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Modification of the existing maximum residue levels for clomazone in chamomiles and plantains

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant LSA (Landesanstalt Sachsen-Anhalt) submitted a request to the competent national authority in Germany to modify the existing maximum residue levels (MRLs) for the active substance clomazone in chamomiles and plantains. The data submitted in support of the request were found to be sufficient to derive MRL proposals for the crops under consideration. Adequate analytical methods for enforcement are available to control the residues of clomazone in plant matrices on the crops under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of clomazone according to the reported agricultural practice is unlikely to present a risk to consumer health. Restrictions on crop rotation as an appropriate risk mitigation measure should be taken into consideration at national level in order to avoid the occurrence of clomazone residues in rotational crops.

Keywords: Clomazone, Chamomile, Plantain, Pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, LSA (Landesanstalt Sachsen-Anhalt) submitted an application to the competent national authority in Germany (evaluating Member State (EMS)) to modify the existing maximum residue levels (MRLs) for the active substance clomazone in chamomiles and plantains. 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) on 23 January 2017. To accommodate for the intended uses of clomazone, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) of 0.05* mg/kg to 0.5 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps for which further clarifications were needed and which were requested from the EMS. On 26 March 2018, the EMS submitted a revised evaluation report (Germany, 2016), which replaced the previously submitted evaluation report.

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 are derived.

The metabolism of clomazone was investigated in crops belonging to the groups of root crops, leafy crops and pulses/oilseeds. A metabolism study in rotational crops is not available but results from primary metabolisms studies involving soil application indicate that the same metabolic pattern is expected in rotational crops.

Based on the metabolic pattern identified in metabolism studies, the residue definitions for plant products were proposed as clomazone for enforcement and risk assessment.

EFSA concluded that for the crops assessed in this application, metabolism of clomazone has been sufficiently addressed and that the previously derived residue definitions are applicable.

Sufficiently validated analytical methods are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in the crops assessed (LOQ).

The available residue trials are sufficient to derive a MRL proposal of 0.5 mg/kg for chamomiles and plantains. As plantain is not a separate commodity but associated to herbal infusions from strawberry leaves, it is proposed to raise the MRL for the entire group of herbal infusions from strawberry leaves.

Specific studies investigating the magnitude of clomazone residues in processed commodities are not required due to the low consumption of the crops under consideration.

Based on the available information, EFSA could not exclude that the use of clomazone according to the proposed good agricultural practice (GAP) will result in significant residues in rotational crops at short plant back interval. Therefore, Member States should consider the need for setting specific risk mitigation measures to avoid the presence of clomazone residues in rotational crops.

Residues of clomazone 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 clomazone 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 0.133 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). Although detailed consumption data on chamomiles and plantains are not available, the residues in these crops are not expected to affect significantly the total chronic dietary exposure. In order to make a rough estimation of the magnitude of the dietary exposure assuming a conservative scenario, EFSA calculated the exposure of a child with a body weight of 10 kg consuming on a daily basis herbal infusions prepared from one tea bag (2 g) containing residues at the proposed MRL of 0.5 mg/kg for chamomiles and herbal infusions from strawberry leaves. Assuming a complete transfer of the residues to the infusion, the exposure of the child is calculated to amount for less than 0.1% of the ADI.

An acute consumer risk was not necessary as no ARfD was derived.

EFSA concluded that the proposed use of clomazone on chamomiles and plantains 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 for the renewal of approval of the active substance in accordance with Regulation (EC) No 1107/2009 is 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.

EFSA proposes to amend the existing MRLs as reported in the summary table below.
Full details of all endpoints 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: clomazone				
0631010	Chamomiles	0.05*	0.5	The submitted data are sufficient to derive a MRL proposal for the NEU use. Risk for consumers unlikely. As plantain (0632010-074) is not a separate commodity in Regulation (EU) No 752/2014 but an associate to herbal infusions from strawberries leaves (0632010), it is proposed to raise the MRL for the entire group in order to accommodate the needs of plantain
0632010	Herbal infusions from strawberry leaves	0.05*	0.5	

MRL: maximum residue level; NEU: northern Europe.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(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 clomazone in chamomiles and plantains, which are the basis for the current maximum residue level (MRL) application, is reported in Appendix A.

Clomazone is the ISO common name for 2-(2-chlorobenzyl)-4,4-dimethyl-1,2-oxazolidin-3-one (IUPAC). The chemical structure of the active substance is in Appendix E.

Clomazone was evaluated in the framework of Directive 91/414/EEC[1] with Denmark designated as rapporteur Member State (RMS) for the representative uses as pre-emergence herbicide applications in potatoes and oilseed rape. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (2007b). Clomazone was approved[2] for the use as a herbicide on 1 November 2008. The process of renewal of the first approval is currently ongoing.

The EU MRLs for clomazone are established in Annexes II of Regulation (EC) No 396/2005[3]. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2011) and the proposed modifications have been implemented in the MRL legislation. EFSA has issued several reasoned opinions on the modification of MRLs for clomazone.

EFSA based its assessment on the evaluation report submitted by the EMS (Germany, 2016), the draft assessment report (DAR) (and its addendum/addenda) (Denmark, 2005, 2007) prepared under Council Directive 91/414/EEC, the Commission review report on clomazone (European Commission, 2007), the conclusion on the peer review of the pesticide risk assessment of the active substance clomazone (EFSA, 2007b), as well as the conclusions from previous EFSA opinion on the review of existing MRLs for clomazone according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011).

For this application, the data requirements established in Regulation (EU) No 544/2011[4] 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, 2013). 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[5].

As the EU pesticides peer review for the renewal of approval of the active substance in accordance with Regulation (EC) No 1107/2009 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 peer review.

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

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

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 clomazone in primary crops was evaluated in the framework of the peer review under Directive 91/414/EEC (EFSA, 2007b) and reviewed in the Article 12 MRL review (EFSA, 2011) in the root, leafy and pulses/oilseeds crop groups. An overview of the key features of the available metabolism studies is presented in Appendix B.

[1] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.

[2] Commission Directive 2007/76/EC of 20 December 2007 amending Council Directive 91/414/EEC to include fludioxonil, clomazone and prosulfocarb as active substances. OJ L 337, 21.12.2007, p. 100–104.

[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, 16.3.2005, p. 1–16.

[4] 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.

[5] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

The metabolism study in leafy crops (tobacco) was found to be not fully representative for the crops under assessment, since the timing of the application and the preharvest interval (PHI) defined in the good agricultural practice (GAP) for chamomile and plantain differed significantly from the conditions tested in the metabolism study. However, since in the metabolism studies in cotton and alfalfa also the leaves were analysed and taking into account that chamomile and plantain are very minor crops, the available metabolism studies are considered sufficient.

Overall, metabolism in all crops investigated was considered to be similar for the different crops and timings of application. The most abundant plant metabolite is 2-chlorobenzyl alcohol (10–48% total radioactive residue (TRR)). The parent compound was almost completely degraded and, if present, only at low levels (0.3–4% TRR). However, for reasons of very rapid conjugation and excretion, a negative Ames test and structural analogy to common ingredients used in household products of very low toxicity (EFSA, 2011), the metabolite was not included in the residue definition, which is clomazone only, for both enforcement and risk assessment.

For the uses on the crops under consideration, EFSA concludes that the metabolism of clomazone is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

The crops under consideration might be grown in rotation with other crops, and therefore, the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed.

Since the DT_{90} value of clomazone in soil is in the range 86–297 days in field studies, metabolism in rotational crops should be assessed. Based on results from primary metabolism studies involving soil application, it was concluded that the same metabolic pattern is expected in rotational crops (EFSA, 2011).

1.1.3. Nature of residues in processed commodities

Studies investigating the nature of clomazone residues in processed commodities are not available and are in principle required as the residues in the raw commodities were above the trigger value of 0.1 mg/kg. Nevertheless, considering the limited contribution of chamomile and plantain to the chronic dietary intake (see also Section 3), such studies are not required in the framework of this application.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of clomazone residues in plant commodities were assessed in the framework of the peer review and the Article 12 MRL review (Denmark, 2005, 2007; EFSA, 2011). Additionally, the Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) method in combination with high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) or gas chromatography with mass spectrometry (GC–MS) in high water content, high oil content, acidic and dry commodities and commodities that are difficult to analyse such as herbs, tea and spices were submitted (Germany, 2016).

Sufficiently validated methods to control residues of clomazone with a LOQ of 0.01 mg/kg in crops under consideration are available.

1.1.5. Stability of residues in plants

The stability of clomazone residues in plant matrices under storage conditions prior to analysis was assessed in the framework of the peer review and the Article 12 MRL review (EFSA, 2007b, 2011). Amongst the tested matrices were corn grain and corn stover, which are considered difficult matrices to be analysed such as dried leaves and flowers of chamomile and plantain. Storage stability of clomazone was demonstrated in theses matrices for a period of 24 months when stored at −18°C. It is therefore anticipated that no substantial decomposition of the residues has occurred in chamomile and plantain samples over the reported storage periods up to 17 months (Germany, 2016).

1.1.6. Proposed residue definitions

The residue definition for monitoring and risk assessment was agreed as clomazone only (EFSA, 2011) and it is valid for the crops under assessment. This residue definition is applicable to rotational crop. No specific residue definition is needed for processed commodities.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

Regarding the magnitude of residues in primary crops, a sufficient number of supervised residue trials are available for the crops under consideration, which allowed EFSA to estimate the expected residue concentrations in the relevant plant commodities and to derive appropriate MRL proposals.

Six field trials on plantain and three trials on chamomile compliant with the intended GAP are available. Data were pooled in order to make the MRL proposal statistically more robust (U-test, 5%).

EFSA concludes that the storage stability data cover the storage time for the supervised residue trials of the crops under consideration and the residue data are valid with regard to storage stability. According to the EMS, the analytical method of the residues in samples from treated crops was fit for purpose and capable of analysing clomazone.

1.2.2. Magnitude of residues in rotational crops

Rotational crops studies are not available. Although according to the metabolism studies and residue trials supporting the existing uses and performed with soil treatment, residues in the harvested commodities were below the LOQ in most commodities, significant levels of clomazone were present in fresh herbs harvested 28 days after soil application (EFSA, 2011). As the crops under assessment might be grown in rotation with other crops having a short growth cycle, occurence of residues in the rotational crops cannot be excluded. Further investigation of clomazone residues in rotational crops is in principle therefore required.

Alternatively, Member States could consider the need to set specific risk mitigation measures to avoid the presence of clomazone residues in rotational crops. In this regard, it is proposed that treated areas may be replanted with crops having a long growth cycle only (e.g. field crops such as oilseed rape).

1.2.3. Magnitude of residues in processed commodities

Specific studies investigating the magnitude of clomazone residues in processed commodities are not required, as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the acceptable daily intake (ADI) (see also Section 3).

1.2.4. Proposed MRLs

EFSA proposes to amend the existing MRLs as reported in the Appendix B.

2. Residues in livestock

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

3. Consumer risk assessment

In the framework of the review of the existing MRLs for clomazone according to Article 12 of Regulation (EC) No 396/2005, a comprehensive long-term exposure assessment was performed taking into account the existing uses at the EU level (EFSA, 2011). EFSA updated this risk assessment with the median residue levels (STMR) derived from the residue trials conducted on the crops under consideration in this MRL application. The input values used for the dietary exposure calculation are summarised in Appendix D.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population (EFSA, 2007a).

The estimated exposure was then compared with the toxicological reference value derived for clomazone.

No long-term consumer intake concern was identified for any of the European diets incorporated in the EFSA PRIMo. Although detailed consumption data on chamomiles and plantains are not available, the residues in these crops are not expected to affect significantly the total chronic dietary exposure. In order to make a rough estimation of the magnitude of the dietary exposure assuming a conservative scenario, EFSA calculated the exposure of a child with a body weight of 10 kg consuming on a daily basis

herbal infusions prepared from one tea bag (2 g) containing residues at the proposed MRL of 0.5 mg/kg for chamomiles and herbal infusions from strawberry leaves. Assuming a complete transfer of the residues to the infusion, the exposure of the child is calculated to amount for less than 1% of the ADI.

An acute consumer risk assessment was not performed as no acute reference dose (ARfD) was considered necessary.

EFSA concludes that the intended uses of clomazone on the commodities under consideration will not result in a consumer exposure exceeding the toxicological reference value and therefore are unlikely to pose a health concern to consumers.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for chamomiles and herbal infusions from strawberry leaves (plantain).

EFSA concluded that the proposed use of clomazone on chamomiles and herbal infusions from strawberry leaves will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers' health.

The MRL recommendations are summarised in the table below and in Appendix B.4.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: clomazone				
0631010	Chamomiles	0.05*	0.5	The submitted data are sufficient to derive a MRL proposal for the NEU use. Risk for consumers unlikely. As plantain (0632010-074) is not a separate commodity in Regulation (EU) No 752/2014 but an associate to herbal infusions from strawberries leaves (0632010), it is proposed to raise the MRL for the entire group in order to accommodate the needs of plantain
0632010	Herbal infusions from strawberry leaves	0.05*	0.5	

MRL: maximum residue level; NEU: northern Europe.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
CS	capsule suspension
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-MS	gas chromatography with mass spectrometry
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
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
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SEU	southern Europe

SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WHO	World Health Organization

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				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	Unit		
Chamomile	NEU	F	Annual dicotyled weeds (TTTDS)	CS	360 g/kg	Spray	After emergence	1	n.a	22.5–45	200–400	90	g/ha	28	Dried leaves and dried flowers
Plantain	NEU	F	Annual dicotyled weeds (TTTDS)	CS	360 g/kg	Spray	After emergence	1	n.a	22.5–45	200–400	90	g/ha	28	Dried leaves and dried flowers

NEU: northern European Union; SEU: southern European Union; MS: Member State; GAP: good agricultural practice; MRL: maximum residue level; a.s.: active substance; CS: capsule suspension.
(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**	**Application**	**Sampling (DAT)**	**Comment/Source**
	Root crops	Sweet potatoes	Pre-emergence, 1 × 3,360 g/ha	118–199	Label position: phenyl-^{14}C, and carbonyl-^{14}C/EFSA (2011)
	Leafy crops	Tobacco	Pre-emergence, 1 × 2,240 g/ha	84, 92, 112	Label position: phenyl-^{14}C, and carbonyl-^{14}C/EFSA (2011)
	Pulses/ oilseeds	Soya	Pre-emergence (G), 1,100–2,200 g/ha	30, 60, 116	Label position: carbonyl-^{14}C, and methylene-^{14}C/EFSA (2011)
	Pulses/ oilseeds	Soya	Pre-emergence (F), 1 × 2,240 g/ha	30, 58, 118	Label position: phenyl-^{14}C, and carbonyl-^{14}C/EFSA (2011)
	Pulses/ oilseeds	Cotton	Post-emergence (G), 1,680–3,250 g/ha	21	Label position:phenyl-^{14}C, and carbonyl-^{14}C/EFSA (2011)
	Pulses/ oilseeds	Alfalfa	Post-emergence 1 × 280 g/ha	0, 3, 7	Label position: phenyl-^{14}C, and methylene-^{14}C/EFSA (2011)
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI** (DAT)	**Comment/Source**
	Confined rotational crop studies not available.				
Processed commodities (hydrolysis study)	**Conditions**		**Stable?**	**Comment/Source**	
	Pasteurisation (20 min, 90°C, pH 4)		not triggered	Although residues in the raw commodities were above 0.1 mg/kg, considering the low contribution of the crops under assessment to the dietary exposure, such studies are not required	
	Baking, brewing and boiling (60 min, 100°C, pH 5)		not triggered		
	Sterilisation (20 min, 120°C, pH 6)		not triggered		

DAT: days after treatment; PBI: plant-back interval; GC–MS: gas chromatography with mass spectrometry; ILV: independent laboratory validation; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification.

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2011)
Rotational crop and primary crop metabolism similar?	Yes	Confined rotational studies are not available but results from primary metabolisms studies involving soil application indicate that the same metabolic pattern is expected in rotational crops
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not triggered	
Plant residue definition for monitoring (RD-Mo)	Clomazone	
Plant residue definition for risk assessment (RD-RA)	Clomazone	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high water content (melons, tomatoes), high oil content (oilseed rape), high acid content (oranges) and dry matrices (wheat): GC–MS, LOQ 0.01 mg/kg Confirmatory method and ILV available (Denmark 2005, 2007, EFSA 2011) The QuEChERS method in combination with HPLC–MS/MS or GC–MS, LOQ 0.01 mg/kg in high water content, high oil content, acidic and dry commodities and commodites that are difficult to analyse such as herbs, tea and spices (Germany, 2016)	

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**	**Comment/ Source**
				Value	**Unit**		
	High water content	Tobacco	−20	30	Months	Parent	EFSA (2011)
	High oil content	Cotton seed	−20	24	Months	Parent	Germany (2016)
	Dry/High starch	Corn	−20	24	Months	Parent	Germany (2016)

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 (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)
Chamomile (90 g/ha, PHI 28 days)	NEU	0.01, 2 × 0.11	Combined data from chamomile and plantain (U-test, 5%) compliant with GAP. MRL_{OECD}: 0.51/0.50	**0.5**	**0.34**	**0.037**
Plantain (90 g/ha, PHI 28 days)	NEU	< 0.01, 0.01, 0.015, 0.037, 0.091, 0.34				

MRL: maximum residue level; PHI: preharvest interval; GAP: good agricultural practice; OECD: Organisation for Economic Co-operation and Development.
(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): Highest residue.
(c): Supervised trials median residue.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Yes	No confined rotational crop study is available. However, according to the results from residue trials in herbs, significant levels of clomazone are present in the primary crops harvested 28 days after a soil application (EFSA, 2011). Therefore, an uptake from the soil cannot be excluded with a short plant-back interval and MSs are recommended to implement proper risk mitigation measures in order to avoid significant residues to occur in rotational crops
Residues in rotational and succeeding crops expected based on field rotational crop study?	Inconclusive	–

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application.

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

Acute risk assessment not relevant since no ARfD has been considered necessary.

ADI	0.133 mg/kg bw per day (EFSA 2011)
Highest IEDI, according to EFSA PRIMo	0.2% ADI (UK toddler) Contribution of crops assessed: Chamomile: < 0.1% of ADI Plantain: < 0.1% of ADI
Assumptions made for the calculations	The calculation is based on the median residue levels derived for raw agricultural commodities The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation

ADI: acceptable daily intake; bw: body weight; PRIMo: (EFSA) Pesticide Residues Intake Model; GAP: good agricultural practice; MRL: maximum residue level.

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: clomazone				
0631010	Chamomiles	0.05*	0.5	The submitted data are sufficient to derive a MRL proposal for the NEU use. Risk for consumers unlikely. As plantain (0632010-074) is not a separate commodity in Regulation (EU) No 752/2014 but an associate to herbal infusions from strawberries leaves (0632010), it is proposed to raise the MRL for the entire group in order to accommodate the needs of plantain
0632010	Herbal infusions from strawberry leaves	0.05*	0.5	

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

Appendix C – Pesticide Residue Intake Model (PRIMo)

Clomazone			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.133**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2011**	Year of evaluation:	**2011**

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity, the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum

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)
0.2	UK Toddler	0.2	Sugar beet (root)	0.0	Potatoes	0.0	Beans	
0.1	UK Infant	0.1	Sugar beet (root)	0.0	Potatoes	0.0	Carrots	
0.1	WHO Cluster diet B	0.0	Tomatoes	0.0	Potatoes	0.0	Maize	
0.1	IE adult	0.0	Sweet potatoes	0.0	Maize	0.0	Potatoes	
0.1	FR toddler	0.0	Potatoes	0.0	Carrots	0.0	Beans (with pods)	
0.1	NL child	0.0	Potatoes	0.0	Tomatoes	0.0	Beans (with pods)	
0.1	WHO cluster diet E	0.0	Potatoes	0.0	Rape seed	0.0	Soya bean	
0.1	FR infant	0.0	Potatoes	0.0	Carrots	0.0	Beans (with pods)	
0.1	PT General population	0.0	Potatoes	0.0	Tomatoes	0.0	Rice	
0.1	WHO cluster diet D	0.0	Potatoes	0.0	Tomatoes	0.0	Soya bean	
0.1	WHO regional European diet	0.0	Potatoes	0.0	Tomatoes	0.0	Carrots	
0.1	SE general population 90th percentile	0.0	Potatoes	0.0	Carrots	0.0	Tomatoes	
0.1	WHO Cluster diet F	0.0	Potatoes	0.0	Soya bean	0.0	Tomatoes	
0.1	UK vegetarian	0.0	Sugar beet (root)	0.0	Potatoes	0.0	Tomatoes	
0.1	DE child	0.0	Potatoes	0.0	Carrots	0.0	Tomatoes	
0.1	UK Adult	0.0	Sugar beet (root)	0.0	Potatoes	0.0	Tomatoes	
0.1	DK child	0.0	Potatoes	0.0	Cucumbers	0.0	Carrots	
0.0	PL general population	0.0	Potatoes	0.0	Tomatoes	0.0	Head cabbage	
0.0	NL general	0.0	Potatoes	0.0	Tomatoes	0.0	Beans (with pods)	
0.0	LT adult	0.0	Potatoes	0.0	Tomatoes	0.0	Head cabbage	
0.0	ES child	0.0	Potatoes	0.0	Tomatoes	0.0	Rice	
0.0	IT kids/toddler	0.0	Tomatoes	0.0	Potatoes	0.0	Rice	
0.0	ES adult	0.0	Potatoes	0.0	Tomatoes	0.0	Rice	
0.0	IT adult	0.0	Tomatoes	0.0	Potatoes	0.0	Courgettes	
0.0	DK adult	0.0	Potatoes	0.0	Carrots	0.0	Tomatoes	
0.0	FR all population	0.0	Potatoes	0.0	Tomatoes	0.0	Carrots	
0.0	FI adult	0.0	Potatoes	0.0	Tomatoes	0.0	Cucumbers	

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

	Acute risk assessment/children – refined calculations			Acute risk assessment/adults/general population – refined calculations		
	Acute risk assessment is not necessary.					
	For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation. In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used. In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3. **Threshold MRL** is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.					
Unprocessed commodities	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
	IESTI 1 *) **)			**IESTI 2** *) **)		
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	No of critical MRLs (IESTI 1) ---			**No of critical MRLs (IESTI 2)** ---		

Processed commodities	**No of commodities for which ARfD/ADI is exceeded:** ---			**No of commodities for which ARfD/ADI is exceeded:** ---		
	***)			***)		
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
**) pTMRL: provisional temporary MRL.
MRL.***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:
As no ARfD was considered necessary, it is concluded that the short-term intake of clomazone residues is unlikely to present a pulbic health concern.

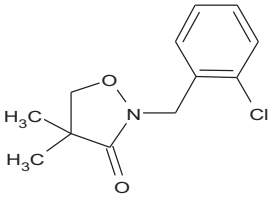
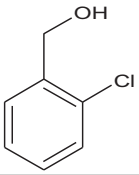
Appendix D – Input values for the consumer risk assessment

D.1. Consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Residue definition for risk assessment: clomazone				
Chamomile	0.037	STMR	Not conducted as no acute reference dose was considered necessary	
Plantain	0.037	STMR		
Other commodities	See MRL review (EFSA, 2011)			

STMR: supervised trials median residue; MRL: maximum residue level.

Appendix E – Used compound codes

Code/trivial name	IUPAC name/SMILES notation/InChiKey[a]	Structural formula[b]
Clomazone	2-(2-chlorobenzyl)-4,4-dimethyl-1,2-oxazolidin-3-one Clc1ccccc1CN1OCC(C)(C)C1=O KIEDNEWSYUYDSN-UHFFFAOYSA-N	
2-chlorobenzyl alcohol	(2-chlorophenyl)methanol OCc1ccccc1Cl MBYQPPXEXWRMQC-UHFFFAOYSA-N	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system.
(a): ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).
(b): ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).