European Food Safety Authority

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REASONED OPINION OF EFSA

Modification of the existing MRL for lambda-cyhalothrin in currants[1]

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2008-732)

Issued on 20 January 2009

SUMMARY

The United Kingdom as an Evaluating Member State (EMS) received an application from the Horticultural Development Council on the modification of the existing MRL for lambda-cyhalothrin in currant (red, black and white). On 26 September 2008, according to Article 9 of Regulation (EC) No 396/2005, the Evaluation Report prepared by the EMS on this subject was submitted to the European Commission and forwarded to EFSA.

The current MRL for lambda-cyhalothrin in currants (black, red and white) is set at 0.1 mg/kg. The applicant proposed to raise the MRLs for all these berries to 0.2 mg/kg.

EFSA derived the following conclusions regarding the application, based on the Evaluation Report and the DAR of the Rapporteur Member State Sweden in the framework of the peer review:

The toxicological profile of the active substance was investigated under the peer review and data were sufficient to conclude on an ADI value of 0.005 mg/kg bw/d, and an ARfD value of 0.0075 mg/kg bw/d.

The metabolism of lambda-cyhalothrin was sufficiently elucidated covering four crop groups and metabolism in all plant commodities was demonstrated to be similar. Definition of the relevant residue for all plant commodities was defined as the parent compound only.

Adequate analytical enforcement methods are available for the determination of lambda-cyhalothrin in high acid content commodities which berries belong to.

Submitted supervised field trials support the intended GAP and are sufficient to propose an MRL of 0.2 mg/kg for lambda-cyhalothrin in black, red and white currant.

The consumer risk assessment is performed with the EFSA PRIMo-rev. 2, using the existing MRLs as established in Annex II and Annex IIIB of Regulation (EC) No 396/2005 as well as the HR and STMR values derived for the intended use on blackcurrant. In addition, EFSA looked for the relevant information in evaluation reports submitted to EC for the MRL

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proposals during 2000-2008 and used the available STMR values of various commodities in the chronic consumer intake calculations.

No acute intake concerns were identified with regard to the black, red and white currants.

The chronic consumer risk assessment revealed chronic intake concerns for NL child diet, representing 108% of the ADI. The main contributors are products of animal origin (milk and cream, swine, bovine). EFSA could not perform refined calculations with regard to animal commodities, since no information is available on STMR values for these products. The MRLs for animal origin products were endorsed with Directive 1994/29/EC. It should be noted that the use of existing MRL values in the intake calculation overestimates the actual consumer exposure. The commodities for which the MRL is set at the lowest LOQ of 0.02 mg/kg, contributes for up to 6% of the overall exposure, meaning that the actual exposure represents approximately 100% of the ADI. The contribution of currants in the chronic intake assessment is 0.2% of the ADI.

Since the ADI was exceeded in the chronic consumer risk assessment, the proposed MRL for currants can be acceptable if further data are made available to refine the intake calculations ensuring that the consumer exposure is less than 100% of the ADI. As an alternative risk management option the deletion of an existing MRL might be considered, provided that deletion results in a chronic consumer intake below 100% of the ADI.

Regarding the risk assessment of current MRLs for lambda-cyhalothrin, they will be subject to a full risk assessment according to Article 12 (2) of Regulation (EC) No 396/2005 by 2 September, 2009.

Key words: Lambda-cyhalothrin, black, red and white currant, MRL application, Regulation (EC) No 396/2005, pyrethroid insecticides

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BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Chapter II of the Regulation, dealing with the procedure to set new MRLs or to amend existing MRLs, entered into force on 2 September 2008.

According to Article 6(2) of Regulation (EC) No 396/2005, the United Kingdom as an Evaluating Member State (EMS) received an application from the Horticultural Development Council on the modification of an existing MRL for lambda-cyhalothrin in currants (red, black and white). On 26 September 2008, according to Article 9 of Regulation (EC) No 396/2005, the Evaluation Report prepared by the EMS on this subject was submitted to the European Commission and forwarded to EFSA.

After the receipt of the Evaluation Report, EFSA included the application in the EFSA Register of Questions with the number EFSA-Q-2008-732 and the following subject:

Lambda-Cyhalothrin - Application to modify the existing MRLs for lambda-cyhalothrin in currants (red, black and white) from 0.1 mg/kg to 0.2 mg/kg.

According to Article 10 of Regulation (EC) No 396/2005, EFSA shall assess MRL applications and evaluation reports prepared by responsible Member State and give a reasoned opinion on the risks to the consumer associated with the setting or modification of MRLs.

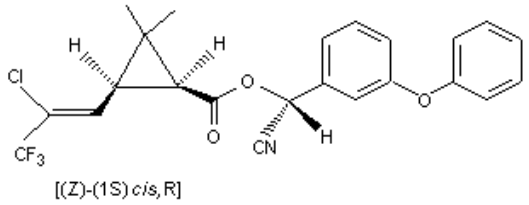
TERMS OF REFERENCE

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 and where relevant to the animals associated with the application. Particular attention shall be given to the requirements set out in that Article.

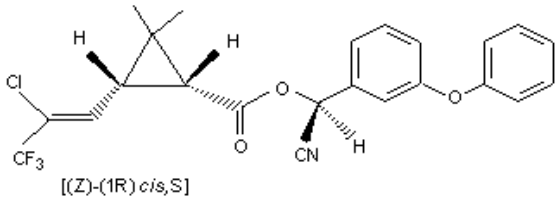
According to Article 11 of Regulation (EC) No 396/2005, the reasoned opinion shall be provided as soon as possible, at the latest within 3 months from the data of receipt of the application. In this case the deadline for submission of the reasoned opinion was 26 December 2008.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Lambda-cyhalothrin is the ISO common name for *(R+S)*-alpha-cyano-3-(phenoxyphenyl) methyl-*(1S+1R)-cis*-3-(*z*-2-chloro-3,3,3,-trifluoroprop-1-enyl)-2,2-methylcyclopropane-carboxylate (IUPAC). The chemical structure is the following:



[(Z)-(1S) *cis*,R]



[(Z)-(1R) *cis*,S]

Lambda-cyhalothrin is synthetic pyrethroid and lipophilic insecticide. Lambda-cyhalothrin is developed from cyhalothrin and comprises two diastereomers of cyhalothrin which have higher biological activity compared to cyhalothrin. It is fat soluble.

Lambda-cyhalothrin is a broad spectrum insecticide which is used to control a large number of noxious insects in a wide range of crops in agriculture, horticulture, viticulture, hops, forestry and stored grains. It is highly active against a wide range of species of Lepidoptera, Hemiptera, Diptera, and Coleoptera. It shows adulticidal, ovicidal and larvicidal activity.

Lambda-cyhalothrin was peer reviewed according to Directive 91/414/EEC with Sweden being the designated Rapporteur Member State. It was included in Annex I by Directive 2000/80/EC which entered into force on 4 December 2000. The Annex I inclusion is restricted to use as an insecticide. Lambda-cyhalothrin was not peer reviewed by EFSA.

The current MRLs for lambda-cyhalothrin are set in the Annex II and IIIB of Regulation (EC) No 396/2005. The current EC MRL for lambda-cyhalothrin in currants (black, red and white) is set at 0.1 mg/kg. Codex Alimentarius has established MRLs for cyhalothrin in few commodities but no MRLs are set for berries.

The GAP for which MRLs are requested is reported in Appendix A. The type of formulation is capsule suspension with an application rate of 0.00175 kg a.s./hl per treatment twice a year from May to September. The minimum waiting period is 14 days.

ASSESSMENT

1. Methods of analysis

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

The analytical methods for determination of lambda-cyhalothrin in the foodstuffs of plant origin were evaluated in the framework of the peer review of Directive 91/414/EEC (Sweden, 1996). All methods for plant products use organic solvents for extraction of lambda-cyhalothrin. Samples were analyzed with GC-ECD and confirmed with GC-MS and the achievable limit of determination was 0.01 mg/kg. The mean recoveries were within the acceptable range. For the determination of lambda-cyhalothrin in small fruits and berries the multi residue method is available.

Aside from the methods provided by the applicant in the framework of the peer review, laboratories responsible for the official control of MRLs have developed their own methods or have included the active substance in the established multi-methods. In the database developed by the Community Reference Laboratories (CRL) for Residue of Pesticides (www.crl-pesticides.eu), in total 619 data sets (status January 2009) have been submitted regarding methods routinely used to determine lambda-cyhalothrin residues in different matrices. For acid containing matrices where currants belong to, the validation data have been obtained for several commodities- orange, lemon, strawberries, raspberries, grapes. The validation data refer to the QuEChERS method. An overview is provided in Table 1-1.

Table 1-1. **Available validation data for analytical methods for lambda-cyhalothrin**

Chr	Matrix Type	Level min	Level max	Rec Median	Rec Mean	CV [%]	# of rec	% Rec (70-120%)	# of Labs
GC	Acidic	0,005	0,25	103	105	10,8	156	92	7
GC	Dry (cereals, dry pulses)	0,01	0,2	103	104	10,4	96	94	1
GC	Sugar containing	0,01	0,2	101	101	8,5	85	99	3
GC	Water containing	0,005	0,6	101	102	11,4	282	94	9

It is concluded that for the enforcement of an MRL for currants adequate analytical methods are available.

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

No analytical method is required in the framework of this application for food of animal origin since berries are not used as a feed.

2. Mammalian toxicology

Toxicological reference values for lambda-cyhalothrin were derived at Community level during the peer review under Directive 91/414/EEC (European Commission, 2001). Lambda-cyhalothrin is highly toxic after oral administration and very highly toxic by inhalation.

Toxicological reference values are summarized in the Table 2-1.

Table 2-1. **Overview of the toxicological reference values**

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
ADI	COM	2001	0.005	1 yr dog	100
ARfD	COM	2001	0.0075	42 d dog	100

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Under the peer review of lambda-cyhalothrin the metabolism studies were submitted for the following crop categories (Sweden, 1996):

-apples (fruits)

-cabbage (leafy vegetables)

-soya, cotton (pulses and oilseeds)

-wheat (cereals)

In these studies lambda-cyhalothrin was radiolabelled in three different positions: cyclopropane-, benzyl- or phenyl-labelling.

The metabolites formed in plants are a result of ester cleavage. The studies demonstrated that the parent compound lambda-cyhalothrin is the major part of the residues in treated plants and that the metabolic pathway is similar in all crops investigated.

The residue definition in plants for the risk assessment and enforcement is defined as “lambda-cyhalothrin”.

No specific metabolism studies were submitted with regard to black, red and white currants. Since the metabolic pathway is considered similar in all plants commodities, it can be considered that the metabolic pattern is known and no additional metabolism studies are needed with regard to primary crops.

3.1.1.2. Magnitude of residues

Storage stability

The available studies submitted in the peer review demonstrate storage stability of lambda-cyhalothrin in high water content commodities, high oil content commodities and dry commodities (Sweden, 1996). Lambda-cyhalothrin is stable in apple, peach, sugar beet roots, cabbage, pea, cotton seed, oil seed rape, potato and wheat grain for up to 26 months when stored at <-18°C. The supervised field trial samples were stored frozen for up to seven months. The applicant has not submitted storage stability studies for the high acid content commodities which berries belong to, but taking into account the wide range of commodities

in which storage stability is demonstrated, the analytical results can be considered as reliable with regard to the storage stability. No decline of residues of lambda-cyhalothrin is expected during the storage.

Analytical methods

For the analysis of supervised field trial samples of blackcurrant, the GC-MSD method was used. The limit of determination was 0.01 mg/kg. According to the evaluation of the EMS, analytical method used in analysing supervised field trial samples was sufficiently validated (The United Kingdom, 2005).

Residue trials data

The applicant submitted a number of supervised field trials on blackcurrants. Only four of them supported the intended GAP with regard to the proposed PHI of 14 days. The submitted supervised field trials were from years 2001/2002 – two trials were performed in France (2002) and two in the United Kingdom (2001). For all trials the residue decline studies were provided (The United Kingdom, 2005).

Trials residue data are summarized in Table 3-1. More details regarding the supervised field residue trials can be found in Appendix B.

The residue levels from all trials were in the range of <0.01 - 0.08 mg/kg. Residue decline studies demonstrate that the highest residue level in backcurrants is on the day 3 after the last application.

Submitted supervised trials data are sufficient to set an MRL of 0.2 mg/kg for black, red and white currants.

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					
Blackcurrant	NEU, SEU	Outdoor	<0.01; 2x 0.07; 0.08	<0.01; 2x 0.07; 0.08	0.07	0.08	0.2	1.0	R_{ber}= 0.140 mg/kg R_{max}= 0.118 mg/kg

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

3.1.1.3. Effect of industrial processing and/or household preparation

The effects of the processing on the nature of the residues have not been investigated under the peer review and in the current application (Sweden, 1996).

The applicant has submitted several studies on the effects of processing on the magnitude of residues of lambda-cyhalothrin in blackcurrants since these berries are mainly consumed in a processed way. The submitted processing procedures involve the technological processes that might have an impact on the nature and magnitude of residues: washing, pasteurization and sterilization. The processing factors obtained and summarized in Table 3-2.

Table 3-2. **Overview of the available processing studies**

Processed commodity	**Number of studies**	**Median PF**	**Comments**
Blackcurrant, washed	2	0.915	-
Blackcurrant, juice	2	0.335	-
Blackcurrant, wet pomace	2	2.835	-
Blackcurrant, jam	2	0.835	-
Blackcurrant, canned	2	0.625	-
Blackcurrant, jelly	2	0.205	-

The submitted processing studies demonstrate that the largest decrease in residue levels are encountered when blackcurrants are processed into jelly and juice. It can be explained by the separation of pulp and peel during the technological process. From the processing factors obtained for canned blackcurrant and blackcurrant jam, it is apparent that significant decrease of residue levels during processing is not expected.

However, since the contribution of currants in the dietary intake is insignificant and the nature of residues during processing has not been investigated and assessed, EFSA did not apply the processing factors in the consumer intake risk assessment.

3.1.2. Rotational crops

Rotational crop studies for lambda-cyhalothrin in black, red and white currants are not relevant since they are perennial crops and such are not grown in rotation.

3.2. Nature and magnitude of residues in livestock

Since black, red and white currants are not consumed by livestock and its by-products are not used as feedingstuff, nature and magnitude studies of residues in livestock are not of relevance.

4. Consumer risk assessment

The consumer risk assessment is performed with the EFSA PRIMo-rev. 2 (Pesticide Residue Intake Model), using the MRLs as established in Annex II and Annex IIIB of Regulation (EC)

No 396/2005 as well as the HR and STMR values derived for the intended use on blackcurrant. In addition, EFSA looked for the relevant information in evaluation reports submitted to the EC for the MRL proposals during 2000-2008 and used the available STMR and HR values of various commodities in the consumer intake calculations.

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**
Currants (red, black and white)	0.07	STMR (The United Kingdom, 2005)	0.08	HR (The United Kingdom, 2005)
Grapefruit,	0.04	STMR (Syngenta, 2002)	The acute risk assessment was performed only with regard to black, red and white currants.	
Oranges	0.04	STMR (Sweden, 2000b)		
Lemons, limes, mandarins	0.055	STMR (Syngenta, 2002)		
Raspberries	0.04	STMR (Sweden, 2006c)		
Bananas	0.03	STMR (Spain, 2007)		
Mangoes	0.05	STMR (France, 2006)		
Tomatoes	0.01	STMR (Sweden, 2001)		
Okra	0.02	STMR(France, 2006)		
Sweet corn	0.01	STMR (Syngenta, (2002)		
Leafy brassica	0.02	STMR (Syngenta, 2002)		
Spinach	0.2	STMR (Spain, 2001)		
Fennel	0.07	STMR (Belgium, 2006)		
Leek	0.085	STMR (Syngenta, 2002)		
Wild fungi	0.17	STMR (Sweden, 2000a)		
Olives for oil production	0.08	STMR (Sweden, 2006a)		
Lettuce	0.22	STMR (Sweden, 2006c)		
Celery	0.07	STMR (Belgium, 2006)		

The summary of the intake calculation can be found in Appendix C.

No acute intake concerns were identified with regard to the black, red and white currants.

The chronic consumer risk assessment revealed chronic intake concerns for NL child diet, representing 108% of the ADI. The main contributors are products of animal origin (milk and cream, swine, bovine). EFSA could not perform refined calculations with regard to animal commodities, since no information is available on STMR values for these products. The MRLs for animal origin products were endorsed with Directive 1994/29/EC. It should be noted that the use of existing MRL values in the intake calculation overestimates the actual consumer exposure. The commodities for which the MRL is set at the lowest LOQ of 0.02

mg/kg, contributes for up to 6% of the overall exposure, meaning that the actual exposure represents approximately 100% of the ADI. The contribution of currants in the chronic intake assessment is 0.2% of the ADI.

Since the ADI was exceeded in the chronic consumer risk assessment, the proposed MRL for currants can be acceptable if further data are made available to refine the intake calculations ensuring that the consumer exposure is less than 100% of the ADI. As an alternative risk management option the deletion of an existing MRL might be considered, provided that deletion results in a chronic consumer intake below 100% of the ADI.

Regarding the risk assessment of current MRLs for lambda-cyhalothrin, they will be subject to a full risk assessment according to Article 12 (2) of Regulation (EC) No 396/2005 by 2 September, 2009.

CONCLUSIONS AND RECOMMENDATIONS

The United Kingdom as an Evaluating Member State (EMS) received an application from the Horticultural Development Council on the modification of the existing MRL for lambda-cyhalothrin in currant (red, black and white). On 26 September 2008, according to Article 9 of Regulation (EC) No 396/2005, the Evaluation Report prepared by the EMS on this subject was submitted to the European Commission and forwarded to EFSA.

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The metabolism of lambda-cyhalothrin was sufficiently elucidated covering four crop groups and metabolism in all plant commodities was demonstrated to be similar. Definition of the relevant residue for all plant commodities was defined as the parent compound only.

Adequate analytical enforcement methods are available for the determination of lambda-cyhalothrin in high acid content commodities which berries belong to.

Submitted supervised field trials support the intended GAP and are sufficient to propose an MRL of 0.2 mg/kg for lambda-cyhalothrin in black, red and white currant.

The consumer risk assessment is performed with the EFSA PRIMo-rev. 2, using the existing MRLs as established in Annex II and Annex IIIB of Regulation (EC) No 396/2005 as well as the HR and STMR values derived for the intended use on blackcurrant. In addition, EFSA looked for the relevant information in evaluation reports submitted to the EC for the MRL proposals during 2000-2008 and used the available STMR values of various commodities in the chronic consumer intake calculations.

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Regarding the risk assessment of current MRLs for lambda-cyhalothrin, they will be subject to a full risk assessment according to Article 12 (2) of Regulation (EC) No 396/2005 by 2 September, 2009.

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APPENDICES

Appendix A – Good Agricultural Practices (GAPs)

Appendix B – Summary of field residue trials

Appendix C – Pesticide Residues Intake Model (PRIMo)

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Crop and/or situation (a)	F or G (b)	Pest or group of pests controlled I	Formulation rate per treatment		Application			Application rate per treatment			PHI (days) (k)	Remarks: (l) e.g. min'm realistic PHI
			Type (d-f)	Conc. Of ai (i)	method, kind , if other than spray (f-h)	growth stage (j)	number (range)	kg ai/hl, where appropriate	water l/ha	kg ai/ha, where appropriate		
Blackcurrant, gooseberry, whitecurrent, bilberry, cranberry, blueberry and other vaccinium species	F	curling midge and sawfly	CS	100 g/L	Spray	May to September	1-2	0.00175	Min 300	Min 0.00525	14	

APPENDIX B – SUMMARY OF FIELD RESIDUE TRIALS

Report-No. Location Country / County	Commodity /Variety	Year of harvest	Application rate per treatment			Dates of treatment(s) or no. of treatments and last date	Growth stage at last treatm. or date	Residues (mg/kg)	PHI (days)	Trial references
			kg a.i./ha	Water (l/ha) (last app)	kg a.i./hl (dip)					
Kent/UK	Blackcurrant/Ben Tiren	2001	0.0219 0.0216	1250 1233	0.00175 0.00175	06/07/01 17/07/01	BBCH 79 BBCH 81	0.10 0.05 0.04 <0.01	0 3 7 14	AF/5839/SY/1
Hereford and Worcester/UK	Blackcurrant/Ben Alder	2001	0.0219 0.0223	1250 1275	0.00175 0.00175	10/07/01 20/07/01	BBCH 79 BBCH 81	0.15 0.15 0.12 0.08	0 3 7 14	AF/5839/SY/2
Saône-et-Loire/N France	Blackcurrant	2002	0.0257 0.0254	1469 1450	0.00175 0.00175	12/06/02 25/06/02	BBCH 85 BBCH 83	0.21 0.14 0.09 0.07 0.06	0 3 7 14 21	AF/6477/SY/1
Maine-et-Loire/ N. France	Blackcurrant	2002	0.0217 0.0223	1240 1275	0.00175 0.00175	18/06/02 02/07/02	BBCH 85 BBCH 87	0.16 0.15 0.08 0.07 0.07	0 3 7 14 21	AF/6477/SY/2

APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Input values in PRIMo

Groups and examples of individual products to which the MRLs apply (a)	Lambda-Cyhalothrin (F) ©
1. FRUIT FRESH OR FROZEN; NUTS	
(i) Citrus fruit	
Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	See Table 4-1
Oranges (Bergamot, bitter orange, chinotto and other hybrids)	See Table 4-1
Lemons (Citron, lemon)	See Table 4-1
Limes	See Table 4-1
Mandarins (Clementine, tangerine and other hybrids)	See Table 4-1
Others	See Table 4-1
(ii) Tree nuts (shelled or unshelled)	0.05
Almonds	0.05
Brazil nuts	0.05
Cashew nuts	0.05
Chestnuts	0.05
Coconuts	0.05
Hazelnuts (Filbert)	0.05
Macadamia	0.05
Pecans	0.05
Pine nuts	0.05
Pistachios	0.05
Walnuts	0.05
Others	0.05
(iii) Pome fruit	0.10
Apples (Crab apple)	0.10
Pears (Oriental pear)	0.10
Quinces	0.10
Medlar	0.10
Loquat	0.10
Others	0.10
(iv) Stone fruit	
Apricots	0.20
Cherries (sweet cherries, sour cherries)	0.10
Peaches (Nectarines and similar hybrids)	0.20
Plums (Damson, greengage, rench as)	0.10
Others	0.10
(v) Berries & small fruit	
(a) Table and wine grapes	0.20
Table grapes	0.20
Wine grapes	0.20
(b) Strawberries	0.50
© Cane fruit	
Blackberries	0.02
Dewberries (Loganberries, Boysenberries, and cloudberries)	0.02
Raspberries (Wineberries)	See Table 4-1
Others	0.02
(d) Other small fruit & berries	
Blueberries (Bilberries cowberries (red bilberries))	0.02
Cranberries	0.02
Currants (red, black and white)	0.10
Gooseberries (Including hybrids with other ribes species)	0.10
Rose hips	0.02
Mulberries (arbutus berry)	0.02
Azarole (mediteranean medlar)	0.02
Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0.02
Others	0.02
(vi) Miscellaneous fruit	
(a) Edible peel	
Dates	0.02
Figs	0.02
Table olives	0.50
Kumquats (Marumi kumquats, nagami kumquats)	0.02
Carambola (Bilimbi)	0.02
Persimmon	0.02
Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0.02
Others	0.02
(b) Inedible peel, small	0.02
Kiwi	0.02

Groups and examples of individual products to which the MRLs apply (a)	Lambda-Cyhalothrin (F) ©
Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0.02
Passion fruit	0.02
Prickly pear (cactus fruit)	0.02
Star apple	0.02
American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0.02
Others	0.02
© Inedible peel, large	
Avocados	0.02
Bananas (Dwarf banana, plantain, apple banana)	See Table 4-1
Mangoes	See Table 4-1
Papaya	0.02
Pomegranate	0.02
Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0.02
Guava	0.02
Pineapples	0.02
Bread fruit (Jackfruit)	0.02
Durian	0.02
Soursop (guanabana)	0.02
Others	0.02
2. VEGETABLES FRESH OR FROZEN	
(i) Root and tuber vegetables	
(a) Potatoes	0.02
(b) Tropical root and tuber vegetables	0.02
Cassava (Dasheen, eddoe (Japanese taro), tannia)	0.02
Sweet potatoes	0.02
Yams (Potato bean (yam bean), Mexican yam bean)	0.02
Arrowroot	0.02
Others	0.02
© Other root and tuber vegetables except sugar beet	
Beetroot	0.02
Carrots	0.02
Celeriac	0.10
Horseradish	0.02
Jerusalem artichokes	0.02
Parsnips	0.02
Parsley root	0.02
Radishes (Black radish, Japanese radish, small radish and similar varieties)	0.10
Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0.02
Swedes	0.02
Turnips	0.02
Others	0.02
(ii) Bulb vegetables	
Garlic	0.02
Onions (Silverskin onions)	0.02
Shallots	0.02
Spring onions (Welsh onion and similar varieties)	0.05
Others	0.02
(iii) Fruiting vegetables	
(a) Solanacea	
Tomatoes (Cherry tomatoes,)	See Table 4-1
Peppers (Chilli peppers)	0.10
Aubergines (egg plants) (Pepino)	0.50
Okra, lady s fingers	See Table 4-1
Others	0.02
(b) Cucurbits – edible peel	0.10
Cucumbers	0.10
Gherkins	0.10
Courgettes (Summer squash, marrow (patisson))	0.10
Others	0.10
© Cucurbits-inedible peel	0.05
Melons (Kiwano)	0.05
Pumpkins (Winter squash)	0.05
Watermelons	0.05
Others	0.05
(d) Sweet corn	See Table 4-1
(e) Other fruiting vegetables	0.02
(iv) Brassica vegetables	
(a) Flowering brassica	0.10
Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0.10
Cauliflower	0.10
Others	0.10
(b) Head brassica	
Brussels sprouts	0.05

Groups and examples of individual products to which the MRLs apply (a)	Lambda-Cyhalothrin (F) ©
Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0.20
Others	0.02
© Leafy brassica	See Table 4-1
Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	See Table 4-1
Kale (Borecole (curly kale), collards)	See Table 4-1
Others ( )	See Table 4-1
(d) Kohlrabi	0.02
(v) Leaf vegetables & fresh herbs	
(a) Lettuce and other salad plants including Brassicacea	
Lamb´s lettuce (Italian cornsalad)	1.00
Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	See Table 4-1
Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	1.00
Cress	1.00
Land cress	1.00
Rocket, Rucola (Wild rocket)	1.00
Red mustard	1.00
Leaves and sprouts of rench as pp (Mizuna)	1.00
Others	1.00
(b) Spinach & similar (leaves)	0.50
Spinach (New Zealand spinach, turnip greens (turnip tops))	See Table 4-1
Purslane (Winter purslane (miner s lettuce), garden purslane, common purslane, sorrel, glassworth)	0.50
Beet leaves (chard) (Leaves of beetroot)	0.50
Others	0.50
© Vine leaves (grape leaves)	0.02
(d) Water cress	0.02
(e) Witloof	0.02
(f) Herbs	1.00
Chervil	1.00
Chives	1.00
Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	1.00
Parsley	1.00
Sage (Winter savory, summer savory,)	1.00
Rosemary	1.00
Thyme (marjoram, oregano)	1.00
Basil (Balm leaves, mint, peppermint)	1.00
Bay leaves (laurel)	1.00
Tarragon (Hyssop)	1.00
Others	1.00
(vi) Legume vegetables (fresh)	
Beans (with pods) (Green bean (rench beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0.20
Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0.02
Peas (with pods) (Mangetout (sugar peas))	0.20
Peas (without pods) (Garden pea, green pea, chickpea)	0.20
Lentils	0.02
Others	0.02
(vii) Stem vegetables (fresh)	
Asparagus	0.02
Cardoons	0.02
Celery	See Table 4-1
Fennel	See Table 4-1
Globe artichokes	0.02
Leek	See Table 4-1
Rhubarb	0.02
Bamboo shoots	0.02
Palm hearts	0.02
Others	0.02
(viii) Fungi	

Groups and examples of individual products to which the MRLs apply (a)	Lambda-Cyhalothrin (F) ©
Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0.02
Wild (Chanterelle, Truffle, Morel ,)	See Table 4-1
Others	0.02
(ix). Sea weeds	0.02
3. PULSES, DRY	0.02
Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0.02
Lentils	0.02
Peas (Chickpeas, field peas, chickling vetch)	0.02
Lupins	0.02
Others	0.02
4. OILSEEDS AND OILFRUITS	
(i) Oilseeds	0.05
Linseed	0.05
Peanuts	0.05
Poppy seed	0.05
Sesame seed	0.05
Sunflower seed	0.05
Rape seed (Bird rapeseed, turnip rape)	0.05
Soya bean	0.05
Mustard seed	0.05
Cotton seed	0.05
Pumpkin seeds	0.05
Safflower	0.05
Borage	0.05
Gold of pleasure	0.05
Hempseed	0.05
Castor bean	0.05
Others	0.05
(ii) Oilfruits	
Olives for oil production	See Table 4-1
Palm nuts (palmoil kernels)	0.05
Palmfruit	0.05
Kapok	0.05
Others	0.05
5. CEREALS	
Barley	0.05
Buckwheat	0.02
Maize	0.02
Millet (Foxtail millet, teff)	0.02
Oats	0.02
Rice	0.02
Rye	0.02
Sorghum	0.02
Wheat (Spelt Triticale)	0.02
Others	0.02
6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	
(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	1.00
(ii) Coffee beans	0.05
(iii) Herbal infusions (dried)	1.00
(a) Flowers	1.00
Camomille flowers	1.00
Hybiscus flowers	1.00
Rose petals	1.00
Jasmine flowers	1.00
Lime (linden)	1.00
Others	1.00
(b) Leaves	1.00
Strawberry leaves	1.00
Rooibos leaves	1.00
Maté	1.00
Others	1.00
© Roots	1.00
Valerian root	1.00
Ginseng root	1.00
Others	1.00
(d) Other herbal infusions	1.00
(iv) Cocoa (fermented beans)	0.05
(v) Carob (st johns bread)	0.05
7. HOPS (dried) , including hop pellets and unconcentrated powder	10.00
8. SPICES	0.05
(i) Seeds	0.05
Anise	0.05
Black caraway	0.05
Celery seed (Lovage seed)	0.05
Coriander seed	0.05
Cumin seed	0.05
Dill seed	0.05
Fennel seed	0.05
Fenugreek	0.05
Nutmeg	0.05

Groups and examples of individual products to which the MRLs apply (a)	Lambda-Cyhalothrin (F) ©
Others	0.05
(ii) Fruits and berries	0.05
Allspice	0.05
Anise pepper (Japan pepper)	0.05
Caraway	0.05
Cardamom	0.05
Juniper berries	0.05
Pepper, black and white (Long pepper, pink pepper)	0.05
Vanilla pods	0.05
Tamarind	0.05
Others	0.05
(iii) Bark	0.05
Cinnamon (Cassia)	0.05
Others	0.05
(iv) Roots or rhizome	0.05
Liquorice	0.05
Ginger	0.05
Turmeric (Curcuma)	0.05
Horse-radish	0.05
Others	0.05
(v) Buds	0.05
Cloves	0.05
Capers	0.05
Others	0.05
(vi) Flower stigma	0.05
Saffron	0.05
Others	0.05
(vii) Aril	0.05
Mace	0.05
Others	0.05
9. SUGAR PLANTS	0.02
Sugar beet (root)	0.02
Sugar cane	0.02
Chicory roots	0.02
Others	0.02
10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	
(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	
(a) Swine	0.50
Meat	0.50
Fat free of lean meat	0.50
Liver	0.50
Kidney	0.50
Edible offal	0.50
Others	0.50
(b) Bovine	0.50
Meat	0.50
Fat	0.50
Liver	0.50
Kidney	0.50
Edible offal	0.50
Others	0.50
© Sheep	0.50
Meat	0.50
Fat	0.50
Liver	0.50
Kidney	0.50
Edible offal	0.50
Others	0.50
(d) Goat	0.50
Meat	0.50
Fat	0.50
Liver	0.50
Kidney	0.50
Edible offal	0.50
Others	0.50
(e) Horses, asses, mules or hinnies	0.50
Meat	0.50
Fat	0.50
Liver	0.50
Kidney	0.50
Edible offal	0.50
Others	0.50
(f) Poultry –chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0.02
Meat	0.02
Fat	0.02
Liver	0.02
Kidney	0.02
Edible offal	0.02
Others	0.02
(g) Other farm animals (Rabbit, Kangaroo)	0.50
Meat	0.50

Groups and examples of individual products to which the MRLs apply (a)	Lambda-Cyhalothrin (F) ©
Fat	0.50
Liver	0.50
Kidney	0.50
Edible offal	0.50
Others	0.50
(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0.05
Cattle	0.05
Sheep	0.05
Goat	0.05
Horse	0.05
Others	0.05

Groups and examples of individual products to which the MRLs apply (a)	Lambda-Cyhalothrin (F) ©
(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	0.02
Chicken	0.02
Duck	0.02
Goose	0.02
Quail	0.02
Others	0.02
(iv) Honey (Royal jelly, pollen)	
(v) Amphibians and reptiles (Frog legs, crocodiles)	
(vi) Snails	
(vii) Other terrestrial animal products	

Lambda cyhalothrin

Status of the active substance:	**Annex I**	Code no.	**#N/A**
LOQ (mg/kg bw):	0.02	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.005**	ARfD (mg/kg bw):	**0.0075**
Source of ADI:	**COM**	Source of ARfD:	**COM**
Year of evaluation:	**2001**	Year of evaluation:	**2001**

Input values for acute RA - currants-0.08; For chronic RA- oranges, grapefruit -0.04; lemons, limes, mandarins- 0.055 mg/kg, raspberries- 0.04, bananas - 0.03, mangoes--0.05, tomatoes-0.01, okra- 0.02, sweet corn - 0.01, leafy brassica - 0.02, lettuce- 0.22, fennel- 0.07, celery -0.07, leek - 0.085, wild fungi- 0.17, spinach-0.2; olives-0.08; currants-0.07 mg/kg.

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	12 108
No of diets exceeding ADI:	1

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
107.8	NL child	29.3	Milk and cream,	16.7	Swine	13.1	Bovine	6.3
93.3	FR toddler	39.6	Milk and cream,	14.6	Bovine	6.2	Strawberries	5.4
79.6	DE child	24.1	Apples	14.3	Milk and cream,	5.1	Table grapes	5.1
75.1	WHO Cluster diet B	11.6	Bovine	9.0	Swine	7.2	Wine grapes	9.5
70.2	DK child	22.3	Swine	13.0	Bovine	12.6	Milk and cream,	6.6
70.0	IE adult	9.6	Swine	7.0	Sheep	6.2	Bovine	7.3
63.4	ES child	14.5	Bovine	13.8	Swine	12.5	Milk and cream,	4.2
62.6	UK Infant	38.7	Milk and cream,	4.0	Sugar beet (root)	3.1	Apples	8.9
58.5	FR infant	25.7	Milk and cream,	6.1	Bovine	5.0	Apples	3.8
57.5	WHO regional European diet	14.7	Swine	11.7	Bovine	4.8	Milk and cream,	4.6
53.1	WHO cluster diet E	8.7	Swine	8.1	Bovine	6.4	Wine grapes	5.6
48.5	UK Toddler	20.7	Milk and cream,	9.1	Sugar beet (root)	3.4	Apples	13.8
46.5	WHO Cluster diet F	12.6	Swine	9.9	Bovine	4.0	Milk and cream,	4.6
42.8	FR all population	16.0	Wine grapes	5.6	Bovine	3.8	Other lettuce and other salad	2.6
40.7	ES adult	7.9	Swine	7.7	Bovine	5.0	Milk and cream,	2.4
38.0	NL general	9.7	Swine	6.6	Milk and cream,	2.5	Wine grapes	2.9
37.3	WHO cluster diet D	7.4	Bovine	5.0	Milk and cream,	2.7	Swine	6.3
35.1	DK adult	9.5	Swine	6.1	Bovine	5.6	Wine grapes	2.4
33.0	SE general population 90th percentile	12.4	Milk and cream,	2.5	Head cabbage	2.1	Apples	4.9
28.7	LT adult	11.2	Swine	4.0	Milk and cream,	3.7	Apples	2.8
25.0	PT General population	10.0	Wine grapes	2.1	Potatoes	2.1	Apples	5.2
20.3	FI adult	5.7	Milk and cream,	3.8	Swine	2.3	Bovine	1.8
20.1	IT kids/toddler	2.7	Wheat	2.2	Other lettuce and other salad plants	1.8	Apples	4.3
19.8	IT adult	3.2	Other lettuce and other salad plants	1.7	Lettuce	1.7	Wheat	2.7
19.4	UK vegetarian	3.3	Milk and cream,	3.3	Wine grapes	1.5	Sugar beet (root)	3.8
18.8	UK Adult	4.3	Wine grapes	3.0	Milk and cream,	1.6	Sugar beet (root)	3.7
12.0	PL general population	4.1	Apples	1.5	Head cabbage	1.4	Potatoes	2.0

Conclusion:

The estimated Theoretical Maximum Daily Intakes based on MS and WHO diets and pTMRLs were in the range of 12 % to 108 % of the ADI.
For 1 diets the ADI is exceeded. Further refinements of the dietary intake estimates have not been performed. A public health risk can not be excluded at the moment.

Acute risk assessment /children - refined calculations	Acute risk assessment / adults / general population - refined calculations

The acute risk assessment is based on the ARfD.

For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1):		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
9.9	Currants (red, black	0.08 / -	9.9	Currants (red,	0.08 / -	2.8	Currants (red, black	0.08 / -	2.8	Currants (red, black and white)	0.08 / -
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)	
87.7	Grape juice	0.2 / -		13.4	Orange juice	0.1 / -	
67.9	Apple juice	0.1 / -		10.3	Wine	0.2 / -	
66.0	Orange juice	0.1 / -		8.8	Apple juice	0.1 / -	
47.8	Peach juice	0.2 / -		5.4	Peach preserved with	0.2 / -	
32.0	Raspberries juice	0.2 / -		2.5	Tomato (preserved-	0.1 / -	

*) 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:

For Lambda cyhalothrin IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

GLOSSARY / ABBREVIATIONS

ADI	Acceptable Daily Intake
ArfD	Acute Reference Dose
CXL	Codex Maximum Residue Limit
CS	Capsule Suspension
DAT	Days After Treatment
EC	European Community
EFSA	European Food Safety Authority
EMS	Evaluating Member State
GAP	Good Agricultural Practice
HR	Highest Residue
ILV	Independent Laboratory Validation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOD	Limit of Detection
LOQ	Limit Of Quantification
MRL	Maximum Residue Limit.
PHI	Pre Harvest Interval
PSD	Pesticide Safety Directorate, United Kingdom
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State
STMR	Supervised Trials Median Residue
TRR	Total Radioactive Residue
TMDI	Theoretical Maximum Daily Intake