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## Modification of the existing maximum residue level for fluopyram in purslanes

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### Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Bayer CropScience submitted a request to the competent national authority in the Netherlands to modify the existing maximum residue level (MRL) for the active substance fluopyram in purslanes. The data submitted in support of the request were found to be sufficient to derive a MRL proposal for purslanes. Adequate analytical methods for enforcement are available to control the residues of fluopyram in plant matrices/on the commodity under consideration. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of fluopyram according to the reported agricultural practice is unlikely to present a risk to consumer health.

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## Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS), the Netherlands, received applications from Bayer CropScience to modify the existing maximum residue level (MRL) for the active substance fluopyram in purslanes. The EMS drafted the evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 11 October 2016. To accommodate for the intended use of fluopyram, the EMS proposed to raise the existing MRL from 0.2 mg/kg to 15 mg/kg.

EFSA bases its assessment on the updated evaluation reports submitted by the EMS, the draft assessment report (DAR) prepared under Directive 91/414/EEC, the conclusion on the peer review of the pesticide risk assessment of the active substance fluopyram, the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) evaluation reports as well as previous EFSA reasoned opinions on fluopyram.

The toxicological profile of fluopyram was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.012 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.5 mg/kg bw.

The metabolism of fluopyram in primary crops was investigated in the fruit (grape, pepper), root (potato) and pulses/oilseeds (bean) crop groups and the residue definition was proposed as 'fluopyram' for enforcement and as 'sum of fluopyram and fluopyram-benzamide (M25) expressed as fluopyram' for risk assessment purposes. The metabolism of fluopyram in rotational crops and the effect of processing on the nature of the residue were assessed in the framework of the peer review and it was concluded that the residue definitions set on primary crops are applicable to rotational crops and processing commodities.

For the use supported in this MRL application, EFSA concludes that the metabolism of fluopyram is sufficiently addressed and that the derived residue definitions are applicable.

Adequate analytical enforcement methods are available to monitor the residues of fluopyram in the plant matrices under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg.

EFSA concludes that the submitted residue trials on lettuces (open leaf varieties) were sufficient to derive a MRL proposal of 20 mg/kg for purslanes. The derived MRL is based on the indoor Good Agricultural Practice (GAP) only.

Since purslanes can grow in rotation and due to the high persistence of fluopyram in soils, residues of fluopyram in a rotational crop scenario need to be further investigated. Results from a confined rotational crop study have shown that at a dose rate up to 534 g/ha (1.3 N the intended application rate) residues in rotational crops cannot be excluded. New field rotational studies have not been submitted.

Based on the available data, EFSA is of the opinion that the MRL proposal derived in this reasoned opinion covers the possible soil uptake of fluopyram residues, in case purslanes are grown in rotation with crops treated with fluopyram; however, EFSA recommends Member States to consider mitigation measures when granting national authorisations for plant protection products containing fluopyram.

EFSA highlights that this MRL proposal may be reconsidered under the framework of the MRL review of fluopyram under Article 12 of the Regulation (EU) 396/2005 or once the approach for setting of MRLs in rotational crops is agreed upon at EU or international level.

Studies investigating the magnitude of fluopyram residues in processed commodities were not submitted and they are not required.

Since purslanes are not used as feed items, transfer of residues to commodities of animal origin was not assessed.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). A long-term consumer intake concern was not identified for any of the European diets incorporated in the EFSA PRIMo. The maximum calculated chronic intake accounted for 58% of the ADI (DE child). The contribution of residues in the crops under consideration to the total consumer exposure was low, accounting for less than 0.1% of the ADI. The highest acute consumer exposure for purslanes was calculated to be 30 % of the ARfD.

EFSA concludes that the intended use of fluopyram on the crop under consideration will not result in a consumer exposure exceeding the toxicological reference values and, therefore, is unlikely to pose a concern for public health.

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

Code <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
<b>Enforcement residue definition:</b> Fluopyram				
0252020	Purslanes	0.2	20	Current MRL based on default MRL for rotational crops MRL proposal derived from residue trials on lettuce (open leaf varieties) and supporting the indoor use of fluopyram MRL proposal is expected to cover the occurrence of residues in a rotational crop scenario A risk for consumers has not been identified

MRL: maximum residue level.

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

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## Background

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

The applicant Bayer CropScience<sup>4</sup> submitted an application to the competent national authority in the Netherlands, hereafter referred to as the evaluating Member State (EMS), to modify the existing MRL for the active substance fluopyram in purslanes. This application was notified to the European Commission and the European Food Safety Authority (EFSA) and was subsequently evaluated by the EMS in accordance with Article 8 of the MRL regulation.

The EMS summarised the data provided by the applicant in an evaluation report which was submitted to the European Commission and forwarded to EFSA on 11 October 2016. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2016-00651 and the following subject:

### *Fluopyram – MRLs in purslanes*

The Netherlands proposed to raise the existing MRL of fluopyram in purslanes from 0.2 mg/kg to 15 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA points which needed further clarification were requested to the EMS. On March 2017, the EMS submitted the requested information in a revised evaluation report (Netherlands, 2016), which replaced the previously submitted evaluation report.

## Terms of Reference

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall assess the application and the evaluation report and give a reasoned opinion on the risks to the consumer and where relevant to animals associated with the setting of the requested MRLs. The opinion shall include:

- an assessment of whether the analytical method for routine monitoring proposed in the application is appropriate for the intended control purposes;
- the anticipated limit of quantification (LOQ) for the pesticide/product combination;
- an assessment of the risks of the acceptable daily intake (ADI) and acute reference dose (ARfD) being exceeded as a result of the modification of the MRL;
- the contribution to the intake due to the residues in the product for which the MRLs was requested;
- any other element relevant to the risk assessment.

In accordance with Article 11 of the MRL regulation, EFSA shall give its reasoned opinion as soon as possible and at the latest within three months from the date of receipt of the application.

The evaluation report submitted by the EMS (Netherlands, 2016) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion. Furthermore, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

## The active substance and its use pattern

The detailed description of the intended uses of fluopyram in purslanes, which is the basis for the current MRL application, is reported in Appendix A.

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

<sup>2</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.

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

<sup>4</sup> Bayer CropScience, Industrieweg 13641 RT, Mijdrecht, the Netherlands.

Fluopyram is the ISO common name for *N*-{2-[3-chloro-5-(trifluoromethyl)-2-pyridyl] ethyl- $\alpha,\alpha$ ,  $\alpha$ -trifluoro-*o*-toluamine (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Fluopyram was evaluated in the framework of Regulation (EC) No 1107/2009 with Germany designated as rapporteur Member State (RMS) for the representative uses as foliar applications on grape, tomato and strawberry. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2013).

Fluopyram was approved<sup>5</sup> for the use as fungicide on 1 February 2014.

The EU MRLs for fluopyram are established in Annex IIIA of Regulation (EC) No 396/2005. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has not yet been completed. EFSA has issued several reasoned opinions on the modification of MRLs for fluopyram. The proposals from these reasoned opinions have been considered in recent regulations,<sup>6,7</sup> for EU MRL legislation.

## Assessment

EFSA has based its assessment on the evaluation report submitted by the EMS (Netherlands, 2016), the DAR and its addendum prepared under Directive 91/414/EEC (Germany, 2011, 2012), the European Commission review report on fluopyram (European Commission, 2013), the conclusion on the peer review of the pesticide risk assessment of the active substance fluopyram (EFSA, 2013), the JMPR Evaluation report (FAO, 2015), as well as the conclusions from previous EFSA opinions on fluopyram under Article 10 of EU Regulation 396/2005 (EFSA, 2014, 2016).

For this application, the data requirements established in Regulation (EU) No 544/2011<sup>8</sup> and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2016; OECD, 2011, 2013).

The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011<sup>9</sup>.

A selected list of end points of the studies assessed by EFSA in the framework of the peer review, including the end points of studies submitted in support of the current MRL application, are presented in Appendix B.

### 1. Residues in plants

#### 1.1. Nature of residues and methods of analysis in plants

##### 1.1.1. Nature of residues in primary crops

The metabolism of fluopyram has been investigated in the framework of EU pesticides peer review in primary crops belonging to the fruit, root and pulses/oilseeds crop categories (EFSA, 2013).

<sup>5</sup> Commission Implementing Regulation (EU) No 802/2013 of 22 August 2013 approving the active substance fluopyram, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 225, 23.8.2013, p. 13–16.

<sup>6</sup> Commission Regulation (EU) 2015/1101 of 8 July 2015 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for difenoconazole, fluopicolide, fluopyram, isopyrazam and pendimethalin in or on certain products, OJ L 181, 9.7.2015, p. 27–53.

<sup>7</sup> Commission Regulation (EU) 2017/171 of 30 January 2017 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aminopyralid, azoxystrobin, cyantraniliprole, cyflufenamid, cyproconazole, diethofencarb, dithiocarbamates, fluazifop-P, fluopyram, haloxyfop, isofetamid, metalaxyl, prohexadione, propaquizafop, pyrimethanil, *Trichoderma atroviride* strain SC1 and zoxamide in or on certain products. C/2017/0401. OJ L 30, 3.2.2017, p. 45–111.

<sup>8</sup> Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

<sup>9</sup> Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

### 1.1.2. Nature of residues in rotational crops

Since purslanes can grow in crop rotation with other crops and due to the high persistence of fluopyram in soils ( $DT_{50} > 300$  days,  $DT_{90} > 1,000$  days) (EFSA, 2013), residues in a rotational crop scenario need to be further considered as result of the use of fluopyram. The metabolism of fluopyram in rotational crops (root, leafy and cereals crops categories) was assessed in the framework of the EU peer review process. The metabolism in rotational crops was shown to be similar to primary crop metabolism and residues occurrence cannot be excluded (EFSA, 2013).

### 1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of fluopyram was investigated in the framework of the EU pesticides peer review. Fluopyram and fluopyram-benzamide (metabolite M25) were found to be stable under standard hydrolysis conditions (EFSA, 2013).

### 1.1.4. Methods of analysis in plants

Analytical methods for the determination of fluopyram residues in plant commodities were assessed during the peer review under Directive 91/414/EEC (EFSA, 2013). An analytical method using gas chromatography with mass spectrometric (GC-MS) detection was concluded to be sufficiently validated for the determination of fluopyram residues in high acid (orange), high oil (oilseed rape), high water (lettuce), dry/protein (pea) and dry/starch (wheat) commodities at the validated LOQ of 0.01 mg/kg.

### 1.1.5. Stability of residues in plants

The stability of fluopyram and its benzamide metabolite in plant matrices under storage conditions prior to analysis was assessed during the peer review under Directive 91/414/EEC (EFSA, 2013) and additional studies were assessed in the previous EFSA reasoned opinion (EFSA, 2014). Based on the available data, it was concluded that residues of fluopyram and its metabolite M25 are stable for at least 3 years in high water (lettuce, cabbage), high starch (wheat), high protein (dry pea), high oil (rapeseeds) and in high acid matrices (orange), when stored at  $-18^{\circ}\text{C}$  (EFSA, 2014).

### 1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies on primary and rotational crops, the results of hydrolysis studies, the toxicological significance of metabolites and/or degradation products, the capabilities of enforcement analytical methods, the following general residue definitions were proposed:

- Residue definition for enforcement: fluopyram;
- Residue definition for risk assessment: sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram.

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above mentioned residue definition as well as the residue definitions proposed by JMPR.

Taking into account the additional information provided with this application, EFSA concluded that these residue definitions are appropriate and applicable for the intended use in purslanes. Since purslanes belong to the high water content commodities category, EFSA concludes that sufficiently validated analytical methods are available to monitor fluopyram residues in the commodity under assessment with an LOQ of 0.01 mg/kg.

## 1.2. Magnitude of residues in primary crops

### 1.2.1. Magnitude of residues in plants

To support the intended use of fluopyram in purslanes, both outdoor and indoor Good Agricultural Practices (GAPs) were included in the MRL application.

In support of the indoor GAP ( $2 \times 200$  g/ha, preharvest interval (PHI) 7 days), 11 GAP-compliant residue trials on lettuces were provided; seven out of 11 residue trials performed in lettuces open leaf varieties. The trials were conducted in different locations over two seasons and their independence has been confirmed.



The samples were analysed for the parent compound and the metabolite included in the residue definition for risk assessment. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose. As the trial samples were stored for less than 36 months (max. 490 days) under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability.

The applicant proposed to extrapolate the residue situation from lettuces to purslanes (0252020) which belong to the spinaches and similar leaves group (0252000). In accordance with the EU extrapolation rules (European Commission, 2016), this extrapolation is acceptable if only residue trials in lettuces open leaf varieties are considered in the MRL calculation. For this reason, four residue trials on head forming varieties initially included in the data set by the EMS were not considered for the MRL setting. This different selection of the trials resulted in the difference between the MRL proposed by the EMS<sup>10</sup> and by EFSA. The number and quality of the trials were sufficient to derive a MRL of 20 mg/kg.

Residue data have not been submitted in support of the outdoor GAPs; therefore, the derived MRL is based on the indoor use only.

### 1.2.2. Magnitude of residues in rotational crops

The confined rotational crop study previously evaluated (EFSA, 2013) shown that residues of fluopyram cannot be excluded in rotational crops. Therefore, rotational field studies were required.

Based on these rotational field studies conducted at a dose rate of 500 g/ha and where the highest residue was found up to 0.09 mg/kg at a plant back interval (PBI) of 28–36 days, a default MRL has been set at 0.2 mg/kg for leafy crops grown in rotation (EFSA, 2014).

The dose rate of the rotational field studies represents 1.3 N of the maximum annual application rate of the GAP under assessment (max. annual rate of 400 g/ha); therefore, EFSA concludes that the data are also fit for purposes in the scenario under assessment and residues of fluopyram in rotational crops might be expected at similar levels.

Based on the available data, EFSA is of the opinion that, in case purslanes are grown in rotation with crops treated with fluopyram, the derived MRL of 20 mg/kg is expected to cover the possible soil uptake of fluopyram residues. However, EFSA emphasises that this MRL proposal may need to be reconsidered in the framework of the MRL review under Article 12 of the Regulation (EU) 396/2005 or once the approach for setting of MRLs in rotational crops has been agreed upon at EU or international level.

For the time being, EFSA recommends Member States to include mitigation measures when granting national authorisations for plant protection products based on fluopyram in order to avoid the possible occurrence of residues in rotational crops due to the high persistence of the active substance.

### 1.2.3. Magnitude of residues in processed commodities

New processing studies were not submitted under the current MRL application. Nevertheless, they are not required in this case as they are not expected to affect the outcome of the risk assessment. If processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

### 1.2.4. Proposed MRLs

The available data are considered sufficient to calculate a MRL proposal of 20 mg/kg using the OECD calculator as well as risk assessment values for purslanes supporting the intended indoor use (indoor,  $2 \times 200$  g/ha, PHI 7 days, interval between applications 7 days) (see Appendix B.1.2.1).

In Section 3, EFSA assessed whether residues on the crop resulting from the intended use of fluopyram in purslanes are likely to pose a consumer health risk.

## 2. Residues in livestock

Not relevant as purslanes are not used for feed purposes.

<sup>10</sup> The MRL proposed by the EMS is 15 mg/kg, considering residues trials performed in lettuces open and close leaves varieties. The combination of lettuces open and close leaf varieties is not foreseen according to the EU extrapolation guidance (European Commission, 2016).

### 3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo (EFSA, 2007). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference values for fluopyram used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the EU pesticides peer review (EFSA, 2013). The metabolites included in the risk assessment residue definition were considered to be of similar toxicity/not more toxic than the parent compound.

#### 3.1. Short-term (acute) dietary risk assessment

The short-term exposure calculations were performed based on the highest residue (HR) derived from supervised field trials and only for the commodity under consideration in this MRL application. The list of input values can be found in Appendix D.2.

The short-term exposure did not exceed the ARfD for the crop assessed and accounted up to 30% of the ARfD (see Appendix B.3).

EFSA concluded that the short-term intake of residues of fluopyram resulting from intended use is unlikely to present a risk to consumer health.

#### 3.2. Long-term (chronic) dietary risk assessment

The long-term exposure assessment was performed, taking into account the supervised trials median residues (STMR) values derived for the commodities assessed in this application; for the remaining commodities covered by the MRL regulation, the existing EU MRLs according to the last implementation under Regulation (EU) 2017/978<sup>11</sup> and STMR values derived in previous MRL applications were selected as input values (EFSA, 2013, 2014, 2016; FAO, 2015). The complete list of input values is presented in Appendix D.2.

The estimated long-term dietary intake accounted for up to 58% of the ADI (German, children). The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is presented in more detail in Appendix B.3.

EFSA concluded that the long-term intake of residues of fluopyram resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

### Conclusions and recommendations

The data submitted in support of this MRL application were found to be sufficient to propose a MRL for fluopyram in purslanes of 20 mg/kg supported by the indoor trials and where residues of fluopyram resulted from the reported agricultural practices are unlikely to pose risk to consumers.

The MRL recommendations are summarised in Appendix B.4.

Due to the high persistence of fluopyram in soils and due to the fact that purslanes can be grown in rotation, in order to minimise the possible occurrence of fluopyram residues in a rotational crop, EFSA recommends Member State to define mitigation measures when granting authorisations at national level.

Furthermore, EFSA emphasises that this MRL proposal may need to be reconsidered under the framework of the MRL review under Article 12 of the Regulation (EU) 396/2005 or once the approach for setting of MRLs in rotational crops has been agreed upon at EU or international level.

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<sup>11</sup> Commission Regulation (EU) 2017/978 of 9 June 2017 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fluopyram; hexachlorocyclohexane (HCH), alpha-isomer; hexachlorocyclohexane (HCH), beta-isomer; hexachlorocyclohexane (HCH), sum of isomers, except the gamma-isomer; lindane (hexachlorocyclohexane (HCH), gamma-isomer); nicotine and profenofos in or on certain products. C/2017/3840. OJ L 151, 14.6.2017, p. 1–37.

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## Abbreviations

a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAS	Chemical Abstract Service

CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex maximum residue limit
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DT <sub>50</sub>	period required for 50% dissipation (define method of estimation)
DT <sub>90</sub>	period required for 90% dissipation (define method of estimation)
EMS	evaluating Member State
ER	Evaluation Report
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC	gas chromatography
GC–MS	gas chromatography with mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
Mo	monitoring
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RD	residue definition
RMS	rapporteur Member State
SC	suspension concentrate
SEU	southern Europe
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
WHO	World Health Organization

## Appendix A – Good Agricultural Practice (GAPs)

Crop and/or situation	NEU, SEU, MS or country	F G or I <sup>(a)</sup>	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days) <sup>(d)</sup>	Remarks
				Type <sup>(b)</sup>	Conc. a.s.	Method kind	Range of growth stages and season <sup>(c)</sup>	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	kg a.s./ha min–max		
Purslanes (sea aster, sea lavender, other purslanes)	Belgium, Netherlands	G	<i>Botrytis cinerea</i> (BOTRCI) <i>Sclerotinia sclerotiorum</i> (SCLESC)	SC	FLU 250 + TFS 250	Foliar spraying	BBCH 12-49	1–2 (7 days)			200–1,000	0.20	7	
Purslanes (sea aster, sea lavender, other purslanes)	Belgium, Netherlands	F	<i>Botrytis cinerea</i> / <i>Botryotinia fuckeliana</i> (BOTRCI) <i>Sclerotinia sclerotiorum</i> (SCLESC)	SC	FLU 250 + TFS 250	Foliar spraying	BBCH 13-40	1			200–800	0.20	7	
Purslanes (sea aster, sea lavender, other purslanes)	Greece Italy	F	<i>Botrytis cinerea</i> (BOTRCI) <i>Sclerotinia</i> <i>sp.</i> : <i>sclerotiorum</i> (SCLESC) <i>Sclerotinia minor</i> (SCLEMI) <i>Rhizoctonia solani</i> SC (RHIZSO)	SC	FLU 250 + TFS 250	Foliar spraying	BBCH 40-49	1–2 (7 days)			300–1,000	0.20	7	
Purslanes (sea aster, sea lavender, other purslanes)	France	F	<i>Botrytis cinerea</i> (BOTRCI) <i>Sclerotinia sclerotiorum</i> (SCLESC) <i>Sclerotinia minor</i> (SCLEMI) <i>Rhizoctonia solani</i> SC (RHIZSO)	SC	FLU 250 + TFS 250	Foliar spraying	BBCH 40-49	1			200–800	0.20	7	

NEU: northern European Union; SEU: southern European Union; MS; Member State; a.s.: active substance.

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

(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system.

(c): 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.

(d): PHI: minimum preharvest interval.

## Appendix B – List of end points

### B.1. Residues in plants

#### B.1.1. Nature of residues and methods of analysis in plants

##### B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

Primary crops (available studies)	Crop groups	Crop(s)	Application(s)	Sampling (DALA)
	Fruit crops	Grape	Foliar, 1 × 100 + 2 × 200 g/ha	18–19
		Pepper	Drip irrigation, 5 and 20 mg/plant	33–97
	Root crops	Potato	Foliar, 3 × 167 g/ha	51
	Pulses/oilseeds	Bean	Foliar, 2 × 250 g/ha	4–29
Radiolabelled active substance: phenyl-UL- <sup>14</sup> C Reference: EFSA (2013)				
Rotational crops (available studies)	Crop groups	Crop(s)	Application(s)	PBI (DAT)
	Root	Turnip	Bare soil, 1 × 534 g/ha	30, 139, 280
	Leafy	Swiss chard	Bare soil, 1 × 534 g/ha	30, 139, 280
	Cereal (small grain)	Wheat	Bare soil, 1 × 534 g/ha	30, 139, 280
Comments: Phenyl-UL- <sup>14</sup> C and Pyridyl-2,6- <sup>14</sup> C Reference: Germany (2011); EFSA (2013)				
Processed commodities (hydrolysis study)	Conditions			Investigated?
	Pasteurisation (20 min, 90°C, pH 4)			Yes
	Baking, brewing and boiling (60 min, 100°C, pH 5)			Yes
	Sterilisation (20 min, 120°C, pH 6)			Yes
Reference: EFSA (2013)				

DALA: days after last application; PBI: plant back interval; DAT: days after treatment.

Can a general residue definition be proposed for primary crops?	Yes
Rotational crop and primary crop metabolism similar?	Yes
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes
Plant residue definition for monitoring (RD-Mo)	Fluopyram
Plant residue definition for risk assessment (RD-RA)	Sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram
Conversion factor (monitoring to risk assessment)	See appendix B.1.2.1
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high water content, high oil content, high acid content and dry matrices: GC–MS, LOQ 0.01 mg/kg (EFSA, 2013; EFSA, 2016)

**B.1.1.2. Stability of residues in plants**

<b>Plant products</b> (available studies)	<b>Category</b>	<b>Commodity</b>	<b>T (°C)</b>	<b>Stability (months)</b>
	High water content	Lettuce, cabbage	-18°C	36
	High oil content	Rapeseed	-18°C	36
	Dry/high starch	Dry pea/wheat	-18°C	36
	High acid content	Orange	-18°C	36
Reference: EFSA (2016)				

## B.1.2. Magnitude of residues in plants

### B.1.2.1. Summary of residues data from the supervised residue trials

Crop (supervised trials)	Region/ indoor <sup>(a)</sup>	Residue levels observed in the supervised residue trials (mg/kg)	Comments (OECD calculations)	MRL proposals (mg/kg)	HR <sub>Mo</sub> <sup>(b)</sup> (mg/kg)	STMR <sub>Mo</sub> <sup>(c)</sup> (mg/kg)	CF <sup>(d)</sup>
Lettuce 2 × 200 g/ha PHI 7 days	Indoor	<b>Mo:</b> 0.83; 0.92; 0.94; 1.60; 3.60; 3.90; 10.00 <b>RA:</b> 0.84; 0.94; 0.95; 1.61; 3.63; 3.91; 10.01	<b>Extrapolation</b> from lettuces open leaf varieties to a minor crop (purslanes) which belongs to the spinaches and similar leaves group (European Commission, 2016) <b>Calculated MRL<sub>OECD</sub>:</b> 16.31/20.00	<b>20</b>	10 HR <sub>RA</sub> <sup>(e)</sup> 10.01	1.6 STMR <sub>RA</sub> <sup>(f)</sup> 1.61	1
	NEU	<b>Mo:</b> – <b>RA:</b> –	GAP included in the MRL application/ER but not supported by residue data	–	–	–	–
	SEU	<b>Mo:</b> – <b>RA:</b> –	GAP included in the MRL application/ER but not supported by residue data	–	–	–	–

PHI: preharvest interval; MRL: maximum residue level; OECD: Organisation for Economic Co-operation and Development; Mo: monitoring; GAP: Good Agricultural Practice.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.

(b): Highest residue according to the residue definition for monitoring (fluopyram).

(c): Supervised trials median residue according to the residue definition for monitoring (fluopyram).

(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment (rounded value).

(e): Highest residue according to the residue definition for risk assessment (sum of fluopyram and its metabolite (M25), express as fluopyram).

(f): Supervised trials median residue according to the residue definition for risk assessment (sum of fluopyram and its metabolite (M25), express as fluopyram).



### B.1.2.2. Residues in succeeding crops

Confined rotational crop study  
(quantitative aspect)

The confined rotational crop studies shown that residues cannot be excluded with a dose application up to 534 g/ha

Field rotational crop study

Field rotational crop studies shown fluopyram residues up to 0.09 mg/kg at PBI between 28 and 36 days in spinaches after an application of 500 g/ha into bare soil. The current EU MRL for rotational crops belonging to the spinaches and similar leaves group has been set according the field rotational crop studies.

### B.1.2.3. Processing factors

No new data submitted.

## B.2. Residues in livestock

Not relevant.

## B.3. Consumer risk assessment

ARfD

0.5 mg/kg bw (EFSA, 2013)

Highest IESTI, according to EFSA PRIMo

Purslanes: 30% of ARfD

Assumptions made for the calculations

The calculation is based on the highest residue levels expected in raw agricultural commodities according to the residue definition for risk assessment

ADI

0.012 mg/kg bw per day (EFSA, 2013)

Highest IEDI, according to EFSA PRIMo

58% ADI (German, children)  
Contribution of crops assessed:  
Purslanes: 0.08% of ADI

Assumptions made for the calculations

The chronic consumers' exposure has been calculated by using the supervised trials median residue (STMR) derived for purslanes according to the risk assessment residue definition and the STMR values previously evaluated and implemented in the MRL Regulation, when available. By default when no available information, the EU MRL already implemented has been used for exposure calculation

For those food commodities where uses have not been evaluated and MRLs were set at the LOQ, the default LOQ has been considered for the exposure estimation

## B.4. Recommended MRLs

Code <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
<b>Enforcement residue definition:</b> Fluopyram				
0252020	Purslanes	0.2	20	Current MRL based on default MRL for leafy crops growing in rotation MRL proposal derived from residue trials on lettuce (open leaf varieties) and supporting the indoor use of fluopyram MRL proposal is expected to cover the occurrence of residues in a rotational crop scenario A risk for consumers has not been identified

MRL: maximum residue level.

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

(F): Fat soluble.

## Appendix C – Pesticide Residue Intake Model (PRIMo)

Fluopyram			
Status of the active substance:	Approved	Code no.	
LOQ (mg/kg bw):	0.01	Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	0.012	ARfD (mg/kg bw):	0.5
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2013	Year of evaluation:	2013

Chronic risk assessment – refined calculations								
			TMDI (range) in % of ADI minimum – maximum					
			7 – 58					
			No of diets exceeding ADI:			---		
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRls at LOQ (in % of ADI)
58	DE child	23	Apples	6	Table grapes	5	Milk and milk products: cattle	0.7
48	NL child	12	Apples	10	Milk and milk products: cattle	4	Table grapes	0.6
42	WHO Cluster diet B	8	Lettuce	5	Peaches	5	Tomatoes	0.9
35	IE adult	7	Peaches	3	Sweet potatoes	2	Lettuce	0.8
28	ES child	9	Lettuce	4	Milk and milk products: cattle	2	Peaches	0.6
27	WHO regional European diet	8	Lettuce	3	Peaches	2	Tomatoes	0.3
26	IT adult	8	Lettuce	5	Peaches	3	Other lettuce and other salad	0.1
25	IT kids/toddler	6	Lettuce	4	Peaches	2	Other lettuce and other salad	0.1
25	FR infant	8	Milk and milk products: cattle	5	Apples	2	Carrots	0.2
25	ES adult	12	Lettuce	3	Peaches	2	Milk and milk products: cattle	0.3
23	WHO cluster diet E	2	Rape seed	2	Lettuce	2	Peaches	0.4
22	FR toddler	5	Apples	2	Strawberries	2	Beans (with pods)	0.4
21	DK child	4	Apples	3	Lettuce	2	Cucumbers	0.1
21	UK Toddler	6	Sugar beet (root)	3	Apples	2	Bananas	0.3
21	WHO Cluster diet F	7	Lettuce	1	Milk and milk products: cattle	1	Apples	0.3
20	SE general population 90th percentile	4	Milk and milk products: cattle	3	Bananas	2	Apples	0.3
18	FR all population	4	Other lettuce and other salad plants	2	Wine grapes	2	Lettuce	0.2
17	NL general	3	Lettuce	2	Apples	2	Milk and milk products: cattle	0.3
17	WHO cluster diet D	2	Tomatoes	2	Milk and milk products: cattle	1	Wheat	0.3
16	PT General population	4	Peaches	2	Apples	1	Tomatoes	0.2
16	UK Infant	3	Apples	3	Sugar beet (root)	2	Bananas	0.3
12	PL general population	4	Apples	2	Table grapes	1	Tomatoes	0.0
11	UK vegetarian	3	Lettuce	1	Apples	1	Sugar beet (root)	0.2
11	LT adult	4	Apples	1	Lettuce	1	Milk and milk products: cattle	0.1
9	UK Adult	3	Lettuce	1	Sugar beet (root)	1	Apples	0.1
8	DK adult	2	Apples	1	Peaches	1	Wine grapes	0.0
7	FI adult	2	Lettuce	1	Apples	1	Tomatoes	0.1

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

<b>Acute risk assessment/children – refined calculations</b>	<b>Acute risk assessment/adults/general population – refined calculations</b>
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The acute risk assessment is based on the ARfD.  
 For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

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

Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---		
	IESTI 1     *)     **)			IESTI 2     *)     **)			IESTI 1     *)     **)			IESTI 2     *)     **)		
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	30	Purslane	10.01/-	22.9	Purslane	10.01/-	20.7	Purslane	10.01/-	18.8	Purslane	10.01/-
<b>No of critical MRLs (IESTI 1)</b>			---			<b>No of critical MRLs (IESTI 2)</b>			---			

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

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

\*\*\*) pTMRL: provisional temporary MRL.

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

**Conclusion:**

For Fluopyram, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

## Appendix D – Input values for the exposure calculations

### D.1. Livestock dietary burden calculations

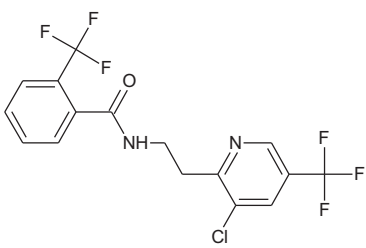
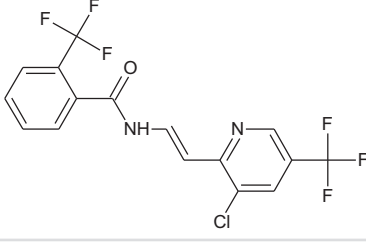
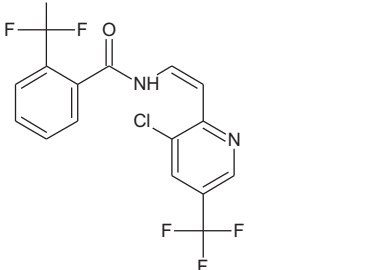
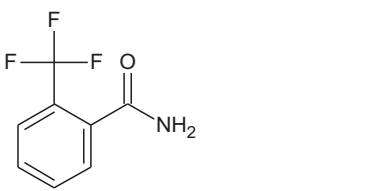
Not relevant.

### D.2. Consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<b>Risk assessment residue definition:</b> Sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram				
Purslanes	1.61	STMR (Table B.1.2.1)	10.01	HR (Table B.1.2.1)
Apricots	0.36	STMR (EFSA, 2016)	Acute risk assessment undertaken only with regard to the crops under consideration	
Peppers	0.22	STMR (EFSA, 2016)		
Spinach and similar leaves, except purslanes	0.2	MRL rotational crop (EFSA, 2014)		
Witloof/Belgian endive	0.14	STMR (EFSA, 2016)		
Herbs/edible flowers	1.19	STMR (EFSA, 2016)		
Peas (with pods)	0.15	STMR (EFSA, 2016)		
Lentils	0.05	STMR (EFSA, 2016)		
Sunflower seed	0.02	STMR (EFSA, 2016)		
Rape seed	0.40	STMR (EFSA, 2016)		
Minor oilseeds	0.12	STMR (EFSA, 2016)		
Barley, oats, buckwheat	0.03	STMR (EFSA, 2016)		
Broccoli	0.05	STMR (FAO, 2015)		
Brussels sprouts	0.06	STMR (FAO, 2015)		
Other plant commodities	STMRs	Table 4-1 (EFSA, 2014)		
	MRL	Regulation (EU) 2017/978		
<b>Risk assessment residue definition (animal products):</b> Sum fluopyram and metabolites M02, M03, M25, expressed as fluopyram				
Animal commodities	STMR MRL	See Table 4-1 of EFSA reasoned opinion (EFSA, 2014); Regulation (EU) 2017/978		

(a): Consumption figures in the EFSA PRIMo are expressed as meat. Since the a.s. is a fat-soluble pesticides, STMR and HR residue values were calculated considering a 80%/90% muscle and 20%/10% fat content for mammal/poultry meat respectively (FAO, 2016).

## Appendix E – Used compound code(s)

Code/trivial name	Chemical name/SMILES notation	Structural formula
Fluopyram	<i>N</i> -{2-[3-chloro-5-(trifluoromethyl)-2-pyridyl]ethyl}- $\alpha,\alpha,\alpha$ -trifluoro- <i>o</i> -toluamide  <chem>FC(F)(F)c1ccccc1C(=O)NCCc2ncc(cc2Cl)C(F)(F)F</chem>	
<b>M02</b> Fluopyram- <i>E</i> -olefine	<i>N</i> -{(E)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]vinyl}-2-(trifluoromethyl)benzamide  <chem>FC(F)(F)c1ccccc1C(=O)N\C=C/c2ncc(cc2Cl)C(F)(F)F</chem>	
<b>M03</b> Fluopyram- <i>Z</i> -olefine	<i>N</i> -{(Z)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]vinyl}-2-(trifluoromethyl)benzamide  <chem>FC(F)(F)c1ccccc1C(=O)N\C=C/c2ncc(cc2Cl)C(F)(F)F</chem>	
<b>M25</b> Fluopyram-benzamide	2-(trifluoromethyl)benzamide  <chem>FC(F)(F)c1ccccc1C(N)=O</chem>	

SMILES: simplified molecular-input line-entry system.