



The evaluation of a new MRL for fluopicolide in or on escaroles/broad-leaved endives

UK Competent Authority Evaluation Report and Reasoned Opinion

Prepared under Article 8 of Assimilated Regulation 396/2005 and Data
Requirements of Assimilated Regulation 544/2011

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Summary

In accordance with Article 6 of Assimilated Regulation 396/2005,¹ HSE received an application on 5 September 2024 to amend the existing MRLs for the active substance fluopicolide in or on escaroles/broad-leaved endives. The application was to support an extension of authorisation for a minor use in GB.

The applicant submitted a dossier in accordance with the data requirements outlined in Assimilated Regulation 544/2011.

In accordance with Article 8 of Assimilated Regulation 396/2005, HSE evaluated the dossier in accordance with the uniform principles as outlined in Article 29(6) of Assimilated Regulation 1107/2009.²

Based on the assessment HSE prepared an Evaluation Report that included its Reasoned Opinion on the risk to consumers associated with amending the MRLs. HSE also took into account the data assessed for the approval of the active substance and previous Reasoned Opinions.

Sufficiently validated analytical methods for the determination of fluopicolide in products of plant origin, in line with the residue definition for enforcement, are available to support the use under consideration in the MRL application.

Toxicological reference values were established for the approval of the active substance: for fluopicolide an ADI of 0.08 mg/kg bw/day and an ARfD of 0.18 mg/kg bw; and for metabolite M-01 (2,6-dichlorobenzamide) an ADI of 0.05 mg/kg bw/d and an ARfD of 0.3 mg/kg bw.

The metabolism of fluopicolide in primary crops was investigated in the fruit, leafy and root crop groups following foliar or soil applications for the approval of the active substance (EFSA, 2009). As a consistent metabolic pathway was observed across crops from three crop groups, the available data are sufficient to support all crop groups including leafy crops which the crop included in this MRL application belongs to.

The residue definition for risk assessment (RD-RA) in plants has been agreed as:

1. Fluopicolide

¹ [Assimilated Regulation No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin](#)

² [Assimilated Regulation No 1107/2009 concerning the placing of plant protection products on the market](#)

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

The residue definition for enforcement (RD-Enf) in plants has been agreed as:

- Fluopicolide

Seven independent protected trials on open leaf lettuce were submitted to support an MRL for escaroles/broad-leaved endives. The trials are supported by validated analytical methods and storage stability data and considered acceptable to support the proposed MRL on escaroles/broad-leaved endives.

Hydrolysis of fluopicolide under representative conditions of pasteurisation, baking, brewing, boiling and sterilisation was evaluated for the approval of the active substance. The hydrolysis data demonstrate that fluopicolide is stable under standard conditions, therefore specific residue definitions for processed commodities are not required.

Residues in rotational crops were considered for the approval of the active substance. Metabolism in rotational crops was found to be via a similar pathway to primary crops but more extensive. It was concluded that specific residue definitions for rotational crops are not required. The metabolism studies demonstrated that residues of fluopicolide and M-01 in rotational crops are expected to be >0.01 mg/kg. As the application rate in the rotational crop trials is significantly greater than (4N) the proposed maximum seasonal rate, no significant residues in rotational crops are expected in food or feed commodities.

Consideration of residues in livestock is not required as the crops under consideration in the MRL application are not fed to animals.

For fluopicolide, the highest UK NEDI was 6% of the ADI (toddler). The highest PRIMo IEDI was 5% of the ADI (NL toddler). For metabolite M-01, the highest UK NEDI was 1% of the ADI (toddler). The highest PRIMo IEDI was 0.4% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of commodities treated with fluopicolide.

For fluopicolide, the highest UK NESTI was 15.8% of the ARfD (4-6 year old child / lettuce (surrogate for escaroles/broad-leaved endives)). The highest PRIMo IESTI was 36% of the ARfD (children / escaroles/broad-leaved endives). For metabolite M-01, the highest UK NESTI was 0.1% of the ARfD (4-6 year old child / lettuce (surrogate for escaroles/broad-leaved endive)). The highest PRIMo IESTI was 0.1% of the ARfD (children / escaroles/broad-leaved endives). Therefore, no health effects due to acute exposure are expected from the consumption of commodities treated with fluopicolide.

A combined risk assessment has been performed for fluopicolide and metabolite M-01. The maximum sum of the chronic intakes for fluopicolide and metabolite M-01 (each expressed as a % of its own ADI) using the UK NEDI model is 7% (toddler). The maximum

sum of the chronic intakes for fluopicolide and metabolite M-01 (each expressed as a % of its own ADI) using the EFSA PRIMo model is 5.4 % (NL toddler). Therefore, no health effects due to chronic combined exposure are expected.

The maximum sum of the acute intakes for fluopicolide and metabolite M-01 (each expressed as a % of its own ARfD) using the UK NESTI model is 15.9% (lettuce; surrogate for escaroles/broad-leaved endive, 4-6 year old child). The maximum sum of the acute intakes for fluopicolide and metabolite M-01 (each expressed as a % of its own ARfD) using the PRIMo model is 36.1% (escarole/broad-leaved endive, children). For proposed use on escaroles/broad-leaved endive, the sum of the acute intakes (UK) fluopicolide and metabolite M-01 each expressed as a % of its own ARfD is <100%. Therefore, no health effects due to acute combined exposure are expected.

HSE concludes that sufficient data have been provided to support the setting of a new MRL for the proposed use of fluopicolide on escaroles/broad-leaved endives. This will not result in consumer exposures exceeding the toxicological reference values and therefore harmful effects on human health are not expected.

HSE recommends that the MRL outlined in Table 0.1 is amended in the GB MRL Statutory Register.

Table 0.1 MRL recommended by HSE

Product code	Product	Existing GB MRL (mg/kg)	New or amended GB MRL (mg/kg)	Comments
Enforcement residue definition for products of plant origin: Fluopicolide				
0251030	Escaroles/broad-leaved endives	1.5	4	The MRL is derived by extrapolation of residue trials on open leaf lettuce. No health effects are expected.

Background

Assimilated Regulation 396/2005 outlines the rules for setting MRLs in GB. Article 6 covers the submission of applications for MRLs, including the parties which can submit an application. Article 7 outlines that a dossier in accordance with the data requirements of Assimilated Regulation 1107/2009 must be provided.

On 5 September 2024 HSE accepted an application to set new MRLs for fluopicolide in or on escaroles/broad-leaved endives.

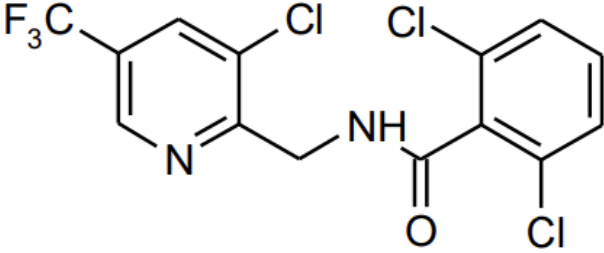
HSE evaluated the information submitted to uniform principles, as defined by Article 8 of Assimilated Regulation 396/2005 and prepared an Evaluation Report. HSE also took into account EFSA Reasoned Opinions and Conclusions on the peer review relating to decisions implemented in GB.

The Evaluation Report is the basis of HSE's Reasoned Opinion.

The active substance and its use pattern

Information on the active substance fluopicolide is outlined in Table 0.2.

Table 0.2 Information on the active substance

Common name (ISO)	Fluopicolide
Chemical name (IUPAC)	2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]benzamide
CAS number	239110-15-7
Structural formula	
Molecular formula	C ₁₄ H ₈ Cl ₃ F ₃ N ₂ O
Molecular mass	383.59 g/mol

Fluopicolide is an approved active substance in GB. An EFSA Conclusion is available (EFSA, 2009). MRLs are established for fluopicolide in Part 3 of the GB MRL Statutory Register.

Appendix A outlines the GAPs (Good Agricultural Practices) supported in this application.

The following CXLs are available for the proposed uses (Codex Pesticide Residues in food online database).

Table 0.3 CXLs relevant to the proposed uses

Commodity	CXL (mg/kg)	Comments	Year of adoption
Leafy vegetables	30	<p>This CXL is applicable to escaroles/broad-leaved endives (GB commodity code 0251030).</p> <p>The CXL is higher than the current GB MRL</p> <p>The CXL for leafy vegetables cannot be adopted due to acute</p>	2011

		human health concerns. The relevant acute consumer risk assessments are presented in Appendix B (Table B.5). These were undertaken based on data provided in JMPR evaluation reports (JMPR, 2009), where the HR for fluopicolide in leafy vegetables was 17 mg/kg. No further consideration is required.	
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The CXL database is available at the following link:

<http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/en/>

Assessment

1 Methods of analysis

1.1 Methods for enforcement and monitoring of residues in food of plant origin

Analytical methods for the determination of fluopicolide in products of plant origin, in line with the residue definition for enforcement, were assessed for the approval of the active substance (EFSA, 2009).

A modified version of multi-residue method DFG S19 (GC-MS) was validated with an LOQ of 0.1 mg/kg for high acid crops and 0.02 mg/kg for high water and dry commodities. Acceptable ILV data were provided.

An additional HPLC-MS/MS method was validated for high water commodities with an LOQ of 0.01 mg/kg in a previous MRL application (EFSA, 2011). Acceptable ILV data were provided.

Further methods are available for high oil commodities and hops (EFSA, 2013, 2015a).

The commodities under consideration in this MRL application (escaroles/broad-leaved endives) are high water commodities and are covered by the analytical methods available.

Extraction efficiency was not addressed for the approval of fluopicolide. In principle further data are required. However, the lack of data is unlikely to impact the MRL calculated or the outcome of the consumer risk assessment. Therefore, no further data are required at this time.

1.2 Methods for enforcement and monitoring of residues in food of animal origin

Not required as the MRL application does not require the setting or amendment of MRLs in products of animal origin.

2 Mammalian toxicology

The toxicological end points established for the approval of the active substance fluopicolide are summarised in Table 2.1a and 2.1b.

Table 2.1a Overview of the toxicological reference values for fluopicolide

TRVs	Source	Year	Value	Study relied upon	Safety factor
ADI	EFSA	2009	0.08 mg/kg bw/d	78-week dietary study in mice, supported by the 2-year rat study	100
ARfD	EFSA	2009	0.18 mg/kg bw	28-day dietary study in rats and rabbit developmental study	100

Table 2.1b Overview of the toxicological reference values for metabolite M-01 (2,6-dichlorobenzamide)

TRVs	Source	Year	Value	Study relied upon	Safety factor
ADI	EFSA	2009	0.05 mg/kg bw/d	2-year rat and dog studies	100
ARfD	EFSA	2009	0.3 mg/kg bw	Developmental study in rabbit	100

For fluopicolide, the ADI was based on the 78-week dietary study in mice, supported by the 2-year rat study with effects at the LOAEL on the liver (non-neoplastic lesions including centrilobular hepatocyte hypertrophy in the liver of rats and mice; and hepatocellular adenomas in mice). For M-01, the ADI was set on the 2-year rat and dog studies where the effects at the LOAEL were decreased body weight gain and liver toxicity (rat only).

Given that liver toxicity was a common effect underlying the ADIs for both fluopicolide and M01, a combined chronic risk assessment is required (see section 7.1).

For fluopicolide, the ARfD was based on 28-day dietary study in rats and the rabbit developmental study. In the rat study, effects at the LOAEL were on liver, kidney, spleen

and red blood cell parameters while in the rabbit developmental study they included reduced body weight and reduced food consumption. For M-01, the ARfD was set on the developmental study in rabbits where the effects at the LOAEL included maternal clinical signs, decreased body weight gain and food consumption.

Given that for both ARfDs there is a common underlying effect on body weight and food consumption, a combined acute risk assessment is required (see section 7.1).

3 Residues in plants

3.1 Nature of residues in primary crops

Metabolism in primary crops was investigated following foliar spray and soil treatment in fruit crops (grapes), leafy crops (lettuce) and root crops (potato) for the approval of the active substance (EFSA Conclusion, 2009).

Table 3.1-1 Summary of the primary plant metabolism studies

Crop groups	Crop(s)	Applications	DAT ^(a) (days)
Fruit	Grape	Foliar, 1 x 170 + 2 x 120 g a.s./ha	21, 28
Root crops	Potato	Foliar, 2 x 200 g a.s./ha	20
Leafy crops	Lettuce	Foliar, 2 x 200 g a.s./ha	14
		Soil drench, 1 x 200 g a.s./ha	21, 35

(a) DAT where identification/characterisation of the residues has been investigated

A summary of the available primary crop metabolism data is presented below (EFSA RO, 2012):

“Following foliar or soil applications of fluopicolide, plant metabolism was found to be limited with fluopicolide being the major component of the total radioactive residues (TRR) at harvest (lettuce/foliar: 96.4 % of TRR; lettuce/soil: 74.5 % of TRR; grapes: 91.2 % of TRR; potato tubers: 70.2 % of TRR). Besides fluopicolide, the metabolites M-01, M-0211 and M-0612 were identified in significant amounts only in potato tubers (M-01 up to 25.4 % of TRR; M-02 up to 12 % of TRR and M-06 up to 2.4 % of TRR) and in lettuce grown after soil drench application (M-01 up to 19.8 % of TRR).

The metabolic pathway of fluopicolide showed to be similar in the three crop groups, involving hydrolysis of the urea bond to form metabolites M-01 and M-02 and hydroxylation of the phenyl ring to form metabolite M-06. With the exception of M-01 for which an ADI and an ARfD were set, the other metabolites were regarded as less toxic than the parent compound.”

As a consistent metabolic pathway was observed across crops from three crop groups, the available data are sufficient to support all crop groups.

The application type in the studies for root crops, leafy crops and fruit is foliar spray, which is the same as the application type for the proposed use. Additionally, the proposed PHI of 14 days is in line with the PHI in the metabolism studies. On this basis the proposed use is supported by the available metabolism studies.

The residue definition for risk assessment (RD-RA) in plants has been agreed as:

1. Fluopicolide
2. Metabolite M-01 (2,6-dichlorobenzamide)

The residue definition for enforcement (RD-Enf) in plants has been agreed as:

- Fluopicolide

3.2 Magnitude of residues in primary crops

The uses notified in the MRL application are outlined in Appendix A.

Residue trials

0251030 Escaroles/broad-leaved endives

The proposed critical protected GAP in GB is 1 x 100 g a.s./ha fluopicolide with a PHI of 14 days.

The applicant has submitted eight trials on open leaf lettuce in the context of this application to support the proposed cGAP. A full analysis of the trials can be found in Appendix C.3.1.2.1.

Eight protected trials on open leaf lettuce were undertaken in greenhouses using a suspension concentrate (SC) formulation. The trials were conducted at 1 x 100 - 108 g a.s./ha fluopicolide in 300 – 650 L/ha of water, BBCH 19 - 48. The trials are within 25% of the proposed cGAP in terms of application rate. Data on residues in lettuce is presented at 7 days after last application (DALA, normal commercial harvest) and 13 - 15 DALA. Residue data has been selected from samples at 13-15 DALA as this reflects the proposed cGAP in this application.

It is noted that trial 12-2060-04 and trial 12-2060-05 were performed in the same location, in the same year with similar application rates (within 8% of one another) and used the same variety of lettuce. As a result, these trials cannot be considered independent and are considered to be replicates. The mean value of the two trials has been selected and reported for calculation of the STMR, HR and MRL.

No significant deviations were noted in the trials and no residues of fluopicolide or metabolite M-01 were detected above the LOQ (0.01 mg/kg) in control samples taken at 7 DALA for all trials. Control samples were not taken at 13-15 DALA, however the decline in residues observed for treated samples between 7 DALA and 13-15 DALA suggest that residues in the control sample at 13-15 DALA will be below LOQ.

In accordance with GB extrapolation guidance 2024, an extrapolation from lettuces (open leaf varieties) to 'Whole subgroup (a) lettuces and salad plants' is permitted before and after formation of the edible part. Therefore, trials on lettuce (open leaf) cover the proposed use on escaroles/broad-leaved endive. Four trials are required on escaroles/broad-leaved endives as they are a minor crop. Seven independent indoor trials on lettuce are available and therefore the trials can be extrapolated to support the proposed use.

The proposed cGAP may account for application after forming of the edible part (BBCH 16), therefore half of the trials should be decline trials. The trials on lettuce were decline

trials albeit with only 2 time points sampled. A decline trial should include 3 – 5 sampling intervals in addition to the target PHI. However, data from all plots show a significant decline in residues between samples taken at 7 and 14 days after last treatment, therefore, the lack of decline samples is not considered to have a significant impact on the validity of the residue data in the trials and it is not expected later sampling timepoints would show higher residue levels.

The trials are considered relevant to the proposed cGAP for escaroles/broad-leaved endives as they are within 25% of the cGAP.

Storage stability

Stability of residues during storage of samples was considered in a number of crop matrices for the approval of the active substance (EFSA, 2009). Fluopicolide and metabolite M-01 were found to be stable in matrices with high acid content (grapes), high starch content (wheat grain) and high water content (potato and cabbage) for at least 30 months at ≤ -18 °C and in wheat straw (miscellaneous) for up to 18 months at ≤ -18 °C.

Samples of lettuce from the supporting residue trials were stored at ≤ -18 °C for a total of 284 days (9 months) prior to analysis. Sufficient storage stability in high water commodities is available from the approval of the active substance to support the maximum storage period of 9 months in the trials on lettuce.

Analytical methods

Analysis for residues of fluopicolide and its metabolite M-01 was performed using LC- MS/ MS method 01209. This method had previously been evaluated in a previous PPP authorisation (HSE internal ref: COP 2016/01040, W 001857165). Method 01209 was successfully validated on potato (high water), grape (high acid), tomato (high water), dry bean (dry), sunflower (high oil) and wheat straw (dry). The analytical method (01209) was satisfactorily validated in accordance with SANCO 3029/99 rev. 4 with an LOQ of 0.01 mg/kg individually for fluopicolide and its metabolite M-01 in all matrices. Reduced validation data was presented in Study 12-2060 for lettuce (high water). Procedural recoveries were performed at two fortifications levels (LOQ, 10xLOQ), with an appropriate number of samples. Mean recoveries for fluopicolide and M-01 were in the range 89 - 100% and deemed acceptable.

Extraction efficiency was not investigated for method 01209. The samples were extracted using acetone/water acidified with formic acid (75/25/1, v/v/v). In the metabolism studies considered for approval of the active substance, samples were extracted using acetonitrile. Given the different solvents used in the metabolism studies versus the data generation method, it is considered that the extraction efficiency for fluopicolide and its metabolites has not been addressed. In principle further data are required. However, extraction efficiency was not addressed for the approval of the active substance and the lack of data

is unlikely to impact the outcome of the consumer risk assessment. Therefore, no further data are required at this time.

Table 3.2 Overview of the available residue trials data

Commodity	Region/ Indoor (a)	Residue levels (mg/kg) observed in the trials representative for the intended GAPs (b)	Recommendations/ comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
RD-RA 1: Fluopicolide RD-RA 2: Metabolite M-01 (2,6-dichlorobenzamide) RD-Enf: Fluopicolide						
Open leaf lettuce → escaroles/broad- leaved endives (1 x 100 – 108 g a.s./ha, BBCH 19 – 48)	GB / greenhouse	Fluopicolide: 0.11 [†] , 0.14, 0.19, 0.20, 0.22, 1.5, 1.6 Metabolite M-01: 4 x < 0.01 [†] , 2 x 0.01, 0.011	MRL _{OECD} : 3.262/4mg/kg [†] Mean of individual residue values from non-independent trials 12-2060-04 and 12- 2060-05 (0.1 mg/kg and 0.11 mg/kg respectively for fluopicolide and 2 x <0.01 mg/ kg for M-01).	4	RD-RA 1 and RD-Enf: 1.6 RD-RA 2: 0.011	RD-RA 1 and RD-Enf: 0.20 RD-RA 2: 0.01

- (a) GB or the country for an import tolerance and whether the GAP is for an outdoor use or an indoor/protected/glasshouse use.
- (b) Residue levels in trials conducted according to GAPs reported in ascending order. When residue definitions for enforcement and risk assessment differ, **Enf/RA** differentiate data expressed according to the residue definition for **Enforcement** and **Risk Assessment**.
- (c) **HR**: Highest residue, according to the residue for risk assessment, (within brackets when expressed according to the residue definition for enforcement: HR_{Enf})
- (d) **STMR**: Supervised Trials Median Residue according to the residue definition risk assessment (within brackets when expressed according to the residue definition for enforcement: STMR_{Enf})

3.3 Conversion factors for risk assessment for products of plant origin

As the residue definitions for enforcement (RD-Enf) and risk assessment 1 (RD-RA1) are equivalent, conversion factors (CFs) for enforcement to risk assessment are not required.

3.4 Effect of industrial processing and/or household preparation

No consideration of residues in processed commodities is required, as the crops concerned are not typically consumed processed (beyond simple physical processes such as washing). As a result, no consideration of the nature and magnitude of residues in processed commodities is required.

The fate of fluopicolide under hydrolysis conditions was investigated for the approval of the active substance (EFSA, 2009) and it was established that the active substance is hydrolytically stable under all tested conditions.

3.5 Rotational crops

For fluopicolide, the maximum field DT₉₀ value is 1,184 days and the metabolite 2,6-dichlorobenzamide (M-01) has a maximum field DT₉₀ of 1,046 days (EFSA, 2012a). Therefore, potential residues in rotated crops needs to be considered.

3.5.1 Nature of residues (Confined metabolism study on rotational crops)

Metabolism in rotational crops was investigated following bare soil treatment in radish (root crops), lettuce (leafy crops) and wheat (cereal/grass crops) for the approval of the active substance (EFSA, 2009). A summary of the rotational crop metabolism data is presented in Table 3.5.1-1 (EFSA, 2018).

Table 3.5.1-1 Summary of the available rotational crop metabolism studies

Crop groups	Crop(s)	PBI (days)	Comments
Root crops	Radish	29, 133 & 365	Trials conducted with an application at 400 g a.s./ha on bare soil (4N cGAP for fluopicolide†).
Leafy crops	Lettuce	29, 133 & 365	
Cereal/grass crops	Wheat	29, 133 & 365	

† 4N compared to maximum seasonal rate of 100 g a.s/ha

A summary of the available rotational crop metabolism data is presented below (EFSA, 2009):

“Confined rotational crop studies are available. [14C] phenyl and pyridinyl ring labelled fluopicolide was applied to soil at a rate of 0.4 kg a.i./ha (notified seasonal application rate for potatoes). Lettuce, wheat and radish were planted after 29, 133 and 365 days of ageing. Translocation of radioactive residues was observed. In crops planted after 29 days of ageing TRR were max. 3 mg/kg in consumable parts and max. 14 mg/ 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 still max. 0.6 mg/kg in consumable parts and max. 2 mg/kg in crop parts used for animal feed.

Metabolism was found to be similar, but more extensive as in primary crops. In lettuce, radish tops and radish roots fluopicolide, M-01 and M-02 were identified as main components of the radioactive residues. Additionally, M-05 and M-09 were found in some of the matrices. The main components of radioactive residues in wheat grain, forage and straw were fluopicolide, M-01, M-02, M-04 and M-05. Low concentrations of M-06, M-08 and M-09 were identified in some of the samples.”

Metabolism in rotational crops was found to be via a similar pathway to primary crops but more extensive. It was concluded that specific residue definitions for rotational crops are not required.

Due to restrictions imposed by the environmental fate risk assessment (see remarks in Appendix A), only one application will be made to crops grown in soil or organic media under protection per year. As such, the proposed greenhouse use will result in one application per year. The other proposed treatment is on crops grown in synthetic media, which is expected to be replaced after each crop cycle therefore consideration of rotational crops is not required.

As the application rate in the rotational crop metabolism studies is greater than the proposed GAP (at least 4N), the results of these studies are applicable to the proposed cGAP. The metabolism studies demonstrate that residues of fluopicolide and M-01 in rotational crops are expected to be >0.01 mg/kg. On this basis consideration of rotational crop trials is required.

3.5.2 Magnitude of residues (Rotational crop field trials)

Residues in rotational crops were investigated following bare soil treatment in beans (pulses and oilseeds), cabbage (leafy vegetables) and wheat (cereals) for the approval of the active substance (EFSA, 2009).

It is noted that the available data suggest that accumulation of fluopicolide and its metabolites' residues in the soil following multiple applications of active must be considered because the parent/metabolite DT₉₀ > 500 days. For assessments under Assimilated Regulation 544/2011, in accordance with SANCO 7524/VI/95 rev.2, the accumulation of residues does not need to be addressed prior to the authorisation of a new use.

Table 3.5.2 Summary of the field rotational crop studies

Crop group	Crop	Application			Highest residue levels (mg/kg)	
		PBI (day)	g a.s./ha	on bare soil or primary crop	Fluopicolide	M-01
Leafy crops	Cabbage	33 - 49	400	Potato	Head: <0.01	Head: 0.04
Cereals/Grass crops	Winter wheat	28 - 39	400	Potato	Grain: <0.01 Straw: 0.09	Grain: <0.01 Straw: 0.01
	Spring wheat	174 - 227	400	Potato	Grain: <0.01 Straw: 0.12	Grain: <0.01 Straw: 0.03
Pulses/Oilseeds	Field beans (green pods)	57 - 227	400	Potato	Green pods: <0.01 Dried pod: <0.01 Dried seeds: <0.01	Green pods: 0.02 Dried pod: 0.07 Dried seed: <0.01

A summary of the available rotational crop trials data is presented below (EFSA, 2009):

“Nine field trials on rotational crops have been submitted. After the harvest of potatoes which were treated with four foliar applications of fluopicolide at a rate of 0.1 kg a.i./ha (N rate), winter and spring wheat, beans and cabbage were planted into the soil after 28-227 days of ageing. Samples were analysed for fluopicolide, M-01 and M-02, wheat samples additionally for M-04 and M-05. Fluopicolide was below the LOQ (0.01 mg/kg) in crops

harvested at maturity with the exception of wheat straw which contained up to 0.12 mg/kg. M-01 was found in quantifiable concentrations in cabbage (max. 0.04 mg/kg) and wheat straw (max. 0.03 mg/kg). Low levels (all below 0.1 mg/kg) of M-02, M-04 and M-05 were found in some samples of wheat grain and straw. On the basis of the residue trials on rotational crops, levels of fluopicolide (proposed residue definition for monitoring for plant matrices) below the LOQ are expected in crop parts intended for the human consumption.”

As the application rate in the rotational crop trials is significantly greater than the yearly application rate in the proposed cGAP (4N), no significant residues in rotational crops are expected in food or feed commodities (as they would be scaled to <0.01 mg/kg for food commodities and <0.05 mg/kg for feed commodities).

4 Residues in livestock

No consideration of residues in products of animal origin is required as the crop is not used as an animal feedstuff.

5 Residues in honey

No consideration of residues in honey is required, as the application is to 'old' data requirements set out under Assimilated Regulation 544/2011.

6 MRLs for products not covered in Sections 3 and 4

This section is to cover MRLs that can be extrapolated to other products included in Part 1 of the GB MRL Statutory Register but are not covered in Sections 3 and 4 of this ER/RO. Examples include MRLs for edible offals (other than liver and kidney) or MRLs to cover products derived from other species such as goat or equine.

No MRL extrapolations are recommended on the basis of this assessment.

7 Consumer risk assessment

7.1 Dietary exposure

Dietary exposures have been estimated using the UK chronic and acute models and the EFSA PRIMo.

As the residue definitions for risk assessment is comprised of fluopicolide and metabolite M-01 which are to be considered separately, consumer risk assessments have been conducted for both compounds separately with respective toxicological reference values considered.

Chronic dietary exposures to fluopicolide and M-01 have been estimated based on the uses of fluopicolide considered in this application, the uses considered in previous assessments supporting existing GB MRLs (EFSA Conclusion, 2009 and EFSA Reasoned Opinions 2011, 2012a, 2012b, 2013, 2015a, 2015b and 2018) and, for the remaining commodities, for fluopicolide, the existing MRLs established in the GB MRL Statutory Register, (residue definition for enforcement is fluopicolide only).

Acute dietary exposures to fluopicolide and M-01 have only been estimated for the uses of fluopicolide considered in this application.

UK NEDIs and NESTIs

The UK NEDIs and NESTIs for the active substance and commodities listed in Table 7.1-1a and Table 7.1-1b have been estimated for ten consumer groups using the UK chronic and acute models (versions 1.1 and 1.2 respectively) as detailed in Regulatory Update 21/2005. The following assumptions have been made:

- For the NESTIs, upper range of normal (97.5th percentile) consumption of each individual crop which may have been treated.
- For the NEDIs, the 'Rees-Day' approach is taken which sums the two highest 97.5th percentile intakes and the mean intakes for all remaining commodities.
- All produce eaten which may have been treated has been treated and contains residues at the levels given in Table 7.1-1a and Table 7.1-1b.
- There is no loss of residue during transport, storage or processing of foods prior to consumption.

As there is no consumption data for escaroles/broad-leaved endives in the UK models, the consumption data for lettuce has been used as a surrogate to ensure that appropriate consumption values are used in the consumer risk assessments. However, the available STMRs for both RD-RA 1 (fluopicolide) and RD-RA 2 (metabolite M-01 (2,6-

dichlorobenzamide)) in lettuce (EFSA, 2011) which support the current MRL for lettuce are more critical than the STMRs for the proposed escaroles/broad-leaved endives MRL from the current assessment. Therefore, for the chronic intake assessment, the risk assessment values for lettuce account for the proposed use on escaroles/broad-leaved endives.

The input values for fluopicolide in the UK consumer risk assessment are given in Table 7.1-1a.

The input values for metabolite M-01 in the UK consumer risk assessment are given in Table 7.1-1b.

Table 7.1-1a Input values for the UK consumer risk assessment for fluopicolide

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment residue definition 1: fluopicolide				
Lettuce (surrogate for escaroles/broad-leaved endives)	1.09	STMR_{RA} (EFSA, 2011)	1.6	HR_{RA} (current assessment)
Table grapes	0.38	STMR (EFSA, 2009)	Acute risk assessment undertaken only for the uses proposed as part of the current assessment	
Wine grapes	0.11	STMR (0.38) x Pf (0.4) x Yield factor (0.7) (EFSA, 2009)		
Blackberries	0.52	STMR (EFSA 2015b)		
Root and tuber vegetables (Beetroot, carrots, celeriac, horseradish, Jerusalem artichokes, parsnips, radishes, salsify, swedes, turnips)	0.03	STMR (EFSA, 2013)		
Yam	0.01	STMR (EFSA, 2013)		
Onions	0.07	STMR (EFSA, 2012a)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Spring onions	2.1	STMR (JMPR, 2010)		
Tomatoes, peppers, aubergines,	0.16	STMR (JMPR, 2010)		
Marrows, cucumbers, gourd, courgettes	0.07	STMR (JMPR, 2010)		
Melons	0.01	STMR (JMPR, 2010)		
Broccoli, cauliflower	0.385	STMR (JMPR, 2010)		
Brussels sprouts	0.04	STMR (JMPR, 2010)		
Head cabbage	0.02	STMR (EFSA, 2011)		
Chinese cabbage	0.75	STMR (EFSA, 2014)		
Kohlrabies	0.01	STMR (EFSA, 2011)		
Cress	1.09	STMR (EFSA, 2011)		
Spinach	0.40	STMR (EFSA 2015b)		
Parsley	1.09	STMR (EFSA, 2012b)		
Leek	0.25	STMR (EFSA, 2011)		
Potatoes	0.01	STMR (EFSA, 2012a)		
Hops (dried 0.25% of beer)	0.23	STMR (EFSA, 2013)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Sugar beet	0.04	STMR (EFSA, 2013)		
All other commodities	MRL (GB MRL Statutory Register and Regulation (EU) 2018/832)			

Table 7.1-1b Input values for the UK consumer risk assessment for metabolite M-01

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment residue definition 2: M-01 (2,6-dichlorobenzamide)				
Lettuce (surrogate for escaroles/broad-leaved endives)	0.02	STMR_{RA} (current assessment)	0.011	HR_{RA} (current assessment)
Table grapes	0.02	STMR (EFSA, 2009)	Acute risk assessment undertaken only for the uses proposed as part of the current assessment	
Wine grapes	0.02	STMR (EFSA, 2009)		
Blackberries	0.01	STMR (EFSA 2015b)		
Root and tuber vegetables (Beetroot, carrots, celeriac, horseradish, Jerusalem artichokes, parsnips, radishes, salsify, swedes, turnips)	0.01	STMR (EFSA, 2013)		
Yam	0.01	STMR (EFSA, 2013)		
Onions	0.01	STMR (EFSA, 2012a)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Spring onions	0.01	STM (JMP, 2010)		
Tomatoes, peppers, aubergines,	0.01	STM (JMP, 2010)		
Marrows, cucumbers, gourd, courgettes	0.01	STM (JMP, 2010)		
Melons	0.01	STM (JMP, 2010)		
Broccoli, cauliflower	0.01	STM (JMP, 2010)		
Brussels sprouts	0.01	STM (JMP, 2010)		
Head cabbage	0.01	STM (EFSA, 2011)		
Chinese cabbage	0.02	STM (EFSA, 2014)		
Kohlrabies	0.01	STM (EFSA, 2011)		
Cress	0.02	STM (EFSA, 2011)		
Spinach	0.05	STM (EFSA 2015b)		
Parsley	0.02	STM (EFSA, 2012b)		
Leek	0.01	STM (EFSA, 2011)		
Potatoes	0.01	STM (EFSA, 2012a)		
Hops (dried 0.25% of beer)	0.34	STM (EFSA, 2013)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Sugar beet	0.01	STMR (EFSA, 2013)		

In bold uses proposed as part of the current assessment.

Model outputs for the UK chronic and acute models (versions 1.1 and 1.2 respectively) are presented in Appendix B.

PRIMo

The PRIMo IEDIs and IESTIs for the active substance and commodities listed in Table 7.1-2a and Table 7.1-2b have been calculated using PRIMo revision 3.1 – Pesticide Residues Intake Model.

The following assumptions have been made:

- All produce eaten which may have been treated, has been treated and contains residues at the levels as given in Table 7.1-2a and Table 7.1.2b.
- There is no loss of residue during transport, storage or processing of foods prior to consumption.

The input values for fluopicolide for the PRIMo risk assessment are given in Table 7.1-2a.

The input values for metabolite M-01 for the PRIMo risk assessment are given in Table 7.1-2b.

Table 7.1-2a Input values for the PRIMo consumer risk assessment for fluopicolide

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment residue definition 1: Fluopicolide				
Escaroles/broad-leaved endives	0.2	STMR_{RA} (current assessment)	1.6	HR_{RA} (current assessment)
Table grapes	0.38	STMR (EFSA, 2009)	Acute risk assessment undertaken only for the	

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Wine grapes	0.11	STMR (0.38) x Pf (0.4) x Yield factor (0.7) (EFSA, 2009)	uses proposed as part of the current assessment	
Blackberries	0.52	STMR (EFSA 2015b)		
Potatoes	0.01	STMR (EFSA, 2012a)		
Tropical root and tuber vegetables (Cassava, sweet potatoes, yams, arrowroot, other tropical root and tuber vegetables)	0.01	STMR (EFSA, 2013)		
Other root and tuber vegetables except sugar beet (Beetroot, carrots, celeriac, horseradish, Jerusalem artichokes, parsnips, parsley root, radishes, salsify, swedes, turnips, other root and tuber vegetables)	0.03	STMR (EFSA, 2013)		
Onions	0.07	STMR (EFSA, 2012a)		
Spring onions	2.1	STMR (JMPR, 2010)		
Solanacea (Tomatoes, aubergines, peppers, okra, other solanacea)	0.16	STMR (JMPR, 2010)		
Cucurbits – edible peel (cucumbers, gherkins, courgettes, other cucurbits – edible peel)	0.07	STMR (JMPR, 2010)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Cucurbits – inedible peel (melons, pumpkins, watermelons, other cucurbits – inedible peel)	0.01	STMR pulp (JMPR, 2010)		
Flowering brassica (broccoli, cauliflowers, other flowering brassica)	0.385	STMR (JMPR, 2010)		
Brussels sprouts	0.04	STMR (JMPR, 2010)		
Head cabbage	0.02	STMR (EFSA, 2011)		
Chinese cabbages/pe-tsai	0.75	STMR (EFSA, 2014)		
Kale	0.75	STMR (EFSA, 2012a)		
Kohlrabies	0.01	STMR (EFSA, 2011)		
Lettuce and other salad plants, except escarole (lamb's lettuce/corn salad, lettuces, cress and other sprouts and shoots, land cress, roman rocket/rucola, red mustards, baby leaf crops, other lettuce and salad plants)	1.09	STMR (EFSA, 2011)		
Spinaches and purslanes	0.40	STMR (EFSA 2015b)		
Chards/beet leaves	0.40	STMR (EFSA, 2018)		
Herbs and edible flowers	1.09	STMR (EFSA, 2012b)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Leek	0.25	STMR (EFSA, 2011)		
Valerian root	0.80	STMR (EFSA, 2015a)		
Hops (dried)	0.23	STMR (EFSA, 2013)		
Sugar beet roots	0.04	STMR (EFSA, 2013)		
All other commodities	MRL (GB MRL Statutory Register and Regulation (EU) 2018/832)			

Table 7.1-2b Input values for the PRIMo consumer risk assessment for metabolite M-01

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment residue definition 2: M-01 (2,6-dichlorobenzamide)				
Escaroles/broad-leaved endives	0.01	STMR_{RA} (current assessment)	0.011	HR_{RA} (current assessment)
Table grapes	0.02	STMR (EFSA, 2009)	Acute risk assessment undertaken only for the uses proposed as part of the current assessment	
Wine grapes	0.02	STMR (EFSA, 2009)		
Blackberries	0.01	STMR (EFSA 2015b)		
Potatoes	0.01	STMR (EFSA, 2012a)		
Tropical root and tuber vegetables (Cassava, sweet potatoes, yams, arrowroot, other tropical root and tuber vegetables)	0.01	STMR (EFSA, 2013)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Other root and tuber vegetables except sugar beet (Beetroot, carrots, celeriac, horseradish, Jerusalem artichokes, parsnips, parsley root, radishes, salsify, swedes, turnips, other root and tuber vegetables)	0.01	STM (EFSA, 2013)		
Onions	0.01	STM (EFSA, 2012a)		
Spring onions	0.01	STM (JMPR, 2010)		
Solanacea (Tomatoes, aubergines, peppers, okra, other solanacea)	0.01	STM (JMPR, 2010)		
Cucurbits – edible peel (cucumbers, gherkins, courgettes, other cucurbits – edible peel)	0.01	STM (JMPR, 2010)		
Cucurbits – inedible peel (melons, pumpkins, watermelons, other cucurbits – inedible peel)	0.01	STM (JMPR, 2010)		
Flowering brassica (broccoli, cauliflowers, other flowering brassica)	0.01	STM (JMPR, 2010)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Brussels sprouts	0.01	STMР (JMРR, 2010)		
Head cabbage	0.01	STMР (EFSA, 2011)		
Chinese cabbages/pe-tsai	0.02	STMР (EFSA, 2014)		
Kale	0.02	STMР (EFSA, 2012a)		
Kohlrabies	0.01	STMР (EFSA, 2011)		
Lettuce and other salad plants, except escarole (lamb's lettuce/corn salad, lettuces, cress and other sprouts and shoots, land cress, roman rocket/rucola, red mustards, baby leaf crops, other lettuce and salad plants)	0.02	STMР (EFSA, 2011)		
Spinaches and purslanes	0.05	STMР (EFSA 2015b)		
Chards/beet leaves	0.01	STMР (EFSA, 2018)		
Herbs and edible flowers	0.02	STMР (EFSA, 2012b)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Leek	0.01	STMR (EFSA, 2011)		
Valerian root	0.40	STMR (EFSA, 2015a)		
Hops (dried)	0.34	STMR (EFSA, 2013)		
Sugar beet roots	0.01	STMR (EFSA, 2013)		

In bold uses proposed as part of the current assessment.

Model outputs for EFSA PRIMo revision 3.1 are presented in Appendix B.

Conclusions

For fluopicolide, the highest UK NEDI was 6% of the ADI (toddler). The highest PRIMo IEDI was 5% of the ADI (NL toddler). For metabolite M-01, the highest UK NEDI was 1% of the ADI (toddler). The highest PRIMo IEDI was 0.4% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of commodities treated with fluopicolide.

For fluopicolide, the highest UK NESTI was 15.8% of the ARfD (4-6 year old child / lettuce (surrogate for escaroles/broad-leaved endives)). The highest PRIMo IESTI was 36% of the ARfD (children / escaroles/broad-leaved endives). For metabolite M-01, the highest UK NESTI was 0.1% of the ARfD (4-6 year old child / lettuce (surrogate for escaroles/broad-leaved endives)). The highest PRIMo IESTI was 0.1% of the ARfD (children / escaroles/broad-leaved endives). Therefore, no health effects due to acute exposure are expected from the consumption of commodities treated with fluopicolide.

Combined dietary exposure

A common underlying effect on liver toxicity (chronic) and body weight and food consumption (acute) are shared by fluopicolide and metabolite M-01 and due to this shared effect on human health, a combined risk assessment is required.

Table 7.1-2c Input values for combined risk assessment for fluopicolide and M-01

Residue definition component	% of ADI/ARfD for each respective component of the residue definition			
	NEDI (toddler)	IEDI (NL Toddler)	NESTI (Lettuce (surrogate for escarole/broad-leaved endive) – 4-6 year old child)	IESTI (children - escarole/broad-leaved endive)
Fluopicolide	6	5	15.8	36
M-01	1	0.4	0.1	0.1
Total intake	7	5.4	15.9	36.1

The maximum sum of the chronic intakes for fluopicolide and metabolite M-01 (each expressed as a % of its own ADI) using the UK NEDI model is 7% (toddler). The maximum sum of the chronic intakes for fluopicolide and metabolite M-01 (each expressed as a % of its own ADI) using the EFSA PRIMo model is 5.4 % (NL toddler). Therefore, no health effects due to chronic combined exposure are expected.

The maximum sum of the acute intakes for fluopicolide and metabolite M-01 (each expressed as a % of its own ARfD) using the UK NESTI model is 15.9% (lettuce; surrogate for escaroles/broad-leaved endive, 4-6 year old child). The maximum sum of the acute intakes for fluopicolide and metabolite M-01 (each expressed as a % of its own ARfD) using the PRIMo model is 36.1% (escarole/broad-leaved endive, children).

For proposed use on escaroles/broad-leaved endive, the sum of the acute intakes (UK) fluopicolide and metabolite M-01 each expressed as a % of its own ARfD is <100%. Therefore, no health effects due to acute combined exposure are expected.

7.2 Other routes of exposure

7.2.1 Drinking water assessment

The estimated PEC_{gw} following treatment to leafy vegetables conducted at 1 x 100 g a.s./ha for fluopicolide is <0.1 µg/L and for M-01 is 4.204 µg/L. Given metabolite M-01 is present in the RD-RA for plants and as it is likely to be present in groundwater at >0.1 µg/L, consideration of its contribution to the ADI from both groundwater and foodstuffs is required. This consideration is not required for fluopicolide as its estimated PEC_{gw} is <0.1 µg/L.

In relation to the drinking water contribution, the highest intake is expected for an infant (< 4 months). EFSA Guidance on pesticides in foods for infants and young children estimates the water consumption of bottle-fed infants as 1.135 L/d (EFSA Journal 2018; 16(6) 5286, 75 pp.).

For M-01, based on the worst case PEC_{gw} (4.204 µg/L), the intake from drinking water for the critical consumer group infants is expected to be ≤ 0.00095 mg/kg bw/d. This is 1.9 % of the established ADI for M-01 (0.05 mg/kg bw/d). The estimated intake from food (plant and animal commodities) of M-01 is up to 1% of the ADI for the critical consumer group from the UK chronic model (toddler) and 0.4% for the PRIMo model (NL toddler). For reference, the values for infants are <1% in the UK Chronic model and 0.2% in the PRIMo model (based on FR infant).

The combined intakes of M-01 from food and drinking water is 2.3% of the ADI when estimating the IEDI (critical consumer: NL toddler) and 2.9% of the ADI while estimating the NEDI (critical consumer: toddler). Whilst toddlers are the critical consumer when intakes are combined, infants remain the critical consumer group for drinking water. The combined intakes of M-01 from food and drinking water for infants are 2.1% of the ADI when estimating the IEDI (critical consumer: FR infant) and <2.9% of the ADI when estimating the NEDI.

As the contribution from groundwater is significantly below the ADI, no health effects are expected.

8 The conclusion of the competent authority

Sufficiently validated analytical methods for the determination of fluopicolide in products of plant origin, in line with the residue definition for enforcement, are available to support the use under consideration in the MRL application.

Toxicological reference values were established for the approval of the active substance: for fluopicolide an ADI of 0.08 mg/kg bw/day and an ARfD of 0.18 mg/kg bw; and for metabolite M-01 (2,6-dichlorobenzamide) an ADI of 0.05 mg/kg bw/d and an ARfD of 0.3 mg/kg bw.

The metabolism of fluopicolide in primary crops was investigated in the fruit, leafy and root crop groups following foliar or soil applications for the approval of the active substance (EFSA, 2009). As a consistent metabolic pathway was observed across crops from three crop groups, the available data are sufficient to support all crop groups including leafy crops which the crop included in this MRL application belongs to.

The residue definition for risk assessment (RD-RA) in plants has been agreed as:

1. Fluopicolide
2. Metabolite M-01 (2,6-dichlorobenzamide)

The residue definition for enforcement (RD-Enf) in plants has been agreed as:

- Fluopicolide

Seven independent protected trials on open leaf lettuce were submitted to support an MRL for escaroles/broad-leaved endives. The trials are supported by validated analytical methods and storage stability data and considered acceptable to support the proposed MRL on escaroles/broad-leaved endives.

Hydrolysis of fluopicolide under representative conditions of pasteurisation, baking, brewing, boiling and sterilisation was evaluated for the approval of the active substance. The hydrolysis data demonstrate that fluopicolide is stable under standard conditions, therefore specific residue definitions for processed commodities are not required.

Residues in rotational crops were considered for the approval of the active substance. Metabolism in rotational crops was found to be via a similar pathway to primary crops but more extensive. It was concluded that specific residue definitions for rotational crops are not required. The metabolism studies demonstrated that residues of fluopicolide and M-01

in rotational crops are expected to be >0.01 mg/kg. As the application rate in the rotational crop trials is significantly greater than (4N) the proposed maximum seasonal rate, no significant residues in rotational crops are expected in food or feed commodities.

Consideration of residues in livestock is not required as the crops under consideration in the MRL application are not fed to animals.

For fluopicolide, the highest UK NEDI was 6% of the ADI (toddler). The highest PRIMo IEDI was 5% of the ADI (NL toddler). For metabolite M-01, the highest UK NEDI was 1% of the ADI (toddler). The highest PRIMo IEDI was 0.4% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of commodities treated with fluopicolide.

For fluopicolide, the highest UK NESTI was 15.8% of the ARfD (4-6 year old child / lettuce (surrogate for escaroles/broad-leaved endives)). The highest PRIMo IESTI was 36% of the ARfD (children / escaroles/broad-leaved endives). For metabolite M-01, the highest UK NESTI was 0.1% of the ARfD (4-6 year old child / lettuce (surrogate for escaroles/broad-leaved endive)). The highest PRIMo IESTI was 0.1% of the ARfD (children / escaroles/broad-leaved endives). Therefore, no health effects due to acute exposure are expected from the consumption of commodities treated with fluopicolide.

A combined risk assessment has been performed for fluopicolide and metabolite M-01. The maximum sum of the chronic intakes for fluopicolide and metabolite M-01 (each expressed as a % of its own ADI) using the UK NEDI model is 7% (toddler). The maximum sum of the chronic intakes for fluopicolide and metabolite M-01 (each expressed as a % of its own ADI) using the EFSA PRIMo model is 5.4 % (NL toddler). Therefore, no health effects due to chronic combined exposure are expected.

The maximum sum of the acute intakes for fluopicolide and metabolite M-01 (each expressed as a % of its own ARfD) using the UK NESTI model is 15.9% (lettuce; surrogate for escaroles/broad-leaved endive, 4-6 year old child). The maximum sum of the acute intakes for fluopicolide and metabolite M-01 (each expressed as a % of its own ARfD) using the PRIMo model is 36.1% (escarole/broad-leaved endive, children). For proposed use on escaroles/broad-leaved endive, the sum of the acute intakes (UK) fluopicolide and metabolite M-01 each expressed as a % of its own ARfD is <100%. Therefore, no health effects due to acute combined exposure are expected.

HSE concludes that sufficient data have been provided to support the setting of a new MRL for the proposed use of fluopicolide on escaroles/broad-leaved endives. This will not result in consumer exposures exceeding the toxicological reference values and therefore harmful effects on human health are not expected.

HSE recommends that the MRL outlined in Table 8.1 is amended in the GB MRL Statutory Register.

Table 8.1 MRL recommended by HSE

Product code	Product	Existing GB MRL (mg/kg)	New or amended GB MRL (mg/kg)	Comments
Enforcement residue definition for products of plant origin: Fluopicolide				
0251030	Escaroles/broad-leaved endives	1.5	4	<p>The MRL is derived by extrapolation of residue trials on open leaf lettuce.</p> <p>No health effects are expected.</p>

References

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EFSA (European Food Safety Authority), 2015a. Reasoned opinion on the modification of the MRL for fluopicolide in valerian. EFSA Journal 2015; 13 (9):4217, 24 pp.

EFSA (European Food Safety Authority), 2015b. Modification of the existing maximum residue level for fluopicolide in blackberries, spinaches and purslanes. EFSA Journal 2015; 13(11):4260, 22 pp.

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Appendix A – GAPs notified in the MRL application

Crop and/or situation (a)	GB or Country For Import Tolerance	Product name	F, G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s./hL min-max (l)	Water (L/ha) min-max	kg a.s./ha min-max (l)		
Escaroles/broad-leaved endives	GB	Infinito	G	Downy mildews on leaf vegetable and fresh herbs including Bremia lactucae, Peronospora belbahrii, Peronospora destructor, Peronospora effusa, Peronospora parastica, Peronospora lamii, Plasmopara petroselini.	SC	62.5 g/L fluopicolide 625 g/L propamocarb hydrochloride	Horizontal boom sprayer Hand-held application – hydraulic nozzle	Earliest: BBCH 10 (cotyledons completely unfolded) Latest: 14 days before harvest	1	N/A	Fluopicolide : 0.02 – 0.05	200 - 500	Fluopicolide : 0.1	14	Multiple crops per year not allowed for crops either grown in soil or grown in organic media under protection or permanent protection with full enclosure (PPFE).

(a) For crops, the GB and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b) State if the use is outdoor, field use (F) or glasshouse (G) or indoor use (I).

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different

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<p>(c) e.g. biting and sucking insects, soil borne insects, foliar fungi, weeds (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide (f) All abbreviations used must be explained (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p>	<p>variants (e.g. fluroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl). (j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application (k) Indicate the minimum and maximum number of applications possible under practical conditions of use (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha (m) PHI - minimum pre-harvest interval</p>
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Appendix B – UK models and Pesticide Residues Intake Model (PRIMo)

Table B.1a Chronic risk assessment undertaken using UK model version 1.1 for fluopicolide

Active substance: Fluopicolide

ADI: 0.08 mg/kg bw/day

Source: EFSA,
: 2009

	TOTAL INTAKE based on 97.5th percentile									
	ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWN HOME)	ELDERLY (RESIDENTIAL)
mg/kg bw/day	0.00227	0.00372	0.00490	0.00357	0.00281	0.00161	0.00159	0.00261	0.00178	0.00138
% of ADI	3%	5%	6%	4%	4%	2%	2%	3%	2%	2%

Commodity	STMR (mg/kg)	P	COMMODITY INTAKES (mg/kg bw/day)									
			ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWN HOME)	ELDERLY (RESIDENTIAL)
Grapefruit	0.01		0.00002	0.00002	0.00006	0.00005	0.00012	0.00002	0.00001	0.00002	0.00002	0.00002
Lemons	0.01		0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Limes	0.01		0.00000	L/C	0.00002	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001
Mandarins	0.01		0.00001	L/C	0.00006	0.00004	0.00003	0.00002	0.00002	0.00001	0.00002	0.00001
Oranges	0.01		0.00004	0.00011	0.00016	0.00011	0.00008	0.00008	0.00007	0.00005	0.00004	0.00003
Almonds	0.01		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Brazil nuts	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C

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Cashew nuts	0.01		0.00000	L/C	0.00001	0.0000 0	0.00000	0.00000	0.0000 0	0.00000	0.00000	0.00000
Chestnuts	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	0.0000 0	0.00000	0.00000	L/C
Coconuts	0.01		0.00000	0.00000	0.00000	0.0000 0	0.00000	0.00000	0.0000 0	0.00000	0.00000	0.00000
Hazelnuts	0.01		0.00000	L/C	0.00000	0.0000 0	0.00000	0.00000	0.0000 0	0.00000	0.00000	0.00000
Pecan nuts	0.01		0.00000	L/C	0.00000	L/C	0.00000	0.00000	L/C	0.00000	0.00000	L/C
Pistachios	0.01		0.00000	L/C	0.00000	L/C	0.00000	L/C	L/C	0.00000	L/C	L/C
Walnuts	0.01		0.00000	L/C	0.00000	0.0000 0	0.00000	0.00000	0.0000 0	0.00000	0.00000	0.00000
Peanuts	0.01		0.00000	0.00001	0.00001	0.0000 1	0.00001	0.00001	0.0000 0	0.00000	0.00000	0.00000
Apples	0.01		0.00003	0.00008	0.00015	0.0000 9	0.00008	0.00004	0.0000 4	0.00003	0.00002	0.00001
Pears	0.01		0.00001	0.00003	0.00007	0.0000 4	0.00002	0.00002	0.0000 1	0.00002	0.00002	0.00001
Apricots	0.01		0.00000	0.00001	0.00001	0.0000 1	0.00000	0.00000	0.0000 0	0.00001	0.00000	0.00000
Peaches	0.01		0.00001	0.00001	0.00003	0.0000 2	0.00001	0.00001	0.0000 0	0.00001	0.00001	0.00000
Plums	0.01		0.00001	0.00000	0.00002	0.0000 1	0.00001	0.00000	0.0000 0	0.00001	0.00001	0.00000
Cherries	0.01		0.00000	0.00001	0.00001	0.0000 2	0.00001	0.00001	0.0000 1	0.00001	0.00000	0.00000
Table grapes	0.38		0.00050	0.00063	0.00178	0.0008 2	0.00098	0.00042	0.0002 4	0.00077	0.00050	0.00018
Wine grapes	0.11		0.00108	0.00013	0.00010	0.0001 0	0.00003	0.00011	0.0003 9	0.00107	0.00073	0.00016
Strawberries	0.01		0.00001	0.00002	0.00002	0.0000 1	0.00001	0.00001	0.0000 1	0.00001	0.00001	0.00001
Blackberries	0.52		0.00006	L/C	0.00101	0.0000 3	0.00017	0.00013	0.0000 5	0.00016	0.00014	0.00002
Loganberries	0.01		0.00000	0.00001	0.00001	0.0000 0	0.00001	0.00000	0.0000 0	0.00000	0.00000	0.00000
Raspberries	0.01		0.00000	L/C	0.00002	0.0000 1	0.00001	0.00000	0.0000 0	0.00000	0.00001	0.00000
Gooseberries	0.01		0.00000	0.00001	0.00001	0.0000 0	0.00000	0.00000	0.0000 0	0.00001	0.00001	0.00000
Blackcurrants	0.01		0.00001	0.00001	0.00002	0.0000 2	0.00001	0.00001	0.0000 1	0.00000	0.00001	0.00000
Red currants	0.01		0.00000	L/C	0.00001	L/C	0.00000	0.00000	0.0000 0	0.00000	0.00000	L/C

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White currants	0.01		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	
Avocados	0.01		0.00001	L/C	0.00001	L/C	L/C	L/C	0.00000		0.00001	0.00001	L/C
Bananas	0.01		0.00002	0.00007	0.00007	0.00004	0.00003	0.00002	0.00001		0.00002	0.00002	0.00002
Dates	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	L/C		0.00000	0.00001	0.00000
Figs	0.01		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000		0.00001	0.00000	0.00000
Kiwi fruit	0.01		0.00001	L/C	0.00002	0.00002	0.00001	0.00001	0.00002		0.00001	0.00001	0.00000
Lychees	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C		L/C	L/C	L/C
Mangoes	0.01		0.00001	L/C	0.00002	0.00001	0.00002	0.00001	0.00004		0.00001	0.00000	L/C
Olives	0.01		0.00000	L/C	0.00001	0.00001	L/C	0.00000	L/C		0.00000	0.00000	L/C
Passion fruit	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C		0.00000	L/C	L/C
Pineapples	0.01		0.00001	0.00005	0.00005	0.00007	0.00002	0.00001	0.00001		0.00001	0.00001	0.00001
Pomegranates	0.01		0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000		0.00001	0.00001	0.00001
Beetroot	0.03		0.00001	L/C	0.00004	0.00001	0.00001	0.00001	0.00001		0.00001	0.00001	0.00001
Carrots	0.03		0.00002	0.00011	0.00007	0.00006	0.00004	0.00003	0.00003		0.00003	0.00003	0.00002
Celeriac	0.03		0.00001	L/C	L/C	0.00000	0.00000	L/C	L/C		L/C	L/C	L/C
Horseradish	0.03		0.00000	L/C	L/C	L/C	L/C	L/C	L/C		L/C	0.00000	L/C
Jerusalem artichokes	0.03		0.00001	L/C	L/C	L/C	L/C	L/C	L/C		L/C	L/C	L/C
Parsnips	0.03		0.00001	0.00003	0.00004	0.00002	0.00001	0.00001	0.00001		0.00001	0.00002	0.00001
Radishes	0.03		0.00001	L/C	0.00003	L/C	0.00001	0.00000	0.00000		0.00001	0.00001	0.00000
Salsify	0.03		L/C	L/C	L/C	L/C	L/C	L/C	L/C		L/C	L/C	L/C
Swedes	0.03		0.00001	0.00008	0.00005	0.00002	0.00002	0.00002	0.00001		0.00001	0.00002	0.00001
Turnips	0.03		0.00001	L/C	0.00003	0.00003	0.00002	0.00002	0.00001		0.00000	0.00002	0.00001
Yam	0.01		0.00003	L/C	L/C	L/C	L/C	L/C	L/C		L/C	L/C	L/C

The evaluation of a new MRL for fluopicolide in or on escaroles/broad-leaved endives

Garlic	0.3		0.00002	L/C	0.00002	0.0000 3	0.00004	0.00002	0.0000 4	0.00004	0.00004	L/C
Onions	0.07		0.00004	0.00008	0.00008	0.0000 6	0.00006	0.00005	0.0000 4	0.00005	0.00004	0.00002
Spring onions	2.1		0.00053	L/C	0.00033	0.0013 7	0.00038	0.00019	0.0002 2	0.00053	0.00053	0.00019
Tomatoes	0.16		0.00022	0.00029	0.00042	0.0003 1	0.00029	0.00017	0.0002 1	0.00028	0.00023	0.00021
Peppers	0.16		0.00006	L/C	0.00013	0.0000 7	0.00011	0.00005	0.0000 5	0.00010	0.00009	0.00003
Aubergines	0.16		0.00005	L/C	0.00024	0.0001 2	0.00004	0.00008	0.0000 6	0.00010	0.00006	L/C
Marrows	0.07		0.00004	L/C	0.00011	0.0000 3	0.00004	0.00004	0.0000 2	0.00004	0.00010	0.00005
Cucumbers	0.07		0.00003	0.00002	0.00017	0.0001 1	0.00007	0.00004	0.0000 3	0.00004	0.00003	0.00001
Gourd	0.07		0.00004	L/C	L/C	L/C	L/C	0.00002	L/C	0.00001	L/C	L/C
Courgettes	0.07		0.00003	0.00010	0.00017	0.0000 9	0.00005	0.00003	0.0000 3	0.00004	0.00004	0.00003
Melons	0.01		0.00002	0.00003	0.00005	0.0000 4	0.00003	0.00002	0.0000 3	0.00003	0.00003	0.00001
Sweet corn	0.01		0.00001	0.00001	0.00002	0.0000 1	0.00001	0.00000	0.0000 1	0.00001	0.00001	0.00000
Broccoli	0.385		0.00025	0.00044	0.00066	0.0004 7	0.00040	0.00028	0.0002 4	0.00026	0.00037	0.00013
Cauliflower	0.385		0.00034	0.00121	0.00084	0.0006 4	0.00033	0.00029	0.0003 3	0.00047	0.00044	0.00026
Brussels sprouts	0.04		0.00002	0.00009	0.00007	0.0000 6	0.00003	0.00004	0.0000 3	0.00003	0.00004	0.00002
Head cabbage	0.02		0.00001	0.00004	0.00003	0.0000 3	0.00001	0.00001	0.0000 1	0.00002	0.00002	0.00001
Chinese cabbage	0.75		0.00037	L/C	L/C	L/C	L/C	L/C	L/C	0.00038	0.00026	L/C
Kohl Rabi	0.01		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Cress	1.09		0.00004	L/C	0.00005	0.0000 7	0.00002	0.00005	0.0000 3	0.00008	0.00010	0.00004
Lettuce	1.09		0.00068	0.00039	0.00093	0.0007 5	0.00079	0.00044	0.0004 8	0.00077	0.00058	0.00030
Spinach	0.4		0.00021	0.00040	0.00063	0.0003 4	0.00035	0.00025	0.0001 4	0.00027	0.00022	0.00014
Watercress	0.01		0.00000	L/C	L/C	0.0000 0	0.00000	0.00000	L/C	0.00000	0.00000	L/C
Chicory	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C

The evaluation of a new MRL for fluopicolide in or on escaroles/broad-leaved endives

Parsley	1.09		0.00019	L/C	0.00012	L/C	0.00017	0.00005	0.00002	0.00019	0.00020	0.00040
Beans with pods	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00000	0.00001	0.00000	0.00001	0.00000
Runner Beans	0.01		0.00001	L/C	0.00001	0.00000	0.00001	0.00001	0.00000	0.00002	0.00001	0.00001
Beans without pods	0.01		0.00000	0.00001	0.00002	0.00000	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001
Peas with pods	0.01		0.00000	L/C	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	L/C
Peas without pods	0.01		0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Beansprouts	0.01		0.00000	L/C	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Asparagus	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00001	0.00000	L/C
Bamboo shoots	0.01		0.00000	L/C	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Celery	0.01		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Fennel	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Globe artichokes	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C
Leeks	0.25		0.00012	L/C	0.00016	0.00009	0.00008	0.00009	0.00006	0.00012	0.00014	0.00009
Rhubarb	0.01		0.00000	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Cultivated mushrooms	0.01		0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Beans	0.01		0.00002	0.00006	0.00005	0.00003	0.00003	0.00002	0.00002	0.00002	0.00001	0.00001
Lentils	0.01		0.00001	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
dried Peas	0.01		0.00001	L/C	0.00002	0.00000	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Oilseeds	0.01		0.00003	0.00006	0.00007	0.00007	0.00006	0.00004	0.00004	0.00005	0.00003	0.00004
Potatoes	0.01		0.00003	0.00011	0.00009	0.00008	0.00007	0.00005	0.00005	0.00004	0.00003	0.00003
Hops (dried 0.25% of beer)	0.23		0.00001	L/C	L/C	L/C	L/C	0.00000	0.00001	0.00001	0.00001	0.00001
Oats	0.01		0.00000	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001	0.00001
Barley	0.01		0.00000	L/C	0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000

The evaluation of a new MRL for fluopicolide in or on escaroles/broad-leaved endives

Millet	0.01		L/C	L/C	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Buckwheat	0.01		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Maize	0.01		0.00000	0.00005	0.00001	0.0000 0	0.00000	0.00000	0.0000 0	0.00000	0.00000	0.00000
Wheat	0.01		0.00004	0.00003	0.00008	0.0000 9	0.00007	0.00005	0.0000 4	0.00004	0.00003	0.00003
Rice	0.01		0.00002	0.00003	0.00005	0.0000 4	0.00005	0.00004	0.0000 3	0.00002	0.00001	0.00000
Rye	0.01		0.00001	0.00001	0.00000	0.0000 0	0.00000	0.00000	0.0000 0	0.00001	0.00000	0.00000
Poultry	0.01		0.00002	0.00002	0.00003	0.0000 3	0.00002	0.00002	0.0000 2	0.00002	0.00002	0.00001
Meat fat	0.01		0.00000	0.00000	0.00001	0.0000 0	0.00000	0.00000	0.0000 0	0.00000	0.00000	0.00000
Meat excl. poultry & offal	0.01		0.00002	0.00004	0.00004	0.0000 3	0.00003	0.00002	0.0000 2	0.00000	0.00002	0.00002
All types of kidney	0.01		0.00000	0.00000	0.00001	0.0000 0	0.00000	0.00000	0.0000 0	L/C	0.00000	0.00000
All types of Liver	0.01		0.00000	0.00002	0.00002	0.0000 0	0.00000	0.00001	0.0000 0	L/C	0.00001	0.00000
Other types of offal	0.01		0.00001	0.00002	0.00002	0.0000 1	0.00001	0.00001	0.0000 0	0.00000	0.00001	0.00001
Eggs	0.01		0.00001	0.00005	0.00003	0.0000 2	0.00002	0.00001	0.0000 1	0.00001	0.00001	0.00001
Milk	0.02		0.00016	0.00195	0.00112	0.0005 9	0.00036	0.00024	0.0001 9	0.00019	0.00017	0.00024
Sugar beet	0.04		0.00056	0.00133	0.00223	0.0013 5	0.00126	0.00080	0.0007 7	0.00048	0.00042	0.00061

* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value \geq 0.000005 is rounded to 0.00001)

L/C Low consumption (<0.1 g/day) or low number of consumers (<4)

The evaluation of a new MRL for fluopicolide in or on escaroles/broad-leaved endives

Turnips	0.01		0.00000	L/C	0.00001	0.0000 1	0.00001	0.00001	0.0000 0	0.00000	0.00001	0.00000
Yam	0.01		0.00003	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Onions	0.01		0.00001	0.00001	0.00001	0.0000 1	0.00001	0.00001	0.0000 1	0.00001	0.00001	0.00000
Spring onions	0.01		0.00000	L/C	0.00000	0.0000 1	0.00000	0.00000	0.0000 0	0.00000	0.00000	0.00000
Tomatoes	0.01		0.00001	0.00002	0.00003	0.0000 2	0.00002	0.00001	0.0000 1	0.00002	0.00001	0.00001
Peppers	0.01		0.00000	L/C	0.00001	0.0000 0	0.00001	0.00000	0.0000 0	0.00001	0.00001	0.00000
Aubergines	0.01		0.00000	L/C	0.00002	0.0000 1	0.00000	0.00001	0.0000 0	0.00001	0.00000	L/C
Marrows	0.01		0.00001	L/C	0.00002	0.0000 0	0.00001	0.00001	0.0000 0	0.00001	0.00001	0.00001
Cucumbers	0.01		0.00000	0.00000	0.00002	0.0000 2	0.00001	0.00001	0.0000 0	0.00001	0.00000	0.00000
Gourd	0.01		0.00001	L/C	L/C	L/C	L/C	0.00000	L/C	0.00000	L/C	L/C
Courgettes	0.01		0.00000	0.00001	0.00002	0.0000 1	0.00001	0.00000	0.0000 0	0.00001	0.00001	0.00000
Melons	0.01		0.00002	0.00003	0.00005	0.0000 4	0.00003	0.00002	0.0000 3	0.00003	0.00003	0.00001
Broccoli	0.01		0.00001	0.00001	0.00002	0.0000 1	0.00001	0.00001	0.0000 1	0.00001	0.00001	0.00000
Cauliflower	0.01		0.00001	0.00003	0.00002	0.0000 2	0.00001	0.00001	0.0000 1	0.00001	0.00001	0.00001
Brussels sprouts	0.01		0.00001	0.00002	0.00002	0.0000 1	0.00001	0.00001	0.0000 1	0.00001	0.00001	0.00000
Head cabbage	0.01		0.00001	0.00002	0.00002	0.0000 1	0.00001	0.00001	0.0000 1	0.00001	0.00001	0.00001
Chinese cabbage	0.02		0.00001	L/C	L/C	L/C	L/C	L/C	L/C	0.00001	0.00001	L/C
Kohl Rabi	0.01		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Cress	0.02		0.00000	L/C	0.00000	0.0000 0	0.00000	0.00000	0.0000 0	0.00000	0.00000	0.00000
Lettuce	0.02		0.00001	0.00001	0.00002	0.0000 1	0.00001	0.00001	0.0000 1	0.00001	0.00001	0.00001
Spinach	0.05		0.00003	0.00005	0.00008	0.0000 4	0.00004	0.00003	0.0000 2	0.00003	0.00003	0.00002
Parsley	0.02		0.00000	L/C	0.00000	L/C	0.00000	0.00000	0.0000 0	0.00000	0.00000	0.00001
Leeks	0.01		0.00000	L/C	0.00001	0.0000 0	0.00000	0.00000	0.0000 0	0.00000	0.00001	0.00000

The evaluation of a new MRL for fluopicolide in or on escaroles/broad-leaved endives

Potatoes	0.01		0.00003	0.00011	0.00009	0.00008	0.00007	0.00005	0.00005	0.00004	0.00003	0.00003
Hops (dried 0.25% of beer)	0.34		0.00002	L/C	L/C	L/C	L/C	0.00000	0.00002	0.00002	0.00002	0.00002
Sugar beet	0.01		0.00014	0.00033	0.00056	0.00034	0.00031	0.00020	0.00019	0.00012	0.00011	0.00015

* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value \geq 0.000005 is rounded to 0.00001)

L/C Low consumption (<0.1 g/day) or low number of consumers (<4)

Table B.2a Chronic risk assessment undertaken using PRIMo revision 3.1 for fluopicolide


 <p>European Food Safety Authority EFSA PRIMo revision 3.1; 2019/03/19</p>		Fluopicolide				Input values						
		LOQs (mg/kg) range from:		to:		Details - chronic risk assessment		Supplementary results - chronic risk assessment				
		Toxicological reference values				Details - acute risk assessment/children		Details - acute risk assessment/adults				
		ADI (mg/kg bw/day):		0.08		ARfD (mg/kg bw):		0.18				
Source of ADI:		EFSA		Source of ARfD:		EFSA						
Year of evaluation:		2009		Year of evaluation:		2009						
Comments:												
Normal mode												
Chronic risk assessment: JMPR methodology (IEDI/TMDI)												
No of diets exceeding the ADI : ---										Exposure resulting from MRLs set at the LOQ (in % of ADI)		
TMDI(NED)/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)		Exposure (µg/kg bw per day)		Highest contributor to MS diet (in % of ADI)		2nd contributor to MS diet (in % of ADI)		3rd contributor to MS diet (in % of ADI)		Commodity / group of commodities	
	MS Diet				Commodity / group of commodities		Commodity / group of commodities		Commodity / group of commodities		Exposure resulting from commodities not under assessment (in % of ADI)	
	5%	NL toddler	3.66	1%	Milk: Cattle	0.7%	Table grapes	0.4%	Spinaches		0.1%	
	3%	DE child	2.07	0.7%	Table grapes	0.5%	Milk: Cattle	0.2%	Tomatoes		0.0%	
	3%	NL child	2.05	0.6%	Milk: Cattle	0.5%	Table grapes	0.4%	Sugar beet roots		0.0%	
	2%	GEMS/Food G06	1.94	0.7%	Tomatoes	0.5%	Table grapes	0.1%	Lettuces		0.0%	
	2%	FR child 3-15 yr	1.57	0.6%	Milk: Cattle	0.2%	Sugar beet roots	0.2%	Tomatoes			
	2%	GEMS/Food G10	1.56	0.4%	Lettuces	0.3%	Tomatoes	0.1%	Chinese cabbages/pe-tsai		0.0%	
	2%	SE general	1.52	0.5%	Lettuces	0.3%	Milk: Cattle	0.2%	Chinese cabbages/pe-tsai			
	2%	FR toddler 2-3 yr	1.42	0.7%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Cauliflowers			
	2%	GEMS/Food G07	1.37	0.3%	Lettuces	0.2%	Tomatoes	0.2%	Wine grapes		0.0%	
	2%	GEMS/Food G08	1.36	0.3%	Lettuces	0.2%	Tomatoes	0.2%	Table grapes		0.0%	
	2%	GEMS/Food G11	1.34	0.2%	Table grapes	0.2%	Milk: Cattle	0.2%	Tomatoes		0.0%	
	2%	IE adult	1.32	0.2%	Wine grapes	0.1%	Table grapes	0.1%	Spring onions/green onions and Wel			
	2%	DE women 14-50 yr	1.28	0.3%	Milk: Cattle	0.2%	Sugar beet roots	0.2%	Lettuces		0.0%	
	2%	RO general	1.28	0.4%	Tomatoes	0.3%	Milk: Cattle	0.2%	Wine grapes			
	2%	UK infant	1.26	1.0%	Milk: Cattle	0.1%	Cauliflowers	0.1%	Tomatoes			
	2%	GEMS/Food G15	1.24	0.2%	Tomatoes	0.2%	Milk: Cattle	0.2%	Table grapes		0.0%	
	2%	ES child	1.24	0.6%	Lettuces	0.3%	Milk: Cattle	0.2%	Tomatoes			
	1%	DE general	1.20	0.3%	Milk: Cattle	0.2%	Sugar beet roots	0.1%	Tomatoes		0.0%	
	1%	ES adult	1.16	0.7%	Lettuces	0.2%	Tomatoes	0.1%	Milk: Cattle			
	1%	IT adult	1.13	0.5%	Lettuces	0.2%	Tomatoes	0.2%	Other lettuce and other salad plants		0.0%	
	1%	NL general	1.08	0.2%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Lettuces		0.0%	
	1%	UK toddler	1.08	0.5%	Milk: Cattle	0.2%	Sugar beet roots	0.1%	Tomatoes			
1%	DK child	1.06	0.3%	Milk: Cattle	0.2%	Lettuces	0.1%	Cucumbers				
1%	IT toddler	1.03	0.4%	Lettuces	0.3%	Tomatoes	0.2%	Other lettuce and other salad plants		0.0%		
1%	PT general	1.02	0.3%	Wine grapes	0.2%	Tomatoes	0.2%	Kales				
1%	FR adult	0.96	0.3%	Wine grapes	0.2%	Other lettuce and other salad plants	0.1%	Milk: Cattle				
1%	FR infant	0.93	0.4%	Milk: Cattle	0.1%	Spinaches	0.1%	Cauliflowers				
0.9%	UK vegetarian	0.74	0.2%	Lettuces	0.1%	Lettuces	0.1%	Tomatoes				
0.8%	DK adult	0.65	0.1%	Milk: Cattle	0.1%	Wine grapes	0.1%	Lettuces				
0.8%	FI 3 yr	0.61	0.1%	Tomatoes	0.1%	Table grapes	0.1%	Cucumbers				
0.8%	UK adult	0.61	0.2%	Lettuces	0.1%	Wine grapes	0.1%	Tomatoes				
0.7%	FI adult	0.57	0.2%	Lettuces	0.1%	Coffee beans	0.1%	Tomatoes				
0.7%	FI 6 yr	0.52	0.1%	Lettuces	0.1%	Tomatoes	0.1%	Table grapes				
0.6%	PL general	0.50	0.2%	Tomatoes	0.2%	Table grapes	0.0%	Cauliflowers				
0.5%	LT adult	0.41	0.1%	Tomatoes	0.1%	Milk: Cattle	0.1%	Lettuces				
0.3%	IE child	0.21	0.1%	Milk: Cattle	0.0%	Broccoli	0.0%	Table grapes				
<p>Conclusion: The estimated long-term dietary intake (TMDI(NED)/IEDI) was below the ADI. The long-term intake of residues of Fluopicolide is unlikely to present a public health concern.</p>												

Table B.2b Chronic risk assessment undertaken using PRIMo revision 3.1 for metabolite M-01


 <p>European Food Safety Authority EFSA PRIMo revision 3.1; 2019/03/19</p>		Metabolite M-01				Input values					
		LOQs (mg/kg) range from:		to:		Details - chronic risk assessment		Supplementary results - chronic risk assessment			
		Toxicological reference values				Details - acute risk assessment/children		Details - acute risk assessment/adults			
		ADI (mg/kg bw/day):	0.05	ARID (mg/kg bw):	0.3						
Source of ADI:	EFSA	Source of ARID:	EFSA								
Year of evaluation:	2009	Year of evaluation:	2009								
Comments:											
Normal mode											
Chronic risk assessment: JMPR methodology (IED/TMDI)											
No of diets exceeding the ADI : ---											
TMDI(NED)I calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
	0.4%	NL toddler	0.21	0.1%	Sugar beet roots	0.1%	Potatoes	0.1%	Spinaches		0.0%
	0.4%	NL child	0.18	0.2%	Sugar beet roots	0.1%	Potatoes	0.0%	Table grapes		0.0%
	0.3%	GEMS/Food G06	0.15	0.1%	Tomatoes	0.0%	Table grapes	0.0%	Potatoes		0.0%
	0.3%	RO general	0.15	0.1%	Potatoes	0.1%	Wine grapes	0.0%	Tomatoes		
	0.3%	IE adult	0.14	0.1%	Sweet potatoes	0.1%	Wine grapes	0.0%	Potatoes		
	0.3%	PT general	0.14	0.1%	Potatoes	0.1%	Wine grapes	0.0%	Tomatoes		
	0.2%	GEMS/Food G15	0.12	0.1%	Potatoes	0.0%	Wine grapes	0.0%	Tomatoes		0.0%
	0.2%	GEMS/Food G08	0.12	0.1%	Potatoes	0.0%	Wine grapes	0.0%	Tomatoes		0.0%
	0.2%	GEMS/Food G07	0.11	0.1%	Potatoes	0.1%	Wine grapes	0.0%	Tomatoes		0.0%
	0.2%	GEMS/Food G11	0.11	0.1%	Potatoes	0.0%	Wine grapes	0.0%	Tomatoes		0.0%
	0.2%	DE child	0.11	0.1%	Table grapes	0.1%	Potatoes	0.0%	Carrots		0.0%
	0.2%	DE women 14-50 yr	0.11	0.1%	Sugar beet roots	0.0%	Wine grapes	0.0%	Potatoes		0.0%
	0.2%	FR child 3 15 yr	0.10	0.1%	Sugar beet roots	0.0%	Potatoes	0.0%	Tomatoes		0.0%
	0.2%	DE general	0.10	0.1%	Sugar beet roots	0.0%	Wine grapes	0.0%	Potatoes		0.0%
	0.2%	GEMS/Food G10	0.10	0.1%	Potatoes	0.0%	Tomatoes	0.0%	Wine grapes		0.0%
	0.2%	SE general	0.10	0.1%	Potatoes	0.0%	Carrots	0.0%	Tomatoes		
	0.2%	NL general	0.10	0.1%	Sugar beet roots	0.0%	Potatoes	0.0%	Wine grapes		0.0%
	0.2%	UK toddler	0.09	0.1%	Potatoes	0.1%	Sugar beet roots	0.0%	Tomatoes		
	0.2%	FI 3 yr	0.09	0.1%	Potatoes	0.0%	Cucumbers	0.0%	Carrots		
	0.2%	FR toddler 2 3 yr	0.09	0.1%	Sugar beet roots	0.0%	Potatoes	0.0%	Spinaches		
	0.2%	FR adult	0.09	0.1%	Wine grapes	0.0%	Sugar beet roots	0.0%	Potatoes		
	0.2%	DK child	0.08	0.0%	Potatoes	0.0%	Cucumbers	0.0%	Carrots		
	0.2%	FR infant	0.08	0.0%	Potatoes	0.0%	Sugar beet roots	0.0%	Spinaches		
	0.1%	UK infant	0.07	0.1%	Potatoes	0.0%	Sugar beet roots	0.0%	Carrots		
	0.1%	FI 6 yr	0.07	0.1%	Potatoes	0.0%	Cucumbers	0.0%	Carrots		
	0.1%	PL general	0.07	0.1%	Potatoes	0.0%	Tomatoes	0.0%	Table grapes		
	0.1%	UK vegetarian	0.06	0.0%	Wine grapes	0.0%	Potatoes	0.0%	Tomatoes		
	0.1%	UK adult	0.06	0.0%	Wine grapes	0.0%	Potatoes	0.0%	Sugar beet roots		
	0.1%	DK adult	0.06	0.0%	Wine grapes	0.0%	Potatoes	0.0%	Tomatoes		
	0.1%	LT adult	0.05	0.1%	Potatoes	0.0%	Tomatoes	0.0%	Head cabbages		
	0.1%	ES child	0.05	0.0%	Potatoes	0.0%	Tomatoes	0.0%	Lettuces		
	0.1%	ES adult	0.05	0.0%	Potatoes	0.0%	Wine grapes	0.0%	Tomatoes		
	0.1%	IT toddler	0.04	0.0%	Tomatoes	0.0%	Potatoes	0.0%	Lettuces		0.0%
0.1%	IT adult	0.04	0.0%	Tomatoes	0.0%	Potatoes	0.0%	Spinaches		0.0%	
0.1%	FI adult	0.04	0.0%	Potatoes	0.0%	Wine grapes	0.0%	Tomatoes			
0.0%	IE child	0.01	0.0%	Potatoes	0.0%	Carrots	0.0%	Table grapes			
<p>Conclusion: The estimated long-term dietary intake (TMDI/NED)I was below the ADI. The long-term intake of residues of Metabolite M-01 is unlikely to present a public health concern.</p>											

Table B.3a Acute risk assessment undertaken using UK model version 1.2 for fluopicolide

Acute Intakes (97.5th percentiles)

commodity	HR	P	adult		infant		toddler		4-6 year old child		7-10 year old child	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Lettuce	1.60		0.01579	8.8	0.02023	11.2	0.01931	10.7	0.02849	15.8	0.02151	12.0

commodity	HR	P	11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Lettuce	1.60		0.01333	7.4	0.01284	7.1	0.01758	9.8	0.01128	6.3	0.00631	3.5

Table B.3b Acute risk assessment undertaken using UK model version 1.2 for metabolite M-01

Acute Intakes (97.5th percentiles)

commodity	HR	P	adult		infant		toddler		4-6 year old child		7-10 year old child	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Lettuce	0.01		0.00011	0.0	0.00014	0.0	0.00013	0.0	0.00020	0.1	0.00015	0.0

commodity	HR	P	11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Lettuce	0.01		0.00009	0.0	0.00009	0.0	0.00012	0.0	0.00008	0.0	0.00004	0.0

Table B.4a Acute risk assessment undertaken using PRIMo revision 3.1 for fluopicolide

Unprocessed commodities	Results for children				Results for adults			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
36%	Escaroles/broad-leaved	4 / 1.6	64	18%	Escaroles/broad-leaved	4 / 1.6	32	
Expand/collapse list								
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								

Table B.4b Acute risk assessment undertaken using PRIMo revision 3.1 for metabolite M-01

Unprocessed commodities	Results for children				Results for adults			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Escaroles/broad-leaved	0 / 0.01	0.44	0.07%	Escaroles/broad-leaved	0 / 0.01	0.22	
Expand/collapse list								
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								

Table B.5 Acute risk assessment undertaken using PRIMo revision 3.1 for fluopicolide, supporting a CXL of 30 mg/kg for leafy vegetables

Unprocessed commodities	Results for children				Results for adults			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	1				1			
	IESTI				IESTI			
			MRL / input for RA (mg/kg)	Exposure (µg/kg bw)			MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
Highest % of ARfD/ADI	Commodities			Highest % of ARfD/ADI	Commodities			
379%	Escaroles/broad-leaved	30 / 17	683	190%	Escaroles/broad-leaved	30 / 17	343	
Expand/collapse list								
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								
1								

Appendix C - Detailed evaluation of the additional studies relied on

C.1 Methods of analysis

No additional studies submitted.

C.2 Mammalian toxicology

No additional studies submitted.

C.3 Residue data

C.3.1 Nature and magnitude of residues in primary crops

C.3.1.1 Nature of residues

No additional studies submitted.

C.3.1.2 Magnitude of residues

C.3.1.2.1 Open leaf lettuce - protected

Reference: Determination of the residues of fluopicolide and propamocarb hydrochloride in/on lettuce, leaf after spray application of Fluopicolide & Propamocarb-Hydrochloride SC 687.5 in the greenhouse in Germany, northern France, Italy, the Netherlands, Belgium, Portugal and Greece, ██████████ 2013, Study ID: 12-2060

Guideline(s): OECD – Guideline for the Testing of Chemicals, Test Guideline 509; Crop field trial, 07/09/2009

SANCO 7029/VI/95 rev.5 - General recommendations for the design, preparation and realization of residue trials, 22/07/1997

Deviations: No

GLP: Yes

Validity of the study: Acceptable

Materials and methods

Eight indoor trials on open leaf lettuce were conducted in greenhouses in Germany, Northern France, the Netherlands, Belgium, Italy, Portugal and Greece, using a suspension concentrate (SC) formulation 'Fluopicolide & Propamocarb-Hydrochloride SC 687.5' which contains 62.5 g/L fluopicolide and 625 g/L propamocarb hydrochloride, in the 2012-2013 growing season.

The magnitude of residues was determined for fluopicolide, M-01 (AE C653711, 2,6-dichlorobenzamide) and M-02 (AE C657188, 3-chloro-5-trifluoromethylpyridine-2-carboxylic acid).

'Fluopicolide & Propamocarb-Hydrochloride SC 687.5' was applied as a foliar spray at a rate of 100 - 108 g a.s./ha fluopicolide in 300 - 650 L/ha of water. Three plots were set up at each trial site where applications of 'Fluopicolide & Propamocarb-Hydrochloride SC 687.5' were made at a nominal rate of 0.1 kg a.s./ha fluopicolide per application. Plots T1 and T2 had application rates of 3 x 0.1 kg a.s./ha and 2 x 0.1 kg a.s./ha respectively and therefore are not relevant to the proposed cGAP which accounts for one application of the product. Therefore, only residue data from Plot T3 has been considered further as this plot is most representative of the cGAP.

In Plot T3, one application was made at BBCH 19 – 48. Data on residues in lettuce is presented at 7 DALA (normal commercial harvest) and 13 - 15 DALA.

The trials were decline trials albeit with only 2 time points sampled. A decline trial should include 3 – 5 sampling intervals in addition to the target PHI. However, data from all plots show a significant decline in residues between samples taken at 7 and 14 days after last treatment, therefore, the lack of decline samples does not have a significant impact on the validity of the residue data in the trials and it is not expected later sampling timepoints would show higher residue levels. Control samples were not taken at 13-15 DALA, (only at 0 DALA and 7 DALA), however the decline in residues observed for treated samples between 7 DALA and 13-15 DALA suggest that residues in the control sample at 13-15 DALA will be below LOQ. In trials 12-2060-04 and 12-2060-05 an additional control sample was taken 14 days after last treatment and the observed residues for fluopicolide and M-01 were < LOQ.

Samples containing at least 1 kg were collected from both treated and control plots, except in trials 12-2060-06 and 12-2060-08 where less than 1 kg of lettuce samples were taken at 0 DALA (> 0.45 kg and >0.42 kg respectively). This was due to bad weather conditions impacting the growth and development of the lettuce and to ensure sufficient quantities of lettuce remained for latter timepoints. This does not have a significant impact as residue data from 0 DALA in trial 12-2060-06 and trial 12-2060-08 are comparable to the other trials. Additionally, in accordance with OECD 509 (2021) sampling from 12 plants is required and at least 15 plants were sampled in the trials.

Weather data were reported for the trials and no exceptional events were noted. Samples were frozen within 24 hours and stored at ≤ -18 °C until analysis. For fluopicolide and metabolite M-01, sufficient storage stability in high water commodities (potato and cabbage) is available from the approval of the active to support the maximum storage period of 284 days in the trials on lettuce.

The study states that the time between the beginning of the sample preparation and the sample analysis did not exceed 24 hours for the whole study except for a few samples relating to analysis of fluopicolide and its metabolites. For these samples, the extracts were stored at 4 +/- 3°C before further dilution. All the recovery determinations were

performed concurrently to the analyses of control and treated samples from the study therefore stability of extracts has been sufficiently addressed. Mean procedural recoveries were in the range 85 – 97% and deemed acceptable.

For fluopicolide and its metabolites M-01 and M-02, analysis was performed using LC- MS/ MS method 01209. This method was successfully validated on potato (high water), grape (high acid), tomato (high water), dry bean (dry), sunflower (high oil) and wheat straw (dry) in a previous PPP authorisation (HSE internal ref: COP 2016/01040, W001857165). The analytical method was satisfactorily validated in accordance with SANCO 3029/99 rev. 4 with an LOQ of 0.01 mg/kg for all compounds in all matrices, except M-02 in wheat straw: 0.05 mg/kg. Reduced validation data was presented in Study 12-2060 for lettuce (high water). Procedural recoveries were performed at two fortifications levels (LOQ, 10xLOQ), with an appropriate number of samples. Mean recoveries for fluopicolide, M-01 and M-02 were in the range 89 - 100% and deemed acceptable.

Extraction efficiency was not investigated in this study. The samples were extracted in this study using acetone/water acidified with formic acid (75/25/1, v/v/v). In the metabolism studies considered for approval of the active substance, samples were extracted using acetonitrile. Given the different solvents used in the metabolism studies versus the data generation method, it is considered that the extraction efficiency for fluopicolide and its metabolites has not been addressed. In principle further data are required. However, extraction efficiency was not addressed for the approval of the active substance and the lack of data is unlikely to impact the outcome of the consumer risk assessment. Therefore, no further data are required at this time.

Results and discussions

Trial 12-2060-04 and trial 12-2060-05 were performed at the same location (2988 CG Ridderkerk, Netherlands), in the same year (2012) with the same application rate (100 g a.s./ha and 108 g a.s./ha; within 8% of one another) and used the same variety of lettuce (Lollo Bionda). As a result, these trials cannot be considered independent and are considered to be replicates. The mean value of the two trials has been selected and reported for calculation of the STMR, HR and MRL (GB extrapolations guidance 2024)

No significant deviations were noted in the trials and no residues of fluopicolide, M-01 or M-02 were detected above LOQ in control samples for all trials.

A summary of the residues trials is given in Table 3.1.2.1-1.

Residues of fluopicolide in lettuce at 13-15 days after last application were between 0.10 – 1.6 mg/kg.

Residues of M-01 in lettuce 13-15 days after last application were between <0.01 – 0.011 mg/kg.

Table C.3.1.2.1-1 Residue trials on lettuce

Reference: Determination of the residues of fluopicolide and propamocarb hydrochloride in/on lettuce, leaf after spray application of Fluopicolide & Propamocarb-Hydrochloride SC 687.5 in the greenhouse in Germany, northern France, Italy, the Netherlands, Belgium, Portugal and Greece, [REDACTED] 2013, Study ID: 12-2060

GLP: Yes Sample storage conditions: Max 318 days at ≤-18 °C

Crop/crop group: Lettuce Analytical method: 01209. Validated

Indoor/outdoor: Protected Limit of Quantification (mg/kg): 0.01

Formulation: SC Residues calculated as: Fluopicolide, AE C653711 (M-01), AE C657188 (M-02)

Content of active substance: 62.5 g/L fluopicolide
625 g/L propamocarb hydrochloride

Trial No Location Year	Commodity Variety	Date of 1.Sowing or planting 2.Flowering 3.Harvest	Application rate per treatment			Dates of treatment or number and last date	Interval between applicatio ns (days)	Growth stage at last treatmen t	Portion analysed	Residues (mg/kg)			PHI (days)	Remarks
			g a.s./ ha	Water (L/ha)	g a.s./ hL					Fluopic olide	M-01 (AE C65371 1)	M-02 (AE C65718 8)		

The evaluation of a new MRL for fluopicolide in or on escaroles/broad-leaved endives

12-2060-01 42799 Leichlingen Germany 2012 Plot T3	Lettuce/ Quelio, Lollo Bionda	1. 02/06/2012 2. – 3. 01/07/2012 – 15/07/2012	100	300	33.3	03/07/2012	N/A	BBCH 48	Head	0.91 <u>0.14</u>	<0.01 <u><0.01</u>	<0.01 <u><0.01</u>	7 14	
12-2060-02 37230 Fondettes France 2012 Plot T3	Lettuce/ Feska, Lollo Rosso	1. 20/03/2012 2. – 3. 25/04/2012 – 15/05/2012	100	600	16.7	20/04/2012	N/A	BBCH 47	Head	3.5 <u>1.5</u>	<0.01 0.011	<0.01 <u><0.01</u>	7 14	
12-2060-03 44042 Cento Italy 2012 Plot T3	Lettuce/ Lollo Rossa, red variety	1. 26/04/2012 2. – 3. 18/05/2012 – 11/06/2012	100	600	16.7	21/05/2012	N/A	BBCH 45	Head	0.74 <u>0.20</u>	0.010 <u><0.01</u>	<0.01 <u><0.01</u>	7 14	
12-2060-04 2988 DA Ridderkerk Netherlands 2012 Plot T3	Lettuce/ Lollo Bionda (summer)	1. 04/06/2012 2. – 3. 09/07/2012 – 16/07/2012	100	300	33.3	02/07/2012	N/A	BBCH 48	Head	0.41 <u>0.10</u> [†]	<0.01 <u><0.01</u> [†]	<0.01 <u><0.01</u> [†]	7 14	[†] Non- independent trials, mean values: Fluopicolide: <u>0.11</u> mg/kg

The evaluation of a new MRL for fluopicolide in or on escaroles/broad-leaved endives

12-2060-05 2988 DA Ridderkerk Netherlands 2012 Plot T3	Lettuce/ Lollo Bionda (summer)	1. 04/06/2012 2. – 3. 09/07/2012 – 16/07/2012	108	325	33.3	02/07/2012	N/A	BBCH 48	Head	0.19 <u>0.11</u> †	<0.01 <u><0.01</u> †	<0.01 <u><0.01</u> †	7 14	M-01: <u><0.01</u> mg/kg
12-2060-06 6210 Villers- Perwin Belgium 2012 Plot T3	Lettuce/ Klausia, oak leaf lettuce	1. 12/03/2012 2. – 3. 10/05/2012 – 25/05/2012	100	650	15.4	17/04/2012	N/A	BBCH 42	Head	0.73 <u>0.22</u>	<0.01 0.010	<0.01 <u><0.01</u>	7 15	
12-2060-07 2040-535 Malaqueijo Portugal 2012 Plot T3	Lettuce/ Invicta	1. 27/08/2012 2. – 3. 01/10/1012 – 31/12/2012	100	500	20	21/09/2021	N/A	BBCH 37	Head	0.54 <u>0.19</u>	0.011 0.010	<0.01 <u><0.01</u>	7 13	
12-2060-08 GR-60100 Aronas, Katerni Greece 2012 Plot T3	Lettuce/ Manchester, Lollo Rosso	1. 28/10/2012 2. – 3. 30/11/2012 – 28/02/2013	100	500	20	26/11/2012	N/A	BBCH 19	Head	3.3 <u>1.6</u>	<0.01 <u><0.01</u>	<0.01 <u><0.01</u>	7 14	

C.3.2 Nature and magnitude of residues in processed commodities

No additional studies submitted.

C.3.3 Nature and magnitude of residues in rotational crops

No additional studies submitted.

C.3.4 Nature and magnitude of residues in livestock

No additional studies submitted.

C.3.5 Residues in honey

No additional studies submitted.

C.3.6 Storage stability

No additional studies submitted.

Appendix D – List of endpoints

The endpoints have not changed as a result of this assessment. The full list of endpoints is outlined in EFSA, 2009 and EFSA, 2018.

Appendix E – Import Tolerances

Not applicable.

Appendix F – Compound codes

No new metabolism studies were evaluated during this assessment and hence this section has not been completed.

Appendix G – Abbreviations

ADI	Acceptable daily intake
ADME	Absorption, distribution, metabolism and excretion
Animal model 2017	EFSA model used to calculate the dietary burden of livestock using the OECD feeding tables
ARfD	Acute reference dose
a.s.	Active substance
BBCH	Growth stages of mono- and dicotyledonous plants
bw	Body weight
CF	Conversion factor
cGAP	Critical GAP
CXL	Codex maximum residue limit
DAR	Draft assessment report
DAT	Days after treatment
DT ₉₀	Period required for 90% dissipation (define method of estimation)
DT ₅₀	Period required for 50% dissipation (define method of estimation)
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GB	Great Britain
GC-MS	Gas chromatography with mass spectrometry

GLP	Good laboratory practice
HPLC-MS/MS (LC-MS/MS)	High-performance liquid chromatography with tandem mass spectrometry
HR	Highest residue
HSE	Health and Safety Executive
IEDI	International estimate of daily intake
IESTI	International estimate of short-term intake
ILV	Independent laboratory validation
ISO	International Organisation for Standardization
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC ₅₀	Lethal concentration, median
LD ₅₀	Lethal dose, median
LOAEL	Lowest observed adverse effect level
LOD	Limit of detection or limit of determination (should be defined)
LoEP	List of endpoints
LOQ	Limit of quantification NB the limit of quantification and limit of determination are the same. Assimilated Regulation 396/2005 refers to the limit of determination Assimilated Regulation 1107/2009 refers to the limit of quantification MRLs marked with an asterisk (e.g. 0.01* mg/kg) are MRLs set at the limit of determination/quantification
MRL	Maximum residue level
NEDI	National estimate of dietary intake
NESTI	National estimate of short-term intake

NOAEL	No observed adverse effect level
NRL	National reference laboratory
OECD	Organisation for Economic Co-operation and Development
PBI	Plant-back interval
PES	Post-extraction solids
Pf	Processing factor
PHI	Preharvest interval
PRIMo	(EFSA) Pesticide Residue Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	Risk assessment
RD	Residue definition
RD-Enf	Residue definition for enforcement (also referred to as RD-Mo i.e. residue definition for monitoring)
RD-RA	Residue definition for risk assessment
RTI	Re-treatment interval
STMR	Supervised trials median residue
TRR	Total radioactive residue
TTC	Threshold of toxicological concern
WG	Water dispersible granule
WHO	World Health Organization

Additional studies relied upon

Author(s)	Year	Title/Testing Facility/Report No/GLP or GEP Status/Published or not
[REDACTED]	2013	Determination of the residues of fluopicolide and propamocarb hydrochloride in/on lettuce, leaf after spray application of Fluopicolide & Propamocarb-Hydrochloride SC 687.5 in the greenhouse in Germany, northern France, Italy, the Netherlands, Belgium, Portugal and Greece, 2013, Study ID: 12-2060. GLP. Non-published

