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Modification of the existing maximum residue level for fluopyram in broccoli

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Bayer Hellas AG submitted a request to the competent national authority in Greece to modify the existing maximum residue level (MRL) for the active substance fluopyram in broccoli. The data submitted in support of the request were found to be sufficient to derive MRL proposals for broccoli. Adequate analytical methods for enforcement are available to control the residues of fluopyram on the commodity under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. 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 for broccoli will not result in consumer exposure exceeding the toxicological reference values and therefore are unlikely to present a risk to consumer health.

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Amendment: An editorial correction was carried out that does not materially affect the contents or outcome of this scientific output. To avoid confusion, the older version has been removed from the EFSA Journal, but is available on request.

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer Hellas AG submitted an application to the competent national authority in Greece (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance fluopyram in broccoli. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 11 July 2018. To accommodate for the intended use of fluopyram, the EMS proposed to raise the existing MRL from the existing MRL 0.3 to 0.4 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification, which were requested from the EMS. In response to the request, the EMS submitted a revised evaluation report on 25 October 2018 which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessment and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of fluopyram in primary crops was investigated in the fruit (grapes, peppers), root (potatoes) and pulses/oilseeds (beans) 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.

Sufficiently validated analytical methods are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in the crops assessed (limit of quantification (LOQ)).

The available residue trials are sufficient to derive a MRL proposal of 0.4 mg/kg for broccoli.

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

The occurrence of fluopyram residues in rotational crops was investigated in the framework of the European Union (EU) pesticides peer review. Based on the available information on the nature and magnitude of residues, it was concluded that significant residue levels are unlikely to occur in rotational crops, provided that the active substance is used according to the proposed good agricultural practice (GAP).

Residues of fluopyram in commodities of animal origin were not assessed since the crop under consideration in this MRL application is normally not fed to livestock.

The toxicological profile of fluopyram was assessed in the framework of the EU pesticides 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 metabolites included in the residue definition are of similar toxicity as the parent active substance.

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 96% of the ADI (NL child). The contribution of residues in the crop under consideration to the total consumer exposure was low, accounting for less than 0.1% of the ADI. The highest acute consumer exposure for broccoli was calculated to be 3% of the ARfD in child and 2.2% of the ARfD in adult.

EFSA concluded that the proposed use of fluopyram on broccoli will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

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

Full details of all end points and the consumer risk assessment can be found in Appendices B–D.

Code ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: fluopyram				
0241010	Broccoli	0.3	0.4	The submitted data are sufficient to derive a MRL proposal for the NEU/SEU use. Data sets for NEU and SEU are similar (U-test 5%), MRL is derived from merged data. Risk for consumers unlikely

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe.

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

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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for fluopyram in broccoli. The detailed description of the intended use of fluopyram in broccoli, which is the basis for the current MRL application, is reported in Appendix A.

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

Fluopyram was evaluated in the framework of Directive 91/414/EEC¹ with Germany designated as rapporteur Member State (RMS); the representative uses assessed were foliar applications on grapes, tomatoes and strawberries. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (2013). Fluopyram was approved² for the use as a fungicide on 1 February 2014.

The European Union (EU) MRLs for fluopyram are established in Annex III of Regulation (EC) No 396/2005³. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) is currently ongoing. EFSA has issued several reasoned opinions on the modification of MRLs for fluopyram (EFSA, 2011, 2014, 2016, 2017). The proposals from these reasoned opinions have been considered in the for EU MRL legislation.⁴ Certain Codex maximum residue limits (CXLs) have been taken over in the EU MRL legislation as well.

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer Hellas AG submitted an application to the competent national authority in Greece (evaluating Member State, EMS) to modify the existing MRL for the active substance fluopyram in broccoli. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 11 July 2018. To accommodate for the intended use of fluopyram, the EMS proposed to raise the existing MRL from the existing MRL 0.3 to 0.4 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

EFSA based its assessment on the evaluation report submitted by the EMS (Greece, 2018), the DAR and its addendum prepared under Directive 91/414/EEC 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), JMPR reports (FAO, 2013, 2015a,b, 2017) as well as the conclusions from previous EFSA opinions on fluopyram under Article 10 of EU Regulation 396/2005 (EFSA, 2011, 2014, 2016, 2017).

For this application, the data requirements established in Regulation (EU) No 544/2011⁵ 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, 2017; 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 546/2011⁶.

As the review of the existing MRLs under Article 12 of Regulation 396/2005 is not yet finalised, the conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the MRL review.

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

¹ 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.

² 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 L225, 23.8.2013, p. 13–16.

³ 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, 16.3.2005, p. 1–16.

⁴ For an overview of all MRL Regulations on this active substance, please consult: <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN>

⁵ 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.

⁶ 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.

The evaluation report submitted by the EMS (Greece, 2018) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo revision 2) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

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 in three crop groups, i.e. fruit, root and pulses/oilseeds crops using the radiolabelled active substance (labelled on the phenyl or the pyridyl moiety) (EFSA, 2013). The metabolism of fluopyram was regarded as qualitatively similar in all plant groups investigated in the framework of EU peer review. While parent fluopyram accounted for a major proportion of the residues in most of the crop parts analysed, metabolite fluopyram-benzamide (M25) resulting from the cleavage of the parent molecule, was observed in significant proportions and levels in the metabolism study in beans (pulses/oilseed crop group) accounting for up to 64% total radioactive residue (TRR) and to less extent in grapes, potatoes and peppers.

For broccoli, the available metabolism studies are considered sufficient to elucidate the metabolic behaviour.

1.1.2. Nature of residues in rotational crops

Since broccoli 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), the possible occurrence of residues in rotational crops had to be investigated. 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 (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). It was therefore concluded that the residue definitions proposed from primary crops are also applicable to processed commodities.

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 spectrometry (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 limit of quantification (LOQ) of 0.01 mg/kg.

1.1.5. Stability of residues in plants

The stability of fluopyram and its benzamide metabolite (metabolite M25) 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 opinions (EFSA, 2014, 2016). 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°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.

Based on the available information, EFSA concluded that these residue definitions are appropriate and applicable for the intended use in broccoli. Since broccoli 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 plants

1.2.1. Magnitude of residues in primary crops

To support the intended use of fluopyram in broccoli (application rate 2×125 g a.s./ha, preharvest interval (PHI) 14 days), 12 residue trials (6 northern EU and 6 southern EU) were submitted within the MRL application. The trials were conducted in different locations over two seasons and their independence has been confirmed.

The samples were analysed for the parent compound fluopyram and the metabolite fluopyram-benzamide (M25) achieving an LOQ of 0.01 mg/kg per analyte. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose. Samples in the residue studies were stored deep-frozen within 24 h after sampling for 36 months; therefore, it is concluded that the residue data are valid with regard to storage stability.

Data sets for northern EU and southern EU are similar (U-test 5%), and therefore, a MRL proposal was derived from the merged data sets.

1.2.2. Magnitude of residues in rotational crops

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

In these rotational field studies conducted in spinach at the exaggerated dose rate of 500 g/ha (2N compared to the annual application rate for the intended good agricultural practice (GAP) on broccoli), residues of up to 0.09 mg/kg were found at a plant-back interval (PBI) of 28–36 days. It was proposed to set a MRL for leafy crops at the level of 0.2 mg/kg, unless a specific use in the leafy crops requires a higher MRL (EFSA, 2014).

For the time being, EFSA does not see the need to amend existing MRLs for crops grown in crop rotation, considering that the existing MRLs for most of these crops are set at a higher level than residue level expected in rotational crops. However, it is recommended that in the framework of the MRL review a detailed assessment of the residue situation in rotational crops should be performed.

1.2.3. Magnitude of residues in processed commodities

Fluopyram and fluopyram-benzamide were stable under standard hydrolysis conditions simulating pasteurisation, boiling/baking and sterilisation (see Section 1.1.3).

A processing study in cooking tomato was submitted in previous assessment (EFSA, 2013) and a processing factor (PF) was proposed. New processing studies were not submitted under the current MRL application.

Considering the low contribution of broccoli to the total exposure, no further information is required. If processing factors were to be required by risk managers, in particular for enforcement purposes (e.g. for blanched frozen broccoli), additional processing studies should be requested.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive an MRL proposal as well as risk assessment values for broccoli (see Appendix B.1.2.1). In Section 3, EFSA assessed whether the expected residues on broccoli resulting from the intended use are likely to pose a consumer health risk.

2. Residues in livestock

Residues of fluopyram in commodities of animal origin were not assessed since the crop under consideration in this MRL application is normally not fed to livestock.

3. Consumer risk assessment

The toxicological reference values for fluopyram used in the risk assessment (i.e. acceptable daily intake (ADI) and acute reference dose (ARfD) values) were derived in the framework of the EU pesticides peer review (EFSA, 2013). The metabolites (M02, M03 and M25) included in the risk assessment residue definitions for plant and animal commodities are considered to be of similar toxicity/not more toxic than the parent compound.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. The PRIMo model contains the relevant European food consumption data for different subgroups of the EU population (EFSA, 2007).

The long-term exposure assessment was performed, taking into account the supervised trials median residue (STMR) value derived for broccoli; for the remaining commodities, the STMR values derived in previous assessments of EFSA (2011, 2013, 2014, 2016, 2017) were selected as input values. For crops for which the CXLs were taken over in the EU legislation, the related STMR values derived by JMPR have been used to estimate the dietary exposure. For the remaining commodities, the MRLs established in most recent MRL regulation were used. The complete list of input values is presented in Appendix D.1.

The estimated long-term dietary intake accounted for up to 96% of the ADI for NL children. Broccoli accounted for up to 0.075% of the ADI. EFSA concludes that the long-term intake of residues of fluopyram resulting from the existing and the intended use is likely to present a risk to consumer health.

The short-term exposure assessment was performed in accordance with the internationally agreed methodology. It was performed only with regard to the commodity under consideration assuming the consumption of a large portion of the food items as reported in the national food surveys containing residues at the highest residue (HR) level as observed in supervised field trials (Appendix B.1.2.1).

The calculated maximum short-term (acute) exposure accounted for 3% in children and 2.2% in adults.

Based on these calculations, EFSA concluded that the proposed use of fluopyram on the crop assessed is unlikely to pose a risk for the consumers.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for broccoli.

EFSA concluded that the proposed use of fluopyram on broccoli will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight

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
DM	dry matter
DT ₉₀	period required for 90% dissipation (define method of estimation)
EMS	evaluating Member State
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC–MS	gas chromatography with mass spectrometry
HPLC–MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
InChiKey	International Chemical Identifier Key
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
Mo	monitoring
MRL	maximum residue level
MS	Member States
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
TRR	total radioactive residue
WHO	World Health Organization

Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

Crop and/or situation	NEU, SEU, MS or country	F G or I ^(a)	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			Unit	PHI (days) ^(d)	Remarks
				Type ^(b)	Conc. a.s.	Method kind	Range of growth stages and season ^(c)	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate			
Broccoli	Austria Belgium Czech R. Germany Hungary Netherlands Poland Romania Slovenia Slovakia United Kingdom	F	<i>Alternaria brassicae</i> / <i>Alternaria brassicola</i> (ALTEBA/ALTEBI) <i>Erysiphe cruciferarum</i> (ERYSCR) <i>Mycosphaerella brassicola</i> (MYCOBR) <i>Leptosphaeria maculans</i> (LEPTMA)	SC	500	Foliar application	BBCH 41–49	2	14	0.016–0.063	200–800	0.125	g a.s./ha	14	
Broccoli	Bulgaria Croatia France Greece Cyprus Italy Portugal Spain	F	<i>Alternaria brassicae</i> / <i>Alternaria brassicola</i> (ALTEBA/ALTEBI) <i>Erysiphe cruciferarum</i> (ERYSCR) <i>Mycosphaerella brassicola</i> (MYCOBR) <i>Leptosphaeria maculans</i> (LEPTMA)	SC	500	Foliar application	BBCH 41–49	2	14	0.016–0.063	200–800	0.125	g a.s./ha	14	

GAP: Good Agricultural Practice; MRL: maximum residue level; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; SC: suspension concentrate.

(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	Grapes	Foliar, 1 × 100 + 2 × 200 g/ha	18–19
		Peppers	Drip irrigation, 5 and 20 mg/plant	33–97
	Root crops	Potatoes	Foliar, 3 × 167 g/ha	51
	Pulses/oilseeds	Beans	Foliar, 2 × 250 g/ha	4–29
Radiolabelled active substance: phenyl-UL- ¹⁴ C Reference: EFSA (2013)				
Rotational crops (available studies)	Crop groups	Crop(s)	Application(s)	PBI (DAT)
	Root	Turnips	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- ¹⁴ C and Pyridyl-2,6- ¹⁴ 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)				

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
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: HPLC–MS/MS, GC–MS, LOQ 0.01 mg/kg (EFSA, 2013; EFSA, 2016; Greece, 2018).

DALA: days after last application; DAT: days after treatment; PBI: plant-back interval; HPLC–MS/MS: high performance liquid chromatography with tandem mass spectrometry; GC–MS: gas chromatography with mass spectrometry; LOQ: limit of quantification.

B.1.1.2. Stability of residues in plants

Plant products (available studies)	Category	Commodity	T (°C)	Stability (Months)
	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 (2014, 2016)				

B.1.2. Magnitude of residues in plants

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

Commodity	Region/ indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
Broccoli 2 × 125 g/ha PHI 14 days	NEU	Mo: < 0.01; 0.013; 0.056; 0.092; 0.096; 0.20 RA: 0.02; 0.023; 0.066; 0.1; 0.11; 0.21	Residue trials on broccoli compliant with GAP. Data sets for NEU and SEU are similar (U-test 5%), MRL is derived from merged data sets	0.4	Mo: 0.25	Mo: 0.08	1.2
	SEU	Mo: 0.011; 0.012; 0.071; 0.084; 0.091; 0.25 RA: 0.021; 0.022; 0.081; 0.094; 0.1; 0.26			RA: 0.26	RA: 0.09	1.2

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment.

(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. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.

(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.

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

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Yes
Residues in rotational and succeeding crops expected based on field rotational crop study?	<p>Yes;</p> <p>A default MRL of 0.1 mg/kg was recommended by the peer review (EFSA, 2013) for root and leafy crops and of 0.01 mg/kg for cereals, oilseed grown in rotation with crops treated with fluopyram. These proposals were derived from the field studies conducted at the exaggerated dose rate of 500 g/ha, representative for the predicted plateau concentration in soil (0.08 mg/kg soil, 20 cm depth) reached after 10 years of consecutive application (EFSA, 2013)</p> <p>In addition, a default MRL of 0.2 mg/kg was proposed for spinach grown in rotation to crops treated with fluopyram (EFSA, 2014)</p> <p>New rotational field studies were not submitted in the framework of the current application</p>

MRL: maximum residue level.

B.1.2.3. Processing factors

No new processing studies were submitted in the framework of the present MRL application.

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	Broccoli: 3% of ARfD (child), 2.2% of ARfD (adult)
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	96% ADI (NL, child) Contribution of crops assessed: Broccoli: 0.075% of ADI
Assumptions made for the calculations	<p>The chronic consumers' exposure has been calculated by using the supervised trials median residue (STMR) derived for broccoli according to the risk assessment residue definition and the STMR values previously evaluated and implemented in the MRL Regulation or the STMR corresponding to the CXL implemented in the EU MRL legislation.</p> <p>For the remaining crops, the existing MRL was used as input value.</p>

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; STMR: supervised trials median residue; MRL: maximum residue level; CXL: Codex maximum residue limit.

B.4. Recommended MRLs

Code ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: fluopyram				
0241010	Broccoli	0.3	0.4	The submitted data are sufficient to derive a MRL proposal for the NEU/SEU use. Data sets for NEU and SEU are similar (U-test 5%), MRL is derived from merged data. Risk for consumers unlikely

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe.

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

Appendix C – Pesticide Residue Intake Model (PRIMo)

Fluopyram			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0.02	Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	0.012	ARfD (mg/kg bw):	0.5
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Chronic risk assessment – refined calculations								
		TMDI (range) in % of ADI minimum – maximum						
		12 96						
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	pTMRs at LOQ (in % of ADI)
96.2	NL child	29.3	Milk and cream	12.2	Apples	6.6	Swine: Meat	0.2
81.1	DE child	23.2	Apples	14.3	Milk and cream	6.3	Table grapes	0.2
78.3	FR toddler	39.6	Milk and cream	5.7	Bovine: Meat	5.0	Apples	0.1
69.1	UK Infant	38.7	Milk and cream	8.4	Sugar beet (root)	5.2	Birds' eggs	0.2
60.7	UK Toddler	20.7	Milk and cream	19.1	Sugar beet (root)	3.4	Birds' eggs	0.1
60.6	WHO Cluster diet B	7.9	Lettuce	5.1	Tomatoes	4.2	Poultry: Meat	1.0
59.1	ES child	12.5	Milk and cream	9.1	Lettuce	6.0	Bovine: Meat	0.3
56.9	IE adult	7.2	Sheep: Liver	5.3	Basil	3.0	Sweet potatoes	0.8
49.8	FR infant	25.7	Milk and cream	4.8	Apples	2.5	Bovine: Meat	0.1
46.1	WHO regional European diet	8.3	Lettuce	5.4	Swine: Meat	4.8	Milk and cream	0.3
39.8	DK child	12.6	Milk and cream	4.5	Apples	4.0	Bovine: Liver	0.1
39.4	ES adult	11.7	Lettuce	5.0	Milk and cream	3.2	Bovine: Meat	0.2
38.2	WHO cluster diet E	4.3	Poultry: Meat	3.0	Bovine: Meat	3.0	Milk and cream	0.3
37.7	WHO Cluster diet F	6.6	Lettuce	4.9	Swine: Meat	4.0	Milk and cream	0.1
33.4	NL general	6.6	Milk and cream	3.9	Swine: Meat	3.0	Bovine: Meat	0.1
31.2	SE general population 90th percentile	12.4	Milk and cream	3.4	Birds' eggs	2.6	Bananas	0.2
28.6	WHO cluster diet D	5.0	Milk and cream	2.5	Bovine: Meat	1.7	Poultry: Meat	0.3
26.1	FR all population	4.2	Other lettuce and other salad plants	2.7	Milk and cream	2.6	Poultry: Meat	0.1
22.9	LT adult	4.1	Swine: Meat	4.0	Milk and cream	3.6	Apples	0.0
22.3	IT adult	8.3	Lettuce	3.5	Other lettuce and other salad plants	1.9	Tomatoes	0.2
21.5	IT kids/toddler	6.4	Lettuce	2.4	Other lettuce and other salad plants	2.4	Tomatoes	0.2
19.7	UK vegetarian	3.3	Milk and cream	3.1	Sugar beet (root)	3.1	Lettuce	0.1
18.0	DK adult	5.4	Milk and cream	2.4	Bovine: Meat	1.7	Bovine: Liver	0.1
17.2	UK Adult	3.3	Sugar beet (root)	3.0	Milk and cream	2.6	Lettuce	0.1
16.4	FI adult	5.7	Milk and cream	1.7	Lettuce	1.6	Other other small fruit & berries	0.0
13.0	PT General population	2.0	Apples	1.5	Tomatoes	1.4	Table grapes	0.2
11.6	PL general population	3.9	Apples	1.6	Table grapes	1.5	Tomatoes	0.1

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

Acute risk assessment/children – refined calculations	Acute risk assessment/adults/general population – refined calculations
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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)
	3.0	Broccoli	0.26/-	2.2	Broccoli	0.26/-	1.1	Broccoli	0.26/-	1.1	Broccoli	0.26/-
No of critical MRLs (IESTI 1)			---			No of critical MRLs (IESTI 2)			---			

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)
	22.4	Elderberry juice	7/-	1.2	Orange juice	0.6/-
14.2	Courant juice	7/-	1.2	Wine	1.5/-	
12.0	Raspberries juice	5/-	0.8	Bread/pizza	0.9/-	
10.2	Blueberries	7/-	0.8	Apple juice	0.6/-	
9.9	Grape juice	1.5/-	0.6	Peach preserved with syrup	1.5/-	

*) 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. Consumer risk assessment

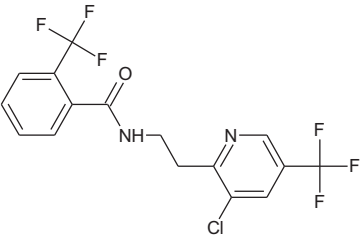
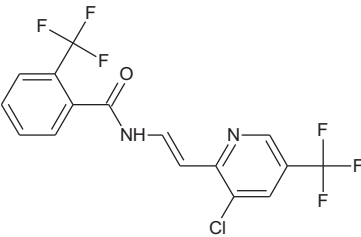
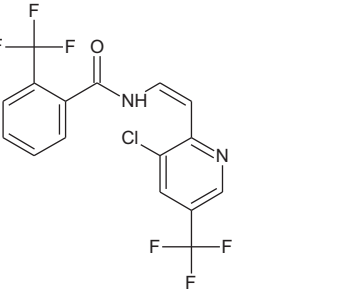
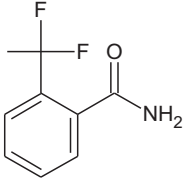
Commodity	Existing/ proposed MRL	Source/type of MRL	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram						
Broccoli	0.3	Current application	0.09	STMR-RAC	0.26	HR-RAC
Grapefruits	0.4	FAO (2017)	0.14	STMR-RAC	Acute risk assessment was performed only for broccoli.	
Oranges	0.6	FAO (2017)	0.15	STMR-RAC		
Lemons	1	FAO (2017)	0.325	STMR-RAC		
Limes	1	FAO (2017)	0.325	STMR-RAC		
Mandarins	0.6	FAO (2017)	0.15	STMR-RAC		
Tree nuts (except coconuts)	0.05	EFSA (2011)	0.011	STMR-RAC		
Coconuts	0.04	FAO (2013)	0.01	STMR-RAC		
Pome fruit	0.6/0.5	EFSA (2011)	0.231	STMR-RAC		
Apricots	1.5	EFSA (2016)	0.36	STMR-RAC		
Cherries (sweet)	2	FAO (2017)	0.57	STMR-RAC		
Peaches	1.5	EFSA (2014)	0.26	STMR-RAC		
Plums	0.5	EFSA (2014)	0.2	STMR-RAC		
Table grapes	1.5	EFSA (2011)	0.6	STMR-RAC		
Wine grapes	1.5	EFSA (2011)	0.065	STMR-RAC		
Strawberries	2	EFSA (2011)	0.44	STMR-RAC		
Cane fruit	5	FAO (2017)	0.83	STMR-RAC		
Blueberries	7	FAO (2017)	1.15	STMR-RAC		
Cranberries	3	EFSA (2014)	0.83	STMR-RAC		
Currants (red, black and white)	7	FAO (2017)	1.15	STMR-RAC		
Gooseberries (green, red and yellow)	7	FAO (2017)	1.15	STMR-RAC		
Rose hips	7	FAO (2017)	1.15	STMR-RAC		
Mulberries (black and white)	7	FAO (2017)	1.15	STMR-RAC		
Elderberries	7	FAO (2017)	1.15	STMR-RAC		
Bananas	0.8	FAO (2013)	0.175	STMR-RAC		
Mangoes	1	FAO (2017)	0.02	STMR-RAC		
Potatoes	0.15	FAO (2017)	0.021	STMR-RAC		
Root and tuber vegetables (except carrots)	0.3	EFSA (2014)	0.1	STMR-RAC		
Carrots	0.4	FAO (2013)	0.09	STMR-RAC		
Bulb vegetables (except spring onions)	0.1	EFSA (2014)	0.02	STMR-RAC		
Spring onions/green onions and Welsh onions	15	FAO (2017)	5.1	STMR-RAC		
Tomatoes	0.9	EFSA (2011)	0.2	STMR-RAC		
Sweet peppers/bell peppers	3	FAO (2017)	0.14	STMR-RAC		

Commodity	Existing/ proposed MRL	Source/type of MRL	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Aubergines/egg plants	0.9	EFSA (2014)	0.2	STMR-RAC		
Cucurbits - edible peel	0.5	EFSA (2011)	0.15	STMR-RAC		
Cucurbits - inedible peel	0.4	EFSA (2011)	0.0117	STMR-RAC		
Cauliflowers	0.2	EFSA (2011)	0.0117	STMR-RAC		
Brussels sprouts	0.3	FAO (2015a)	0.06	STMR-RAC		
Head cabbages	0.3	EFSA (2011)	0.03	STMR-RAC		
Chinese cabbages/pe-tsai	0.7	EFSA (2011)	0.18	STMR-RAC		
Lettuces (except escaroles)	15	EFSA (2011)	2.63	STMR-RAC		
Spinaches	0.2	EFSA (2014)	0.09	STMR-RAC		
Purslanes	20	EFSA et al. (2017)	1.61	STMR-RAC		
Chards/beet leaves	0.2	EFSA (2016)	0.2	STMR-RAC		
Witloofs/Belgian endives	0.3	EFSA (2016)	0.14	STMR-RAC		
Herbs (except basil)	8	EFSA (2016)	1.19	STMR-RAC		
Basil and edible flowers	70	FAO (2017)	19	STMR-RAC		
Beans (with pods)	1	FAO (2015b)	0.2	STMR-RAC		
Beans (without pods)	0.2	FAO (2015b)	0.03	STMR-RAC		
Peas (with pods)	1.5	EFSA (2016)	0.15	STMR-RAC		
Peas (without pods)	0.2	FAO (2015b)	0.03	STMR-RAC		
Lentils (fresh)	0.2	EFSA (2016)	0.05	STMR-RAC		
Globe artichokes	0.5	EFSA (2011)	0.18	STMR-RAC		
Leeks	0.7	EFSA (2011)	0.14	STMR-RAC		
Pulses	0.4	EFSA (2011)	0.045	STMR-RAC		
Linseeds	0.3	EFSA (2014)	0.12	STMR-RAC		
Peanuts/groundnuts	0.2	FAO (2017)	0.033	STMR-RAC		
Sesame seeds	0.3	EFSA (2016)	0.12	STMR-RAC		
Sunflower seeds	0.7	FAO (2017)	0.066	STMR-RAC		
Rapeseeds/canola seeds	1	FAO (2014)	0.33	STMR-RAC		
Soya beans	0.3	FAO (2017)	0.0205	STMR-RAC		
Cotton seeds	0.8	FAO (2017)	0.0585	STMR-RAC		
Other minor oil seeds	0.3	EFSA (2016)	0.12	STMR-RAC		
Barley	0.2	EFSA (2016)	0.03	STMR-RAC		
Buckwheat and other pseudo-cereals	0.2	EFSA (2016)	0.03	STMR-RAC		
Maize/corn	0.02	EFSA (2011)	0.011	STMR-RAC		
Oat	0.2	EFSA (2016)	0.03	STMR-RAC		
Rye	0.9	FAO (2017)	0.19	STMR-RAC×PF		
Sorghum	1.5	EFSA (2011)	0.429	STMR-RAC		
Wheat	0.9	FAO (2017)	0.19	STMR-RAC×PF		
Herbal infusions (dried roots)	2.5	EFSA (2014)	0.72	STMR-RAC		
HOPS (dried)	50	FAO (2017)	10.35	STMR-RAC		
Dill seed	70	FAO (2017)	19	STMR-RAC		

Commodity	Existing/ proposed MRL	Source/type of MRL	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Spices (roots)	0.3	EFSA (2014)	0.72	STMR-RAC		
Risk assessment residue definition (animal products): Sum fluopyram and metabolites M02, M03, M25, expressed as fluopyram						
Mammalians (all species) Muscle/meat	1.5	FAO (2017)	0.51	STMR-RAC		
Mammalians (all species) Fat tissue	1.5	FAO (2017)	0.67	STMR-RAC		
Mammalians (all species) Liver	8	FAO (2017)	3.8	STMR-RAC		
Mammalians (all species) Kidney	8	FAO (2017)	0.6	STMR-RAC		
Mammalians (all species) Edible offals (other than liver and kidney)	8	FAO (2017)	0.67	STMR-RAC		
Poultry: Muscle/meat	1.5	FAO (2017)	0.51	STMR-RAC		
Poultry: Fat tissue	1	FAO (2017)	0.67	STMR-RAC		
Poultry: Liver	5	FAO (2017)	3.8	STMR-RAC		
Poultry: Kidney	5	FAO (2017)	0.6	STMR-RAC		
Poultry: Edible offals (other than liver and kidney)	5	FAO (2017)	0.67	STMR-RAC		
Milk (all species)	0.6	FAO (2015a,b)	0.12	STMR-RAC		
Eggs (all species)	2	FAO (2017)	0.46	STMR-RAC		
Wild terrestrial vertebrate animals	1.5	FAO (2017)	0.51	STMR-RAC		
Other crops/ commodities	MRL	Regulation (EC) 396/2005				

MRL: maximum residue level; STMR: supervised trials median residue; HR: highest residue; PF: processing factor; RAC: raw agricultural commodity.

Appendix E – Used compound codes

Code/trivial name ^(a)	IUPAC name/SMILES notation/InChiKey ^(b)	Structural formula ^(c)
Fluopyram	<i>N</i> -{2-[3-chloro-5-(trifluoromethyl)-2-pyridyl]ethyl}- α,α,α -trifluoro- <i>o</i> -toluamide <chem>FC(F)(F)c1cccc1C(=O)NCCc2ncc(cc2Cl)C(F)(F)F</chem>	
M02 fluopyram-E-olefine	<i>N</i> -{(E)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]vinyl}-2-(trifluoromethyl)benzamide <chem>FC(F)(F)c1cccc1C(=O)N\C=C\c2ncc(cc2Cl)C(F)(F)F</chem>	
M03 fluopyram-Z-olefine	<i>N</i> -{(Z)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]vinyl}-2-(trifluoromethyl)benzamide <chem>FC(F)(F)c1cccc1C(=O)N\C=C/c2ncc(cc2Cl)C(F)(F)F</chem>	
M25 fluopyram-benzamide	2-(trifluoromethyl)benzamide <chem>FC(F)(F)c1cccc1C(N)=O</chem>	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.

(a): The metabolite name in bold is the name used in the conclusion.

(b): ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).

(c): ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).