

APPROVED: 20 December 2017

doi: 10.2903/j.efsa.2018.5149

Modification of the existing maximum residue levels for clopyralid in spring/green/Welsh onions and leeks

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the Agriculture and Horticulture Development Board (AHDB) submitted a request to the competent national authority in the United Kingdom, to modify the existing maximum residue levels (MRL) for the active substance clopyralid in spring onions and leeks. The data submitted in support of the request were found to be sufficient to derive MRL proposals for spring onions/green onions and Welsh onions and for leeks based on the residue definition for enforcement in Regulation (EC) No 396/2005. An adequate analytical method for enforcement is available to control the residues on the commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the available information, EFSA concluded that the long-term intake of residues resulting from the use of clopyralid according to the reported agricultural practices is unlikely to present a risk to consumer health. The reliable end points, appropriate for use in regulatory risk assessment, are presented.

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Keywords: clopyralid, spring/green/Welsh onions, leeks, pesticide, MRL, consumer risk assessment

Requestor: European Commission

Question number: EFSA-Q-2015-00419

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Suggested citation: EFSA (European Food Safety Authority), Brancato A, Brocca D, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Medina P, Miron I, Molnar T, Nougadere A, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2018. Reasoned Opinion on the modification of the existing maximum residue levels for clopyralid in spring/green/Welsh onions and leeks. *EFSA Journal* 2018;16(1):5149, 19 pp. <https://doi.org/10.2903/j.efsa.2018.5149>

ISSN: 1831-4732

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the Horticultural Development Company submitted a request to the competent national authority in the United Kingdom (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance clopyralid in spring onions and leeks. The EMS 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). To accommodate for the intended uses of clopyralid, the EMS proposed to raise the existing MRLs for spring onions and leeks to 0.7 mg/kg. EFSA identified points which needed further clarification, which were addressed from the EMS in a revised evaluation report in July and November 2017.

EFSA assessed the application and the revised evaluation report as required by Article 10 of the MRL regulation.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under a previous MRL assessment and the additional data provided by the EMS in the framework of this application, the following conclusions were derived.

The metabolism of clopyralid following foliar application was investigated in primary crops belonging to the groups of root crops, leafy crops and pulses/oilseeds and in rotational crops in root/tuber crops, leafy crops and cereals during the European Union (EU) pesticides peer review. Studies investigating the effect of processing (hydrolysis studies) were submitted in the framework of the ongoing renewal of approval in accordance with Regulation (EC) No 1107/2009. The studies demonstrated that clopyralid is stable under standard processing conditions.

Based on the metabolic pattern identified in metabolism studies and the outcome of the hydrolysis studies, the residue definitions in plant products for enforcement and risk assessment are defined as 'clopyralid, including its salts and conjugates, expressed as clopyralid'. These residue definitions are applicable to primary crops, rotational crops and processed products, including the crops under assessment. It is noted that the current residue definition for enforcement reported in Regulation (EC) No 396/2005 does not include the conjugates and is limited to clopyralid only.

Sufficiently validated analytical methods are available to quantify residues in the crops assessed in this application according to the enforcement residue definition as proposed during the EU pesticide peer review, which includes the conjugates of clopyralid. The methods enable quantification of residues at or above 0.01 mg/kg in the crops assessed.

The available residue trials are sufficient to derive a MRL proposal of 0.7 mg/kg for leeks and, by extrapolation, for spring onions/green onions and Welsh onions based on the residue definition for enforcement in Regulation (EC) No 396/2005.

Specific studies investigating the magnitude of clopyralid residues in processed commodities were not submitted. It is unlikely that major processing types for spring onions/green onions and Welsh onions and for leeks will result in a concentration of residues in processed commodities. A refinement of the consumer dietary intake estimates is currently not necessary.

Based on the available information, EFSA could not exclude that the uses of clopyralid in the crops under assessment according to the proposed good agricultural practice (GAP) will not result in significant residues in rotational crops. Therefore, Member States should consider the need for specific risk mitigation measures to avoid the presence of clopyralid residues in rotational and/or succeeding crops.

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

The toxicological profile of clopyralid was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.15 mg/kg body weight (bw) per day. An acute reference dose (ARfD) was deemed unnecessary.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRiMo). For the calculation of the chronic exposure, EFSA used the median residue values derived for the commodities assessed in this MRL application and in a previous EFSA reasoned opinion. For the remaining commodities of plant and animal origin, the existing MRL values were considered. It was not necessary to perform a short-term risk assessment.

Based on the available information, EFSA concluded that the proposed uses of clopyralid on spring onions/green onions/Welsh onions and leeks will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers' health.

The peer review of the renewal of approval of the active substance in accordance with Regulation (EC) No 1107/2009 and the review of the existing MRLs under Article 12 of Regulation 396/2005 are not yet finalised, and 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 peer review and/or the MRL review.

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

Full details of all end points and the consumer risk assessment can be found in Appendices B–D.

Code ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Clopyralid				
0220040	Spring onions/green onions and Welsh onions	0.5	0.7	NEU use supported by trials where samples were analysed for parent clopyralid only.
0270060	Leeks	0.5	0.7	Risk for consumers unlikely.

EU MRL: European Union maximum residue level; NEU: northern Europe.

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

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Assessment

The detailed description of the intended uses of clopyralid in spring onions and leeks, which are the basis for the current maximum residue level (MRL) application, is reported in Appendix A.

Clopyralid is the ISO common name for 3,6-dichloropyridine-2-carboxylic acid (or 3,6-dichloropicolinic acid) (IUPAC). The chemical structure of the active substance is reported in Appendix E.

Clopyralid was evaluated in the framework of Directive 91/414/EEC¹ with Finland designated as rapporteur Member State (RMS) for the representative uses as post-emergence applications on cereals, pasture, oilseed rapes and sugar beets. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2005). Clopyralid was approved² for the use as herbicide on 1 May 2007. The process for renewal of the first approval is currently ongoing.

The EU MRLs for clopyralid are established in Annex IIIA of Regulation (EC) No 396/2005³. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has not yet been completed. EFSA has issued one reasoned opinion on the modification of MRLs for clopyralid in various commodities (EFSA, 2011). The proposals from this reasoned opinion have been considered in an EU MRL regulation.⁴

In accordance with Article 6 of Regulation (EC) No 396/2005, the Agriculture and Horticulture Development Board (AHDB) submitted a request to the competent national authority in the United Kingdom (evaluating Member State, EMS), to modify the existing MRLs for the active substance clopyralid in spring onions and leeks. The EMS 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 EFSA on 7 July 2015. To accommodate for the intended uses of clopyralid, the EMS proposed to raise the existing MRLs for spring onions and leeks from 0.5 mg/kg to 0.7 mg/kg. EFSA identified points which needed further clarification, which were requested from the EMS. In July and November 2017, the EMS provided the missing information and submitted a revised evaluation report, which replaced the previously submitted evaluation report.

EFSA assessed the application and the revised evaluation report as required by Article 10 of the MRL regulation.

EFSA based its assessment on the revised evaluation report submitted by the EMS (United Kingdom, 2017), the DAR and its addendum (Finland, 2003, 2005) prepared under Directive 91/414/EEC, the Commission review report on clopyralid (European Commission, 2006), the conclusion on the peer review of the pesticide risk assessment of the active substance clopyralid (EFSA, 2005) as well as the conclusions from a previous EFSA opinion on clopyralid (EFSA, 2011).

For this application, the data requirements established in Regulation (EU) No 544/2011⁵ and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011⁶.

As the EU pesticides peer review of the renewal of approval of clopyralid in accordance with Regulation (EC) No 1107/2009 and the review of the existing MRLs under Article 12 of Regulation 396/2005 are 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 peer review and/or the MRL review.

¹ 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.

² Commission Directive 2006/64/CE of 18 July 2006 amending Council Directive 91/414/EEC to include clopyralid, cyprodinil, fosetyl and trinexapac as active substances. OJ L 206, 27.7.2006, p. 107–111.

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

⁴ For an overview of all MRL Regulations on this active substance, please consult: <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN>

⁵ Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

⁶ 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.

A selected list of end points of the studies assessed by EFSA in the framework of the this MRL application, including the end points of relevant studies assessed previously, is presented in Appendix B.

The revised evaluation report submitted by the EMS (United Kingdom, 2017) 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 as background documents to this reasoned opinion. Furthermore, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of clopyralid following foliar application was investigated in crops belonging to the groups of root crops (sugar beets), leafy crops (head cabbages) and pulses/oilseeds (oilseed rapeseeds) in the framework of the EU pesticides peer review (EFSA, 2005). Unchanged clopyralid represented the major component of the residues in mature cabbages (up to 92–99% of the total radioactive residue (TRR)) with clopyralid conjugates observed only in sugar beets (< 1% of TRR) and rapeseeds (18–30% of TRR).

For the intended uses, the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Clopyralid is proposed to be used on crops that can be grown in rotation with other crops. The available soil degradation laboratory studies demonstrated that the degradation rate of clopyralid in soil is slow with the maximum DT_{90lab} of 217 days which exceeds the trigger value of 100 days. The field degradation studies, however, showed faster degradation of clopyralid with a maximum $DT_{90field}$ of 79 days (EFSA, 2005).

Two confined rotational crop studies were submitted and assessed in the framework of a previous MRL application (EFSA, 2011). Details of the studies are presented in Appendix B.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of clopyralid residues (hydrolysis study) was investigated in the framework of the ongoing renewal of approval in accordance with Regulation (EC) No 1107/2009 (Finland, 2017) and is presented in the updated evaluation report (United Kingdom, 2017). Clopyralid was stable under standard processing conditions.

1.1.4. Methods of analysis in plants

The EU pesticides peer review concluded that an analytical method using gas chromatography with mass spectrometry detection (GC–MSD) was sufficiently validated to quantify residues of clopyralid and its conjugates measured as clopyralid in high water content commodities, to which the crops under assessment belong. The method allows quantifying residues at or above the limit of quantification (LOQ) of 0.01 mg/kg (EFSA, 2005). It is noted that the current residue definition in Regulation (EC) No 396/2005 is limited to clopyralid. The potential slight overestimation resulting from the inclusion of a hydrolytic step in the proposed method which releases free clopyralid from its conjugates has a limited impact on final residues in leeks and the bulb vegetable under consideration. It can reasonably be assumed that conjugated clopyralid will be present at a low level in these crops (see Section 1.1.1).

1.1.5. Stability of residues in plants

The storage stability of clopyralid in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2005). It was demonstrated that in the crop group relevant for this application, residues were stable during frozen storage for 18 months.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies and the capability of the enforcement analytical method, the following residue definitions for primary and rotational crops were proposed during the EU pesticides peer review:

- residue definitions for risk assessment and enforcement: Clopyralid, including its salts and conjugates, expressed as clopyralid

The hydrolysis studies submitted in the framework of the ongoing renewal of approval in accordance with Regulation (EC) No 1107/2009 and presented in the updated evaluation report, demonstrated that clopyralid is stable under standard processing conditions. Hence, the same residue definition as for raw commodities is applicable to processed products as well.

It is noted that the residue definition for enforcement in Regulation (EC) No 396/2005 refers to parent clopyralid only.

EFSA concluded that these residue definitions are applicable and no further information is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, eight good agricultural practices (GAP)-compliant supervised residue trials conducted over two seasons in the UK were submitted. Extrapolation from residues in leeks to spring onions is possible (European Commission, 2017).

Samples in the trials were analysed for clopyralid only in line with the residue definition for enforcement in force in the MRL Regulation.

Samples were not analysed with an analytical method capable to release the clopyralid conjugates, in compliance with the residue definition for risk assessment in plants. According to the EMS, this deficiency of the residue trials is of minor relevance since the metabolism study of clopyralid in leafy and root crops demonstrated that clopyralid occurred mainly under its free form (see Section 1.1.1). The result from the metabolism study in oilseeds where conjugated form of clopyralid accounted for a substantial proportion of the TRR is considered not relevant. Thus, the deviation in the submitted residue trials that were analysed for the parent compound only is expected to have a minor impact on the results as it can reasonably be assumed that conjugated clopyralid will be present at a low level in leeks and bulb onion vegetables.

According to the assessment of the EMS, the analytical method used was sufficiently validated, and the trial samples were stored under conditions for which integrity was demonstrated.

1.2.2. Magnitude of residues in rotational crops

Studies on the magnitude of clopyralid residues in rotational crops are not available. In the rotational crops studies under confined conditions, evidence was insufficient to conclude that residues above the LOQ of 0.01 mg/kg will not be present in rotational crops planted within short plant back periods (i.e. < 125 days) after the harvest of a primary crop. New information to address potential residues in rotational crops was not provided in the framework of the current MRL application.

Therefore, EFSA confirms the previous recommendation that Member States, when granting authorisations on the use of clopyralid on primary crops, might apply risk mitigation measures to avoid clopyralid residues in rotational and/or succeeding crops (EFSA, 2011).

1.2.3. Magnitude of residues in processed commodities

Processing studies investigating the magnitude of clopyralid residues in processed spring onions/green onions/Welsh onions and leeks are not submitted. It is unlikely that major processing types for these crops will result in a concentration of residues in processed commodities. A refinement of the consumer dietary intake estimates is currently not necessary.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals based on the residue definition for enforcement in Regulation (EC) No 396/2005.

In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as spring onions/green onions/Welsh onions and leeks are not used for feed purposes.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo (EFSA, 2007). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference value for clopyralid used in the risk assessment (i.e. acceptable daily intake(ADI)) was derived in the framework of the EU pesticides peer review for clopyralid (European Commission, 2006).

3.1. Short-term (acute) dietary risk assessment

An acute consumer exposure assessment was not performed, since the setting of an acute reference dose (ARfD) was concluded to be unnecessary for clopyralid.

3.2. Long-term (chronic) dietary risk assessment

The long-term exposure assessment was performed taking into account the supervised trials median residue (STMR) values derived in the commodities assessed in this application and in a previous EFSA reasoned opinion (EFSA, 2011). For the remaining commodities covered by the MRL regulation, the existing EU MRLs were used.

The complete list of input values is presented in Appendix D.2.

The estimated long-term dietary intake was in the range of 3–27% of the ADI. The contribution of residues expected in spring onions/green onions/Welsh onions and leeks to the overall long-term exposure is presented in more detail in Appendix B.3.

The STMRs derived by EFSA in 2011 are fully in compliance with the residue definition for risk assessment derived during the EU pesticides peer review. Residues were analysed with a method capable to release and determine conjugated forms of clopyralid. The STMRs derived for the crops under assessment in this MRL application do not include clopyralid-conjugated forms. Consequences on the risk assessment are likely to be limited as clopyralid-conjugated residues are expected to be present at low levels in these crops. For the remaining commodities, not considered by the current or previous assessment (EFSA, 2011), the existing MRLs were used. The chronic exposure assessment should therefore be regarded as indicative. A more accurate risk assessment will be conducted in the framework of the MRL review when additional information on the contribution of conjugates to the final residues for the authorised uses of clopyralid will be provided to EFSA.

Based on the available information, EFSA concluded that the long-term intake of residues resulting from the existing and the intended uses on clopyralid is unlikely to present a risk to consumer health.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive MRL proposals for spring onions/green onions and Welsh onions and leeks according to the residue definition for enforcement in Regulation (EC) No 396/2005.

Based on the available information, EFSA concluded that the proposed uses of clopyralid on spring onions/green onions and Welsh onions and leeks will not result in a consumer exposure exceeding the toxicological reference value and therefore are unlikely to pose a risk to consumers' health.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
AHDB	Agriculture and Horticulture Development Board
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
DAR	draft assessment report
DAT	days after treatment
DT ₉₀	period required for 90% dissipation (define method of estimation)
EMS	evaluating Member State
FAO	Food and Agriculture Organization of the United Nations

GAP	Good Agricultural Practice
GC	gas chromatography
GC-MSD	gas chromatography with mass spectrometry detection
GLP	Good Laboratory Practice
IEDI	international estimated daily intake
ILV	independent laboratory validation
ISO	International Organization for Standardization
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
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RD	residue definition
RMS	rapporteur Member State
SEU	southern Europe
SL	soluble concentrate
STMR	supervised trials median residue
TRR	total radioactive residue

Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

Crop and/or situation	NEU, SEU, MS or country	F G or I ^(a)	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			Unit	PHI (days) ^(d)	Remarks
				Type ^(b)	Conc. a.s.	method kind	range of growth stages & season ^(c)	number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate			
Spring onions, Leeks	NEU	F	Perennial weeds	SL	400 g/L	Conventional hydraulic sprayers	BBCH 12 (1st appl.) + BBCH 15 (2nd appl.)	1–2		50–100	Min 200	100 (1st appl.) + 200 (2nd appl.)	g/ha	42	

NEU: northern European Union; SEU: southern European Union; MS; Member State.

(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 formulation types and international coding system.

(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 – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and methods of analysis in plants

B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

Primary crops (available studies)	Crop groups	Crop(s)	Application(s)	Sampling (DAT)	Comment/Source
	Root crops	Sugar beet	Foliar, 1 × 300 g/ha, at BBCH 36	0, 28, 105	Radiolabelled ¹⁴ C-clopyralid position not reported. No qualitative differences among the tested crops (EFSA, 2005)
	Leafy crops	Cabbage	Foliar, 1 × 420 g/ha, at 8–10 leaf stage	0, 5, 38	
	Pulses/Oilseeds	Oilseed rape	Foliar, 1 × 300 g/ha, at BBCH 36	0, 28, 77	
	Miscellaneous	Pasture	1 × 1.121 kg /ha	7, 14, 28, 56, 126	
Rotational crops (available studies)	Crop groups	Crop(s)	Application(s)	PBI (DAT)	Comment/Source
	Root/tuber crops	Turnip	1 × 0.28 kg/ha to bare soil	125 or 319	Radiolabelled 3,6-dichloro-2-6- ¹⁴ C-2-pyridinecarboxylic acid. In rotational crops, clopyralid was metabolised in a similar pathway as in primary crops (EFSA, 2011)
	Leafy crops	Lettuce	1 × 0.28 kg/ha to bare soil	125 or 319	
	Cereal (small grain)	Wheat	1 × 0.28 kg/ha to bare soil	125 or 319	
	Other	Soybean	1 × 0.28 kg/ha to bare soil	125	
		Green bean	1 × 0.28 kg/ha to bare soil	319	
Processed commodities (hydrolysis study)	Conditions	Stable?		Comment/Source	
	Pasteurisation (20 min, 90°C, pH 4)	yes		Radiolabelled 3,6-dichloro-2-6- ¹⁴ C-2-pyridinecarboxylic acid. Clopyralid was stable (99.3, 96.9, 97.1 AR, respectively)	
	Baking, brewing and boiling (60 min, 100°C, pH 5)	yes			
	Sterilisation (20 min, 120°C, pH 6)	yes			
	Other processing conditions				

Can a general residue definition be proposed for primary crops?

Yes	EFSA (2005)
Yes	EFSA (2011)
Yes	Finland (2017) and United Kingdom (2017)
Clopyralid (Regulation (EC) No 396/2005) Clopyralid, its salts and conjugates, expressed as clopyralid (EFSA, 2005)	

Rotational crop and primary crop metabolism similar?

Residue pattern in processed commodities similar to residue pattern in raw commodities?

Plant residue definition for monitoring (RD-Mo)

Plant residue definition for risk assessment (RD-RA)

Clopyralid, its salts and conjugates, expressed as clopyralid

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

Matrices with high water content and dry matrices (GC-MSD) and with high oil content (GC/NCI-MS), LOQ 0.01 mg/kg
 Confirmatory method available. ILV available (EFSA, 2005)
 Note: This method involves a hydrolysis step that releases free clopyralid from its conjugates

B.1.1.2. Stability of residues in plants

Plant products (available studies)	Category	Commodity	T (°C)	Stability period		Comment/Source
				Value	Unit	
High water content		Pasture	-18	18	months	EFSA (2005)
		Maize forage/fodder	-20	12	months	EFSA (2005)
High oil content		Rape seed	-20	18	months	EFSA (2005)
High protein content		-				
Dry/high starch		Maize grain	-20	12	months	EFSA (2005)
High acid content		-				
Processed products		-				
Others		-				

B.1.2. Magnitude of residues in plants

B.1.2.1. Summary of residues data from the supervised residue trials

Commodity	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials ^(b) (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(c) (mg/kg)	STMR ^(d) (mg/kg)	CF ^(e)
Leeks	NEU	Mo: 0.08, 0.10, 0.11, 0.13, 0.22, 0.24, 0.33, 0.43 RA: -	Residue trials compliant with the GAP. Samples analysed for clopyralid do not comply with the residue definitions for risk assessment proposed in the EU pesticides peer review, which included the conjugates. Based on the metabolism data on clopyralid in representative leafy and root crops, conjugates of clopyralid are expected to be present at low levels in leeks and bulb onions and their contribution to the residue level for risk assessment is considered trivial Extrapolation to spring onions possible.	0.7	0.43	0.18	-

(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): Mo: residue level according to the monitoring residue definition in Regulation (EC) No 396/2005 (clopyralid). RA: residue level according to the residue definition for risk assessment (clopyralid, its salts and conjugates, expressed as clopyralid) are not available.

(c): Highest residue according to the residue definition for monitoring in in Regulation (EC) No 396/2005.

(d): Supervised trials median residue according to the residue definition for monitoring in in Regulation (EC) No 396/2005.

(e): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment not calculated.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?

Significant residues (total residue levels <0.01 mg eq/kg) of clopyralid and/or its metabolites were not observed in rotational crops planted 125 (10.5 months) and 319 days after application of clopyralid at rate of 280 g/ha (0.94N the intended total application rate in spring/green/Welsh onions and leeks)
Shorter PBIs not investigated

Residues in rotational and succeeding crops expected based on field rotational crop study?

Field trials not available

B.1.2.3. Processing factors

Processing studies not provided.

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

ARfD

Not necessary (European Commission, 2006)

ADI

0.15 mg/kg bw per day (European Commission, 2006)

Highest IEDI, according to EFSA PRIMo

27% ADI (DK child)
Contribution of crops assessed:
Spring onions/green onions/Welsh onion: < 0.01% of ADI
Leeks: < 0.09% of ADI

Assumptions made for the calculations

The calculation is based on the median residue levels derived for raw agricultural commodities that would be expected on spring/ green/Welsh onion and on leeks according to the intended uses and on the uses assessed by EFSA in 2011 plus the existing EU MRLs
Contribution of clopyralid conjugated to consumer dietary burden not considered for spring onions/green onions/Welsh onions and leeks (but expected to be of low relevance on these crops) and for the existing EU MRL

B.4. Recommended MRLs

Code ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Clopyralid				
0220040	Spring onions/green onions and Welsh onions	0.5	0.7	NEU use supported by trials where samples were analysed for parent clopyralid only. Risk for consumers unlikely.
0270060	Leeks	0.5	0.7	

EU MRL: European Union maximum residue level; NEU: northern Europe.

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

Appendix C – Pesticide Residue Intake Model (PRIMo)

Clopyralid			
Status of the active substance:	Approved	Code no.:	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	0.15	ARfD (mg/kg bw):	n.n.
Source of ADI:	COM	Source of ARfD:	
Year of evaluation:	2006	Year of evaluation:	

MRLs according to Regulation (EU) No 322/2012, except for spring onions and leeks.

Chronic risk assessment – refined calculations								
		TMDI (range) in % of ADI minimum – maximum						
		3		27				
		No of diets exceeding ADI:		---				
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)		2nd contributor to MS diet (in % of ADI)		3rd contributor to MS diet (in % of ADI)		pTMRLs at LOQ (in % of ADI)
		Commodity/ group of commodities	Commodity/ group of commodities	Commodity/ group of commodities	Commodity/ group of commodities	Commodity/ group of commodities		
26.8	DK child	14.7	Rye	7.3	Wheat	0.8	Potatoes	
25.5	WHO Cluster diet B	11.4	Wheat	3.3	Maize	1.0	Tomatoes	
19.5	DE child	5.5	Wheat	4.0	Apples	2.6	Rye	
18.9	IE adult	3.1	Maize	3.1	Maize	2.4	Sweet potatoes	
17.4	NL child	6.3	Wheat	2.1	Apples	2.0	Potatoes	
16.5	WHO cluster diet D	8.7	Wheat	1.4	Potatoes	1.4	Rye	
15.8	UK Toddler	5.3	Sugar beet (root)	5.2	Wheat	1.2	Potatoes	
14.8	WHO cluster diet E	5.3	Wheat	1.4	Rye	1.3	Potatoes	
13.9	IT kids/toddler	8.9	Wheat	2.0	Other cereal	0.5	Tomatoes	
13.0	WHO Cluster diet F	4.8	Wheat	2.5	Rye	1.1	Potatoes	
12.5	UK Infant	3.5	Wheat	2.4	Sugar beet (root)	1.4	Maize	
12.5	PT General population	5.2	Wheat	1.8	Potatoes	1.0	Rice	
11.3	ES child	5.9	Wheat	0.7	Oranges	0.6	Rice	
11.1	FR toddler	3.5	Wheat	1.7	Potatoes	0.9	Apples	
11.0	SE general population 90th percentile	4.3	Wheat	1.4	Potatoes	1.0	Rye	
9.7	WHO regional European diet	4.0	Wheat	1.3	Potatoes	0.4	Barley	
9.2	IT adult	5.5	Wheat	0.9	Other cereal	0.4	Tomatoes	
8.3	LT adult	3.6	Rye	1.4	Wheat	1.1	Potatoes	
8.1	FR all population	4.4	Wheat	1.3	Wine grapes	0.4	Potatoes	
7.8	NL general	2.8	Wheat	0.9	Potatoes	0.5	Barley	
7.5	DK adult	2.7	Wheat	2.3	Rye	0.5	Potatoes	
7.3	ES adult	3.1	Wheat	0.7	Barley	0.4	Oranges	
6.8	UK vegetarian	2.7	Wheat	0.9	Sugar beet (root)	0.5	Rice	
6.8	FR infant	1.4	Potatoes	1.1	Wheat	0.9	Carrots	
5.8	UK Adult	2.2	Wheat	0.9	Sugar beet (root)	0.5	Rice	
5.8	FI adult	2.3	Rye	1.3	Wheat	0.4	Potatoes	
3.2	PL general population	1.1	Potatoes	0.7	Apples	0.3	Tomatoes	

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

Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

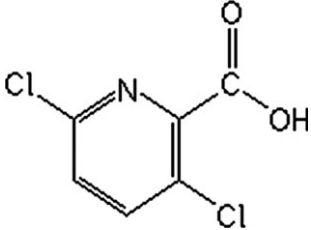
Not relevant.

D.2. Consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Swedes, turnips	0.35	STMR (EFSA, 2011)	Not necessary	
Spring onions	0.18	STMR		
Broccoli	0.30	STMR (EFSA, 2011)		
Cauliflowers	0.29	STMR (EFSA, 2011)		
Head cabbages	0.23	STMR (EFSA, 2011)		
Leeks	0.18	STMR		
Linseeds	4.46	STMR (EFSA, 2011)		
Sugar beets	0.35	STMR (EFSA, 2011)		
Swine, meat, fat tissue, liver and kidney	0.05	STMR (EFSA, 2011)		
Bovine, sheep, goats, meat, fat tissue and liver	0.05	STMR (EFSA, 2011)		
Bovine, sheep, goats, kidney	0.30	STMR (EFSA, 2011)		
Poultry, meat, fat tissue, liver and kidney	0.05	STMR (EFSA, 2011)		
Milk	0.01	STMR (EFSA, 2011)		
Birds eggs	0.05	STMR (EFSA, 2011)		
Other commodities of plant and animal origin	MRL	See Regulation (EU) No 322/2012 ⁷		

⁷ Commission Regulation (EU) No 322/2012 of 16 April 2012 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for clopyralid, dimethomorph, fenpyrazamine, folpet and pendimethalin in or on certain products. OJ L 105, 17.4.2012, p. 1–40.

Appendix E – Used compound code

Code/trivial name	Chemical name/SMILES notation ^(a)	Structural formula ^(a)
Clopyralid	3,6-dichloropyridine-2-carboxylic acid	 The image shows the chemical structure of 3,6-dichloropyridine-2-carboxylic acid. It consists of a pyridine ring with a nitrogen atom at the top position. There are chlorine atoms (Cl) at the 3 and 6 positions. At the 2 position, there is a carboxylic acid group (-COOH) with a double bond to the oxygen and a single bond to the hydroxyl group.

(a): (ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008)).