

ADOPTED: 18 August 2015

PUBLISHED: 2 September 2015

doi:10.2903/j.efsa.2015.4217

## **Modification of the existing maximum residue level for fluopicolide in valerian**

### **European Food Safety Authority (EFSA)**

#### **Abstract**

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS), the Netherlands, received an application from Bayer Environmental S.A. for the active substance fluopicolide in valerian. In order to accommodate the residues occurring in valerian roots grown in rotation with potato crops treated with fluopicolide, the Netherlands proposed to raise the existing MRL for valerian, from the limit of quantification to 5 mg/kg. The Netherlands drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA.

From the use on potatoes where valerian is then planted as a following crop, adequate information was provided to propose raising the MRL in valerian to 7 mg/kg. Adequate analytical enforcement methods are available to control the residues of fluopicolide in valerian roots. Based on the risk assessment results, EFSA concludes that the practice of growing valerian following potato crops treated with fluopicolide will not result in consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

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**Keywords:** fluopicolide, potatoes, valerian, MRL application, consumer risk assessment

**Requestor:** European Commission

**Question number:** EFSA-Q-2015-00281

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**Suggested citation:** EFSA (European Food Safety Authority), 2015. Reasoned opinion on the modification of the MRL for fluopicolide in valerian. EFSA Journal 2015;13(9):4217, 24 pp. doi:10.2903/j.efsa.2015.4217

**ISSN:** 1831-4732

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## Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS) the Netherlands, received an application from Bayer Environmental S.A. for the active substance fluopicolide in valerian. In order to accommodate for the uses of fluopicolide, the Netherlands proposed to raise the existing MRL from the limit of quantification (LOQ) to the proposed MRL of 5 mg/kg. The Netherlands drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 8 May 2015.

EFSA bases its assessment on the evaluation report submitted by the EMS, the draft assessment report (DAR) (and its addenda) prepared under Council Directive 91/414/EEC, the Commission review report on fluopicolide, the conclusions on the peer review of the pesticide risk assessment of the active substance fluopicolide, the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) Evaluation report as well as the conclusions from previous EFSA opinions on fluopicolide.

The toxicological profile of fluopicolide and its transformation product 2,6-dichlorobenzamide (BAM or M-01) were assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive acceptable daily intakes (ADI) of 0.08 mg/kg bw per day for fluopicolide and 0.05 mg/kg body weight (bw) per day for BAM (M-01). The data were also sufficient to derive Acute reference doses (ARfD) of 0.18 mg/kg bw and 0.3 mg/kg bw for fluopicolide and BAM (M01), respectively.

The metabolism of fluopicolide in primary crops was investigated in the fruit, root and leafy crop groups. The residue definitions were concluded as fluopicolide for enforcement and as fluopicolide and 2,6-dichlorobenzamide (BAM, M-01) reported separately for risk assessment. Adequate analytical enforcement methods are available to monitor the residues of fluopicolide in valerian roots at the validated LOQ of 0.01 mg/kg.

Studies investigating the nature of fluopicolide residues under standard hydrolysis conditions were assessed during the peer review and showed the active substance to be hydrolytically stable. Therefore for processed commodities the same residue definition as for raw commodities (RAC) is applicable.

The occurrence of fluopicolide residues in rotational crops was investigated in the framework of the peer review. Based on the available information on the nature and magnitude of residues, this reasoned opinion concluded that significant residues are likely to occur in rotated root crops, when fluopicolide is used according to the proposed good agricultural practice (GAP) on potatoes, which the EMS proposed would represent the critical primary crop GAP. It was concluded that the residue definition for assessment in following root crops should be the same as that in primary crops (i.e. fluopicolide for enforcement and fluopicolide and 2,6-dichlorobenzamide (BAM, M-01) reported separately for risk assessment).

Rotational field studies on residues in fresh valerian roots following applications of fluopicolide to potato crops as primary crop were provided. As the MRL for valerian according to the crop definition in Annex I of Regulation (EC) No 396/2005 specifies that residues are for the dried product (root), a dehydration factor of 8 was considered to estimate the residues in dried roots from the levels measured in fresh roots. EFSA concludes that the submitted data are sufficient to derive an MRL proposal of 7 mg/kg in valerian (dried).

Residues of fluopicolide in commodities of animal origin were not assessed, since valerian roots are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRiMo). Regarding fluopicolide, a long-term consumer intake concern was not identified for any of the European diets. The total calculated chronic intake accounted for up to 3 % of the ADI (WHO Cluster B). An acute consumer risk was not identified in relation to the MRL proposal for valerian. The highest acute consumer exposure was calculated to be 2.5 % of the ARfD (UK, vegetarian).

Regarding BAM (M-01), a long-term consumer intake concern was not identified for any of the European diets. The contribution of residues in valerian roots to the total consumer exposure accounted for a maximum of 0.1% of the ADI (Irish, adult). An acute consumer risk was not identified in relation to the MRL proposal for valerian. The highest acute consumer exposure was calculated to be 0.8 % of the ARfD (UK, vegetarian).

EFSA concludes that the use of fluopicolide on potatoes preceding a valerian crop will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a concern for public health.

EFSA proposes to amend the existing MRL as reported in the summary table below.

Code <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
<b>Enforcement residue definition:</b> fluopicolide				
0633010	Valerian	0.02*	7	Supported by NEU rotational crop field studies, following use of fluopicolide on potatoes as the primary crop.

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005

(\*): indicates that the MRL is set at the limit of analytical quantification (LOQ)

## Table of contents

Abstract.....	1
Summary.....	3
Background.....	6
The active substance and its use pattern .....	6
Assessment.....	7
1. Method of analysis .....	8
1.1. Methods for enforcement of residues in food of plant origin.....	8
1.2. Methods for enforcement of residues in food of animal origin .....	8
2. Mammalian toxicology .....	8
3. Residues.....	8
3.1. Nature and magnitude of residues in plant .....	8
3.1.1. Primary crops .....	8
3.1.2. Rotational crops.....	9
3.2. Nature and magnitude of residues in livestock .....	12
4. Consumer risk assessment.....	12
Conclusions and recommendations .....	13
References.....	14
Abbreviations .....	16
Appendix A – Good Agricultural Practice (GAPs).....	19
Appendix B – Pesticide Residue Intake Model (PRIMo) .....	20
Appendix C – Used compound codes.....	24

## Background

Regulation (EC) No 396/2005<sup>1</sup> establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at European Union (EU) level. Article 6 of the Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC,<sup>2</sup> repealed by Regulation (EC) No 1107/2009,<sup>3</sup> shall submit to a Member State, when appropriate, an application to modify a MRL in accordance with the provisions of Article 7 of the Regulation.

The Netherlands, hereafter referred to as the evaluating Member State (EMS), received an application from the company Bayer Environmental S.A.<sup>4</sup> to modify the existing MRL for the active substance fluopicolide in valerian to account for residues that will occur consequent to treating a preceding potato crop. This application was notified to the European Commission and the European Food Safety Authority (EFSA) and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation. After completion, the evaluation report was submitted to the European Commission and to EFSA on 8 May 2015.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2015-00281 and the following subject:

*Fluopicolide - Modification of existing MRLs in valerian (dried)*

The Netherlands proposed to raise the existing MRL of fluopicolide in valerian from the limit of quantification to 5 mg/kg.

EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

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

In accordance with Article 11 of the 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 if more detailed evaluations need to be carried out) from the date of receipt of the application. If EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

## The active substance and its use pattern

Fluopicolide is the ISO common name for 2,6-dichloro-*N*-[3-chloro-5-(trifluoromethyl)-2-pyridyl methyl]benzamide (IUPAC). The chemical structures of the active substance and its main metabolites are reported in appendix C. Fluopicolide has been approved for use as a fungicide.

Fluopicolide was evaluated in the framework of Directive 91/414/EEC with the United Kingdom designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Directive 2010/15/EU<sup>5</sup> which entered into force on 1 June 2010, for use only as a fungicide. In accordance with Commission Implementing Regulation (EU) No 540/2011<sup>6</sup> fluopicolide is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC.

<sup>1</sup> Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1–16.

<sup>2</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1–32.

<sup>3</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

<sup>4</sup> Bayer CropScience, Rue Jean Marie Leclair 16, 690098, Lyon, France

<sup>5</sup> Commission Directive 2010/15/EU of 8 March 2010 amending Council Directive 91/414/EEC to include fluopicolide as active substance, OJ L 58, 9.3.2010, p. 5-7

<sup>6</sup> Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.06.2011, p. 1–186.

The representative uses evaluated in the peer review were foliar applications on potatoes and vine. The draft assessment report (DAR) has been peer reviewed by EFSA (EFSA, 2009a).

The EU MRLs for fluopicolide are established in Annex IIIA of Regulation (EC) No 396/2005. Since the entry into force of this regulation, EFSA has issued several reasoned opinions on the modification of MRLs for fluopicolide, proposals from which have been considered in the EU legislation. The MRL changes that were reported in the EU legislation since the entry into force of the regulation are summarised in Table 1.

**Table 1:** Overview of the MRL changes since the entry into force of Regulation (EC) No 396/2005

Procedure <sup>(a)</sup>	Considered by Regulation	Remarks
Art. 10 (EFSA, 2009)	(EC) No 1050/2009	Import tolerance on peppers
Art. 10 (EFSA, 2011)	(EU) No 520/2011	Modification of MRLs in various crops (onions, tomatoes, cucurbits-edible peel, flowering brassica and Brussels sprouts)
Art. 10 (EFSA, 2012a)	(EU) No 592/2013	Modification of MRLs in potatoes, radish, kale and onions
Art. 10 (EFSA, 2012b)	(EU) No 251/2013	Modification of MRLs in carrots, radishes, sugar beet, lettuce and other salad plants including brassicaceae, herbs and spinach and similar leaves
Art. 10 (EFSA, 2013c)	(EU) No 737/2014	Modification of MRLs in hops and the group of tuber and root vegetables
Art. 10 (EFSA, 2014)	Not yet included in a regulation	Modification of the MRL for Chinese cabbage. Codex Alimentarius has established a maximum residue limit (CXL)

(a): Art. 10: Assessment of MRL application according to Article 6 to 10 of Regulation (EC) No 396/2005

Codex Alimentarius has established maximum residue limits (CXL) for a wide range of commodities, but a CXL has not been set for valerian.

The details of the authorised GAP for fluopicolide on potatoes, considered the critical use by the EMS that may result in residues in valerian roots when valerian is planted as a following crop, is given in Appendix A.

## Assessment

EFSA bases its assessment on the evaluation report submitted by the EMS (the Netherlands, 2015), the DAR (and its addenda) prepared under Directive 91/414/EEC (the United Kingdom, 2005, 2008), the Commission review report on fluopicolide (European Commission, 2010a), the conclusion on the peer review of the pesticide risk assessment of the active substance fluopicolide (EFSA, 2009a), the JMPR Evaluation reports (FAO 2010, 2011) as well as the conclusions from previous EFSA opinions on fluopicolide (EFSA, 2009b, 2011, 2012a, b, 2013 and 2014). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011<sup>7</sup> and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a–g, 2000, 2010b, c, 2011; OECD, 2011).

<sup>7</sup> Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127–175.

## 1. Method of analysis

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

Analytical methods for the determination of fluopicolide residues in plant commodities were assessed during the peer review under Directive 91/414/EEC (EFSA, 2009a). Several analytical methods for the determination of fluopicolide residues in high water, high acid and dry commodities using GC-MS and HPLC-MS/MS detection at limit of quantifications (LOQs) from 0.01 mg/kg for high water content commodities to 0.1 mg/kg for acidic commodities are available and independent laboratory validation (ILV) was submitted. There is also an analytical method for the determination of the metabolite 2,6-dichlorobenzamide (BAM or M01) available (EFSA, 2009b, 2011, 2013).

The multi-residue Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) analytical method described in the European Standard EN 15662:2008 is also applicable. The HPLC-MS/MS method analyses fluopicolide residues in high water, high acid, high oil and dry content matrices at or above the LOQ of 0.01 mg/kg (CEN, 2008).

Since the commodity under consideration belongs to the group of dry commodities, EFSA concludes that sufficiently validated analytical methods are available for enforcing the proposed MRL for fluopicolide in valerian.

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

Analytical methods for the determination of residues in food of animal origin are not assessed in the current application, since valerian roots are normally not fed to livestock.

## 2. Mammalian toxicology

The toxicological profile of the active substance fluopicolide was assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2009a). For the metabolite 2,6-dichlorobenzamide (BAM or M01), which is a metabolite common to the active substance dichlobenil (EFSA, 2010), specific toxicological reference values were also assessed (EFSA, 2009a). The data were sufficient to derive the toxicological reference values compiled in Table 2.

**Table 2:** Overview of the toxicological reference values

	Source	Year	Value	Study	Safety factor
<b>fluopicolide</b>					
ADI	EFSA	2009	0.08 mg/kg bw per day	Mouse, 18-month dietary study	100
ARfD	EFSA	2009	0.18 mg/kg bw	Rat, 28-day dietary study	100
<b>Metabolite: 2,6-dichlorobenzamide (BAM or M-01)</b>					
ADI	EFSA	2009	0.05 mg/kg bw per day	Rat and dog, 2-year studies	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 evaluated in the framework of the peer review under Directive 91/414/EEC (EFSA, 2009a) in the fruit, root and leafy crop groups, where it was concluded that the enforcement residue definition would be fluopicolide and that for risk assessment would be fluopicolide and 2,6-dichlorobenzamide (BAM, M-01) separately. The nature of residues in primary crops is not considered further under this application as this is not relevant for characterising the nature of residues in an untreated valerian crop that is planted following the harvest of the treated crop potatoes. Regarding the nature of residues in such a valerian crop, see section 3.1.2.1.

### 3.1.1.2. Magnitude of residues

The determination of residue levels in primary crops is not relevant for this application as the MRL is only requested for the crop valerian as a following crop consequent to applications of fluopicolide to the primary crop potatoes.

### 3.1.1.3. Effect of industrial processing and/or household preparation

Standard hydrolysis studies simulating the effect on the nature of fluopicolide residues under processing conditions representative of pasteurisation, boiling and sterilisation were assessed in the conclusion of the peer review (EFSA, 2009a). It was concluded that fluopicolide is hydrolytically stable under the representative conditions. However information on the BAM (M-01) metabolite is not available. Thus, for processed commodities, the same monitoring residue definition as for raw agricultural commodities (RAC) would appear applicable.

Studies investigating the effect of processing on the magnitude of fluopicolide residues were not provided and are not requested, since the contribution of the fluopicolide residues in valerian roots to the consumer intake is far below 10% of the ADI (European Commission, 1997d)

Because the MRL for valerian according to the crop definition in Annex I of Regulation (EC) No 396/2005 (herbal infusions group No 0630000) specifies that residues are for the dried product (root), residue levels determined in fresh roots need a drying factor to be applied in order to propose an MRL. Studies relating to this specifically for valerian root were not provided to support of this MRL application.

Since specific data on valerian roots were not available, the applicant made reference to information in the United States Department of Agriculture (USDA) national nutrient database (USDA, 2013) on the moisture content of fresh carrot roots, to propose a drying factor value of 8 for valerian roots. This database indicates that the water content in raw carrots is 88.3% w/w. Comparable European data sources report similar carrot moisture contents (85.7–92.3%, average 89.4% (ANSES, 2012); 90% (RIVM, 2013) and 88.8% (McCance and Widdowson's, 2015). Making the assumption that the water content in dehydrated valerian root is only 4% w/w and that raw fresh valerian root is 11.7% w/w dry matter (as identified by USDA for carrot), the concentration factor of 8 is calculated ( $100/(1.04 \times 11.7)$ ). EFSA agrees with this approach and therefore, a factor of 8 was considered in this MRL application to estimate the residue levels in dried valerian root.

## 3.1.2. Rotational crops

Studies on the nature and magnitude of fluopicolide residues in rotational crops were assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2009a). Based on the information available in that assessment it has to be concluded that the residue definitions set for primary crops are also applicable to rotational crops and that significant residues are expected in rotational root crops when the active substance is applied on primary (preceding) crops up to a total annual dose rate of 400 g/ha. (It is noted that positive MRLs have been set for the whole crop group tuber and root vegetables in Regulation (EU) No 737/2014 consequent to the MRL proposals of the opinion, EFSA 2013c, consequent to fluopicolide applications made directly to the root crops in this group).

### 3.1.2.1. Nature of residues

The rotational crop metabolism information submitted in the framework of the peer review under Directive 91/414/EEC (EFSA, 2009a) is outlined below. The overview of the study designs is presented in Table 3.

**Table 3:** Overview of the available confined rotational crop studies

Crop group	Rotational crops	Application			Remarks
		Method	Rate (g/ha)	PBI <sup>(a)</sup> (days)	
Leafy crops	Lettuce	Bare soil	400	29, 133, 365	400 g/ha is the seasonal total application rate to potatoes peer reviewed in EFSA, 2009a. Either [ <sup>14</sup> C] phenyl and pyridinyl ring labelled fluopicolide was applied to test plots
Root crops	radish	Bare soil	400	29, 133, 365	
Cereals	Wheat	Bare soil	400	29, 133, 365	

(a): Plant back interval (interval between the application of the a.s. and the sowing/planting of the rotational crop)

Translocation of radioactive residues was observed. In crops planted after 29 days of ageing total radioactive residue (TRR) were max. 3 mg/kg in consumable parts and max. 14 mg/kg in crop parts used for animal feed. Due to the relatively high stability of fluopicolide in soil, TRR found in crops after 365 days of ageing were max. 0.6 mg/kg in consumable parts and max. 2 mg/kg in crop parts used for animal feed (all parent equivalents).

Metabolism was found to be similar, but more extensive than seen in primary crops. In lettuce, radish tops and radish roots fluopicolide, BAM (M-01) and M-02 were identified as the main components of the radioactive residues. At the 29 day plant back interval (PBI) in radish roots BAM (M-01) accounted for 0.06 mg/kg parent equivalents, M-02 for 0.04 mg/kg parent equivalents with fluopicolide accounting for 0.05-0.07 mg/kg. At 133 days PBI these values were 0.01, <0.01 and <0.01-0.01 respectively. At 365 days PBI these values were 0.02, <0.01 and <0.01-0.02 respectively. The main components of radioactive residues in wheat grain, forage and straw were fluopicolide, M-01, M-02, M-04 and M-05.

From the metabolites identified in radish as a succeeding crop EFSA considers that it is appropriate to set the same residue definition for risk assessment in root crops when grown as succeeding crops as that set for primary crops, which is fluopicolide and 2,6-dichlorobenzamide (BAM, M-01) reported separately.

### 3.1.2.2. Magnitude of residues

Studies conducted in a total of 11 different sites in the Netherlands were submitted in the framework of this MRL application and assessed by the EMS (the Netherlands, 2015). Valerian root samples were collected in fields, where valerian was grown the following year or two years later, in rotation with a potato crop treated with fluopicolide at a total seasonal application rate of 324 to 400 g/ha (*ca.* 1 N annual rate). The field phase of these studies was not conducted under Good Laboratory Practice (GLP). However, the study design was reported in sufficient detail to conclude that the data provided were scientifically appropriate to support a proposal to set a MRL in a following valerian crop.

Valerian root samples harvested at maturity were only analysed for fluopicolide. Information was not provided on the residue levels of the 2,6-dichlorobenzamide (BAM, M-01) metabolite. In the radiolabeled rotational crop studies, fluopicolide and BAM (M-01) were observed at similar levels at the different PBI in radish roots, grown as succeeding crops (see section 3.1.2.1). Consequently it was considered that on a molar basis, a factor of 1 is the best estimate possible for BAM (M-01) residues from the fluopicolide residues estimated for dried valerian roots, from the available analysed fresh weight values. Considering the differences in their respective molecular weights<sup>8</sup> a factor of 0.5 was proposed by EFSA to derive the BAM residue levels from the measured fluopicolide residue levels. This approach was only accepted for use because of the insignificant contribution of valerian root to the overall consumer intakes (see section 4). Had contribution to consumer intakes been higher, residue investigations for BAM (M-01) would have been essential to support a satisfactory risk assessment.

The results of the available residue investigations, the related risk assessment input values (highest residue, median residue) and the MRL proposal are summarised in Table 4.

EFSA concludes that the data are sufficient to derive the following MRL proposals:

- 7 mg/kg valerian dried, in northern Europe (NEU)

<sup>8</sup> Molecular weight; fluopicolide 383 BAM: 190

**Table 4:** Overview of the available residues data

Crop (GAPs)	Region/ Indoor <sup>(a)</sup>	Residue levels observed in the supervised residue trials <sup>(b)</sup> (mg/kg)	Recommendations/comments <sup>(c)</sup>	MRL proposal (mg/kg)	HR <sup>(d)</sup> (mg/kg)	STMR <sup>(e)</sup> (mg/kg)
<b>Valerian</b>	NEU	Fresh roots: 2x 0.04, <u>0.05</u> , 0.08, <u>0.09</u> , 0.10, <u>0.14</u> , 0.18, 0.19, <u>0.38</u> , 0.62  Dried roots: 2x 0.32, <u>0.4</u> , 0.64, <u>0.72</u> , 0.80, <u>1.12</u> , 1.44, 1.52, <u>3.04</u> , 4.96  Residues of 2,6-dichlorobenzamide (BAM, M-01) were not measured.	Valerian grown in rotation to a potato crop (following year or two years later) where fluopicolide had been applied at annual total doses of 324 to 400 g/ha ( <i>ca.</i> 1 N seasonal rate)  Residue levels were determined in fresh roots and the residue levels in dried roots were calculated using a factor from fresh to dried roots of 8 (see section 3.1.1.3) MRL <sub>OECD</sub> : (7.07/7)	7	4.96	0.80

HR: highest residue; NEU: northern Europe; STMR: supervised trials median residue

(a): NEU: Outdoor monitoring conducted in northern Europe

(b): Individual residue levels considered for MRL calculation are reported in ascending order,

Underlined values: samples taken from crops planted with a years gap after the harvest of the potatoes

(c): Any information/comment supporting the decision and OECD MRL calculation (unrounded/rounded values)

(d): HR: Highest residue level according to residue definition for monitoring.

(e): STMR: Median residue level according to residue definition for monitoring.

### 3.2. Nature and magnitude of residues in livestock

As valerian roots and their by-products are not normally fed to livestock, the nature and magnitude of fluopicolide residues in livestock is not assessed in the framework of this application (EC, 1996).

## 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<sup>9</sup> (EFSA, 2007). Note as PRIMo does not contain consumption data for dried valerian roots or for the whole subgroup herbal infusions from roots (0633000), their consumption was assumed to be that equivalent to that for dried black tea (0600010), which is expected to be an overestimation of real consumption patterns.

To calculate the chronic exposure, EFSA used the median residue value (STMR) derived from the residue studies conducted for valerian root in this MRL application and reported in Table 5 **Error! Reference source not found.** and an STMR value for Chinese cabbage from residues trials reported in a previous EFSA reasoned opinion (EFSA, 2014) that is not yet implemented in the EU legislation. STMR were also selected where available from trials on other commodities assessed under article 10 of Regulation (EC) No 396/2005 (see Table 4-1 in Reasoned Opinion on MRLs amendment (EFSA, 2013)). For the remaining commodities of plant and animal origin, the existing MRLs as established in Regulation (EU) No 737/2014 were used as input values.

The acute exposure assessment was performed only with regard to dried valerian root assuming the consumption of a large portion of the food item dried black tea as reported in the national food surveys and that this item contained residues at the highest residue level (HR) as observed in supervised field trials (see Table 4). A variability factor accounting for the inhomogeneous distribution was not used, in line with the usual parameterisation considered for dried black tea (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised in Table 5.

**Table 5:** Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
<b>Risk assessment residue definition:</b> fluopicolide				
Valerian (dried roots)	0.80	STMR	4.96	HR
Chinese cabbage	0.75	STMR (EFSA, 2014)	Acute risk assessment undertaken only with regard to the crop under consideration	
Commodities in a previous Art. 10 of Reg. 396/2005	STMR	See Table 4-1 in Reasoned Opinion (EFSA, 2013)		
Other plant and animal commodities	MRL	MRLs in Regulation (EU) 737/2014		
<b>Risk assessment residue definition:</b> 2,6-dichlorobenzamide (BAM, M-01)				
Valerian (dried roots)	0.40	STMR (STMR fluopicolide x 0.5)	2.48	HR (HR fluopicolide x 0.5)
Chinese cabbage	0.02	STMR (EFSA, 2014)	Acute risk assessment undertaken only with regard to the crop under consideration	
Commodities in a previous Art. 10 of Reg. 396/2005	STMR	See Table 4-1 in Reasoned Opinion (EFSA, 2013)		
Other plant and animal commodities	-	No data available		

The estimated exposure was then compared with the toxicological reference values derived for fluopicolide and its metabolite 2,6-dichlorobenzamide (BAM, M-01) (see Table 2). The results of the intake calculations are presented in Appendix B of this reasoned opinion (B1: fluopicolide, B2: 2,6-dichlorobenzamide (BAM, M-01)).

<sup>9</sup> 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).

#### a. Fluopicolide

A long-term consumer intake concern was not identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated chronic intake accounted for up to 3 % of the ADI (WHO Cluster diet B). The contribution of residues in valerian roots to the total consumer exposure accounted for a maximum of 0.13 % of the ADI (Irish, adult).

An acute consumer risk was not identified in relation to the MRL proposal for valerian. The highest acute consumer exposure was calculated to be 2.5 % of the ARfD (UK, vegetarian).

#### b. 2,6-dichlorobenzamide (BAM, M-01)

A long-term consumer intake concern was not identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated chronic intake accounted for less than 1 % of the ADI (UK, toddler). The contribution of residues in valerian roots to the total consumer exposure accounted for a maximum of 0.10 % of the ADI (Irish, adult).

An acute consumer risk was not identified in relation to the MRL proposal for valerian. The highest acute consumer exposure was calculated to be 0.8 % of the ARfD (UK, vegetarian).

EFSA concludes that the use of fluopicolide on potatoes preceding a valerian crop will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a concern for public health.

## Conclusions and recommendations

The submitted information was sufficient to derive the MRL proposals summarised in the table below:

Code <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
<b>Enforcement residue definition: fluopicolide</b>				
0633010	Valerian	0.02*	7	Supported by NEU rotational crop field trials, following use of fluopicolide on potatoes as the primary crop.

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005

(\*): indicates that the MRL is set at the limit of analytical quantification (LOQ)

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## Abbreviations

a.s.	active substance
ACD	Advanced Chemistry Development
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CCPR	Codex Committee on Pesticide Residues
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
CF	conversion factor for enforcement to risk assessment residue definition
cGAP	critical GAP
CIPAC	Collaborative International Pesticide Analytical Council
CIRCA	(EU) Communication & Information Resource Centre Administrator
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
CXL	Codex maximum residue limit (Codex MRL)
d	day
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT <sub>90</sub>	period required for 90 % dissipation (define method of estimation)
ECD	electron capture detector
EFSA	European Food Safety Authority
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
ESI	electrospray ionisation
EU	European Union
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organization of the United Nations
FID	flame ionisation detector
FLD	fluorescence detector
FPD	flame photometric detector
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly International Group of National Associations of Manufacturers of Agrochemical Products (GIFAP))

GLP	Good Laboratory Practice
GS	growth stage
HPLC	high performance liquid chromatography
HR	highest residue
IPCS	International Programme of Chemical Safety
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC	Liquid chromatography
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
NOAEL	no observed adverse effect level
NPD	nitrogen/phosphorous detector
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PBI	plant back interval
Pow	partition coefficient between n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
RPF	relative potency factor
SANCO	Directorate-General for Health and Consumers
SCPAFF	Standing Committee on Plants, Animals, Food and Feed (formerly: Standing Committee on the Food Chain and Animal Health; SCFAH)
SEU	southern Europe
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue

UV	ultra-violet (detector)
WHO	World Health Organization
wk	week
YF	yield factor
yr	year

## Appendix A – Good Agricultural Practice (GAPs)

Crop and/or situation <sup>(a)</sup>	NEU or SEU	F G or I <sup>(b)</sup>	Pest or group of pests controlled <sup>(c)</sup>	Formulation		Application			Application rate per treatment			PHI (days) <sup>(l)</sup>	Remarks <sup>(m)</sup>	
				type <sup>(d-f)</sup>	conc. a.s. <sup>(i)</sup>	Method kind <sup>(f-h)</sup>	Growth stage & season <sup>(j)</sup>	Number min-max <sup>(k)</sup>	Interval min-max	g/hL min-max	Water L/ha min-max			g/ha min-max
<b>Potatoes</b> (following which Valerian may be planted)	NEU & SEU	F	Phytophthora infestans	SC	62.5	foliar	BBCH 11-95	1-5	-	18.7-50	200-400	75-100	7	Max 400g a.s./ha/year

BBCH: growth stages of mono- and dicotyledonous plants; NEU: northern Europe; PHI: pre-harvest interval; SEU: southern Europe

### Remarks:

- |  |   |
|--|---|
| <p>(a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the usage situation should be described (e.g. fumigation of a structure)</p> <p>(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and sucking insects, soil-born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), water soluble granule (WG)</p> <p>(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989</p> <p>(f) all abbreviations must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants. type of equipment used must be indicated</p> | <p>(i) g/kg or µg/L</p> <p>(j) Growth stage at last treatment (Meier U, 2001. Growth Stages of mono- and dicotyledonous plants. BBCH Monograph, 2<sup>nd</sup> Ed., Federal Biological Research Centre of Agriculture and Forestry, Braunschweig, Germany, 2001), including where relevant, information on season at time of application</p> <p>(k) The minimum and maximum number of application possible under practical conditions of use must be provided</p> <p>(l) minimum PHI</p> <p>(m) Remarks may include: Extent of use/economic importance/restrictions</p> |
|--|---|

## Appendix B – Pesticide Residue Intake Model (PRIMO)

### B1: Fluopicolide

Fluopicolide			
Status of the active substance:	included	Code no.:	
LOQ (mg/kg bw):	0.01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.08	ARfD (mg/kg bw):	0.18
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2010a	Year of evaluation:	2010a

Prepare workbook for refined calculations

Undo refined calculations

Explain choice of toxicological reference values.

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

#### Chronic risk assessment - 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)	
2.8	WHO Cluster diet B	0.6	Tomatoes	0.5	Lettuce	0.2	Wine grapes	0.4	
2.7	NL child	0.7	Milk and cream,	0.4	Table grapes	0.2	Cauliflower	0.4	
2.6	FR toddler	1.0	Milk and cream,	0.2	Spinach	0.2	Leek	0.3	
2.4	UK Toddler	1.1	Sugar beet (root)	0.5	Milk and cream,	0.1	Tomatoes	0.2	
2.2	DE child	0.6	Table grapes	0.4	Milk and cream,	0.2	Tomatoes	0.4	
2.1	UK Infant	1.0	Milk and cream,	0.5	Sugar beet (root)	0.1	Cauliflower	0.2	
1.8	IE adult	0.2	Wine grapes	0.1	Tea	0.1	Table grapes	0.4	
1.7	WHO regional European diet	0.5	Lettuce	0.2	Tomatoes	0.1	Milk and cream,	0.2	
1.5	FR infant	0.6	Milk and cream,	0.2	Spinach	0.1	Broccoli	0.2	
1.5	ES child	0.6	Lettuce	0.3	Milk and cream,	0.2	Tomatoes	0.3	
1.5	FR all population	0.6	Wine grapes	0.3	Other lettuce and other salad plants	0.1	Lettuce	0.1	
1.4	ES adult	0.7	Lettuce	0.2	Tomatoes	0.1	Milk and cream,	0.2	
1.4	IT adult	0.5	Lettuce	0.2	Tomatoes	0.2	Other lettuce and other salad	0.1	
1.3	DK child	0.3	Milk and cream,	0.2	Lettuce	0.1	Cucurbits - edible peel	0.3	
1.3	WHO Cluster diet F	0.4	Lettuce	0.1	Tomatoes	0.1	Milk and cream,	0.2	
1.3	WHO cluster diet E	0.2	Wine grapes	0.1	Lettuce	0.1	Tomatoes	0.3	
1.3	WHO cluster diet D	0.2	Tomatoes	0.2	Chinese cabbage	0.1	Milk and cream,	0.2	
1.3	NL general	0.2	Milk and cream,	0.2	Lettuce	0.1	Cauliflower	0.2	
1.3	SE general population 90th percentile	0.3	Milk and cream,	0.2	Chinese cabbage	0.2	Tomatoes	0.2	
1.3	IT kids/toddler	0.4	Lettuce	0.3	Tomatoes	0.2	Other lettuce and other salad	0.2	
1.1	UK vegetarian	0.2	Lettuce	0.2	Sugar beet (root)	0.1	Tomatoes	0.1	
1.0	UK Adult	0.2	Sugar beet (root)	0.2	Lettuce	0.1	Wine grapes	0.1	
1.0	PT General population	0.3	Wine grapes	0.2	Tomatoes	0.1	Table grapes	0.2	
0.7	DK adult	0.2	Wine grapes	0.1	Milk and cream,	0.1	Tomatoes	0.1	
0.6	PL general population	0.2	Tomatoes	0.2	Table grapes	0.0	Cauliflower	0.1	
0.6	FI adult	0.1	Milk and cream,	0.1	Lettuce	0.1	Tomatoes	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						
<p>The acute risk assessment is based on the ARfD.</p> <p>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.</p> <p>In the <b>IESTI 1</b> calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.</p> <p>In the <b>IESTI 2</b> calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.</p> <p><b>Threshold MRL</b> is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.</p>												
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)
2.5	Tea	4.96 / -	2.5	Tea	4.96 / -	0.8	Tea	4.96 / -	0.8	Tea	4.96 / -	
<p><b>Conclusion:</b></p> <p>For Fluopicolide IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.</p> <p>No exceedance of the ARfD/ADI was identified for any unprocessed commodity.</p> <p>For processed commodities, no exceedance of the ARfD/ADI was identified.</p>												

**B2: 2,6-dichlorobenzamide (BAM, M-01)**

<b>M-01 (2,6-dichlorobenzamide)</b> (from the use of fluopicolide)			
Status of the active substance:	n/a	Code no.	
LOQ (mg/kg bw):	0.01	proposed LOQ:	
<b>Toxicological end points</b>			
ADI (mg/kg bw/day):	0.05	ARfD (mg/kg bw):	0.3
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2009b	Year of evaluation:	2009b

Prepare workbook for refined calculations

Undo refined calculations

**Chronic risk assessment - refined calculations**

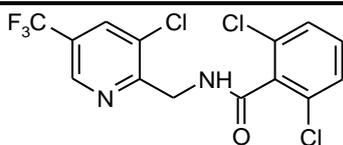
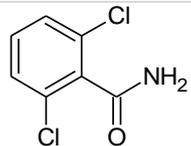
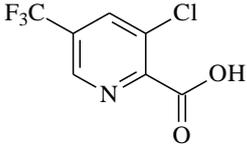
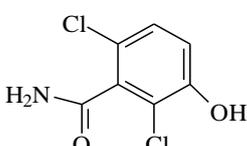
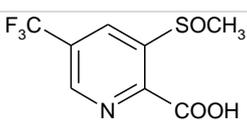
		TMDI (range) in % of ADI minimum - maximum							
		0	1	<b>No of diets exceeding ADI:</b>		---			
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRs at LOQ (in % of ADI)	
0.6	UK Toddler	0.5	Sugar beet (root)	0.1	Potatoes	0.0	Tea	0.6	
0.4	WHO Cluster diet B	0.1	Wine grapes	0.1	Tomatoes	0.1	Potatoes	0.3	
0.4	IE adult	0.1	Tea	0.1	Sweet potatoes	0.1	Wine grapes	0.2	
0.4	UK Infant	0.2	Sugar beet (root)	0.1	Potatoes	0.0	Tea	0.3	
0.3	FR toddler	0.1	Potatoes	0.1	Spinach	0.0	Carrots	0.2	
0.3	NL child	0.1	Potatoes	0.0	Spinach	0.0	Table grapes	0.2	
0.3	PT General population	0.1	Potatoes	0.1	Wine grapes	0.0	Tomatoes	0.2	
0.3	WHO cluster diet E	0.1	Potatoes	0.1	Wine grapes	0.0	Tea	0.2	
0.2	FR all population	0.2	Wine grapes	0.0	Potatoes	0.0	Tomatoes	0.1	
0.2	UK Adult	0.1	Sugar beet (root)	0.0	Wine grapes	0.0	Tea	0.1	
0.2	UK vegetarian	0.1	Sugar beet (root)	0.0	Tea	0.0	Wine grapes	0.1	
0.2	WHO cluster diet D	0.1	Potatoes	0.0	Tea	0.0	Tomatoes	0.2	
0.2	FR infant	0.1	Potatoes	0.1	Carrots	0.0	Spinach	0.2	
0.2	WHO regional European diet	0.1	Potatoes	0.0	Tea	0.0	Tomatoes	0.2	
0.2	DE child	0.1	Potatoes	0.1	Table grapes	0.0	Carrots	0.1	
0.2	SE general population 90th percentile	0.1	Potatoes	0.0	Carrots	0.0	Tomatoes	0.2	
0.2	WHO Cluster diet F	0.1	Potatoes	0.0	Wine grapes	0.0	Tomatoes	0.1	
0.2	NL general	0.1	Potatoes	0.0	Wine grapes	0.0	Spinach	0.1	
0.2	DK child	0.0	Potatoes	0.0	Cucurbits - edible peel	0.0	Carrots	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	Carrots	0.1	
0.1	ES child	0.0	Potatoes	0.0	Tomatoes	0.0	Lettuce	0.1	
0.1	ES adult	0.0	Lettuce	0.0	Potatoes	0.0	Wine grapes	0.1	
0.1	IT adult	0.0	Tomatoes	0.0	Lettuce	0.0	Potatoes	0.1	
0.1	IT kids/toddler	0.0	Tomatoes	0.0	Potatoes	0.0	Lettuce	0.1	
0.1	LT adult	0.1	Potatoes	0.0	Tomatoes	0.0	Cucurbits - edible peel	0.1	
0.1	FI adult	0.0	Potatoes	0.0	Wine grapes	0.0	Tea	0.0	

**Conclusion:**

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI. A long-term intake of residues of M-01 (2,6-dichlorobenzamide) (from the use of fluopicolide) is unlikely to present a public health concern.

Acute risk assessment /children - refined calculations						Acute risk assessment / adults / general population - refined calculations						
<p>The acute risk assessment is based on the ARfD.</p> <p>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.</p> <p>In the <b>IESTI 1</b> calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.</p> <p>In the <b>IESTI 2</b> calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.</p> <p><b>Threshold MRL</b> is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.</p>												
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):		
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	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)
	0.8	Tea	2.48 / -	0.8	Tea	2.48 / -	0.3	Tea	2.48 / -	0.3	Tea	2.48 / -
<b>No of critical MRLs (IESTI 1)</b>						<b>No of critical MRLs (IESTI 2)</b>						
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<p><b>Conclusion:</b></p> <p>For M-01 (2,6-dichlorobenzamide)</p> <p>No exceedance of the ARfD/ADI was identified for any unprocessed commodity.</p> <p>For processed commodities, no exceedance of the ARfD/ADI was identified.</p>												

## Appendix C – Used compound codes

Code/Trivial name	Chemical name(a)	Structural formula <sup>(a)</sup>
fluopicolide	2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]benzamide  MW: 383g/kg	
BAM or M-01	2,6-dichlorobenzamide	
M-02 (AE C657188)	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	

(a): ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).