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Modification of the existing maximum residue level for pendimethalin in lettuce

European Food Safety Authority (EFSA)

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State, the United Kingdom, received an application from UK Horticultural Development Company to modify the existing maximum residue level (MRL) for the active substance pendimethalin in lettuce. In order to accommodate for the intended use of pendimethalin, UK proposed to raise the existing MRL from the limit of quantification to 0.15 mg/kg. According to EFSA, data are sufficient to derive an MRL proposal of 0.1 mg/kg to support the use of pendimethalin on lettuce. Adequate analytical enforcement methods are available to control the residues of pendimethalin in lettuce at the validated LOQ of 0.05 mg/kg. Based on the risk assessment results, EFSA concludes that the proposed use of pendimethalin on lettuce will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk.

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Keywords: pendimethalin, lettuce, MRL application, consumer risk assessment

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Correspondence: pesticides.mrl@efsa.europa.eu

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS) the United Kingdom, received an application from the UK Horticultural Development Company to modify the existing maximum residue level (MRL) for the active substance pendimethalin in lettuce. In order to accommodate for the intended use of pendimethalin, the United Kingdom proposed to raise the existing MRL from the limit of quantification (LOQ) of 0.05 mg/kg to 0.15 mg/kg. The United Kingdom 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 31 October 2014.

EFSA bases its assessment on the evaluation report submitted by the EMS, the draft assessment report (DAR) prepared under Directive 91/414/EEC, the Commission review report on pendimethalin as well as the conclusions from previous EFSA opinions on pendimethalin, including the review of all existing MRLs according to Article 12 of Regulation (EC) No 396/2005.

The toxicological profile of pendimethalin 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 0.125 mg/kg bw per day. No acute reference dose (ARfD) was deemed necessary.

The metabolism of pendimethalin in primary crops was investigated in the root, cereal and pulses/oilseeds crop groups following foliar and soil applications. From these studies the peer review established the residue definition for enforcement and for risk assessment as pendimethalin. For the use on lettuce, EFSA concludes that the metabolism of pendimethalin in primary crops has been sufficiently addressed and that the residue definitions derived are applicable.

EFSA concludes, based on the supervised residue trials submitted by the applicant, the MRL of 0.1 mg/kg is sufficient to support the use of pendimethalin on lettuce. Adequate analytical enforcement methods are available to monitor the residues of pendimethalin on the commodity under consideration at the validated LOQ of 0.05 mg/kg.

Specific studies investigating the magnitude of pendimethalin residues in processed commodities are not required, as lettuce is consumed as fresh product.

The occurrence of pendimethalin residues in rotational crops was investigated in the framework of the peer review and during the MRL review under Article 12 of Regulation (EC) No 396/2005, where the same residue definition as for raw agricultural commodity (RAC) was proposed. Pendimethalin residues are not expected in rotational crops for applications with a plant back interval (PBI) of more than 180 days.

Residues of pendimethalin in commodities of animal origin were not assessed, since lettuce is 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 long-term consumer exposure assessment conducted in the framework of the Article 12 MRL review, taking into account the short-term median residue (STMR) derived for lettuce and considering the STMR values derived for some commodities assessed in previous MRL applications under Article 10 of Regulation (EU) 396/2005. The highest chronic consumer exposure was calculated to be 1.4% of the ADI (NL, Child).

EFSA concludes that the proposed use of pendimethalin on lettuce 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: pendimethalin(F)				
0251000	Lettuce	0.05*	0.10	Supported by NEU trials only

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005

(*): indicates that the MRL is set at the limit of analytical quantification (LOQ)

(F): fat soluble

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Background

Regulation (EC) No 396/2005¹ 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 Council Directive 91/414/EEC,² repealed by Regulation (EC) No 1107/2009³, 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 United Kingdom, hereafter referred to as the evaluating Member State (EMS), received an application from the company UK Horticultural Development Company⁴ to modify the existing MRL for the active substance pendimethalin in lettuce. 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 31 October 2014.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2014-00789 and the following subject:

Pendimethalin: Modification of the existing MRL in lettuce

The United Kingdom proposed to raise the existing MRL of pendimethalin in lettuce from the limit of quantification to 0.15 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

Pendimethalin is the ISO common name for *N*-(1-ethylpropyl)-2,6-dinitro-3,4-xylidene (IUPAC). The chemical structure of the active substance is reported in Appendix C. Pendimethalin has been approved for the uses as herbicide.

Pendimethalin was evaluated in the framework of Directive 91/414/EEC with Spain designated as rapporteur Member State (RMS). It was included in Annex I by Directive 2003/31/EC⁵ which entered into force on 1 January 2004 for use as herbicide only. In accordance with Commission Implementing Regulation (EU) No 540/2011⁶ pendimethalin is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC. The representative uses evaluated in the peer review were on fruits, grapes, vegetables, oilseeds, cereals, tobacco and ornamentals. The draft assessment report (DAR) of pendimethalin was not peer reviewed by EFSA, therefore no EFSA conclusion is available.

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 UK Horticultural Development Company, AHDB, Stoneleigh Park, CV8 2TL Warwickshire, United Kingdom

⁵ Commission Directive 2003/31/EC of 11 April 2003 amending Council Directive 91/414/EEC to include 2,4-DB, beta-cyfluthrin, cyfluthrin, iprodione, linuron, maleic hydrazide and pendimethalin as active substances. OJ L 101, 23.04.2003, p. 3–9.

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, 11.06.2011, p. 1–186.

It is noted that the peer review for the renewal of the approval of the active substance pendimethalin in accordance with Regulation (EC) No 844/2012 is on-going and not yet finalised. Therefore, the conclusions reported in this reasoned opinion should be taken as provisional and might need to be reconsidered in the light of the outcome of the on-going peer review.

The EU MRLs for pendimethalin are established in Annex II of Regulation (EC) No 396/2005. Since the entry into force of this regulation, EFSA has issued several reasoned opinions on the modification of MRLs for pendimethalin whose proposals were considered in the EU legislation. The MRL changes reported in the EU legislation after the Article 12 review of existing MRLs are summarised in Table 1.

Table 1: Overview of the MRL changes after the Article 12 (Regulation (EC) No 396/2005) review of existing MRLs

Procedure ^(a)	Considered by Regulation	Remarks
Art. 12 (EFSA, 2012)	(EC) No 1004/2013	Review of existing MRLs
Art. 10 (EFSA, 2013)	(EC) No 1127/2014	Roots and seeds
Art. 10 (EFSA, 2014)	Not yet implemented	Roots, tuber vegetables and spices

(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

No CXLs are established for pendimethalin.

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

Assessment

EFSA bases its assessment on the evaluation report submitted by the EMS (United Kingdom, 2014), the DAR (and its addendum/addenda) prepared under Directive 91/414/EEC (Spain, 1998a, 1998b, 2000), the Commission review report on pendimethalin (European Commission, 2003) as well as the conclusions from previous EFSA opinions on pendimethalin (EFSA, 2012, 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 546/2011⁷ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a–g, 2000, 2010a, b, 2011; OECD, 2011).

As the peer review of the renewal of the active substance in accordance with Regulation (EC) No 844/2012 is not yet finalised, the conclusions reported in this reasoned opinion should be taken as provisional and might need to be reconsidered in the light of the outcome of the on-going peer review.

1. Method of analysis

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

Methods to analyse pendimethalin residues in plant commodities were assessed in the DAR during the peer review under Directive 91/414/EC (Spain, 1998a) and in the framework of the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2012). These methods based on GC-ECD, are able to achieve an LOQ of 0.05 mg/kg in high water content commodities.

The multi-residue QuEChERS method in combination with HPLC-MS/MS or GC-MS quantification and described in European Standard EN 15662:2008 is also available to analyse parent pendimethalin with an LOQ of 0.005 mg/kg in acidic and high water content commodities and an LOQ of 0.01 mg/kg in dry commodities (CEN, 2008).

⁷ 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.

Additionally, a method using GC-NPD quantification and its ILV were evaluated during the Article 12 MRL review and concluded to be validated for determination of pendimethalin in high water, high acid content commodities and dry matrices (cereals) (EFSA, 2012).

As the commodity under consideration belongs to the high water commodity group, EFSA concludes that sufficiently validated analytical methods are available for enforcing the proposed MRL for pendimethalin in lettuce.

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 lettuce is normally not fed to livestock.

2. Mammalian toxicology

The toxicological profile of the active substance pendimethalin was assessed in the framework of the peer review under Directive 91/414/EEC (European Commission, 2003). The data were sufficient to derive toxicological reference values compiled in Table 2.

Table 2: Overview of the toxicological reference values

	Source	Year	Value	Study	Safety factor
pendimethalin					
ADI	EC	2003	0.125 mg/kg bw per day	Dog, 2-year study	100
ARfD	EC	2003	Not necessary		

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 pendimethalin in primary crops was investigated during the peer review (Spain, 1998a) and during the Article 12 MRL review under Regulation (EC) No 396/2005 (EFSA, 2012). An overview of the available metabolism studies is presented in Table 3

Table 3: Summary of available metabolism studies in plants

Crop group	Crops	Application	Sampling ^(a) (day, DAT)	Comments
Root	Potatoes	Soil (2x 2200 g/ha)	120 DAT ₁	Studies conducted with ¹⁴ C-phenyl, ¹⁴ C-ethylpropyl and 3,4- ¹⁴ C-dimethyl labelled pendimethalin
	Onions	Foliar (3000x2 g/ha)	77 DAT ₁	
Cereals	Sweet corn	Foliar (1x 2240 g/ha)	81 DAT ₄	
		Soil (1x 2240 g/ha)	90 DAT ₃	
	Wheat	Soil (1x1650 g/ha)	120 DAT ₃	
Oilseed	Soya bean	Soil (165 g/ha)	120 DAT ₃	

(a): DAT_x, days after treatment x, e.g. DAT₂: day after 2nd treatment.

Based on these metabolism studies, the residue definition for monitoring and risk assessment was proposed as pendimethalin in the conclusion of the peer review and confirmed under the Article 12 MRL review. 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 lettuce, EFSA concludes that the metabolism of pendimethalin is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed during the peer review and confirmed under the MRL review are applicable.

3.1.1.2. Magnitude of residues

In support of the MRL application, the EMS submitted eight residue trials performed on lettuce (three on head lettuce and five on open leaf varieties). All the trials were performed in the United Kingdom during the growing seasons 2010 and 2011, according to the intended GAP; pendimethalin residues ranged from <0.05 mg/kg to 0.07 mg/kg. Based on these residues, the EMS proposed an MRL of 0.15 mg/kg however, since the value derived by the OECD MRL calculator (OECD, 2011) is 0.10 mg/kg, EFSA proposes to set the MRL for pendimethalin in lettuce at this level.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Table 4.

Residues of pendimethalin were found to be stable at -20 °C for up to 24 months in matrices with high water, high acid and high oil content as well as in dry matrices and wheat straw (EFSA, 2012). Since the lettuce samples were stored at -180 C less than three months prior to analysis (United Kingdom, 2014), 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 (United Kingdom, 2014).

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

- 0.1 mg/kg lettuce in NEU (outdoor)

Table 4: Overview of the available residues trials data

Crop (GAPs)	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)
Lettuce (2x 364 g/ha, PHI 24 d)	NEU	3x <0.05, 2x < <u>0.05</u> , <u>0.05</u> , 2x <u>0.07</u> ,	MRL _{OECD} : 0.1/0.1 mg/kg	0.1	0.07	0.05

(a): NEU: Outdoor trials conducted in northern Europe,

(b): Underlined values: Residue trials performed on lettuce open leaf varieties

(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

Specific studies to assess the magnitude of pendimethalin residues during the processing of lettuce are not necessary as this crop is mostly eaten raw (European Commission, 1997d).

3.1.2. Rotational crops

Lettuce 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 field studies measuring degradation in the soil showed that the degradation rate of pendimethalin is slow. The maximum DT_{90} was more than one year (European Commission, 2003), exceeding the trigger value of 100 days therefore, further investigations on the nature and magnitude of the compound uptake in rotational crops are required (European Commission, 1997c).

3.1.2.1. Nature and magnitude of residues

Confined rotational crop studies were assessed in the framework of the peer review and under the Article 12 MRL review; it was concluded that the residue definitions set for primary crops are also applicable to rotational crops and that low total radioactive residues (TRR) are expected in rotational crops when the active substance is applied on primary crops up to a total annual dose rate of 2200 g/ha (EFSA, 2012). In addition, several rotational crop studies conducted after application of the active substance on bare soil at 840 to 6720 g/ha at plant back intervals (PBI) of approximately 180 and 365 days confirmed that low residues levels, generally below the LOQ of 0.05 mg/kg, are expected in all mature plant parts at harvest.

Considering that the application rates proposed under the current MRL application is limited to a maximum of 728 g/ha, EFSA concludes that pendimethalin residues are not expected to be present in rotational crops with PBI of more than 180 days, provided that the active substance is applied on lettuce according to the proposed GAP.

It should be noted that phytotoxic effects of pendimethalin were observed in the metabolism studies in several crops (radishes, cereals) rotated within the shorted plant back intervals of 30 and 90 days.

3.2. Nature and magnitude of residues in livestock

As lettuce is not normally fed to livestock, the nature and magnitude of pendimethalin 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 Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population⁸ (EFSA, 2007).

In the framework of the review of the existing MRLs 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 EU level (EFSA, 2012). Now EFSA updated this risk assessment with the median residue levels (STMR) derived from the residue trials conducted on lettuce (Table 4) and considering the STMRs derived for the crop commodities assessed under Article 10 MRL applications after the reviewing of the Article 12 MRL review and reported in the previous reasoned opinions (EFSA, 2013, 2014). 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 pendimethalin on these crops.

An acute consumer exposure assessment was not performed, since the setting of an ARfD was concluded to be unnecessary for pendimethalin.

⁸ The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised in Table 5.

Table 5: 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: Pendimethalin				
Lettuce	0.05	STMR	The acute exposure was not performed since no ARfD is established for pendimethalin	
Other plant and animal commodities	Input values listed in Tables 4-1 of the reasoned opinions issued under Art. 12 (EFSA, 2012) and Art. 10 of Regulation (EC) 396/2005 (EFSA, 2013, 2014)			

The estimated exposure was then compared with the toxicological reference values derived for pendimethalin (see Table 2). The results of the intake calculation are presented in Appendix B of this reasoned opinion.

No long-term consumer intake concern was identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated chronic intake accounted 1.4% of the ADI (NL, child). The contribution of residues in lettuce to the total consumer exposure accounted for a maximum of 0.02 % of the ADI (ES, adult).

EFSA concludes that the intended use of pendimethalin on lettuce 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 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: pendimethalin ^(F)				
0251000	Lettuce	0.05*	0.10	Supported by NEU trials only

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005

(*): indicates that the MRL is set at the limit of analytical quantification (LOQ)

(F): fat soluble

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Abbreviations

a.s.	active substance
ACD	Advanced Chemistry Development
ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
CS	Capsule suspension
CXL	Codex maximum residue limit (Codex MRL)
DAR	draft assessment report
DAT	days after treatment
ECD	electron capture detector
EFSA	European Food Safety Authority
EMS	evaluating Member State
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly International Group of National Associations of Manufacturers of Agrochemical Products (GIFAP))
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
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
NPD	nitrogen/phosphorous detector
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RAC	raw agricultural commodity
RMS	rapporteur Member State
STMR	supervised trials median residue

TMDI	theoretical maximum daily intake
TRRs	total radioactive residues
yr	year

Appendix A – Good Agricultural Practice (GAPs)

Crop and/or situation ^(a)	MS or NEU/SEU or Country	F G or I ^(b)	Pest or group of pests controlled ^(c)	Formulation		Application			Application rate per treatment			PHI ^(l) (days)	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
Lettuce	UK	F	Weeds	CS	455 g/L	-	-	2	7 days	182	200	364	24	

Remarks:

- | | |
|---|--|
| <p>(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)</p> <p>(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and sucking insects, soil-born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), water soluble granule (WG)</p> <p>(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989</p> <p>(f) all abbreviations must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, eg. overall, broadcast, aerial spraying, row, individual plant, between the plants. type of equipment used must be indicated</p> | <p>(i) g/kg or µg/L</p> <p>(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</p> <p>(k) The minimum and maximum number of application possible under practical conditions of use must be provided</p> <p>(l) PHI - minimum pre-harvest interval</p> <p>(m) Remarks may include: Extent of use/economic importance/restrictions</p> |
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Appendix B – Pesticide Residue Intake Model (PRIMO)

Pendimethalin									
Status of the active substance:		approved		Code no.					
LOQ (mg/kg bw):				proposed LOQ:					
Toxicological end points									
ADI (mg/kg bw/day):		0.125		ARID (mg/kg bw):		n.n.			
Source of ADI:		EC		Source of ARID:		EC			
Year of evaluation:		2003		Year of evaluation:		2003			
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	pTMRs at LOQ (in % of ADI)	
1.4	NL child	0.3	Apples	0.2	Potatoes	0.2	Milk and milk products: Cattle		
1.3	WHO Cluster diet B	0.3	Wheat	0.1	Tomatoes	0.1	Potatoes		
1.3	DE child	0.5	Apples	0.2	Wheat	0.1	Milk and milk products: Cattle		
1.0	WHO cluster diet D	0.3	Wheat	0.2	Potatoes	0.1	Chinese cabbage		
1.0	IE adult	0.1	Maize	0.1	Maize	0.1	Potatoes		
0.9	WHO cluster diet E	0.2	Wheat	0.2	Potatoes	0.1	Wine grapes		
0.9	DK child	0.2	Wheat	0.2	Rye	0.1	Potatoes		
0.8	FR toddler	0.2	Potatoes	0.1	Apples	0.1	Apples		
0.8	FR infant	0.2	Milk and milk products: Cattle	0.2	Potatoes	0.1	Carrots		
0.8	SE general population 90th percentile	0.2	Potatoes	0.1	Wheat	0.1	Milk and milk products: Cattle		
0.8	PT General population	0.2	Potatoes	0.2	Wheat	0.1	Wine grapes		
0.7	WHO Cluster diet F	0.1	Wheat	0.1	Potatoes	0.03	Milk and milk products: Cattle		
0.7	WHO regional European diet	0.2	Potatoes	0.1	Wheat	0.04	Tomatoes		
0.7	ES child	0.2	Wheat	0.1	Milk and milk products: Cattle	0.1	Potatoes		
0.6	UK Toddler	0.2	Wheat	0.1	Potatoes	0.1	Apples		
0.6	NL general	0.1	Potatoes	0.1	Wheat	0.1	Milk and milk products: Cattle		
0.6	UK Infant	0.1	Potatoes	0.1	Wheat	0.1	Apples		
0.5	IT kids/toddler	0.3	Wheat	0.1	Tomatoes	0.04	Potatoes		
0.5	FR all population	0.2	Wine grapes	0.1	Wheat	0.04	Potatoes		
0.4	ES adult	0.1	Wheat	0.0	Milk and milk products: Cattle	0.04	Potatoes		
0.4	LT adult	0.1	Potatoes	0.1	Apples	0.04	Rye		
0.4	IT adult	0.2	Wheat	0.05	Tomatoes	0.03	Apples		
0.4	DK adult	0.1	Wheat	0.1	Potatoes	0.1	Wine grapes		
0.4	PL general population	0.1	Potatoes	0.1	Apples	0.04	Tomatoes		
0.4	UK vegetarian	0.1	Wheat	0.1	Potatoes	0.03	Wine grapes		
0.3	UK Adult	0.1	Wheat	0.1	Potatoes	0.04	Wine grapes		
0.2	FI adult	0.05	Potatoes	0.0	Wheat	0.03	Rye		
Conclusion:									
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI. A long-term intake of residues of Pendimethalin is unlikely to present a public health concern.									

Appendix C – Used compound code

Code/Trivial name	Chemical name	Structural formula
pendimethalin	<i>N</i> -(1-ethylpropyl)-2,6-dinitro-3,4-xylidene MW: 281.31 g/mol	