

REASONED OPINION OF EFSA

Modification of the existing MRL for clomazone in rice¹

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2008-715)

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SUMMARY

According to Article 6(2) of Regulation (EC) No 396/2005, Denmark received an application from the company FMC Chemical APG to modify the existing MRL of clomazone in rice. In particular, the applicant proposed to raise the analytical limit of quantification for rice, which is currently set at 0.01 mg/kg, to 0.02* mg/kg. Following the application, an evaluation report was drafted by Denmark and received by EFSA on 02 September 2008 according to Article 9 of the Regulation. On 12 November 2008 EFSA identified some data requirements which were addressed by Denmark on 19 December 2008 by means of a position paper.

Based on the evaluation report and the position paper submitted by Denmark as well as 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. 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. Clomazone itself was almost completely degraded and, if present, only at low levels. With respect to the use evaluated in this framework, the amount of neither clomazone nor 2-chlorobenzyl alcohol will be significant in rice grain (i.e. below the trigger value of 0.01 mg/kg). Therefore, the relevant residue for enforcement and risk assessment of rice is defined by default as clomazone.

A sufficient number of valid residue trials in support of the evaluated use have been submitted and all residue levels in the harvested rice grain were found to be below the LOQ. Although the LOQ in the supervised residues trials amounted to 0.02 mg/kg it is proposed by EFSA to maintain the existing MRL for rice at 0.01 mg/kg, which is the LOQ derived at European

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level for enforcement of clomazone in dry commodities. As the residues trials were overdosed and clomazone levels observed in the available metabolism studies were very low, there is enough evidence that clomazone levels will not exceed 0.01 mg/kg, provided that clomazone is applied according to the reported use.

Studies in succeeding crops or rotational crops are not required. Based on the currently available information it was assessed that no residues in rotational crops are expected after treatment of rice according to critical GAP.

Residues in commodities of animal origin were not assessed in the framework of this application considering that neither rice grain nor rice straw is usually fed to livestock.

Although a modification of the existing MRLs for clomazone is not recommended, chronic intake calculations were performed considering the existing MRLs of clomazone. The calculations are based on revision 2 of the EFSA PRIMo and no chronic intake concerns were identified for the available European diets. Acute intake calculations were not undertaken due to the low acute toxicity of the active substance.

Key words: clomazone, rice, MRL application, Regulation (EC) No 396/2005, isoxazolidinone herbicides

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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.

In particular, Denmark, hereafter referred to as the Evaluating Member State (EMS), received from the company FMC Chemical APG² an application to modify the existing MRL for the active substance clomazone in rice. 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 02 September 2008. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2008-715 and the following subject:

Clomazone – Application to modify the existing MRL for clomazone in rice from 0.01 mg/kg to 0.02* mg/kg.*

EFSA finally proceeded with the assessment of the application as required by Article 10 of the Regulation but some data requirements were identified on 12 November 2008 which prevented EFSA to conclude on the consumer risk assessment. A position paper addressing these data requirements was submitted by the EMS on 19 December 2008.

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. Particular attention shall be given to the requirements set out in that Article.

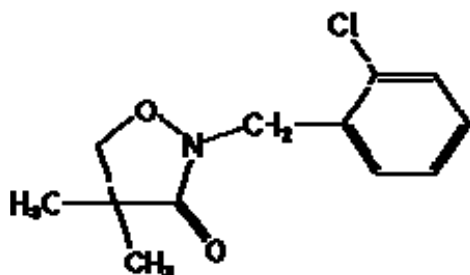
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been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

In this particular case the calculated deadline for providing the reasoned opinion is 07 January 2009.

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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 a 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 of 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 (Annex III of Regulation (EC) 396/2005). These temporary MRLs have been derived from the MRLs that have been set at national level before Regulation (EC) 396/2005 entered into force. The MRL for rice was established at the level of 0.01 mg/kg, which is equivalent to the analytical limit of quantification (LOQ). There are no Codex MRLs for clomazone.

Following the MRL setting at Community level, the applicant became aware that the MRL set for rice would not accommodate for the existing authorizations in Southern Member States. An application to modify the existing MRL from 0.01* to 0.02* mg/kg was therefore submitted to the RMS. A detailed overview of the GAPs authorized in Spain and Italy is available in Appendix A to this document. They include pre-emergence and early post-emergence treatments at application rates up to 0.360 kg a.i./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 rice with a LOQ of 0.01 mg/kg.

It is noted that in the evaluation report prepared by Denmark (2008a) an LOQ of 0.02 mg/kg is mentioned for enforcement of residues in rice. However, this LOQ refers to the analytical methods used in the residue trials only and should not be used as a reference for the enforcement analytical methods. To derive the LOQ for enforcement the complete method validation provided in the peer review, including an independent laboratory validation, should be considered.

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. Rice grains and rice straw are usually not fed to animals and residues in animal commodities resulting from the reported GAP are therefore not expected.

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

The nature of clomazone residues resulting from the proposed GAP was not addressed by Denmark in its evaluation report.

According to the EFSA conclusion on clomazone (EFSA, 2007) metabolism studies with pre-emergence treatment were conducted in tobacco, sweet potatoes and soy bean. 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 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. The latter was almost completely degraded and, if present, only at low levels. 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 would 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.

As the GAP supported for rice in the framework of this application is not covered by the representative uses evaluated under Directive 91/414/EEC, the EMS and the applicant were requested by EFSA to address the possible occurrence of 2-chlorobenzyl alcohol in rice. A position paper was prepared by Denmark (2008b) summarizing the levels of clomazone and 2-chlorobenzylalcohol identified in metabolism studies performed with soya beans (pre-sowing), potatoes (pre-planting) and tobacco (pre-planting). In general, residue levels in the edible plant parts at harvest were found to be very low and considering that these studies were performed at application rates 6 to 10 times higher than the maximum application rate supported in the framework of this application, it can be expected that levels of both clomazone and 2-chlorobenzylalcohol will be well below the trigger value of 0.01 mg/kg in the harvested plant parts. These findings are further supported by other metabolism studies reported in the revised DAR on clomazone (Denmark, 2005). In a metabolism study, performed on cotton seed with a post-emergence application, residue levels of clomazone and its metabolite at harvest only amounted to 0.0013 mg/kg and 0.0258 mg/kg respectively, while the application rate was approximately 10 times higher than the application rate reported for rice. A metabolism study with a pre-sowing application in maize (approximately twice the supported application rate for rice) was also reported in the DAR but not further considered due to its low level of metabolite identification. Nevertheless, the TRR level measured in the harvested maize grain which amounted to 0.0054 mg/kg only, should be considered valid.

Consequently, with respect to the GAP supported in the framework of this application, the amount of neither clomazone nor 2-chlorobenzyl alcohol in rice grains would be significant. The relevant residue for enforcement and risk assessment of clomazone in rice is therefore also defined by default as clomazone. It is however not possible to apply this residue definition for all plant commodities, as proposed by Denmark (2008b), since these residue definitions have been derived specifically for the proposed GAP. In order to propose robust

residue definitions generally applicable to all plant commodities, further data and information on 2-chlorobenzyl alcohol would be required.

An analytical method for enforcement of the proposed residue definition has been validated for all dry commodities with a LOQ of 0.01 mg/kg, including rice grain (see also section 1.1).

3.1.1.2. Magnitude of residues

A total of 24 supervised residues trials have been reported by the EMS (Denmark, 2008a). One Southern European trial on dry rice complied with the supported GAP. Additionally, 5 trials on paddy rice were conducted on several locations in Southern Europe. Apart from the number of applications (2 instead of 1) these trials were also in compliance with the supported GAP. Finally, 18 trials on paddy rice are reported for the South of the USA, all of which were conducted with approximately twice the proposed application rate. Although not fully representative for the growing conditions in Southern Europe, these trials can be used to give indications on the overall residue behaviour of clomazone.

In all above mentioned trials residue levels of clomazone in both rice grain and rice straw at harvest were found to be below the LOQ. The LOQ of the analytical method used in the trials being 0.02 mg/kg, both the applicant and the EMS propose to raise the existing MRL of 0.01 mg/kg to 0.02 mg/kg.

According to EFSA however an LOQ of 0.01 mg/kg was derived for enforcement of clomazone residues in dry commodities (see also section 1.1) and residues trials should in principle have been conducted using an analytical method achieving that LOQ. Moreover, 23 out of the 24 residues trials have been performed with twice the recommended application rate and under section 3.1.1.1 it was already concluded that residues levels of clomazone and 2-chlorobenzyl alcohol would be well below the trigger values. It is therefore very unlikely that clomazone levels in rice grain will exceed the enforcement LOQ of 0.01 mg/kg following an application of the active substance according to the proposed GAP. EFSA concludes that there is no need to modify the existing MRL of clomazone in rice in order to accommodate for the authorized uses in Spain and Italy.

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 rice considering that residue levels identified in treated rice are very low and that exposure resulting from treated rice contributes to less than 10% of the ADI.

3.1.2. Rotational crops

The possible occurrence of clomazone residues in rotational crops was not addressed by Denmark its evaluation report and also in the framework of the peer review no data on residues in rotational crops have been submitted. Even though the DT₉₀ of clomazone was calculated to be in the range of 86 to 297 days in field studies, EFSA (2007) concluded that a rotational crop study was not necessary with regard to the representative uses supported in oilseed rape and potatoes. In the supervised residue trials with pre-emergence application no residues exceeding the LOQ were observed in immature leaves and stems of oil seed rape and in potatoes tubers at around 30 days after application, neither at later sampling stages. It was therefore not expected that residues of clomazone exceeding 0.01 mg/kg would occur in any rotational crop growing after crop failure of the primary crop.

The above conclusion was based on the representative uses supported in the framework of the peer review but for the use supported in the framework of this MRL application a similar conclusion can be drawn. Rice is very often grown in rotation with other crops, but due to the very specific growing conditions of rice, rotation usually takes place after harvest only and not after crop failure. Residue levels measured in the rice forage are therefore not considered relevant in this particular case. Also knowing that at harvest all residue levels in rice grain are expected to be below the enforcement LOQ of 0.01 mg/kg (see section 3.1.1.2), occurrence of significant residues in rotational crops grown following the rice harvest is very unlikely.

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. Rice grains and rice straw are usually not fed to animals and residues in animal commodities resulting from the reported GAP are therefore not expected.

4. Consumer risk assessment

Although a modification of the existing MRLs for clomazone is not recommended, chronic intake calculations considering the existing MRLs of clomazone were performed using revision 2 of the EFSA PRIMo. 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 B to this document. Intake calculations for all European diets resulted in a chronic exposure not higher than 0.3% of the ADI.

CONCLUSIONS AND RECOMMENDATIONS

According to Article 6(2) of Regulation (EC) No 396/2005, Denmark received an application from the company FMC Chemical APG to modify the existing MRL of clomazone in rice. In particular, the applicant proposed to raise the analytical limit of quantification for rice, which is currently set at 0.01 mg/kg, to 0.02* mg/kg. Following the application, an evaluation report was drafted by Denmark and received by EFSA on 02 September 2008 according to Article 9 of the Regulation. On 12 November 2008 EFSA identified some data requirements which were addressed by Denmark on 19 December 2008 by means of a position paper.

Based on the evaluation report and the position paper submitted by Denmark as well as 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. 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. Clomazone itself was almost completely degraded and, if present, only at low levels. With respect to the use evaluated in this framework, the amount of neither clomazone nor 2-chlorobenzyl alcohol will be significant in rice grain (i.e. below the trigger value of 0.01 mg/kg). Therefore, the relevant residue for enforcement and risk assessment of rice is defined by default as clomazone.

A sufficient number of valid residue trials in support of the evaluated use have been submitted and all residue levels in the harvested rice grain were found to be below the LOQ. Although the LOQ in the supervised residues trials amounted to 0.02 mg/kg it is proposed by EFSA to maintain the existing MRL for rice at 0.01 mg/kg, which is the LOQ derived at European level for enforcement of clomazone in dry commodities. As the residues trials were overdosed and clomazone levels observed in the available metabolism studies were very low, there is enough evidence that clomazone levels will not exceed 0.01 mg/kg, provided that clomazone is applied according to the reported use.

Studies in succeeding crops or rotational crops are not required. Based on the currently available information it was assessed that no residues in rotational crops are expected after treatment of rice according to critical GAP.

Residues in commodities of animal origin were not assessed in the framework of this application considering that neither rice grain nor rice straw is usually fed to livestock.

Although a modification of the existing MRLs for clomazone is not recommended, chronic intake calculations were performed considering the existing MRLs of clomazone. The calculations are based on revision 2 of the EFSA PRIMo and no chronic intake concerns were identified for the available European diets. Acute intake calculations were not undertaken due to the low acute toxicity of the active substance.

REFERENCES

- Denmark, 2005. Revised Draft Assessment Report on clomazone prepared under Directive 91/414/EEC by the Rapporteur Member State Denmark.
- Denmark, 2008a. Proposal to change the temporary MRL for clomazone prepared under Regulation (EC) No 396/2005 by the DTU.
- Denmark, 2008b. Position paper on clomazone intake and risk assessment for rice prepared under Regulation (EC) No 396/2005 by the DTU.
- EFSA, 2007. Conclusion of EFSA prepared by the Pesticides Unit (PRAPeR) on the peer review of the active substance clomazone. *EFSA Scientific Report* (2007) 109, 1-73.

APPENDICES

Appendix A – Good Agricultural Practice (GAP)

Appendix B – Pesticide Residues Intake Model (PRIMo)

APPENDIX A – GOOD AGRICULTURAL PRACTICE (GAP)

Crop	Field use (F) Glasshouse (G)	Application			Application rate per treatment			PHI (days)	Country	Registration Status	Remarks
		Method	Growth stage & season	No.	Product (L/ha)	a.s. (g/ha)	Spray solution (L/ha)				
Southern Europe											
Rice	F	spray	pre-emergence/ up to early post emergence	1	1.0	360	300	n.a.	Spain	approved	
Rice (dry)	F	spray	pre-emergence	1	0.70	252	300 - 800	n.a.	Italy	approved	
Rice (paddy)	F	spray	pre-seeding	1	0.70 – 1.0	252 - 360	300 - 800	n.a.	Italy	approved	
Rice (paddy)	F	spray	early post-emergence (up to 2 leaves stage)	1	0.50 – 0.70	180 - 252	300 - 800	n.a.	Italy	approved	

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Pesticides - Web Version - EU MRLs (File created on 13/01/2009 18:15)

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 (Shaddocks, 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	Mandarins (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 cloudberries)	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	Azarole (mediteranean medlar)	0,01*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea shallowthorn), 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), pomerac, 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*	231030	Aubergines (egg plants) (Pepino)	0,01*
163030	Mangoes	0,01*	231040	Okra, lady s fingers	0,01*
163040	Papaya	0,01*	231990	Others	0,01*
163050	Pomegranate	0,01*	232000	(b) Cucurbits - edible peel	0,01*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,01*	232010	Cucumbers	0,01*
163070	Guava	0,01*	232020	Gherkins	0,01*
163080	Pineapples	0,01*	232030	Courgettes (Summer squash, marrow (patisson))	0,01*
163090	Bread fruit (Jackfruit)	0,01*	232990	Others	0,01*
163100	Durian	0,01*	233000	(c) Cucurbits-inedible peel	0,01*
163110	Soursop (guanabana)	0,01*	233010	Melons (Kiwano)	0,01*
163990	Others	0,01*	233020	Pumpkins (Winter squash)	0,01*
200000	2. VEGETABLES FRESH OR FROZEN	0,01*	233030	Watermelons	0,01*
210000	(i) Root and tuber vegetables	0,01*	233990	Others	0,01*
211000	(a) Potatoes	0,01*	234000	(d) Sweet corn	0,01*
212000	(b) Tropical root and tuber vegetables	0,01*	239000	(e) Other fruiting vegetables	0,01*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,01*	240000	(iv) Brassica vegetables	0,01*
212020	Sweet potatoes	0,01*	241000	(a) Flowering brassica	0,01*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,01*	241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,01*
212040	Arrowroot	0,01*	241020	Cauliflower	0,01*
212990	Others	0,01*	241990	Others	0,01*
213000	(c) Other root and tuber vegetables except sugar beet	0,01*	242000	(b) Head brassica	0,01*
213010	Beetroot	0,01*	242010	Brussels sprouts	0,01*
213020	Carrots	0,01*	242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,01*
213030	Celeriac	0,01*	242990	Others	0,01*
213040	Horseradish	0,01*	243000	(c) Leafy brassica	0,01*
213050	Jerusalem artichokes	0,01*	243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,01*
213060	Parsnips	0,01*	243020	Kale (Borecole (curly kale), collards)	0,01*
213070	Parsley root	0,01*	243990	Others ()	0,01*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,01*	244000	(d) Kohlrabi	0,01*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,01*	250000	(v) Leaf vegetables & fresh herbs	0,01*
213100	Swedes	0,01*	251000	(a) Lettuce and other salad plants including Brassicacea	0,01*
213110	Turnips	0,01*	251010	Lamb´s lettuce (Italian cornsalad)	0,01*
213990	Others	0,01*	251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,01*
220000	(ii) Bulb vegetables	0,01*	251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,01*
220010	Garlic	0,01*	251040	Cress	0,01*
220020	Onions (Silverskin onions)	0,01*	251050	Land cress	0,01*
220030	Shallots	0,01*	251060	Rocket, Rucola (Wild rocket)	0,01*
220040	Spring onions (Welsh onion and similar varieties)	0,01*	251070	Red mustard	0,01*
220990	Others	0,01*			
230000	(iii) Fruiting vegetables	0,01*			
231000	(a) Solanacea	0,01*			
231010	Tomatoes (Cherry tomatoes,)	0,01*			
231020	Peppers (Chilli peppers)	0,01*			

251080	Leaves and sprouts of Brassica spp (Mizuna)	0,01*	270070	Rhubarb	0,01*
251990	Others	0,01*	270080	Bamboo shoots	0,01*
252000	(b) Spinach & similar (leaves)	0,01*	270090	Palm hearts	0,01*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,01*	270990	Others	0,01*
252020	Purslane (Winter purslane (miner s lettuce), garden purslane, common purslane, sorrel, glassworth)	0,01*	280000	(viii) Fungi	0,01*
252030	Beet leaves (chard) (Leaves of beetroot)	0,01*	280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,01*
252990	Others	0,01*	280020	Wild (Chanterelle, Truffle, Morel ,)	0,01*
253000	(c) Vine leaves (grape leaves)	0,01*	280990	Others	0,01*
254000	(d) Water cress	0,01*	290000	(ix). Sea weeds	0,01*
255000	(e) Witloof	0,01*	300000	3. PULSES, DRY	0,01*
256000	(f) Herbs	0,01*	300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,01*
256010	Chervil	0,01*	300020	Lentils	0,01*
256020	Chives	0,01*	300030	Peas (Chickpeas, field peas, chickling vetch)	0,01*
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	0,01*	300040	Lupins	0,01*
256040	Parsley	0,01*	300990	Others	0,01*
256050	Sage (Winter savory, summer savory,)	0,01*	400000	4. OILSEEDS AND OILFRUITS	
256060	Rosemary	0,01*	401000	(i) Oilseeds	
256070	Thyme (marjoram, oregano)	0,01*	401010	Linseed	0,01*
256080	Basil (Balm leaves, mint, peppermint)	0,01*	401020	Peanuts	0,01*
256090	Bay leaves (laurel)	0,01*	401030	Poppy seed	0,01*
256100	Tarragon (Hyssop)	0,01*	401040	Sesame seed	0,01*
256990	Others	0,01*	401050	Sunflower seed	0,01*
260000	(vi) Legume vegetables (fresh)	0,01*	401060	Rape seed (Bird rapeseed, turnip rape)	0,02
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,01*	401070	Soya bean	0,01*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,01*	401080	Mustard seed	0,01*
260030	Peas (with pods) (Mangetout (sugar peas))	0,01*	401090	Cotton seed	0,01*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,01*	401100	Pumpkin seeds	0,05
260050	Lentils	0,01*	401110	Safflower	0,01*
260990	Others	0,01*	401120	Borage	0,01*
270000	(vii) Stem vegetables (fresh)	0,01*	401130	Gold of pleasure	0,01*
270010	Asparagus	0,01*	401140	Hempseed	0,01*
270020	Cardoons	0,01*	401150	Castor bean	0,01*
270030	Celery	0,01*	401990	Others	0,01*
270040	Fennel	0,01*	402000	(ii) Oilfruits	0,01*
270050	Globe artichokes	0,01*	402010	Olives for oil production	0,01*
270060	Leek	0,01*	402020	Palm nuts (palmoil kernels)	0,01*
			402030	Palmfruit	0,01*
			402040	Kapok	0,01*
			402990	Others	0,01*
			500000	5. CEREALS	0,01*
			500010	Barley	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*	820990	Others	0,02*
500990	Others	0,01*	830000	(iii) Bark	0,02*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,02*	830010	Cinnamon (Cassia)	0,02*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,02*	830990	Others	0,02*
620000	(ii) Coffee beans	0,02*	840000	(iv) Roots or rhizome	0,02*
630000	(iii) Herbal infusions (dried)	0,02*	840010	Liquorice	0,02*
631000	(a) Flowers	0,02*	840020	Ginger	0,02*
631010	Camomille flowers	0,02*	840030	Turmeric (Curcuma)	0,02*
631020	Hybiscus flowers	0,02*	840040	Horse-radish	0,02*
631030	Rose petals	0,02*	840990	Others	0,02*
631040	Jasmine flowers	0,02*	850000	(v) Buds	0,02*
631050	Lime (linden)	0,02*	850010	Cloves	0,02*
631990	Others	0,02*	850020	Capers	0,02*
632000	(b) Leaves	0,02*	850990	Others	0,02*
632010	Strawberry leaves	0,02*	860000	(vi) Flower stigma	0,02*
632020	Rooibos leaves	0,02*	860010	Saffron	0,02*
632030	Maté	0,02*	860990	Others	0,02*
632990	Others	0,02*	870000	(vii) Aril	0,02*
633000	(c) Roots	0,02*	870010	Mace	0,02*
633010	Valerian root	0,02*	870990	Others	0,02*
633020	Ginseng root	0,02*	900000	9. SUGAR PLANTS	0,01*
633990	Others	0,02*	900010	Sugar beet (root)	0,01*
639000	(d) Other herbal infusions	0,02*	900020	Sugar cane	0,01*
640000	(iv) Cocoa (fermented beans)	0,02*	900030	Chicory roots	0,01*
650000	(v) Carob (st johns bread)	0,02*	900990	Others	0,01*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,02*	1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	
800000	8. SPICES	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	
810000	(i) Seeds	0,02*	1011000	(a) Swine	
810010	Anise	0,02*	1011010	Meat	
810020	Black caraway	0,02*	1011020	Fat free of lean meat	
810030	Celery seed (Lovage seed)	0,02*	1011030	Liver	
810040	Coriander seed	0,02*	1011040	Kidney	
810050	Cumin seed	0,02*	1011050	Edible offal	
810060	Dill seed	0,02*	1011990	Others	
810070	Fennel seed	0,02*	1012000	(b) Bovine	
810080	Fenugreek	0,02*	1012010	Meat	
810090	Nutmeg	0,02*	1012020	Fat	
810990	Others	0,02*	1012030	Liver	
820000	(ii) Fruits and berries	0,02*	1012040	Kidney	
820010	Allspice	0,02*	1012050	Edible offal	
820020	Anise pepper (Japan pepper)	0,02*	1012990	Others	
820030	Caraway	0,02*	1013000	(c) Sheep	
820040	Cardamom	0,02*	1013010	Meat	
820050	Juniper berries	0,02*	1013020	Fat	
820060	Pepper, black and white (Long pepper, pink pepper)	0,02*	1013030	Liver	
820070	Vanilla pods	0,02*	1013040	Kidney	
820080	Tamarind	0,02*	1013050	Edible offal	

1013990	Others			
1014000	(d) Goat			
1014010	Meat			
1014020	Fat			
1014030	Liver			
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	(ii) 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	(iii) 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			

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								
		TMDI (range) in % of ADI minimum - maximum 0						
		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	Commodity / group of commodities	
0.3	UK Toddler	0.2	SUGAR PLANTS	0.0	FRUIT (FRESH OR FROZEN)	0.0	VEGETABLES	0.3
0.3	WHO Cluster diet B	0.1	VEGETABLES	0.1	CEREALS	0.1	FRUIT (FRESH OR FROZEN)	0.3
0.3	FR infant	0.2	VEGETABLES	0.1	FRUIT (FRESH OR FROZEN)	0.0	CEREALS	0.3
0.3	DE child	0.2	FRUIT (FRESH OR FROZEN)	0.1	VEGETABLES	0.0	CEREALS	0.3
0.2	NL child	0.1	FRUIT (FRESH OR FROZEN)	0.1	VEGETABLES	0.0	CEREALS	0.2
0.2	FR toddler	0.1	VEGETABLES	0.1	FRUIT (FRESH OR FROZEN)	0.0	CEREALS	0.2
0.2	IE adult	0.1	FRUIT (FRESH OR FROZEN)	0.1	VEGETABLES	0.0	CEREALS	0.2
0.2	UK infant	0.1	SUGAR PLANTS	0.0	VEGETABLES	0.0	FRUIT (FRESH OR FROZEN)	0.2
0.2	WHO cluster diet E	0.1	VEGETABLES	0.0	CEREALS	0.0	FRUIT (FRESH OR FROZEN)	0.2
0.2	DK child	0.1	CEREALS	0.1	VEGETABLES	0.0	FRUIT (FRESH OR FROZEN)	0.2
0.2	WHO cluster diet D	0.1	VEGETABLES	0.1	CEREALS	0.0	FRUIT (FRESH OR FROZEN)	0.2
0.2	SE general population 90th percentile	0.1	VEGETABLES	0.0	FRUIT (FRESH OR FROZEN)	0.0	CEREALS	0.2
0.1	WHO Cluster diet F	0.1	VEGETABLES	0.0	CEREALS	0.0	FRUIT (FRESH OR FROZEN)	0.1
0.1	PT General population	0.0	FRUIT (FRESH OR FROZEN)	0.0	VEGETABLES	0.0	CEREALS	0.1
0.1	ES child	0.0	FRUIT (FRESH OR FROZEN)	0.0	CEREALS	0.0	VEGETABLES	0.1
0.1	WHO regional European diet	0.1	VEGETABLES	0.0	CEREALS	0.0	FRUIT (FRESH OR FROZEN)	0.1
0.1	IT kids/toddler	0.1	CEREALS	0.0	VEGETABLES	0.0	FRUIT (FRESH OR FROZEN)	0.1
0.1	UK vegetarian	0.0	SUGAR PLANTS	0.0	VEGETABLES	0.0	FRUIT (FRESH OR FROZEN)	0.1
0.1	FR all population	0.0	FRUIT (FRESH OR FROZEN)	0.0	VEGETABLES	0.0	CEREALS	0.1
0.1	NL general	0.0	VEGETABLES	0.0	FRUIT (FRESH OR FROZEN)	0.0	CEREALS	0.1
0.1	UK Adult	0.0	SUGAR PLANTS	0.0	VEGETABLES	0.0	FRUIT (FRESH OR FROZEN)	0.1
0.1	ES adult	0.0	FRUIT (FRESH OR FROZEN)	0.0	VEGETABLES	0.0	CEREALS	0.1
0.1	IT adult	0.0	CEREALS	0.0	VEGETABLES	0.0	FRUIT (FRESH OR FROZEN)	0.1
0.1	LT adult	0.0	VEGETABLES	0.0	CEREALS	0.0	FRUIT (FRESH OR FROZEN)	0.1
0.1	DK adult	0.0	VEGETABLES	0.0	FRUIT (FRESH OR FROZEN)	0.0	CEREALS	0.1
0.1	PL general population	0.0	VEGETABLES	0.0	FRUIT (FRESH OR FROZEN)	0.0	PULSES, DRY	0.1
0.1	FI adult	0.0	VEGETABLES	0.0	FRUIT (FRESH OR FROZEN)	0.0	CEREALS	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	Acute risk assessment / adults / general population
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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	Highest % of ARfD/ADI Commodities	Highest % of ARfD/ADI Commodities	Highest % of ARfD/ADI Commodities
	pTMRL/ threshold MRL (mg/kg)	pTMRL/ threshold MRL (mg/kg)	pTMRL/ threshold MRL (mg/kg)	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

ADI	Acceptable Daily Intake
ARfD	Acute Reference Dose
CXL	Codex Maximum Residue Limit
DAR	Draft Assessment Report (prepared under Directive 91/414/EEC)
DT ₉₀	Degradation Time required for a given chemical compound to achieve 90 % of degradation compared to the amount initially present
DTU	Danish Technical University
EC	European Community
EFSA	European Food Safety Authority
EMS	Evaluating Member State
GAP	Good Agricultural Practice
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LOQ	Limit Of Quantification
MRL	Maximum Residue Limit.
PHI	Pre Harvest Interval
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State
TRR	Total Radioactive Residue