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Modification of the existing maximum residue level for fluopicolide in blackberries, spinaches and purslanes

European Food Safety Authority (EFSA)

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, two evaluating Member States (EMS), Germany and Belgium, sent an application to modify the maximum residue level (MRL) for the active substance fluopicolide in blackberries, spinaches and purslanes. In order to accommodate for the intended use of fluopicolide, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) of 0.01 mg/kg to 3 mg/kg for blackberries and from 4 mg/kg to 6 mg/kg for spinaches and purslanes. Germany and Belgium drafted the evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which were submitted to the European Commission and forwarded to EFSA. According to EFSA the data are sufficient to derive MRL proposals of 3 mg/kg for the proposed use on blackberries and 6 mg/kg on spinaches and purslanes. Adequate analytical enforcement methods are available to control the residues of fluopicolide in blackberries at the validated LOQ of 0.01 mg/kg. Based on the risk assessment results, EFSA concludes that the proposed use of fluopicolide on blackberries, spinaches and purslanes will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

Keywords: fluopicolide, blackberry, spinach, purslane, MRL application, consumer risk assessment

Requestor: European Commission

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS) Germany, received an application from Landwirtschaftliches Technologiezentrum Augustenberg to set a new maximum residue level MRL for the active substance fluopicolide in blackberries. Additionally Belgium compiled an application to modify the existing MRL for fluopicolide in spinaches and purslanes. In order to accommodate for the intended use of fluopicolide, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) of 0.01 mg/kg to 3 mg/kg for blackberries and from 4 mg/kg to 6 mg/kg for spinaches and purslanes. The EMS (Germany and Belgium) drafted two evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which were submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 21 May 2015 for blackberries and on 18 June 2015 for spinaches and purslanes.

EFSA bases its assessment on the evaluation reports submitted by the EMS (Germany and Belgium), the draft assessment report (DAR) (and its addendum) prepared under Council Directive 91/414/EEC, the Commission review report on fluopicolide, the conclusion on the peer review of the pesticide risk assessment of the active substance fluopicolide, the JMPR Evaluation report as well as the conclusions from previous EFSA opinions on fluopicolide.

The toxicological profile of fluopicolide was assessed in the framework of the peer review and the data were sufficient to derive an ADI of 0.08 mg/kg bw per day and an ARfD of 0.18 mg/kg bw for the active substance fluopicolide. In addition an ADI of 0.05 mg/kg bw per day and an ARfD of 0.3 mg/kg bw was proposed for its metabolite M-01 (2,6-dichlorobenzamide).

The metabolism of fluopicolide in primary crops was investigated in the leafy, fruit and root crop groups. From these studies the peer review concluded to establish the residue definition for enforcement as fluopicolide. For risk assessment two residue separate definitions were proposed: 1) fluopicolide and 2) metabolite M-01 (2,6-dichlorobenzamide). For the use on the crops under consideration, EFSA concludes that the metabolism of fluopicolide in primary crops is sufficiently addressed and that the residue definitions derived under the peer review are applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to derive MRL proposals of 3 mg/kg for blackberries and 6 mg/kg for spinaches and purslanes. Adequate analytical enforcement methods are available to monitor the residues of fluopicolide on the commodity under consideration at the validated LOQ of 0.01 mg/kg.

Studies investigating the nature of fluopicolide residues in processed commodities were assessed in the peer review and showed fluopicolide is stable under standard hydrolysis conditions simulating pasteurisation, boiling and sterilisation. Specific studies for the magnitude of fluopicolide residues in processed commodities are not required, as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10 % of the ADI for fluopicolide and its metabolite M-01.

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 in succeeding crops, it was concluded that significant residue levels are unlikely to occur in rotational crops provided that the compound is used on spinaches and purslanes according to the proposed GAP (Good Agricultural Practice).

Residues of fluopicolide in commodities of animal origin were not assessed, since the crops under consideration are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). No long-term or acute consumer intake concerns were identified. For fluopicolide, the highest estimated chronic intake accounted for 3 % of the ADI (WHO Cluster B) and the highest acute exposure was calculated to be 39% of the ARfD for spinaches.

For the metabolite M-01, no long-term or acute consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. It is noted that the chronic risk assessment for the metabolite M-01 is not finalised since no information is available on its concentration in all commodities for which existing MRLs were used as input values. However, it is unlikely that the

metabolite would pose a public health concern due to the very low residues levels observed in crops for human consumption.

EFSA concludes that the proposed uses of fluopicolide on blackberries, spinaches and purslanes will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a health risk to the consumers.

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

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
Enforcement residue definition: Fluopicolide				
0153010	Blackberries	0.01*	3	Supported by indoor residue trials
0252010	Spinaches	4	6	By extrapolation from indoor residue trials on lettuce (open leaf varieties). MRL of 6 mg/kg covers the indoor and outdoor uses of fluopicolide on spinaches and purslanes.
0252020	Purslanes	4	6	

(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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Background

Regulation (EC) No 396/2005[1] 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[2], repealed by Regulation (EC) No 1107/2009[3], shall submit to a Member State, when appropriate, an application to set a MRL.

Germany, hereafter referred to as the evaluating Member State (EMS), received an application from the company Landwirtschaftliches Technologiezentrum Augustenberg[4] to modify the existing MRL for the active substance fluopicolide in blackberries. In addition, Belgium, hereafter referred to as the evaluating Member State, compiled an application to modify the existing MRLs for the active substance fluopicolide in spinaches and purslanes. These applications were notified to the European Commission and the European Food Safety Authority (EFSA) and were subsequently evaluated by the EMS in accordance with Article 8 of the Regulation. After completion, the evaluation reports were submitted to the European Commission and to EFSA on 21 May 2015 and on 8 June 2015 respectively.

The applications were included in the EFSA Register of Questions with the following reference numbers and the following subject:

- EFSA-Q- 2015-00357: *Fluopicolide – Modification MRL in blackberries.*
- EFSA-Q- 2015-00420: *Fluopicolide – Modification of the existing MRL in various crops.*

For reasons of efficiency EFSA combined both applications in a single reasoned opinion.

Germany proposed to raise the existing MRL of fluopicolide in blackberries from the limit of quantification of 0.01 mg/kg to 3 mg/kg and Belgium proposed to raise the MRLs for spinaches and purslanes from 4 mg/kg to 6 mg/kg.

Further clarifications/information were requested on 18 June 2015 to Germany which were uploaded on 2 September 2015 on the EFSA DMS (document management system) together with an updated evaluation report. Clarification on the GAPs was also requested to Belgium on 22 July 2015 which were submitted to EFSA in the form of an updated evaluation report on 4 September 2015.

EFSA proceeded with the assessment of the applications and the evaluation reports as required by Article 10 of the Regulation.

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 the uses as fungicide only.

Fluopicolide was evaluated in the framework of Directive 91/414/EEC with United Kingdom designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Commission

[1] 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.

[2] 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.

[3] 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.

[4] Landwirtschaftliches Technologiezentrum Augustenberg, Neßlerstraße 25, 76227, Karlsruhe, Germany

Directive 2010/15/EU[5] which entered into force on 1 June 2010 for use as fungicide only. In accordance with Commission Implementing Regulation (EU) No 540/2011[6] fluopicolide is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC.

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. The proposals from these reasoned opinions have been considered in the preparation of 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[(a)]	Considered by Regulation	Remarks
Art. 10 (EFSA, 2009a)	(EC) No 1050/2009	peppers
Art. 10 (EFSA, 2011)	(EU) No 812/2011	various commodities
Art. 10 (EFSA, 2012a)	(EU) No 592/2012 (EU) 2015/1101	radishes, onions, kale and potatoes
Art. 10 (EFSA, 2012b)	(EU) No 251/2013	various crops (carrot, radish, sugar beet, leafy vegetables)
Art. 10 (EFSA, 2013)	(EU) No 737/2014	hops and certain root and tuber vegetables
Art. 10 (EFSA, 2014)	(EU) 2015/846	Chinese cabbage
Art 10 (EFSA, 2015)	Not yet implemented in EU legislation	Valerian root

(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 including leafy vegetables for which the CXL is 30 mg/kg but no CXLs have been set for the blackberries.

The details of the intended GAP for fluopicolide are given in Appendix A.

Assessment

EFSA bases its assessment on the evaluation reports submitted by the EMS (Germany, Belgium, 2015), the DAR (and its addendum) prepared under Directive 91/414/EEC (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, 2009b), the JMPR Evaluation report (FAO, 2009a, 2009b) as well as the conclusions from previous EFSA opinions on fluopicolide (EFSA, 2009a, 2011, 2012, 2013, 2014, 2015). 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[7] 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).

[5] 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

[6] 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.

[7] 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, 2009b).

Several analytical methods for the determination of fluopicolide residues in high water, high acid content commodities and in dry commodities using GC-MSD, LC-MS/MS and HPLC-MS/MS at LOQs from 0.01 mg/kg for high water commodities to 0.1 mg/kg for acidic commodities are available. Independent laboratory validation (ILV) was performed for GC-MSD and HPLC-MS/MS methods. There is also an analytical method for determination of the metabolite M-01 available (EFSA, 2009b, 2011, 2013).

The multi-residue QuEChERS method described in the European Standard EN 15662:2008 and using HPLC-MS/MS detection is also applicable to analyse fluopicolide residues in high water, high acid, high oil content commodities and in dry matrices at the LOQ of 0.01 mg/kg (Germany, 2015).

As the crops under consideration belong to high acid and high water commodity groups, EFSA concludes that sufficiently validated analytical methods are available for enforcing the proposed MRL for fluopicolide in blackberries, spinaches and purslanes

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 the crops under consideration 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, 2009b). For the metabolite M-01, which is not unique to fluopicolide, but was also observed from the use of the active substance dichlobenil (EFSA, 2010), specific toxicological reference values were derived (EFSA, 2009b). The toxicological reference values derived for the active substance and its metabolite M-01 are compiled in Table 2.

Table 2: Overview of the toxicological reference values

	Source	Year	Value	Study	Safety factor
Fluopicolide					
ADI	EC	2010a	0.08 mg/kg bw per day	Mice, 18-month dietary	100
ARfD	EC	2010a	0.18 mg/kg bw	Rat, 28-day dietary study	100
Metabolite M-01					
ADI	EC	2010a	0.05 mg/kg bw per day	Rat and dog, 2-year study	100
ARfD	EC	2010a	0.3 mg/kg bw	Rabbit, developmental study	100

It is noted that JMPR established an ADI of 0.08 mg/kg bw per day and an ARfD of 0.6 mg/kg bw for fluopicolide (FAO, 2009a, 2009b).

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

In the framework of the peer review under Directive 91/414/EEC, the metabolism of fluopicolide in primary crops was evaluated in the fruit (grapes), leafy (lettuce) and root (potato) crop groups (EFSA, 2009b). An overview of the available metabolism studies is presented in Table 3.

Table 3: Summary of available metabolism studies in plants

Crop group	Crops	Application	Sampling[(a)] (day, DAT)	Comments
Fruit	Grapes	Foliar: (3x 170 g/ha)	21, 28 DAT_3	[^{14}C]-phenyl and pyridinyl ring labelled fluopicolide
Root	Potato	Post-harvest: (2x 200 g/ha)	20 DAT_2	
Leafy	Lettuce	Foliar: (2x 200 g/ha,)	14 DAT_2	
		Soil drench: (2x 200 g/ha)	35 DAT_2	

(a): DATx, days after treatment x, e.g. DAT_2: day after 2nd treatment.

Based on these metabolism studies, the residue definition was proposed as fluopicolide for monitoring. Considering the two different toxicological end-points set for fluopicolide and its metabolite M-01, two separate residue definitions were proposed for risk assessment, as fluopicolide and M-01 respectively (EFSA, 2009b). The current residue definition for enforcement set in Regulation (EC) No 396/2005 is identical to the residue definition derived in the peer review.

For the uses on the crops under consideration, EFSA concludes that the metabolism of fluopicolide is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed during the peer review are applicable.

3.1.1.2. Magnitude of residues

a. Blackberries

In support of the MRL application, Germany submitted four indoor and four outdoor trials conducted in compliance with the proposed GAPs, with a total of two applications in the range of 120 to 130 g/ha and pre-harvest intervals of 14 and 21 days for the indoor and outdoor trials respectively. All samples were analysed for fluopicolide. In contrast, data on metabolite M-01 were missing for three trials. Having regard to the low residue levels for the metabolite M-01 (<0.01 to 0.018 mg/kg) and considering its limited contribution to the consumer intakes (see Section 4), additional data are not required and it is concluded that a sufficient number of trials have been submitted.

Since the results from the indoor trials are higher than whose from the outdoor trials, an MRL proposal of 3 mg/kg is derived based on the indoor use, where fluopicolide levels were in the range from 0.13 to 1.10 mg/kg.

b. Spinaches and purslanes

Eight trials performed on open leaf varieties of lettuce under indoor conditions during the 2012 growing season were submitted. Fluopicolide residues were in the range of 0.18 to 3.10 mg/kg, resulting in an MRL proposal of 6 mg/kg. Metabolite M-01 was observed in much lower levels, ranging from the LOQ of 0.01 mg/kg up to 0.032 mg/kg.

Since all trials were conducted on open leaf varieties, according to the guidance document SANCO 7525/VI/95 (European Commission, 2011) the derived MRL of 6 mg/kg can be extrapolated to spinaches and purslanes.

It is noted that the MRL proposal of 6 mg/kg covers also the outdoor uses of fluopicolide on spinaches and purslanes, since a lower MRL of 4 mg/kg was set, based on NEU (northern Europe) and SEU

(southern Europe) trials conducted outdoor on spinaches according to a more critical GAP (3x 100 g/ha, PHI 14 days) (EFSA, 2012b).

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

The stability of fluopicolide residues in plant matrices under storage conditions prior to analysis was assessed during the peer review under Directive 91/414/EEC (EFSA, 2009b). Residues of fluopicolide were found to be stable at ≤ -18°C for at least 30 months in high water, high acid and in dry matrices. As lettuce samples were stored for a maximum period of 10 months and blackberry samples for 12 months under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability (Belgium, 2015; Germany, 2015).

According to the EMS, the analytical method used to analyse the residue trial samples has been sufficiently validated and was proven to be fit for purpose.

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

- 3 mg/kg blackberries (indoor use)
- 6 mg/kg spinaches and purslanes, by extrapolation from indoor trials on lettuce (open leaf varieties).

Table 4: Overview of the available residues trials data

Crop (GAPs)	**Region/ Indoor**[a]	**Residue levels observed in the supervised residue trials**[b] (mg/kg)	**Comments**[c]	**MRL proposal** (mg/kg)	**HR**[d] (mg/kg)	**STMR**[e] (mg/kg)
Blackberries (2x 115 g/ha, PHI 14 days)	Indoor	Fluopicolide: 0.13, 0.43, 0.60, 1.10 M-01: 3x <0.01	Since resulting in higher residue levels, MRL, HR and STMR were derived from the indoor trials (more critical GAP). MRL_{OECD}: 2.2/3 (indoor) MRL_{OECD}: 0.9/1 (outdoor)	3	1.1	0.52
Blackberries (2x 115 g/ha, PHI 21 days)	NEU	Fluopicolide: 0.20, 0.25, 0.38, 0.49 M-01: 0.015, 0.018		-	0.49	0.32
Lettuce (2x 100 g/ha, PHI 14 days)	Indoor	Fluopicolide: 0.18, 0.21, 0.27, 0.30, 0.49, 1.10, 2.80, 3.10 M-01: 4x <0.01; 0.01; 0.014, 0.018, 0.032	Since all trials were conducted on open leaf varieties, the MRL proposal of 6 mg/kg is extrapolated to spinach and purslane. MRL_{OECD}: 5.9/6	6	3.1	0.40

(*): Indicates that the MRL is proposed at the limit of analytical quantification (LOQ).
(a): NEU: Outdoor trials conducted in northern Europe
(b): Individual residue levels considered for MRL calculation are reported in ascending order (the values in bold resulted from a more critical GAP)
(c): Any information/comment supporting the decision and OECD MRL calculation (unrounded/rounded values)
(d): HR: Highest residue level according to the residue definition for risk assessment.
(e): STMR: Median residue level according to residue definition for risk assessment.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of fluopicolide was investigated during the peer review. Fluopicolide was shown to be hydrolytically stable under standard hydrolysis conditions representing pasteurisation, boiling and sterilisation. Thus, for processed commodities the same residue definition as for raw agricultural commodities (RAC) is applicable (EFSA, 2009b).

Specific studies to assess the magnitude of fluopicolide residues during the processing of the cops under consideration were not provided and are not required as the total theoretical maximum daily intake (TMDI) amounts to less than 10 % of the ADI (European Commission, 1997d).

3.1.2. Rotational crops

The residues of fluopicolide in rotational crops are of no relevance for blackberries as these crops are permanent, but spinach and purslane can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the primary use must be investigated.

The metabolism in rotational crops showed to be similar to the pathway observed in primary crops (EFSA, 2009b, 2012).

Field trials conducted on winter wheat, spring wheat, beans and cabbage grown in rotation to potatoes treated with four foliar applications of fluopicolide at a total dose rate of 400 g/ha (4x 100 g/ha) were evaluated during the peer review. At maturity fluopicolide residues were below the LOQ (<0.01 mg/kg), except in wheat straw (0.12 mg/kg) and metabolite M-01 was found in quantifiable levels in wheat straw and cabbage only, up to 0.03 and 0.04 mg/kg respectively (EFSA, 2009b, 2012a).

Considering that the application rate of the intended uses of fluopicolide on spinach and purslane is lower than the one investigated in the peer review (0.5N), EFSA concludes that significant residue levels are unlikely to occur in rotational crops provided that the active substance is used on spinach and purslane according to the proposed GAP.

3.2. Nature and magnitude of residues in livestock

As the crops under consideration and their by-products are normally not fed to livestock, the nature and magnitude of fluopicolide residues in livestock is not assessed in the framework of this application (European Commission, 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[8] (EFSA, 2007).

For the calculation of chronic exposure, EFSA used the median residue values as derived for fluopicolide and M-01 from the residue trials on the crops under consideration (see Table 4) and the median residue values reported in previously issued EFSA reasoned opinions (EFSA, 2009a, 2011, 2012a, 2012b, 2013, 2014, 2015). For the remaining commodities of plant and animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values for fluopicolide. It is noted that the chronic risk assessment for the metabolite M-01 is not finalised as no information is available on its concentration in the commodities for which the existing MRLs are used as input values. A full chronic risk assessment for M-01 will be performed in the framework of Article 12 of the Regulation (EC) No 396/2005. However, it is unlikely that the metabolite would pose a public health concern due to the very low residues levels observed in crops for human consumption.

[8] 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).

The acute exposure assessment was performed only with regard to blackberries, spinach and purslane assuming the consumption of a large portion of the food items as reported in the national food surveys and that these items 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 on the individual items consumed was included in the calculation, when required (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**
Risk assessment residue definition: fluopicolide				
Blackberries	0.52	STMR	1.1	HR
Spinaches and purslanes	0.40	STMR	3.1	HR
Other commodities of plant and animal origin	See Table 5 from the Reasoned Opinion under Article 10 of Reg. 396/2005 (EFSA, 2015)			
Risk assessment residue definition 2: Metabolite M-01 (2,6-dichlorobenzamide)				
Blackberries	0.01	STMR	0.01	HR
Spinaches and purslanes	0.01	STMR	0.032	HR
Other commodities of plant and animal origin	See Table 5 from the Reasoned Opinion under Article 10 of Reg. 396/2005 (EFSA, 2015)			

The estimated exposure was then compared with the toxicological reference values derived for fluopicolide and its metabolite M-01 (see Table 2). The results of the intake calculation are presented in Appendix B to this reasoned opinion (B1 Fluopicolide; B2-M01).

a. Fluopicolide

Long-term consumer intake concerns were not identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for up to 3 % of the ADI (WHO Cluster B). The contribution to the total consumer exposure of residues in spinach was 0.45 % of the ADI (FR toddler) and lower than 0.1 % of the ADI in blackberries and purslanes.

An acute consumer risk was not identified in relation to the MRL proposals for the crops under consideration. The acute consumer exposure was calculated to be 39 % of the ARfD for spinaches, 26% for purslanes and 6.5 % for blackberries.

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

Long-term consumer intake concerns were not identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted less than 1 % of the ADI (UK toddler).

The contribution of residues to the total long-term exposure for the crops under consideration was insignificant, being lower than 0.04 % of the ADI.

An acute consumer risk was not identified; the highest acute exposure was calculated to be 0.2 % of the ARfD for spinaches and purslanes and 0.04% for blackberries.

EFSA concludes that the intended use of fluopicolide on blackberries, spinaches and purslanes 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 information submitted was sufficient to propose the MRL summarised in the table below.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
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0153010	Blackberries	0.01*	3	Supported by indoor residue trials
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0252020	Purslanes	4	6	

(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
ArfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CEN	European Committee for Standardization (Comité Européen de Normalisation)
CIPAC	Collaborative International Pesticide Analytical Council
CXL	Codex maximum residue limit (Codex MRL)
DAR	draft assessment report
DAT	days after treatment
DMS	Document management system
EMS	evaluating Member State
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly International Group of National Associations of Manufacturers of Agrochemical Products (GIFAP))
GS	growth stage
HPLC	high performance liquid chromatography
HR	highest residue
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
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
OECD	Organisation for Economic Co-operation and Development
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RAC	raw agricultural commodity
SC	suspension concentrate
SEU	southern Europe
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake

WG	water dispersible granule
yr	year

Appendix A – Good Agricultural Practice (GAPs)

Crop and/or situation[a]	MS or NEU /SEU	F G or I [b]	Pest or group of pests controlled [c]	Formulation		Application				Application rate per treatment			PHI (days) [i]	Remarks
				type [d]	conc. a.s.[e]	Method kind[f]	Growth stage & season[g]	Number min-max [h]	Interval min-max	g/hL min-max	Water L/ha min-max	g/ha min-max		
Blackberries	DE	G	*Peronospora sparsa*	WG	44.4 g/l	spraying	BBCH 60-85	1-2	(10-14)		1000	115.4	14	
		F											21	
Spinach & purslane	BE (NEU)	G	Mildew	SC	62.5 g/l	spraying	BBCH 14-47	1-2				100	14	

Remarks:

(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)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil-born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), water soluble granule (WG)
(e) g/kg or µg/L
(f) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants. type of equipment used must be indicated
(g) Growth stage at last treatment (Meier U, 2001. Growth Stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., Federal Biological Research Centre of Agriculture and Forestry, Braunschweig, Germany, 2001), including where relevant, information on season at time of application
(h) The minimum and maximum number of application possible under practical conditions of use must be provided
(i) PHI - minimum pre-harvest interval

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

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
2.8	NL child	0.7	Milk and cream,	0.4	Table grapes	0.2	Spinach	0.4
2.7	FR toddler	1.0	Milk and cream,	0.4	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
2.0	UK Infant	1.0	Milk and cream,	0.5	Sugar beet (root)	0.1	Cauliflower	0.2
1.7	IE adult	0.2	Wine grapes	0.1	Table grapes	0.1	Spring onions	0.4
1.7	FR infant	0.6	Milk and cream,	0.3	Spinach	0.1	Broccoli	0.2
1.6	WHO regional European diet	0.5	Lettuce	0.2	Tomatoes	0.1	Milk and cream,	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	NL general	0.2	Milk and cream,	0.2	Lettuce	0.1	Cauliflower	0.2
1.3	WHO Cluster diet F	0.4	Lettuce	0.1	Tomatoes	0.1	Milk and cream,	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	WHO cluster diet E	0.2	Wine grapes	0.1	Lettuce	0.1	Tomatoes	0.3
1.3	IT kids/toddler	0.4	Lettuce	0.3	Tomatoes	0.2	Other lettuce and other salad	0.2
1.3	WHO cluster diet D	0.2	Tomatoes	0.2	Chinese cabbage	0.1	Milk and cream,	0.2
1.1	UK vegetarian	0.2	Lettuce	0.2	Sugar beet (root)	0.1	Tomatoes	0.1
1.0	PT General population	0.3	Wine grapes	0.2	Tomatoes	0.1	Table grapes	0.2
0.9	UK Adult	0.2	Sugar beet (root)	0.2	Lettuce	0.1	Wine grapes	0.1
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**

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)
38.9	Spinach	3.1 / -	38.9	Spinach	3.1 / -	17.8	Purslane	3.1 / -	16.2	Purslane	3.1 / -
26.0	Purslane	3.1 / -	19.7	Purslane	3.1 / -	15.4	Spinach	3.1 / -	15.4	Spinach	3.1 / -
6.5	Blackberries	1.1 / -	6.5	Blackberries	1.1 / -	1.3	Blackberries	1.1 / -	1.3	Blackberries	1.1 / -

B2-M01

M-01 (2,6-dichlorobenzamide)
(from the use of fluopicolide)

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

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:	2009b	Year of evaluation:	2009b

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI
minimum - maximum
0 1

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)
0.6	UK Toddler	0.5	Sugar beet (root)	0.1	Potatoes	0.0	Tomatoes	0.6
0.4	WHO Cluster diet B	0.1	Wine grapes	0.1	Tomatoes	0.1	Potatoes	0.3
0.3	UK Infant	0.2	Sugar beet (root)	0.1	Potatoes	0.0	Carrots	0.3
0.3	IE adult	0.1	Sweet potatoes	0.1	Wine grapes	0.0	Potatoes	0.2
0.3	PT General population	0.1	Potatoes	0.1	Wine grapes	0.0	Tomatoes	0.2
0.2	NL child	0.1	Potatoes	0.0	Table grapes	0.0	Tomatoes	0.2
0.2	FR toddler	0.1	Potatoes	0.0	Carrots	0.0	Tomatoes	0.2
0.2	FR all population	0.2	Wine grapes	0.0	Potatoes	0.0	Tomatoes	0.1
0.2	WHO cluster diet E	0.1	Potatoes	0.1	Wine grapes	0.0	Other tropical root and tuber	0.2
0.2	WHO cluster diet D	0.1	Potatoes	0.0	Tomatoes	0.0	Cucurbits - inedible peel	0.2
0.2	DE child	0.1	Potatoes	0.1	Table grapes	0.0	Carrots	0.1
0.2	WHO regional European diet	0.1	Potatoes	0.0	Tomatoes	0.0	Lettuce	0.2
0.2	FR infant	0.1	Potatoes	0.1	Carrots	0.0	Cucurbits - edible peel	0.2
0.2	SE general population 90th percentile	0.1	Potatoes	0.0	Carrots	0.0	Tomatoes	0.2
0.2	UK Adult	0.1	Sugar beet (root)	0.0	Wine grapes	0.0	Potatoes	0.1
0.2	UK vegetarian	0.1	Sugar beet (root)	0.0	Wine grapes	0.0	Potatoes	0.1
0.2	WHO Cluster diet F	0.1	Potatoes	0.0	Wine grapes	0.0	Tomatoes	0.1
0.2	DK child	0.0	Potatoes	0.0	Cucurbits - edible peel	0.0	Carrots	0.1
0.1	NL general	0.1	Potatoes	0.0	Wine grapes	0.0	Table grapes	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	LT adult	0.1	Potatoes	0.0	Tomatoes	0.0	Cucurbits - edible peel	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	0.1

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)
(from the use of fluopicolide) is unlikely to present a public health concern.

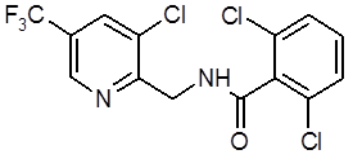
Acute risk assessment /children - refined calculations | **Acute risk assessment / adults / general population - refined calculations**

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)
0.24	Spinach	0.032 / -	0.24	Spinach	0.032 / -	0.1	Purslane	0.032 / -	0.1	Purslane	0.032 / -
0.16	Purslane	0.032 / -	0.1	Purslane	0.032 / -	0.1	Spinach	0.032 / -			
0.04	Blackberries	0.01 / -	0.0	Blackberries	0.01 / -	0.0	Blackberries	0.01 / -			

Appendix C – Used compound codes

Code/Trivial name	Chemical name	Structural formula
Fluopicolide	2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]benzamide (IUPAC) MW: 383.59 g/mol	
M-01 or BAM	2,6-dichlorobenzamide