

REASONED OPINION OF EFSA

Setting of an import tolerance for fluopicolide on peppers¹

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2009-00212)

Issued on 20 May 2009

SUMMARY

The United Kingdom as RMS for the active substance fluopicolide has received an application from the company Bayer CropScience AG to set an import tolerance for the active substance fluopicolide in peppers from the USA. The evaluation report prepared by the RMS on this subject and the application were submitted to the European Commission and forwarded to EFSA on 14 January 2009.

Based on this evaluation report and the Draft Assessment Report (DAR) prepared by the Rapporteur Member State (RMS) United Kingdom under Directive 91/414/EEC, EFSA derives the following conclusions regarding the application.

The toxicological profile of fluopicolide was investigated in the peer review under Directive 91/414/EEC and data were sufficient to conclude on an ADI value of 0.08 mg/kg bw/d and an ARfD of 0.18 mg/kg bw/d. In addition, separate toxicological end points have been set for one of its main metabolite, the M-01 metabolite (2,5-dichlorobenzamide) (ADI: 0.05 mg/kg bw/d; ARfD: 0.30 mg/kg bw/d).

The metabolism of fluopicolide was investigated in three plant groups: leafy crops (lettuce), fruit crops (grape) and root/tuber crops (potato). Based on these studies, the residue definition for monitoring was limited to the parent compound fluopicolide only. For risk assessment, considering that different toxicological end points were proposed for fluopicolide and its metabolite M-01, it was decided to propose two separate residue definitions for fluopicolide and M-01, respectively and to perform two separate risk assessments based on their respective toxicological values.

A multi-residue method (DFG-S19 modified) is available to enforce fluopicolide residues in peppers.

The submitted residue trials performed in the USA and based on the US GAP were considered sufficient to derive an import tolerance of 1.0 mg/kg for peppers.

¹ For citation purposes: Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the Setting of an import tolerance for fluopicolide on peppers. *EFSA Scientific Report (2009) 292, 1-19*

The possible occurrence of residues in rotational crops was not considered in the framework of this evaluation since this application refers to an authorisation outside the EC. The nature and magnitude of fluopicolide residues in livestock was not assessed since peppers are not fed to animals.

For fluopicolide, the chronic and acute intakes resulting from the proposed import tolerance were calculated using the EFSA PRIMo rev.2 model, the STMR and HR derived from the supervised residue trials on peppers and the existing MRLs listed in the Annex II of the Regulation EC 396/2005. No chronic or acute concerns were identified for all available European diets.

In addition, no chronic or acute concerns are expected from the presence of the metabolite 2,5-dichlorobenzamide on peppers considering its very poor contribution to the overall dietary burden (less than 0.2% of the ADI and the ARfD).

The EFSA recommendation resulting from the assessment is summarized in the table below.

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: fluopicolide			
peppers	0.01*	1.0	The proposed MRL is fully supported by data and no risk for consumers was identified.

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

Key words: fluopicolide, peppers, import tolerance application, Regulation (EC) No 396/2005, benzamido-pyridine fungicides, 2,5-dichlorobenzamide, BAM

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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 any party having a legitimate commercial interest may submit to the Rapporteur Member State designated pursuant to Directive 91/414/EEC an application to set an import tolerance in accordance with the provisions of Article 7 of that regulation.

In particular, United Kingdom, hereafter referred to as the Evaluating Member State (EMS), received from the company Bayer CropScience AG² an application to set an import tolerance for the active substance fluopicolide in peppers from USA. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 14 January 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00212 and the following subject:

Fluopicolide – Application to modify the existing MRL for fluopicolide in peppers from 0.01 mg/kg to 1 mg/kg*

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

TERMS OF REFERENCE

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

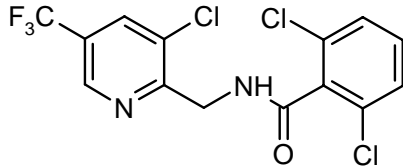
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the data of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been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

In this particular case the calculated deadline for providing the reasoned opinion was 14 April 2009. In order to avoid conflicting EFSA scientific opinions on the active substance fluopicolide EFSA awaited the finalisation of the EFSA Conclusion in the framework of the Directive 91/414/EEC before issuing this reasoned opinion.

² Bayer CropScience AG, Global Regulatory Affairs, Alfred Nobel Strasse 50, 40789 Monheim Germany]

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Fluopicolide is the ISO common name for 2,6-dichloro-*N*-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]benzamide (IUPAC).



Fluopicolide belongs to the class of benzamido-pyridine fungicides. Its biochemical mode of action is currently not fully known, but it was shown that fluopicolide modifies the distribution of fungal spectrin-like proteins. It is effective against a wide range of Oomycete (Phycomycete) diseases including downy mildews (*Plasmopara*, *Peronospora*, *Bremia*, *Pseudoperonospora*), late blight (*Phytophthora*) and some *Pythium* species. Fluopicolide has protectant, antispore activity and potential for curative activity. Fluopicolide has contact activity on several stages of the development of *Plasmopara viticola* and *Phytophthora infestans* and is best used before infection of the leaves occurs.

Fluopicolide was evaluated in the framework of the Directive 91/414/EEC as a new active substance, the United Kingdom being designated as Rapporteur Member State (RMS). The representative uses evaluated under this peer review refer to foliar applications on grapes and potatoes. The peer review for this active substance was finalised recently and the final conclusion prepared by EFSA will be issued within the next weeks (EFSA, 2009). The decision on the inclusion of this active substance in Annex I of the Directive 91/414/EEC is pending.

At EU level, temporary MRLs have been established by Regulation 839/2008 which are based on national MRLs in place before Regulation (EC) No 396/2005 entered into force (see Appendix B). It should be noted that no MRLs are set for products of animal origin.

The RMS United Kingdom reported GAP for peppers authorised in USA and which required the setting of an import tolerances. The US GAP on peppers detailed in the Appendix A concerns foliar outdoor applications close to harvest.

In support of this MRL application the United Kingdom has submitted an evaluation report but since some issues were not fully addressed in this report, EFSA also relied on the DAR prepared under the Directive 91/414/EEC (UK, 2005).

It is noted that no CXLs have been established for fluopicolide.

ASSESSMENT

1. Methods of analysis

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

The availability of an analytical method for enforcement of fluopicolide residues was not addressed by the United Kingdom in its evaluation report.

However, in the framework of the peer review under the Directive 91/414/EEC (UK, 2005) it was concluded that fluopicolide residues in foodstuffs can be analysed using a modified version of the German multi-residues method DFG-S19. This method has been validated for fluopicolide in grapes, potatoes and wheat grains achieving LOQs of 0.1 mg/kg (grapes) and 0.02 mg/kg (potatoes and wheat grain). An independent laboratory validation performed on grapes, potatoes, apples and oilseed rape is also available, the LOQs being 0.1 mg/kg for grapes and 0.02 mg/kg for the other matrices.

The evaluated multi-residue method validated on high water content matrices (grapes, potatoes and apples) is also appropriate to analyse fluopicolide residues in peppers, as requested in this application.

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

Analytical methods for the products of animal origin were not submitted since pepper crops are not used as a livestock feed.

2. Mammalian toxicology

Toxicological reference values were derived in the peer review process under the Directive 91/414/EEC (EFSA, 2009) and are compiled in the table 2-1 below. It must be noted that separate toxicological end points have been proposed for the parent compound fluopicolide and its metabolite 2,5-dichlorobenzamide (also referenced as M-01 or BAM).

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
Parent compound fluopicolide					
ADI	EFSA	2009	0.08	Mice, 78-week dietary study	100
ARfD	EFSA	2009	0.18	Rat, 28-day dietary study	100
Metabolite 2,6-dichlorobenzamide (BAM, M-01)					
ADI	EFSA	2009	0.05	Rat and dog, 2-year study	100
ARfD	EFSA	2009	0.30	Rabbit, developmental study	100

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

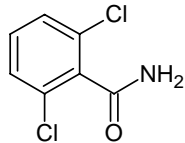
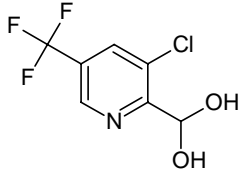
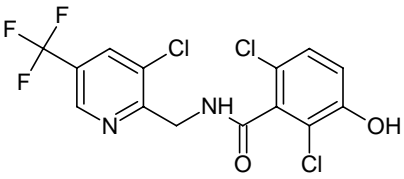
3.1.1.1. Nature of residues

Plant metabolism for fluopicolide was investigated in leafy vegetables (lettuce), fruits (grapes) and root and tuber vegetables (potatoes). A detailed evaluation of these studies is provided in the DAR (UK, 2005). In addition to foliar applications, the metabolism was also investigated following soil application on lettuce.

The metabolic pathway was found to be similar in the three plant groups, involving hydrolysis of the urea bond to form metabolites M-01 and M-02 and hydroxylation of the phenyl ring to form metabolite M-06. Following foliar applications, the metabolism of fluopicolide was shown to be limited, the parent fluopicolide being the main compound of the radioactive residues accounting at harvest for more than 90% of the TRR in lettuce, grape and potato leaves with low concentrations of the metabolites M-01, M-02 and M-06 (<2% of TRR). However, these metabolites were found in higher levels in lettuce after soil application and in potato tubers, up to 25% (M-01), 12% (M-02) and 2% (M-06). All the metabolites identified in primary crops were also found in the rat metabolism studies.

From the results of these plant metabolism studies, the residue definition for enforcement purpose derived under the peer review was set as fluopicolide parent compound alone. For risk assessment, considering the different toxicological end points set for fluopicolide and M-01 and taking into account that M-01 is also a possible metabolite from other actives substances (e.g. dichlobenil) it was decided to propose two separate residue definitions for fluopicolide and M-01 respectively and to perform two separate risk assessments based on their respective toxicological values.

Table 3-1. Overview of the metabolites identified in primary crops

Metabolite Trivial name	Chemical name (CAS)	Structural formula
M-01 BAM	2,5-dichlorobenzamide	
M-02	3-chloro-5-(trifluoromethyl)pyridine-2-carboxylic acid	
M-06	2,6-dichloro-N-[[3-chloro-5-(trifluoromethyl)pyridin-2-yl]methyl]-3-hydroxybenzamide	

3.1.1.2. Magnitude of residues

In support of the proposed GAP on peppers, 10 supervised residue trials performed in USA in 2002 have been reported in the evaluation report submitted by United Kingdom. Trials were conducted outdoor according to the GAP with a total of 3 applications at a rate of *c.a.* 0.140 kg a.s./ha. The number of trials is deemed to be sufficient to derive an MRL.

Samples were analysed for the parent fluopicolide and its metabolite M-01 according to the residue definition for risk assessment proposed under the European peer review (EFSA, 2009). The method involving an acetone extraction followed by a solvent partition and LC/MS/MS quantification was considered sufficiently validated on bell peppers and chilli peppers with recoveries in the range of 71% to 105% and a LOQ of 0.01 mg/kg. Each sample was analysed twice and the mean figure used for the MRL calculation is reported in the table 3-1 above.

According to the DAR (UK, 2005), fluopicolide and M-01 residues are stable up to 30 months in high water content matrices (grapes, potatoes and cabbages) when stored at -18°C. These results are relevant for the trials performed on peppers where samples were stored frozen for up to 6 months before being analysed.

It is then concluded that the available residue data are sufficient to propose an import tolerance on peppers and to perform a risk assessment for the crop under evaluation. It is noted that the RMS based its MRL calculations on the highest value from the duplicate analyses of the same sample. According to the EU guideline (7039/VI/95 EN, 22/07/1997) EFSA has reconsidered these calculations taking into account the mean value.

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					
Enforcement residue definition fluopicolide									
Peppers	USA	Outdoor	Fluopicolide: 0.043; 0.044; 0.076; 0.090; 0.126; 0.131; 0.149; 0.300; 0.516; 0.523	Fluopicolide: 0.043; 0.044; 0.076; 0.090; 0.126; 0.131; 0.149; 0.300; 0.516; 0.523	0.13	0.52	1.0	1.0	Each value is the mean of two separate analyses; R _{max} : 0.73 R _{ber} : 0.71
				M-01: 10x <0.01	0.01	0.01			

(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 effect of processing on the nature of residues was reported in the DAR (UK, 2005). Fluopicolide was shown to be stable in buffer solutions under conditions simulating pasteurisation, boiling and sterilisation.

Studies on the magnitude of the residues in processed commodities were investigated on grapes only. These processing studies are not relevant for peppers but considering the low contribution of this crop to the consumer intake (see section 4), EFSA is of the opinion that no additional information is necessary in the framework of this application.

3.1.2. Rotational crops

As the GAP supported in the framework of this application is authorised outside the EC, possible occurrence of residues in rotational crops is not considered relevant for the European consumer exposure.

3.2. Nature and magnitude of residues in livestock

Nature and magnitude of fluopicolide residues in livestock was not assessed with regard to the current application since peppers are not fed to animals.

4. Consumer risk assessment

The chronic and acute consumer risk assessments were performed with the EFSA PRIMo rev.2 using the MRLs as established in Annex II of Regulation (EC) No 396/2005 and the STMR and HR values derived for the use on peppers. 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
Risk assessment residue definition: fluopicolide				
Peppers	0.13	STMR	0.52	HR
Other crops	See Appendix B	MRLs	Not relevant	
Risk assessment residue definition: 2,5-dichlorobenzamide (M-01)				
Peppers	0.01	STMR	0.01	HR

For fluopicolide, results of the chronic intake and acute calculations are reported in Appendix C. No chronic concern was identified for any of the European diets, the maximum TMDI value representing 11% of the ADI (FR All population) and pepper crops contributing to a very minor extent to the overall dietary burden (maximum 0.1% of the ADI for WHO Cluster B diet). No acute intake risk was identified for peppers since IESTI is 18% of the ARfD.

In addition, no chronic or acute concerns are expected from the presence of the metabolite 2,5-dichlorobenzamide on peppers considering its poor contribution to the overall dietary burden (less than 0.1% of the ADI and ca. 0.2% of the ARfD).

It is concluded that the setting of an import tolerance of 1 mg/kg for fluopicolide on peppers is acceptable with regards to the consumer safety.

CONCLUSIONS AND RECOMMENDATIONS

The United Kingdom as RMS for the active substance fluopicolide has received an application from the company Bayer CropScience AG to set an import tolerance for the active substance fluopicolide in peppers from the USA. The evaluation report prepared by the RMS on this subject and the application were submitted to the European Commission and forwarded to EFSA on 14 January 2009.

Based on this evaluation report and the Draft Assessment Report (DAR) prepared by the Rapporteur Member State (RMS) United Kingdom under Directive 91/414/EEC, EFSA derives the following conclusions regarding the application.

The toxicological profile of fluopicolide was investigated in the peer review under Directive 91/414/EEC and data were sufficient to conclude on an ADI value of 0.08 mg/kg bw/d and an ARfD of 0.18 mg/kg bw/d. In addition, separate toxicological end points have been set for one of its main metabolite, the M-01 metabolite (2,5-dichlorobenzamide) (ADI: 0.05 mg/kg bw/d; ARfD: 0.30 mg/kg bw/d).

The metabolism of fluopicolide was investigated in three plant groups: leafy crops (lettuce), fruit crops (grape) and root/tuber crops (potato). Based on these studies, the residue definition for monitoring was limited to the parent compound fluopicolide only. For risk assessment, considering that different toxicological end points were proposed for fluopicolide and its metabolite M-01, it was decided to propose two separate residue definitions for fluopicolide and M-01, respectively and to perform two separate risk assessments based on their respective toxicological values.

A multi-residue method (DFG-S19 modified) is available to enforce fluopicolide residues in peppers.

The submitted residue trials performed in the USA and based on the US GAP were considered sufficient to derive an import tolerance of 1.0 mg/kg for peppers.

The possible occurrence of residues in rotational crops was not considered in the framework of this evaluation since this application refers to an authorisation outside the EC. The nature and magnitude of fluopicolide residues in livestock was not assessed since peppers are not fed to animals.

For fluopicolide, the chronic and acute intakes resulting from the proposed import tolerance were calculated using the EFSA PRIMo rev.2 model, the STMR and HR derived from the supervised residue trials on peppers and the existing MRLs listed in the Annex II of the Regulation EC 396/2005. No chronic or acute concerns were identified for all available European diets.

In addition, no chronic or acute concerns are expected from the presence of the metabolite 2,5-dichlorobenzamide on peppers considering its very poor contribution to the overall dietary burden (less than 0.2% of the ADI and the ARfD).

The EFSA recommendation resulting from the assessment is summarized in the table below.

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: fluopicolide			
peppers	0.01*	1.0	The proposed MRL is fully supported by data and no risk for consumers was identified.

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

DOCUMENTATION PROVIDED TO EFSA

1. Evaluation report on the setting of an import tolerance for fluopicolide on peppers under Regulation (EC) No 396/2005, prepared by the Pesticide Safety Directorate, UK, and submitted to EFSA by 14 January 2009.

REFERENCES

- EFSA, 2009. Conclusion of EFSA prepared by PRAPeR on the peer review of pesticide risk assessment of the active substance fluopicolide. *EFSA Scientific Report (2009)*, under preparation.
- UK, 2005. Draft Assessment Report on fluopicolide (AE C638206) prepared by The United Kingdom under Directive 91/414/EEC. November 2005.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

Crop and/or situation	Member state or Country	Product name	F G or I (a)	Pests or Groups of pests controlled	Formulation		Application			Application rate per treatment			PHI (days) (b)	Remarks
					Type	Conc. of as	method kind	growth stage	number min max	kg as/hL min max	water L/ha min max	kg as/ha max min		
Peppers	USA	V-10161 4 SC	F	Fungi (unspecified)	SC	480g/L	Spray	/	1 - 3	/	/	0.140	2	

(a): Outdoor or field use (F), Glasshouse application (G) or indoor application (I)

(b): PHI - minimum pre-harvest interval

APPENDIX B – EXISTING EC MRLs

Pesticides - Web Version - EU MRLs (File created on 20/03/2009)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fluopicolide
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,01*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,01*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,01*
110030	Lemons (Citron, lemon)	0,01*
110040	Limes	0,01*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,01*
110990	Others	0,01*
120000	(ii) Tree nuts (shelled or unshelled)	0,01*
120010	Almonds	0,01*
120020	Brazil nuts	0,01*
120030	Cashew nuts	0,01*
120040	Chestnuts	0,01*
120050	Coconuts	0,01*
120060	Hazelnuts (Filbert)	0,01*
120070	Macadamia	0,01*
120080	Pecans	0,01*
120090	Pine nuts	0,01*
120100	Pistachios	0,01*
120110	Walnuts	0,01*
120990	Others	0,01*
130000	(iii) Pome fruit	0,01*
130010	Apples (Crab apple)	0,01*
130020	Pears (Oriental pear)	0,01*
130030	Quinces	0,01*
130040	Medlar	0,01*
130050	Loquat	0,01*
130990	Others	0,01*
140000	(iv) Stone fruit	0,01*
140010	Apricots	0,01*
140020	Cherries (sweet cherries, sour cherries)	0,01*
140030	Peaches (Nectarines and similar hybrids)	0,01*
140040	Plums (Damson, greengage, mirabelle)	0,01*
140990	Others	0,01*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	2
151010	Table grapes	2
151020	Wine grapes	2
152000	(b) Strawberries	0,01*
153000	(c) Cane fruit	0,01*
153010	Blackberries	0,01*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,01*
153030	Raspberries (Wineberries)	0,01*
153990	Others	0,01*
154000	(d) Other small fruit & berries	0,01*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,01*
154020	Cranberries	0,01*
154030	Currants (red, black and white)	0,01*
154040	Gooseberries (Including hybrids with other ribes species)	0,01*
154050	Rose hips	0,01*
154060	Mulberries (arbutus berry)	0,01*
154070	Azarole (mediteranean medlar)	0,01*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,01*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fluopicolide
154990	Others	0,01*
160000	(vi) Miscellaneous fruit	0,01*
161000	(a) Edible peel	0,01*
161010	Dates	0,01*
161020	Figs	0,01*
161030	Table olives	0,01*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,01*
161050	Carambola (Bilimbi)	0,01*
161060	Persimmon	0,01*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,01*
161990	Others	0,01*
162000	(b) Inedible peel, small	0,01*
162010	Kiwi	0,01*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,01*
162030	Passion fruit	0,01*
162040	Prickly pear (cactus fruit)	0,01*
162050	Star apple	0,01*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammy sapote)	0,01*
162990	Others	0,01*
163000	(c) Inedible peel, large	0,01*
163010	Avocados	0,01*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,01*
163030	Mangoes	0,01*
163040	Papaya	0,01*
163050	Pomegranate	0,01*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,01*
163070	Guava	0,01*
163080	Pineapples	0,01*
163090	Bread fruit (Jackfruit)	0,01*
163100	Durian	0,01*
163110	Soursop (guanabana)	0,01*
163990	Others	0,01*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	0,02
212000	(b) Tropical root and tuber vegetables	0,01*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,01*
212020	Sweet potatoes	0,01*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,01*
212040	Arrowroot	0,01*
212990	Others	0,01*
213000	(c) Other root and tuber vegetables except sugar beet	0,01*
213010	Beetroot	0,01*
213020	Carrots	0,01*
213030	Celeriac	0,01*
213040	Horseradish	0,01*
213050	Jerusalem artichokes	0,01*
213060	Parsnips	0,01*
213070	Parsley root	0,01*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,01*
213090	Salsify (Scorzoneria, Spanish salsify (Spanish oysterplant))	0,01*
213100	Swedes	0,01*
213110	Tumips	0,01*
213990	Others	0,01*
220000	(ii) Bulb vegetables	0,01*
220010	Garlic	0,01*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fluopicolide
220020	Onions (Silverskin onions)	0,01*
220030	Shallots	0,01*
220040	Spring onions (Welsh onion and similar varieties)	0,01*
220990	Others	0,01*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	0,4
231020	Peppers (Chilli peppers)	0,01*
231030	Aubergines (egg plants) (Pepino)	0,01*
231040	Okra, lady's fingers	0,01*
231990	Others	0,01*
232000	(b) Cucurbits - edible peel	
232010	Cucumbers	0,2
232020	Gherkins	0,01*
232030	Courgettes (Summer squash, marrow (patisson))	0,01*
232990	Others	0,01*
233000	(c) Cucurbits-inedible peel	0,01*
233010	Melons (Kiwano)	0,01*
233020	Pumpkins (Winter squash)	0,01*
233030	Watermelons	0,01*
233990	Others	0,01*
234000	(d) Sweet corn	0,01*
239000	(e) Other fruiting vegetables	0,01*
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	0,01*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,01*
241020	Cauliflower	0,01*
241990	Others	0,01*
242000	(b) Head brassica	
242010	Brussels sprouts	0,01*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,2
242990	Others	0,01*
243000	(c) Leafy brassica	0,1
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,1
243020	Kale (Borecole (curly kale), collards)	0,1
243990	Others	0,1
244000	(d) Kohlrabi	0,01*
250000	(v) Leaf vegetables & fresh herbs	0,01*
251000	(a) Lettuce and other salad plants including Brassicacea	0,01*
251010	Lamb's lettuce (Italian comsalad)	0,01*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce), Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leave endive, sugar loaf)	0,01*
251030	Cress	0,01*
251040	Land cress	0,01*
251050	Rocket, Rucola (Wild rocket)	0,01*
251060	Red mustard	0,01*
251070	Leaves and sprouts of Brassica spp (Mizuna)	0,01*
251990	Others	0,01*
252000	(b) Spinach & similar (leaves)	0,01*
252010	Spinach (New Zealand spinach, tumip greens (tumip tops))	0,01*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,01*
252030	Beet leaves (chard) (Leaves of beetroot)	0,01*
252990	Others	0,01*
253000	(c) Vine leaves (grape leaves)	0,01*
254000	(d) Water cress	0,01*
255000	(e) Witloof	0,01*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fluopicolide
256000	(f) Herbs	0,01*
256010	Chervil	0,01*
256020	Chives	0,01*
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	0,01*
256040	Parsley	0,01*
256050	Sage (Winter savory, summer savory,)	0,01*
256060	Rosemary	0,01*
256070	Thyme (marjoram, oregano)	0,01*
256080	Basil (Balm leaves, mint, peppermint)	0,01*
256090	Bay leaves (laurel)	0,01*
256100	Tarragon (Hyssop)	0,01*
256990	Others	0,01*
260000	(vi) Legume vegetables (fresh)	0,01*
260010	Beans (with pods) (Green bean (french beans, snap beans, scarlet runner bean, slicing bean, yardlong beans)	0,01*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,01*
260030	Peas (with pods) (Mangetout (sugar peas))	0,01*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,01*
260050	Lentils	0,01*
260990	Others	0,01*
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	0,01*
270020	Cardoons	0,01*
270030	Celery	0,01*
270040	Fennel	0,01*
270050	Globe artichokes	0,01*
270060	Leek	0,3
270070	Rhubarb	0,01*
270080	Bamboo shoots	0,01*
270090	Palm hearts	0,01*
270990	Others	0,01*
280000	(viii) Fungi	0,01*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,01*
280020	Wild (Chanterelle, Truffle, Morel,)	0,01*
280990	Others	0,01*
290000	(ix) Sea weeds	0,01*
300000	3. PULSES, DRY	0,01*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,01*
300020	Lentils	0,01*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,01*
300040	Lupins	0,01*
300990	Others	0,01*
400000	4. OILSEEDS AND OILFRUITS	0,01*
401000	(i) Oilseeds	0,01*
401010	Linseed	0,01*
401020	Peanuts	0,01*
401030	Poppy seed	0,01*
401040	Sesame seed	0,01*
401050	Sunflower seed	0,01*
401060	Rape seed (Bird rapeseed, tumip rape)	0,01*
401070	Soya bean	0,01*
401080	Mustard seed	0,01*
401090	Cotton seed	0,01*
401100	Pumpkin seeds	0,01*
401110	Safflower	0,01*
401120	Borage	0,01*
401130	Gold of pleasure	0,01*
401140	Hempseed	0,01*
401150	Castor bean	0,01*
401990	Others	0,01*
402000	(ii) Oilfruits	0,01*
402010	Olives for oil production	0,01*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fluopicolide
402020	Palm nuts (palmoil kernels)	0,01*
402030	Palmfruit	0,01*
402040	Kapok	0,01*
402990	Others	0,01*
500000	5. CEREALS	0,01*
500010	Barley	0,01*
500020	Buckwheat	0,01*
500030	Maize	0,01*
500040	Millet (Foxtail millet, teff)	0,01*
500050	Oats	0,01*
500060	Rice	0,01*
500070	Rye	0,01*
500080	Sorghum	0,01*
500090	Wheat (Spelt Triticale)	0,01*
500990	Others	0,01*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,02*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of <i>Camellia sinensis</i>)	0,02*
620000	(ii) Coffee beans	0,02*
630000	(iii) Herbal infusions (dried)	0,02*
631000	(a) Flowers	0,02*
631010	Camomille flowers	0,02*
631020	Hybiscus flowers	0,02*
631030	Rose petals	0,02*
631040	Jasmine flowers	0,02*
631050	Lime (linden)	0,02*
631990	Others	0,02*
632000	(b) Leaves	0,02*
632010	Strawberry leaves	0,02*
632020	Rooibos leaves	0,02*
632030	Maté	0,02*
632990	Others	0,02*
633000	(c) Roots	0,02*
633010	Valerian root	0,02*
633020	Ginseng root	0,02*
633990	Others	0,02*
639000	(d) Other herbal infusions	0,02*
640000	(iv) Cocoa (fermented beans)	0,02*
650000	(v) Carob (<i>st johns bread</i>)	0,02*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,02*
800000	8. SPICES	0,02*
810000	(i) Seeds	0,02*
810010	Anise	0,02*
810020	Black caraway	0,02*
810030	Celery seed (<i>Lovage seed</i>)	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fluopicolide
810040	Coriander seed	0,02*
810050	Cumin seed	0,02*
810060	Dill seed	0,02*
810070	Fennel seed	0,02*
810080	Fenugreek	0,02*
810090	Nutmeg	0,02*
810990	Others	0,02*
820000	(ii) Fruits and berries	0,02*
820010	Allspice	0,02*
820020	Anise pepper (<i>Japan pepper</i>)	0,02*
820030	Caraway	0,02*
820040	Cardamom	0,02*
820050	Juniper berries	0,02*
820060	Pepper, black and white (<i>Long pepper, pink pepper</i>)	0,02*
820070	Vanilla pods	0,02*
820080	Tamarind	0,02*
820990	Others	0,02*
830000	(iii) Bark	0,02*
830010	Cinnamon (<i>Cassia</i>)	0,02*
830990	Others	0,02*
840000	(iv) Roots or rhizome	0,02*
840010	Liquorice	0,02*
840020	Ginger	0,02*
840030	Turmeric (<i>Curcuma</i>)	0,02*
840040	Horseradish	0,02*
840990	Others	0,02*
850000	(v) Buds	0,02*
850010	Cloves	0,02*
850020	Capers	0,02*
850990	Others	0,02*
860000	(vi) Flower stigma	0,02*
860010	Saffron	0,02*
860990	Others	0,02*
870000	(vii) Aril	0,02*
870010	Mace	0,02*
870990	Others	0,02*
900000	9. SUGAR PLANTS	0,01*
900010	Sugar beet (root)	0,01*
900020	Sugar cane	0,01*
900030	Chicory roots	0,01*
900990	Others	0,01*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	No MRLs

(*) Indicates lower limit of analytical determination

APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Fluopicolide			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0.01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.08	ARfD (mg/kg bw):	0.18
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2009	Year of evaluation:	2009

Input values: STMR 0.13 mg/kg (chronic risk) and HR 0.52 mg/kg (acute risk) for peppers. MRL values listed in the Regulation (EC) N° 396/2005 for all the other commodities

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

Chronic risk assessment								
		TMDI (range) in % of ADI minimum - maximum						
		1		11				
		No of diets exceeding ADI:		---				
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
10.7	FR all population	10.3	Table and wine grapes	0.2	Tomatoes	0.1	Leek	0.1
7.7	PT General population	6.9	Table and wine grapes	0.4	Tomatoes	0.1	Potatoes	0.1
7.6	WHO Cluster diet B	5.4	Table and wine grapes	1.5	Tomatoes	0.1	CEREALS	0.4
5.2	WHO cluster diet E	4.5	Table and wine grapes	0.3	Tomatoes	0.1	Potatoes	0.2
4.3	DE child	3.2	Table and wine grapes	0.5	Tomatoes	0.2	Pome fruit	0.4
4.1	DK adult	3.7	Table and wine grapes	0.2	Tomatoes	0.1	Cucumbers	0.1
3.7	IE adult	2.9	Table and wine grapes	0.2	Tomatoes	0.1	Leek	0.3
3.3	UK Adult	2.8	Table and wine grapes	0.2	Tomatoes	0.0	SUGAR PLANTS	0.1
2.9	NL child	1.9	Table and wine grapes	0.3	Tomatoes	0.1	Potatoes	0.3
2.8	UK vegetarian	2.2	Table and wine grapes	0.3	Tomatoes	0.0	SUGAR PLANTS	0.2
2.7	NL general	2.1	Table and wine grapes	0.2	Tomatoes	0.1	Leek	0.1
2.6	WHO Cluster diet F	1.8	Table and wine grapes	0.3	Tomatoes	0.1	Potatoes	0.1
2.3	WHO cluster diet D	1.4	Table and wine grapes	0.5	Tomatoes	0.1	CEREALS	0.2
1.9	WHO regional European diet	1.0	Table and wine grapes	0.6	Tomatoes	0.1	Potatoes	0.1
1.7	ES adult	1.2	Table and wine grapes	0.4	Tomatoes	0.0	CEREALS	0.1
1.6	UK Toddler	0.7	Table and wine grapes	0.3	Tomatoes	0.3	SUGAR PLANTS	0.5
1.5	SE general population 90th percentile	0.6	Table and wine grapes	0.4	Tomatoes	0.2	Head cabbage	0.2
1.5	FR toddler	0.5	Table and wine grapes	0.4	Tomatoes	0.3	Leek	0.2
1.5	PL general population	0.8	Table and wine grapes	0.4	Tomatoes	0.1	Head cabbage	0.1
1.5	DK child	0.5	Table and wine grapes	0.4	Cucumbers	0.3	Tomatoes	0.2
1.2	FI adult	0.8	Table and wine grapes	0.2	Tomatoes	0.1	Cucumbers	0.1
1.2	IT kids/toddler	0.7	Tomatoes	0.3	Table and wine grapes	0.1	CEREALS	0.2
1.1	IT adult	0.6	Tomatoes	0.3	Table and wine grapes	0.1	CEREALS	0.1
0.9	ES child	0.5	Tomatoes	0.1	Table and wine grapes	0.1	CEREALS	0.2
0.7	UK Infant	0.2	Tomatoes	0.1	SUGAR PLANTS	0.1	Table and wine grapes	0.3
0.7	FR infant	0.2	Table and wine grapes	0.2	Leek	0.1	Potatoes	0.2
0.7	LT adult	0.3	Tomatoes	0.1	Head cabbage	0.1	Cucumbers	0.1

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

Acute risk assessment /children	Acute risk assessment / adults / general population
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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 variability factor of 3.

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

Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):			No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):		
	---			---			---			---		
	IESTI 1	*)	**)	IESTI 2	*)	**)	IESTI 1	*)	**)	IESTI 2	*)	**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
18.2	Peppers	0.52 / -	13.0	Peppers	0.52 / -	4.7	Peppers	0.52 / -	3.4	Peppers	0.52 / -	
No of critical MRLs (IESTI 1)			---			No of critical MRLs (IESTI 2)			---			

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

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

***) pTMRL: provisional temporary MRL

***) pTMRL: provisional temporary MRL for unprocessed commodity

Conclusion:

For Fluopicolide 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

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
CAS	Chemical Abstract Service
CXL	Codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Directive 91/414/EEC)
EC	European Community
EFSA	European Food Safety Authority
EMS	Evaluating Member State
EU	European Union
GAP	good agricultural practice
ha	hectare
hL	hectolitre
HR	highest residue
ILV	independent laboratory validation
L	litre
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
PHI	pre harvest interval
PRIMo	Pesticide Residues Intake Model
PSD	Pesticide Safety Directorate, United Kingdom
RMS	Rapporteur Member State
SC	suspension concentrate
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue