

REASONED OPINION OF EFSA

Modification of the existing MRL for clomazone in herbs¹

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2009-00205)

Issued on 14 April 2009

SUMMARY

According to Article 6(1) of Regulation (EC) No 396/2005, The United Kingdom received an application from the Horticultural Development Council to modify the existing MRL of clomazone in herbs. In order to accommodate for a new use in these crops, the applicant proposes to raise the existing MRL, which is currently set at the analytical limit of quantification, to 0.2 mg/kg. Following the application, an evaluation report was drafted by The United Kingdom and received by EFSA on 14 January 2009 according to Article 9 of the Regulation. Based on the evaluation report and the EFSA conclusion on the peer review of the active substance clomazone, EFSA derives the following conclusions regarding the application.

Metabolism studies with pre-emergence treatment were conducted in tobacco, sweet potatoes and soy bean. In addition, there are two studies on cotton and alfalfa with post-emergence application, covering different plant parts. The metabolism is considered to be similar for the different crops and timings of application. Clomazone itself was almost completely degraded and, if present, only at low levels. The most abundant plant metabolite, 2-chlorobenzyl alcohol, was not found in rat metabolism, and it could not be demonstrated that it is of lower toxicity than clomazone. With respect to the use of clomazone in herbs, the amount of both clomazone and 2-chlorobenzyl alcohol are expected to be significant at harvest (i.e. exceeding the trigger value of 0.01 mg/kg) due to the short growth cycle of herbs. Therefore, the relevant residue for risk assessment in herbs is defined as the sum of clomazone and 2-chlorobenzyl alcohol, expressed as clomazone. For enforcement purposes however it is proposed to define clomazone only as the relevant residue because proper enforcement of 2-chlorobenzyl alcohol cannot be ensured.

In support of the proposed GAPs for clomazone in herbs, a sufficient number of supervised residues trials is available. These trials allow estimating the expected residue concentrations in the relevant plant commodities and deriving appropriate MRLs. It is noted that residue levels according to the residue definition for risk assessment are not reported in the available residues trials, which is usually considered as essential for deriving a conversion factor

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between enforcement and risk assessment. An approximate conversion factor was therefore derived from the available metabolism studies. As the consumer exposure to clomazone residues is low in comparison with the toxicological reference values, the use of the approximate conversion factor is considered acceptable in this particular case.

The effect of processing on the nature and magnitude of residues was not investigated considering that consumer exposure resulting from treated herbs contributes to less than 10% of the ADI.

Studies on the occurrence of clomazone residues in rotational crops are not available. Further investigation is however required because DT₉₀ values for clomazone exceed 100 days and herbs are often grown in rotation with other crops having a short growth cycle. **Alternatively, appropriate risk mitigation measures might be taken at national level in order to avoid the occurrence of clomazone residues in rotational crops.**

Residues in commodities of animal origin were not assessed in the framework of this application considering that herbs are not fed to livestock.

Chronic intake calculations considering the new proposed MRL as well as the existing MRLs for clomazone were performed with revision 2 of the EFSA PRIMo. Acute intake calculations were not undertaken due to the low acute toxicity of clomazone. As no intake concerns were identified for all available European diets, the proposed use is not expected to pose any risk to the European consumer. The recommendation resulting from the assessment is summarized in the table below.

Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Residue definition for enforcement: <i>clomazone</i>			
Herbs	0.01*	0.2	MRL proposal is sufficiently supported by data and no risk to consumers was identified.

(*): Indicates that the MRL is set at the limit of analytical quantification.

Key words: clomazone, herbs, MRL application, Regulation (EC) No 396/2005, isoxazolidinone herbicides, 2-chlorobenzyl alcohol

TABLE OF CONTENTS

Background 4

Terms of reference..... 4

The active substance and its use pattern..... 5

Assessment 6

1. Methods of analysis 6

 1.1. Methods for enforcement of residues in food of plant origin 6

 1.2. Methods for enforcement of residues in food of animal origin 6

2. Mammalian toxicology 6

3. Residues..... 6

 3.1. Nature and magnitude of residues in plant..... 6

 3.1.1. Primary crops..... 6

 3.1.1.1. Nature of residues 6

 3.1.1.2. Magnitude of residues..... 7

 3.1.1.3. Effect of industrial processing and/or household preparation 9

 3.1.2. Rotational crops..... 9

 3.2. Nature and magnitude of residues in livestock 9

4. Consumer risk assessment 9

Conclusions and recommendations 11

Documentation provided to EFSA 12

References 12

Appendix A – Good Agricultural Practices (GAPs) 13

Appendix B – List of existing EC MRLs 14

Appendix C – Pesticide Residues Intake Model (PRIMo) 19

Glossary / Abbreviations..... 22

BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that a party requesting an authorisation for the use of a plant protection product in accordance with Directive 91/414/EEC, shall submit to a Member State, when appropriate, an application to set or modify an MRL in accordance with the provisions of Article 7 of that regulation.

The United Kingdom, hereafter referred to as the Evaluating Member State (EMS), received an application from the Horticultural Development Council² to modify the existing MRL for the active substance clomazone in herbs. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 14 January 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00205 and the following subject:

Clomazone - Application to modify the existing MRLs for clomazone in chervil from 0.01 mg/kg to 0.2 mg/kg, in chives from 0.01* mg/kg to 0.2 mg/kg, in celery leaves from 0.01* mg/kg to 0.2 mg/kg, in parsley from 0.01* mg/kg to 0.2 mg/kg, in sage from 0.01* mg/kg to 0.2 mg/kg, in rosemary from 0.01* mg/kg to 0.2 mg/kg, in thyme from 0.01* mg/kg to 0.2 mg/kg, in basil from 0.01* mg/kg to 0.2 mg/kg, in bay leaves (laurel) from 0.01* mg/kg to 0.2 mg/kg and in tarragon from 0.01* mg/kg to 0.2 mg/kg. Applicable to all herbs (incl. "others").*

EFSA then proceeded with the assessment of the application as required by Article 10 of the Regulation.

TERMS OF REFERENCE

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

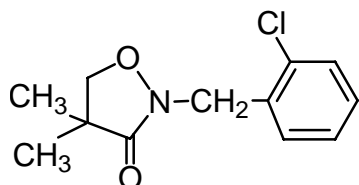
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the calculated deadline for providing the reasoned opinion is 14 April 2009.

² Horticultural Development Council, Bradbourne House, East Malling, ME19 6DZ Kent, The United Kingdom

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Clomazone is the ISO common name for 2-(2-chlorobenzyl)-4,4-dimethyl-1,2-oxazolidin-3-one (IUPAC).



Clomazone is an isoxazolidinone herbicide but there are no other compounds currently in this class of compounds. It is a selective herbicide which is absorbed by the roots and shoots and translocated upwards. It inhibits carotenoid biosynthesis; the target enzyme remains unclear.

Clomazone was evaluated in the framework of Directive 91/414/EEC in stage 3 with Denmark being the designated Rapporteur Member State (RMS). The representative uses supported for the peer review process were pre-emergence applications in potatoes and oilseed rape resulting in a decision on inclusion of the active substance in Annex I to the Directive. This decision was published by Directive 2007/76/EC and entered into force on 01 November 2008.

In the European Community temporary MRLs are currently established for clomazone (Appendix B). These temporary MRLs have been derived from the MRLs that have been set at national level before Regulation (EC) No 396/2005 entered into force. The MRL for herbs was established at the level of 0.01 mg/kg, which is equivalent to the analytical limit of quantification (LOQ). There are no CXLs for clomazone.

The United Kingdom now intends to authorize the use of clomazone in herbs requiring a modification of the existing MRL. A detailed overview of the GAP is available in Appendix A. It concerns a pre-emergence outdoor treatment with an application rate of 90 g a.s./ha.

ASSESSMENT

1. Methods of analysis

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

According to the EFSA conclusion on the peer review of clomazone (EFSA, 2007) an analytical method for enforcement of clomazone has been validated for matrices with a high content of water, acid or oil as well as for dry commodities. The analytical method reported uses gas chromatography with detection by mass spectrometry and a LOQ of 0.01 mg/kg was derived for all commodities. Consequently, it is possible to enforce clomazone in herbs with a LOQ of 0.01 mg/kg.

1.2. Methods for enforcement of residues in food of animal origin

The availability of an analytical method for enforcement of residues in food of animal origin was not considered in the framework of this application as herbs are not fed to livestock.

2. Mammalian toxicology

The toxicological assessment of clomazone was peer reviewed under Directive 91/414/EEC and toxicological reference values for the active substance have been derived by EFSA (2007). These values are summarized in the table below.

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
ADI	EFSA	2007	0.133	1 year dog study	100
ARfD	EFSA	2007	n.n.	-	-

n.n.: 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

According to the EFSA conclusion on clomazone (EFSA, 2007), metabolism studies with pre-emergence treatment were conducted in tobacco, sweet potatoes and soybean. In addition, there were two studies on cotton and alfalfa with post-emergence application, covering different plant parts. The metabolism is considered to be similar for the different crops and timings of application. The parent compound was almost completely degraded and, if present, only at low levels. The most abundant plant metabolite, 2-chlorobenzyl alcohol, was not found in rat metabolism, and it could not be demonstrated that it is of lower toxicity than clomazone. With respect to the representative uses evaluated under Directive 91/414/EEC

(potatoes and rape seed), the amount of neither clomazone nor 2-chlorobenzyl alcohol are expected to be significant in food and feed items (i.e. below the trigger value of 0.01 mg/kg). Therefore, the relevant residue was defined by default as clomazone for those representative uses. A similar conclusion was reached by EFSA for the pre-emergence or early post-emergence use of clomazone in rice (EFSA, 2009). In both cases it was also concluded that a general residue definition for all plant commodities could not be proposed as these residue definitions were derived specifically for the proposed GAPs.

Although the pre-emergence use of clomazone is proposed for herbs, significant amounts of clomazone and 2-chlorobenzyl alcohol in the harvested crops are to be expected (i.e. exceeding the trigger value of 0.01 mg/kg). Due to the short growth cycle of these crops (approximately 30 days), it is expected that clomazone residues are not yet dissipated by the time of harvest. This is also confirmed by the levels of clomazone found in the available residues trials for coriander (see section 3.1.1.2). As it could not be demonstrated that 2-chlorobenzyl alcohol is of lower toxicity than the parent compound both clomazone and 2-chlorobenzyl alcohol are considered relevant for risk assessment in herbs. For enforcement purposes however it is proposed to define clomazone only as the relevant residue because proper enforcement of 2-chlorobenzyl alcohol cannot be ensured.

An analytical method for enforcement of clomazone in commodities with high water content, which includes herbs, was validated with a LOQ of 0.01 mg/kg (see also section 1.1).

3.1.1.2. Magnitude of residues

The EMS reported 8 residues trials on coriander complying with the intended GAP for herbs. The results of these trials are summarized in Table 3-1. According to the current guidance on extrapolation of residues trials (European Commission, 2008), extrapolation to herbs is typically done from lettuce, spinach or parsley but other extrapolations might be considered on a case by case basis. As coriander is closely related to parsley, both morphologically as botanically, it is considered acceptable to extrapolate the available trials for coriander to the whole group of herbs.

It is noted that residue levels according to the residue definition for risk assessment are not reported in the available trials, which is usually considered essential for deriving a conversion factor between enforcement and risk assessment. However, based on the available metabolism studies for cotton, soybean and corn, where immature plants were sampled between 20 and 30 days after treatment, an approximate conversion factor can be estimated for herbs. The ratios of parent compound and the metabolite are summarized in Table 3-2. The worst case situation was identified in the soybean study where a conversion factor of 10 was derived. As the total consumer exposure to clomazone residues represents less than 1% of the ADI, the use of this approximate conversion factor is considered acceptable in this particular case.

There is no need to investigate storage stability of clomazone in the framework of this application since the coriander samples were stored under freezer conditions for less than 1 month prior to analysis. According to the EMS, analytical methods used in the residues trials were found to be reliable as well.

It is therefore concluded that the available trials are sufficient to derive MRL proposals and risk assessment values for clomazone in herbs (see also Table 3-1).

Table 3-1. Overview of the available residues trials data

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Approx. CF	Comments
			Enforcement	Risk assessment					
Residue definition for enforcement: <i>clomazone</i>									
Residue definition for risk assessment: <i>sum of clomazone and 2-chlorobenzyl alcohol, expressed as clomazone</i>									
Chervil Chives Celery leaves Parsley Sage Rosemary Thyme Basil Bay leaves Tarragon	NEU (UK)	Outdoor	0.011; 0.028; 0.035; 0.042; 0.061; 0.062; 0.078; 0.089	Not available	0.05	0.09	0.2	10.0	Trials performed on coriander can be extrapolated to all herbs. As no data are available for risk assessment, the conversion factor was derived from the available metabolism studies. $R_{\max} = 0.132$ $R_{\text{ber}} = 0.135$

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

(*): Indicates that the MRL is set at the limit of analytical quantification.

Table 3-2. Overview of the metabolite ratios in immature plant samples

	Cotton	Corn	Soybean
Application rate (kg a.s./ha)	3.25	1.12	3.36
Days after treatment (days)	21	30	30
Levels of clomazone (%TRR)	17	22	5
Levels of 2-chlorobenzyl alcohol (%TRR)	34	n.a.	47
Approximate conversion factor	3	<5	10

n.a.: not available

3.1.1.3. Effect of industrial processing and/or household preparation

There is no need to investigate the effect of processing on the nature and magnitude of clomazone residues in herbs considering that consumer exposure resulting from treated herbs contributes to less than 10% of the ADI.

3.1.2. Rotational crops

Even though the DT₉₀ value of clomazone ranges between 86 and 297 days in several field studies, rotational crop studies for clomazone are not available. Still, for the representative uses supported in the framework of the peer review (oilseed rape and potatoes) it was concluded that residues of clomazone exceeding 0.01 mg/kg would not be expected in any rotational crop grown after crop failure of the primary crop (EFSA, 2007). This conclusion was based on the residue behaviour in the primary crops where no residues exceeding the LOQ were observed in immature plant parts. Later on a similar conclusion was reached for the use of clomazone in rice (EFSA, 2009).

For the use of clomazone in herbs, however, significant residues of both clomazone and 2-chlorobenzyl alcohol are present in the primary crops at harvest, although a pre-emergence treatment is supported (see also section 3.1.1.2). As herbs might be grown in rotation with other crops having a short growth cycle (e.g. lettuce, lamb's lettuce, rucola), occurrence of residues in the rotational crops cannot be excluded. Further investigation of clomazone residues in rotational crops would therefore be required. Alternatively, appropriate risk mitigation measures might be taken at national level in order to avoid the occurrence of clomazone residues in rotational crops.

3.2. Nature and magnitude of residues in livestock

In the framework of this MRL application there is no need to investigate the occurrence of clomazone residues in products of animal origin as herbs are not fed to livestock.

4. Consumer risk assessment

Chronic intake calculations considering the proposed MRL for clomazone in herbs were performed using revision 2 of the EFSA PRIMo. The input values derived for this MRL proposal are detailed in Table 4-1. For the chronic intake calculations, EFSA is also required to consider other crops with authorized uses. As this information is currently not available to EFSA, the existing MRLs for clomazone, which are all set at the limit of analytical

quantification (Appendix B), were included in the calculation. Acute intake calculations were not conducted because an ARfD for clomazone was not deemed necessary.

The detailed results of the chronic intake calculations are reported in Appendix C to this document. Intake calculations for all European diets resulted in a chronic exposure not higher than 0.3% of the ADI with the contribution of herbs being less than 0.05 %. The proposed use of clomazone in herbs is therefore not expected to be of concern for the European consumer.

Table 4-1. **Input values for the consumer risk assessment**

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<u>Residue definition for risk assessment:</u> <i>sum of clomazone and 2-chlorobenzyl alcohol, expressed as clomazone</i>				
Herbs	0.5	STMR * 10 (CF derived from metabolism studies)	n.n.	-

n.n. not necessary

CONCLUSIONS AND RECOMMENDATIONS

According to Article 6(1) of Regulation (EC) No 396/2005, The United Kingdom received an application from the Horticultural Development Council to modify the existing MRL of clomazone in herbs. In order to accommodate for a new use in these crops, the applicant proposes to raise the existing MRL, which is currently set at the analytical limit of quantification, to 0.2 mg/kg. Following the application, an evaluation report was drafted by The United Kingdom and received by EFSA on 14 January 2009 according to Article 9 of the Regulation. Based on the evaluation report and the EFSA conclusion on the peer review of the active substance clomazone, EFSA derives the following conclusions regarding the application.

Metabolism studies with pre-emergence treatment were conducted in tobacco, sweet potatoes and soy bean. In addition, there are two studies on cotton and alfalfa with post-emergence application, covering different plant parts. The metabolism is considered to be similar for the different crops and timings of application. Clomazone itself was almost completely degraded and, if present, only at low levels. The most abundant plant metabolite, 2-chlorobenzyl alcohol, was not found in rat metabolism, and it could not be demonstrated that it is of lower toxicity than clomazone. With respect to the use of clomazone in herbs, the amount of both clomazone and 2-chlorobenzyl alcohol are expected to be significant at harvest (i.e. exceeding the trigger value of 0.01 mg/kg) due to the short growth cycle of herbs. Therefore, the relevant residue for risk assessment in herbs is defined as the sum of clomazone and 2-chlorobenzyl alcohol, expressed as clomazone. For enforcement purposes however it is proposed to define clomazone only as the relevant residue because proper enforcement of 2-chlorobenzyl alcohol cannot be ensured.

In support of the proposed GAPs for clomazone in herbs, a sufficient number of supervised residues trials is available. These trials allow estimating the expected residue concentrations in the relevant plant commodities and deriving appropriate MRLs. It is noted that residue levels according to the residue definition for risk assessment are not reported in the available residues trials, which is usually considered as essential for deriving a conversion factor between enforcement and risk assessment. An approximate conversion factor was therefore derived from the available metabolism studies. As the consumer exposure to clomazone residues is low in comparison with the toxicological reference values, the use of the approximate conversion factor is considered acceptable in this particular case.

The effect of processing on the nature and magnitude of residues was not investigated considering that consumer exposure resulting from treated herbs contributes to less than 10% of the ADI.

Studies on the occurrence of clomazone residues in rotational crops are not available. Further investigation is however required because DT_{90} values for clomazone exceed 100 days and herbs are often grown in rotation with other crops having a short growth cycle. **Alternatively, appropriate risk mitigation measures might be taken at national level in order to avoid the occurrence of clomazone residues in rotational crops.**

Residues in commodities of animal origin were not assessed in the framework of this application considering that herbs are not fed to livestock.

Chronic intake calculations considering the new proposed MRL as well as the existing MRLs for clomazone were performed with revision 2 of the EFSA PRIMo. Acute intake calculations were not undertaken due to the low acute toxicity of clomazone. As no intake concerns were

identified for all available European diets, the proposed use is not expected to pose any risk to the European consumer. The recommendation resulting from the assessment is summarized in the table below.

Table 5-1. Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
<i>Residue definition for enforcement: clomazone</i>			
Herbs	0.01*	0.2	MRL proposal is sufficiently supported by data and no risk to consumers was identified.

(*): Indicates that the MRL is set at the limit of analytical quantification.

DOCUMENTATION PROVIDED TO EFSA

1. Residues Filenote on the modification of the MRL of clomazone in herbs prepared by the Evaluating Member State The United Kingdom under Regulation (EC) No 396/2005. Forwarded to EFSA on 14 January 2009.
2. Additional information regarding the modification of the MRL of clomazone in herbs compiled by the Evaluating Member State The United Kingdom under Regulation (EC) No 396/2005. Submitted to EFSA on 06 April 2009.

REFERENCES

- EFSA, 2007. Conclusion of EFSA prepared by the Pesticides Unit (PRAPeR) on the peer review of the pesticide risk assessment of the active substance clomazone. *EFSA Scientific Report* (2007) 109, 1-73.
- EFSA, 2009. Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the modification of the existing MRL for clomazone in rice. *EFSA Scientific Report* (2009) 228, 1-21.
- European Commission, 2008. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. SANCO 7525/VI/95 – rev.8. 1 February 2008.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

Pesticide(s) (common name(s)):	Clomazone	Responsible body for reporting (name, address):	PSD
Trade name(s):	Gamit 36 CS	Reporting Country:	UK
Main uses:	Herbicide	Date application submitted:	03/02/2008

Crop and/or situation (a)	F or G (b)	Pest or group of pests controlled (c)	Formulation rate per treatment		Application			Application rate per treatment			PHI (days) (k)	Remarks: (l) e.g. minimum realistic PHI
			Type (d-f)	Conc. of a.s. (i)	method, kind if other than spray (f-h)	growth stage (j)	number (range)	kg a.s./ha, where appropriate	water L/ha	kg a.s./hL, where appropriate		
Herbs	F	Weeds	CS	360 g/L	High volume spray	Pre-emergence / planting	one	0.09 (0.25 L product/ha)	200		28*	*However this is a pre-emergence use

- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure).
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application.
- (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds.
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR).
- (e) GCPF Codes – GIFAP Technical Monograph No 2, 1989.
- (f) All abbreviations used must be explained.
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench.
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated.
- (i) g/kg or g/L.
- (j) Growth stage at 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.
- (k) Indicate the minimum and maximum number of application possible under practical conditions of use.
- (l) PHI – minimum pre-harvest interval.
- (m) Remarks may include: extent of use/economic importance/restrictions.

APPENDIX B – LIST OF EXISTING EC MRLs

Pesticides - Web Version - EU MRLs (File created on 24/02/2009 14:09)		
Code number	Groups and examples of individual products to which the MRLs apply (a)	Clomazone
100000	1. FRUIT FRESH OR FROZEN; NUTS	0,01*
110000	(i) Citrus fruit	0,01*
110010	Grapefruit (Shaddock, pomelos, sweeties, tangelo, ugli and other hybrids)	0,01*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,01*
110030	Lemons (Citron, lemon)	0,01*
110040	Limes	0,01*
110050	Mandarin (Clementine, tangerine and other hybrids)	0,01*
110990	Others	0,01*
120000	(ii) Tree nuts (shelled or unshelled)	0,01*
120010	Almonds	0,01*
120020	Brazil nuts	0,01*
120030	Cashew nuts	0,01*
120040	Chestnuts	0,01*
120050	Coconuts	0,01*
120060	Hazelnuts (Filbert)	0,01*
120070	Macadamia	0,01*
120080	Pecans	0,01*
120090	Pine nuts	0,01*
120100	Pistachios	0,01*
120110	Walnuts	0,01*
120990	Others	0,01*
130000	(iii) Pome fruit	0,01*
130010	Apples (Crab apple)	0,01*
130020	Pears (Oriental pear)	0,01*
130030	Quinces	0,01*
130040	Medlar	0,01*
130050	Loquat	0,01*
130990	Others	0,01*
140000	(iv) Stone fruit	0,01*
140010	Apricots	0,01*
140020	Cherries (sweet cherries, sour cherries)	0,01*
140030	Peaches (Nectarines and similar hybrids)	0,01*
140040	Plums (Damson, greengage, mirabelle)	0,01*
140990	Others	0,01*
150000	(v) Berries & small fruit	0,01*
151000	(a) Table and wine grapes	0,01*
151010	Table grapes	0,01*
151020	Wine grapes	0,01*
152000	(b) Strawberries	0,01*
153000	(c) Cane fruit	0,01*

153010	Blackberries	0,01*
153020	Dewberries (Loganberries, Boysenberries, and cloudberry)	0,01*
153030	Raspberries (Wineberries)	0,01*
153990	Others	0,01*
154000	(d) Other small fruit & berries	0,01*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,01*
154020	Cranberries	0,01*
154030	Currants (red, black and white)	0,01*
154040	Gooseberries (Including hybrids with other ribes species)	0,01*
154050	Rose hips	0,01*
154060	Mulberries (arbutus berry)	0,01*
154070	Azorele (mediterranean medlar)	0,01*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sawtooth), hawthorn, service berries, and other treeberries)	0,01*
154990	Others	0,01*
160000	(vi) Miscellaneous fruit	0,01*
161000	(a) Edible peel	0,01*
161010	Dates	0,01*
161020	Figs	0,01*
161030	Table olives	0,01*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,01*
161050	Carambola (Bilimbi)	0,01*
161060	Persimmon	0,01*
161070	Jambolan (Java plum) (Java apple (water apple), pomegranate, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,01*
161990	Others	0,01*
162000	(b) Inedible peel, small	0,01*
162010	Kiwi	0,01*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,01*
162030	Passion fruit	0,01*
162040	Prickly pear (cactus fruit)	0,01*
162050	Star apple	0,01*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,01*
162990	Others	0,01*
163000	(c) Inedible peel, large	0,01*
163010	Avocados	0,01*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,01*
163030	Mangoes	0,01*
163040	Papaya	0,01*
163050	Pomegranate	0,01*

163060	Cherimoya (Custard apple, sugar apple (sweetsop), lama and other medium sized Annonaceae)	0,01*	232020	Gherkins	0,01*
163070	Guava	0,01*	232030	Courgettes (Summer squash, marrow (patisson))	0,01*
163080	Pineapples	0,01*	232990	Others	0,01*
163090	Breadfruit (Jackfruit)	0,01*	233000	(c) Cucurbits - inedible peel	0,01*
163100	Durian	0,01*	233010	Melons (Kiwano)	0,01*
163110	Soursop (guanabana)	0,01*	233020	Pumpkins (Wintersquash)	0,01*
163990	Others	0,01*	233030	Watermelons	0,01*
200000	2. VEGETABLES FRESH OR FROZEN	0,01*	233990	Others	0,01*
210000	(i) Root and tuber vegetables	0,01*	234000	(d) Sweet corn	0,01*
211000	(a) Potatoes	0,01*	239000	(e) Other fruiting vegetables	0,01*
212000	(b) Tropical root and tuber vegetables	0,01*	240000	(iv) Brassica vegetables	0,01*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,01*	241000	(a) Flowering brassica	0,01*
212020	Sweet potatoes	0,01*	241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,01*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,01*	241020	Cauliflower	0,01*
212040	Arrowroot	0,01*	241990	Others	0,01*
212990	Others	0,01*	242000	(b) Head brassica	0,01*
213000	(c) Other root and tuber vegetables except sugar beet	0,01*	242010	Brussels sprouts	0,01*
213010	Beetroot	0,01*	242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,01*
213020	Carrots	0,01*	242990	Others	0,01*
213030	Celeriac	0,01*	243000	(c) Leafy brassica	0,01*
213040	Horseradish	0,01*	243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,01*
213050	Jerusalem artichokes	0,01*	243020	Kale (Borecole (curly kale), collards)	0,01*
213060	Parsnips	0,01*	243990	Others ()	0,01*
213070	Parsley root	0,01*	244000	(d) Kohlrabi	0,01*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,01*	250000	(v) Leaf vegetables & fresh herbs	0,01*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oyster plant))	0,01*	251000	(a) Lettuce and other salad plants including Brassicaceae	0,01*
213100	Swedes	0,01*	251010	Lamb's lettuce (Italian corn salad)	0,01*
213110	Tunips	0,01*	251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,01*
213990	Others	0,01*	251030	Scarole (broad leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leave endive, sugar leaf)	0,01*
220000	(i) Bulb vegetables	0,01*	251040	Cress	0,01*
220010	Garlic	0,01*	251050	Land cress	0,01*
220020	Onions (Silverskin onions)	0,01*	251060	Rocket, Rucola (Wild rocket)	0,01*
220030	Shallots	0,01*	251070	Red mustard	0,01*
220040	Spring onions (Welsh onion and similar varieties)	0,01*	251080	Leaves and sprouts of Brassica spp (Mizuna)	0,01*
220990	Others	0,01*	251990	Others	0,01*
230000	(ii) Fruiting vegetables	0,01*	252000	(b) Spinach & similar (leaves)	0,01*
231000	(a) Solanacea	0,01*	252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,01*
231010	Tomatoes (Cherry tomatoes,)	0,01*			
231020	Peppers (Chili peppers)	0,01*			
231030	Aubergines (egg plants) (Pepino)	0,01*			
231040	Okra, lady fingers	0,01*			
231990	Others	0,01*			
232000	(b) Cucurbits - edible peel	0,01*			
232010	Cucumbers	0,01*			

252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,01*	280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,01*
252030	Beet leaves (chard) (Leaves of beetroot)	0,01*	280020	Wild (Chanterelle, Truffle, Morel,)	0,01*
252990	Others	0,01*	280990	Others	0,01*
253000	(c) Vine leaves (grape leaves)	0,01*	290000	(ix) Sea weeds	0,01*
254000	(d) Watercress	0,01*	300000	3. PULSES, DRY	0,01*
255000	(e) Witloof	0,01*	300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,01*
256000	(f) Herbs	0,01*	300020	Lentils	0,01*
256010	Chervil	0,01*	300030	Peas (Chickpeas, field peas, chickling vetch)	0,01*
256020	Chives	0,01*	300040	Lupins	0,01*
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	0,01*	300990	Others	0,01*
256040	Parsley	0,01*	400000	4. OILSEEDS AND OILFRUITS	
256050	Sage (Winter savory, summer savory,)	0,01*	401000	(i) Oilseeds	
256060	Rosemary	0,01*	401010	Linseed	0,01*
256070	Thyme (marjoram, oregano)	0,01*	401020	Peanuts	0,01*
256080	Basil (Balm leaves, mint, peppermint)	0,01*	401030	Poppy seed	0,01*
256090	Bay leaves (laurel)	0,01*	401040	Sesame seed	0,01*
256100	Tarragon (Hyssop)	0,01*	401050	Sunflower seed	0,01*
256990	Others	0,01*	401060	Rape seed (Bird rapeseed, turnip rape)	0,02
260000	(vi) Legume vegetables (fresh)	0,01*	401070	Soya bean	0,01*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,01*	401080	Mustard seed	0,01*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,01*	401090	Cotton seed	0,01*
260030	Peas (with pods) (Mangelout (sugar peas))	0,01*	401100	Pumpkin seeds	0,05
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,01*	401110	Safflower	0,01*
260050	Lentils	0,01*	401120	Borage	0,01*
260990	Others	0,01*	401130	Gold of pleasure	0,01*
270000	(vii) Stem vegetables (fresh)	0,01*	401140	Hempseed	0,01*
270010	Asparagus	0,01*	401150	Castor bean	0,01*
270020	Carbons	0,01*	401990	Others	0,01*
270030	Celery	0,01*	402000	(ii) Oilfruits	0,01*
270040	Fennel	0,01*	402010	Olives for oil production	0,01*
270050	Globe artichokes	0,01*	402020	Palm nuts (palm oil kernels)	0,01*
270060	Leek	0,01*	402030	Palmfruit	0,01*
270070	Rhubarb	0,01*	402040	Kapok	0,01*
270080	Bamboo shoots	0,01*	402990	Others	0,01*
270090	Palm hearts	0,01*	500000	5. CEREALS	0,01*
270990	Others	0,01*	500010	Barley	0,01*
280000	(viii) Fungi	0,01*	500020	Buckwheat	0,01*
			500030	Maize	0,01*
			500040	Millet (Foxtail millet, teff)	0,01*
			500050	Oats	0,01*
			500060	Rice	0,01*
			500070	Rye	0,01*
			500080	Sorghum	0,01*
			500090	Wheat (Spelt/Triticale)	0,01*
			500990	Others	0,01*
			600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,02*

610000	(i) Tea (dried leaves and stalks, fermented or otherwise of <i>Camellia sinensis</i>)	0,02*	840000	(iv) Roots or rhizome	0,02*
620000	(i) Coffee beans	0,02*	840010	Liquorice	0,02*
630000	(ii) Herbal infusions (dried)	0,02*	840020	Ginger	0,02*
631000	(a) Flowers	0,02*	840030	Turmeric (Curcuma)	0,02*
631010	Camomile flowers	0,02*	840040	Horse-radish	0,02*
631020	Hibiscus flowers	0,02*	840990	Others	0,02*
631030	Rose petals	0,02*	850000	(v) Buds	0,02*
631040	Jasmine flowers	0,02*	850010	Cloves	0,02*
631050	Lime (linden)	0,02*	850020	Capers	0,02*
631990	Others	0,02*	850990	Others	0,02*
632000	(b) Leaves	0,02*	860000	(vi) Flower stigma	0,02*
632010	Strawberry leaves	0,02*	860010	Saffron	0,02*
632020	Rooibos leaves	0,02*	860990	Others	0,02*
632030	Maté	0,02*	870000	(vii) Ail	0,02*
632990	Others	0,02*	870010	Mace	0,02*
633000	(c) Roots	0,02*	870990	Others	0,02*
633010	Valerian root	0,02*	900000	9. SUGAR PLANTS	0,01*
633020	Ginseng root	0,02*	900010	Sugar beet (root)	0,01*
633990	Others	0,02*	900020	Sugarcane	0,01*
639000	(d) Other herbal infusions	0,02*	900030	Chicory roots	0,01*
640000	(iv) Cocoa (fermented beans)	0,02*	900990	Others	0,01*
650000	(v) Carb (stjohns bread)	0,02*	1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	0,02*	1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	
800000	8. SPICES	0,02*	1011000	(a) Swine	
810000	(i) Seeds	0,02*	1011010	Meat	
810010	Anise	0,02*	1011020	Fat free of lean meat	
810020	Black caraway	0,02*	1011030	Liver	
810030	Celery seed (Lovage seed)	0,02*	1011040	Kidney	
810040	Coriander seed	0,02*	1011050	Edible offal	
810050	Cumin seed	0,02*	1011990	Others	
810060	Dill seed	0,02*	1012000	(b) Bovine	
810070	Fennel seed	0,02*	1012010	Meat	
810080	Fenugreek	0,02*	1012020	Fat	
810090	Nutmeg	0,02*	1012030	Liver	
810990	Others	0,02*	1012040	Kidney	
820000	(i) Fruits and berries	0,02*	1012050	Edible offal	
820010	Allspice	0,02*	1012990	Others	
820020	Anise pepper (Japan pepper)	0,02*	1013000	(c) Sheep	
820030	Caraway	0,02*	1013010	Meat	
820040	Cardamom	0,02*	1013020	Fat	
820050	Juniper berries	0,02*	1013030	Liver	
820060	Pepper, black and white (Long pepper, pink pepper)	0,02*	1013040	Kidney	
820070	Vanilla pods	0,02*	1013050	Edible offal	
820080	Tamarind	0,02*	1013990	Others	
820990	Others	0,02*	1014000	(d) Goat	
830000	(ii) Bark	0,02*	1014010	Meat	
830010	Cinnamon (Cassia)	0,02*	1014020	Fat	
830990	Others	0,02*			

1014030	Liver		Pesticide residues and maximum residue levels (mg/kg) (*) Indicates lower limit of analytical determination
1014040	Kidney		
1014050	Edible offal		
1014990	Others		
1015000	(e) Horses, asses, mules or hinnies		
1015010	Meat		
1015020	Fat		
1015030	Liver		
1015040	Kidney		
1015050	Edible offal		
1015990	Others		
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl, ostrich, pigeon		
1016010	Meat		
1016020	Fat		
1016030	Liver		
1016040	Kidney		
1016050	Edible offal		
1016990	Others		
1017000	(g) Other farm animals (Rabbit, Kangaroo)		
1017010	Meat		
1017020	Fat		
1017030	Liver		
1017040	Kidney		
1017050	Edible offal		
1017990	Others		
1020000	(i) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd		
1020010	Cattle		
1020020	Sheep		
1020030	Goat		
1020040	Horse		
1020990	Others		
1030000	(ii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter		
1030010	Chicken		
1030020	Duck		
1030030	Goose		
1030040	Quail		
1030990	Others		
1040000	(iv) Honey (Royal jelly, pollen)		
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)		
1060000	(vi) Snails		
1070000	(vii) Other terrestrial animal products		

APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Clomazone			
Status of the active substance:	Included	Code no.	
LOQ (mg/kg bw):	0.01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.133	ARfD (mg/kg bw):	n.n.
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2007	Year of evaluation:	2007

Explain choice of toxicological reference values.

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						
		0						

Highest calculated TMDI values in % of ADI		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)
MS Diet	Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities	
0.3	WHO Cluster diet B	0.1	Wheat	0.0	Tomatoes	0.0	Potatoes	0.3
0.3	UK Toddler	0.2	Sugar beet (root)	0.0	Wheat	0.0	Potatoes	0.3
0.3	DE child	0.1	Apples	0.0	Wheat	0.0	Oranges	0.3
0.3	IE adult	0.0	Sweet potatoes	0.0	Maize	0.0	Maize	0.2
0.2	NL child	0.0	Apples	0.0	Potatoes	0.0	Wheat	0.2
0.2	UK Infant	0.1	Sugar beet (root)	0.0	Potatoes	0.0	Wheat	0.2
0.2	WHO cluster diet E	0.0	Wheat	0.0	Potatoes	0.0	Herbs	0.2
0.2	WHO cluster diet D	0.0	Wheat	0.0	Potatoes	0.0	Herbs	0.2
0.2	FR toddler	0.0	Potatoes	0.0	Apples	0.0	Apples	0.2
0.2	DK child	0.0	Wheat	0.0	Rye	0.0	Potatoes	0.2
0.2	PT General population	0.0	Potatoes	0.0	Wheat	0.0	Wine grapes	0.2
0.2	SE general population 90th percentile	0.0	Potatoes	0.0	Wheat	0.0	Bananas	0.1
0.1	WHO regional European diet	0.0	Potatoes	0.0	Wheat	0.0	Herbs	0.1
0.1	WHO Cluster diet F	0.0	Wheat	0.0	Potatoes	0.0	Oranges	0.1
0.1	ES child	0.0	Wheat	0.0	Oranges	0.0	Potatoes	0.1
0.1	IT kids/toddler	0.0	Wheat	0.0	Other cereal	0.0	Tomatoes	0.1
0.1	FR infant	0.0	Potatoes	0.0	Carrots	0.0	Apples	0.1
0.1	NL general	0.0	Potatoes	0.0	Wheat	0.0	Oranges	0.1
0.1	UK vegetarian	0.0	Sugar beet (root)	0.0	Wheat	0.0	Potatoes	0.1
0.1	FR all population	0.0	Wine grapes	0.0	Wheat	0.0	Potatoes	0.1
0.1	IT adult	0.0	Wheat	0.0	Herbs	0.0	Tomatoes	0.1
0.1	UK Adult	0.0	Sugar beet (root)	0.0	Wheat	0.0	Potatoes	0.1
0.1	ES adult	0.0	Wheat	0.0	Oranges	0.0	Potatoes	0.1
0.1	PL general population	0.0	Potatoes	0.0	Apples	0.0	Tomatoes	0.1
0.1	LT adult	0.0	Potatoes	0.0	Apples	0.0	Rye	0.1
0.1	DK adult	0.0	Wheat	0.0	Potatoes	0.0	Wine grapes	0.1
0.1	FI adult	0.0	Potatoes	0.0	Wheat	0.0	Oranges	0.1

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
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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 variability 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): ---			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 *) **)			IESTI 1 *) **)			IESTI 2 *) **)		
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	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

***) 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 public health concern.

GLOSSARY / ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CS	capsule suspension
CXL	codex maximum residue limit
d	day
DT ₉₀	period required for 90 percent dissipation (define method of estimation)
EC	European Community
EFSA	European Food Safety Authority
EMS	Evaluating Member State
EU	European union
GAP	good agricultural practice
ha	hectare
hL	hectolitre
HR	highest residue
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
MRL	maximum residue limit
NEU	Northern European Union
PF	processing factor
PHI	pre harvest interval
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State
STMR	supervised trials median residue
TRR	total radioactive residue
UK	United Kingdom