review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005 concluded that a validated analytical method using HPLC-MS/MS detection is available to enforce kresoxim-methyl in food of plant origin with an LOQ of 0.05 mg/kg in high water, high oil, high acid matrices and dry/starch commodities.

The LOQ of 0.05 mg/kg is achieved in high water content commodities, to which group leeks belong.

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 leeks are not normally fed to livestock.

2. Mammalian toxicology

The toxicological profile of the active substance kresoxim-methyl was reviewed during the renewal of the Annex I inclusion. The previously established toxicological reference values, compiled in Table 2, were confirmed (EFSA, 2010a, European Commission, 1998, 2011a, 2014).

Table 2: Overview of the toxicological reference values

	Source	Year[(a)]	Value	Study	Safety factor
kresoxim-methyl					
ADI	European	1998	0.4 mg/kg bw per day	Rat, 2-yr oral toxicity study	100
ARfD	Commission	1998	Not necessary		

Furthermore, the toxicity of the plant metabolites BF 490-1, BF 490-2 and BF 490-9, which were observed in the rat metabolism and are part of different residue definitions, was considered covered by the reference toxicological value derived for the parent compound (EFSA, 2010a, 2014).

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 kresoxim-methyl in primary crops was evaluated in the framework of the peer review under Directive 91/414/EEC and the Article 12 MRL review (EFSA, 2010a, 2014). The details of the metabolism studies are reported in a previous EFSA reasoned opinion (EFSA, 2014). The overview of the metabolism study designs is presented in Table 3.

Table 3: Summary of available metabolism studies in plants

Crop group	Crops	Application	Sampling[(a)]	Comments
Fruit	Apple	Foliar, 2 and 6× 400 g/ha	149 (2×) or 14 (6×) DALA	
		Direct onto fruit, 2× 800 g/ha	14 DALA	
	Grape	Foliar, 5× 500 g/ha	14 DALA	
Root	Sugar beets	Foliar, 2× 150 g/ha	0 DAT_2, 0, 28 DALA	
Cereal	Wheat	Foliar, 2× 250/1250 g/ha	55 DAT_1, 64 (grain, straw) DALA	

(a): DALA, days after last application; DAT_1 day after 1st treatment; DAT_2 day after 2nd treatment.

The review of the existing MRLs for kresoxim-methyl performed under Article 12 of Regulation (EC) No 396/2005 confirmed the conclusion of the peer review that after foliar applications the relevant residue for enforcement is kresoxim-methyl. The current residue definition set in Regulation (EC) No 396/2005 for plant origin commodities is identical to the residue definition for enforcement derived in the peer review. The residue definition for risk assessment was defined as the sum of kresoxim-methyl and the metabolites BF 490-2 and BF 490-9, free and conjugated, expressed as parent (EFSA 2010a, 2014).

For the uses on leeks, EFSA concludes that the metabolism of kresoxim-methyl is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed during the peer review and in the framework of the Article 12 MRL review are applicable.

3.1.1.2. Magnitude of residues

In support of this MRL application, eight GAP compliant residue trials (3× 375 g/ha, PHI 14 days) were submitted. The trials were conducted in the NEU over the growing seasons 2012 and 2013 and resulted in an MRL proposal of 10 mg/kg.

The EMS proposed to derive a MRL of 9 mg/kg by combining the results of these trials with the results of eight additional trials already assessed under the Article 12 MRL review and conducted in the NEU during the growing seasons 1996 and 1997 according to a more critical use (6× 375 g/ha, PHI 14 days) (EFSA, 2014). However, since the statistical analysis (U-test, 5 %) suggests that the two individual datasets belong to different populations, EFSA would not recommend the merging of these data and proposes to set the MRL for leeks at the value of 10 mg/kg, based on the 2012/2013 trials only.

It should be noted that, although conducted with 3 applications at 375 g/ha, the 2012/2013 trials result in significantly higher residue levels than the 1996/1997 trials assessed during the Article 12 MRL review and conducted with a total of 6 applications at 375 g/ha. No sufficient information was made available to identify the possible factors which may have influenced the residue variability observed (i.e. crop varieties, leek size at harvest, sample preparation before shipment, etc).

The results of the residue trials, the related risk assessment input values (HR, STMR) and the MRL proposal are summarised in Table 4. In addition, conversion factors (CFs) for risk assessment derived from the submitted trials are reported in Table 5.

Storage stability of kresoxim-methyl and its metabolites BF 490-2 (glycoside conjugates) and BF 490-9 was demonstrated for a period of 12 months at -10 °C in commodities with high water content. As the samples from the trials assessed in this reasoned opinion were stored for less than 7 months under deep frozen conditions, it is concluded that the residue data are valid with regard to storage stability.

According to the EMS, the analytical methods used to analyse the residue trial samples have been sufficiently validated and were proven to be fit for the purpose (Netherlands, 2015). EFSA concludes that the data are sufficient to derive the following MRL proposal:

– 10 mg/kg leeks in NEU

Table 4: Overview of the available residues trials data

Crop (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 (3× 375 g/ha, PHI 14 d) (2012/2013 trials)	NEU	Mo: 2.70; 2.80; 3.10; 3.10; 3.30; 3.30; 3.40; 4.50 RA: 2.77; 2.86; 3.14; 3.16; 3.35; 3.36; 3.45; 4.55	Although conducted according to a less critical use (3 applications), the 2012/2013 trials result in significantly higher residue levels than the 1996/1997 trials (U-Test, 5%). MRL_{OECD}: 9.8/10	10	4.55	3.26
(6× 375 g/ha, PHI 14 d) (1996/1997 trials)		Mo: 1.48; 1.67; 2.25; 2.52; 2.60; 2.68; 2.78; 2.79 RA: 1.63; 1.87; 2.42; 2.73; 2.81; 2.91; 2.92; 2.95	The 1996/1997 trials were already assessed under Article 12 MRL review (EFSA, 2014). Underlined values: samples taken at a longer PHI.	6[(f)]	2.95	2.77

(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, whereas the residue levels for RA are reported in the respective order.
Mo: residue level according to the monitoring residue definition (kresoxim-methyl).
RA: residue level according to the residue definition for risk assessment (sum kresoxim-methyl and metabolites BF 490-2 and BF 490-9, free and conjugated, expressed as parent).
(c): Any information/comment supporting the decision and OECD MRL calculation (unrounded/rounded values). RA residue levels calculated as sum of kresoxim-methyl + BF 490-2 + BF 490-9, without correction for molecular weights to express the metabolites as parent compound, since negligible.
(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.
(f): MRL recommended in the framework of the Article 12 review is based on EU methodology, R_{ber}: 5.5, R_{max} 4.0 (European Commission, 1997g).

All samples were analysed for kresoxim-methyl and for the metabolites BF 490-2 and BF 490-9, which are included in the residue definition for risk assessment of primary crops. CFs for risk assessment were therefore derived at the different PHIs and are summarised in Table 5.

Table 5: Median conversion factors calculated at the different pre-harvest intervals

PHI[(a)] (days)	**0+**	**7**	**14**	**20**	**Comments**
Leek	1.01	1.01	1.02	1.04	CF at supported PHI is underlined.

(a): 0+ for samples collected just after the last application.

Considering that the contribution of the metabolites BF 490-2 and BF 490-9 to the total residue level is negligible as resulting to a CF value close to 1, EFSA concludes that the setting of a CF for risk assessment is not necessary for leeks.

3.1.1.3. Effect of industrial processing and/or household preparation

Kresoxim-methyl was shown to be stable under standard hydrolytic conditions simulating pasteurisation and boiling. In contrast, the active substance was almost totally degraded to the acid metabolite BF 490-1 under sterilisation conditions. Therefore, for processed commodities, this metabolite was added to the residue definition for enforcement and risk assessment set in primary crops (EFSA, 2010a). The Article 12 MRL review confirmed the specific residue definitions for processed commodities (EFSA, 2014).

Specific studies to assess the magnitude of kresoxim-methyl residues in processed leek products were not provided and are not required as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10 % of the ADI (European Commission, 1997d).

3.1.2. Rotational crops

Leeks can be grown in rotation with other plants and the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed. The soil degradation field studies demonstrated that the degradation rate of kresoxim-methyl is rapid (DT_{90} less than 1 day), but the soil metabolite BF 490-1, with a DT_{90} filed up to 284 days, exceeds the trigger value of 100 days (EFSA, 2010a, 2014). Thus, investigations on rotational crops are required (European Commission, 1997c).

The occurrence of kresoxim-methyl residues in rotational crops (wheat, carrot, bean and lettuce) was assessed in the framework of the peer review and the same residue definition as for primary crops was established for rotational crops.

Nevertheless, considering that the confined rotational crop study was conducted at an application rate limited to a total dose rate of 300 g/ha (ca. 0.27N the dose rate under consideration in this MRL application and 0.14N the dose rate assessed during the Article 12 review) and considering a plant-back interval (PBI) of 30 days only, the Article 12 MRL review concluded that the metabolism study is not sufficient to confirm that the use of the active substance on a primary crop will not result in the presence of residues exceeding 0.01 mg/kg in rotational crops, in particular in leafy vegetables, cereal forage and straw (EFSA, 2014).

The conclusions reached during the Article 12 MRL review are still valid and the data gap for field crop rotational trials identified is also relevant for this MRL application. Meanwhile, Member States should consider this point when granting authorisations and, where relevant, take appropriate risk mitigation measures in order to avoid the presence of kresoxim-methyl residues in rotational crops.

3.2. Nature and magnitude of residues in livestock

As leeks are not normally fed to livestock, the nature and magnitude of kresoxim-methyl residues in livestock is not assessed in the framework of this application (European Commission, 1996).

4. Consumer risk assessment

In the framework of the review of the existing MRLs for kresoxim-methyl 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 and the acceptable CXLs. 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 on these crops (EFSA, 2014). 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[9] (EFSA, 2007).

The chronic risk assessment is now updated with the STMR as derived from the residue trials on leeks assessed in this MRL application (see Table 4). No acute consumer exposure assessment was performed, since the setting of an ARfD was concluded to be not necessary for kresoxim-methyl. The input values used for the dietary exposure calculation are summarised in Table 6.

Table 6: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment	
	Input (mg/kg)	**Comment**
Risk assessment residue definition: kresoxim-methyl and metabolites BF 490-2 and BF 490-9, free and conjugated, expressed as parent		
Leeks	3.26	STMR
Other plant and animal commodities, except leeks[(a)]	See Table 4.2 in Reasoned opinion on the review of the existing MRLs according to Article 12 of Reg. (EC) No 396/2005 (EFSA, 2014).	

(a): The consumer risk assessment under the Article 12 MRL review was conducted with a lower STMR value (2.77 mg/kg).

The estimated exposure was then compared with the toxicological reference value derived for kresoxim-methyl (see Table 2). The results of the intake calculation are presented in Appendix B of 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 chronic intake accounted for 1.1 % of the ADI (WHO Cluster B). The contribution of residues in leeks to the total consumer exposure accounted for a maximum of 0.6 % of the ADI (French toddler).

EFSA concludes that the intended use of kresoxim-methyl on leeks will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a concern for public health.

Conclusions and recommendations

The submitted information was sufficient to derive the MRL proposal summarised in the table below:

Code[(a)]	Commodity	Existing EU MRL mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
Enforcement residue definition: kresoxim-methyl (R)				
0270060	Leeks	6	10	NEU use supported.

(a): Commodity code number according to Annex I of Regulation (EC) 396/2005.
(R): The residue definition differs for the following combinations pesticide-code number:
Kresoxim-methyl — code 1000000 except 1040000: kresoxim methyl (BF 490-9, expressed as parent)
Metabolite BF 490-9 = 2-[2-(4-hydroxy-2-methylphenoxymethyl)phenyl]-2-methoxy-iminoacetic acid.

[9] 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).

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
AIR	Annex I (of Directive 91/414/EEC) Renewal
ARfD	acute reference dose
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)
d	day
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DT_{90}	period required for 90 % dissipation (define method of estimation)
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly International Group of National Associations of Manufacturers of Agrochemical Products (GIFAP))
HR	highest residue
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
MRL	maximum residue level
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
WHO	World Health Organization

Appendix A – Good Agricultural Practice (GAPs)

Crop [a]	MS or NEU/ SEU	F G or I (b)	Pest or group of pests controlled[c]	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d-f)	conc. a.s.[i]	Method kind[f-h]	Growth stage & season[j]	Number min-max (k)	Interval min-max	g/hL min-max	Water L/ha min-max	g/ha min-max		
Leek	NEU (NL)	F	*Phytophthora porri, Alternaria porii, Cladosporium allii-porri, Stemphylium, Puccinia porri*	SC	500 g/L	Spraying	BBCH 11-49	1-3	10 days	470-188	200-800	375	14	April-August

Remarks:

(a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the usage 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-borne insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), water soluble granule (WG)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) all abbreviations must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, eg. overall, broadcast, aerial spraying, row, individual plant, between the plants. type of equipment used must be indicated
(i) g/kg or µg/L
(j) Growth stage at last treatment (Meier U, 2001. Growth Stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., Federal Biological Research Centre of Agriculture and Forestry, Braunschweig, Germany, 2001), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

Appendix B – Pesticide Residue Intake Model (PRIMo)

Kresoxim methyl			
Status of the active substance:	**Approved**	Code no.	
LOQ (mg/kg bw):	0.05	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.4**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**1998**	Year of evaluation:	**1998**

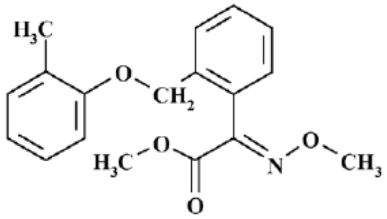
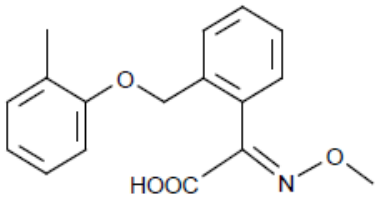
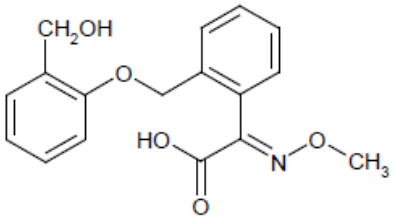
Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	0 1
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)
1.1	WHO Cluster diet B	0.3	Wheat	0.2	Tomatoes	0.2	Wine grapes	0.1
1.1	FR toddler	0.6	Leek	0.1	Milk and cream,	0.1	Strawberries	0.1
1.0	DE child	0.4	Apples	0.1	Table grapes	0.1	Wheat	0.1
0.8	NL child	0.2	Apples	0.2	Leek	0.1	Wheat	0.1
0.8	IE adult	0.3	Leek	0.1	Wine grapes	0.1	Wheat	0.0
0.8	FR all population	0.4	Wine grapes	0.1	Leek	0.1	Wheat	0.0
0.7	UK Toddler	0.3	Sugar beet (root)	0.1	Wheat	0.1	Milk and cream,	0.4
0.6	FR infant	0.3	Leek	0.1	Apples	0.1	Strawberries	0.1
0.6	DK child	0.2	Wheat	0.1	Rye	0.1	Apples	0.1
0.6	PT General population	0.3	Wine grapes	0.1	Wheat	0.1	Tomatoes	0.0
0.6	WHO cluster diet E	0.2	Wine grapes	0.1	Wheat	0.1	Leek	0.0
0.5	WHO cluster diet D	0.2	Wheat	0.1	Tomatoes	0.0	Wine grapes	0.0
0.5	NL general	0.2	Leek	0.1	Wine grapes	0.1	Wheat	0.0
0.5	UK Infant	0.1	Sugar beet (root)	0.1	Milk and cream,	0.1	Wheat	0.2
0.4	IT kids/toddler	0.2	Wheat	0.1	Tomatoes	0.0	Apples	0.0
0.4	ES child	0.1	Wheat	0.1	Tomatoes	0.0	Apples	0.1
0.4	WHO Cluster diet F	0.1	Wheat	0.1	Wine grapes	0.1	Tomatoes	0.0
0.4	WHO regional European diet	0.1	Wheat	0.1	Tomatoes	0.0	Leek	0.0
0.4	DK adult	0.2	Wine grapes	0.1	Wheat	0.0	Tomatoes	0.0
0.4	SE general population 90th percentile	0.1	Wheat	0.1	Tomatoes	0.0	Leek	0.0
0.4	UK vegetarian	0.1	Wine grapes	0.1	Wheat	0.0	Tomatoes	0.1
0.3	ES adult	0.1	Wheat	0.1	Tomatoes	0.0	Wine grapes	0.0
0.3	IT adult	0.1	Wheat	0.1	Tomatoes	0.0	Apples	0.0
0.3	UK Adult	0.1	Wine grapes	0.1	Wheat	0.0	Sugar beet (root)	0.1
0.2	PL general population	0.1	Tomatoes	0.1	Apples	0.0	Table grapes	0.0
0.2	LT adult	0.1	Apples	0.0	Tomatoes	0.0	Rye	0.0
0.2	FI adult	0.0	Tomatoes	0.0	Wine grapes	0.0	Wheat	0.0

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

Appendix C – Used compound codes

Code/Trivial name	Chemical name	Structural formula
kresoxim-methyl (BASF 490 F)	(*E*)-methoxyimino[α-(*o*-tolyloxy)-*o*-tolyl] acetate	
BF 490-1 (490M1)	(*E*)-methoxyamino(*o*-(o-tolyloxy)-*o*-tolyl] acetic acid or 2-methoxyimino-2-[2-(*o*-tolyloxymethyl) phenyl]acetic acid	
BF 490-2 (490M2)	(2*E*)-(2-{[2-(hydroxymethyl)phenoxy] methyl}phenyl)(methoxyimino)acetic acid	
BF 490-9 (490M9)	(2*E*)-{2-[(4-hydroxy-2-methylphenoxy) methyl]phenyl}(methoxyimino)acetic acid or 2-[2-(4-hydroxy- 2-methylphenoxymethyl) phenyl]-2-methoxy-iminoacetic acid