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## Modification of the existing maximum residue levels for cyflufenamid in blackberries and raspberries

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### Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the Federal Public Service (FPS) Health, Food chain Safety and Environment submitted a request on behalf of Belgium (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance cyflufenamid in blackberries and raspberries (red and yellow). The data submitted in support of the request were found to be sufficient to derive MRL proposals for blackberries and raspberries (red and yellow). Adequate analytical methods are available to control the residues of cyflufenamid according to the enforcement residue definition on the commodities 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 cyflufenamid according to the reported agricultural practices 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, Federal Public Service (FPS) Health, Food chain safety and Environment, submitted an application on behalf of Belgium (EMS) to modify the existing maximum residue levels (MRLs) for the active substance cyflufenamid in blackberries and raspberries (red and yellow). 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 3 June 2021. To accommodate for the intended uses of cyflufenamid, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) of 0.01 to 0.08 mg/kg for both blackberries and raspberries.

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

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

The metabolism of cyflufenamid in plants was investigated in crops belonging to the groups of fruit crops (apples, cucumbers), cereals/grass (wheat) and pulses/oilseeds (rapeseeds). As the proposed uses of cyflufenamid are on permanent/semi-permanent crops, investigations of the nature of residues in rotational crops are not required. Investigation of the nature of residues in processed commodities (hydrolysis studies) is also not required due to the low residues expected in these crops. Nevertheless, a standard hydrolysis study with cyflufenamid radiolabelled in the fluorinated phenyl ring was submitted in the context of the previous MRL application. The results from this study show that the active substance is stable under standard processing conditions of pasteurisation, baking, brewing, boiling and sterilisation. Hydrolysis studies with the compound radiolabelled in the cyclopropyl ring were not provided.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of *E*-isomer and metabolites, the capability of the analytical method and the potential isomerisation observed in the storage stability studies, the residue definition for enforcement set in the MRL legislation is the 'sum of cyflufenamid (*Z*-isomer) and its *E*-isomer, expressed as cyflufenamid'. EFSA proposed a slightly different residue definition for risk assessment in plant products as 'sum of cyflufenamid (*Z*-isomer) and its *E*-isomer'. However, there is not a fundamental difference between the two expressions. The residue definition is applicable to primary and rotational crops.

EFSA concluded that for the crops assessed in this application, the metabolism of cyflufenamid has been sufficiently addressed and that the previously derived residue definitions are applicable.

Sufficiently validated analytical methods based on gas chromatography with mass spectrometry (GC-MS) and liquid chromatography with tandem mass spectrometry (LC-MS/MS) are available to quantify residues in the crops assessed in this application. The methods enable quantification of residues at or above the limit of quantification (LOQ) of 0.01 mg/kg in the crops assessed.

The available residue trials are sufficient to derive an MRL proposal of 0.07 mg/kg for blackberries and raspberries (red and yellow).

Specific studies investigating the magnitude of cyflufenamid residues in processed commodities were not submitted and are not required, considering the low levels of cyflufenamid residues in the crops under assessment and the low dietary exposure of the consumers. Residues of cyflufenamid in commodities of animal origin were not assessed since the crops under consideration in this MRL application are normally not fed to livestock.

The toxicological profile of cyflufenamid 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 0.04 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.05 mg/kg bw. The *E*-isomer of cyflufenamid and the metabolite 149-F1, included in their respective residue definitions, was considered of similar toxicity as the parent active substance.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The short-term exposure assessment was performed only with regard to the commodities assessed in the present MRL application, in accordance with the internationally agreed methodology. The acute consumer exposure was calculated to be 0.6% of ARfD for blackberries and 0.6% of ARfD for raspberries. The highest estimated long-term dietary intake accounted for 6% of the ADI (NL toddler diet). The contribution of residues of cyflufenamid expected from the commodities assessed in the present MRL application to the overall long-term exposure was low (0.01% of the ADI for blackberries and 0.01% of the ADI for raspberries).

EFSA concluded that the proposed use of cyflufenamid on blackberries and raspberries will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health. However, this conclusion shall be regarded as indicative considering that some risk assessment values derived by EFSA during the MRL review for certain commodities were not fully supported by data and would require further confirmatory information.

EFSA proposes to amend the existing MRLs 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 <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
<b>Enforcement residue definition:</b> Cyflufenamid (sum of cyflufenamid ( <i>Z</i> -isomer) and its <i>E</i> -isomer, expressed as cyflufenamid) <sup>(F)</sup>				
0153010	Blackberries	0.01*	0.07	The submitted data are sufficient to derive an MRL proposal for EU uses in greenhouse. Risk for consumers unlikely.
0153030	Raspberries (red and yellow)	0.01*	0.07	

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; EU: Europe; GAP: Good Agricultural Practice.

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

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

(F): Fat soluble.

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## Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue levels (MRLs) for cyflufenamid in blackberries and raspberries. The detailed description of the intended uses of cyflufenamid, which are the basis for the current MRL application, is reported in Appendix A.

Cyflufenamid is the ISO common name for (*Z*)-*N*-[(cyclopropylmethoxyimino)-2,3-difluoro-6-(trifluoromethyl)benzyl]-2-phenylacetamide (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Cyflufenamid was evaluated in the framework of Directive 91/414/EEC<sup>1</sup> with United Kingdom designated as rapporteur Member State (RMS) for the representative uses as a foliar treatment on wheat, rye and barley. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2009). Cyflufenamid was approved<sup>2</sup> for the use as fungicide only on 1 April 2010.

The EU MRLs for cyflufenamid are established in Annexes II of Regulation (EC) No 396/2005<sup>3</sup>. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) been performed (EFSA, 2018b) and the proposed modifications have been implemented in the MRL legislation.<sup>4</sup> After completion of the MRL review, EFSA has issued a reasoned opinion on the setting of an import tolerance for cyflufenamid in hops (EFSA, 2021). The proposals from this reasoned opinion has been included in the recent draft MRL Regulation (SANTE/10518/2021) and not yet implemented.

In accordance with Article 6 of Regulation (EC) No 396/2005, FPS Health, Food chain safety and Environment submitted an application on behalf of Belgium (EMS) to set maximum residue levels MRLs for the active substance cyflufenamid in blackberries and raspberries. 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 3 June 2021. To accommodate for the intended uses of cyflufenamid, the EMS proposed to raise the existing MRLs from the LOQ of 0.01 to 0.08 mg/kg for both blackberries and raspberries.

EFSA based its assessment on the evaluation report submitted by the EMS (Belgium, 2021), the draft assessment report (DAR) and its addendum (United Kingdom, 2006, 2008) prepared under Directive 91/414/EEC, the Commission review report on cyflufenamid (European Commission, 2009), the conclusion on the peer review of the pesticide risk assessment of the active substance cyflufenamid (EFSA, 2009) as well as the conclusion from the previous EFSA opinions, including the opinion on the review of the existing maximum residue levels for cyflufenamid according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011, 2014, 2016, 2018b, 2021).

For this application, the data requirements established in Regulation (EU) No 544/2011<sup>5</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, 2017, 2020; OECD, 2011). 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>6</sup>.

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, is presented in Appendix B.

The evaluation report submitted by the EMS (Belgium, 2021) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this

<sup>1</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>2</sup> Commission Directive 2009/154/EC of 30 November 2009 amending Council Directive 91/414/EEC to include cyflufenamid as active substance. OJ L 314, 1.12.2009, p. 69–71.

<sup>3</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, 16.3.2005, p. 1–16.

<sup>4</sup> Commission Regulation (EU) 2019/1559 of 16 September 2019 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 cyflufenamid, fenbuconazole, fluquinconazole and tembotrione in or on certain products. OJ L 239, 17.9.2019, p. 1–15.

<sup>5</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>6</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.

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 cyflufenamid following foliar applications in primary crops belonging to the groups of fruit crops (apples and cucumbers), cereals/grass (wheat), pulses/oilseeds (rapeseeds) has been investigated in the framework of the EU pesticides peer review and previous MRL applications (EFSA, 2009, 2011, 2016). These studies were re-assessed during the MRL review under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2018b).

In the crops tested, the metabolic pathway of cyflufenamid was similar. The parent compound was the main residue, representing between 99% (forage) and 7% (grain and seeds, with very low absolute residue levels) of the total radioactive residues (TRR).

Although the metabolism of cyflufenamid radiolabelled in both the phenyl ring and the cyclopropyl ring was investigated in only one wheat study, the existence of cleavage products was examined during the peer review (EFSA, 2009) and it was concluded that the metabolic pathway of cyflufenamid was sufficiently elucidated. Further studies were not required (EFSA, 2018b).

For the intended use, the metabolic behaviour in primary crops is sufficiently addressed.

#### 1.1.2. Nature of residues in rotational crops

As the proposed uses of cyflufenamid are on permanent/semi-permanent crops, the assessment of the nature of residues in rotational crops is not required. However, metabolism in rotational crops was assessed in the framework of the EU pesticides peer review and the MRL review (EFSA, 2009, 2018b). The studies showed that translocation of radioactive residues from soil to plants was limited.

#### 1.1.3. Nature of residues in processed commodities

Since residues are expected to be below the trigger value of 0.1 mg/kg for the commodities under assessment and the total theoretical maximum daily intake (TMDI) is expected to be below the trigger value of 10% of the ADI, investigation of the nature of residues in processed commodities (hydrolysis studies) is not required (European Commission, 1997d).

However, the effect of processing on the nature of cyflufenamid was investigated in the framework of the previous MRL application on hops (EFSA, 2021). These studies, which were performed with cyflufenamid radiolabelled in the fluorinated phenyl ring, showed that cyflufenamid is hydrolytically stable under standard processing conditions of pasteurisation, baking, brewing, boiling and sterilisation (see Appendix B.1.1.1). It was noted that studies with the compound radiolabelled in the cyclopropyl ring or either arguments for waiving the requirement were not provided.

#### 1.1.4. Methods of analysis in plants

Analytical methods for the determination of residues of cyflufenamid in plants were assessed during the EU pesticides peer review, previous MRL applications and the MRL review (EFSA, 2009, 2011, 2018b, 2021).

The gas chromatography with mass spectrometry (GC–MS) method is sufficiently validated for the determination of residues of cyflufenamid (*Z*-isomer) and its *E*-isomer, according to the residue definition for enforcement, in high water and high acid content commodities and dry commodities. The multiresidue QuEChERS (Quick, Easy, Cheap, Effective, Rugged and Safe) method using liquid chromatography with tandem mass spectrometry (LC–MS/MS) is sufficiently validated for the determination of residues of cyflufenamid (*Z*-isomer) in high water, high acid content and dry commodities. According to the MRL review (EFSA, 2018b), the available QuEChERS method could cover both isomers measured as *Z*-isomer. Both methods allow for the determination of residues at or above the limit of quantification (LOQ) of 0.01 mg/kg for each analyte (see Section B.1.1.1). A variation of the QuEChERS method for vegetable oil samples (QuOil method) was also reported for routine analysis although a validated primary analytical method for enforcement in high oil content commodities is not available (EFSA, 2018b).



Raspberries and blackberries belong to the high acid content commodity group; therefore, sufficiently validated analytical methods are available for the determination of residues of cyflufenamid (*Z*-isomer) and its *E*-isomer in the plant commodities under consideration.

EFSA noted that the extraction efficiency of the analytical methods proposed for enforcement was not proven as indicated according to the requirements of the extraction efficiency Guidance SANTE 2017/10632 (European Commission, 2017). EFSA would therefore recommend reconsidering this point in the framework of the peer review for the renewal of approval of the active substance.

### 1.1.5. Storage stability of residues in plants

The storage stability of cyflufenamid (*Z*-isomer) and its *E*-isomer in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review and in a previous MRL application (EFSA, 2009, 2014).

It was demonstrated that for the commodities belonging to the high acid content group, residues of cyflufenamid (*Z*-isomer) and its *E*-isomer were stable for a period of 24 months when stored at  $-18^{\circ}\text{C}$ .

### 1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of *E*-isomer and metabolites, the capabilities of enforcement analytical methods, which cannot specifically discriminate between both isomers, and the storage stability studies, showing that potential isomerisation might occur, EFSA proposed the residue definition in primary crops as follow:

- residue definition for enforcement: sum of cyflufenamid (*Z*-isomer) and its *E*-isomer
- residue definition for risk assessment: sum of cyflufenamid (*Z*-isomer) and its *E*-isomer

However, EFSA proposal for the enforcement residue definition has not been implemented in the MRL legislation. Therefore, the residue definition for enforcement set in Regulation (EC) No 396/2005 is:

- residue definition for enforcement: sum of cyflufenamid (*Z*-isomer) and its *E*-isomer, expressed as cyflufenamid

Based on the metabolism data and the capability of the analytical methods available, there is not a fundamental difference between the two expressions (EFSA, 2018b, 2021).

The residue definitions are also applicable to rotational crops.

EFSA concluded that these residue definitions are appropriate for the crops under assessment.

## 1.2. Magnitude of residues in plants

### 1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted four indoor residue trials performed in raspberries. Two trials were conducted in Southern France during the growing season of 2016 and two trials were conducted in Northern France during the growing seasons of 2016 and 2017. All trials were independent and compliant with the intended GAP. Two trials were designed as decline studies (samples taken immediately, 3 (corresponding to the intended preharvest interval, PHI) and 7 days after treatment).

The applicant proposed to extrapolate residue data from the trials performed on raspberries to blackberries. In accordance with the EU technical guideline on extrapolation (European Commission, 2020), such an extrapolation is acceptable and an MRL proposal of  $0.07\text{ mg/kg}^7$  is derived for the berry fruits under consideration.

The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

The samples were analysed for the parent compound (*Z*-isomer) and its *E*-isomer, according to the residue definitions for enforcement and risk assessment. The method used in the analysis of samples

<sup>7</sup> The EMS has derived an MRL proposal at the MRL class of  $0.08\text{ mg/kg}$ , by including a result from the trial S16-04198-07 at the LOQ of  $0.02\text{ mg/kg}$  instead of below the LOQ of  $0.02\text{ mg/kg}$  in the OECD MRL calculator (Belgium, 2021).



in the context of the residue trials is based on LC–MS/MS (QuEChERS). According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Belgium, 2021).

It is acknowledged that the efficiency of the extraction of the analytical method used in the residue trials was not investigated according to SANTE 2017/10632 (European Commission, 2017); therefore, uncertainties on the validity of measurements cannot be excluded.

The residue data from the supervised residue trials in primary crops are summarised in Appendix B.1.2.1.

### 1.2.2. Magnitude of residues in rotational crops

As the proposed uses of cyflufenamid are on permanent/semi-permanent crops, investigations of residues in rotational crops are not required.

### 1.2.3. Magnitude of residues in processed commodities

Specific studies investigating the magnitude of cyflufenamid residues in processed commodities were not submitted and are not required, considering that residues are expected to be below the trigger value of 0.1 mg/kg and that the overall dietary exposure is expected to be below 10% of the ADI (European Commission, 1997d).

### 1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for the commodities under evaluation (see Appendix B.1.2.1). In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

## 2. Residues in livestock

Not relevant as blackberries and raspberries are not used for feed purposes.

## 3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018a, 2019). 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 cyflufenamid used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the EU pesticides peer review (European Commission, 2009). The *E*-isomer, included in the risk assessment residue definition in plants and animals, and the metabolite 149-F1, included in the risk assessment residue definition in animals, were considered to be of similar toxicity as the parent (*Z*-isomer) (EFSA, 2009).

### *Short-term (acute) dietary risk assessment*

The short-term exposure assessment was performed for the commodities assessed in this application in accordance with the internationally agreed methodology (FAO, 2016). The calculations were based on the highest residue (HR) values derived from supervised field trials and the complete list of input values can be found in Appendix D.1.

The estimated short-term exposure did not exceed the ARfD for any the crops assessed in this application. The acute consumer exposure was calculated to be 0.6% of ARfD for blackberries and 0.6% of ARfD for raspberries (red and yellow) (see Appendix B.3).

### *Long-term (chronic) dietary risk assessment*

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level (EFSA, 2018b). EFSA updated the calculation with the relevant supervised trials median residue (STMR) values derived from the residue trials submitted in support of this MRL application for blackberries and raspberries and for hops from an EFSA opinion published after the MRL review (EFSA, 2021). The input values used in the exposure calculations are summarised in Appendix D.1.

The estimated long-term dietary intake was up to 6% of the ADI (NL toddler diet). 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 D.1.

EFSA concluded that the long-term intake of residues of cyflufenamid resulting from the existing and the intended uses is unlikely to present a risk to consumer health. However, this conclusion shall be regarded as indicative considering that some risk assessment values derived by EFSA during the MRL review for certain commodities were not fully supported by data and would require further confirmatory information.

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 blackberries (red and yellow) and raspberries.

EFSA concluded that the proposed use of cyflufenamid on blackberries and raspberries will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health. However, this conclusion shall be regarded as indicative considering that some risk assessment values derived by EFSA during the MRL review for certain commodities were not fully supported by data and would require further confirmatory information. The MRL recommendations are summarised in Appendix B.4.

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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
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CF	conversion factor for enforcement to risk assessment residue definition
cGAP	critical GAP
CIRCA	(EU) Communication & Information Resource Centre Administrator
CS	capsule suspension
CV	coefficient of variation (relative standard deviation)
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DS	powder for dry seed treatment
EDI	estimated daily intake
EMS	evaluating Member State
FAO	Food and Agriculture Organization of the United Nations

FID	flame ionisation detector
GAP	Good Agricultural Practice
GC	gas chromatography
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography with mass spectrometry
GC-MS/MS	gas chromatography with tandem mass spectrometry
GS	growth stage
HPLC	high-performance liquid chromatography
HPLC-MS	high-performance liquid chromatography with mass spectrometry
HPLC-MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IENTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
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
SL	soluble concentrate
SP	water-soluble powder
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
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 <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 (days) min–max	g a.s./hL min–max	Water (L/ha) min–max	Rate min–max	Unit		
Blackberries	EU	G	Powdery mildew	SC	100 g/L	Foliar treatment – broadcast spraying	Not mentioned	1–2	10	1.5 3.8	400– 1,000	15	g a.i./ha	3	BE will recalculate the dose rate as a.s./ha leaf wall area (LWA) using the standard
Raspberries (red and yellow)	EU	G	Powdery mildew	SC	100 g/L	Foliar treatment – broadcast spraying	Not mentioned	1–2	10	1.5 3.8	400– 1,000	15	g a.i./ha	3	Belgian CF of 2. Hence, BE will authorise a dose rate of 7.5 g a.s./ha LWA

MRL: maximum residue level; GAP: Good Agricultural Practice; 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, 7th Edition. Revised March 2017. 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 (DAT)	Comment/Source
	Fruit crops	Apples		Foliar: 1 × 270 g a.s./ha	21, 42, 92 (fruit) 0, 21, 42, 92 (leaf)
	Cucumbers		Not specified: 1 × 50 g a.s./ha	0–31 (fruit, leaf)	
			Not specified: 1 × 200 g a.s./ha	7–35 (fruit, leaf)	
Cereals/ grass	Wheat		Foliar: 2 × 25 g a.s./ha; BBCH 32/59 (Study A)	0 (forage and root) At maturity (straw, husk, grain)	Fluorinated phenyl-U- <sup>14</sup> C labelled cyflufenamid (EFSA, 2009).
			Foliar: 2 × 25 or 100 g a.s./ha; BBCH 32/39 (Study B)	0 (forage and root) At maturity (straw, husk, grain)	
			Foliar: 2 × 25 or 100 g a.s./ha; BBCH 32/59 (Study C)	0 (forage and root) At maturity (straw, husk, grain)	Cyclopropyl-2-3- <sup>14</sup> C labelled cyflufenamid (EFSA, 2009).
Pulses/ oilseeds	Rapeseeds		Foliar: 1 × 12.5 g a.s./ha; BBCH 14 or 69	14 (whole plant) At maturity (seed)	Fluorinated phenyl-U- <sup>14</sup> C labelled cyflufenamid (EFSA, 2016).
			Foliar: 5 × 12.5 g a.s./ha; BBCH 69		
Rotational crops (available studies)	Crop groups	Crop(s)	Application(s)	PBI (DAT)	Comment/Source
	Root/tuber crops	Carrots	Bare soil application: 1 × 50 g a.s./ha	30, 120	Fluorinated phenyl-U- <sup>14</sup> C labelled cyflufenamid (EFSA, 2009).
	Leafy crops	Lettuces	Bare soil application: 1 × 50 g a.s./ha	30	
	Cereal (small grain)	Wheat	Bare soil application: 1 × 50 g a.s./ha	30, 120, 270	

Processed commodities (hydrolysis study)	Conditions	Stable?	Comment/Source
	Pasteurisation (20 min, 90°C, pH 4)	Yes	Fluorinated phenyl-U- <sup>14</sup> C labelled a.s. cyflufenamid (92.4% AR); ( <i>E</i> )-isomer (6.7% AR) (EFSA, 2021)
	Baking, brewing and boiling (60 min, 100°C, pH 5)	Yes	Fluorinated phenyl-U- <sup>14</sup> C labelled a.s. cyflufenamid (91.1% AR); ( <i>E</i> )-isomer (5.8% AR) (EFSA, 2021)
	Sterilisation (20 min, 120°C, pH 6)	Yes	Fluorinated phenyl-U- <sup>14</sup> C labelled a.s. cyflufenamid (91% AR); ( <i>E</i> )-isomer (5.7% AR), 149-F (1.2% AR), others/unknown (4.9% AR) (EFSA, 2021)
	Other processing conditions	–	

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2018b)
Rotational crop and primary crop metabolism similar?	Yes	EFSA (2018b)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not triggered	Hydrolysis study with fluorinated phenyl-radiolabelled cyflufenamid available (EFSA, 2021)
Plant residue definition for monitoring (RD-Mo)	Regulation (EC) No 396/2005: Cyflufenamid (sum of cyflufenamid ( <i>Z</i> -isomer) and its <i>E</i> -isomer, expressed as cyflufenamid)  EFSA (2018b): Sum of cyflufenamid ( <i>Z</i> -isomer) and its <i>E</i> -isomer	
Plant residue definition for risk assessment (RD-RA)	Sum of cyflufenamid ( <i>Z</i> -isomer) and its <i>E</i> -isomer (EFSA, 2018b)	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	<p><b>High water and high acid content commodities:</b></p> <ul style="list-style-type: none"> <li>GC–MS, LOQ = 0.01 mg/kg for the sum of isomers: cyflufenamid (<i>Z</i>-isomer) and its <i>E</i>-isomer. Confirmation by monitoring 2 additional fragment ions. ILV available (GC–MS) (EFSA, 2011).</li> <li>QuEChERS (LC–MS/MS), LOQ = 0.01 mg/kg for cyflufenamid (<i>Z</i>-isomer) (EFSA, 2018b).</li> </ul> <p><b>High oil content commodities:</b></p> <ul style="list-style-type: none"> <li>QuOil (LC–MS-QToF), LOQ = 0.01 mg/kg for cyflufenamid (<i>Z</i>-isomer) (EFSA, 2018b).</li> </ul> <p><b>Dry commodities:</b></p> <ul style="list-style-type: none"> <li>GC–MS, LOQ = 0.01 mg/kg for the sum of isomers: cyflufenamid (<i>Z</i>-isomer) and its <i>E</i>-isomer. Confirmation by monitoring 2 additional fragment ions. ILV available (GC–MS) (EFSA, 2009)</li> <li>QuEChERS (LC–MS/MS) LOQ = 0.01 mg/kg for cyflufenamid (<i>Z</i>-isomer) (EFSA, 2018b).</li> </ul> <p><b>Hops:</b></p> <ul style="list-style-type: none"> <li>HPLC–MS/MS, LOQ = 0.01 mg/kg for cyflufenamid (<i>Z</i>-isomer). Confirmation by monitoring 1 additional fragment ion. ILV not available and not strictly necessary since ILV available in high water, high acid, high oil content and dry matrices (EFSA, 2021).</li> </ul>	

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; MRL: maximum residue level; GC–MS: gas chromatography with mass spectrometry; LC–MS/MS: liquid chromatography with tandem mass spectrometry; HPLC–MS/MS: high performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method); QuOil: variation of QuEChERS method for vegetable oil samples; ILV: independent laboratory validation.



### B.1.1.2. Storage stability of residues in plants

Plant products (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/ Source
				Value	Unit		
	High water content	Immature barley shoots	-18	25	Months	Sum of cyflufenamid (Z-isomer) and its E-isomer	EFSA (2009)
	High oil content	Oilseed rape	-18	18	Months	Sum of cyflufenamid (Z-isomer) and its E-isomer	EFSA (2014) <sup>(a)</sup>
	High protein content	Dry beans	-18	24	Months	Sum of cyflufenamid (Z-isomer) and its E-isomer	EFSA (2014) <sup>(a)</sup>
	Dry/High starch content	Wheat grains	-18	24	Months	Sum of cyflufenamid (Z-isomer) and its E-isomer	EFSA (2014) <sup>(a)</sup>
	High acid content	Grape	-18	24	Months	Sum of cyflufenamid (Z-isomer) and its E-isomer	EFSA (2014) <sup>(a)</sup>

(a): Samples were fortified separately with cyflufenamid (Z-isomer) and E-isomer and residues were analysed for each isomer separately. Isomerisation to cyflufenamid in samples with E-isomer occurred during sample preparation (EFSA, 2014).

## B.1.2. Magnitude of residues in plants

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

Commodity	Region/ Indoor <sup>(a)</sup>	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR <sup>(b)</sup> (mg/kg)	STMR <sup>(c)</sup> (mg/kg)	CF <sup>(d)</sup>
<b>Monitoring residue definition:</b> sum of cyflufenamid ( <i>Z</i> -isomer) and its <i>E</i> -isomer, expressed as cyflufenamid							
<b>Risk assessment residue definition:</b> sum of cyflufenamid ( <i>Z</i> -isomer) and its <i>E</i> -isomer							
Raspberries (red and yellow), Blackberries	EU (indoor)	< 0.02, 0.021, 2 × 0.033	Residue trials on raspberries compliant with GAP. Extrapolation to blackberries is possible. Cyflufenamid ( <i>Z</i> -isomer): < 0.01, 0.011, 2 × 0.023 <i>E</i> -isomer: 4 × < 0.01	0.07	0.03	0.03	1

MRL: maximum residue level; cGAP: critical Good Agricultural Practice; Mo: monitoring; RA: risk assessment; a.s.: active substance.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: 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?	Not triggered	Permanent/semi-permanent crops  For other uses: No. Residue levels of cyflufenamid in rotational commodities are not expected to exceed 0.01 mg/kg, provided that cyflufenamid is applied in compliance with the GAPs reported in Appendix A of the MRL review (EFSA, 2018b).
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	No study available and not required.

GAP: Good Agricultural Practice; MRL: maximum residue level.

### B.1.2.3. Processing factors

No 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	0.05 mg/kg bw (European Commission, 2009)
Highest IESTI, according to EFSA PRIMo	Blackberries: 0.6% of ARfD Raspberries (red and yellow): 0.6% of ARfD
Assumptions made for the calculations	Calculations performed with PRIMo revision 3.1.  The calculation is based on the highest residue levels (HR values) expected in raw agricultural commodities under assessment.
ADI	0.04 mg/kg bw per day (European Commission, 2009)
Highest IEDI, according to EFSA PRIMo	6% ADI (NL toddler diet)  Contribution of crops assessed: Blackberries: 0.01% (IE adult diet) Raspberries (red and yellow): 0.01% (FI 3-year diet)
Assumptions made for the calculations	Calculations performed with PRIMo revision 3.1.  The calculation is based on the median residue levels (STMR values) derived for raw agricultural commodities according to the risk assessment residue definition. For the remaining commodities covered by the MRL regulation, the STMR values derived in the MRL review and a previous MRL application were selected as input values (EFSA, 2018b, 2021).  In order to take into consideration possible contribution of the <i>E</i> -isomer from hops, the conversion factor (CF) of 1.025 derived from metabolism studies in fruit crops in a previous MRL application was used (EFSA, 2021).

The crops on which no uses have been reported in the MRL review or in the subsequent EFSA output, were not included in the exposure calculation.

The consumer risk assessment shall be regarded as indicative, considering that some STMR values derived by EFSA during the MRL review for certain commodities were not fully supported by data and require further confirmatory information.

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; MRL: maximum residue level; STMR: supervised trials median residue; CXL: codex maximum residue limit.

#### 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> Cyflufenamid (sum of cyflufenamid ( <i>Z</i> -isomer) and its <i>E</i> -isomer, expressed as cyflufenamid) <sup>(F)</sup>				
0153010	Blackberries	0.01*	0.07	The submitted data are sufficient to derive an MRL proposal for EU uses in greenhouse. Risk for consumers unlikely.
0153030	Raspberries (red and yellow)	0.01*	0.07	

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.

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

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

(F): Fat soluble.

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



Cyflufenamid (F)			
LOQs (mg/kg) range from:		0.01	to: 0.05
Toxicological reference values			
ADI (mg/kg bw per day):		0.04	ARID (mg/kg bw): 0.05
Source of ADI:		EC	Source of ARID: Ec
Year of evaluation:		2009	Year of evaluation: 2009

Input values

- Details – chronic risk assessment
- Supplementary results – chronic risk assessment
- Details – acute risk assessment/children
- Details – acute risk assessment/adults

Comments:											
Refined calculation mode											
Chronic risk assessment: JMPR methodology (EDI/TMDI)											
No of diets exceeding the ADI: ---											
TMDI(NED)/EDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from	
										MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI(NED)/EDI calculation (based on average food consumption)	6%	NL toddler	2.35	4%	Milk: Cattle	0.4%	Apples	0.2%	Wheat	0.2%	6%
	3%	UK infant	1.36	3%	Milk: Cattle	0.1%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	3%
	3%	FR toddler 2-3 yr	1.10	2%	Milk: Cattle	0.2%	Wheat	0.1%	Apples	0.1%	3%
	3%	DE child	1.07	1%	Milk: Cattle	0.5%	Apples	0.2%	Wheat	0.1%	3%
	3%	NL child	1.06	2%	Milk: Cattle	0.2%	Apples	0.2%	Wheat	0.1%	3%
	2%	FR child 3-15 yr	0.98	2%	Milk: Cattle	0.2%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	2%
	2%	UK toddler	0.84	2%	Milk: Cattle	0.2%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	2%
	2%	DK child	0.77	0.9%	Milk: Cattle	0.3%	Rye	0.2%	Wheat	0.1%	2%
	2%	SE general	0.66	0.9%	Milk: Cattle	0.3%	Bovine: Muscle/meat	0.2%	Wheat	0.1%	2%
	2%	RO general	0.66	0.9%	Milk: Cattle	0.3%	Wheat	0.1%	Wine grapes	0.1%	2%
	2%	ES child	0.63	0.9%	Milk: Cattle	0.2%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	2%
	1%	FR infant	0.59	1%	Milk: Cattle	0.1%	Apples	0.0%	Wheat	0.0%	1%
	1%	DE general	0.58	0.9%	Milk: Cattle	0.1%	Wheat	0.1%	Apples	0.0%	1%
	1%	DE women 14-50 yr	0.58	0.9%	Milk: Cattle	0.1%	Wheat	0.1%	Apples	0.0%	1%
	1%	GEMIS/Food G15	0.51	0.5%	Milk: Cattle	0.2%	Wheat	0.1%	Wine grapes	0.1%	1%
	1%	GEMIS/Food G06	0.49	0.4%	Wheat	0.2%	Milk: Cattle	0.2%	Tomatoes	0.1%	1%
	1%	GEMIS/Food G07	0.48	0.5%	Milk: Cattle	0.2%	Wheat	0.1%	Wine grapes	0.1%	1%
	1%	GEMIS/Food G11	0.47	0.6%	Milk: Cattle	0.2%	Wheat	0.1%	Wine grapes	0.1%	1%
	1%	GEMIS/Food G10	0.44	0.4%	Milk: Cattle	0.2%	Wheat	0.1%	Poultry: Muscle/meat	0.1%	1%
	1%	GEMIS/Food G08	0.44	0.4%	Milk: Cattle	0.2%	Wheat	0.1%	Wine grapes	0.1%	1%
	1%	NL general	0.41	0.6%	Milk: Cattle	0.1%	Wheat	0.1%	Apples	0.0%	1%
	0.9%	IE adult	0.36	0.3%	Milk: Cattle	0.1%	Wheat	0.1%	Wine grapes	0.0%	0.9%
	0.8%	FR adult	0.33	0.3%	Milk: Cattle	0.2%	Wine grapes	0.1%	Wheat	0.0%	0.8%
	0.8%	ES adult	0.33	0.4%	Milk: Cattle	0.1%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	0.8%
	0.7%	DK adult	0.30	0.4%	Milk: Cattle	0.1%	Wine grapes	0.1%	Wheat	0.0%	0.7%
	0.6%	LT adult	0.25	0.3%	Milk: Cattle	0.1%	Apples	0.1%	Rye	0.0%	0.6%
	0.6%	UK adult	0.23	0.2%	Milk: Cattle	0.1%	Wheat	0.1%	Wine grapes	0.0%	0.6%
	0.6%	PT general	0.23	0.2%	Wheat	0.2%	Wine grapes	0.0%	Tomatoes	0.0%	0.6%
	0.5%	UK vegetarian	0.22	0.2%	Milk: Cattle	0.1%	Wheat	0.1%	Wine grapes	0.0%	0.5%
	0.5%	IT toddler	0.21	0.3%	Wheat	0.1%	Tomatoes	0.0%	Apples	0.0%	0.5%
0.4%	IT adult	0.16	0.2%	Wheat	0.1%	Tomatoes	0.0%	Apples	0.0%	0.4%	
0.4%	IE child	0.15	0.3%	Milk: Cattle	0.1%	Wheat	0.0%	Apples	0.0%	0.4%	
0.3%	FI 3 yr	0.14	0.1%	Wheat	0.1%	Cucumbers	0.0%	Apples	0.0%	0.3%	
0.3%	FI 6 yr	0.10	0.0%	Wheat	0.0%	Cucumbers	0.0%	Rye	0.0%	0.3%	
0.2%	PL general	0.08	0.1%	Apples	0.0%	Tomatoes	0.0%	Table grapes	0.0%	0.2%	
0.2%	FI adult	0.07	0.0%	Rye	0.0%	Tomatoes	0.0%	Apples	0.0%	0.2%	

**Conclusion:**  
 The estimated long-term dietary intake (TMDI(NED)/EDI) was below the ADI.  
 The long-term intake of residues of cyflufenamid (F) is unlikely to present a public health concern.  
**DISCLAIMER:** Dietary data from the UK were included in PRIMo when the UK was a member of the European Union.

<b>Acute risk assessment/children</b>	<b>Acute risk assessment/adults/general population</b>
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARID. **DISCLAIMER:** Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.  
 The calculation is based on the large portion of the most critical consumer group.

**Show results for all crops**

Unprocessed commodities	<b>Results for children</b>				<b>Results for adults</b>			
	No. of commodities for which ARID/ADI is exceeded (IESTI):				No. of commodities for which ARID/ADI is exceeded (IESTI):			
	---				---			
	<b>IESTI</b>				<b>IESTI</b>			
	Highest % of ARID/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
	18%	Table grapes	0.2/0.12	8.8	8%	Table grapes	0.2/0.12	4.1
	10%	Pears	0.06/0.04	4.8	6%	Wine grapes	0.2/0.12	2.8
	9%	Melons	0.05/0.03	4.5	2%	Watermelons	0.05/0.03	1.2
	8%	Apples	0.06/0.04	3.8	2%	Melons	0.05/0.03	1.2
	7%	Milk: Cattle	0.02/0.03	3.7	2%	Milk: Cattle	0.02/0.03	1.2
7%	Watermelons	0.05/0.03	3.7	2%	Cucumbers	0.05/0.04	1.1	
6%	Peaches	0.06/0.03	2.9	2%	Pears	0.06/0.04	1.1	
5%	Cucumbers	0.05/0.04	2.6	2%	Apples	0.06/0.04	0.98	
4%	Courgettes	0.05/0.04	1.9	2%	Courgettes	0.05/0.04	0.93	
4%	Sweet peppers/bell peppers	0.06/0.03	1.8	1%	Peaches	0.06/0.03	0.56	
3%	Tomatoes	0.04/0.03	1.7	1%	Milk: Goat	0.02/0.03	0.55	
3%	Plums	0.07/0.03	1.3	1%	Aubergines/egg plants	0.02/0.02	0.54	
2%	Wine grapes	0.2/0.12	1.1	1%	Plums	0.07/0.03	0.53	
2%	Apricots	0.06/0.03	1.0	1%	Quinces	0.06/0.04	0.53	
2%	Quinces	0.06/0.04	0.86	1%	Cherries (sweet)	0.1/0.05	0.50	
2%	Pumpkins	0.05/0.03	0.80	1.0%	Sweet peppers/bell peppers	0.06/0.03	0.49	
1%	Milk: Goat	0.02/0.03	0.73	1.0%	Tomatoes	0.04/0.03	0.48	
1%	Cherries (sweet)	0.1/0.05	0.61	0.9%	Milk: Sheep	0.02/0.03	0.45	
1%	Aubergines/egg plants	0.02/0.02	0.50	0.9%	Pumpkins	0.05/0.03	0.44	
1.0%	Strawberries	0.04/0.03	0.49	0.8%	HOPS (dried)	5/2.26	0.41	
1.0%	Medlar	0.06/0.04	0.48	0.7%	Apricots	0.06/0.03	0.33	
0.7%	Globe artichokes	0.04/0.02	0.35	0.6%	Strawberries	0.04/0.03	0.28	
0.7%	Poultry: Muscle/meat	0.02/0.02	0.34	0.5%	Globe artichokes	0.04/0.02	0.25	
0.6%	Blackberries	0.07/0.03	0.32	0.5%	Blackberries	0.07/0.03	0.25	
0.6%	Wheat	0.04/0.02	0.29	0.5%	Gherkins	0.05/0.04	0.24	
0.6%	Raspberries (red and yellow)	0.07/0.03	0.28	0.5%	Medlar	0.06/0.04	0.24	
0.5%	Eggs: Chicken	0.02/0.02	0.25	0.5%	Poultry: Muscle	0.02/0.02	0.23	
0.5%	Bovine: Liver	0.02/0.03	0.24	0.3%	Bovine: Muscle	0.02/0.03	0.17	
0.4%	Bovine: Edible offals (other than liver and kidney)	0.02/0.03	0.22	0.3%	Wheat	0.04/0.02	0.17	
0.4%	Bovine: Muscle/meat	0.02/0.03	0.22	0.3%	Raspberries (red and yellow)	0.07/0.03	0.16	
<a href="#">Expand/collapse list</a>								
<b>Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI calculation)</b>								

Processed commodities	<b>Results for children</b>				<b>Results for adults</b>			
	No. of processed commodities for which ARID/ADI is exceeded (IESTI):				No. of processed commodities for which ARID/ADI is exceeded (IESTI):			
	---				---			
	<b>IESTI</b>				<b>IESTI</b>			
	Highest % of ARID/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
	5%	Pumpkins/boiled	0.05/0.03	2.7	3%	Pumpkins/boiled	0.05/0.03	1.7
	3%	Courgettes/boiled	0.05/0.04	1.4	2%	Wine grapes/wine	0.2/0.12	1.1
	2%	Wine grapes/juice	0.2/0.03	1.2	2%	Courgettes/boiled	0.05/0.04	0.91
	2%	Gherkins/pickled	0.05/0.04	0.92	1%	Table grapes/raisins	0.2/0.56	0.69
	2%	Apples/juice	0.06/0.02	0.84	1%	Wine grapes/juice	0.2/0.03	0.56
2%	Peaches/canned	0.06/0.03	0.78	1%	Apples/juice	0.06/0.02	0.52	
1%	Pears/juice	0.06/0.02	0.51	0.5%	Hops/beer	5/0.01	0.27	
0.8%	Tomatoes/juice	0.04/0.02	0.38	0.5%	Peaches/canned	0.06/0.03	0.25	
0.7%	Raspberries/juice	0.07/0.03	0.35	0.3%	Tomatoes/sauce/puree	0.04/0.02	0.16	
0.7%	Peaches/juice	0.06/0.02	0.33	0.3%	Barley/beer	0.1/0	0.14	
0.5%	Wheat/milling (flour)	0.04/0.02	0.24	0.3%	Maize/oil	0.01/0.25	0.13	
0.5%	Maize/oil	0.01/0.25	0.23	0.2%	Wheat/bread/pizza	0.04/0.02	0.09	
0.4%	Tomatoes/sauce/puree	0.04/0.02	0.19	0.2%	Wheat/pasta	0.04/0.02	0.08	
0.4%	Plums/juice	0.07/0.02	0.19	0.1%	Wheat/bread (wholemeal)	0.04/0.02	0.07	
0.2%	Wheat/milling (wholemeal)-baking	0.04/0.02	0.11	0.08%	Rice/milling (polishing)	0.01/0	0.04	
<a href="#">Expand/collapse list</a>								

**Conclusion:**  
 No exceedance of the toxicological reference value was identified for any unprocessed commodity.  
 A short-term intake of residue of cyflufenamid (F) is unlikely to present a public health risk.  
 For processed commodities, no exceedance of the ARID/ADI was identified.

## Appendix D – Input values for the exposure calculations

### D.1. Consumer risk assessment

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment <sup>(a)</sup>
<b>Risk assessment residue definition for plant commodities:</b> sum of cyflufenamid (Z-isomer) and its E-isomer						
<b>Blackberries</b>	0.07	MRL proposal	0.03	STMR-RAC	0.03	HR-RAC
<b>Raspberries (red and yellow)</b>	0.07	MRL proposal	0.03	STMR-RAC	0.03	HR-RAC
Apples	0.06	EFSA (2018b)	0.02	STMR-RAC	0.04	HR-RAC
Pears	0.06	EFSA (2018b)	0.02	STMR-RAC	0.04	HR-RAC
Quinces	0.06	EFSA (2018b)	0.02	STMR-RAC	0.04	HR-RAC
Medlar	0.06	EFSA (2018b)	0.02	STMR-RAC	0.04	HR-RAC
Loquats/Japanese medlars	0.06	EFSA (2018b)	0.02	STMR-RAC	0.04	HR-RAC
Other pome fruit	0.06	EFSA (2018b)	0.02	STMR-RAC	–	
Apricots	0.06	EFSA (2018b)	0.02	STMR-RAC	0.03	HR-RAC
Cherries (sweet)	0.1	EFSA (2018b)	0.04	STMR-RAC	0.05	HR-RAC
Peaches	0.06	EFSA (2018b)	0.02	STMR-RAC	0.03	HR-RAC
Plums	0.07	EFSA (2018b)	0.02	STMR-RAC	0.03	HR-RAC
Table grapes	0.2	EFSA (2018b)	0.03	STMR-RAC	0.12	HR-RAC
Wine grapes	0.2	EFSA (2018b)	0.03	STMR-RAC	0.12	HR-RAC
Strawberries	0.04	EFSA (2018b)	0.02	STMR-RAC	0.03	HR-RAC
Tomatoes	0.04	EFSA (2018b)	0.02	STMR-RAC	0.03	HR-RAC
Sweet peppers/bell peppers	0.06	EFSA (2018b)	0.02	STMR-RAC	0.03	HR-RAC
Aubergines/egg plants	0.02	EFSA (2018b)	0.02	STMR-RAC	0.02	HR-RAC
Cucumbers	0.05	EFSA (2018b)	0.02	STMR-RAC	0.04	HR-RAC
Gherkins	0.05	EFSA (2018b)	0.02	STMR-RAC	0.04	HR-RAC
Courgettes	0.05	EFSA (2018b)	0.02	STMR-RAC	0.04	HR-RAC
Other cucurbits - edible peel	0.05	EFSA (2018b)	0.02	STMR-RAC	–	
Melons	0.05	EFSA (2018b)	0.02	STMR-RAC	0.03	HR-RAC
Pumpkins	0.05	EFSA (2018b)	0.02	STMR-RAC	0.03	HR-RAC
Watermelons	0.05	EFSA (2018b)	0.02	STMR-RAC	0.03	HR-RAC
Other cucurbits - inedible peel	0.05	EFSA (2018b)	0.02	STMR-RAC	–	
Globe artichokes	0.04	EFSA (2018b)	0.02	STMR-RAC	0.02	HR-RAC
Barley	0.1	EFSA (2018b)	0.02	STMR-RAC	0.02	STMR-RAC
Buckwheat and other pseudo-cereals	0.1	EFSA (2018b)	0.02	STMR-RAC	0.02	STMR-RAC
Maize/corn	0.01*	existing MRL <sup>(a)</sup>	0.01	LOQ	0.01	LOQ
Common millet/proso millet	0.01*	existing MRL <sup>(a)</sup>	0.01	LOQ	0.01	LOQ
Oat	0.1	EFSA (2018b)	0.02	STMR-RAC	0.02	STMR-RAC
Rice	0.01*	existing MRL <sup>(a)</sup>	0.01	LOQ	0.01	LOQ
Rye	0.04	EFSA (2018b)	0.02	STMR-RAC	0.02	STMR-RAC



Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment <sup>(a)</sup>
Sorghum	0.01*	existing MRL <sup>(a)</sup>	0.01	LOQ	0.01	LOQ
Wheat	0.04	EFSA (2018b) <sup>(a)</sup>	0.02	STMR-RAC	0.02	STMR-RAC
Hops (dried)	5	EFSA (2021) <sup>(b)</sup>	1.89	STMR-RAC (1.84) × CF (1.025)	2.26	HR-RAC (2.2) × CF (1.025)
<b>Risk assessment residue definition for animal commodities:</b> sum of cyflufenamid ( <i>Z</i> -isomer), its <i>E</i> -isomer and metabolite 149-F1, expressed as cyflufenamid						
Bovine: Muscle/meat	0.02*	EFSA (2018b) <sup>(c),(d)</sup>	0.03	0.8 × STMR muscle + 0.2 × STMR fat <sup>(d)</sup>	0.03	0.8 × HR muscle + 0.2 × HR fat <sup>(d)</sup>
Bovine: Fat tissue	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	0.03	HR-RAC
Bovine: Liver	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	0.03	HR-RAC
Bovine: Kidney	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	0.03	HR-RAC
Bovine: Edible offals (other than liver and kidney)	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	0.03	HR-RAC
Bovine: Other products	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	0.03	HR-RAC
Sheep: Muscle/meat	0.02*	EFSA (2018b) <sup>(c),(d)</sup>	0.03	0.8 × STMR muscle + 0.2 × STMR fat <sup>(d)</sup>	0.03	0.8 × HR muscle + 0.2 × HR fat <sup>(d)</sup>
Sheep: Fat tissue	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	0.03	HR-RAC
Sheep: Liver	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	0.03	HR-RAC
Sheep: Kidney	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	0.03	HR-RAC
Sheep: Edible offals (other than liver and kidney)	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	0.03	HR-RAC
Sheep: other products	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	–	
Goat: Muscle/meat	0.02*	EFSA (2018b) <sup>(c),(d)</sup>	0.03	0.8 × STMR muscle + 0.2 × STMR fat <sup>(d)</sup>	0.03	0.8 × HR muscle + 0.2 × HR fat <sup>(d)</sup>
Goat: Fat tissue	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	0.03	HR-RAC
Goat: Liver	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	0.03	HR-RAC
Goat: Kidney	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	0.03	HR-RAC
Goat: Edible offal (other than liver and kidney)	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	0.03	HR-RAC
Goat: other products	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	–	
Equine: Muscle/meat	0.02*	EFSA (2018b) <sup>(c),(d)</sup>	0.03	0.8 × STMR muscle + 0.2 × STMR fat <sup>(d)</sup>	0.03	0.8 × HR muscle + 0.2 × HR fat <sup>(d)</sup>
Equine: Fat tissue	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	0.03	HR-RAC
Equine: Liver	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	0.03	HR-RAC
Equine: Kidney	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	0.03	HR-RAC

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment <sup>(a)</sup>
Equine: Edible offal (other than liver and kidney)	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	0.03	HR-RAC
Equine: Other products	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	–	
Poultry: Muscle/meat	0.02*	Existing MRL <sup>(a)</sup>	0.02	LOQ	0.02	LOQ
Poultry: Fat tissue	0.02*	Existing MRL <sup>(a)</sup>	0.02	LOQ	0.02	LOQ
Poultry: Liver	0.02*	Existing MRL <sup>(a)</sup>	0.02	LOQ	0.02	LOQ
Poultry: Kidney	0.02*	Existing MRL <sup>(a)</sup>	0.02	LOQ	0.02	LOQ
Poultry: Edible offals (other than liver and kidney)	0.02*	Existing MRL <sup>(a)</sup>	0.02	LOQ	0.02	LOQ
Poultry: Other products	0.02*	Existing MRL <sup>(a)</sup>	0.02	LOQ	–	
Milk: Cattle	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	0.03	STMR-RAC
Milk: Sheep	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	0.03	STMR-RAC
Milk: Goat	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	0.03	STMR-RAC
Milk: Horse	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	0.03	STMR-RAC
Milk: Others	0.02*	EFSA (2018b) <sup>(c)</sup>	0.03	STMR-RAC	0.03	STMR-RAC
Eggs: Chicken	0.02*	Existing MRL <sup>(a)</sup>	0.02	LOQ	0.02	LOQ
Eggs: Duck	0.02*	Existing MRL <sup>(a)</sup>	0.02	LOQ	0.02	LOQ
Eggs: Goose	0.02*	Existing MRL <sup>(a)</sup>	0.02	LOQ	0.02	LOQ
Eggs: Quail	0.02*	Existing MRL <sup>(a)</sup>	0.02	LOQ	0.02	LOQ
Eggs: Others	0.02*	Existing MRL <sup>(a)</sup>	0.02	LOQ	–	

STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.

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

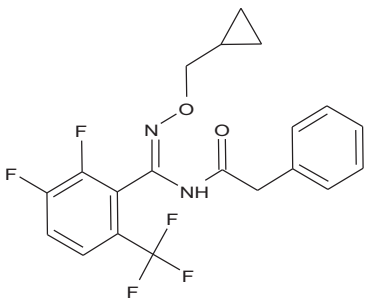
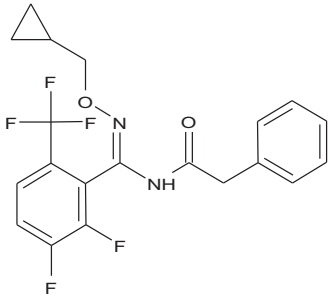
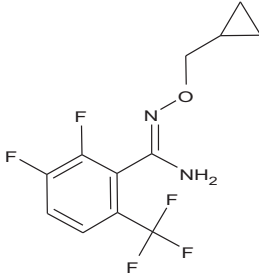
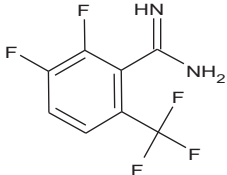
(a): Data gaps were identified in the MRL review (EFSA, 2018b).

(b): MRL on hops voted at the Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals – Pesticide Residues on 14–15 June 2021 and included in a draft MRL Regulation (SANTE/10518/2021), not yet implemented.

(c): STMR and HR values for food commodities derived from ruminants were established at the LOQ of 0.03 mg/kg based on the results of the metabolism study in goats (EFSA, 2018b).

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

## Appendix E – Used compound codes

Code/trivial name <sup>(a)</sup>	IUPAC name/SMILES notation/InChiKey <sup>(b)</sup>	Structural formula <sup>(c)</sup>
Cyflufenamid 149-(Z)-FB	(Z)-N-[ $\alpha$ -(cyclopropylmethoxyimino)-2,3-difluoro-6-(trifluoromethyl)benzyl]-2-phenylacetamide  <chem>FC(F)(F)c1ccc(F)c(F)c1C(\NC(=O)Cc1ccccc1)=N\OCC1CC1</chem>  ACMXQHFNODYQAT-TWGOXAJXNA-N	
149-(E)-FB	(E)-N-[ $\alpha$ -(cyclopropylmethoxyimino)-2,3-difluoro-6-(trifluoromethyl)benzyl]-2-phenylacetamide  <chem>FC(F)(F)c1ccc(F)c(F)c1C(\NC(=O)Cc1ccccc1)=N\OCC1CC1</chem>  ACMXQHFNODYQAT-UHFFFAOYSA-N	
149-F	<i>N'</i> -(cyclopropylmethoxy)-2,3-difluoro-6-(trifluoromethyl)benzene-1-carboximidamide  <chem>N/C(=N\OCC1CC1)c1c(ccc(F)c1F)C(F)(F)F</chem>  GATGRGDKTXQMNK-UHFFFAOYSA-N	
149-F1	2,3-difluoro-6-(trifluoromethyl)benzene-1-carboximidamide  <chem>Fc1c(C(=N)N)c(ccc1F)C(F)(F)F</chem>  JYSBNJJWTHMPOC-UHFFFAOYSA-N	

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 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116563, 15 June 2020).

(c): ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C25H41, Build 121153, 22 March 2021).