

## REASONED OPINION

# Reasoned opinion on the modification of the existing MRLs for cyflufenamid in pome fruits, cucurbits (inedible peel) and gherkins<sup>1</sup>

European Food Safety Authority<sup>2</sup>

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### ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, France, hereafter referred to as the evaluating Member State (EMS), received an application from the company Nisso Chemical Europe GmbH to modify the existing MRLs for the active substance cyflufenamid in pome fruit (quinces, medlar, loquat), cucurbits with inedible peel (pumpkins, watermelons) and gherkins. In order to accommodate for the intended uses of cyflufenamid, France proposed to raise the existing MRLs from the limit of quantification of 0.02 mg/kg to 0.05 mg/kg in pome fruit and gherkins and 0.04 mg/kg in cucurbits with inedible peel. France 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. According to EFSA the data are sufficient to derive a MRL proposal of 0.06 mg/kg for the intended use on quinces, medlar and loquat in France, 0.05 mg/kg for the intended use on pumpkins and watermelons in France and 0.08 mg/kg for the intended use on gherkins in France. Alternatively, the existing MRLs of 0.05 mg/kg on apples and pears and 0.04 mg/kg on melons, which were derived from the same residue data using the previous valid statistically-based calculation method, could be extrapolated to the whole group of pome fruit and cucurbits with inedible peel, respectively. Adequate analytical enforcement methods are available to control the residues of cyflufenamid in the commodities under consideration. Based on the risk assessment results, EFSA concludes that the proposed use of cyflufenamid on quinces, medlar, loquat, pumpkins, watermelons and gherkins will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

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### KEY WORDS

cyflufenamid, pome fruits, cucurbits and gherkins, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, phenylacetamide fungicide, E-isomer.

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## SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, France, hereafter referred to as the evaluating Member State (EMS), received an application from the company Nisso Chemical Europe GmbH to modify the existing MRLs for the active substance cyflufenamid in pome fruit (quinces, medlar, loquat), cucurbits with inedible peel (pumpkins, watermelons) and gherkins. In order to accommodate for the intended uses of cyflufenamid, France proposed to raise the existing MRLs from the limit of quantification of 0.02 mg/kg to 0.05 mg/kg in pome fruit and gherkins and 0.04 mg/kg in cucurbits with inedible peel. France 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 4 December 2012.

EFSA bases its assessment on the evaluation report, the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC, the Commission Review Report on cyflufenamid, the conclusion on the peer review of the pesticide risk assessment of the active substance cyflufenamid as well as the conclusions from previous EFSA opinions on cyflufenamid.

The toxicological profile of cyflufenamid was assessed in the framework of the peer review under Council Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.04 mg/kg bw per day and an ARfD of 0.05 mg/kg bw.

The metabolism of cyflufenamid in primary crops was investigated in wheat (cereals), apples and cucumbers (fruits and fruiting vegetable). For these crop groups the residue definition for enforcement and risk assessment has been established as the sum of cyflufenamid (*Z*-isomer) and its *E*-isomer. For the crops under consideration, EFSA concludes that the metabolism of cyflufenamid is sufficiently addressed and that the residue definitions agreed in the peer review are applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 0.06 mg/kg for the intended use on quinces, medlar and loquat in France, 0.05 mg/kg for the intended use on pumpkins and watermelons in France and 0.08 mg/kg for the intended use on gherkins in France. Alternatively, the existing MRLs of 0.05 mg/kg on apples and pears and 0.04 mg/kg on melons, which were derived from the same residue data using the previous valid statistically-based calculation method, could be extrapolated to the whole group of pome fruit and cucurbits with inedible peel, respectively. Adequate analytical enforcement methods are available to control the residues of cyflufenamid in the commodities under consideration at the validated LOQ of 0.01 mg/kg.

Specific studies investigating the magnitude of cyflufenamid residues in processed commodities are not required as the residues expected in the raw agricultural commodities (RAC) are low and the total theoretical maximum daily intake (TMDI) is below the trigger value of 10 % of the ADI.

The occurrence of cyflufenamid residues in rotational crops was investigated in the framework of the peer review. Based on the available information, EFSA concludes that significant residue levels are unlikely to occur in rotational crops provided that the compound is used on cucurbits according to the proposed GAP (Good Agricultural Practice).

Residues of cyflufenamid in commodities of animal origin were not assessed in the framework of this application, since quinces, medlar, loquat, pumpkins, watermelons and gherkins are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). For the calculation of chronic exposure, EFSA used the median residue values as derived for the intended uses on the crops under consideration and the median residue values for commodities covered by previously issued EFSA reasoned opinions. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values. The acute exposure assessment was performed only with regard

to the commodities under consideration. The estimated exposure was then compared with the toxicological reference values derived for cyflufenamid.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for up to 4.6 % of the ADI (FR toddler diet). The contribution of cyflufenamid residues in watermelons to the total consumer exposure accounted for a maximum of 0.025 % of the ADI (WHO Cluster diet B), whereas the individual contribution for the remaining crops under consideration accounted for no more than 0.011 % of the ADI. No acute consumer risk was identified in relation to the MRL proposals for the crops under consideration.

EFSA concludes that the proposed use of cyflufenamid on quinces, medlar, loquat, pumpkins, watermelons and gherkins will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

Thus EFSA proposes to amend the existing MRLs as reported in the summary table.

### Summary table

Code number <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
<b>Enforcement residue definition: cyflufenamid, sum of cyflufenamid (Z-isomer) and its E-isomer.</b>				
130030	Quinces	0.02*	0.05 or 0.06	The MRL proposals derived by extrapolation from data on apples and pears are sufficiently supported by data. No consumer health risk was identified for the intended uses on these pome fruits in France. The MRL proposals of 0.05 mg/kg and 0.06 mg/kg were derived using the previous and the current calculation methodology ( $R_{ber}/R_{max}$ and OECD calculator, respectively).
130040	Medlar	0.02*		
130050	Loquat	0.02*		
130990	Others pome fruit <sup>(b)</sup>	0.02*		
232020	Gherkins	0.02*	0.08	The MRL proposal derived by extrapolation from data on courgettes is considered as sufficiently supported by data no consumer health risk was identified for the intended use on gherkins in France.
233020	Pumpkins (Winter squash, marrow (late variety))	0.02*	0.04 or 0.05	The MRL proposals derived by extrapolation from data on melons are sufficiently supported by data. No consumer health risk was identified for the intended uses on these cucurbits in France. The MRL proposals of 0.04 mg/kg and 0.05 mg/kg were derived using the previous and the current calculation methodology ( $R_{ber}/R_{max}$ and OECD calculator, respectively).
233030	Watermelons	0.02*		
233990	Others cucurbits, inedible peel <sup>(c)</sup>	0.02*		

(a): According to Annex I of Regulation (EC) No 396/2005.

(b): Except commodities classified in code numbers from 130010 to 130050 (apples, pears, quinces, medlar and loquat).

(c): Except commodities classified in code numbers from 233010 to 233030 (melons, pumpkins and watermelons).

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

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## BACKGROUND

Regulation (EC) No 396/2005<sup>3</sup> establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC<sup>4</sup>, repealed by Regulation (EC) No 1107/2009<sup>5</sup>, shall submit to a Member State, when appropriate, an application to set a MRL in accordance with the provisions of Article 7 of that Regulation.

France, hereafter referred to as the evaluating Member State (EMS), received an application from the company Nisso Chemical Europe GmbH<sup>6</sup> to modify the existing MRLs for the active substance cyflufenamid in pome fruit (quinces, medlar, loquat), cucurbits with inedible peel (pumpkins, watermelons) and gherkins. This application was notified to the European Commission and EFSA, and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 4 December 2012.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2012-00972 and the following subject:

*Cyflufenamid - Application to modify the existing MRLs in gherkins, pome fruit and cucurbits-inedible peel.*

France proposed to raise the existing MRLs of cyflufenamid in the crops under consideration from the limit of quantification of 0.02 mg/kg to 0.05 mg/kg in pome fruit and gherkins and 0.04 mg/kg in cucurbits with inedible peel.

EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

## TERMS OF REFERENCE

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the deadline for providing the reasoned opinion is 4 March 2013.

<sup>3</sup> Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005. OJ L 70, 16.03.2005, p. 1-16.

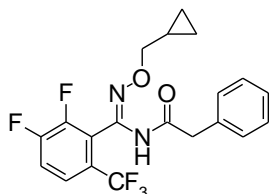
<sup>4</sup> Council Directive 91/414/EEC of 15 July 1991. OJ L 230, 19.08.1991, p. 1-32.

<sup>5</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009. OJ L 309, 24.11.2009, p. 1-50.

<sup>6</sup> Nisso Chemical Europe GmbH, Berliner Allee 42, 40212 Düsseldorf, Germany.

## THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Cyflufenamid is the ISO common name for (*Z*)-*N*-[-(cyclopropylmethoxyimino)-2,3-difluoro-6-(trifluoromethyl)benzyl]-2-phenylacetamide (IUPAC). The compound cyflufenamid represents the (*Z*)-isomer; the technical grade material contains small amounts of the (*E*)-isomer<sup>7</sup> (maximum 1.5 %) (EFSA, 2009a). The chemical structure of the compound is reported below.



Molecular weight: 412.36 g/mol

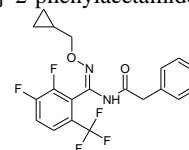
Cyflufenamid is a fungicide belonging to the phenylacetamide chemical class. Although its mode of action is still unknown, the compound has shown to be effective against powdery/downy mildew in plants. Cyflufenamid has good translaminar movement and vapour action, but is poorly translocated within the plant.

Cyflufenamid was evaluated in the framework of Council Directive 91/414/EEC with the United Kingdom designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Commission Directive 2009/154/EC<sup>8</sup> which entered into force on 1 April 2010 for use as fungicide. In accordance with Commission Implementing Regulation (EU) No 540/2011<sup>9</sup> cyflufenamid is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC. The representative uses evaluated in the peer review were foliar applications on wheat, rye and barley. The Draft Assessment Report (DAR) of cyflufenamid has been peer reviewed by EFSA, therefore an EFSA conclusion is available (EFSA, 2009a).

The EU MRLs for cyflufenamid are established in Annex IIIA of Regulation (EC) No 396/2005 (Appendix C). MRL proposals for oats, animal products, apples, pears, grapes, cucumbers, courgettes and melons were evaluated by EFSA (EFSA, 2009b, 2011) and new temporary MRLs were established through the Commission Regulation (EC) No 1050/2010<sup>10</sup> and Commission Regulation (EC) No 978/2011<sup>11</sup>. The existing EU MRLs for cyflufenamid on the crops under consideration are set at the LOQ of 0.02 kg/kg. Codex Alimentarius has not established CXLs for cyflufenamid.

The details of the intended GAPs for cyflufenamid in France are given in Appendix A.

<sup>7</sup>(*E*)-isomer: *N*-{(*E*)-[(cyclopropylmethoxy)imino][2,3-difluoro-6-(trifluoromethyl)phenyl]methyl}-2-phenylacetamide.



<sup>8</sup> Commission Directive 2009/154/EC of 30 November 2009. OJ L 314, 01.12.2009, p. 69-71.

<sup>9</sup> Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011. OJ L 153, 11.06.2011, p. 1-186.

<sup>10</sup> Commission Regulation (EC) No 1050/2009 of 28 October 2009, OJ L 290, 06.11.2009, p. 7-55.

<sup>11</sup> Commission Regulation (EU) No 978/2011 of 3 October 2011, OJ L 258, 04.10.2011, p. 12-69.

## ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (France, 2012), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (United Kingdom, 2006), the Commission Review Report on cyflufenamid (EC, 2009), the conclusion on the peer review of the pesticide risk assessment of the active substance cyflufenamid (EFSA, 2009a) as well as the conclusions from previous EFSA reasoned opinions on cyflufenamid (EFSA, 2009b, 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>12</sup> and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011a; OECD, 2011).

### 1. Method of analysis

#### 1.1. Methods for enforcement of residues in food of plant origin

Analytical methods for the determination of cyflufenamid residues in plant commodities were assessed during the peer review under Council Directive 91/414/EEC and in a previously issued EFSA reasoned opinion on cyflufenamid (United Kingdom, 2006; EFSA, 2009a, 2011).

An analytical enforcement method using chromatography equipped with mass spectrum detection (GC-MSD) has been sufficiently validated in dry commodities and in commodities with high water and high acid content. The method is compliant with the enforcement residue definition in plants, which includes the (*Z*)-isomer (cyflufenamid) and the (*E*)-isomer, and was validated at the LOQ of 0.01 mg/kg for the sum of isomers (EFSA, 2009a, 2011).

The multi-residue QuEChERS method described in the European Standard EN 15662:2008 is also applicable. The liquid chromatography coupled with tandem mass spectrometry detection (LC-MS/MS) method analyses cyflufenamid residues in matrices with high water, high acid, high oil content and dry commodities at the LOQ of 0.01 mg/kg for the sum of isomers (CEN, 2008).

Since the commodities under consideration belong to the group of high water content commodities, EFSA concludes that sufficiently validated analytical methods for enforcing the proposed MRLs for cyflufenamid on pome fruit, cucurbits with inedible peel and gherkins are available.

#### 1.2. Methods for enforcement of residues in food of animal origin

Analytical methods for the determination of residues in food of animal origin are not assessed in the current application, since quinces, medlar, loquat, pumpkins, watermelons and gherkins are normally not fed to livestock.

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<sup>12</sup> Commission Regulation (EU) No 546/2011 of 10 June 2011. OJ L 155, 11.06.2011, p. 127-175.

## 2. Mammalian toxicology

The toxicological profile of the active substance cyflufenamid was assessed in the framework of the peer review under Council Directive 91/414/EEC (EC, 2009). The data were sufficient to derive toxicological reference values for cyflufenamid which are compiled in Table 2-1.

**Table 2-1:** Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
<b>Cyflufenamid</b>					
ADI	EC	2009	0.04 mg/kg bw per day	2-yr rat and 1-yr dog studies	100
ARfD	EC	2009	0.05 mg/kg bw	Rabbit, developmental toxicity study (maternal toxicity)	100

The residue definitions for enforcement and risk assessment also comprise the (*E*)-isomer of cyflufenamid (residue definition for plant and animal commodities) and the metabolite 2,3-difluoro-6-(trifluoromethyl)benzamidine (149-F1)<sup>13</sup> (residue definition for animal commodities) (EFSA, 2009a).

Based on the information reported in the DAR (United Kingdom, 2006), the peer review concluded that the (*E*)-isomer is not expected to be of higher toxicity than cyflufenamid (EFSA, 2009a). The metabolite 149-F1, which was observed in significant amounts (31 to 62 % of the TRR) in tissues and milk in the livestock metabolism study with ruminants (goats), was also found in rat metabolism. Since the submitted genotoxicity studies showed negative results and the oral toxicity was lower than that of cyflufenamid, the peer review concluded that the toxicity of the metabolite 149-F1 is covered by the toxicological reference values set for cyflufenamid (EFSA, 2009a).

## 3. Residues

### 3.1. Nature and magnitude of residues in plant

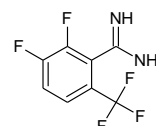
#### 3.1.1. Primary crops

##### 3.1.1.1. Nature of residues

The metabolism of cyflufenamid in primary crops was investigated after foliar applications in wheat (cereals) during the peer review and in apples and cucumbers (fruits and fruiting vegetables) in the framework of a previous MRL application (EFSA, 2009a; 2011). The studies were performed with the compound radiolabelled in the phenyl ring or the cyclopropyl ring (wheat only). The details of the metabolism studies are reported in the DAR and the EFSA reasoned opinion on the modification of the existing MRLs in various crops (United Kingdom, 2006; EFSA, 2011).

The major component of the total radioactive residues (TRR) in wheat, apples and cucumbers was cyflufenamid (wheat: 99 % of the TRR in forage, 37 % of the TRR in straw and 7 % of the TRR in grain; apples: 66 % of the TRR; cucumbers: 96 % to 55 % of the TRR). The (*E*)-isomer was quantified in wheat at up to 4 % of the TRR, but represented only 1-1.3 % of the TRR in cucumbers and apples, respectively. A number of other minor metabolites were detected in low concentrations (individually <10 % of the TRR). Since the (*E*)-isomer was quantified in wheat samples at levels up to approximately 10 % of the level of cyflufenamid, which are significantly higher than the content of the

<sup>13</sup> Metabolite 149-F1: 2,3-difluoro-6-(trifluoromethyl)benzamidine.





(*E*)-isomer in the technical material of cyflufenamid, a shift of isomer ratio of the (*Z*)-isomer to the (*E*)-isomer is expected in cereals.

The peer review established the residue definition for both enforcement and risk assessment as the sum of cyflufenamid (*Z*-isomer) and its *E*-isomer for cereals. The (*E*)-isomer was included in the residue definition for enforcement because the analytical method does not quantify the two isomers separately (EFSA, 2009a, 2009b). Although in the apple and cucumber metabolism studies no significant isomeric conversion from the (*Z*)-isomer to the (*E*)-isomer occurred, EFSA proposed to apply the residue definitions derived by the peer review for cereals also to fruits and fruiting vegetables (EFSA, 2011). The current enforcement residue definition in plants set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived for cereals and for fruits and fruiting vegetables (EFSA, 2009a, 2011).

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

### 3.1.1.2. Magnitude of residues

#### a. Pome fruit (quinces, medlar, loquat).

In support of the intended use the applicant proposed to derive the MRL by extrapolation from sixteen residue trials on apples and pears already assessed by EFSA (EFSA, 2011). Eight trials (six of them on apples) are available per each geographical area, the Northern (NEU) and the Southern (SEU) Europe and are compliant with the intended GAP on quinces, medlar and loquat. The extrapolation of residue data from apples/pears to the whole group of pome fruit is acceptable and the number of residue trials is sufficient (EC, 2011a). EFSA concludes that the data are sufficient to support the MRL proposal of 0.06 mg/kg for quinces, medlar and loquat from the critical intended use in NEU. Instead of this value, the MRL of 0.05 mg/kg set for apples and pears can be extrapolated to the whole group of pome fruit and should be considered as alternative option by risk managers.

It is noted that the MRL of 0.05 mg/kg for apples and pears was calculated according to the statistical methodology described in the previously valid guidance document (EC, 1997g). For MRL applications submitted as from 15 September 2011 the Standing Committee on the Food Chain and Animal Health agreed to use the OECD calculator to derive MRL proposals (EC, 2011b). Using the OECD approach, a slightly higher MRL proposal of 0.06 mg/kg is derived.

#### b. Cucurbits, inedible peel (pumpkins, watermelons)

In support of the intended use the applicant proposed to derive the MRL by extrapolation from sixteen GAP-complaint residue trials (eight NEU and eight SEU trials) on melons already assessed by EFSA (EFSA, 2011a). The extrapolation of residue data from melons to the whole group of cucurbits with inedible peel is acceptable and the number of residue trials is sufficient (EC, 2011a). EFSA concludes that the data are sufficient to support the MRL proposal of 0.05 mg/kg for pumpkins and watermelons derived with the OECD calculator from the critical intended use in SEU. Alternatively, the MRL of 0.04 mg/kg set for melons can be extrapolated to the whole group of cucurbits, inedible peel.

#### c. Cucurbits, edible peel (gherkins)

In support of the intended use the applicant proposed to derive the MRL by extrapolation from four field residue trials performed on courgettes in each of the Northern and the Southern Europe and eight indoor residue trials on cucumbers already assessed by EFSA (EFSA, 2011). The trials on cucumbers do not represent the intended use because conducted indoor, whereas the trials on courgettes are in compliance with the intended GAP on gherkins. According to the EU guidance document the extrapolation of residue data on cucumbers or courgettes (if courgettes alone, eight trials) to the whole group of cucurbits with edible peel is acceptable (EC, 2011a). Since only four NEU and four SEU trials are available, the conditions for extrapolation to the whole group are not fulfilled. However,

considering that gherkins are a minor crop which is morphologically very similar to courgettes, the proposed extrapolation would be acceptable in this case. The MRL proposal of 0.08 mg/kg for gherkins is derived by extrapolation from the critical SEU use on courgettes.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Table 3-1.

In the framework of a previous reasoned opinion on cyflufenamid, EFSA concluded that the above mentioned residue data were valid with regard to storage stability and that the analytical methods used to quantify the residues were proven to be fit for the purpose and in compliance with the cyflufenamid residue definition for monitoring (EFSA, 2011).

EFSA concludes that the data are sufficient to derive a MRL proposal of 0.06 mg/kg for the intended use on quinces, medlar and loquat in France, 0.05 mg/kg for the intended use on pumpkins and watermelons in France and 0.08 mg/kg for the intended use on gherkins in France. Alternatively, the existing MRLs of 0.05 mg/kg on apples and pears and 0.04 mg/kg on melons, which were derived from the same residue data using the previous valid statistically-based calculation method, could be extrapolated to the whole group of pome fruit and cucurbits with inedible peel, respectively.

**Table 3-1:** Overview of the available residues trials data

Commodity	Residue region (a)	Outdoor/Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement (cyflufenamid, sum of cyflufenamid (Z-isomer) and its E-isomer)	Risk assessment (cyflufenamid, sum of cyflufenamid (Z-isomer) and its E-isomer)					
<b>Enforcement residue definition: cyflufenamid, sum of cyflufenamid (Z-isomer) and its E-isomer</b>									
Apples, pears→ quinces, medlar, loquat (pome fruit group)	NEU	Outdoor	<0.01; <0.01; 3 x 0.01; 0.02; 0.02 <sup>(f)</sup> ; 0.035 <sup>(f)</sup>	<0.01; <0.01; 3 x 0.01; 0.02; 0.02 <sup>(f)</sup> ; 0.035 <sup>(f)</sup>	0.01	<b>0.035</b>	<b>0.05<sup>(g)</sup> or 0.06</b>	1	R <sub>ber</sub> = 0.04 R <sub>max</sub> = 0.044 MRL <sub>OECD</sub> = 0.052/0.06
	SEU	Outdoor	<0.01; 2 x 0.01; 0.015; 0.016 <sup>(f)</sup> ; 0.023 <sup>(f)</sup> ; 0.026; 0.029	<0.01; 2 x 0.01; 0.015; 0.016 <sup>(f)</sup> ; 0.023 <sup>(f)</sup> ; 0.026; 0.029	<b>0.016</b>	0.029	0.05	1	R <sub>ber</sub> = 0.051 R <sub>max</sub> = 0.042 MRL <sub>OECD</sub> = 0.048/0.05
Melons→ pumpkins, watermelons (cucurbits, inedible peel group)	NEU	Outdoor	2 x <0.01; 0.011; 0.013; 0.0158; 0.0159; 0.0164; 0.0245	2x<0.01; 0.011; 0.013; 0.0158; 0.0159; 0.0164; 0.0245	<b>0.014</b>	0.025	0.04	1	R <sub>ber</sub> = 0.033 R <sub>max</sub> = 0.03 MRL <sub>OECD</sub> = 0.036/0.04
	SEU	Outdoor	5 x <0.01; 0.0124; 0.0245; 0.027	5x<0.01; 0.0124; 0.0245; 0.027	0.01	<b>0.027</b>	<b>0.04<sup>(g)</sup> or 0.05</b>	1	R <sub>ber</sub> = 0.043 R <sub>max</sub> = 0.037 MRL <sub>OECD</sub> = 0.043/0.05
Courgettes→ gherkins	NEU	Outdoor	2 <0.01; 0.014; 0.02	2 <0.01; 0.014; 0.02	0.012	0.02	0.04	1	R <sub>ber</sub> = 0.037 R <sub>max</sub> = 0.038 MRL <sub>OECD</sub> = 0.04/0.04
	SEU	Outdoor	3 x 0.02; 0.04	3 x 0.02; 0.04	<b>0.02</b>	<b>0.04</b>	<b>0.08</b>	1	R <sub>ber</sub> = 0.07 R <sub>max</sub> = 0.076 MRL <sub>OECD</sub> = 0.075/0.08

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e. indoor use) or Import (country code) (EC, 2011a).

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residue trial.

(e): Statistical estimation of MRLs according to the EU methodology (R<sub>ber</sub>, R<sub>max</sub>; EC, 1997g) and unrounded/rounded values according to the OECD methodology (OECD, 2011).

(f): Studies conducted on pears.

(g): MRL calculated with the R<sub>ber</sub>/R<sub>max</sub> method and proposed for apples, pears and melons in a previously issued reasoned opinion (EFSA, 2011).

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

### 3.1.1.3. Effect of industrial processing and/or household preparation

The nature of cyflufenamid residues after processing has not been assessed and the peer review concluded that such studies were not required for the representative use on cereals (EFSA, 2009a). Even though under the current application hydrolysis studies investigating the nature of cyflufenamid residues would not be required, performing such studies would be desirable.

Specific studies to assess the magnitude of cyflufenamid residues during the processing of the crops under consideration are not necessary as the residue levels in raw agricultural commodities (RAC) did not exceed the trigger value of 0.1 mg/kg and the total theoretical maximum daily intake (TMDI) amounts to less than 10 % of the ADI (EC, 1997d).

## 3.1.2. Rotational crops

### 3.1.2.1. Preliminary considerations

Cucurbits can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed. The assessment is not required for pome fruit trees, which are permanent crops. The soil degradation studies demonstrated that the degradation rate of cyflufenamid is slow (EFSA, 2009a). The maximum  $DT_{90}$  for cyflufenamid in field studies was 300 days, which exceeds the trigger value of 100 days. Thus further studies investigating the nature and magnitude of the compound uptake in rotational crops are required (EC, 1997c).

### 3.1.2.2. Nature and magnitude of residues

The nature of cyflufenamid residues in rotational crops was investigated following different plant-back intervals in a confined rotational crop study using radiolabelled cyflufenamid applied to bare soil at an application rate of 0.05 kg a.s./ha (corresponding to 1.6N the maximum application rate for cucurbits). Rotational crops representative of the root and tuber vegetables (carrots), small grain (wheat) and leafy vegetables (lettuce) were grown on the treated and aged soil. The details of the confined rotational crop study are reported in the DAR and the EFSA reasoned opinion on the modification of the existing MRLs in various crops (United Kingdom, 2006; EFSA, 2011).

Based on the results of the confined rotational crop study, the peer review concluded that quantifiable residue (above the LOQ) of cyflufenamid and its soil metabolites are not expected in parts of rotational crops intended for human consumption and that field studies on rotational crops are not necessary (EFSA, 2009a).

With regard to the current application, EFSA confirms that significant residue levels (exceeding 0.01 mg/kg) are unlikely to occur in rotational crops provided that cyflufenamid is applied on cucurbits according to the proposed GAP.

## 3.2. Nature and magnitude of residues in livestock

Since quinces, medlar, loquat, pumpkins, watermelons and gherkins or their by-products are not normally fed to livestock, the nature and magnitude of cyflufenamid residues in livestock is not assessed in the framework of this application (EC, 1996).

It should be noted that in 2009 (EFSA, 2009a, 2009b) EFSA proposed the following enforcement residue definition for food of animal origin: Sum of cyflufenamid, the *E*-isomer and metabolite 149-F1, (2,3-difluoro-6-(trifluoromethyl)benzamidine) expressed as cyflufenamid. This residue definition was implemented in Commission Regulation (EC) No 1050/2009, but was then modified in 2011 (Commission Regulation (EU) No 978/2011) to cyflufenamid (sum of cyflufenamid (*Z*-isomer and its *E*-isomer). Since cyflufenamid was found to be not a suitable marker for liver and kidney and the existing MRLs set on animal commodities reflect the combined LOQ value which can be achieved by the method of analysis, EFSA proposes to amend the enforcement residue definition for food of

animal origin again to: Sum of cyflufenamid, the *E*-isomer and metabolite 149-F1, (2,3-difluoro-6-(trifluoromethyl)benzamidine) expressed as cyflufenamid.

#### 4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residue Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population<sup>14</sup> (EFSA, 2007).

For the calculation of chronic exposure, EFSA used the median residue values as derived for the intended uses on the crops under consideration (see Table 3-1) and the median residue values for commodities covered by previously issued EFSA reasoned opinions (EFSA, 2009b, 2011). For the remaining commodities of plant and animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values.

The model assumptions for the long-term exposure assessment are considered to be sufficiently conservative for a first tier exposure assessment, assuming that all food items consumed have been treated with the active substance under consideration. In reality, it is not likely that all food consumed will contain residues at the MRL or at levels of the median residue values identified in supervised field trials. However, if this first tier exposure assessment does not exceed the toxicological reference value for long-term exposure (i.e. the ADI), a consumer health risk can be excluded with a high probability.

The acute exposure assessment was performed only with regard to the commodities under consideration assuming the consumption of a large portion of the food items as reported in the national food surveys and that these items contained residues at the highest level as observed in supervised field trials. A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation, when required (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised in Table 4-1.

**Table 4-1:** Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<b>Risk assessment residue definition: cyflufenamid, sum of cyflufenamid (Z-isomer) and its E-isomer.</b>				
Quinces, medlar, loquat, other pome fruit (except apples and pears)	0.016	Median residue (apple/pear, SEU)	0.035	Highest residue (apple/pear, NEU)
Pumpkins, watermelons, other cucurbits, inedible peel (except melons)	0.014	Median residue (melon, NEU)	0.027	Highest residue (melon, SEU)
Gherkins	0.02	Median residue (courgette, SEU)	0.04	Highest residue (courgette, SEU)
Apples, pears	0.016	Median residue (EFSA, 2011)	Acute risk assessment was undertaken only with regard to the crops under consideration.	
Table and wine grapes	0.027	Median residue (EFSA, 2011)		

<sup>14</sup> The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Cucumbers	0.01	Median residue (EFSA, 2011)		
Courgettes	0.02	Median residue (EFSA, 2011)		
Melons	0.014	Median residue (EFSA, 2011)		
Oats	0.02	Median residue (EFSA, 2009b)		
Other commodities of plant origin	MRL	See Appendix C		
<b>Risk assessment residue definition: Sum of cyflufenamid, the <i>E</i>-isomer and metabolite 149-FI (2,3-difluoro-6-(trifluoromethyl)benzamidine), expressed as cyflufenamid</b>				
Other commodities of animal origin	MRL	See Appendix C	Acute risk assessment was undertaken only with regard to the crops under consideration.	

The estimated exposure was then compared with the toxicological reference values derived for cyflufenamid (see Table 2-1). The results of the intake calculation are presented in Appendix B to this reasoned opinion.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for up to 4.6 % of the ADI (FR toddler diet). The contribution of cyflufenamid residues in watermelons to the total consumer exposure accounted for a maximum of 0.025 % of the ADI (WHO Cluster diet B), whereas the individual contribution for the remaining crops under consideration accounted no more than 0.011 % of the ADI.

No acute consumer risk was identified in relation to the MRL proposals for the crops under consideration. The calculated maximum exposure in percentage of the ARfD was 6.6 % for watermelons (DE child diet), 1.8 % for pumpkins, 1.3 mg/kg for gherkins, 1 % for quinces and 0.8 % for medlar.

EFSA concludes that the intended use of cyflufenamid on quinces, medlar, loquat, pumpkins, watermelons and gherkins will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

## CONCLUSIONS AND RECOMMENDATIONS

### CONCLUSIONS

The toxicological profile of cyflufenamid was assessed in the framework of the peer review under Council Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.04 mg/kg bw per day and an ARfD of 0.05 mg/kg bw.

The metabolism of cyflufenamid in primary crops was investigated in wheat (cereals), apples and cucumbers (fruits and fruiting vegetable). For these crop groups the residue definition for enforcement and risk assessment has been established as the sum of cyflufenamid (Z-isomer) and its E-isomer. For the crops under consideration, EFSA concludes that the metabolism of cyflufenamid is sufficiently addressed and that the residue definitions agreed in the peer review are applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 0.06 mg/kg for the intended use on quinces, medlar and loquat in France, 0.05 mg/kg for the intended use on pumpkins and watermelons in France and 0.08 mg/kg for the intended use on gherkins in France. Alternatively, the existing MRLs of 0.05 mg/kg on apples and pears and 0.04 mg/kg on melons, which were derived from the same residue data using the previous valid statistically-based calculation method, could be extrapolated to the whole group of pome fruit and cucurbits with inedible peel, respectively. Adequate analytical enforcement methods are available to control the residues of cyflufenamid in the commodities under consideration at the validated LOQ of 0.01 mg/kg.

Specific studies investigating the magnitude of cyflufenamid residues in processed commodities are not required as the residues expected in the raw agricultural commodities (RAC) are low and the total theoretical maximum daily intake (TMDI) is below the trigger value of 10 % of the ADI.

The occurrence of cyflufenamid residues in rotational crops was investigated in the framework of the peer review. Based on the available information, EFSA concludes that significant residue levels are unlikely to occur in rotational crops provided that the compound is used on cucurbits according to the proposed GAP (Good Agricultural Practice).

Residues of cyflufenamid in commodities of animal origin were not assessed in the framework of this application, since quinces, medlar, loquat, pumpkins, watermelons and gherkins are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). For the calculation of chronic exposure, EFSA used the median residue values as derived for the intended uses on the crops under consideration and the median residue values for commodities covered by previously issued EFSA reasoned opinions. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values. The acute exposure assessment was performed only with regard to the commodities under consideration. The estimated exposure was then compared with the toxicological reference values derived for cyflufenamid.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for up to 4.6 % of the ADI (FR toddler diet). The contribution of cyflufenamid residues in watermelons to the total consumer exposure accounted for a maximum of 0.025 % of the ADI (WHO Cluster diet B), whereas the individual contribution for the remaining crops under consideration accounted for no more than 0.011 % of the ADI. No acute consumer risk was identified in relation to the MRL proposals for the crops under consideration.

EFSA concludes that the proposed use of cyflufenamid on quinces, medlar, loquat, pumpkins, watermelons and gherkins will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

**RECOMMENDATIONS**

Code number <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
<b>Enforcement residue definition: cyflufenamid, sum of cyflufenamid (Z-isomer) and its E-isomer.</b>				
130030	Quinces	0.02*	0.05 or 0.06	The MRL proposals derived by extrapolation from data on apples and pears are sufficiently supported by data. No consumer health risk was identified for the intended uses on these pome fruits in France. The MRL proposals of 0.05 mg/kg and 0.06 mg/kg were derived using the previous and the current calculation methodology ( $R_{ber}/R_{max}$ and OECD calculator, respectively).
130040	Medlar	0.02*		
130050	Loquat	0.02*		
130990	Others pome fruit <sup>(b)</sup>	0.02*		
232020	Gherkins	0.02*	0.08	The MRL proposal derived by extrapolation from data on courgettes is considered as sufficiently supported by data no consumer health risk was identified for the intended use on gherkins in France.
233020	Pumpkins (Winter squash, marrow (late variety))	0.02*	0.04 or 0.05	The MRL proposals derived by extrapolation from data on melons are sufficiently supported by data. No consumer health risk was identified for the intended uses on these cucurbits in France. The MRL proposals of 0.04 mg/kg and 0.05 mg/kg were derived using the previous and the current calculation methodology ( $R_{ber}/R_{max}$ and OECD calculator, respectively).
233030	Watermelons	0.02*		
233990	Others cucurbits, inedible peel <sup>(c)</sup>	0.02*		

(a): According to Annex I of Regulation (EC) No 396/2005.

(b): Except commodities classified in code numbers from 130010 to 130050 (apples, pears, quinces, medlar and loquat).

(c): Except commodities classified in code numbers from 233010 to 233030 (melons, pumpkins and watermelons).

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

Code number <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
<b>Enforcement residue definition: cyflufenamid, sum of cyflufenamid (Z-isomer) and its E-isomer.</b>				
130030	Quinces	0.02*	0.05 or 0.06	The MRL proposals derived by extrapolation from data on apples and pears are sufficiently supported by data. No consumer health risk was identified for the intended uses on these pome fruits in France. The MRL proposals of 0.05 mg/kg and 0.06 mg/kg were derived using the previous and the current calculation methodology ( $R_{ber}/R_{max}$ and OECD calculator, respectively).
130040	Medlar	0.02*		
130050	Loquat	0.02*		
130990	Others pome fruit <sup>(b)</sup>	0.02*		
232020	Gherkins	0.02*	0.08	The MRL proposal derived by extrapolation from data on courgettes is considered as sufficiently supported by



Code number <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
				data no consumer health risk was identified for the intended use on gherkins in France.
233020	Pumpkins (Winter squash, marrow (late variety))	0.02*	0.04 or 0.05	The MRL proposals derived by extrapolation from data on melons are sufficiently supported by data. No consumer health risk was identified for the intended uses on these cucurbits in France. The MRL proposals of 0.04 mg/kg and 0.05 mg/kg were derived using the previous and the current calculation methodology ( $R_{ber}/R_{max}$ and OECD calculator, respectively).
233030	Watermelons	0.02*		
233990	Others cucurbits, inedible peel <sup>(c)</sup>	0.02*		

(a): According to Annex I of Regulation (EC) No 396/2005.

(b): Except commodities classified in code numbers from 130010 to 130050 (apples, pears, quinces, medlar and loquat).

(c): Except commodities classified in code numbers from 233010 to 233030 (melons, pumpkins and watermelons).

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

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## APPENDICES

### Appendix A. Good Agricultural Practice (GAPs)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d - f)	conc. of a.s. (i)	method kind (f - h)	growth stage & season (j)	number min max (k)	interval min max	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
Quinces, medlar, loquat	FR	F	Powdery mildew	EW	50 g/L	Foliar spray	BBCH 19-87	1-2	7 days	0.003-0.005	500-1000	0.025	14	Application on March-October
Pumpkins, watermelons	FR	F	Powdery mildew	SC	100 g/L	Foliar spray	BBCH 20-89	1-2	7 days	0.002-0.005	300-1000	0.015	1	Application on May-September
Gherkins	FR	F	Powdery mildew	SC	100 g/L	Foliar spray	BBCH 21-89	1-2	7 days	0.002-0.005	300-1000	0.015	1	Application on May-September

- Remarks:
- (a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
  - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
  - (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
  - (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
  - (e) GCPF Technical Monograph No 2, 4<sup>th</sup> Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used
  - (f) All abbreviations used must be explained
  - (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
  - (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
  - (i) g/kg or g/l
  - (j) Growth stage at last treatment (Growth stages of mono- and dicotyledonous plants. BBCH Monograph, 2<sup>nd</sup> Ed., 2001), including where relevant, information on season at time of application
  - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
  - (l) PHI - minimum pre-harvest interval
  - (m) Remarks may include: Extent of use/economic importance/restrictions (i.e. feeding, grazing)

## Appendix B. Pesticide Residue Intake Model (PRIMO)

<b>Cyflufenamid</b>									
Status of the active substance:		approved		Code no.					
LOQ (mg/kg bw):		0.02		proposed LOQ:					
<b>Toxicological end points</b>									
ADI (mg/kg bw/day):		0.04		ARfD (mg/kg bw):		0.05			
Source of ADI:		EC		Source of ARfD:		EC			
Year of evaluation:		2009		Year of evaluation:		2009			
<b>Chronic risk assessment - refined calculations</b>									
				TMDI (range) in % of ADI minimum - maximum					
				1                      5					
				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)	
4.6	FR toddler	3.0	Milk and cream,	0.3	Wheat	0.3	Potatoes	1.0	
4.6	UK infant	2.9	Milk and cream,	0.5	Sugar beet (root)	0.3	Wheat	1.2	
4.5	NL child	2.2	Milk and cream,	0.6	Wheat	0.3	Potatoes	1.3	
4.0	UK Toddler	1.5	Milk and cream,	1.1	Sugar beet (root)	0.5	Wheat	1.8	
3.3	DE child	1.1	Milk and cream,	0.5	Wheat	0.5	Apples	1.3	
3.2	WHO Cluster diet B	1.1	Wheat	0.2	Milk and cream,	0.2	Tomatoes	1.3	
3.1	DK child	0.9	Milk and cream,	0.7	Wheat	0.6	Rye	0.6	
2.9	FR infant	1.9	Milk and cream,	0.2	Potatoes	0.1	Carrots	0.8	
2.6	ES child	0.9	Milk and cream,	0.6	Wheat	0.1	Bovine	0.6	
2.5	IE adult	0.3	Barley	0.3	Wheat	0.2	Milk and cream,	1.3	
2.2	SE general population 90th percentile	0.9	Milk and cream,	0.4	Wheat	0.2	Potatoes	0.8	
2.1	WHO cluster diet E	0.5	Wheat	0.2	Milk and cream,	0.2	Barley	0.7	
2.1	WHO cluster diet D	0.8	Wheat	0.4	Milk and cream,	0.2	Potatoes	0.6	
1.9	WHO Cluster diet F	0.5	Wheat	0.3	Milk and cream,	0.2	Potatoes	0.6	
1.9	WHO regional European diet	0.4	Wheat	0.4	Milk and cream,	0.2	Potatoes	0.7	
1.6	NL general	0.5	Milk and cream,	0.3	Wheat	0.1	Potatoes	0.5	
1.5	ES adult	0.4	Milk and cream,	0.3	Wheat	0.1	Barley	0.4	
1.4	PT General population	0.5	Wheat	0.3	Potatoes	0.2	Wine grapes	0.7	
1.3	FR all population	0.4	Wheat	0.3	Wine grapes	0.2	Milk and cream,	0.3	
1.3	IT kids/toddler	0.8	Wheat	0.1	Other cereal	0.1	Tomatoes	0.5	
1.3	DK adult	0.4	Milk and cream,	0.3	Wheat	0.1	Wine grapes	0.3	
1.1	UK vegetarian	0.3	Wheat	0.2	Milk and cream,	0.2	Sugar beet (root)	0.5	
1.1	LT adult	0.3	Milk and cream,	0.2	Potatoes	0.1	Rye	0.4	
1.0	UK Adult	0.2	Milk and cream,	0.2	Wheat	0.2	Sugar beet (root)	0.5	
1.0	FI adult	0.4	Milk and cream,	0.1	Wheat	0.1	Rye	0.2	
0.9	IT adult	0.5	Wheat	0.1	Tomatoes	0.04	Other cereal	0.4	
0.5	PL general population	0.2	Potatoes	0.1	Apples	0.04	Tomatoes	0.4	
<b>Conclusion:</b>									
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI. A long-term intake of residues of Cyflufenamid is unlikely to present a public health concern.									

Acute risk assessment /children - refined calculations						Acute risk assessment / adults / general population - refined calculations						
The acute risk assessment is based on the ARfD.												
For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.												
In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.												
In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a 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)
	6.6	Watermelons	0.027 / -	6.6	Watermelons	0.027 / -	2.9	Pumpkins	0.027 / -	2.9	Pumpkins	0.027 / -
	1.8	Pumpkins	0.027 / -	1.8	Pumpkins	0.027 / -	2.2	Watermelons	0.027 / -	2.2	Watermelons	0.027 / -
	1.3	Gherkins	0.04 / -	0.9	Gherkins	0.04 / -	0.6	Quinces	0.035 / -	0.4	Quinces	0.035 / -
	1.0	Quinces	0.035 / -	0.8	Quinces	0.035 / -	0.4	Medlar	0.035 / -	0.3	Medlar	0.035 / -
	0.8	Medlar	0.035 / -	0.6	Medlar	0.035 / -	0.4	Gherkins	0.04 / -	0.3	Gherkins	0.04 / -
	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:			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)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.												
**) pTMRL: provisional temporary MRL												
***) pTMRL: provisional temporary MRL for unprocessed commodity												
<b>Conclusion:</b>												
For Cyflufenamid 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 C. Existing EU maximum residue levels (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 19/06/2013 14:15))

Code number	Groups and examples of individual products to which the MRLs apply	Cyflufenamid: sum of cyflufenamid ( <i>Z</i> -isomer) and its <i>E</i> -isomer
100000	1. FRUIT FRESH OR FROZEN NUTS	
110000	(i) Citrus fruit	0,02*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), uglı and other hybrids)	0,02*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,02*
110030	Lemons (Citron, lemon, Buddha's hand (Citrus medica var. sarcodactylis))	0,02*
110040	Limes	0,02*
110050	Mandarins (Clementine, tangerine, mineola and other hybrids tangor (Citrus reticulata x sinensis))	0,02*
110990	Others	0,02*
120000	(ii) Tree nuts	0,02*
120010	Almonds	0,02*
120020	Brazil nuts	0,02*
120030	Cashew nuts	0,02*
120040	Chestnuts	0,02*
120050	Coconuts	0,02*
120060	Hazelnuts (Filbert)	0,02*
120070	Macadamia	0,02*
120080	Pecans	0,02*
120090	Pine nuts	0,02*
120100	Pistachios	0,02*
120110	Walnuts	0,02*
120990	Others	0,02*
130000	(iii) Pome fruit	
130010	Apples (Crab apple)	0,05
130020	Pears (Oriental pear)	0,05
130030	Quinces	0,02*
130040	Medlar	0,02*
130050	Loquat	0,02*
130990	Others	0,02*
140000	(iv) Stone fruit	0,02*
140010	Apricots	0,02*
140020	Cherries (Sweet cherries, sour cherries)	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Cyflufenamid: sum of cyflufenamid ( <i>Z</i> -isomer) and its <i>E</i> -isomer
140030	Peaches (Nectarines and similar hybrids)	0,02*
140040	Plums (Damson, greengage, mirabelle, sloe, red date/Chinese date/Chinese jujube (Ziziphus zizyphus))	0,02*
140990	Others	0,02*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	0,15
151010	Table grapes	0,15
151020	Wine grapes	0,15
152000	(b) Strawberries	0,02*
153000	(c) Cane fruit	0,02*
153010	Blackberries	0,02*
153020	Dewberries (Loganberries, tayberries, boysenberries, cloudberry and other Rubus hybrids)	0,02*
153030	Raspberries (Wineberries, arctic bramble/raspberry, (Rubus arcticus), nectar raspberries (Rubus arcticus x Rubus idaeus))	0,02*
153990	Others	0,02*
154000	(d) Other small fruit & berries	0,02*
154010	Blueberries (Bilberries)	0,02*
154020	Cranberries (Cowberries/red bilberries (V. vitis-idaea))	0,02*
154030	Currants (red, black and white)	0,02*
154040	Gooseberries (Including hybrids with other Ribes species)	0,02*
154050	Rose hips	0,02*
154060	Mulberries (Arbutus berry)	0,02*
154070	Azarole (Mediterranean medlar) (Kiwiberry (Actinidia arguta))	0,02*
154080	Elderberries (Black chokeberry/appleberry, mountain ash, buckthorn/sea sallowthorn, hawthorn, serviceberries, and other	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Cyflufenamid: sum of cyflufenamid ( <i>Z</i> -isomer) and its <i>E</i> -isomer
	treeberries)	
154990	Others	0,02*
160000	(vi) Miscellaneous fruit	0,02*
161000	(a) Edible peel	0,02*
161010	Dates	0,02*
161020	Figs	0,02*
161030	Table olives	0,02*
161040	Kumquats (Marumi kumquats, nagami kumquats, limequats (Citrus aurantiifolia x Fortunella spp.))	0,02*
161050	Caranbola (Bilimbi)	0,02*
161060	Persimmon	0,02*
161070	Jambolan (Java plum) (Java apple/water apple, pomegranate, rose apple, Brazilian cherry, Surinam cherry/grumichama (Eugenia uniflora))	0,02*
161990	Others	0,02*
162000	(b) Inedible peel, small	0,02*
162010	Kiwi	0,02*
162020	Lychee (Litchi) (Pulasan, rambutau/hairy litchi, longan, mangosteen, langsat, salak)	0,02*
162030	Passion fruit	0,02*
162040	Prickly pear (cactus fruit)	0,02*
162050	Star apple	0,02*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel/yellow sapote, mammey sapote)	0,02*
162990	Others	0,02*
163000	(c) Inedible peel, large	0,02*
163010	Avocados	0,02*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,02*
163030	Mangoes	0,02*
163040	Papaya	0,02*
163050	Pomegranate	0,02*
163060	Cherimoya (Custard apple, sugar apple/sweetsop, ilama (Annona diversifolia) and	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Cyflufenamid: sum of cyflufenamid ( <i>Z</i> -isomer) and its <i>E</i> -isomer
	other medium sized Annonaceae fruits)	
163070	Guava (Red pitaya/dragon fruit (Hylocereus undatus))	0,02*
163080	Pineapples	0,02*
163090	Bread fruit (Jackfruit)	0,02*
163100	Durian	0,02*
163110	Soursop (guanabana)	0,02*
163990	Others	0,02*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	0,02*
211000	(a) Potatoes	0,02*
212000	(b) Tropical root and tuber vegetables	0,02*
212010	Cassava (Dasheen, eddoe/Japanese taro, tannia)	0,02*
212020	Sweet potatoes	0,02*
212030	Yams (Potato bean/yam bean, Mexican yam bean)	0,02*
212040	Arrowroot	0,02*
212990	Others	0,02*
213000	(c) Other root and tuber vegetables except sugar beet	0,02*
213010	Beetroot	0,02*
213020	Carrots	0,02*
213030	Celeriac	0,02*
213040	Horseradish (Angelica roots, lovage roots, gentiana roots)	0,02*
213050	Jerusalem artichokes (Crosne)	0,02*
213060	Parsnips	0,02*
213070	Parsley root	0,02*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties, tiger nut (Cyperus esculentus))	0,02*
213090	Salsify (Scorzoneria, Spanish salsify/Spanish oysterplant, edible burdock)	0,02*
213100	Swedes	0,02*
213110	Tumips	0,02*
213990	Others	0,02*
220000	(ii) Bulb vegetables	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Cyflufenamid: sum of cyflufenamid (Z-isomer) and its E-isomer
220010	Garlic	0,02*
220020	Onions (Other bulb onions, silverskin onions)	0,02*
220030	Shallots	0,02*
220040	Spring onions and welsh onions (Other green onions and similar varieties)	0,02*
220990	Others	0,02*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	0,02*
231010	Tomatoes (Cherry tomatoes, Physalis spp., gojiberry, wolfberry (Lycium barbarum and L. chinense), tree tomato)	0,02*
231020	Peppers (Chilli peppers)	0,02*
231030	Aubergines (egg plants) (Pepino, antroewa/white eggplant (S. macrocarpon))	0,02*
231040	Okra (lady's fingers)	0,02*
231990	Others	0,02*
232000	(b) Cucurbits — edible peel	
232010	Cucumbers	0,04
232020	Cherkins	0,02*
232030	Courgettes (Summer squash, marrow (patisson), lauki (Lagenaria siceraria), chayote, sopropo/bitter melon, snake gourd, angled luffa/teroi)	0,05
232990	Others	0,02*
233000	(c) Cucurbits-inedible peel	
233010	Melons (Kiwano)	0,04
233020	Pumpkins (Winter squash, marrow (late variety))	0,02*
233030	Watermelons	0,02*
233990	Others	0,02*
234000	(d) Sweet corn (Baby corn)	0,02*
239000	(e) Other fruiting vegetables	0,02*
240000	(iv) Brassica vegetables	0,02*
241000	(a) Flowering brassica	0,02*
241010	Broccoli (Calabrese, Broccoli raab, Chinese broccoli)	0,02*
241020	Cauliflower	0,02*
241990	Others	0,02*
242000	(b) Head brassica	0,02*
242010	Brussels sprouts	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Cyflufenamid: sum of cyflufenamid (Z-isomer) and its E-isomer
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,02*
242990	Others	0,02*
243000	(c) Leafy brassica	0,02*
243010	Chinese cabbage (Indian or Chinese) mustard, pak choi, Chinese flat cabbage/ai goo choi, choi sum, Peking cabbage/pe-tsa)	0,02*
243020	Kale (Borecole/curly kale, collards, Portuguese Kale, Portuguese cabbage, cow cabbage)	0,02*
243990	Others	0,02*
244000	(d) Kohlrabi	0,02*
250000	(v) Leaf vegetables & fresh herbs	0,02*
251000	(a) Lettuce and other salad plants including Brassicaceae	0,02*
251010	Lamb's lettuce (Italian corn salad)	0,02*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,02*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curly leaf endive, sugar loaf (C. endivia var. crispum/C. intybus var. foliosum), dandelion greens)	0,02*
251040	Cress (Mung bean sprouts, alfalfa sprouts)	0,02*
251050	Land cress	0,02*
251060	Rocket, Rucola (Wild rocket (Diplotaxis spp.))	0,02*
251070	Red mustard	0,02*
251080	Leaves and sprouts of Brassica spp. including tumip greens (Mizuna, leaves of peas and radish and other babyleaf crops, including brassica crops (crops harvested up to 8 true leaf stage), kohlrabi leaves)	0,02*
251990	Others	0,02*
252000	(b) Spinach & similar (leaves)	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Cyflufenamid: sum of cyflufenamid (Z-isomer) and its E-isomer
252010	Spinach (New Zealand spinach, amaranthus spinach (pak-khom, tampara), tajar leaves, bitterblad/bitawiri)	0,02*
252020	Purslane (Winter purslane/miner's lettuce, garden purslane, common purslane, sorrel, glasswort, agretti (Salsola soda))	0,02*
252030	Beet leaves (chard) (Leaves of beetroot)	0,02*
252990	Others	0,02*
253000	(c) Vine leaves (grape leaves) (Malabar nightshade, banana leaves, climbing wattle (Acacia pennata))	0,02*
254000	(d) Water cress (Morning glory/Chinese convolvulus/water convolvulus/water spinach/kangkung (Ipomea aquatica), water clover, water mimosa)	0,02*
255000	(e) Witloof	0,02*
256000	(f) Herbs	0,02*
256010	Chervil	0,02*
256020	Chives	0,02*
256030	Celery leaves (Fennel leaves, coriander leaves, dill leaves, caraway leaves, lovage, angelica, sweet cicely and other Apiacea leaves, culantro/stinking/long coriander/stink weed (Eryngium foetidum))	0,02*
256040	Parsley (leaves of root parsley)	0,02*
256050	Sage (Winter savory, summer savory, Borago officinalis leaves)	0,02*
256060	Rosemary	0,02*
256070	Thyme (Marjoram, oregano)	0,02*
256080	Basil (Balm leaves, mint, peppermint, holy basil, sweet basil, hairy basil, edible flowers (marigold flower and others), pennywort, wild betel leaf, curry leaves)	0,02*
256090	Bay leaves (laurel) (Lemon)	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Cyflufenamid: sum of cyflufenamid (Z-isomer) and its E-isomer
	grass)	
256100	Taragon (Hyssop)	0,02*
256990	Others	0,02*
260000	(vi) Legume vegetables (fresh)	0,02*
260010	Beans (with pods) (Green bean/French beans/snap beans, scarlet runner bean, slicing bean, yard long beans, guar beans, soya beans)	0,02*
260020	Beans (without pods) (Broad beans, flageolets, jack bean, lima bean, cowpea)	0,02*
260030	Peas (with pods) (Mangout/sugar peas/snow peas)	0,02*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,02*
260050	Lentils	0,02*
260990	Others	0,02*
270000	(vii) Stem vegetables (fresh)	0,02*
270010	Asparagus	0,02*
270020	Cardoons (Borago officinalis stems)	0,02*
270030	Celery	0,02*
270040	Fennel	0,02*
270050	Globe artichokes (Banana flower)	0,02*
270060	Leek	0,02*
270070	Rhubarb	0,02*
270080	Bamboo shoots	0,02*
270090	Palm hearts	0,02*
270990	Others	0,02*
280000	(viii) Fungi	0,02*
280010	Cultivated fungi (Common mushroom, oyster mushroom, shiitake, fungus mycelium (vegetative parts))	0,02*
280020	Wild fungi (Chanterelle, truffle, morel, cep)	0,02*
280990	Others	0,02*
290000	(ix) Sea weeds	0,02*
300000	3. PULSES, DRY	0,02*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,02*
300020	Lentils	0,02*



Code number	Groups and examples of individual products to which the MRLs apply	Cyflufenamid: sum of cyflufenamid (Z-isomer) and its E-isomer
300030	Peas (Chickpeas, field peas, chickling vetch)	0,02*
300040	Lupins	0,02*
300990	Others	0,02*
400000	4. OILSEEDS AND OILFRUITS	0,02*
401000	(i) Oilseeds	0,02*
401010	Linseed	0,02*
401020	Peanuts	0,02*
401030	Poppy seed	0,02*
401040	Sesame seed	0,02*
401050	Sunflower seed	0,02*
401060	Rape seed (Bird rapeseed, turnip rape)	0,02*
401070	Soya bean	0,02*
401080	Mustard seed	0,02*
401090	Cotton seed	0,02*
401100	Pumpkin seeds (Other seeds of Cucurbitaceae)	0,02*
401110	Safflower	0,02*
401120	Borage (Purple viper's bugloss/Canary flower (Echium plantagineum), Corn Gromwell (Buglossoides arvensis))	0,02*
401130	Gold of pleasure	0,02*
401140	Hempseed	0,02*
401150	Castor bean	0,02*
401990	Others	0,02*
402000	(ii) Oilfruits	0,02*
402010	Olives for oil production	0,02*
402020	Palm nuts (palmoil kernels)	0,02*
402030	Palmfruit	0,02*
402040	Kapok	0,02*
402990	Others	0,02*
500000	5. CEREALS	
500010	Barley	0,1
500020	Buckwheat (Amaranthus, quinoa)	0,02*
500030	Maize	0,02*
500040	Millet (Foxtail millet, teff, finger millet, pearl millet)	0,02*
500050	Oats	0,1
500060	Rice (Indian/wild rice (Zizania aquatica))	0,02*
500070	Rye	0,05
500080	Sorghum	0,02*
500090	Wheat (Spelt, triticale)	0,05

Code number	Groups and examples of individual products to which the MRLs apply	Cyflufenamid: sum of cyflufenamid (Z-isomer) and its E-isomer
500990	Others (Canary grass seeds (Phalaris canariensis))	0,02*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,05*
610000	(i) Tea	0,05*
620000	(ii) Coffee beans	0,05*
630000	(iii) Herbal infusions (dried)	0,05*
631000	(a) Flowers	0,05*
631010	Camomille flowers	0,05*
631020	Hybiscus flowers	0,05*
631030	Rose petals	0,05*
631040	Jasmine flowers (Elderflowers (Sambucus nigra))	0,05*
631050	Lime (linden)	0,05*
631990	Others	0,05*
632000	b) Leaves	0,05*
632010	Strawberry leaves	0,05*
632020	Rooibos leaves (Ginkgo leaves)	0,05*
632030	Maté	0,05*
632990	Others	0,05*
633000	(c) Roots	0,05*
633010	Valerian root	0,05*
633020	Ginseng root	0,05*
633990	Others	0,05*
639000	(d) Other herbal infusions	0,05*
640000	(iv) Cocoa beans (fermented or dried)	0,05*
650000	(v) Carob (st.johns bread)	0,05*
700000	7. HOPS (dried)	0,05*
800000	8. SPICES	0,05*
810000	(i) Seeds	0,05*
810010	Anise	0,05*
810020	Black caraway	0,05*
810030	Celery seed (Lovage seed)	0,05*
810040	Coriander seed	0,05*
810050	Cumin seed	0,05*
810060	Dill seed	0,05*
810070	Fennel seed	0,05*
810080	Fenugreek	0,05*
810090	Nutmeg	0,05*
810990	Others	0,05*
820000	(ii) Fruits and berries	0,05*
820010	Allspice	0,05*
820020	Sichuan pepper (Anise pepper, Japan pepper)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Cyflufenamid: sum of cyflufenamid (Z-isomer) and its E-isomer
820030	Caraway	0,05*
820040	Cardamom	0,05*
820050	Juniper berries	0,05*
820060	Pepper, black, green and white (Long pepper, pink pepper)	0,05*
820070	Vanilla pods	0,05*
820080	Tamarind	0,05*
820990	Others	0,05*
830000	(iii) Bark	0,05*
830010	Cinnamon (Cassia)	0,05*
830990	Others	0,05*
840000	(iv) Roots or rhizome	0,05*
840010	Liquorice	0,05*
840020	Ginger	0,05*
840030	Turmeric (Curcuma)	0,05*
840040	Horseradish	0,05*
840990	Others	0,05*
850000	(v) Buds	0,05*
850010	Cloves	0,05*
850020	Capers	0,05*
850990	Others	0,05*
860000	(vi) Flower stigma	0,05*
860010	Saffron	0,05*
860990	Others	0,05*
870000	(vii) Aril	0,05*
870010	Mace	0,05*
870990	Others	0,05*
900000	9. SUGAR PLANTS	0,02*
900010	Sugar beet (root)	0,02*
900020	Sugar cane	0,02*
900030	Chicory roots	0,02*
900990	Others	0,02*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	0,03*
1010000	(i) Tissue	0,03*
1011000	(a) Swine	0,03*
1011010	Muscle	0,03*
1011020	Fat	0,03*
1011030	Liver	0,03*
1011040	Kidney	0,03*
1011050	Edible offal	0,03*
1011990	Others	0,03*
1012000	(b) Bovine	0,03*
1012010	Muscle	0,03*
1012020	Fat	0,03*

Code number	Groups and examples of individual products to which the MRLs apply	Cyflufenamid: sum of cyflufenamid (Z-isomer) and its E-isomer
1012030	Liver	0,03*
1012040	Kidney	0,03*
1012050	Edible offal	0,03*
1012990	Others	0,03*
1013000	(c) Sheep	0,03*
1013010	Muscle	0,03*
1013020	Fat	0,03*
1013030	Liver	0,03*
1013040	Kidney	0,03*
1013050	Edible offal	0,03*
1013990	Others	0,03*
1014000	(d) Goat	0,03*
1014010	Muscle	0,03*
1014020	Fat	0,03*
1014030	Liver	0,03*
1014040	Kidney	0,03*
1014050	Edible offal	0,03*
1014990	Others	0,03*
1015000	(e) Horses, asses, mules or hinnies	0,03*
1015010	Muscle	0,03*
1015020	Fat	0,03*
1015030	Liver	0,03*
1015040	Kidney	0,03*
1015050	Edible offal	0,03*
1015990	Others	0,03*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,03*
1016010	Muscle	0,03*
1016020	Fat	0,03*
1016030	Liver	0,03*
1016040	Kidney	0,03*
1016050	Edible offal	0,03*
1016990	Others	0,03*
1017000	(g) Other farm animals (Rabbit, kangaroo, deer)	0,03*
1017010	Muscle	0,03*
1017020	Fat	0,03*
1017030	Liver	0,03*
1017040	Kidney	0,03*
1017050	Edible offal	0,03*
1017990	Others	0,03*
1020000	(ii) Milk	0,03*
1020010	Cattle	0,03*
1020020	Sheep	0,03*
1020030	Goat	0,03*
1020040	Horse	0,03*

1020990	Others	0,03*
1030000	(iii) Bird eggs	0,03*
1030010	Chicken	0,03*
1030020	Duck	0,03*
1030030	Goose	0,03*

1030040	Quail	0,03*
1030990	Others	0,03*
1040000	(iv) Honey (Royal jelly, pollen, honey comb with honey (comb honey))	0,03*

1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,03*
1060000	(vi) Snails	0,03*
1070000	(vii) Other terrestrial animal products (Wild game)	0,03*

(\*) Indicates lower limit of analytical determination

## ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CEN	European Committee for Standardisation (Comité Européen de Normalisation, <i>French</i> )
CIPAC	Collaborative International Pesticide Analytical Council
CXL	Codex maximum Residue Limit (Codex MRL)
d	day
DAR	Draft Assessment Report
DM	dry matter
DT <sub>90</sub>	period required for 90 % dissipation (define method of estimation)
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
EW	emulsion, oil in water
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (former GIFAP)
ha	hectare
hL	hectolitre
i.e.	that is (id est, <i>Latin</i> )
IPCS	International Programme of Chemical Safety
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
L	litre
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MSD	mass spectrometry detector
MS/MS	tandem mass spectrometry
NEU	northern European Union

OECD	Organisation for Economic Co-operation and Development
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (method)
$R_{ber}$	statistical calculation of the MRL by using a non-parametric method
$R_{max}$	statistical calculation of the MRL by using a parametric method
RAC	raw agricultural commodity
RMS	rappporteur Member State
SC	suspension concentrate
SCFCAH	Standing Committee on the Food Chain and Animal Health
SEU	Southern European Union
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WHO	World Health Organisation
yr	year