REASONED OPINION

Modification of the existing MRLs for fluopicolide in radishes, onions, kale and potatoes[1]

European Food Safety Authority[2]

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SUMMARY

According to Article 6 of the Regulation (EC) No 396/2005, Greece, herewith referred to as the Evaluating Member State Greece (EMS EL), received an application from the company Bayer CropScience to modify the existing MRL for fluopicolide in radishes, onions and kale. In order to accommodate for the intended uses of fluopicolide on radishes in Germany and Switzerland, on kale in the Netherlands and France and on onions in all the European zones, it is proposed to raise the existing MRLs. The EMS Greece drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 13 September 2011. The United Kingdom, herewith referred to as the EMS UK, also received an application from the company Bayer CropScience to modify the existing MRL for fluopicolide in potatoes in the Northern and Southern Member States. The EMS UK drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 23 June 2011.

EFSA derives the following conclusions based on the submitted evaluation reports prepared respectively by Greece and the United Kingdom as well as the Draft Assessment Report (DAR) prepared by the United Kingdom under Council Directive 91/414/EC.

The toxicological profile of fluopicolide was investigated in the peer review under Council Directive 91/414/EC 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. In addition, separate toxicological end points have been set for one of its main metabolite, the M-01 metabolite (2,6-dichlorobenzamide) (ADI: 0.05 mg/kg bw/d; ARfD: 0.30 mg/kg bw).

The metabolism of fluopicolide was investigated in three plant groups: leafy crops (lettuce), fruit crops (grapes) and root/tuber crops (potatoes). Based on these studies, the residue definition for monitoring was limited to the parent compound fluopicolide only. For risk assessment two separate residue definitions were proposed (fluopicolide and M-01, respectively) since the metabolite M-01 was recovered at significant levels in potato tuber (foliar treatment) and in lettuce (soil drench

[1] On request from the European Commission, Question No EFSA-Q-2011-01030 and Question No EFSA-Q-2011-00830, approved on 07 February 2012.

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Suggested citation: European Food Safety Authority; Modification of the existing MRLs for fluopicolide in radishes, onions, kale and potatoes. EFSA Journal 2012; 10(2):2581. [39 pp.] doi:10.2903/j.efsa.2012.2581. Available online: www.efsa.europa.eu/efsajournal

treatment) and considering also the different toxicological profile of metabolite M-01 and the parent compound.

The supervised residue trials are sufficient and adequate to derive MRL proposals for the intended uses on radishes, kale and potatoes. The studies demonstrated that the following MRLs would be appropriate for the intended uses: 0.06 mg/kg for radishes, 2 mg/kg for kale and 0.03 mg/kg for potatoes while the existing MRL of 1 mg/kg on onions remains unchanged. Analytical methods are available to enforce the proposed MRLs on the commodities under consideration.

The effects of processing on the nature of fluopicolide residues have been investigated in the peer review. Under core processing conditions no degradation of fluopicolide occurs and therefore for processed commodities the same residue definition as for raw agricultural commodities is applicable. It is noted that the effect of processing under hydrolytic conditions on the potential degradation of the metabolite M-01 was not addressed. However this data gap has a negligible impact on the overall dietary risk assessment considering the low residue levels of M-01 recovered in the crops under consideration.

Although the residue levels of fluopicolide in onions and kale exceeded the trigger value of 0.1 mg/kg, specific studies to assess the magnitude of fluopicolide residues in cooked onions and kale are not relevant in view of the low dietary intake calculated for the crops under consideration (TMDI<10 % of the ADI).

The possible occurrence of fluopicolide residues in rotational and/or succeeding crops was also investigated. The metabolism of fluopicolide in rotational crops and primary crops is expected to be similar and therefore the same residue definitions are applicable. EFSA concludes that significant fluopicolide residues (exceeding 0.01 mg/kg) are not expected in the edible parts of the rotational crops provided that fluopicolide is applied according to the use pattern.

The calculated livestock dietary burden for fluopicolide exceeded the trigger value of 0.1 mg/kg DM for ruminants, poultry and pigs and were mainly driven by the residue levels recovered in kale. The existing EU MRLs for animal commodities are CXLs which were taken over into EU legislation. These CXL levels were derived by JMPR on the basis of a dietary burden calculation which was significantly higher than the dietary burden calculated for the EU situation. Thus, EFSA concludes that there is not need to modify the existing EU MRLs for animal commodities.

EFSA performed a consumer risk assessment with the EFSA Pesticide Residues Intake Model (PRIMo, rev. 2). With regard to **fluopicolide**, no long-term consumer intake concerns were identified for any of the European diets. The total calculated intake values ranged from 0.5 – 3.1 % of the ADI (WHO Cluster diet B). The contribution of residues in crops under consideration to the total long-term exposure was insignificant.

No acute consumer risk was identified in relation to the MRL proposals for fluopicolide in plant commodities under consideration. The calculated maximum exposure in percentage of the ARfD was 31.5 % for kale, 12.8 % for onions, 1.7 % for potatoes and 0.4 % for radish.

With regard to **metabolite M-01** (2,6-dichlorobenzamide), no long-term consumer intake concerns were identified for any of the European diets. The total calculated intake values accounted for a maximum of 0.3 % of the ADI (WHO Cluster diet B). The contribution of residues in crops under consideration to the total long-term exposure was negligible.

No acute consumer risk was identified in relation to the exposure to metabolite M-01 from the intake of fluopicolide treated kale, radish and potato. The calculated maximum exposure in percentage of the ARfD was 0.5 % for potato, onions and kale and 0.1 % for radish.

The recommendations of EFSA are compiled in the table below:

Code number[a]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition : *Fluopicolide*				
0211000	Potato	0.02	0.03	The submitted potato residue trials were considered as acceptable assuming that the storage time interval of the residue samples is covered by the available frozen storage stability data.
0213080	Radish	0.01*	0.06	
0220020	Onion, bulb	1	1	The notified NEU GAP does not require a modification of the existing MRL for onions. The data for the SEU GAP are not sufficient to derive a MRL proposal, but there is strong evidence that the use in NEU is more critical.
0243020	Kale	0.1	2	

(*): Indicates that the MRL is set at the limit of analytical quantification.
[a] according to Annex I of Regulation (EC) No 396/2005

KEY WORDS

Fluopicolide, radish, kale, onion, potato, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, benzamido-pyridine fungicides

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BACKGROUND

Commission Regulation (EC) No 396/2005[3] 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 Council Directive 91/414/EC[4], 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.

Greece, hereafter referred to as the evaluating Member State Greece (EMS EL), received an application from the company Bayer CropScience[5] to modify the existing MRLs for the active substance fluopicolide in radishes, onions and kale. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

The United Kingdom, hereafter referred to as the EMS UK, received an application from the same company to modify the existing MRL for the active substance fluopicolide in potatoes.

After completion, the evaluation reports of the respective EMSs were submitted to the European Commission who forwarded the applications and the corresponding evaluation reports and supporting dossiers to EFSA on 23 June and 13 September 2011, respectively. The applications were included in the EFSA Register of Questions with the reference numbers EFSA-Q-2011-01030 and EFSA-Q-2011-00830 with the following subjects:

Fluopicolide - Application to modify the existing MRLs in radishes, onions and kale.

Fluopicolide - Application to modify the existing MRL in potatoes.

The applicant proposed the following MRLs: 0.05 mg/kg in potatoes, 0.05 mg/kg in radishes, 1.5 mg/kg in kale, 1 mg/kg in onions, bulb. After the assessment of the applications, the EMSs confirmed the MRLs proposed by the applicant for the crops under consideration.

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

TERMS OF REFERENCE

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member States, provide a reasoned opinion on the risks to the consumer associated with these applications.

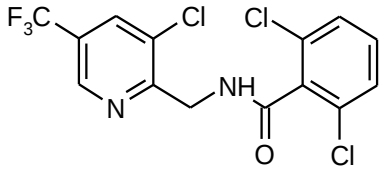
In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

[3] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005. OJ L 70, 16.3.2005, p. 1-16.
[4] Council Directive 91/414/EC of 15 July 1991, OJ L 230, 19.8.1991, p. 1-32.
[5] Bayer CropScience, Milton Road, 230 Cambridge Science Park, CB4 0WD, Cambridge, UK

In this particular case the calculated deadlines for providing the reasoned opinions were respectively 23 September 2011 and 13 December 2011.

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). The chemical structure is as follows:



Molecular weight: 383.59 g/mol

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*, *Pseudoperonospara*), late blight (*Phytophthora*) and some *Pythium* species. Fluopicolide has protectant, antisporulant 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 Council Directive 91/414/EC 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 and the final conclusion prepared by EFSA was issued on 4 June 2009 (EFSA, 2009). By Commission Directive 2010/15/EU[6], fluopicolide is included in Annex I to Council Directive 91/414/EC for uses as fungicide only.

At EU level, MRLs for fluopicolide have been established in Annex III of Regulation (EC) No 396/2005. Recently the MRLs were modified by Regulation (EC) No 520/2011[7] which implements newly adopted CXLs and by Regulation (EC) No 812/2011[8] which takes into account new uses of fluopicolide in EU Member States. The existing EU MRLs for potatoes, radishes, onions and kale are 0.02 mg/kg, 0.01*mg/kg, 1 mg/kg and 0.1 mg/kg, respectively.

The details of the GAPs for which the authorisations are intended now in various Southern and Northern European countries are reported in Appendix A.

[6] Commission Directive 2010/15/EU of 8 March 2010, OJ L 58, 9.3.2010, p.5-7
[7] Regulation (EC) No 520/2011 of the European Parliament and of the Council of 25 May 2011. OJ L 140, 27.5.2011, p. 1-46.
[8] Regulation (EC) No 812/2011 of the European Parliament and of the Council of 10 August 2011. OJ L 208, 13.8.2011, p. 1-22.

ASSESSMENT

EFSA bases its assessment on the evaluation reports submitted respectively by the United Kingdom (2011) and Greece (2011), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EC (UK, 2005), the EFSA conclusion on the peer review (EFSA, 2009), the CCPR Report (CAC, 2010) and the JMPR Evaluation report 2009 (FAO, 2010). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation of the Authorization of Plant Protection Products set out in Annex VI to Council Directive 91/414/EC and the currently valid EU guidance documents for consumer risk assessment (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011, EFSA, 2007, FAO, 2009, OECD, 2011a, 2011b).

1. Methods of analysis

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

The analytical enforcement method for the determination of fluopicolide residues in plant commodities was investigated in the framework of the peer review of Council Directive 91/414/EC (UK, 2005). The peer review 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.

An analytical method based on HPLC-MS/MS for the determination of fluopicolide residues in matrices with high water content was reported in the evaluation report submitted for the setting/modification of MRLs for fluopicolide in various commodities of plant origin (Germany, 2010). The method was sufficiently validated for the determination of residues at the LOQ of 0.01 mg/kg. An ILV was provided for the method.

EFSA concludes that there are adequate enforcement methods available to analyse fluopicolide residues in high water content matrices – radishes, kale, onion and potatoes as requested under the current applications.

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

Sufficiently validated analytical methods are available to analyse residues of fluopicolide in the food commodities of animal origin. In the framework of this reasoned opinion, EFSA concluded that there is no need to modify the existing MRLs for animal commodities.

2. Mammalian toxicology

The toxicological reference values for fluopicolide were derived at Community level during the peer review under Council Directive 91/414/EC (EFSA, 2009). It must be noted that separate toxicological end points have been proposed for the parent compound fluopicolide and its metabolite M-01[9] (2,6-dichlorobenzamide). They are compiled in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Fluopicolide					
ADI	EFSA	2009	0.08 mg/kg bw/d	Mice, 78-week dietary study	100
ARfD	EFSA	2009	0.18 mg/kg bw	Rat, 28-day dietary study	100
Metabolite (BAM, M-01): 2,6-dichlorobenzamide					
ADI	EFSA	2009	0.05 mg/kg bw/d	Rat and dog, 2-year study	100
ARfD	EFSA	2009	0.3 mg/kg bw	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

The metabolism of fluopicolide in primary crops was investigated in the framework of the peer review under Council Directive 91/414/EC (UK, 2005). The overview of the metabolism studies is presented in the table below.

Table 3-1. Overview of the available metabolism studies

Crop group	Crop	Label location	Application details				Comments
			Type	Rate (kg a.s./ha)	No	Sampling time interval (days)	
Leafy vegetables	Lettuce	Phenyl	Foliar	0.2	2	0, 21 and 35 (maturity) after the first application	Indoor conditions
		Pyridinyl	Foliar	0.2	2		
		Phenyl	Soil drench	0.2	1	35	
Fruits and	Grapes	Phenyl	Foliar	0.17 (1st)	3	0, 27-28 and 111-112	Indoor

[9] BAM, M-01 (2,6-dichlorobenzamide): see Appendix D

Crop group	Crop	Label location	Application details				Comments
			Type	Rate (kg a.s./ha)	No	Sampling time interval (days)	
fruiting vegetables				0.12 (2nd and 3rd)		(maturity) after the first application	conditions
		Pyridinyl	Foliar	0.17 (1st) and 1.7* 0.12 (2nd and 3rd) and 1.2*	3		
Root and tuber vegetables	Potato	Phenyl	Foliar	0.2 and 2*	2	0, 41 and 69-70 (maturity) after the first application – PHI: 20 days	1N rate - PHI of 7 days is intended.
		Pyridinyl	Foliar	0.2 and 2*	2		

* exaggerated application rates for metabolite identification purposes.

The metabolic pathway of fluopicolide was found to be similar in the three crop groups, involving hydrolysis of the urea bond to form metabolites M-01 and M-02[10] and hydroxylation of the phenyl ring to form metabolite M-06[11].

Following foliar applications, the parent fluopicolide constituted the main compound of the total radioactive residues in all crops accounting at harvest for up to 96.4 % TRR (14.0 mg/kg) in lettuce, 91.2 % TRR (1.15 mg/kg) in grapes and 70.2 % TRR (0.04 mg/kg) in potato tubers for both the phenyl and pyridinyl labelling forms. Low proportions of the related metabolites M-01, M-02 and M-06 occurred in foliar treated lettuce (<4 % TRR) and grapes (<2.3 % TRR). In potato tubers, the metabolites M-01, M-02 and M-06 were recovered at significant levels (25.4 %, 12 % and 2.4 % TRR, respectively) whilst the actual concentrations of these metabolites were rather low at the 1 N rate (<0.01-0.02 mg/kg). It should be highlighted that the metabolic pattern of fluopicolide in potato was depicted at a PHI of 20 days whereas the supported PHI is 7 days. It can therefore be reasonably assumed that the recovered levels of these metabolites in potato tubers at harvest would be even lower at the intended PHI of 7 days.

An additional metabolism study was conducted on lettuce after soil drench application with the phenyl labelling form only. Fluopicolide remained the valid indicator of the total radioactive residues in lettuce at harvest (up to 74.5 % TRR-0.06 mg/kg) along with the metabolite M-01 (up to 19.8 % TRR-0.03 mg/kg) and into a minor extent M-06 (2.8 % TRR-<0.01 mg/kg).

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 purposes derived under the peer review was set as fluopicolide parent compound alone. For risk assessment, based on the outcome of the metabolism data, considering the different toxicological end points derived for fluopicolide and M-01, respectively and taking into account that M-01 is also a common metabolite to other actives substances (e.g. dichlobenil) it was decided by the peer review experts to propose two separate residue definitions for fluopicolide and M-01, respectively and to perform two separate risk assessments based on their respective toxicological end points.

[10] M-02: 3-chloro-5-(trifluoromethyl)pyridine-2-carboxylic acid . See Appendix D

[11] M-06: 2,6-dichloro-*N*-{[3-chloro-5-(trifluoromethyl) pyridin-2-yl]methyl}-3-hydroxybenzamide: See Appendix D

The available metabolism studies cover the crops for which MRL modifications are requested. Therefore the residue definitions for enforcement purposes and risk assessment established during the peer review are also applicable.

3.1.1.2. Magnitude of residues

In support to the MRL application, acceptable residue trials were provided on radishes, kale, onions and potatoes. Samples from all residue trials were analysed for parent fluopicolide and its metabolite M-01. The validation data package for the analytical method (LC/MS/MS) used to determine the residues of fluopicolide and its metabolite M-01 in potato tuber was considered as complete (EC, 2000). The summary of residue trials data is given in Table 3-2 and the derived MRL proposals are highlighted in bold.

a. Radishes

NEU critical GAP: 2 x 0.1 kg a.s./ha; BBCH GS 13-47, PHI=14 d

4 decline residue trials were conducted in Germany in 2007 in compliance with the critical GAP to determine the residue levels of fluopicolide and its metabolite M-01. According to the EU guidance (EC, 2011), the data are sufficient to derive a MRL proposal.

b. Kale

NEU critical GAP: 3 x 0.1 kg a.s./ha; BBCH GS 13-49, PHI=14 d
SEU critical GAP: 2 x 0.1 kg a.s./ha; BBCH GS 13-49, PHI=14 d

4 GAP compliant declined residue trials covering Northern Europe were performed in 2006 in Germany. According to the EU guidance (EC, 2011), the data are sufficient to derive a MRL proposal.

c. Onions, bulb

NEU and SEU critical GAP: 3 x 0.1 kg a.s./ha; BBCH GS 11-49, PHI=7 d

10 and 5 decline residue trials were conducted in 2006 and 2007 (France, Germany, Belgium, United Kingdom, the Netherlands, Italy, Portugal and Spain) in compliance with the critical GAPs covering Northern and Southern Europe, respectively. The data are sufficient to derive a MRL proposal for the NEU zone. It is noted that the notified NEU GAP does not require a modification of the existing MRL for onions which is set at the level of 1 mg/kg. For Southern Europe the number of trials is not sufficient (EC, 2011), but the available data give a strong evidence that the use in SEU is less critical than the NEU use.

d. Potatoes

NEU and SEU critical GAP: 4 x 0.1 kg a.s./ha; PHI=7 d

17 residue trials complying with the critical GAP were submitted covering respectively Northern and Southern Europe. The Member States for which the authorizations on potato were requested were not specified. According to the EU guidance (EC, 2011), the data are sufficient to derive a MRL proposal.

The storage stability of fluopicolide in primary crops was investigated in the framework of the peer review under Council Directive 91/414/EC (UK, 2005). Fluopicolide and M-01 residues are stable up to 30 months in high acid and high water content matrices (grapes, potatoes and cabbages) when stored at -18°C. The maximum storage interval of the supervised residue trials samples on radishes, onions and kale prior to analysis was covered by the storage stability data on fluopicolide and its metabolite M-01. The submitted potato residue trials were considered as acceptable assuming that the storage time interval of the residue samples is covered by the available frozen storage stability data.

EFSA concludes that for the intended uses of fluopicolide, the existing MRLs need to be raised to 0.06 mg/kg in radishes, 2 mg/kg in kale, 0.03 mg/kg in potatoes while the existing MRL of 1 mg/kg on onions remains unchanged. For the intended use on onions in SEU the data are not sufficient to derive a MRL proposal, but there is evidence that this use is covered by the existing MRL.

Table 3-2. Overview of the available residue trials data on fluopicolide

Commodity	Region [(a)]	Outdoor/Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [(b)]	Highest residue (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement	Risk assessment					
Enforcement residue definition: *Fluopicolide* **Risk assessment residue definition (1):** *Fluopicolide*									
Radishes	NEU	Outdoor	<0.01; <0.01; 0.02; 0.03	<0.01; <0.01; 0.02; 0.03	**0.02**	**0.03**	**0.06**	1.0	R_{ber}=0.06 R_{max}=0.07 OECD MRL(x)=0.06
Kale	NEU/SEU	Outdoor	0.16; 0.69; 0.80; 0.84	0.16; 0.69; 0.80; 0.84	**0.75**	**0.84**	**2**	1.0	R_{ber}=1.66 R_{max}=2.24 OECD MRL(x)=2.0
Onions, bulb	NEU	Outdoor	2x<0.01; 0.02; 3x0.03; 2x0.06; 0.07; 0.21	2x<0.01; 0.02; 3x0.03; 2x0.06; 0.07; 0.21	**0.03**	**0.21**	**0.3**	1.0	R_{ber}=0.13 R_{max}=0.22 OECD MRL(x)=0.30
	SEU		3x<0.01; 2x0.01	3x<0.01; 2x0.01					data not sufficient
Potatoes	NEU	Outdoor	17x<0.01	17x<0.01	0.01	0.01	0.01*	1.0	Not relevant
	SEU		14x<0.01; 2x0.01; 0.02	14x<0.01; 2x0.01; 0.02	**0.01**	**0.02**	**0.03**	1.0	R_{ber}=0.02 R_{max}=0.02 OECD MRL(x)=0.02

(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.
(e): The existing EU MRL for onions is a CXL value which was adopted by CAC in 2010 and taken over into EU legislation.
(*): Indicates that the MRL is set at the limit of analytical quantification.
(x) : MRL calculated using the OECD MRL calculator (OECD, 2011b)
N/A: Not applicable

Table 3-3. Overview of the available residue trials data on 2,6-dichlorobenzamide (M-01)

Commodity	Region [(a)]	Outdoor/Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [(b)]	Highest residue (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF	Comments
			Enforcement	Risk assessment					
Enforcement residue definition: *Fluopicolide* **Risk assessment residue definition (2):** *2,6-dichlorobenzamide (M-01)*									
Radishes	NEU	Outdoor	<0.01; <0.01; 0.02; 0.03	4x<0.01	0.01	0.01	-	-	
Kale	NEU	Outdoor	0.16; 0.69; 0.80; 0.84	2x<0.01; 2x0.02	0.02	0.02	-	-	
Onions, bulb	NEU	Outdoor	2x<0.01; 0.02; 3x0.03; 2x0.06; 0.07; 0.21	7x<0.01; 0.02; 0.03; 0.04	0.01	0.04	-	-	
	SEU		3x<0.01; 2x0.01	5x<0.01	-	-	-	-	Data set not sufficient
Potatoes	NEU	Outdoor	17x<0.01	17x<0.01	0.01	0.01	-	-	
	SEU		14x<0.01; 2x0.01; 0.02	17x<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 **risk assessment residue definition**.
(c): Highest value of the individual trial results according to the **risk assessment residue definition**.
(*): 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 the residues was investigated in the peer review (UK, 2005). Fluopicolide was shown to be stable in buffer solutions under conditions simulating pasteurisation, boiling and sterilisation. It is noted that there is a lack of data on the effect of processing under hydrolytic conditions on the potential degradation of the metabolite M-01. EFSA considers however that this data gap has a negligible impact on the overall dietary risk assessment considering the low residue levels of M-01 recovered in the crops under consideration.

Although the residue levels of fluopicolide in onions and kale exceeded the trigger value of 0.1 mg/kg, specific studies to assess the magnitude of fluopicolide residues in cooked onions and kale are not required in view of the low dietary intake calculated for the crops under consideration (TMDI<10 % of the ADI) (EC, 1997d).

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

All crops supported in the framework of this application might be grown in rotation with other crops. Under the peer review the rate of degradation of fluopicolide in soil was investigated in field and laboratory studies (UK, 2005). The studies indicated that fluopicolide is highly to very highly persistent in soil with a maximum DT_{90f} of 1184 days. Metabolite M-01 is very highly persistent in soil with a maximum DT_{90f} of 1046 days. The rate of degradation in soil was investigated for other fluopicolide metabolites out of which metabolites M-05[12] and M-10[13] were found to be moderatly to highly persistent in the soil (max DT_{90lab} M-05=432 d; max DT_{90lab} M-10=840 d).

In this case a special consideration should be given to fluopicolide residues in rotational crops.

3.1.2.2. Nature of residues

The metabolism of fluopicolide in rotational crops was investigated in the framework of the peer review under Council Directive 91/414/EC (UK, 2005) using phenyl and pyridinyl ring labelled (^{14}C) fluopicolide. The overview of the study conditions is presented in the table below.

Table 3-4. Overview of the available metabolism studies

Crop group	Crop sown	Label position	Rate (kg a.s./ha)	Plant back intervals (days)	Remarks
Fluopicolide					
Root and tuber vegetables	Radish	Phenyl Pyridinyl	0.4 (1N)	29, 133, 365	Soil application
Cereals	Wheat				
Leafy vegetables	Lettuce				

[12] M-05: 3-methylsulfinyl-5-trifluoro-methylpyridine-2-carboxylic acid - See Appendix D
[13] M-10: 3-sulfo-5-(trifluoromethyl) pyridine-2-carboxylic acid - See Appendix D

Translocation of the radioactive residues was observed at all plant back intervals. In crops planted at 29 days of plant back interval, the total radioactive residues accounted for 1.01 mg equiv./kg in lettuce, 0.14 mg equiv./kg in radish root and 0.16 mg equiv./kg in wheat grain for the phenyl label while the total residues amounted the concentrations of 0.30, 0.12 and 2.60 mg equiv./kg respectively in lettuce, radish root and wheat grain for the pyridinyl label. Non negligible total residues were also recovered in wheat straw for both the 2 labelling forms (7.0-13.6 mg equiv./kg). Due to the very high persistence of fluopicolide in soil, the total radioactive residues found in the rotated lettuce and wheat grain after 365 days of plant back interval remained non negligible with respectively up to 0.6 mg equiv./kg (phenyl label) and 0.18 mg equiv./kg (pyridinyl label) while in radish roots, the total residues decreased significantly (0.04 mg equiv./kg for the phenyl and pyridinyl labels).

The metabolism was found to be similar, but more extensive than in primary crops. In lettuce and radish tops and roots, fluopicolide, M-01 and M-02 were identified as the major components of the total radioactive residues at all plant back intervals. The metabolites M-05 and M-09[14] were also found in some of the matrices. The predominant compounds of the total radioactive residues in wheat grain, forage and straw at all plant back intervals were the parent compound and its metabolites M-01 and M-04[15], M-02, and M-05. Low concentrations of M-06, M-08[16] and M-09 were detected in some of the samples.

From the metabolites identified in rotational crops, M-05, M-08 and M-09 were not found in the rat metabolism studies. However, the peer review regarded these substances as less toxic than fluopicolide and therefore were not included in the residue definition for risk assessment.

The peer review concluded that the metabolism of fluopicolide in rotational crops proceeds according to the same pathway as in primary crops. It can be concluded that the same residue definitions for monitoring and risk assessment are also applicable to the crops in rotation to the crops under consideration.

3.1.2.3. Magnitude of residues

The magnitude of fluopicolide residues in rotational crops was investigated in the framework of the peer review in field studies (UK, 2005). Nine rotational crops field trials have been submitted. After the harvest of potatoes which were treated according to the representative use with four foliar applications of fluopicolide at a rate of 0.1 kg a.s./ha, winter and spring wheat, field beans and cabbage were planted into the soil (28-227 days of soil ageing). Samples were analysed for fluopicolide, M-01 and M-02, wheat samples additionally for M-04 and M-05. Fluopicolide residue levels were below the LOQ (0.01 mg/kg) in all the edible parts of the rotated crops harvested at maturity with the exception of wheat straw (0.12 mg/kg). The metabolite M-01 was found in quantifiable concentrations in field beans (0.02 mg/kg), in cabbage (max. 0.04 mg/kg) and in wheat straw (max. 0.03 mg/kg) while metabolites M-02 and M-04 were detected in wheat grain (0.02 and 0.08 mg/kg, respectively) and metabolites M-04 and M-05 in wheat straw (0.07 and 0.08 mg/kg, respectively).

The peer review concluded that on the basis of the residue trials on rotational crops and in view of the use pattern, no quantifiable residue levels of fluopicolide are expected in the edible parts of the rotated crops.

[14] M-09: 3-chloro-2-hydroxy-5-trifluoromethylpyridine - See Appendix D
[15] M-04: 2,6-dichloro-3-hydroxy-benzamide - See Appendix D
[16] M-08: 3-chloro-5-trifluoromethyl pyridine-2-carboxamide - See Appendix D

3.2. Nature and magnitude of residues in livestock

Kale and potatoes can be fed to livestock according to EU Guidance documents (EC, 1996) and therefore the potential livestock exposure to fluopicolide residues has to be assessed. In addition, livestock can be exposed to metabolite M-01 from the intake of crops treated with fluopicolide. Therefore also the livestock exposure to metabolite M-01 has to be assessed.

The median and maximum dietary burdens were calculated for the different types of livestock using the agreed European methodology (EC, 1996). The livestock exposure was assessed considering the livestock intake of potatoes and kale.

The input values for the dietary burden calculation are summarized in the Table 3-5.

Table 3-5. Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Fluopicolide				
Head cabbage	0.02	Median (EFSA, 2011)	0.18	HR (EFSA, 2011)
Kale	0.75	Median	0.84	HR
Potatoes	0.01	Median	0.02	HR
M-01: 2,6-dichlorobenzamide				
Head cabbage	0.01	Median (EFSA, 2011)	0.01	HR (EFSA, 2011)
Kale	0.02	Median	0.02	HR
Potatoes	0.01	Median	0.01	HR

The results of the dietary burden calculation for fluopicolide and its metabolite M-01 are presented separately in Table 3-6.

Table 3-6. Results of the dietary burden calculation

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded?
Risk assessment residue definition: Fluopicolide					
Dairy ruminants	0.077	0.068	Kale	2.139	Yes
Meat ruminants	0.093	0.082	Kale	2.176	Yes

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded?
Poultry	0.020	0.017	Kale	0.325	Yes
Pigs	0.039200	0.033743	Kale	0.98	Yes
Risk assessment residue definition: M-01 (2,6-dichlorobenzamide)					
Dairy ruminants	0.0025	0.0025	Kale	0.069	No
Meat ruminants	0.0038	0.0038	Kale	0.089	No
Poultry	0.0012	0.0012	Potatoes	0.0204	No
Pigs	0.0024	0.0024	Potatoes	0.0614	No

The calculated dietary burdens for metabolite M-01 were below the trigger value of 0.1 mg/kg DM for all livestock species. Considering the low exposure of livestock to metabolite M-01, there is no need to further investigate the setting of the MRLs for metabolite M-01 in food commodities of animal origin.

The calculated dietary burdens for fluopicolide exceed the trigger value of 0.1 mg/kg DM for ruminants, poultry and pigs and are mainly driven by the residue levels in kale. As significant livestock exposure has been identified, the occurrence of fluopicolide residues in the food commodities of animal origin has to be further assessed.

The existing EU MRLs for animal commodities are CXLs which were taken over into EU legislation. These CXL levels were derived by JMPR on the basis of a dietary burden calculation which was significantly higher[17] (FAO, 2010) than the dietary burden calculated for the EU situation (Table 3-6). Thus, EFSA concludes that there is no need to modify the existing EU MRLs for animal commodities.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population [18] (EFSA, 2007).

Separate consumer exposure assessments were performed with regard to the exposure to fluopicolide and metabolite M-01 residues.

[17] Maximum dietary burden meat and dairy ruminants: 0.185 mg/kg bw/d; median dietary burden for dairy ruminants: 0.069 mg/kg bw/d; maximum dietary burden poultry: 0.047 mg/kg bw/d (FAO, 2010)

[18] The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

For the calculation of the chronic exposure to respectively **fluopicolide and metabolite M-01** residues, EFSA used the median residue values as derived from the residue trials on radish, kale and potato as well as the median values from the residue trials on head cabbage, lettuce, kohlrabi and leek established in the previous EFSA Reasoned opinion on fluopicolide (EFSA, 2011). For several plant commodities (among them also for onions) for which the CXLs have been taken over in the EU legislation, the median residue values derived by the JMPR were used as input values (FAO, 2010). For the other food commodities of plant origin, the existing MRLs for fluopicolide as established in Annex III of Regulation (EC) No 396/2005 were used as input values.

The acute exposure assessment was performed only with regard to the plant commodities under consideration using the highest residue values observed in supervised residue field trials as input values. For onions, the highest residues of fluopicolide and M-01 found in the data submitted in support of the CXL were used as input values.

For commodities of animal origin the adopted CXLs were used as input values both for the long-term and short-term exposure assessment since the median and HR values for fluopicolide and M-01 in animal tissues, milk and eggs are 0.

The input values used for the dietary exposure calculation are summarized in Table 4-1.

Table 4-1. Input values for the consumer exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Risk assessment residue definition 1: *Fluopicolide*				
Kale	0.75	Median residue	0.84	HR
Radish	0.02	Median residue	0.03	HR
Potato	0.01	Median residue	0.02	HR
Onions, bulb	0.07	Median residue (FAO, 2010)	0.58	HR (FAO, 2010)
Head cabbage	0.02	Median residue $_{(NEU)}$ (EFSA, 2011)	Not relevant	
Kohlrabi	0.01	Median residue (EFSA, 2011)		
Lettuce	1.09	Median residue $_{(indoor)}$ (EFSA, 2011)		
Leek	0.25	Median residue (EFSA, 2011)		
Brussels sprouts	0.04	Median residue (FAO, 2010)		
Flowering brassica	0.385	Median residue (FAO, 2010)		
Cucurbits – edible peel	0.07	Median residue (FAO, 2010)		
Cucurbits – inedible peel	0.01	Median residue (FAO, 2010)		

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Tomatoes, peppers, aubergines, okra	0.16	Median residue (FAO, 2010)		
Table and wine grapes	0.38	Median residue (EFSA, 2009; FAO, 2010)		
Spring onions	2.1	Median residue (FAO, 2010)		
Other food commodities of plant and animal origin	MRL	See Appendix C		
Risk assessment residue definition 2: *M-01 (2,6-dichlorobenzamide)*				
Kale	0.02	Median residue	0.02	HR
Radish	0.01	Median residue	0.01	HR
Potato	0.01	Median residue	0.01	HR
Onion, bulb	0.01	Median residue (FAO, 2010)	0.04	HR
Head cabbage	0.01	Median residue (EFSA, 2011)	Not relevant	
Kohlrabi	0.01	Median residue (EFSA, 2011)		
Lettuce	0.017	Median residue (indoor) (EFSA, 2011)		
Leek	0.01	Median residue (EFSA, 2011)		
Brussels sprouts	0.01	Median residue (FAO, 2010)		
Flowering brassica	0.01	Median residue (FAO, 2010)		
Cucurbits – edible peel	0.01	Median residue (FAO, 2010)		
Cucurbits – inedible peel	0.01	Median residue (FAO, 2010)		
Tomatoes, peppers, aubergines, okra	0.01	Median residue (FAO, 2010)		
Spring onions	0.01	Median residue (FAO, 2010)		
Table and wine grapes	0.02	Median residue (EFSA, 2009)		
Other commodities of plant and animal origin	-	No data available		

The calculated exposure was compared with the toxicological reference values as derived for fluopicolide and metabolite M-01, respectively (Table 2-1). The results of the calculation with the EFSA PRIMo are presented in Appendix B.

With regard to **fluopicolide**, no long-term consumer intake concerns were identified for any of the European diets. The total calculated intake values ranged from 0.5 – 3.1 % of the ADI (WHO Cluster diet B). The contribution of residues in crops under consideration to the total long-term exposure was insignificant.

No acute consumer risk was identified in relation to the MRL proposals for fluopicolide in plant commodities under consideration. The calculated maximum exposure in percentage of the ARfD was 31.5 % for kale, 12.8 % for onions, 1.7 % for potatoes and 0.4 % for radish.

With regard to **metabolite M-01** (2,6-dichlorobenzamide), no long-term consumer intake concerns were identified for any of the European diets. The total calculated intake values accounted for a maximum of 0.3 % of the ADI (WHO Cluster diet B). The contribution of residues in crops under consideration to the total long-term exposure was insignificant.

No acute consumer risk was identified in relation to the exposure to metabolite M-01 from the intake of fluopicolide treated kale, radish and potato. The calculated maximum exposure in percentage of the ARfD was 0.5 % for potato, onions and kale and 0.1 % for radish.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of fluopicolide was investigated in the peer review under Council Directive 91/414/EC 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. In addition, separate toxicological end points have been set for one of its main metabolite, the M-01 metabolite (2,6-dichlorobenzamide) (ADI: 0.05 mg/kg bw/d; ARfD: 0.30 mg/kg bw).

The metabolism of fluopicolide was investigated in three plant groups: leafy crops (lettuce), fruit crops (grapes) and root/tuber crops (potatoes). Based on these studies, the residue definition for monitoring was limited to the parent compound fluopicolide only. For risk assessment two separate residue definitions were proposed (fluopicolide and M-01, respectively) since the metabolite M-01 was recovered at significant levels in potato tuber (foliar treatment) and in lettuce (soil drench treatment) and considering also the different toxicological profile of metabolite M-01 and the parent compound.

The supervised residue trials are sufficient and adequate to derive MRL proposals for the intended uses on radishes, kale and potatoes. The studies demonstrated that the following MRLs would be appropriate for the intended uses: 0.06 mg/kg for radishes, 2 mg/kg for kale and 0.03 mg/kg for potatoes while the existing MRL of 1 mg/kg on onions remains unchanged. Analytical methods are available to enforce the proposed MRLs on the commodities under consideration.

The effects of processing on the nature of fluopicolide residues have been investigated in the peer review. Under core processing conditions no degradation of fluopicolide occurs and therefore for processed commodities the same residue definition as for raw agricultural commodities is applicable. It is noted that the effect of processing under hydrolytic conditions on the potential degradation of the metabolite M-01 was not addressed. However this data gap has a negligible impact on the overall dietary risk assessment considering the low residue levels of M-01 recovered in the crops under consideration.

Although the residue levels of fluopicolide in onions and kale exceeded the trigger value of 0.1 mg/kg, specific studies to assess the magnitude of fluopicolide residues in cooked onions and kale are not relevant in view of the low dietary intake calculated for the crops under consideration (TMDI<10 % of the ADI).

The possible occurrence of fluopicolide residues in rotational and/or succeeding crops was also investigated. The metabolism of fluopicolide in rotational crops and primary crops is expected to be similar and therefore the same residue definitions are applicable. EFSA concludes that significant fluopicolide residues (exceeding 0.01 mg/kg) are not expected in the edible parts of the rotational crops provided that fluopicolide is applied according to the use pattern.

The calculated livestock dietary burden for fluopicolide exceeded the trigger value of 0.1 mg/kg DM for ruminants, poultry and pigs and were mainly driven by the residue levels recovered in kale. The existing EU MRLs for animal commodities are CXLs which were taken over into EU legislation. These CXL levels were derived by JMPR on the basis of a dietary burden calculation which was significantly higher than the dietary burden calculated for the EU situation. Thus, EFSA concludes that there is not need to modify the existing EU MRLs for animal commodities.

EFSA performed a consumer risk assessment with the EFSA Pesticide Residues Intake Model (PRIMo, rev. 2). With regard to **fluopicolide**, no long-term consumer intake concerns were identified for any of the European diets. The total calculated intake values ranged from 0.5 – 3.1 % of the ADI

(WHO Cluster diet B). The contribution of residues in crops under consideration to the total long-term exposure was insignificant.

No acute consumer risk was identified in relation to the MRL proposals for fluopicolide in plant commodities under consideration. The calculated maximum exposure in percentage of the ARfD was 31.5 % for kale, 12.8 % for onions, 1.7 % for potatoes and 0.4 % for radish.

With regard to **metabolite M-01** (2,6-dichlorobenzamide), no long-term consumer intake concerns were identified for any of the European diets. The total calculated intake values accounted for a maximum of 0.3 % of the ADI (WHO Cluster diet B). The contribution of residues in crops under consideration to the total long-term exposure was negligible.

No acute consumer risk was identified in relation to the exposure to metabolite M-01 from the intake of fluopicolide treated kale, radish and potato. The calculated maximum exposure in percentage of the ARfD was 0.5 % for potato, onions and kale and 0.1 % for radish.

RECOMMENDATIONS

Code number[a]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition : *Fluopicolide*				
0211000	Potato	0.02	0.03	The submitted potato residue trials were considered as acceptable assuming that the storage time interval of the residue samples is covered by the available frozen storage stability data.
0213080	Radish	0.01*	0.06	
0220020	Onion, bulb	1	1	The notified NEU GAP does not require a modification of the existing MRL for onions. The data for the SEU GAP are not sufficient to derive a MRL proposal, but there is strong evidence that the use in NEU is more critical.
0243020	Kale	0.1	2	

(*): Indicates that the MRL is set at the limit of analytical quantification.
[a] according to Annex I of Regulation (EC) No 396/2005

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Appendix A. GOOD AGRICULTURAL PRACTICES (GAPs)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d - f)	conc. of a.s. (i)	method kind (f - h)	growth stage & season (j) BBCH GS	number min max (k)	interval min max	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
Potatoes	F	NEU/SEU	*Phytophthora infestans*	SC	62.5 g/L	Foliar Spray	-	4	-	0.008-0.07	150-1200	0.1	7	
Radishes	F	NEU (Germany, Switzerland)	*Phytophthora DE BARY spp.*	SC	687.5 g/L	Foliar Spray	13-47	1-2	-	0.0167-0.0333	300-600	0.1	14	
Onions	F	Bulgaria	*Peronospora destructor*	SC	687.5 g/L	Foliar Spray	14-49	1-3	-	Max. 0.0375	200-500	Max. 0.075	7	
	F	France	*Peronospora destructor*	SC	687.5 g/L	Foliar Spray	13-49	1-2	-	Max. 0.025	400-1000	Max. 0.1	7	
	F	Estonia	*Peronospora destructor*	SC	687.5 g/L	Foliar Spray	41-47	1-3	-	0.02-0.033	300-500	Max. 0.1	7	
	F	Latvia	*Peronospora destructor*	SC	687.5 g/L	Foliar Spray	41-47	1-2	-	0.02-0.033	300-500	Max. 0.1	7	
	F	Lithuania	*Peronospora destructor*	SC	687.5 g/L	Foliar Spray	41-47	1-3	-	0.02-0.033	300-500	Max. 0.1	7	
	F	Greece	*Peronospora destructor*	SC	687.5 g/L	Foliar Spray	After BBCH 21	1	-	0.01	1000	0.1	7	
	F	Italy	*Peronospora destructor*	SC	687.5 g/L	Foliar Spray	13-49	1-3	-	Max. 0.01	1000	Max. 0.1	7	

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d - f)	conc. of a.s. (i)	method kind (f - h)	growth stage & season (j) BBCH GS	number min max (k)	interval min max	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
	F	Poland	*Peronospora destructor*	SC	687.5 g/L	Foliar Spray	11-47	1-3	-	Max. 0.0143	Max 700	Max. 0.1	7	
	F	Romania	*Peronospora destructor*	SC	687.5 g/L	Foliar Spray	19-48	1-2	-	Max. 0.0167	600-1000	Max. 0.1	7	
	F	Spain	*Peronospora destructor*	SC	687.5 g/L	Foliar Spray	13-49	1-3	-	0.01-0.02	500-1000	Max. 0.1	7	
Kale	F	NEU (The Netherlands)	*Phytophthora brassicae*	SC	687.5 g/L	Foliar Spray	13-49	1-3	-	0.0125-0.05	200-800	0.1	14	
	F	NEU (The Netherlands)	*Phytophthora brassicae*	SC	687.5 g/L	Foliar Spray	14-49	1-3	-	0.0125-0.05	200-800	0.1	14	
	F	NEU (France)	*Phytophthora brassicae*	SC	687.5 g/L	Foliar Spray	13-49	1-2	-	0.025-0.05	200-400	0.1	14	
	F	SEU (France)	*Phytophthora brassicae*	SC	687.5 g/L	Foliar Spray	13-49	1-2	-	0.025-0.05	200-400	0.1	14	

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation type (d - f)	Formulation conc. of a.s. (i)	Application method kind (f - h)	Application growth stage & season (j) BBCH GS	Application number min max (k)	Application interval min max	Application rate per treatment kg as/hL min max	Application rate per treatment water L/ha min max	Application rate per treatment kg a.s./ha min max	PHI (days) (l)	Remarks (m)

Remarks:	(a)	For crops, EU or other classifications, e.g.Codex, should be used; where relevant, the use situation should be described (e.g. fumigation	(h)	Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
	(b)	of a structure)	(i)	g/kg or g/l
	(c)	Outdoor or field use (F), glasshouse application (G) or indoor	(j)	Growth stage at last treatment (Growth stages of mono-and dicotyledonous
	(d)	application (I)		plants. BBCH Monograph, 2nd Ed., 2001), including where relevant,
	(e)	e.g. biting and suckling insects, soil born insects, foliar fungi, weeds		information on season at time of application
		e.g. wettable powder (WP), emulsifiable concentrate (EC), granule	(k)	The minimum and maximum number of application possible under practical
	(f)	(GR)		conditions of use must be provided
	(g)	GCPF Technical Monograph No 2, 4th Ed., 1999 or other codes, e.g.	(l)	PHI - minimum pre-harvest interval
		OECD/CIPAC, should be used	(m)	Remarks may include: Extent of use/economic importance/restrictions (i.e.
		All abbreviations used must be explained		feeding, grazing)
		Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench		

Appendix B. PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Fluopicolide

Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):	0.01	proposed LOQ:	0.01
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**

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	1 – 3
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)
3.1	WHO Cluster diet B	0.9	Wine grapes	0.6	Tomatoes	0.5	Lettuce	0.4
2.5	FR all population	1.9	Wine grapes	0.1	Lettuce	0.1	Tomatoes	0.1
2.4	NL child	0.7	Milk and cream,	0.4	Table grapes	0.2	Cauliflower	0.4
2.2	FR toddler	1.0	Milk and cream,	0.2	Leek	0.2	Broccoli	0.3
2.0	DE child	0.6	Table grapes	0.4	Milk and cream,	0.2	Tomatoes	0.4
1.9	IE adult	0.6	Wine grapes	0.1	Table grapes	0.1	Spring onions	0.4
1.8	PT General population	1.2	Wine grapes	0.2	Tomatoes	0.1	Table grapes	0.2
1.6	WHO cluster diet E	0.8	Wine grapes	0.1	Lettuce	0.1	Tomatoes	0.3
1.6	WHO regional European diet	0.5	Lettuce	0.2	Tomatoes	0.1	Milk and cream,	0.2
1.6	UK Infant	1.0	Milk and cream,	0.1	Sugar beet (root)	0.1	Cauliflower	0.3
1.5	ES adult	0.7	Lettuce	0.2	Wine grapes	0.2	Tomatoes	0.2
1.4	ES child	0.6	Lettuce	0.3	Milk and cream,	0.2	Tomatoes	0.3
1.4	UK Toddler	0.5	Milk and cream,	0.3	Sugar beet (root)	0.1	Tomatoes	0.5
1.4	WHO Cluster diet F	0.4	Lettuce	0.3	Wine grapes	0.1	Tomatoes	0.2
1.4	NL general	0.3	Wine grapes	0.2	Milk and cream,	0.2	Lettuce	0.2
1.3	FR infant	0.6	Milk and cream,	0.1	Broccoli	0.1	Leek	0.2
1.3	DK child	0.3	Milk and cream,	0.2	Lettuce	0.1	Cucumbers	0.3
1.2	UK vegetarian	0.4	Wine grapes	0.2	Lettuce	0.1	Tomatoes	0.1
1.1	DK adult	0.7	Wine grapes	0.1	Milk and cream,	0.1	Tomatoes	0.1
1.1	UK Adult	0.5	Wine grapes	0.2	Lettuce	0.1	Tomatoes	0.1
1.1	WHO cluster diet D	0.2	Tomatoes	0.2	Wine grapes	0.1	Milk and cream,	0.2
1.0	IT adult	0.5	Lettuce	0.2	Tomatoes	0.1	Table grapes	0.1
1.0	IT kids/toddler	0.4	Lettuce	0.3	Tomatoes	0.1	Wheat	0.2
1.0	SE general population 90th percentile	0.3	Milk and cream,	0.2	Tomatoes	0.1	Potatoes	0.2
0.6	FI adult	0.1	Wine grapes	0.1	Milk and cream,	0.1	Lettuce	0.1
0.6	PL general population	0.2	Tomatoes	0.2	Table grapes	0.0	Cauliflower	0.1
0.5	LT adult	0.1	Tomatoes	0.1	Milk and cream,	0.1	Lettuce	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 - 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)
	31.5	Kale	0.84 / -	22.5	Kale	0.84 / -	9.5	Kale	0.84 / -	7.1	Kale	0.84 / -
	12.8	Onions	0.58 / -	9.2	Onions	0.58 / -	4.8	Onions	0.58 / -	3.4	Onions	0.58 / -
	1.7	Potatoes	0.02 / -	1.2	Potatoes	0.02 / -	0.3	Potatoes	0.02 / -	0.3	Potatoes	0.02 / -
	0.4	Radishes	0.03 / -	0.3	Radishes	0.03 / -	0.2	Radishes	0.03 / -	0.1	Radishes	0.03 / -

M-01 (2,6-dichlorobenzamide)

Status of the active substance:	**N/A**	Code no.	
LOQ (mg/kg bw):	0.01	proposed LOQ:	0.01
Toxicological end points			
ADI (mg/kg bw/day):	**0.05**	ARfD (mg/kg bw):	**0.3**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2009**	Year of evaluation:	**2009**

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI
minimum - maximum
0

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	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)
0.3	WHO Cluster diet B	0.1	Wine grapes	0.1	Tomatoes	0.1	Potatoes	0.2
0.2	PT General population	0.1	Potatoes	0.1	Wine grapes	0.0	Tomatoes	0.1
0.2	FR all population	0.2	Wine grapes	0.0	Potatoes	0.0	Tomatoes	0.1
0.2	NL child	0.1	Potatoes	0.0	Table grapes	0.0	Tomatoes	0.2
0.2	WHO cluster diet E	0.1	Potatoes	0.1	Wine grapes	0.0	Tomatoes	0.1
0.2	WHO cluster diet D	0.1	Potatoes	0.0	Tomatoes	0.0	Wine grapes	0.2
0.2	WHO regional European diet	0.1	Potatoes	0.0	Tomatoes	0.0	Lettuce	0.1
0.2	IE adult	0.1	Wine grapes	0.0	Potatoes	0.0	Melons	0.1
0.2	FR toddler	0.1	Potatoes	0.0	Tomatoes	0.0	Leek	0.2
0.2	DE child	0.1	Potatoes	0.1	Table grapes	0.0	Tomatoes	0.1
0.2	SE general population 90th percentile	0.1	Potatoes	0.0	Tomatoes	0.0	Head cabbage	0.1
0.1	WHO Cluster diet F	0.1	Potatoes	0.0	Wine grapes	0.0	Tomatoes	0.1
0.1	NL general	0.1	Potatoes	0.0	Wine grapes	0.0	Table grapes	0.1
0.1	DK child	0.0	Potatoes	0.0	Cucumbers	0.0	Tomatoes	0.1
0.1	FR infant	0.1	Potatoes	0.0	Courgettes	0.0	Leek	0.1
0.1	PL general population	0.1	Potatoes	0.0	Tomatoes	0.0	Table grapes	0.1
0.1	DK adult	0.1	Wine grapes	0.0	Potatoes	0.0	Tomatoes	0.1
0.1	UK Toddler	0.1	Potatoes	0.0	Tomatoes	0.0	Table grapes	0.1
0.1	UK vegetarian	0.0	Wine grapes	0.0	Potatoes	0.0	Tomatoes	0.1
0.1	UK Adult	0.0	Wine grapes	0.0	Potatoes	0.0	Tomatoes	0.0
0.1	LT adult	0.1	Potatoes	0.0	Tomatoes	0.0	Head cabbage	0.1
0.1	ES child	0.0	Potatoes	0.0	Tomatoes	0.0	Lettuce	0.1
0.1	UK Infant	0.1	Potatoes	0.0	Tomatoes	0.0	Cauliflower	0.1
0.1	ES adult	0.0	Potatoes	0.0	Lettuce	0.0	Wine grapes	0.1
0.1	IT kids/toddler	0.0	Tomatoes	0.0	Potatoes	0.0	Lettuce	0.1
0.1	IT adult	0.0	Tomatoes	0.0	Lettuce	0.0	Potatoes	0.1
0.1	FI adult	0.0	Potatoes	0.0	Wine grapes	0.0	Tomatoes	0.0

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.

A long-term intake of residues of M-01 (2,6-dichlorobenzamide) is unlikely to present a public health concern.

	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)
	0.5	Onions	0.04 / -	0.4	Onions	0.04 / -	0.2	Onions	0.04 / -	0.1	Onions	0.04 / -
	0.5	Potatoes	0.01 / -	0.4	Potatoes	0.01 / -	0.1	Kale	0.02 / -	0.1	Kale	0.02 / -
	0.5	Kale	0.02 / -	0.3	Kale	0.02 / -	0.1	Potatoes	0.01 / -	0.1	Potatoes	0.01 / -
	0.1	Radishes	0.01 / -	0.1	Radishes	0.01 / -	0.0	Radishes	0.01 / -	0.0	Radishes	0.01 / -

Appendix C. EXISTING EU MAXIMUM RESIDUE LIMITS (MRLs)

(Pesticides – Web Version – EU MRLs (File created on 13/01/2012 09:23)

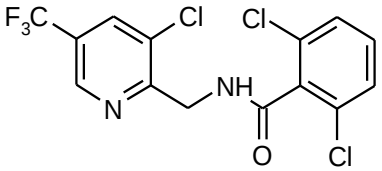
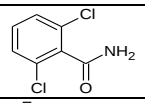
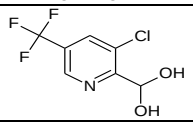
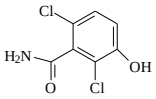
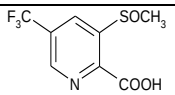
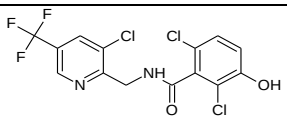
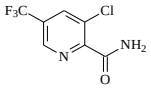
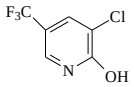
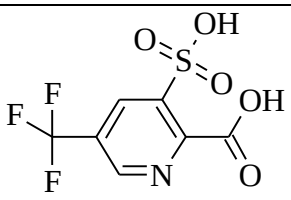
Code number	**Groups and examples of individual products to which the MRLs apply**	Fluopicolide
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,01*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,01*
110020	Oranges (Bergamot, bitter orange, chinotto 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*
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, Brazilean cherry (grumichama), Surinam cherry)	0,01*
161990	Others	0,01*
162000	(b) Inedible peel, small	0,01*
162010	Kiwi	0,01*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,01*
162030	Passion fruit	0,01*
162040	Prickly pear (cactus fruit)	0,01*
162050	Star apple	0,01*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,01*
162990	Others	0,01*
163000	(c) Inedible peel, large	0,01*
163010	Avocados	0,01*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,01*
163030	Mangoes	0,01*
163040	Papaya	0,01*
163050	Pomegranate	0,01*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , 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 (Scorzonera, Spanish salsify (Spanish oysterplant))	0,01*
213100	Swedes	0,01*
213110	Turnips	0,01*
213990	Others	0,01*
220000	(ii) Bulb vegetables	0,01*
220010	Garlic	0,01*
220020	Onions (Silverskin onions)	1
220030	Shallots	0,01*
220040	Spring onions (Welsh onion and similar varieties)	10
220990	Others	0,01*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	1
231020	Peppers (Chilli peppers)	1
231030	Aubergines (egg plants) (Pepino)	1

231040	Okra, lady's fingers	1
231990	Others	1
232000	(b) Cucurbits - edible peel	0,5
232010	Cucumbers	0,5
232020	Gherkins	0,5
232030	Courgettes (Summer squash, marrow (patisson))	0,5
232990	Others	0,5
233000	(c) Cucurbits-inedible peel	0,5
233010	Melons (Kiwano)	0,5
233020	Pumpkins (Winter squash)	0,5
233030	Watermelons	0,5
233990	Others	0,5
234000	(d) Sweet corn	0,01*
239000	(e) Other fruiting vegetables	0,01*
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	2
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	2
241020	Cauliflower	2
241990	Others	2
242000	(b) Head brassica	
242010	Brussels sprouts	0,2
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	0,03
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	
251010	Lamb´s lettuce (Italian cornsalad)	0,01*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	8
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,01*
251040	Cress	0,01*
251050	Land cress	0,01*
251060	Rocket, Rucola (Wild rocket)	0,01*
251070	Red mustard	0,01*
251080	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, turnip greens (turnip tops))	0,01*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth)	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*
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 cisely 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	1,5
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, turnip 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*
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 Camellia sinensis)	0,02*
	(ii) Coffee beans	
620000	(iii) Herbal infusions (dried)	0,02*
630000	(a) Flowers	0,02*
631000	Camomille flowers	0,02*
631010	Hybiscus flowers	0,02*
631020	Rose petals	0,02*
631030	Jasmine flowers	0,02*
631040	Lime (linden)	0,02*
631050	Others	0,02*
631990	(b) Leaves	0,02*
632000	Strawberry leaves	0,02*
632010	Rooibos leaves	0,02*
632020	Maté	0,02*
632030	Others	0,02*
632990	(c) Roots	0,02*
633000	Valerian root	0,02*
633010	Ginseng root	0,02*
633020	Others	0,02*
633990	(d) Other herbal infusions	0,02*
639000	(iv) Cocoa (fermented beans)	0,02*
640000	(v) Carob (st johns bread)	0,02*
650000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,02*
700000	8. SPICES	0,02*
800000	(i) Seeds	0,02*
810000	Anise	0,02*
810010	Black caraway	0,02*
810020	Celery seed (Lovage seed)	0,02*
810030	Coriander seed	0,02*
810040	Cumin seed	0,02*
810050	Dill seed	0,02*
810060	Fennel seed	0,02*
810070	Fenugreek	0,02*
810080	Nutmeg	0,02*
810090	Others	0,02*
810990	(ii) Fruits and berries	0,02*
820000	Allspice	0,02*
820010	Anise pepper (Japan pepper)	0,02*
820020	Caraway	0,02*
820030	Cardamom	0,02*
820040	Juniper berries	0,02*
820050	Pepper, black and white (Long pepper, pink pepper)	0,02*
820060	Vanilla pods	0,02*
820070	Tamarind	0,02*
820080	Others	0,02*
820990	(iii) Bark	0,02*
830000	Cinnamon (Cassia)	0,02*
830010	Others	0,02*
830990	(iv) Roots or rhizome	0,02*
840000	Liquorice	0,02*
840010	Ginger	0,02*
840020	Turmeric (Curcuma)	0,02*
840030	Horseradish	0,02*
840040	Others	0,02*
840990	(v) Buds	0,02*
850000	Cloves	0,02*
850010	Capers	0,02*
850020	Others	0,02*
850990	(vi) Flower stigma	0,02*
860000	Saffron	0,02*
860010	Others	0,02*
860990	(vii) Aril	0,02*
870000	Mace	0,02*
870010	Others	0,02*
870990	9. SUGAR PLANTS	0,02*
900000	Sugar beet (root)	0,01*
900010	Sugar cane	0,01*
900020	Chicory roots	0,01*
900030	Others	0,01*
900990	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	0,01*
1000000	(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	
1010000	(a) Swine	0,01*
1011000	Meat	0,01*
1011010	Fat free of lean meat	0,01*
1011020	Liver	0,01*
1011030	Kidney	0,01*
1011040	Edible offal	0,01*
1011050	Others	0,01*
1011990	(b) Bovine	0,01*
1012000	Meat	0,01*
1012010	Fat	0,01*
1012020	Liver	0,01*
1012030	Kidney	0,01*
1012040	Edible offal	0,01*
1012050	Others	0,01*
1012990	(c) Sheep	0,01*
1013000	Meat	0,01*
1013010	Fat	0,01*
1013020	Liver	0,01*
1013030	Kidney	0,01*
1013040	Edible offal	0,01*
1013050	Others	0,01*
1013990	(d) Goat	0,01*
1014000	Meat	0,01*
1014010	Fat	0,01*
1014020	Liver	0,01*
1014030	Kidney	0,01*
1014040	Edible offal	0,01*
1014050	Others	0,01*
1014990	(e) Horses, asses, mules or hinnies	0,01*
1015000	Meat	0,01*
1015010	Fat	0,01*
1015020	Liver	0,01*
1015030	Kidney	0,01*
1015040	Edible offal	0,01*
1015050	Others	0,01*
1015990	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,01*
1016000	Meat	0,01*
1016010	Fat	0,01*
1016020	Liver	0,01*
1016030	Kidney	0,01*
1016040	Edible offal	0,01*
1016050	Others	0,01*
1016990	(g) Other farm animals (Rabbit, Kangaroo)	0,01*
1017000	Meat	0,01*
1017010	Fat	0,01*
1017020	Liver	0,01*
1017030	Kidney	0,01*
1017040	Edible offal	0,01*
1017050	Others	0,01*
1017990	(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*
1020000	Cattle	0,02
1020010	Sheep	0,02
1020020	Goat	0,02
1020030	Horse	0,02
1020040	Others	0,02
1020990	(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
1030000	Chicken	0,01*
1030010	Duck	0,01*
1030020	Goose	0,01*
1030030	Quail	0,01*
1030040	Others	0,01*
1030990	(iv) Honey (Royal jelly, pollen)	0,01*
1040000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,01*
1050000	(vi) Snails	0,01*
1060000	(vii) Other terrestrial animal products	0,01*

1070000	[a] MRL value as proposed by EFSA in its reasoned opinion(s) (EFSA,YYYY, YYYY) and voted at the SCFCAH on *dd mm yyyy*. SANCO NNNN/YYYY. Not legally enforced by *dd mm yyyy*.	0,01*

Appendix D. LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Common name	IUPAC name	Structure
Fluopicolide	2,6-dichloro-*N*-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]benzamide	
M-01 or BAM	2,6-dichlorobenzamide	
M-02	3-chloro-5-(trifluoromethyl)pyridine-2-carboxylic acid	
M-04	2,6-dichloro-3-hydroxy-benzamide	
M-05	3-methylsulfinyl-5-trifluoro-methylpyridine-2-carboxylic acid	
M-06	2,6-dichloro-*N*-{[3-chloro-5-(trifluoromethyl) pyridin-2-yl]methyl}-3-hydroxybenzamide	
M-08	3-chloro-5-trifluoromethyl pyridine-2-carboxamide	
M-09	3-chloro-2-hydroxy-5-trifluoromethylpyridine	
M-10	3-sulfo-5-(trifluoromethyl) pyridine-2-carboxylic acid	

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CCPR	Codex Committee on Pesticide Residues
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DM	dry matter
DT_{90f}	period required for 90% dissipation (field method)
DT_{90lab}	period required for 90% dissipation (laboratory method)
EC	European Community
EFSA	European Food Safety Authority
EL	Greece
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	Highest residue
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	kilogram
L	litre

LC	liquid chromatography
LOQ	limit of quantification (determination)
MRL	maximum residue limit
MS	Member States
MS/MS	tandem mass spectrometry
NEU	northern European Union
OECD	Organization for Economic Co-operation and Development
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RMS	rapporteur Member State
SC	suspension concentrate
SEU	Southern European Union
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UK	United Kingdom
WHO	World Health Organisation