

REASONED OPINION OF EFSA

Modification of the existing MRLs for propyzamide in cardoons, cauliflower, broccoli and sugar beets (roots)¹

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2009-00216)

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SUMMARY

Sweden received an application from Dow AgroSciences to modify the existing MRLs for propyzamide in cardoon, broccoli, cauliflower and sugar beet (roots). Sweden as the Evaluating Member State (EMS) drafted the evaluation report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 14 January 2009. In order to accommodate for intended uses on cardoons, cauliflower and broccoli the applicant asked to amend the existing MRL of 0.02* mg/kg (equivalent to the limit of quantification) to 0.02 mg/kg. For sugar beet the EMS proposed to lower the existing MRL from 0.3 mg/kg to 0.1 mg/kg, based on intended uses in Southern Member States. It should be mentioned that these requests refer to intended uses in Northern and Southern Member States for which according to EFSA's current knowledge new authorizations have not yet been requested in the Member States concerned.

EFSA derives the following conclusions regarding the application, based on the evaluation report and the Draft Assessment Report prepared by Sweden in the framework of Directive 91/414/EEC.

The toxicological profile of propyzamide was investigated in the peer review and the data were sufficient to conclude on an ADI value of 0.02 mg/kg bw/d. No ARfD was established. Adequate analytical methods are available to enforce the MRLs of propyzamide in cardoons, broccoli, cauliflower and sugar beet (roots). The limit of quantification that can be achieved in routine enforcement practice is 0.01 mg/kg.

In the peer review metabolism of propyzamide was assessed in leafy vegetables (lettuce), leguminous vegetables (alfalfa) and in oilseeds (rape seeds) and risk assessment and enforcement residue definition was set as parent propyzamide in all commodities of plant origin. Since no metabolism studies are available for crops belonging to the group of root and tuber vegetables, EFSA assessed the rotational crop studies for this crop group which are supposed to reflect the metabolism in these crops sufficiently. From the metabolism studies in

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carrots grown as rotational crops it is apparent that significant differences in metabolic pathways are not expected between different crop groups. EFSA therefore concludes that a sufficient number of crop categories is covered to propose a general residue definition as parent propyzamide for all commodities of plant origin.

Submitted supervised field trials support the proposed MRLs by the EMS for cardoon, cauliflower, broccoli and sugar beets. Under the current application, no processing studies have been submitted. Because of low dietary intake and because of low levels of propyzamide in primary crops, specific processing studies are not considered necessary for cardoons, cauliflower and broccoli. For sugar beets a concentration of residues may be expected in molasse therefore a processing study would be desirable.

The possible occurrence of propyzamide residues in rotational crops was also investigated. In general, it can be concluded that metabolism of propyzamide in rotational crops proceeds in a similar pathway than in primary crops. However, taking into account the persistence of propyzamide in the soil, it is recommended that the Member States before granting an authorization for the use of propyzamide should reconsider the need for establishing the plant back intervals for rotational crops that have short vegetation periods.

Nature and magnitude of propyzamide residues in livestock could not be assessed because no data have been provided by the applicant. To avoid residues in food of animal origin arising from residues in sugar beet it has to be ensured that treated sugar beet (roots, leaves and tops) are not fed to animals. Member States intending to grant an authorisation for sugar beets have to establish adequate risk mitigation measures regarding the use of propyzamide on sugar beets, e.g., establishing restrictions that sugar beets (roots, leaves and tops) are not fed to animals.

Consumer intake calculations were performed with revision 2 of the EFSA PRIMo. The existing MRLs as set in Regulation (EC) No 396/2005 and the STMR values as obtained from intended uses on crops under consideration were used as input values for chronic intake calculations. No chronic consumer intake concerns were identified for any of European diets. The calculated total intake values ranged from 1-7%. Acute risk assessment was not performed since the ARfD is not established.

It is concluded that the intended use of propyzamide on sugar beet, broccoli, cardoon and cauliflower is acceptable with regard to consumer safety. The use of propyzamide on sugar beets in the SEU can be authorized only when ensured that sugar beets are not used as a livestock feed. However, before the risk management decision is taken on these MRL proposals, the following questions should be clarified:

- whether it is acceptable to amend MRLs on the basis of intended GAPs notified by the manufacturer of the active substance
- whether it is acceptable to lower the MRL for sugar beet (roots) not knowing if other existing authorisation in Member States justifies the current MRL proposal of 0.1 mg/kg. The RMS Sweden in the framework of the review of the existing MRLs (Article 12(2) of Regulation (EC) No 396/2005) has not reported any existing use of propyzamide on sugar beets.

Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Cardoons	0.02*	0.02	The MRL proposal is supported by data and no risk for consumers was identified for the proposed uses. The MRL proposal is based on the SEU use only.
Cauliflower, broccoli	0.02*	0.02	The MRL proposal is supported by data and no risk for consumers was identified for the proposed uses. The MRL proposal is based on the NEU use only.
Sugar beet (roots)	0.3	0.1	The MRL proposal is supported by data and no risk for consumers was identified for the proposed uses. The MRL proposal is based on the SEU use only. The use of propyzamide on sugar beets in the SEU can be authorized only when ensuring that sugar beets are not used as a livestock feed.

*- limit of quantification

Key words: Propyzamide, cardoons, broccoli, cauliflower, sugar beet (roots), MRL application, Regulation (EC) No 396/2005, consumer risk assessment, benzamide herbicide

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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.

Sweden, hereafter referred to as the Evaluating Member State (EMS), received an application from Dow AgroSciences² to modify the existing MRL for propyzamide in cardoons, cauliflower, broccoli, sugar beet (root). 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 Questions with the reference number EFSA-Q-2009-00216 and the following subject:

Propyzamide - Application to modify the existing MRLs for propyzamide in cardoons from 0,02 mg/kg to 0,02 mg/kg, in cauliflower from 0,02* mg/kg to 0,02 mg/kg, in broccoli from 0,02* mg/kg to 0,02 mg/kg and in sugar beet (root) from 0,3 mg/kg to 0,1 mg/kg.*

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

On 14 April 2009 some data requirements were identified, which prevented EFSA to conclude on the consumer risk assessment. An updated evaluation report, addressing those data requirements, was submitted by the EMS on 3 July 2009 and taken into consideration by EFSA for finalization of this reasoned opinion.

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.

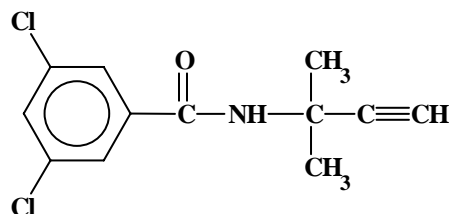
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been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

In this particular case the calculated deadline for providing the reasoned opinion is 3 July 2009.

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THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Propyzamide is the ISO common name for 3,5-dichloro-N-(1,1-dimethyl-prop-2-ynyl) benzamide (IUPAC). The chemical structure of propyzamide is following:



Propyzamide is a soil acting systemic herbicide which is used to control annual and perennial grasses and some broadleaved weeds in agriculture, horticulture, viticulture and forestry. Propyzamide stops plant growth by inhibiting cell division in shoots and roots. Uptake occurs through the roots and the action sites are the meristem cells in roots and shoots. Propyzamide is fat soluble.

Propyzamide was peer reviewed as a stage one substance according to Directive 91/414/EEC with Sweden being the designated Rapporteur Member State. It was included in Annex I to this Directive by Directive 2003/39/EC which entered into force on 15 May 2003. The Annex I inclusion is restricted to the use as herbicide only. The representative uses supported under the peer review cover foliar application of propyzamide on a wide range of crops: pome fruit, stone fruit, grapes, strawberries, salsify, seed brassicas, pulses, soya bean, sunflower at an application rates ranging from 0.75 – 1.4 kg a.s./ha and with the PHI of more than 150 days. Since EFSA was not involved in the peer review of that time, no EFSA conclusion is available for this active substance.

In the European Community current MRLs for propyzamide are established in Annexes II and IIIB of Regulation (EC) No 396/2005 and are summarized in Appendix B. The current EC MRLs for cardoon, cauliflower and broccoli is set at the LOQ of 0.02 mg/kg, since no uses of propyzamide so far have been authorized on these crops. For sugar beet (roots) the current EC MRL is 0.3 mg/kg. Codex Alimentarius has not established CXLs for propyzamide.

The applicant Dow AgroSciences intends to apply for an authorization of the use of propyzamide on cardoons, cauliflower, broccoli, sugar beet (root). The applicant has submitted multiple GAPS for the uses of propyzamide in Southern and Northern Member States for each crop and they are summarized in Appendix A. **Currently no information is available if an application has already been submitted in the Member States of concern.**

ASSESSMENT

1. Methods of analysis

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

The analytical methods for the determination of propyzamide in the foodstuffs of plant origin were evaluated in the framework of the peer review of Directive 91/414/EEC (Sweden 1998). In general two methods were sufficiently validated: method DFG 350 and method DFG S19 with the LOQ of 0.01 mg/kg for the commodities with high water content (apples, lettuce, peaches, plums), high acid content (red currants, grapes) and high oil content commodities (rape seeds).

Since all crops referred to in the MRL application belong to the group of high water content commodities, it is concluded that adequate analytical methods exist for the enforcement of the proposed MRL.

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. Crops under consideration except sugar beet (leaves, roots and tops) are not expected to be fed to livestock. For sugar beet roots, leaves and tops EFSA proposed restrictions (see section 3.2.) due to lack of information necessary for assessment of livestock exposure to propyzamide residues.

2. Mammalian toxicology

The toxicological reference values for propyzamide were derived in the review process of propyzamide under Directive 91/414/EEC (European Commission, 2007) and are compiled in Table 2-1. Since propyzamide does not exhibit acute toxicological properties, no ARfD value was established.

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
ADI	COM	2007	0.02	2 yr rat	100
ARfD	COM	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

During the peer review of Directive 91/414/EEC the metabolism of propyzamide was investigated in lettuce, alfalfa and rape seed (Sweden, 1998, 2003):

- lettuce - pre-emergence application of propyzamide on bare soil at an application rate of 2.24 kg a.s./ha (lettuce were planted 23 DAT) and post-emergence application at an application rate of 2.24 kg a.s./ha 103 days after the first application. Lettuce was collected prior and after the post-emergence spray;
- alfalfa – application to plots at an application rate of 4.48 kg a.s./ha 4 days after alfalfa plants were cut to 10 cm;
- winter rape - application on rape plants at the 3-4 leaf stage at a total application rate of 1.6 kg a.s./ha.

The metabolism studies in alfalfa and lettuce indicate that the parent compound is rapidly degraded, but is still the major compound of the TRR. In the study with oilseed rape, parent propyzamide was the main component of the TRR in the seeds and in forage. Metabolites RH-26702³ and RH-24644⁴ were also identified, but their amount did not exceed 10% of the TRR. The highest residue levels were found in roots of rape, where parent propyzamide amounted for up to 13.9 % of the TRR while metabolite RH-24644 was the major compound amounting for up to 45% of the TRR. Metabolite RH-24644 is known to be the one of the main propyzamide residues in soil. The toxicological properties of the metabolite were not assessed in the framework of the peer review.

In the peer review it was concluded that similar metabolism of propyzamide can be assumed in the crop categories investigated (leafy vegetables (lettuce), leguminous vegetables (alfalfa) and in oilseeds (rape seeds)). Propyzamide (parent compound only) was proposed as residue definition for both risk assessment and enforcement for all commodities of plant origin. However, EFSA is of the opinion that only two crop categories have been covered - leafy vegetables and pulses and oilseeds, which is insufficient to propose a general residue definition for all commodities of plant origin. No studies are available regarding root and tuber vegetables where sugar beets belong to.

Since propyzamide is mainly applied during early growth stages of the crop or during dormancy, EFSA is of the opinion that rotational crop studies for root and tuber vegetables could be taken into account to address the metabolic pathway of propyzamide in the primary crops belonging to this crop category. From these metabolism studies it is apparent that basically in root and tuber vegetables the pattern of metabolites is comparable with the metabolites observed in primary crops. In addition to the metabolites observed in primary crops, sugar conjugates of RH-24644 were identified in rotational crops (see 3.1.2.2).

³ RH-26702: N-(1,1-dimethyl-3-hydroxyacetyl)-3,5-dichlorobenzamide

⁴ RH-24644: 2-(3,5-dichlorophenyl)-4,4-dimethyl-5-methylene-oxazoline

EFSA concludes that with regard to the crops under consideration metabolism is adequately elucidated. There is no need to change the current residue definition which comprises the parent propyzamide only.

3.1.1.2. Magnitude of residues

In support of the proposed GAPs the applicant submitted the following supervised residues field trials:

- ten field trials on cauliflower and four trials on broccoli for NEU use. EFSA considered that extrapolation from cauliflower to broccoli is acceptable and combined the data for deriving an MRL proposal. Two of the supervised residues field trials on broccoli were performed differing by more than 25% to the critical GAP (higher dose rate and lower PHI). As this could be regarded as a worst case situation resulting in a very low residues (0.018 and 0.02 mg/kg), these studies are considered acceptable;
- two field trials on cardoon for SEU use. Since in both trials the residues are <0.02 mg/kg, these trials can be considered acceptable for deriving an MRL proposal since no-residue situation is confirmed;
- eight trials on sugar beet (roots) for SEU use.

Supervised residues field trials data are summarized in Table 3-1.

The applicant had requested authorization for propyzamide also on alfalfa (fodder) and on sugar beet for seed treatment (NEU use). These uses were not favoured by the EMS because data gaps with regard to nature and magnitude of propyzamide in livestock were identified.

The storage stability of propyzamide residues in treated crops was evaluated under the peer review of Directive 91/414/EEC (Sweden, 1998). The stability of propyzamide was demonstrated for at least 3 years under deep freezer storage conditions in commodities with high acid content and high water content.

According to the evaluation of the EMS, the supervised residues field trial data are considered valid both with regards to analytical methods and storage stability.

From the supervised field trials it is concluded that for cauliflower, broccoli and cardoon a MRL of 0.02 mg/kg is required. This value is equal to the currently established MRLs. However, the EMS proposed to delete the footnote indicating that the MRL is equal to the LOQ because according to the validated method a lower LOQ would be applicable for these crops.

For sugar beet the EMS proposed to lower the MRL from 0.3 to 0.1 mg/kg which is justified by the supervised field trials submitted in support of the GAP intended for SEU. However, no information is available if for existing authorisations in EU Member States the current MRL of 0.3 mg/kg has to be maintained.

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)	Median CF (d)	Comments
			Enforcement	Risk assessment					
Residue definition for enforcement and risk assessment: propyzamide									
Cauliflower, broccoli	NEU	Outdoor	12 x <0.01; 0.018; 0.02	12 x <0.01; 0.018; 0.02	0.01	0.02	0.02	1.0	R _{ber} =0.02 mg/kg R _{max} =0.02 mg/kg
Sugar beet roots	SEU	Outdoor	0.01; 4 x 0.02; 0.03; 0.04; 0.05	0.01; 4 x 0.02; 0.03; 0.04; 0.05	0.02	0.05	0.1	1.0	R _{ber} =0.08 mg/kg R _{max} =0.07 mg/kg
Cardoon	SEU	Outdoor	2 x <0.02	2 x <0.02	0.02	0.02	0.02	1.0	

(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.

(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of the processing on the nature of propyzamide was not investigated in the peer review (Sweden, 1998).

In the peer review the effect of processing on the magnitude of propyzamide was investigated in the study with oilseed rape by processing to oil. Oilseed rape was treated post emergence with propyzamide at a rate of 0.75 kg a.s./ha. The seeds and oil had non-detectable propyzamide residues with the LOD for seeds at 0.02 mg/kg and the LOD for oil at 0.05 mg/kg. No formation of toxicologically significant metabolites was observed during the study.

Under the current application, no processing studies have been submitted. Because of low dietary intake and because of low levels of propyzamide in primary crops, specific processing studies are not considered necessary for cardoons, cauliflower and broccoli. For sugar beets a concentration of residues may be expected in molasse therefore a processing study would be desirable.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

All crops under consideration can be grown in rotation. From the laboratory studies on the degradation of propyzamide in soil, the highest DT₉₀ value for propyzamide was 140 days and 126 days for its metabolite RH-24644. Similar data were obtained in the field degradation studies, where DT₉₀ value for propyzamide was reported to be 184 days (Sweden, 1998).

3.1.2.2. Nature of residues

The rotational crop study was performed applying ¹⁴C-propyzamide on bare soil at an exaggerated application rate of 4.48 kg a.s./ha. Crops – lettuce, carrots, wheat - were planted 30 DAT (lettuce), at 6 months plant back interval (lettuce, carrots) and at 1 year plant back interval (lettuce, carrots, wheat). Lettuce were sampled 3 times at different growth stage intervals. Carrots were sampled only at harvest. In rotational crops at the given application rate most of the TRR exceeding the trigger value of 10% consisted of sugar conjugates and parent propyzamide, the latter being at slightly lower levels. This could be explained by slow degradation of propyzamide in soil, when in the course of time propyzamide is partially transformed to one of its main soil metabolite RH-24644, which subsequently degrades to secondary metabolites, in this case sugar conjugates – mannose conjugate (RH-25337) and glucose conjugate (RH-26702).

Consequently, in the peer review it was concluded that metabolic pattern in primary and rotational crops is comparable and the same residue definition is applicable.

3.1.2.3. Magnitude of residues

The studies from the peer review (see section 3.1.2.2.) indicate that in lettuce at harvest (119 DAT) the TRR consisted of 37% (0.27 mg/kg) of glucose conjugate, 16% (0.118 mg/kg) of mannose conjugate and 15% (0.11 mg/kg) of parent propyzamide. In lettuce harvested 264 DAT the mannose conjugate was 11.9% (0.007 mg/kg) of the TRR and glucose conjugate was 24.5% (0.013 mg/kg) of the TRR; parent did not exceed 10% of the TRR. In carrots at

harvest (294 DAT) propyzamide was 16.8% (0.02 mg/kg) of the TRR, while mannose conjugate formed 17.5% (0.021) of the TRR. In wheat forage (456 DAT) only the mannose conjugate was present at the levels of 26.6% (0.027 mg/kg) of the total radioactive residue.

On order to avoid propyzamide residues in rotational crops it is recommended that the Member States before granting an authorization for the use of propyzamide should consider the need for establishing the plant back intervals for rotational crops that have short vegetation periods.

3.2. Nature and magnitude of residues in livestock

According to the EU Guidance document on livestock feeding studies Appendix G (Document 7031/VI/95 rev.4), sugar beet leaves, roots and tops are potential feed item for chicken, dairy ruminants, meat ruminants and pig (European Commission, 1996).

Since the evaluation report did not contain sufficient information on the nature and magnitude of residues in livestock, EFSA asked for additional studies. The EMS informed that the applicant could not provide this information. However, according to the applicant such data are not required because sugar beets and sugar beet related products are not intended to be used as a livestock feed in the countries where the use in sugar beets will be requested (SEU).

Because of this data gap the exposure of livestock to propyzamide residues and the potential transfer to products of animal origin could not be assessed by EFSA.

To avoid potential residues in food of animal origin arising from residues in sugar beet it has to be ensured that treated sugar beet (roots, leaves and tops) are not fed to animals. Member States intending to grant an authorisation for sugar beets have to establish adequate risk mitigation measures regarding the use of propyzamide on sugar beets, e.g., establishing restrictions that sugar beets (roots, leaves and tops) are not fed to animals.

EFSA would like to highlight that the current MRL for sugar beet is higher than the MRL derived from the supervised field trials. The current MRLs for animal products which have been established under the previous MRL legislation in 1996 (Directive 96/33/EC) have been established at the LOQ (0.02*mg/kg for meat, 0.05*mg/kg for fat, liver and kidney, 0.02*mg/kg for eggs and 0.01*mg/kg for milk). The assessments which lead to the setting of these MRLs are not available to EFSA.

4. Consumer risk assessment

The consumer intake calculations were performed using revision 2 of the EFSA PRIMo. The existing MRLs as established in Regulation (EC) No 396/2005 were used as input values in the chronic intake calculations. For the crops under consideration the STMR values as obtained from the intended uses were used as input values.

Acute risk assessment was not performed since the ARfD value was not established.

Input values are summarized in Table 4-1.

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: propyzamide				
Sugar beet (roots)	0.02	STMR	Acute risk assessment was not undertaken since no ARfD value is established.	
Broccoli, cauliflower	0.01	STMR		
Cardoon	0.02	STMR		
Other crops	MRL	See Appendix B		

Summary of consumer intake calculations can be found in Appendix C.

No chronic consumer concerns were identified for any of European diets. The calculated total dietary intake values ranged from 1-7%. The contribution of crops to the total dietary intake amounted for up to 2.3% of the ADI for sugar beets, less than 0.02 mg/kg of the ADI for broccoli and cauliflower and less than 0.001% of the ADI for cardoons.

It is concluded that the intended use of propyzamide on sugar beet (roots), broccoli, cardoon and cauliflower is acceptable with regard to consumer safety. However, before taking a decision to lower the MRL for sugar beet (roots) it has to be ensured that this amendment is not in contradiction with other uses on sugar beet already authorized at EC level, which will require keeping the currently existing MRL of 0.3 mg/kg.

CONCLUSIONS AND RECOMMENDATIONS

Sweden received an application from Dow AgroSciences to modify the existing MRLs for propyzamide in cardoon, broccoli, cauliflower and sugar beet (roots). Sweden as the Evaluating Member State (EMS) drafted the Evaluation Report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 14 January 2009. In order to accommodate for intended uses in cardoons, cauliflower and broccoli the applicant asked to amend the existing MRL of 0.02*mg/kg (equivalent to the limit of quantification) to 0.02 mg/kg. For sugar beet the EMS proposed to lower the existing MRL from 0.3 mg/kg to 0.1 mg/kg, based on intended uses in Southern Member States. It should be mentioned that these requests refers to intended uses in Northern and Southern Member States for which according to EFSA's current knowledge new authorizations have not yet been requested in the Member States concerned.

EFSA derives the following conclusions regarding the application, based on the Evaluation Report and the Draft Assessment Report prepared by Sweden in the framework of Directive 91/414/EEC.

The toxicological profile of propyzamide was investigated in the peer review and the data were sufficient to conclude on an ADI value of 0.02 mg/kg bw/d. No ARfD was established. Adequate analytical methods are available to enforce the MRLs of propyzamide in cardoons, broccoli, cauliflower and sugar beet (roots). The limit of quantification that can be achieved in routine enforcement practice is 0.01 mg/kg.

In the peer review metabolism of propyzamide was assessed in leafy vegetables (lettuce), leguminous vegetables (alfalfa) and in oilseeds (rape seeds) and risk assessment and enforcement residue definition was set as parent propyzamide in all commodities of plant origin. Since no metabolism studies are available for crops belonging to the group of root and tuber vegetables, EFSA assessed the rotational crop studies for this crop group which are supposed to reflect the metabolism in these crops sufficiently. From the metabolism studies in carrots grown as rotational crops it is apparent that significant differences in metabolic pathways are not expected between different crop groups. EFSA therefore concludes that a sufficient number of crop categories is covered to propose a general residue definition as parent propyzamide for all commodities of plant origin.

Submitted supervised field trials support the proposed MRLs by the EMS for cardoons, cauliflower, broccoli and sugar beets. Under the current application, no processing studies have been submitted. Because of low dietary intake and because of low levels of propyzamide in primary crops, specific processing studies are not considered necessary for cardoons, cauliflower and broccoli. For sugar beets a concentration of residues may be expected in molasse therefore a processing study would be desirable.

The possible occurrence of propyzamide residues in rotational crops was also investigated. In general, it can be concluded that metabolism of propyzamide in rotational crops proceeds in a similar pathway than in primary crops. However, taking into account the persistence of propyzamide in the soil, it is recommended that the Member States before granting an authorization for the use of propyzamide should reconsider the need for establishing the plant back intervals for rotational crops that have short vegetation periods.

Nature and magnitude of propyzamide residues in livestock could not be assessed because no data have been provided by the applicant. To avoid residues in food of animal origin arising from residues in sugar beet it has to be ensured that treated sugar beet (roots, leaves and tops)

are not fed to animals. Member States intending to grant an authorisation for sugar beets have to establish adequate risk mitigation measures regarding the use of propyzamide on sugar beets, eg. establishing restrictions that sugar beets (roots, leaves and tops) are not fed to animals.

Consumer intake calculations were performed with revision 2 of the EFSA PRIMo. The existing MRLs as set in Regulation (EC) No 396/2005 and the STMR values as obtained from intended uses on crops under consideration were used as input values for chronic intake calculations. No chronic consumer intake concerns were identified for any of European diets. The calculated total intake values ranged from 1-7%. Acute risk assessment was not performed since the ARfD is not established.

It is concluded that the intended use of propyzamide on sugar beet, broccoli, cardoon and cauliflower is acceptable with regard to consumer safety. The use of propyzamide on sugar beets in the SEU can be authorized only when ensured that sugar beets are not used as a livestock feed. However, before the risk management decision is taken on these MRL proposals, the following questions should be clarified:

- whether it is acceptable to amend MRLs on the basis of intended GAPs notified by the manufacturer of the active substance
- whether it is acceptable to lower the MRL for sugar beet (roots) not knowing if other existing authorisation in Member States justifies the current MRL proposal of 0.1 mg/kg. The RMS Sweden in the framework of the review of the existing MRLs (Article 12(2) of Regulation (EC) No 396/2005) has not reported any existing use of propyzamide on sugar beets.

Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Cardoons	0.02*	0.02	The MRL proposal is supported by data and no risk for consumers was identified for the proposed uses. The MRL proposal is based on the SEU use only.
Cauliflower, broccoli	0.02*	0.02	The MRL proposal is supported by data and no risk for consumers was identified for the proposed uses. The MRL proposal is based on the NEU use only.
Sugar beet (roots)	0.3	0.1	The MRL proposal is supported by data and no risk for consumers was identified for the proposed uses. The MRL proposal is based on the SEU use only. The use of propyzamide on sugar beets in the SEU can be authorized only when ensuring that sugar beets are not used as a livestock feed.

*- limit of quantification

DOCUMENTATION PROVIDED TO EFSA

1. Evaluation report on the modification of the existing MRLs for propyzamide in alfalfa, cardoon, cauliflower, broccoli and sugar beet prepared by the National Food Administration (Livsmedelsverket) under Regulation (EC) No 396/2005. 29 October 2009.

REFERENCES

- European Commission, 2007. Review report for the active substance propyzamide. 6502/VI/99-final. 9 October 2007.
- European Commission, 1996. Livestock Feeding Studies. 7031/VI/95 rev.4, 22 July 1996.
- Sweden, 1998. Draft Assessment Report on propyzamide prepared by Sweden under the Directive 91/414/EEC. May, 1998.
- Sweden, 2003. Addendum to the Draft Assessment Report. Rev.6. February, 2003.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

Crop and/or situation (a)	Country	F or G (b)	Formulation rate per treatment		Application			Application rate per treatment			PHI (days) (k)	Remarks
			Type (d-f)	Conc. of a.s. (i)	method, kind, if other than spray (f-h)	growth stage (j)	No appl.	kg a.s./hl, where appropriate	water L/ha	kg a.s./ha, where appropriate		
Beet (sugar)	Greece	F	WP	500 g/kg	BROAD-FORL	15-19 (spring)	1	0.281/0.225	400-500	1.13/1.13	100	
Beet (sugar)	Italy	F	WG	800 g/kg	BROAD-FORL	16-19 (spring)	1	0.333/0.2	600-800	1.6/2	100	One appl.at whole rate on established dodder or split application at low rate on dodder at first growth stage
Beet (sugar)	Italy	F	WG	800 g/kg	BROAD-FORL	13 to 15 (spring)	1/2	0.1/0.035	600/800	0.28/0.6	100	One appl.at whole rate on established dodder or split application at low rate on dodder at first growth stage. 10 days interval between applications

Modification of the existing MRLs for propyzamide in cardoons, cauliflower, broccoli and sugar beets (roots)

Crop and/or situation (a)	Country	F or G (b)	Formulation rate per treatment		Application			Application rate per treatment			PHI (days) (k)	Remarks
			Type (d-f)	Conc. of a.s. (i)	method, kind, if other than spray (f-h)	growth stage (j)	No appl.	kg a.s./hl, where appropriate	water L/ha	kg a.s./ha, where appropriate		
Beet (sugar)	Italy	F	WG	400 g/L	BROAD-FORL	16 to 19 (spring)	1	0.333/0.2	600/800	1.6/2	100	One appl.at whole rate on established dodder or split application at low rate on dodder at first growth stage
Beet (sugar)	Italy	F	WG	400 g/L	BROAD-FORL	13 to 14 (spring)	1/2	0.1/0.035	600/800	0.28/0.6	100	One appl.at whole rate on established dodder or split application at low rate on dodder at first growth stage. 10 days interval between applications
Beet (sugar)	Romania	F	WP	500 g/kg	BROAD-FORL	15-19 (spring)	1	0.4/0.333	500/600	2/2	100	
Broccoli	Belgium	F	SC	400 g/L	BROAD-FORL	10 to 19	1	0.5/0.25	200/600	0.75/0.75	60	
Broccoli	France	F	SC	400 g/L	BROAD-FORL	postplant	1	0.5/0.166	200/600	0.75/1	60	
Broccoli	Luxembourg	F	SC	400 g/L	BROAD-FORL	10 to 19	1	0.5/0.25	200/400	0.75/0.75	60	

Crop and/or situation (a)	Country	F or G (b)	Formulation rate per treatment		Application			Application rate per treatment			PHI (days) (k)	Remarks
			Type (d-f)	Conc. of a.s. (i)	method, kind, if other than spray (f-h)	growth stage (j)	No appl.	kg a.s./hl, where appropriate	water L/ha	kg a.s./ha, where appropriate		
Cardoon	France	F	SC	400 g/L	BROAD-FORL	Postplant or after harvest	1	0.75/0.25	200/600	1.5/1.5	120	
Cauliflower	Belgium	F	SC	400 g/L	BROAD-FORL	10 to 19	1	0.5/0.25	200/400	0.75/0.75	60	
Cauliflower	France	F	SC	400 g/L	BROAD-FORL	postplant	1	0.75/0.25	200/600	1/1.5	60	
Cauliflower	Netherlands	F	SC	400 g/L	BROAD-FORL	10 to 19	1	0.5/0.25	200/400	0.75/0.75	60	

- (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 – EXISTING EC MRLs

Code number	Groups and examples of individual products to which the MRLs apply	Propyzamide
100000	1. FRUIT FRESH OR FROZEN; NUTS	0,02*
110000	(i) Citrus fruit	0,02*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,02*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,02*
110030	Lemons (Citron, lemon)	0,02*
110040	Limes	0,02*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,02*
110990	Others	0,02*
120000	(ii) Tree nuts (shelled or unshelled)	0,02*
120010	Almonds	0,02*
120020	Brazil nuts	0,02*
120030	Cashew nuts	0,02*
120040	Chestnuts	0,02*
120050	Coconuts	0,02*
120060	Hazelnuts (Filbert)	0,02*
120070	Macadamia	0,02*
120080	Pecans	0,02*
120090	Pine nuts	0,02*
120100	Pistachios	0,02*
120110	Walnuts	0,02*
120990	Others	0,02*
130000	(iii) Pome fruit	0,02*
130010	Apples (Crab apple)	0,02*
130020	Pears (Oriental pear)	0,02*
130030	Quinces	0,02*
130040	Medlar	0,02*
130050	Loquat	0,02*
130990	Others	0,02*
140000	(iv) Stone fruit	0,02*
140010	Apricots	0,02*
140020	Cherries (sweet cherries, sour cherries)	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Propyzamide
140030	Peaches (Nectarines and similar hybrids)	0,02*
140040	Plums (Damson, greengage, mirabelle)	0,02*
140990	Others	0,02*
150000	(v) Berries & small fruit	0,02*
151000	(a) Table and wine grapes	0,02*
151010	Table grapes	0,02*
151020	Wine grapes	0,02*
152000	(b) Strawberries	0,02*
153000	(c) Cane fruit	0,02*
153010	Blackberries	0,02*
153020	Dewberries (Loganberries, Boysenberries, and cloudberrries)	0,02*
153030	Raspberries (Wineberries)	0,02*
153990	Others	0,02*
154000	(d) Other small fruit & berries	0,02*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,02*
154020	Cranberries	0,02*
154030	Currants (red, black and white)	0,02*
154040	Gooseberries (Including hybrids with other ribes species)	0,02*
154050	Rose hips	0,02*
154060	Mulberries (arbutus berry)	0,02*
154070	Azarole (mediteranean medlar)	0,02*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,02*
154990	Others	0,02*
160000	(vi) Miscellaneous	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Propyzamide
	fruit	
161000	(a) Edible peel	0,02*
161010	Dates	0,02*
161020	Figs	0,02*
161030	Table olives	0,02*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,02*
161050	Carambola (Bilimbi)	0,02*
161060	Persimmon	0,02*
161070	Jambolan (java plum) (Java apple (water apple), pomegranate, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,02*
161990	Others	0,02*
162000	(b) Inedible peel, small	0,02*
162010	Kiwi	0,02*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,02*
162030	Passion fruit	0,02*
162040	Prickly pear (cactus fruit)	0,02*
162050	Star apple	0,02*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,02*
162990	Others	0,02*
163000	(c) Inedible peel, large	0,02*
163010	Avocados	0,02*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,02*
163030	Mangoes	0,02*
163040	Papaya	0,02*
163050	Pomegranate	0,02*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Propyzamide
163070	Guava	0,02*
163080	Pineapples	0,02*
163090	Bread fruit (Jackfruit)	0,02*
163100	Durian	0,02*
163110	Soursop (guanabana)	0,02*
163990	Others	0,02*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	0,02*
211000	(a) Potatoes	0,02*
212000	(b) Tropical root and tuber vegetables	0,02*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,02*
212020	Sweet potatoes	0,02*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,02*
212040	Arrowroot	0,02*
212990	Others	0,02*
213000	(c) Other root and tuber vegetables except sugar beet	0,02*
213010	Beetroot	0,02*
213020	Carrots	0,02*
213030	Celeriac	0,02*
213040	Horseradish	0,02*
213050	Jerusalem artichokes	0,02*
213060	Parsnips	0,02*
213070	Parsley root	0,02*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,02*
213090	Salsify (Scorzoneria, Spanish salsify (Spanish oysterplant))	0,02*
213100	Swedes	0,02*
213110	Turnips	0,02*
213990	Others	0,02*
220000	(ii) Bulb vegetables	0,02*
220010	Garlic	0,02*
220020	Onions (Silverskin onions)	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Propyzamide
220030	Shallots	0,02*
220040	Spring onions (Welsh onion and similar varieties)	0,02*
220990	Others	0,02*
230000	(iii) Fruiting vegetables	0,02*
231000	(a) Solanacea	0,02*
231010	Tomatoes (Cherry tomatoes,)	0,02*
231020	Peppers (Chilli peppers)	0,02*
231030	Aubergines (egg plants) (Pepino)	0,02*
231040	Okra, lady's fingers	0,02*
231990	Others	0,02*
232000	(b) Cucurbits - edible peel	0,02*
232010	Cucumbers	0,02*
232020	Gherkins	0,02*
232030	Courgettes (Summer squash, marrow (patisson))	0,02*
232990	Others	0,02*
233000	(c) Cucurbits-inedible peel	0,02*
233010	Melons (Kiwano)	0,02*
233020	Pumpkins (Winter squash)	0,02*
233030	Watermelons	0,02*
233990	Others	0,02*
234000	(d) Sweet corn	0,02*
239000	(e) Other fruiting vegetables	0,02*
240000	(iv) Brassica vegetables	0,02*
241000	(a) Flowering brassica	0,02*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,02*
241020	Cauliflower	0,02*
241990	Others	0,02*
242000	(b) Head brassica	0,02*
242010	Brussels sprouts	0,02*
242020	Head cabbage (Pointed head cabbage, red cabbage,	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Propyzamide
	savoy cabbage, white cabbage)	
242990	Others	0,02*
243000	(c) Leafy brassica	0,02*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,02*
243020	Kale (Borecole (curly kale), collards)	0,02*
243990	Others	0,02*
244000	(d) Kohlrabi	0,02*
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	
251010	Lamb's lettuce (Italian cornsalad)	1
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	1
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	1
251040	Cress	1
251050	Land cress	1
251060	Rocket, Rucola (Wild rocket)	1
251070	Red mustard	0,02*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,02*
251990	Others	1
252000	(b) Spinach & similar (leaves)	
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Propyzamide
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	1
252030	Beet leaves (chard) (Leaves of beetroot)	0,02*
252990	Others	0,02*
253000	(c) Vine leaves (grape leaves)	0,02*
254000	(d) Water cress	0,02*
255000	(e) Witloof	0,02*
256000	(f) Herbs	1
256010	Chervil	1
256020	Chives	1
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	1
256040	Parsley	1
256050	Sage (Winter savory, summer savory,)	1
256060	Rosemary	1
256070	Thyme (marjoram, oregano)	1
256080	Basil (Balm leaves, mint, peppermint)	1
256090	Bay leaves (laurel)	1
256100	Tarragon (Hyssop)	1
256990	Others	1
260000	(vi) Legume vegetables (fresh)	0,02*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,02*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,02*
260030	Peas (with	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Propyzamide
	peas) (Mangetout (sugar peas))	
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,02*
260050	Lentils	0,02*
260990	Others	0,02*
270000	(vii) Stem vegetables (fresh)	0,02*
270010	Asparagus	0,02*
270020	Cardoons	0,02*
270030	Celery	0,02*
270040	Fennel	0,02*
270050	Globe artichokes	0,02*
270060	Leek	0,02*
270070	Rhubarb	0,02*
270080	Bamboo shoots	0,02*
270090	Palm hearts	0,02*
270990	Others	0,02*
280000	(viii) Fungi	0,02*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,02*
280020	Wild (Chanterelle, Truffle, Morel,)	0,02*
280990	Others	0,02*
290000	(ix) Sea weeds	
300000	3. PULSES, DRY	0,02*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,02*
300020	Lentils	0,02*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,02*
300040	Lupins	0,02*
300990	Others	0,02*
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	0,05*
401010	Linseed	0,05*
401020	Peanuts	0,05*
401030	Poppy seed	0,05*
401040	Sesame seed	0,05*
401050	Sunflower seed	0,05*
401060	Rape seed (Bird rapeseed, turnip rape)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Propyzamide
401070	Soya bean	0,05*
401080	Mustard seed	0,05*
401090	Cotton seed	0,05*
401100	Pumpkin seeds	0,05*
401110	Safflower	0,05*
401120	Borage	0,05*
401130	Gold of pleasure	0,05*
401140	Hempseed	0,05*
401150	Castor bean	0,05*
401990	Others	0,05*
402000	(ii) Oilfruits	
402010	Olives for oil production	0,02*
402020	Palm nuts (palmoil kernels)	0,05*
402030	Palmfruit	0,05*
402040	Kapok	0,05*
402990	Others	0,05*
500000	5. CEREALS	0,02*
500010	Barley	0,02*
500020	Buckwheat	0,02*
500030	Maize	0,02*
500040	Millet (Foxtail millet, teff)	0,02*
500050	Oats	0,02*
500060	Rice	0,02*
500070	Rye	0,02*
500080	Sorghum	0,02*
500090	Wheat (Spelt Triticale)	0,02*
500990	Others	0,02*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,05*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,05*
620000	(ii) Coffee beans	0,05*
630000	(iii) Herbal infusions (dried)	0,05*
631000	(a) Flowers	0,05*
631010	Camomille flowers	0,05*
631020	Hybiscus flowers	0,05*
631030	Rose petals	0,05*
631040	Jasmine	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Propyzamide
	flowers	
631050	Lime (linden)	0,05*
631990	Others	0,05*
632000	(b) Leaves	0,05*
632010	Strawberry leaves	0,05*
632020	Rooibos leaves	0,05*
632030	Maté	0,05*
632990	Others	0,05*
633000	(c) Roots	0,05*
633010	Valerian root	0,05*
633020	Ginseng root	0,05*
633990	Others	0,05*
639000	(d) Other herbal infusions	0,05*
640000	(iv) Cocoa (fermented beans)	0,05*
650000	(v) Carob (st johns bread)	0,05*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,05*
800000	8. SPICES	0,05*
810000	(i) Seeds	0,05*
810010	Anise	0,05*
810020	Black caraway	0,05*
810030	Celery seed (Lovage seed)	0,05*
810040	Coriander seed	0,05*
810050	Cumin seed	0,05*
810060	Dill seed	0,05*
810070	Fennel seed	0,05*
810080	Fenugreek	0,05*
810090	Nutmeg	0,05*
810990	Others	0,05*
820000	(ii) Fruits and berries	0,05*
820010	Allspice	0,05*
820020	Anise pepper (Japan pepper)	0,05*
820030	Caraway	0,05*
820040	Cardamom	0,05*
820050	Juniper berries	0,05*
820060	Pepper, black and white (Long pepper, pink pepper)	0,05*
820070	Vanilla pods	0,05*
820080	Tamarind	0,05*
820990	Others	0,05*
830000	(iii) Bark	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Propyzamide
830010	Cinnamon (Cassia)	0,05*
830990	Others	0,05*
840000	(iv) Roots or rhizome	0,05*
840010	Liquorice	0,05*
840020	Ginger	0,05*
840030	Turmeric (Curcuma)	0,05*
840040	Horseradish	0,05*
840990	Others	0,05*
850000	(v) Buds	0,05*
850010	Cloves	0,05*
850020	Capers	0,05*
850990	Others	0,05*
860000	(vi) Flower stigma	0,05*
860010	Saffron	0,05*
860990	Others	0,05*
870000	(vii) Aril	0,05*
870010	Mace	0,05*
870990	Others	0,05*
900000	9. SUGAR PLANTS	
900010	Sugar beet (root)	0,3
900020	Sugar cane	0,02*
900030	Chicory roots	0,02*
900990	Others	0,02*
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	
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	
1011000	(a) Swine	
1011010	Meat	0,02*
1011020	Fat free of lean meat	0,05*
1011030	Liver	0,05*
1011040	Kidney	0,05*
1011050	Edible offal	0,02*
1011990	Others	0,02*
1012000	(b) Bovine	
1012010	Meat	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Propyzamide
1012020	Fat	0,05*
1012030	Liver	0,05*
1012040	Kidney	0,05*
1012050	Edible offal	0,02*
1012990	Others	0,02*
1013000	(c) Sheep	
1013010	Meat	0,02*
1013020	Fat	0,05*
1013030	Liver	0,05*
1013040	Kidney	0,05*
1013050	Edible offal	0,02*
1013990	Others	0,02*
1014000	(d) Goat	
1014010	Meat	0,02*
1014020	Fat	0,05*
1014030	Liver	0,05*
1014040	Kidney	0,05*
1014050	Edible offal	0,02*
1014990	Others	0,02*
1015000	(e) Horses, asses, mules or hinnies	
1015010	Meat	0,02*
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
1015050	Edible offal	0,02*
1015990	Others	0,02*
1016000	(f) Poultry - chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	
1016010	Meat	0,02*
1016020	Fat	0,05*
1016030	Liver	0,05*
1016040	Kidney	0,05*
1016050	Edible offal	0,02*
1016990	Others	0,02*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	
1017010	Meat	0,02*
1017020	Fat	0,05*
1017030	Liver	0,05*
1017040	Kidney	0,05*
1017050	Edible offal	0,02*
1017990	Others	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Propyzamide
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,01*
1020010	Cattle	0,01*
1020020	Sheep	0,01*
1020030	Goat	0,01*
1020040	Horse	0,01*
1020990	Others	0,01*
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	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Propyzamide
	not containing added sugar or sweetening matter	
1030010	Chicken	0,02*
1030020	Duck	0,02*
1030030	Goose	0,02*
1030040	Quail	0,02*
1030990	Others	0,02*
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)

Propyzamide			
Status of the active substance:	Included	Code no.	#N/A
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.02	ARfD (mg/kg bw):	n.n.
Source of ADI:	COM	Source of ARfD:	COM
Year of evaluation:	2007	Year of evaluation:	2007

Chronic risk assessment - refined calculations

		TMDI (range) in % of ADI minimum - maximum						
		1 7						
		No of diets exceeding ADI:		---				
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRs at LOQ (in % of ADI)
6.9	WHO Cluster diet B	1.8	Lettuce	0.9	Wheat	0.3	Tomatoes	
6.8	NL child	1.5	Milk and cream,	1.0	Scarole (broad-leaf endive)	0.6	Apples	
5.3	DE child	1.2	Apples	0.7	Milk and cream,	0.4	Wheat	
5.3	UK Toddler	2.3	Sugar beet (root)	1.0	Milk and cream,	0.4	Wheat	
5.1	ES child	2.1	Lettuce	0.6	Milk and cream,	0.4	Wheat	
5.0	FR toddler	2.0	Milk and cream,	0.5	Potatoes	0.3	Scarole (broad-leaf endive)	
4.8	UK Infant	1.9	Milk and cream,	1.0	Sugar beet (root)	0.3	Potatoes	
4.7	WHO regional European diet	1.9	Lettuce	0.4	Potatoes	0.3	Wheat	
4.4	ES adult	2.7	Lettuce	0.2	Milk and cream,	0.2	Wheat	
4.4	IE adult	0.4	Lettuce	0.4	Sweet potatoes	0.2	Maize	
4.2	WHO cluster diet E	0.5	Lettuce	0.4	Wheat	0.4	Potatoes	
4.1	IT adult	1.9	Lettuce	0.8	Other lettuce and other salad plants	0.4	Wheat	
4.1	WHO Cluster diet F	1.5	Lettuce	0.4	Wheat	0.3	Potatoes	
3.8	IT kids/toddler	1.5	Lettuce	0.7	Wheat	0.6	Other lettuce and other salad	
3.7	DK child	0.7	Lettuce	0.6	Milk and cream,	0.6	Wheat	
3.4	FR all population	1.0	Other lettuce and other salad plants	0.5	Lettuce	0.4	Wine grapes	
3.3	NL general	0.6	Lettuce	0.6	Scarole (broad-leaf endive)	0.3	Milk and cream,	
3.1	FR infant	1.3	Milk and cream,	0.4	Potatoes	0.3	Carrots	
3.1	WHO cluster diet D	0.7	Wheat	0.4	Potatoes	0.3	Herbs	
2.7	SE general population 90th percentile	0.6	Milk and cream,	0.4	Potatoes	0.3	Wheat	
2.3	UK vegetarian	0.7	Lettuce	0.4	Sugar beet (root)	0.2	Wheat	
2.2	PT General population	0.5	Potatoes	0.4	Wheat	0.2	Wine grapes	
2.0	UK Adult	0.6	Lettuce	0.4	Sugar beet (root)	0.2	Wheat	
1.8	LT adult	0.3	Potatoes	0.3	Lettuce	0.2	Milk and cream,	
1.5	FI adult	0.4	Lettuce	0.3	Milk and cream,	0.1	Potatoes	
1.3	DK adult	0.3	Milk and cream,	0.2	Wheat	0.1	Potatoes	
1.1	PL general population	0.3	Potatoes	0.2	Apples	0.1	Tomatoes	

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

GLOSSARY / ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
bw	body weight
CAC	Codex Alimentarius Commission
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DT ₉₀	period required for 90 percent dissipation
dw	dry weight
EC	European Community
EFSA	European Food Safety Authority
EMS	Evaluating Member State
EU	european union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC	gas chromatography
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification

MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
NOAEL	no observed adverse effect level
PHI	pre harvest interval
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State
SC	suspension concentrate
SE	Sweden
SEU	Southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WG	water dispersible granule
WHO	World Health Organisation
WP	wettable powder