Review of the existing maximum residue levels for cyflufenamid according to Article 12 of Regulation (EC) No 396/2005

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Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance cyflufenamid. To assess the occurrence of cyflufenamid residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC as well as the European authorisations reported by Member States (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was missing. Hence, the consumer risk assessment is considered indicative only and some MRL proposals derived by EFSA still requires further consideration by risk managers.

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Keywords: cyflufenamid, MRL review, regulation (EC) No 396/2005, consumer risk assessment, amide, fungicide

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Summary

Cyflufenamid was included in Annex I to Directive 91/414/EEC on 1 April 2010 by Commission Directive 2009/154/EC, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011.

As the active substance was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation.

As the basis for the MRL review, on 16 June 2017 EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 16 July 2017 their national Good Agricultural Practices (GAPs) in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State, the United Kingdom, to identify the critical GAPs in the format of a specific GAP overview file. Subsequently, Member States were requested to provide residue data supporting the critical GAPs, within a period of 1 month, by 12 November 2017. On the basis of all the data submitted by Member States and by the European Union Reference Laboratories for Pesticide Residues (EURL), EFSA asked the RMS to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report, together with Pesticide Residues Intake Model (PRIMo) calculations and updated GAP overview file were provided by the RMS to EFSA on 14 March 2018. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Based on the information provided by the RMS, Member States and the EURL, and taking into account the conclusions derived by EFSA in the framework of Directive 91/414/EEC, EFSA prepared in July 2018 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 2 August 2018 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of cyflufenamid in plant was investigated in representatives of three primary crops categories, i.e. fruit and fruiting vegetables, pulses and oilseeds, and cereals, as well as in rotational crops (root and tuber vegetables, leafy vegetables and cereals). According to the results of the metabolism studies and considering the results of the trials, where the levels of the E-isomer never exceeded the limit of quantification (LOQ), the residue definition could be, in principle, simplified to cyflufenamid (Z-isomer) only. However, taking into account the available analytical methods, which cannot specifically discriminate between both isomers, and the storage stability studies, where potential isomerisation might occur, the residue definition for enforcement and risk assessment proposed in the peer-review as sum of cyflufenamid (Z-isomer) and its E-isomer, is still considered valid in this review. This residue definition is applicable to all primary and rotational crops and to processed commodities.

Validated analytical methods are available for the enforcement of the proposed residue definition in high water and high acid content commodities, as well as dry commodities at the LOQ of 0.01 mg/kg. According to the EURL, the same LOQ of 0.01 mg/kg is achievable in all the main four matrix groups in routine analyses by the use of different QuEChERS methods. According to the EURL, an analytical standard of 149-(E)-FB (E-isomer) is not commercially available.

Available residue trials data were considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for maize, millet, rice and sorghum for which no data are available to derive MRLs and risk assessment values.

Cyflufenamid is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were thus performed for different groups of livestock according to OECD guidance. The dietary burdens calculated for all groups of livestock, except for swine, were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). However, the behaviour of residues was only assessed in ruminants since a metabolism study on poultry was not available.

The metabolism of cyflufenamid residues in ruminants was investigated in lactating goats at a dose rate covering the maximum dietary burdens calculated in this review. According to the results of these studies, the residue definition for enforcement and risk assessment in milk and ruminants tissues was proposed as sum of cyflufenamid (Z-isomer), its E-isomer and metabolite 149-F1, expressed as cyflufenamid. An analytical method for the enforcement of the proposed residue definition at the combined LOQ of 0.03 mg/kg in all matrices is available. According to the EURL, analytical standards of 149-(E)-FB (E-isomer) and metabolite 149-F1 are not commercially available.
For ruminants, the metabolism study is sufficient to conclude that, at the calculated dietary burden, residue levels would remain below the enforcement LOQ of 0.03 mg/kg in milk and tissues. Hence, MRLs and risk assessment values for the relevant commodities can be established at the LOQ level.

For poultry, no metabolism study is available on laying hens, and thus, it is not possible to derive a residue definition, nor MRLs.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to derive a MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure represented 3.6% of the acceptable daily intake (ADI) (FR toddler) and the highest acute exposure amounted to 15.7% of the acute reference dose (ARfD) (table grapes). Although uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumer’s health.
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Background

Regulation (EC) No 396/2005 (hereinafter referred to as ‘the Regulation’) establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC a reasoned opinion on the review of the existing MRLs for that active substance.

Cyufenamid was included in Annex I to Council Directive 91/414/EEC on 1 April 2010 by means of Commission Directive 2009/154/EC which has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. Therefore, EFSA initiated the review of all existing MRLs for that active substance.

By way of background information, in the framework of Directive 91/414/EEC cyufenamid was evaluated by the United Kingdom, designated as rapporteur Member State (RMS). Subsequently, a peer review on the initial evaluation of the RMS was conducted by EFSA, leading to the conclusions as set out in the EFSA scientific report (EFSA, 2009a). The approval of Cyufenamid is restricted to uses as fungicide only.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC repealed by Regulation (EC) No 1107/2009. It should be noted, however, that, in the framework of Regulation (EC) No 1107/2009, only a few representative uses are evaluated, whereas MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the European Union (EU), and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Regulation (EC) No 1107/2009 is therefore insufficient for the assessment of all existing MRLs for a given active substance.

To gain an overview of the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residues Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities;
- the analytical methods for enforcement of the proposed MRLs.

As the basis for the MRL review, on 16 June 2017 EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 16 July 2017 their Good Agricultural Practices (GAPs) that are authorised nationally, in a standardised way, in the format of specific GAP forms. In the framework of this consultation 17 Member States provided feedback on their national authorisations of cyufenamid. Based on the GAP data submitted, the designated RMS the United Kingdom was asked to identify the critical GAPs (cGAPs) to be further considered in the assessment, in the format of a specific GAP overview file. Subsequently, in a second step, Member States were requested to provide residue data supporting the cGAPs by 12 November 2017.

On the basis of all the data submitted by Member States and the EU Reference Laboratories for Pesticides Residues (EURL), EFSA asked the United Kingdom to complete the PROFile and to prepare a...
supporting evaluation report. The PROFile and the supporting evaluation report, together with the Pesticide Residues Intake Model (PRIMo) calculations and updated GAP overview file, were submitted to EFSA on 14 March 2018. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Considering all the available information, EFSA prepared in July 2018 a draft reasoned opinion, which was circulated to Member States for commenting via a written procedure. All comments received by 2 August 2018 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (United Kingdom, 2018), taking into account also the information provided by Member States during the collection of data, and the EURL report on analytical methods (EURL, 2018) are considered as main supporting documents to this reasoned opinion and, thus, made publicly available. The evaluation reports on the additional data provided by France and Spain (France 2017, Spain 2017) and the evaluation report submitted by the United Kingdom in the frame of the MRL application on various crops (United Kingdom, 2011) were also consulted in the course of this evaluation and thus are considered as supporting documents to this reasoned opinion.

In addition, further supporting documents to this reasoned opinion are the completeness check report (EFSA, 2018a) and the Member States consultation report (EFSA, 2018b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Furthermore, the exposure calculations for all crops reported in the framework of this review performed using the PRIMo and the PROFile as well as the GAP overview file listing all authorised uses are key supporting documents and made publicly available as background documents to this reasoned opinion. A screenshot of the report sheet of the PRIMo is presented in Appendix C.

Terms of Reference

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

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 chemical structure of the active substance and its main metabolites are reported in Appendix F. The EU MRLs for cyflufenamid are established in Annexes IIIA of Regulation (EC) No 396/2005. Codex maximum residue limits (CXLs) for cyflufenamid are not available. An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below (Table 1).

Table 1: Overview of the MRL changes since the entry into force of Regulation (EC) No 396/2005

| Procedure        | Legal implementation | Remarks                                      |
|------------------|----------------------|----------------------------------------------|
| MRL application  | Commission Regulation (EC) No 1050/2009(a) | Oats (EFSA, 2009a)                           |
| MRL application  | Commission Regulation (EU) No 978/2011(a)  | Various crops (EFSA, 2011)                   |
| MRL application  | Commission Regulation (EU) No 36/2014(b)   | Pome fruits, cucurbits (inedible peel) and gherkins (EFSA, 2013) |
| MRL application  | Commission Regulation (EU) No 737/2014(c)  | Strawberries and peppers (EFSA, 2014)       |
| MRL application  | Commission Regulation (EU) No 2017/171(d)  | Stone fruits and globe artichokes (EFSA, 2016) |

(a): Commission Regulation (EU) No 978/2011 of 3 October 2011 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 acetamiprid, biphenyl, captan, chlorantraniliprole, cyflufenamid, cymoxanil, dichlorprop-P, dienoconazole, dimethomorph, dithiocarbamates, epoxiconazole, etephon, fluatriafol, fluxapyroxad, isopyrazam, propamocarb, pyraclostrobin, pyrimethanil and spirotetramat in or on certain products. OJ L 258, 4.10.2011, 12-69.
For the purpose of this MRL review, all the uses of cyflufenamid currently authorised within the EU as submitted by the Member States during the GAP collection, have been reported by the RMS in the GAP overview file. The cGAPs identified in the GAP overview file were then summarised in the PROFile and considered in the assessment. The details of the authorised cGAPs for cyflufenamid are given in Appendix A. No import tolerances were reported by the RMS.

Assessment

EFSA has based its assessment on the following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (United Kingdom, 2018);
- the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (United Kingdom, 2006, 2008);
- the conclusion on the peer review of the pesticide risk assessment of the active substance cyflufenamid (EFSA, 2009a);
- the previous reasoned opinions on cyflufenamid (EFSA, 2009b, 2011, 2013, 2014, 2016);
- the evaluation reports on the additional data (France, 2017; Spain, 2017);
- the evaluation report submitted in the frame of the MRL application on various crops (United Kingdom, 2011).

The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011 and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013).

More detailed information on the available data and on the conclusions derived by EFSA can be retrieved from the list of end points reported in Appendix B.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of cyflufenamid was investigated after foliar treatment in cereals (wheat) (United Kingdom, 2006) and assessed in the framework of the peer review (EFSA, 2009a). Two studies were conducted with fluorinated phenyl-U-\(^{14}\)C-labelled cyflufenamid, applied at twice the representative dose rate, i.e. 2\(\times\)25 g a.s./ha (2\(\times\)1N) (study A), and 2\(\times\)25 or 100 g a.s./ha (2\(\times\)1N or 4N) (study B). In a third study (study C), cyflufenamid was radiolabelled in the cyclopropyl ring of the molecule and applied at 2\(\times\)25 or 100 g a.s./ha.

The major component of radioactive residues in all samples was cyflufenamid (149-(Z)-FB), accounting for up to 99% of the total radioactive residues (TRR) in forage at 0 days after treatment.

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(b): Commission Regulation (EU) No 36/2014 of 16 January 2014 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 aminopyralid, chlorantraniliprole, cyflufenamid, metipquat, metalaxyl-M, propamocarb, pyriproxyfen and quinoxyfen in or on certain products. OJ L 17, 21.1.2014, p. 1–41.

(c): Commission Regulation (EU) No 737/2014 of 24 June 2014 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 2-phenylphenol, chlormequat, cyflufenamid, cyfluthrin, dicamba, fluopicolide, flutriafol, fosetyl, indoxacarb, isoprothiolane, mandipropamid, metaldehyde, metconazole, phosmet, picloram, propyzamide, pyriproxyfen, saflufenacil, spinosad and trifloxystrobin in or on certain products. OJ L 202, 10.7.2014, p. 1–63.

(d): Commission Regulation (EU) 2017/171 of 30 January 2017 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aminopyralid, azoxystrobin, cyantraniliprole, cyflufenamid, cyproconazole, diethofencarb, dithiocarbamates, fluazifop-P, fluopyram, haloxypol, isofetamid, metalaxyl, prohexadione, propaquizafop, pyrimethanil, Trichoderma atroviride strain SC1 and zoamidic in or on certain products. OJ L 30, 3.2.2017, p. 45–111.
(DAT). At maturity, cyflufenamid represented up to 65% of TRR in straw (1.27 mg eq/kg) and 20% in husk (0.20 mg eq/kg) for the cyclopropyl labelled, and 37% and 17% of TRR in straw (0.86 mg eq/kg) and husk (0.09 mg eq/kg), respectively, for the fluorinated phenyl labelled. The maximum TRR extracted in grain (0.004 mg eq/kg) at maturity was 7%, obtained when applying the high dose rate (2 × 4N). The E-isomer of cyflufenamid (149-(E)-FB) was found in mature straw and husk at levels of up to 4% of TRR in cyclopropyl label. Residue levels of E-isomer were up to 0.08 mg eq/kg and 0.006 mg eq/kg in straw and husk, respectively, representing up to approximately 10% of the residue levels of cyflufenamid.

In addition, the metabolism of cyflufenamid labelled only in the fluorinated phenyl ring was investigated in fruits and fruiting vegetables (apples and cucumbers) and pulses and oilseeds (rapeseeds) in the frame of two previous MRL applications (EFSA, 2011, 2016).

After one foliar application of 270 g a.s./ha on apple, the major component identified at 92 DAT was cyflufenamid, representing 66% and 17% of TRR in fruit and leaves, respectively, while the following minor metabolites were also detected: E-isomer of cyflufenamid (1% and 0.7% TRR, in fruit and leaves), 149-F4B-Glu (< 0.5% and 7% TRR, in fruit and leaves) and 149-F-4-OH-B-Glu (< 0.5% and 8% TRR, in fruit and leaves). Residue levels of cyflufenamid were 0.012 and 0.13 mg eq/kg in fruit and leaves, respectively. Only metabolites 149-F-4-OH-B-Glu and 149-F4B-Glu exhibited residues levels higher than 0.01 mg eq/kg. More specifically, they accounted for 0.062 and 0.051 mg eq/kg, respectively, in leaves (EFSA, 2011).

Cucumbers were treated (application method not specified) with fluorinated phenyl 14C-radiolabelled cyflufenamid at 1 × 50 and 1 × 200 g a.s./ha. In fruit, at 14 DAT, cyflufenamid constituted the major compound of the total residues (55% TRR, 0.019 mg eq/kg), while other minor metabolites were also identified (residue levels < 0.01 mg eq/kg), namely, the E-isomer (1% TRR), 149-F-4-OH-B-Glu (8.5% TRR) and 149-F-4-OH-B (7% TRR). A similar pattern was observed in leaves, with cyflufenamid as the most prominent TRR (42%, 0.54 mg eq/kg) at 31 DAT.

A similar metabolic pathway was observed in rapeseed following 1 × 12.5 and 5 × 12.5 g a.s./ha applications, as the major component identified was cyflufenamid, accounting for 80% of TRR in forage (0.38 mg eq/kg) at 14 DAT, and 7% TRR in seeds (0.006 mg eq/kg), at maturity. The E-isomer was found at low concentrations in forage and seeds, representing a maximum of 2% (0.01 mg eq/kg) and 0.5% TRR (< 0.001 mg eq/kg), respectively (EFSA, 2016).

The metabolic pathway of cyflufenamid was similar in fruits and fruiting vegetables, cereals and oilseeds. Although the fate of cyflufenamid in the plant was investigated with regard to the cyclopropyl ring in only one wheat study, the existence of cleavage products was examined during the peer-review (EFSA, 2009a) and it was concluded that the fate of cyflufenamid in primary crops was sufficiently elucidated (see also Section 1.1.2).

### 1.1.2. Nature of residues in rotational crops

Cyflufenamid is authorised on crops that may be grown in rotation. According to the soil degradation studies performed in the framework of the peer review (EFSA, 2009a), the DT90 values were derived for cyflufenamid and its relevant soil metabolites. Under aerobic soil conditions, cyflufenamid exhibits low to high persistence and forms its relevant soil metabolites: 149-F, 149-F11, 149-F1 and 149-F6 (United Kingdom, 2006). The DT90 values for cyflufenamid and its metabolites 149-F1 and 149-F6 exceed 100 days, and thus, an investigation of residues in rotational crops is required.

One confined rotational crop study with cyflufenamid radiolabelled only on the fluorinated phenyl ring was assessed during the peer-review (United Kingdom, 2006; EFSA, 2009a). Cyflufenamid was applied at a rate of 50 g a.s./ha (1N compared to the most cGAP for rotational crops) onto bare soil. Spring wheat (cereals) was planted at nominal plant-back intervals (PBI) of 30, 120 and 270 DAT, carrots (root and tuber vegetables) at 30 and 120 DAT, and lettuce (leafy vegetables) at 30 DAT.

Translocation of radioactive residues was low. The maximum TRR in crop parts intended for human consumption was found in lettuce sampled 80 days after sowing at 30 PBI, accounting for 0.006 mg eq/kg. The highest levels of TRR were found in wheat straw, with a maximum of 0.09 mg eq/kg at 30 PBI. Parent cyflufenamid was not found in the plants. Due to the low TRR, limited characterisation was performed and only a single compound in carrot foliage was identified as 149-F6 (33% TRR, corresponding to 0.041 mg eq/kg).

Since the metabolism studies on cereals primary crops and soil were conducted with only 14C-fluorinated phenyl label (except the 14C-cyclopropyl single study), the occurrence of cleavage products was investigated in the DAR (United Kingdom, 2006) within the context of the peer review (EFSA, 2009a). Soil metabolism indicated hydrolysis of cyflufenamid to 149-F, potentially via conversion to...
149-F11, which most likely involved oxidation of the non-fluorinated phenyl ring. This would lead to either 149-F-2-OH-B or 149-F-4-OH-B, as seen in plants. Alternative pathways to 149-F11, releasing phenyl acetic acid or phenyl acetamide, were considered highly unlikely. Hence, a further rotational crop metabolism study using an alternative labelling position was deemed unnecessary as the metabolism of primary and rotational crops was similar.

1.1.3. Nature of residues in processed commodities

There were no studies investigating the nature of residues of cyflufenamid in processed commodities available for this review. Residues were below the trigger value of 0.1 mg/kg for all commodities under review, except for table and wine grapes. However, considering the low contribution of table and wine grapes to the acceptable daily intake (ADI) (0.27% ADI), the investigation of the nature of residues in processed commodities is not required (European Commission, 1997d). Nevertheless, EFSA is of the opinion that it would be still desirable to further investigate the effect of processing on the nature and magnitude of residues in grapes and apples (production of juice and wine).

1.1.4. Methods of analysis in plants

The validation of a gas chromatography with mass spectrometry (GC-MS) analytical method, with a limit of quantification (LOQ) of 0.01 mg/kg for the determination of cyflufenamid residues in dry commodities (cereals) was assessed in the DAR (United Kingdom, 2006). In the EFSA conclusion (EFSA, 2009a), a data requirement was set to clarify whether the method was able to distinguish Z- and E-isomers. Within the context of a MRL application (EFSA, 2009b), the evaluating Member State (EMS) confirmed that the aforementioned analytical method covers both isomers, as expressed in the residue definition, and it is, therefore, valid for the enforcement of cyflufenamid residues in dry commodities.

In the framework of a previous MRL application (EFSA, 2011), a hyphenated analytical method based on GC-MS detection was validated in high water and high acid content commodities, with a LOQ of 0.01 mg/kg for cyflufenamid (Z-isomer) and its E-isomer. Two additional fragment ions were monitored for confirmation purposes. This primary method is supported by an independent laboratory validation (ILV) on apples and grapes.

During the completeness check, the EURL provided a QuEChERS multiresidue analytical method using liquid chromatography with tandem mass spectrometry (LC-MS/MS), with a LOQ of 0.01 mg/kg for enforcement of cyflufenamid (Z-isomer) in routine analysis, in high water and high acid commodities, as well as dry commodities (EURL, 2018). A method coupling LC to MS-QToF detection, with a LOQ of 0.01 mg/kg for enforcement of cyflufenamid (Z-isomer) in high oil content commodities, was also provided. The QuEChERS methods were validated only for the Z-isomer; however, in their report, EURL points out that there is a rapid conversion of the E- to the Z-isomer during the analysis, and thus, from the theoretical point of view, the QuEChERS method is not specific to the Z-isomer, but could cover both isomers measured as Z-isomer.

1.1.5. Stability of residues in plants

The storage stability of cyflufenamid (Z-isomer) and its E-isomer was investigated in the framework of the peer review (United Kingdom, 2006, considered in EFSA, 2009a) and in additional studies submitted within the context of a MRL application (EFSA, 2014). The storage stability of the sum of isomers, Z and E, was examined in high water content (immature barley shoots) commodities (EFSA, 2009a), whereas the stability of the two isomers separately was investigated in high oil (oilseed rape), high protein (dry beans), high starch (wheat grain) and high acid (grape) content commodities (EFSA, 2014).

The data showed that residues of cyflufenamid (sum of isomers) are stable at −18°C in high water content commodities for at least 25 months.

In high acid, high starch and high protein content matrices, the available studies demonstrated the storage stability of cyflufenamid (Z-isomer) and its E-isomer, separately, for a period of 24 months when stored at −18°C. Cyflufenamid was stable in high oil content commodities for at least 18 months when frozen at −18°C, while for the E-isomer, recoveries below 70% were observed at the sampling points of 3 (63% recovery) and 18 months (67%). Although it was not clearly elucidated whether these low recoveries were related to isomerisation to the Z-isomer, it is not expected that this has an impact on the assessment, as no degradation was observed for the sum of isomers.
1.1.6. Proposed residue definitions

In the light of the metabolism studies in primary and rotational crops and the results of the trials, where the levels of the E-isomer never exceeded the LOQ, the residue definition could be, in principle, simplified to cyflufenamid (Z-isomer) only. However, taking into account the available analytical methods, which cannot specifically discriminate between both isomers, and the storage stability studies, where potential isomerisation might occur, the residue definition for enforcement and risk assessment proposed in the peer review as sum of cyflufenamid (Z-isomer) and its E-isomer, is still considered valid in this review. This residue definition is applicable to all primary and rotational crops and to processed commodities.

Analytical methods for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in high water and high acid content commodities and dry commodities are available (United Kingdom, 2006; EFSA, 2009b, 2011). Although a validated primary analytical method for enforcement in high oil content commodities is not available, the EURL informed EFSA that an LOQ of 0.01 mg/kg is achievable in routine analyses by using a variation of QuEChERS method for vegetable oil samples (QuOil method) with LC-MS-QToF detection (EURL, 2018). According to the information provided by the EURL during the consultation of Member States, an analytical standard of cyflufenamid (Z-isomer) is commercially available, while for 149-(E)-FB (E-isomer) an analytical standard is not commercially available (EFSA, 2018b).

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of cyflufenamid residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (United Kingdom, 2018), the supporting trials submitted by Member States (France, 2017; Spain, 2017) as well as the residue trials evaluated in the framework of the peer review (EFSA, 2009a) and in the framework of a previous MRL application (EFSA, 2011, 2014, 2016; United Kingdom, 2011). All residue trial samples considered in the framework of this review were stored in compliance with the conditions for which storage stability of residues was demonstrated. Decline of residues during storage of the trial samples is therefore not expected.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2017).

Residue trials are not available to support the authorisations on maize, millet, rice and sorghum grain. Therefore, MRL and risk assessment values could not be derived for these crops and the following data gaps were identified:

- Maize: eight trials on maize compliant with the southern outdoor GAP are required.
- Millet: four trials on millet compliant with the southern outdoor GAP are required.
- Rice: eight trials on rice compliant with the southern outdoor GAP are required.
- Sorghum: eight trials on sorghum compliant with the southern outdoor GAP are required.

For all other crops, available residue trials are sufficient to derive (tentative) MRL and risk assessment values, taking note of the following considerations:

- Tomatoes: although MRL and risk assessment values can be derived from the southern European Union (SEU) data, eight trials compliant with the northern European Union (NEU) outdoor GAP are still required.
- Aubergines/eggplants: although MRL and risk assessment values can be derived from the SEU and indoor EU data, eight trials compliant with the NEU outdoor GAP are still required (it is noted that this data gap will be covered by the northern trials requested on tomatoes – see just above; northern GAPs on tomatoes and aubergines are similar and trials on tomatoes can be extrapolated to aubergines).
- Sweet peppers/bell peppers: although MRL and risk assessment values can be derived from the indoor EU data, four additional trials compliant with the SEU outdoor GAP are still required.

1.2.2. Magnitude of residues in rotational crops

There were no studies investigating the magnitude of residues in rotational crops available for this review.
Nevertheless, based on the results of the rotational confined crop study and considering that cyflufenamid was applied to a bare soil (interception of active substance by the plants is expected in practice), it can be concluded that 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.

1.2.3. Magnitude of residues in processed commodities

The effect of peeling was assessed with the data available on trials conducted with melons (United Kingdom, 2011). An overview of all available peeling studies is available in Appendix B.1.2.3. Robust peeling factors (fully supported by data) could be derived for melons and watermelons.

Further processing studies are not required as they are not expected to affect the outcome of the risk assessment. However, if more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for maize, millet, rice and sorghum for which no data are available to derive MRLs and risk assessment values.

Tentative MRLs were also derived for feed crops (cereal straw) in view of the future need to set MRLs in feed items.

2. Residues in livestock

Cyflufenamid is authorised for use on fruit pomace and cereals that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D. The dietary burdens calculated for cattle (all diets and dairy only), sheep (all diets and ewe only) and poultry (all diets and layer only) were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). Behaviour of residues was only assessed in ruminants.

It is highlighted that for several feed items, namely maize/corn, common millet, rice and sorghum grains, common millet and rice straw, as well as maize/corn and sorghum stover, no residue data were available. The animal intake of cyflufenamid residues via these commodities has therefore not been assessed and may have been underestimated.

The metabolism of cyflufenamid residues in livestock was investigated in lactating goats dosed at approximately 4N and 37N rates compared to the maximum dietary burden calculated in this review (United Kingdom, 2006). These studies were assessed in the framework of the peer-review (EFSA, 2009a). In all the studies, cyflufenamid was radiolabelled only in the fluorinated phenyl ring of the molecule. The majority of applied radioactivity was excreted. The levels of 14C-cyflufenamid equivalents transferred into milk and edible organ/tissues were low. More precisely, residues in milk, fat, kidney, liver and muscle were found to be 0.005, 0.014, 0.015, 0.113 and 0.003 mg eq/kg, respectively, for the goat dosed with the low rate. A residue plateau in milk was reached after 2 days.

In fat, parent cyflufenamid was the dominant residue, representing 80% of the TRR (0.12 mg eq/kg). On the other hand, the E-isomer represented the 2.5% of TRR. Other minor metabolites were also detected (< 10% TRR).

Parent cyflufenamid was not found in milk nor tissue samples, with the exception of muscle, where it represented 22% of the TRR (0.007 mg eq/kg, with high dose rate). The main compound in milk, muscle, liver and kidney was metabolite 149-F1, ranging from 30% TRR in liver (0.277 mg eq/kg, with high dose rate) to 62% (0.025 mg eq/kg, with high dose rate) in milk. Lower levels of 149-F6 (3–30% TRR) were also found. 149-F (15% TRR, 0.016 mg eq/kg, with low dose rate) was additionally found in liver.

It is noted that the ruminants’ metabolism study has only involved labelling in the fluorinated phenyl ring. However, it was concluded that the metabolism of cyflufenamid in ruminants was adequately elucidated during the peer-review (EFSA, 2009a). Bearing in mind that metabolite 149-F1 was the most prominent component of the residue (31–62% TRR) in milk, liver, kidney and muscle, and cyflufenamid was not a suitable marker in kidney and liver, the residue definition for monitoring and risk assessment in ruminants was proposed as sum of cyflufenamid (Z-isomer), its E-isomer and metabolite 149-F1, expressed as cyflufenamid.
A metabolism study on laying hens is not available and it is required. An analytical method for the enforcement of the proposed residue definition at the combined LOQ of 0.03 mg/kg in all matrices is available (EFSA, 2009b, 2013). Although only one selected reaction monitoring (SRM) transition was monitored in the primary detection, an ILV is available and no additional data are required. Hence, the method is considered sufficiently validated. In the EUR-L-DataPool, only screening methods are available for livestock commodities (EURL, 2018). According to the information provided by the EURL during the consultation of Member States, an analytical standard of cyflufenamid (Z-isomer) is commercially available. However, analytical standards of 149-(E)-FB (E-isomer) and metabolite 149-F1 are not commercially available (EFSA, 2018b).

For ruminants, the metabolism study (performed at about 4N rate compared to the maximum dietary burden calculated for sheep-all diets) is sufficient to conclude that residue levels would remain below the enforcement LOQ of 0.03 mg/kg in milk and tissues. Therefore, MRLs and risk assessment values for the relevant commodities can be established at the LOQ level. For poultry, since no metabolism study is available on laying hens, it is not possible to derive a residue definition, nor MRLs.

3. Consumer risk assessment

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA PRIMo (EFSA, 2007). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where a (tentative) MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). For those commodities where data were insufficient to derive a MRL in Sections 1 and 2, EFSA considered the existing EU MRL for an indicative calculation. All input values included in the exposure calculations are summarised in Appendix D.

The exposure values calculated were compared with the toxicological reference values for cyflufenamid, derived by EFSA in the framework of the peer review (EFSA, 2009a). The highest chronic exposure was calculated for FR toddler, accounting for 3.6% of the ADI. The highest acute exposure was calculated for table grapes, representing 15.7% of the ARfD. Although uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumer’s health.

Conclusions

The metabolism of cyflufenamid in plant was investigated in representatives of three primary crops categories, i.e. fruit and fruiting vegetables, pulses and oilseeds, and cereals, as well as in rotational crops (root and tuber vegetables, leafy vegetables and cereals). According to the results of the metabolism studies and considering the results of the trials, where the levels of the E-isomer never exceeded the LOQ, the residue definition could be, in principle, simplified to cyflufenamid (Z-isomer) only. However, taking into account the available analytical methods, which cannot specifically discriminate between both isomers, and the storage stability studies, where potential isomerisation might occur, the residue definition for enforcement and risk assessment proposed in the peer-review as sum of cyflufenamid (Z-isomer) and its E-isomer, is still considered valid in this review. This residue definition is applicable to all primary and rotational crops and to processed commodities.

Validated analytical methods are available for the enforcement of the proposed residue definition in high water and high acid content commodities, as well as dry commodities at the LOQ of 0.01 mg/kg. According to the EURL, the same LOQ of 0.01 mg/kg is achievable in all the main four matrix groups in routine analyses by the use of different QuEChERS methods. According to the EURL, an analytical standard of 149-(E)-FB (E-isomer) is not commercially available.

Available residue trials data were considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for maize, millet, rice and sorghum for which no data are available to derive MRLs and risk assessment values. Cyflufenamid is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were thus performed for different groups of livestock according to OECD guidance. The dietary burdens calculated for all groups of livestock, except for swine, were found to exceed the trigger value of 0.1 mg/kg DM. However, the behaviour of residues was only assessed in ruminants since a metabolism study on poultry was not available.
The metabolism of cyflufenamid residues in ruminants was investigated in lactating goats at a dose rate covering the maximum dietary burdens calculated in this review. According to the results of these studies, the residue definition for enforcement and risk assessment in milk and ruminants tissues was proposed as sum of cyflufenamid (Z-isomer), its E-isomer and metabolite 149-F1, expressed as cyflufenamid. An analytical method for the enforcement of the proposed residue definition at the combined LOQ of 0.03 mg/kg in all matrices is available. According to the EURL, analytical standards of 149-(E)-FB (E-isomer) and metabolite 149-F1 are not commercially available.

For ruminants, the metabolism study is sufficient to conclude that, at the calculated dietary burden, residue levels would remain below the enforcement LOQ of 0.03 mg/kg in milk and tissues. Hence, MRLs and risk assessment values for the relevant commodities can be established at the LOQ level.

For poultry, no metabolism study is available on laying hens, and thus, it is not possible to derive a residue definition, nor MRLs.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to derive a MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure represented 3.6% of the ADI (FR toddler) and the highest acute exposure amounted to 15.7% of the ARfD (table grapes). Although uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumer's health.

Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 2). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see Table 2 footnotes for details). In particular, some tentative MRLs and existing EU MRLs need to be confirmed by the following data:

- residue trials supporting the authorisations on maize, millet, rice and sorghum;
- metabolism study on poultry and, eventually, poultry feeding studies (data gap relevant for the authorised use on wheat as main contributor of the dietary burden for poultry).

It is highlighted, however, that some of the MRLs derived result from a GAP in one climatic zone only, whereas other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gaps which are not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- Eight trials on tomatoes compliant with the NEU outdoor GAP for tomatoes and aubergines/eggplants;
- Four additional trials on sweet peppers/bell peppers compliant with the outdoor SEU GAP.

If the above-reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

Minor deficiencies were also identified in the assessment but these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data are therefore considered desirable but not essential:

- hydrolysis studies simulating pasteurisation, boiling and sterilisation, processing of the products under consideration, in particular for grapes and apples.

| Code number | Commodity | Existing EU MRL (mg/kg) | Outcome of the review | Comment |
|-------------|-----------|------------------------|-----------------------|---------|
| 130010      | Apples    | 0.05                   | 0.06                  | Recommended(a) |
| 130020      | Pears     | 0.05                   | 0.06                  | Recommended(a) |
| 130030      | Quinces   | 0.05                   | 0.06                  | Recommended(a) |
| Code number | Commodity                        | Existing EU MRL (mg/kg) | Outcome of the review |
|-------------|----------------------------------|-------------------------|-----------------------|
| 130040      | Medlars                          | 0.05                    | 0.06                  | Recommended<sup>(a)</sup> |
| 130050      | Loquats/Japanese medlars         | 0.05                    | 0.06                  | Recommended<sup>(a)</sup> |
| 140010      | Apricots                         | 0.06                    | 0.06                  | Recommended<sup>(a)</sup> |
| 140020      | Cherries (sweet)                 | 0.1                     | 0.1                   | Recommended<sup>(a)</sup> |
| 140030      | Peaches                          | 0.06                    | 0.06                  | Recommended<sup>(a)</sup> |
| 140040      | Plums                            | 0.06                    | 0.07                  | Recommended<sup>(a)</sup> |
| 151010      | Table grapes                     | 0.15                    | 0.2                   | Recommended<sup>(a)</sup> |
| 151020      | Wine grapes                      | 0.15                    | 0.2                   | Recommended<sup>(a)</sup> |
| 152000      | Strawberries                     | 0.04                    | 0.04                  | Recommended<sup>(a)</sup> |
| 231010      | Tomatoes                         | 0.02*                   | 0.04                  | Recommended<sup>(a)</sup> |
| 231020      | Sweet peppers/bell peppers       | 0.04                    | 0.06                  | Recommended<sup>(a)</sup> |
| 231030      | Aubergines/eggplants             | 0.02*                   | 0.02                  | Recommended<sup>(a)</sup> |
| 232010      | Cucumbers                        | 0.04                    | 0.05                  | Recommended<sup>(a)</sup> |
| 232020      | Gherkins                         | 0.08                    | 0.05                  | Recommended<sup>(a)</sup> |
| 232030      | Courgettes                       | 0.05                    | 0.05                  | Recommended<sup>(a)</sup> |
| 233010      | Melons                           | 0.04                    | 0.05                  | Recommended<sup>(a)</sup> |
| 233020      | Pumpkins                         | 0.04                    | 0.05                  | Recommended<sup>(a)</sup> |
| 233030      | Watermelons                      | 0.04                    | 0.05                  | Recommended<sup>(a)</sup> |
| 270050      | Globe artichokes                 | 0.03                    | 0.04                  | Recommended<sup>(a)</sup> |
| 500010      | Barley grains                    | 0.1                     | 0.1                   | Recommended<sup>(a)</sup> |
| 500030      | Maize/corn grains                | 0.02*                   | 0.02                  | Further consideration needed<sup>(b)</sup> |
| 500040      | Common millet/proso millet grains| 0.02*                   | 0.02                  | Further consideration needed<sup>(b)</sup> |
| 500050      | Oat grains                       | 0.1                     | 0.1                   | Recommended<sup>(a)</sup> |
| 500060      | Rice grains                      | 0.02*                   | 0.02                  | Further consideration needed<sup>(b)</sup> |
| 500070      | Rye grains                       | 0.05                    | 0.04                  | Recommended<sup>(a)</sup> |
| 500080      | Sorghum grains                   | 0.02*                   | 0.02                  | Further consideration needed<sup>(b)</sup> |
| 500090      | Wheat grains                     | 0.05                    | 0.04                  | Further consideration needed<sup>(c)</sup> |

**Enforcement residue definition for animals (existing):** sum of cyflufenamid (Z-isomer) and its E-isomer

**Enforcement residue definition for animals (proposed):** sum of cyflufenamid (Z-isomer), its E-isomer and metabolite 149-F1, expressed as cyflufenamid
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Abbreviations

a.i. active ingredient
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
CF conversion factor for enforcement residue definition to risk assessment residue definition
cGAP critical GAP
CXL codex maximum residue limit
DAR draft assessment report
DAT days after treatment
DB dietary burden
DC dispersible concentrate
| Abbreviation | Description |
|--------------|-------------|
| DM           | dry matter  |
| DT<sub>90</sub> | period required for 90% dissipation (define method of estimation) |
| EC           | emulsifiable concentrate |
| EMS          | evaluating Member State |
| EO           | emulsion, water in oil |
| eq           | residue expressed as a.s. equivalent |
| ESI          | electrospray ionisation |
| EURL         | European Union Reference Laboratories for Pesticide Residues (former CRLs) |
| EW           | emulsion, oil in water |
| FAO          | Food and Agriculture Organization of the United Nations |
| GAP          | Good Agricultural Practice |
| GC           | gas chromatography |
| GC-MS/MS     | gas chromatography with tandem mass spectrometry |
| HR           | highest residue |
| IEDI         | international estimated daily intake |
| IESTI        | international estimated short-term intake |
| ILV          | independent laboratory validation |
| ISO          | International Organisation for Standardization |
| IUPAC        | International Union of Pure and Applied Chemistry |
| LC-ESI-MS/MS | liquid chromatography-electrospray ionization with tandem mass spectrometry |
| LC-MS/MS     | liquid chromatography with tandem mass spectrometry |
| LC-MS-QToF   | liquid chromatography quadrupole time-of-flight mass spectrometry |
| LOQ          | limit of quantification |
| Mo           | monitoring |
| MRL          | maximum residue level |
| NESTI        | national estimated short-term intake |
| NEU          | northern European Union |
| NTMDI        | national theoretical maximum daily intake. |
| OECD         | Organisation for Economic Co-operation and Development |
| PBI          | plant-back interval |
| PF           | processing factor |
| PHI          | preharvest interval |
| PRIMO        | (EFSA) Pesticide Residues Intake Model |
| PROFILe      | (EFSA) Pesticide Residues Overview File |
| QuEChERS     | Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method) |
| QuOil        | variation of QuEChERS method for vegetable oil samples |
| 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 European Union |
| SMILES       | simplified molecular-input line-entry system |
| SRM          | selected reaction monitoring |
| STMR         | supervised trials median residue |
| TAR          | total applied radioactivity |
| TMDI         | theoretical maximum daily intake |
| TRR          | total radioactive residue |
| WHO          | World Health Organization |
### Appendix A – Summary of authorised uses considered for the review of MRLs

#### A.1. Authorised outdoor uses in northern EU

| Crop and/or situation | MS or country | F | Preparation | Application | Application rate per treatment | Remarks |
|-----------------------|---------------|---|-------------|-------------|--------------------------------|---------|
| **Apples**            | BE            | F | Powdery mildew | Foliar treatment – general (see also comment field) | 50 g/L | **19–87** | **1–2** | **–** | **28 g a.i./ha** | 14 |
| **Pears**             | FR            | F | Powdery mildew | Foliar treatment – spraying | 1–2 | 7 | – | – | 25 g a.i./ha | 14 |
| **Quinces**           | FR            | F | Powdery mildew | Foliar treatment – spraying | 2 | 7 | – | – | 25 g a.i./ha | 14 |
| **Medlars**           | FR            | F | Foliar treatment | Foliar treatment – spraying | 2 | 7 | – | – | 25 g a.i./ha | 14 |
| **Loquats**           | FR            | F | Foliar treatment | Foliar treatment – spraying | 2 | 7 | – | – | 25 g a.i./ha | 14 |
| **Table grapes**      | AT            | F | *Erysiphe necator* | Foliar treatment – general | 51.4 g/L | **9–79** | **2** | – | – | 25.7 g a.i./ha | 21 |
| **Wine grapes**       | AT            | F | *Erysiphe necator* | Foliar treatment – general | 51.4 g/L | **9–79** | **2** | – | – | 25.7 g a.i./ha | 21 |
| **Strawberries**      | BE            | F | Powdery mildew | Foliar treatment – general | 100 g/L | **40–89** | **1–2** | **10** | 18.8 g a.i./ha | 3 |
| **Tomatoes**          | HU            | F | DC* | Foliar treatment – broadcast spraying | 15 g/L | **20–89** | **2** | **10** | – | – | 15 g a.i./ha | 3 |
| **Sweet peppers**     | HU            | F | DC* | Foliar treatment – broadcast spraying | 15 g/L | **20–89** | **2** | **10** | – | – | 15 g a.i./ha | 3 |
| Crop and/or situation | MS or country | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|-----------------------------------|-------------|-------------|-------------------------------|---------------|---------|
| **Aubergines**        | HU            | F                                 | DC          | Foliar treatment – broadcast spraying | 20-89          | 2 10  –  – | 15 g a.i./ha | 3     |
| **Cucumbers**         | UK            | F                                 | DC          | Foliar treatment – general            | 2              |  –  –   | 15 g a.i./ha | 1     |
| **Gherkins**          | BE            | Powdery mildew                    | SC          | Foliar treatment – general            | n.a.           | 1-2 7   | 15 g a.i./ha | 1     |
| **Courgettes**        | BE            | Powdery mildew                    | SC          | Foliar treatment – general            | n.a.           | 1-2 7   | 15 g a.i./ha | 1     |
| **Melons**            | UK            | F                                 | DC          | Foliar treatment – general            | 2              |  –  –   | 15 g a.i./ha | 1     |
| **Pumpkins**          | BE            | Powdery mildew                    | SC          | Foliar treatment – general            | n.a.           | 1-2 7   | 15 g a.i./ha | 1     |
| **Watermelons**       | HU            | F                                 | DC          | Foliar treatment – broadcast spraying | 20-89          | 2 10  –  – | 15 g a.i./ha | 3     |
| **Globe artichokes**  | FR            | Powdery mildew                    | EW          | Foliar treatment – broadcast spraying | 89             | 2       | 15 g a.i./ha | 21    |
| **Barley**            | NL            | Powdery mildew (Erysiphe graminis) | EW          | Foliar treatment – broadcast spraying | 30-59          | 2       | 26 g a.i./ha | 49    |
| **Oat**               | AT            | Erysiphe graminis                 | EO          | Foliar treatment – general            | 59             | 2 14    | 25.7 g a.i./ha | 49   |
| **Rye**               | NL            | Powdery mildew (Erysiphe graminis) | EW          | Foliar treatment – broadcast spraying | 30-59          | 2       | 26 g a.i./ha | 49    |
### A.2. Authorised outdoor uses in southern EU

| Crop and/or situation | MS or country | F G or T(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) |
|-----------------------|---------------|-------------|-----------------------------------|-------------|-----------------|---------------------------------|---------------|
|                       |               |             |                                   |             |                 |                                 |               |
| **Wheat**             | NL            | F           | Powdery mildew *(Erysiphe graminis)* | EW          | 51 g/L          | Foliar treatment – broadcast spraying | 30–59         |
|                       |               |             |                                   |             |                 |                                 | 2            |
|                       |               |             |                                   |             |                 |                                 | 26 g a.i./ha  |
|                       |               |             |                                   |             |                 |                                 | 49           |
|                       |               |             |                                   |             |                 |                                 | First application after BBCH 29 |
|                       |               |             |                                   |             |                 |                                 | Second application after BBCH 49 |
| **Apples**            | ES            | F           |                                   | EW          | 51.3 g/L        | Foliar treatment – spraying      | 19–87         |
|                       |               |             |                                   |             |                 |                                 | 1–2          |
|                       |               |             |                                   |             |                 |                                 | 7            |
|                       |               |             |                                   |             |                 |                                 | 25.65 g a.i./ha |
|                       |               |             |                                   |             |                 |                                 | 14           |
|                       |               |             |                                   |             |                 |                                 | Water 400–1,600 L/ha |
| **Pears**             | ES            | F           |                                   | EW          | 51.3 g/L        | Foliar treatment – spraying      | 19–87         |
|                       |               |             |                                   |             |                 |                                 | 1–2          |
|                       |               |             |                                   |             |                 |                                 | 7            |
|                       |               |             |                                   |             |                 |                                 | 25.65 g a.i./ha |
|                       |               |             |                                   |             |                 |                                 | 14           |
|                       |               |             |                                   |             |                 |                                 | Water 400–1,600 L/ha |
| **Quinces**           | ES            | F           |                                   | EW          | 51.3 g/L        | Foliar treatment – spraying      | 19–87         |
|                       |               |             |                                   |             |                 |                                 | 1–2          |
|                       |               |             |                                   |             |                 |                                 | 7            |
|                       |               |             |                                   |             |                 |                                 | 25.65 g a.i./ha |
|                       |               |             |                                   |             |                 |                                 | 14           |
|                       |               |             |                                   |             |                 |                                 | Water 400–1,600 L/ha |
| **Medlars**           | ES            | F           |                                   | EW          | 51.3 g/L        | Foliar treatment – spraying      | 19–87         |
|                       |               |             |                                   |             |                 |                                 | 1–2          |
|                       |               |             |                                   |             |                 |                                 | 7            |
|                       |               |             |                                   |             |                 |                                 | 25.65 g a.i./ha |
|                       |               |             |                                   |             |                 |                                 | 14           |
|                       |               |             |                                   |             |                 |                                 | Water 400–1,600 L/ha |
| Crop and/or situation | MS or country | Pests or group of pests controlled | Preparation | Method | Range of growth stages and season | Number min–max | Interval between application (min) | Application rate per treatment a.s./hL min–max | Water L/ha min–max | PH (days) | Remarks |
|-----------------------|---------------|-----------------------------------|-------------|--------|-----------------------------------|----------------|-----------------------------------|-----------------------------------------------|-------------------|-----------|---------|
| Loquats               | ES F          | EW                                | 51.3 g/L    | Foliar treatment – spraying      | 19–87           | 1–2                               | 7                 | –                               | –       | 25.65 g a.i./ha                    | 14        | Water 400–1,600 L/ha               |
| Apricots              | ES F          | EW                                | 51.3 g/L    | Foliar treatment – spraying      | 19–87           | 1–2                               | 7                 | –                               | –       | 25.65 g a.i./ha                    | 14        | Water 400–1,600 L/ha               |
| Cherries              | ES F          | EW                                | 51.3 g/L    | Foliar treatment – spraying      | 19–87           | 1–2                               | 7                 | –                               | –       | 25.65 g a.i./ha                    | 14        | Water 400–1,600 L/ha               |
| Peaches               | ES F          | EW                                | 51.3 g/L    | Foliar treatment – spraying      | 19–87           | 1–2                               | 7                 | –                               | –       | 25.65 g a.i./ha                    | 14        | Water 400–1,600 L/ha               |
| Plums                 | ES F          | EW                                | 51.3 g/L    | Foliar treatment – spraying      | 19–87           | 1–2                               | 7                 | –                               | –       | 25.65 g a.i./ha                    | 14        | Water 400–1,600 L/ha               |
| Table grapes          | IT F          | Erysiphe necator                   | EW          | Foliar treatment – broadcast spraying | 60–79           | 1–2                               | 10                | –                               | –       | 25.65 g a.i./ha                    | 21        | 40–50 mL product/hl (max 500 mL product/ha) |
| Wine grapes           | IT F          | Erysiphe necator                   | EW          | Foliar treatment – broadcast spraying | 60–79           | 1–2                               | 10                | –                               | –       | 25.65 g a.i./ha                    | 21        | 40–50 mL product/hl (max 500 mL product/ha) |
| Strawberries          | FR F          |                                    |             | Foliar treatment – broadcast spraying | 89              | 2                                 | 10                | –                               | –       | 15 g a.i./ha                       | 3         |                  |
| Crop and/or situation | MS or country | F G or T | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|------------------------|---------------|----------|-----------------------------------|-------------|-------------|------------------------------|------------|---------|
|                        |               |          |                                   |             | Type(b) Conc. a.s. | Method kind | Range of growth stages and season(c) | Number min-max | Interval between application (min) | a.s./hL min-max | Water L/ha min-max | Rate and unit |          |
| Tomatoes               | ES            | F        | SC                                 | 100 g/L     | Foliar treatment – general (see also comment field) | 1-2         | 7                          | –          | –                   | 15 g a.i./ha | –                   | –          | 1        |
|                        |               |          |                                   |             | SC                                     |             |                            |            |                     |                  |                      |                |          |
|                        |               |          |                                   |             | SC                                     |             |                            |            |                     |                  |                      |                |          |
|                        |               |          |                                   |             | SC                                     |             |                            |            |                     |                  |                      |                |          |
|                        |               |          |                                   |             | SC                                     |             |                            |            |                     |                  |                      |                |          |
| Sweet peppers         | ES            | F        | SC                                 | 100 g/L     | Foliar treatment – general (see also comment field) | 1-2         | 7                          | –          | –                   | 15 g a.i./ha | –                   | –          | 1        |
|                        |               |          |                                   |             | SC                                     |             |                            |            |                     |                  |                      |                |          |
|                        |               |          |                                   |             | SC                                     |             |                            |            |                     |                  |                      |                |          |
|                        |               |          |                                   |             | SC                                     |             |                            |            |                     |                  |                      |                |          |
|                        |               |          |                                   |             | SC                                     |             |                            |            |                     |                  |                      |                |          |
| Aubergines             | ES            | F        | SC                                 | 100 g/L     | Foliar treatment – general (see also comment field) | 1-2         | 7                          | –          | –                   | 15 g a.i./ha | –                   | –          | 3        |
|                        |               |          |                                   |             | SC                                     |             |                            |            |                     |                  |                      |                |          |
|                        |               |          |                                   |             | SC                                     |             |                            |            |                     |                  |                      |                |          |
|                        |               |          |                                   |             | SC                                     |             |                            |            |                     |                  |                      |                |          |
|                        |               |          |                                   |             | SC                                     |             |                            |            |                     |                  |                      |                |          |
| Cucumbers              | ES            | F        | SC                                 | 100 g/L     | Foliar treatment – general (see also comment field) | 1-2         | 7                          | –          | –                   | 15 g a.i./ha | –                   | –          | 1        |
|                        |               |          |                                   |             | SC                                     |             |                            |            |                     |                  |                      |                |          |
|                        |               |          |                                   |             | SC                                     |             |                            |            |                     |                  |                      |                |          |
|                        |               |          |                                   |             | SC                                     |             |                            |            |                     |                  |                      |                |          |
|                        |               |          |                                   |             | SC                                     |             |                            |            |                     |                  |                      |                |          |
| Gherkins               | EL            | F        | SC                                 | 100 g/L     | Foliar treatment – general                | 20-89       | 1-2                         | 7          | –                   | 15 g a.i./ha | 1                  | –          | 1        |
|                        |               |          |                                   |             | SC                                     |             |                            |            |                     |                  |                      |                |          |
|                        |               |          |                                   |             | SC                                     |             |                            |            |                     |                  |                      |                |          |
|                        |               |          |                                   |             | SC                                     |             |                            |            |                     |                  |                      |                |          |
|                        |               |          |                                   |             | SC                                     |             |                            |            |                     |                  |                      |                |          |
| Courgettes             | FR            | F        | SC                                 | 100 g/L     | Foliar treatment – broadcast spraying     | 2           | 7                          | –          | –                   | 15 g a.i./ha | 1                  | –          | 1        |
|                        |               |          |                                   |             | SC                                     |             |                            |            |                     |                  |                      |                |          |
|                        |               |          |                                   |             | SC                                     |             |                            |            |                     |                  |                      |                |          |
|                        |               |          |                                   |             | SC                                     |             |                            |            |                     |                  |                      |                |          |
|                        |               |          |                                   |             | SC                                     |             |                            |            |                     |                  |                      |                |          |
| Crop and/or situation | MS or country | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | Remarks |
|-----------------------|--------------|----------------------------------|-------------|-------------|-------------------------------|---------|
|                       |              |                                  | Type(b)     | Method kind | Range of growth stages and season(c) | Number min-max | Interval between application (min) | a.s./hL min-max | Water L/ha min-max | Rate and unit | PHI (days)(d) |         |
| Melons                | FR           |                                  | F           | Foliar      | Foliar treatment – broadcast spraying | 2 - 7         | – – | 15 g a.i./ha | 1 |
| Pumpkins              | ES           | SC                               | SC          | 100 g/L     | Foliar treatment – general           | 1 - 2          | 7 – – | 15 g a.i./ha | 1 |
| Watermelons           | ES           | SC                               | SC          | 100 g/L     | Foliar treatment – general           | 1 - 2          | 7 – – | 15 g a.i./ha | 1 |
| Globe artichokes      | EL           | Pest                             | SC          | 100 g/L     | Foliar treatment – general           | 2 – 14         | – – | 15 g a.i./ha | 14 |
| Barley                | ES           | F                                | EW          | 51.3 g/L    | Foliar treatment – general           | 20 - 59        | 1 - 2 | 28 – – | 25.65 g a.i./ha | 60 |
| Buckwheat             | ES           | F                                | EW          | 51.3 g/L    | Foliar treatment – general           | 20 - 59        | 1 - 2 | 28 – – | 25.65 g a.i./ha | 60 |
| Maize                 | ES           | F                                | EW          | 51.3 g/L    | Foliar treatment – general           | 20 - 59        | 1 - 2 | 28 – – | 25.65 g a.i./ha | 60 |
| Common millet         | ES           | F                                | EW          | 51.3 g/L    | Foliar treatment – general           | 20 - 59        | 1 - 2 | 28 – – | 25.65 g a.i./ha | 60 |
| Oat                   | ES           | F                                | EW          | 51.3 g/L    | Foliar treatment – general           | 20 - 59        | 1 - 2 | 28 – – | 25.65 g a.i./ha | 60 |
### A.2. Authorised outdoor uses in EU

| Crop and/or situation | MS or country | F G or Y | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|----------|------------------------------------|-------------|------------|--------------------------------|------------|---------|
| Rice                  | ES            | F        |                                    | EW 51.3 g/L | Foliar treatment – general | 20-59, 1-2, 28 | – | – | 25.65 g a.i./ha | 60 | 200-400 L/ha. First application during tillering; second during inflorescence emergence |
| Rye                   | ES            | F        |                                    | EW 51.3 g/L | Foliar treatment – general | 20-59, 1-2, 28 | – | – | 25.65 g a.i./ha | 60 |
| Sorghum               | ES            | F        |                                    | EW 51.3 g/L | Foliar treatment – general | 20-59, 1-2, 28 | – | – | 25.65 g a.i./ha | 60 |
| Wheat                 | ES            | F        |                                    | EW 51.3 g/L | Foliar treatment – general | 20-59, 1-2, 28 | – | – | 25.65 g a.i./ha | 60 |

### A.3. Authorised indoor uses in EU

| Crop and/or situation | MS or country | F G or Y | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|----------|------------------------------------|-------------|------------|--------------------------------|------------|---------|
| Strawberries          | BE            | I        | Powdery mildew                     | SC 100 g/L  | Foliar treatment – general | 40-89, 1-2, 10 | – | – | 18.8 g a.i./ha | 3 |
| Crop and/or situation | MS or country | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | Remarks |
|-----------------------|--------------|-----------------------------------|-------------|-------------|-------------------------------|---------|
| | | | Type(b) | Conc. a.s. | Method kind | Range of growth stages and season(c) | Number min-max | Interval between application (min) | a.s./hl min-max | Water L/ha min-max | Rate and unit | PHI (days)(d) | |
| Tomatoes | ES | I | SC | 100 g/L | Foliar treatment – general (see also comment field) | 1-2 | 7 | – | – | 15 g a.i./ha | 1 | 500-1,500 L/ha; 1-3 g a.i./hl (not exceeding 0.15 L product/ha) |
| Sweet peppers | FR | I | | | Foliar treatment – broadcast spraying | 2 | 7 | – | – | 15 g a.i./ha | 1 |
| Aubergines | ES | I | SC | 100 g/L | Foliar treatment – general (see also comment field) | 1-2 | 7 | – | – | 15 g a.i./ha | 3 | 500-1,500 L/ha; 1-3 g a.i./hl (not exceeding 0.15 L product/ha) |
| Cucumbers | FR | I | | | Foliar treatment – broadcast spraying | 2 | 7 | – | – | 15 g a.i./ha | 1 |
| Gherkins | BE | I | Powdery mildew | SC | 100 g/L | Foliar treatment – general | n.a. | 1-2 | 7 | – | 15 g a.i./ha | 1 |
| Courgettes | FR | I | | | Foliar treatment – broadcast spraying | 2 | 7 | – | – | 15 g a.i./ha | 1 |
| Melons | FR | I | | | Foliar treatment – broadcast spraying | 2 | 7 | – | – | 15 g a.i./ha | 1 |
## Review of the existing MRLs for cyflufenamid

| Crop and/or situation | MS or country | F or G or I<sup>(a)</sup> | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | Remarks |
|-----------------------|---------------|---------------------------|------------------------------------|-------------|-----------------------------|-----------------------------|---------|
|                       |               |                           |                                    | Type<sup>(b)</sup> | Conc. a.s. | Method kind | Range of growth stages and season<sup>(c)</sup> | Number min–max | Interval between application (min) | a.s./hL min–max | Water L/ha min–max | Rate and unit | PHI (days)<sup>(d)</sup> | |
| Pumpkins              | BE            | I                         | Powdery mildew                    | SC          | 100 g/L       | Foliar treatment – general | n.a.                       | 1–2          | 7                        | –              | –              | 15 g a.i./ha | 1                   |
| Watermelons           | ES            | I                         | SC                                 | 100 g/L     | Foliar treatment – general | 1–2                         | 7                        | –             | –             | 15 g a.i./ha | 1                   |

MS: Member State; MRL: maximum residue level; a.s.: active substance; a.i.: active ingredient; EW: emulsion, oil in water; CF: conversion factor for enforcement residue definition to risk assessment residue definition; EO: emulsion, water in oil; SC: suspension concentrate; DC: dispersible concentrate.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(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                      | Apple       | Foliar: 1 x 270 g a.s./ha | 0, 21, 42, 92 (leaves) | Fluorinated phenyl-U-14C-labelled cyflufenamid (EFSA, 2011) |
|                                 |             |         |                | 21, 42, 92 (fruit) |
|                                 | Cucumber    | Not specified: 1 x 50 g a.s./ha | 0–31 (fruit and leaves) |
|                                 |             | Not specified: 1 x 200 g a.s./ha | 7–35 (fruit and leaves) |
| Cereals/grass                    | Wheat       | Foliar: 2 x 25 g a.s./ha; BBCH 32/59 (Study A) | 0 (fruit and root) At maturity (straw, husk, grain) | Fluorinated phenyl-U-14C-labelled cyflufenamid (EFSA, 2009a) |
|                                 |             | Foliar: 2 x 25 or 100 g a.s./ha; BBCH 32/39 (Study B) | 0 (forage and root) At maturity (straw, husk, grain) |
|                                 |             | Foliar: 2 x 25 or 100 g a.s./ha; BBCH 32/59 (Study C) | 0 (forage and root) At maturity (straw, husk, grain) |
| Pulses/oilseeds                 | Rapeseed    | Foliar: 1 x 12.5 g a.s./ha; BBCH 14 or 69 | 14 (whole plant) At maturity (seed) | Fluorinated phenyl-U-14C-labelled cyflufenamid (EFSA, 2016) |
|                                 |             | Foliar: 5 x 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                   | Carrot      | Bare soil application: 1 x 50 g a.s./ha | 30, 120 | Fluorinated phenyl-U-14C-labelled cyflufenamid (EFSA, 2009a) |
| Leafy crops                        | Lettuce     | Bare soil application: 1 x 50 g a.s./ha | 30 | |
| Cereal (small grain)               | Wheat       | Bare soil application: 1 x 50 g a.s./ha | 30, 120, 270 | |
| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/source |
|-----------------------------------------|------------|--------|----------------|
| Pasteurisation (20 min, 90°C, pH 4) | Not triggered | | |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Not triggered | | |
| Sterilisation (20 min, 120°C, pH 6) | Not triggered | | |
| Other processing conditions | Not triggered | | |

**Can a general residue definition be proposed for primary crops?**
Yes

**Rotational crop and primary crop metabolism similar?**
Yes

**Residue pattern in processed commodities similar to residue pattern in raw commodities?**
No study available, but desirable

**Plant residue definition for monitoring (RD-Mo)**
Sum of cyflufenamid (Z-isomer) and its E-isomer
**Plant residue definition for risk assessment (RD-RA)**
Sum of cyflufenamid (Z-isomer) and its E-isomer

**Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)**

- **High water and high acid content commodities (EFSA, 2011):**
  - GC-MS
  - LOQ = 0.01 mg/kg for the sum of isomers: cyflufenamid (Z-isomer) and its E-isomer
  - Confirmation by monitoring two additional fragment ions
  - ILV available (GC-MS)
  - QuEChERS (LC-MS/MS) for enforcement in routine analysis, LOQ = 0.01 mg/kg (EURL, 2018)

- **High oil content commodities:**
  - QuOil (LC-MS-QToF) for enforcement in routine analysis, LOQ = 0.01 mg/kg (EURL, 2018)

- **Dry commodities (United kingdom, 2006; EFSA, 2009b):**
  - GC-MS
  - LOQ = 0.01 mg/kg for the sum of isomers: cyflufenamid (Z-isomer) and its E-isomer.
  - Confirmation by monitoring 2 additional fragment ions
  - ILV available (GC-MS)
  - QuEChERS (LC-MS/MS) for enforcement in routine analysis, LOQ = 0.01 mg/kg (EURL, 2018)

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a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; GC-MS/MS: gas chromatography with tandem mass spectrometry; LC-MS/MS: liquid chromatography with tandem mass spectrometry; LC-MS-QToF: liquid chromatography quadrupole time-of-flight mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method); QuOil: variation of QuEChERS method for vegetable oil samples; LOQ: limit of quantification; ILV: independent laboratory validation.
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period | Compounds covered | Comment/source |
|-----------------------------------|----------|-----------|--------|------------------|-------------------|----------------|
|                                   | High water content | Immature barley shoots | –18 | 25 Months | Sum of cyflufenamid (Z-isomer) and its E-isomer | United Kingdom (2006) |
|                                   | High oil content | Oilseed rape | –18 | 18 Months | Sum of cyflufenamid (Z-isomer) and its E-isomer | Residues were analysed for each isomer separately (EFSA, 2014) |
|                                   | High protein content | Dry beans | –18 | 24 Months | Sum of cyflufenamid (Z-isomer) and its E-isomer | Residues were analysed for each isomer separately (EFSA, 2014) |
|                                   | High starch content | Wheat grain | –18 | 24 Months | Sum of cyflufenamid (Z-isomer) and its E-isomer | Residues were analysed for each isomer separately (EFSA, 2014) |
|                                   | High acid content | Grape | –18 | 24 Months | Sum of cyflufenamid (Z-isomer) and its E-isomer | Residues were analysed for each isomer separately (EFSA, 2014) |

### B.1.2. Magnitude of residues in plants

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

| Commodity | Region/ indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/source | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) |
|-----------|-------------------|---------------------------------------------------------------|-----------------|----------------------|---------------|----------------|
| Pome fruits | NEU | 2 × < 0.01; 3 × 0.01; 2 × 0.02; 0.035 | Combined data set on apples (6) and pears (2) performed with dose rates within 25% deviation (EFSA, 2011). Extrapolation to quinces, medlars and loquats is applicable MRL\(_{OECD}\) = 0.05 | 0.06 | 0.04 | 0.01 |
| | SEU | < 0.01; 2 × 0.01; 0.015; 0.016; 0.023; 0.026; 0.029 | Combined data set on apples (6) and pears (2) performed with dose rates within 25% deviation (EFSA, 2011). Extrapolation to quinces, medlars and loquats is applicable MRL\(_{OECD}\) = 0.05 | 0.05 | 0.03 | 0.02 |
| Apricots and peaches | SEU | 2 × < 0.02; 5 × 0.02; 0.03 | Combined data set on apricots (4) and peaches (4) performed with dose rates within 25% deviation (EFSA, 2016). MRL\(_{OECD}\) = 0.05 | 0.06 | 0.03 | 0.02 |
| Commodity                  | Region/ indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/source                                                                 | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) |
|---------------------------|------------------|---------------------------------------------------------------|-------------------------------------------------------------------------------|------------------------|---------------|-----------------|
| Cherries (sweet)          | SEU              | 2 × 0.02; 2 × 0.03; 3 × 0.04; 0.05                             | Trials on cherries performed with dose rates within 25% deviation (EFSA, 2016) MRL\_\text{OECD} = 0.1 | 0.1                   | 0.05          | 0.04            |
| Plums                     | SEU              | 7 × 0.02; 0.03                                               | Trials on plums performed with dose rates within 25% deviation (EFSA, 2016) MRL\_\text{OECD} = 0.06 | 0.07                  | 0.03          | 0.02            |
| Table and wine grapes     | NEU              | 0.015; 0.016; 0.02; 2 × 0.027; 0.03; 0.037; 0.04; 0.07        | Trials on table and wine grapes performed with dose rates within 25% deviation (EFSA, 2011) MRL\_\text{OECD} = 0.1 | 0.1                   | 0.07          | 0.03            |
|                           | SEU              | 6 × < 0.01; 0.024; 0.03; 0.12                                 | Trials on table and wine grapes performed with dose rates within 25% deviation (EFSA, 2011) MRL\_\text{OECD} = 0.17 | 0.2                   | 0.12          | 0.01            |
| Strawberries              | NEU              | 5 × < 0.02; 2 × 0.02; 0.03                                   | Trials on strawberries performed with dose rates within 25% deviation (EFSA, 2014) MRL\_\text{OECD} = 0.04 | 0.04                  | 0.03          | 0.02            |
|                           | SEU              | 6 × < 0.02; 0.02; 0.03                                      | Trials on strawberries performed with dose rates within 25% deviation (EFSA, 2014) MRL\_\text{OECD} = 0.04 | 0.04                  | 0.03          | 0.02            |
|                           | EU               | 7 × < 0.02; 0.03                                             | Trials on strawberries performed with dose rates within 25% deviation (EFSA, 2014) MRL\_\text{OECD} = 0.04 | 0.04                  | 0.03          | 0.02            |
| Tomatoes                  | NEU              | –                                                             | No trials available                                                          | –                     | –             | –               |
|                           | SEU              | 7 × < 0.02; 0.03                                             | Trials on tomato compliant with GAP (Spain, 2017) MRL\_\text{OECD} = 0.04 | 0.04                  | 0.03          | 0.02            |
|                           | EU               | 8 × < 0.02                                                  | Trials on tomato compliant with GAP (Spain, 2017) MRL\_\text{OECD} = 0.02 | 0.02                  | 0.02          | 0.02            |
| Aubergines/ eggplants     | NEU              | –                                                             | No trials available                                                          | –                     | –             | –               |
|                           | SEU              | 8 × < 0.02                                                  | Trials on tomato compliant with GAP on aubergines (Spain, 2017) MRL\_\text{OECD} = 0.02 | 0.02                  | 0.02          | 0.02            |
|                           | EU               | 8 × < 0.02                                                  | Trials on tomato compliant with GAP on aubergines (Spain, 2017) MRL\_\text{OECD} = 0.02 | 0.02                  | 0.02          | 0.02            |
| Commodity                          | Region/indoor | Residue levels observed in the supervised residue trials (mg/kg) | Comments/source                                                                 | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) |
|-----------------------------------|---------------|---------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|---------------|----------------|
| Sweet peppers/bell peppers        | NEU           | 6 × < 0.02; 0.02; 0.03(d)                                      | Trials on peppers compliant with GAP (EFSA, 2014) MRL_{OECD} = 0.04              | 0.04                   | 0.03          | 0.02           |
|                                   | SEU           | 3 × < 0.02; 0.02                                              | Trials on peppers performed with dose rates within 25% deviation (Spain, 2017) MRL_{OECD} = 0.03 | 0.04(e) (tentative)   | 0.02          | 0.02           |
|                                   | EU            | 4 × < 0.02; 2 × 0.02; 2 × 0.03                                 | Trials on peppers performed with dose rates within 25% deviation (EFSA, 2014) MRL_{OECD} = 0.05 | 0.06                   | 0.03          | 0.02           |
| Cucumbers, gherkins and courgettes| NEU           | 2 × < 0.01; 3 × < 0.02; 0.014; 0.02; 0.03                    | Trials on courgettes compliant with GAP (EFSA, 2011; France, 2017) Extrapolation to gherkins and cucumber is applicable MRL_{OECD} = 0.04 | 0.05                   | 0.03          | 0.02           |
|                                   | SEU           | 4 × < 0.02; 3 × 0.02; 0.04                                     | Trials on courgettes compliant with GAP (EFSA, 2011; France, 2017). Extrapolation to gherkins and cucumber is applicable MRL_{OECD} = 0.05 | 0.05                   | 0.04          | 0.02           |
|                                   | EU            | 3 × < 0.01; 2 × 0.01; 0.016; 2 × 0.02                          | Trials on cucumbers compliant with GAP (EFSA, 2011). Extrapolation to courgettes and gherkins is applicable MRL_{OECD} = 0.05 | 0.04                   | 0.02          | 0.01           |
| Melons and pumpkins               | NEU           | 2 × < 0.01; 0.011; 0.013; 0.0158; 0.0159; 0.0164; 0.0245      | Trials on melons compliant with GAP (EFSA, 2011). Extrapolation to pumpkins is applicable MRL_{OECD} = 0.03 | 0.04                   | 0.02          | 0.01           |
|                                   | SEU           | 5 × < 0.01; 0.0124; 0.0245; 0.027                             | Trials on melons compliant with GAP (EFSA, 2011). Extrapolation to pumpkins is applicable MRL_{OECD} = 0.04 | 0.05                   | 0.03          | 0.01           |
|                                   | EU            | 4 × < 0.01; 2 × 0.0147; 0.0152; 0.0174; 0.02; 0.0211; 0.0228; 0.0299 | Trials on melons compliant with GAP (EFSA, 2011; France, 2017). Extrapolation to pumpkins is applicable MRL_{OECD} = 0.04 | 0.05                   | 0.03          | 0.02           |
| Commodity | Region/ indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/source | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) |
|-----------|------------------|---------------------------------------------------------------|----------------|------------------------|--------------|--------------|
| Watermelons | NEU              | 3 × < 0.01; 0.0104; 0.0148; 0.0159; 0.0165; 0.0174 | Trials on melons compliant with GAP on watermelons (United Kingdom, 2011) MRL<sub>OECD</sub> = 0.03 | 0.04 | 0.02 | 0.01 |
|            | SEU              | 5 × < 0.01; 0.0124; 0.0245; 0.027 | Trials on melons compliant with GAP (EFSA, 2011). Extrapolation to watermelons is applicable MRL<sub>OECD</sub> = 0.04. | 0.05 | 0.03 | 0.01 |
|            | EU               | 4 × < 0.01; 2 × 0.0147; 0.0152; 0.0174; 0.02; 0.0211; 0.0228; 0.0299 | Trials on melons compliant with GAP (EFSA, 2011; France, 2017). Extrapolation to watermelons is applicable MRL<sub>OECD</sub> = 0.04 | 0.05 | 0.03 | 0.02 |
| Globe artichokes | NEU          | 5 × < 0.02 | Trials on globe artichokes performed with dose rates within 25% deviation (France, 2017) MRL<sub>OECD</sub> = 0.02 | 0.02 | 0.02 | 0.02 |
|            | SEU              | 3 × < 0.02; 0.02 | Trials on globe artichokes compliant with GAP (EFSA, 2016) MRL<sub>OECD</sub> = 0.03 | 0.04 | 0.02 | 0.02 |
| Barley, oat grains, buckwheat and other pseudo-cereal grains | NEU          | 3 × < 0.02; 3 × 0.02; 3 × 0.03; 0.05 | Trials on barley grain performed with dose rates within 25% deviation (EFSA, 2009a) Extrapolation to oat grain is applicable. No authorisation for use on buckwheat in NEU MRL<sub>OECD</sub> = 0.06 | 0.07 | 0.05 | 0.02 |
|            | SEU              | 5 × < 0.02; 0.02; 2 × 0.03; 0.04; 0.07 | Trials on barley grain performed with dose rates within 25% deviation (EFSA, 2009a). Extrapolation to oat grain is applicable and to buckwheat acceptable (EFSA, 2016) MRL<sub>OECD</sub> = 0.09 | 0.1 | 0.07 | 0.02 |
| Barley and oat straw | NEU          | 4 × < 0.1; 0.1; 0.11; 2 × 0.12; 0.16; 0.24 | Trials on barley straw performed with dose rates within 25% deviation (EFSA, 2009a). Extrapolation to oat straw is applicable MRL<sub>OECD</sub> = 0.3 | 0.3(f) (tentative) | 0.24 | 0.11 |
|            | SEU              | < 0.1; 2 × 0.11; 0.18; 0.19; 0.22; 0.24; 0.34; 0.45; 0.54 | Trials on barley straw performed with dose rates within 25% deviation (EFSA, 2009a). Extrapolation to oat straw is applicable MRL<sub>OECD</sub> = 0.85 | 0.9(f) (tentative) | 0.54 | 0.21 |
| Maize/corn grains | SEU            | – | No trials available | – | – | – |
| Maize/corn stover | SEU            | – | No trials available | – | – | – |
### Commodity Region/indoor (a) Residue levels observed in the supervised residue trials (mg/kg) Comments/source Calculated MRL (mg/kg) HR (b) STMR (c) (mg/kg)

| Commodity                        | Region/indoor (a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/source | Calculated MRL (mg/kg) | HR (b) | STMR (c) (mg/kg) |
|----------------------------------|-------------------|------------------------------------------------------------------|-----------------|------------------------|--------|------------------|
| Common millet/proso millet grains | SEU               | --                                                              | No trials available |                        |        |                  |
| Common millet straw              | SEU               | --                                                              | No trials available |                        |        |                  |
| Rice grains                      | SEU               | --                                                              | No trials available |                        |        |                  |
| Rice straw                       | SEU               | --                                                              | No trials available |                        |        |                  |
| Sorghum grains                   | SEU               | --                                                              | No trials available |                        |        |                  |
| Sorghum stover                   | SEU               | --                                                              | No trials available |                        |        |                  |
| Wheat and rye grains             | NEU               | 9 × < 0.02; 0.02                                                  | Trials on wheat grain compliant with GAP (EFSA, 2009a). Extrapolation to rye grain is applicable MRL_{OECD} = 0.02 | 0.04 | 0.02 | 0.02 |
|                                  | SEU               | 10 × < 0.02                                                     | Trials on wheat grain compliant with GAP (EFSA, 2009a). Extrapolation to rye grain is applicable MRL_{OECD} = 0.02 | 0.02 | 0.02 | 0.02 |
| Wheat and rye straw              | NEU               | 4 × < 0.10; 0.1; 0.12; 0.13; 0.14; 0.16; 0.22                   | Trials on wheat straw compliant with GAP (EFSA, 2009a). Extrapolation to rye straw is applicable MRL_{OECD} = 0.28 | 0.3\(^{(f)}\) (tentative) | 0.22 | 0.11 |
|                                  | SEU               | 2 × 0.12; 0.15; 0.17; 0.19; 0.20; 0.21; 2 × 0.22; 0.56         | Trials on wheat straw compliant with GAP (EFSA, 2009a). Extrapolation to rye straw is applicable MRL_{OECD} = 0.72 | 0.8\(^{(f)}\) (tentative) | 0.56 | 0.20 |

**GAP:** Good Agricultural Practice; **OECD:** Organisation for Economic Co-operation and Development; **MRL:** maximum residue level.

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

(b): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

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

(d): Selected value corresponds to higher residue levels observed at a longer PHI.

(e): Tentative MRL derived from a reduced number of trials.

(f): Tentative MRLs are derived for feed commodities in view of the future need to set MRLs in these commodities.
B.1.2.2. Residues in rotational crops

**Overall summary**

Residues in rotational and succeeding crops expected based on confined rotational crop study?

| Residues | Reason |
|----------|--------|
| No       | Based on the results of the rotational confined crop study and considering that cyflufenamid was applied to a bare soil (interception of active substance by the plants is expected in practice), it can be concluded that 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. |

Residues in rotational and succeeding crops expected based on field rotational crop study?

| Residues | Reason |
|----------|--------|
| Not triggered | No study available and not required. |

GAP: Good Agricultural Practice.

B.1.2.3. Processing factors

| Processed commodity | Number of valid studies | Individual values | Median PF | Comment/source |
|---------------------|-------------------------|-------------------|-----------|---------------|
| Melons, peeled       | 6                       | 0.77; 0.84; 0.63; 0.41; 0.63; 0.61 | 0.63      | United Kingdom (2011) |
| Watermelons, peeled  | 5                       | 0.96, 0.63; 0.57; 0.67; 0.61 | 0.63      | United Kingdom (2011) |

PF: processing factor (=Residue level in processed commodity expressed according to RD-Mo/Residue level in raw commodity expressed according to RD-Mo).

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day Median | Maximum | mg/kg DM Median | Maximum | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) | Comments |
|-----------------------------|----------------------------------------------------|---------|-----------------|---------|---------------------------|---------------------------|-------------------------|----------|
| Cattle (all)                | 0.0048                                             | 0.0092  | 0.13            | 0.24    | Cattle (dairy)            | Barley, straw             | Yes                     | –        |
| Cattle (dairy only)         | 0.0048                                             | 0.0092  | 0.13            | 0.24    | Cattle (dairy)            | Barley, straw             | Yes                     | –        |
| Sheep (all)                 | 0.0086                                             | 0.0182  | 0.20            | 0.43    | Sheep (lamb)              | Barley, straw             | Yes                     | –        |
| Sheep (ewe only)            | 0.0067                                             | 0.0143  | 0.20            | 0.43    | Sheep (ram/ewe)           | Barley, straw             | Yes                     | –        |
| Swine (all)                 | 0.0027                                             | 0.0027  | 0.09            | 0.09    | Swine (finishing)         | Wheat, milled by-products | No                      | –        |

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## Relevant groups (subgroups)

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) | Comments |
|-----------------------------|---------------------------------------------|---------------------------|---------------------------|------------------------|----------|
| Poultry (all)               | Median 0.0048  Maximum 0.0076               | Poultry (layer)           | Wheat, straw              | Yes                    | –        |
|                             | Median 0.07  Maximum 0.11                  |                           |                           |                        |          |
| Poultry (layer only)        | Median 0.0048  Maximum 0.0076               | Poultry (layer)           | Wheat, straw              | Yes                    | –        |
|                             | Median 0.07  Maximum 0.11                  |                           |                           |                        |          |

bw: body weight; DM: dry matter.
(a): When one group of livestock includes several subgroups (e.g. poultry ‘all’ including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as ‘mg/kg bw per day’.
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.

## B.2.1. Nature of residues and methods of analysis in livestock

### B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

| Livestock (available studies) | Animal       | Dose (mg/kg bw/d) | Duration (days) | Comment/source                                                                 |
|-------------------------------|--------------|-------------------|-----------------|-------------------------------------------------------------------------------|
|                               | Laying hen   | –                 | –               | No study available (data gap)                                                 |
|                               | Lactating goat | 0.073  0.66    | 5  5            | 4 N compared to the maximum dietary burden calculated for sheep (all diets).
Fluorinated phenyl-U-^1^C-labelled cyflufenamid only (EFSA, 2009a)
37 N compared to the maximum dietary burden calculated for sheep (all diets).
Fluorinated phenyl-U-^1^C-labelled cyflufenamid only (EFSA, 2009a)
Time needed to reach a plateau concentration in milk and eggs (days)
Metabolism in rat and ruminant similar
Can a general residue definition be proposed for animals?
Animal residue definition for monitoring (RD-Mo)
Animal residue definition for risk assessment (RD-RA)
Fat soluble residues
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability period | Compounds covered | Comment/source |
|------------------------------------|--------|-----------|--------|------------------|-------------------|---------------|
|                                    | Bovine | All tissues | –      | –                | –                 | Not available and not required |
|                                    | Bovine | Milk       | –      | –                | –                 | Not available and not required |
|                                    | Poultry| Eggs       | –      | –                | –                 | Not available  |

Milk: 2 days
Yes

Inconclusive
Available study do not allow to conclude (data gap)

Ruminants: Sum of cyflufenamid (Z-isomer), its E-isomer and metabolite 149-F1, expressed as cyflufenamid.
Ruminants: Sum of cyflufenamid (Z-isomer), its E-isomer and metabolite 149-F1, expressed as cyflufenamid.

Yes

Milk, eggs, muscle, fat, liver and kidney (EFSA, 2009b and 2013):
- LC-ESI–MS/MS
- Combined LOQ=0.03 mg/kg for the sum of cyflufenamid (Z-isomer), its E-isomer and metabolite 149-F1. No confirmation simultaneous to primary detection
- ILV available (LC-ESI–MS/MS) (EFSA, 2013)
- QuEChERS-citrate (LC–MS-QToF) for screening in routine analysis (EURL, 2018)

ESI: electrospray ionisation; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LC–MS-QToF: liquid chromatography quadrupole time-of-flight mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method); LOQ: limit of quantification; ILV: independent laboratory validation.

B.2.1.2. Stability of residues in livestock

See table for details.

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B.2.2. Magnitude of residues in livestock

B.2.2.1. Summary of the residue data from livestock feeding studies

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N (mg/kg) | MRL proposal (mg/kg) |
|------------------|---------------------------------------------|-----------------------------|---------------------|
|                  | Mean | Highest | STMR<sup>(a)</sup> | HR<sup>(b)</sup> |
| Cattle (all) – Metabolism study as surrogate of feeding study (0.073 mg/kg bw; 8.1 N rate)<sup>(c)</sup> |      |          |                  |                   |
| Muscle           | n.r. | 0.003    | < 0.03         | < 0.03             | 0.03*             |
| Fat              | n.r. | 0.014    | < 0.03         | < 0.03             | 0.03*             |
| Liver            | n.r. | 0.113    | < 0.03         | < 0.03             | 0.03*             |
| Kidney           | n.r. | 0.015    | < 0.03         | < 0.03             | 0.03*             |
| Cattle (dairy only) – Metabolism study as surrogate of feeding study (0.073 mg/kg bw; 8.1 N rate)<sup>(c)</sup> |      |          |                  |                   |
| Milk             | n.r. | 0.005    | < 0.03         | < 0.03             | 0.03*             |
| Sheep (all)<sup>(d)</sup> – Metabolism study as surrogate of feeding study (0.073 mg/kg bw; 4 N rate)<sup>(c)</sup> |      |          |                  |                   |
| Muscle           | n.r. | 0.003    | < 0.03         | < 0.03             | 0.03*             |
| Fat              | n.r. | 0.014    | < 0.03         | < 0.03             | 0.03*             |
| Liver            | n.r. | 0.113    | < 0.03         | < 0.03             | 0.03*             |
| Kidney           | n.r. | 0.015    | < 0.03         | < 0.03             | 0.03*             |
| Sheep (ewe only)<sup>(d)</sup> – Metabolism study as surrogate of feeding study (0.073 mg/kg bw; 5.2 N rate)<sup>(c)</sup> |      |          |                  |                   |
| Milk             | n.r. | 0.005    | < 0.03         | < 0.03             | 0.03*             |
| Swine (all) – The need for MRL is not triggered for this group of livestock |      |          |                  |                   |
| Muscle           |      |          |                  |                   |
| Fat              |      |          |                  |                   |
| Liver            |      |          |                  |                   |
| Kidney           |      |          |                  |                   |
| Poultry (all) – Data were insufficient to derive MRL for this group of livestock (data gap) |      |          |                  |                   |
| Muscle           |      |          |                  |                   |
| Fat              |      |          |                  |                   |
| Liver            |      |          |                  |                   |
| Poultry (layer only) – Data were insufficient to derive MRL for this group of livestock (data gap) |      |          |                  |                   |
| Eggs             |      |          |                  |                   |

STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level; bw: body weight; n.a.: not applicable; n.r.: not reported.

*: Indicates that the MRL is proposed at the limit of quantification.
(a): Median residues recalculated at the 1N rate for the median dietary burden.
(b): Highest residues recalculated at the 1N rate for the maximum dietary burden.
(c): N dose rate related to the maximum dietary burden.
(d): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock metabolism study on ruminants were relied upon to derive the tentative MRL and risk assessment values in sheep.
### B.3. Consumer risk assessment

| ARfD                 | 0.05 mg/kg bw (EFSA, 2009a) |
|----------------------|-----------------------------|
| Highest IESTI, according to EFSA PRIMo (rev. 2) | Table grapes: 15.7% of ARfD |
| NESTI (% ARfD)       | Not assessed in this review. |
| **Assumptions made for the calculations** | The calculation is based on the highest residue levels expected in raw agricultural commodities |

| ADI                  | 0.04 mg/kg bw per day (EFSA, 2009a) |
|----------------------|------------------------------------|
| TMDI according to EFSA PRIMo | Not assessed in this review. |
| NTMDI, according to (to be specified) | Not assessed in this review. |
| Highest IEDI, according to EFSA PRIMo (rev. 2) | 3.6% ADI (FR toddler) |
| NEDI (% ADI)         | Not assessed in this review. |
| **Assumptions made for the calculations** | The calculation is based on the median residue levels derived for raw agricultural commodities. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation |

**Consumer exposure assessment through drinking water resulting from groundwater metabolite(s) according to European Commission (2003)**

| Metabolite(s)        | Not assessed in this review |
|----------------------|------------------------------|
| ADI (mg/kg bw per day) | Not assessed in this review |
| Intake of groundwater metabolites (% ADI) | Not assessed in this review |

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ARfD: acute reference dose; bw: body weight; NESTI: national estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; IESTI: international estimated short-term intake. 

ADI: acceptable daily intake; bw: body weight; NEDI: national estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; TMDI: theoretical maximum daily intake; NTMDI: national theoretical maximum daily intake.
### B.4. Proposed MRLs

| Code number | Commodity | Existing EU MRL (mg/kg) | Outcome of the review |
|-------------|-----------|-------------------------|-----------------------|
| 130010      | Apples    | 0.05                    | 0.06                  | Recommended<sup>(a)</sup> |
| 130020      | Pears     | 0.05                    | 0.06                  | Recommended<sup>(a)</sup> |
| 130030      | Quinces   | 0.05                    | 0.06                  | Recommended<sup>(a)</sup> |
| 130040      | Medlars   | 0.05                    | 0.06                  | Recommended<sup>(a)</sup> |
| 130050      | Loquats/Japanese medlars | 0.05 | 0.06 | Recommended<sup>(a)</sup> |
| 140010      | Apricots  | 0.06                    | 0.06                  | Recommended<sup>(a)</sup> |
| 140020      | Cherries (sweet) | 0.1  | 0.1   | Recommended<sup>(a)</sup> |
| 140030      | Peaches   | 0.06                    | 0.06                  | Recommended<sup>(a)</sup> |
| 140040      | Plums     | 0.06                    | 0.07                  | Recommended<sup>(a)</sup> |
| 151010      | Table grapes | 0.15  | 0.2    | Recommended<sup>(a)</sup> |
| 151020      | Wine grapes | 0.15  | 0.2    | Recommended<sup>(a)</sup> |
| 152000      | Strawberries | 0.04  | 0.04   | Recommended<sup>(a)</sup> |
| 231010      | Tomatoes  | 0.02*                   | 0.04                  | Recommended<sup>(a)</sup> |
| 231020      | Sweet peppers/bell peppers | 0.04  | 0.06 | Recommended<sup>(a)</sup> |
| 231030      | Aubergines/eggplants | 0.02* | 0.02 | Recommended<sup>(a)</sup> |
| 232010      | Cucumbers | 0.04                    | 0.05                  | Recommended<sup>(a)</sup> |
| 232020      | Gherkins  | 0.08                    | 0.05                  | Recommended<sup>(a)</sup> |
| 232030      | Courgettes| 0.05                    | 0.05                  | Recommended<sup>(a)</sup> |
| 233010      | Melons    | 0.04                    | 0.05                  | Recommended<sup>(a)</sup> |
| 233020      | Pumpkins  | 0.04                    | 0.05                  | Recommended<sup>(a)</sup> |
| 233030      | Watermelons | 0.04  | 0.05   | Recommended<sup>(a)</sup> |
| 270050      | Globe artichokes | 0.03  | 0.04 | Recommended<sup>(a)</sup> |
| 500010      | Barley grains | 0.1   | 0.1    | Recommended<sup>(a)</sup> |
| 500020      | Buckwheat and other pseudo-cereal grains | 0.02* | 0.1    | Recommended<sup>(a)</sup> |
| 500030      | Maize/corn grains | 0.02* | 0.02 | Further consideration needed<sup>(b)</sup> |
| 500040      | Common millet/proso millet grains | 0.02* | 0.02 | Further consideration needed<sup>(b)</sup> |
| 500050      | Oat grains | 0.1   | 0.1    | Recommended<sup>(a)</sup> |
| 500060      | Rice grains | 0.02* | 0.02 | Further consideration needed<sup>(b)</sup> |
| 500070      | Rye grains | 0.05  | 0.04   | Recommended<sup>(a)</sup> |
| 500080      | Sorghum grains | 0.02* | 0.02 | Further consideration needed<sup>(b)</sup> |
| 500090      | Wheat grains | 0.05  | 0.04   | Further consideration needed<sup>(b)</sup> |

**Enforcement residue definition for plants:** sum of cyflufenamid (Z-isomer) and its E-isomer

**Enforcement residue definition for animals (existing):** sum of cyflufenamid (Z-isomer) and its E-isomer

**Enforcement residue definition for animals (proposed):** sum of cyflufenamid (Z-isomer), its E-isomer and metabolite 149-F1, expressed as cyflufenamid

| Code number | Commodity   | Existing EU MRL (mg/kg) | MRL (mg/kg) | Comment                            |
|-------------|-------------|-------------------------|-------------|------------------------------------|
| 1012010     | Bovine muscle | 0.03*                   | 0.03*       | Recommended<sup>(a)</sup>          |
| 1012020     | Bovine fat tissue | 0.03*                   | 0.03*       | Recommended<sup>(a)</sup>          |
| 1012030     | Bovine liver | 0.03*                   | 0.03*       | Recommended<sup>(a)</sup>          |
| 1012040     | Bovine kidney | 0.03*                   | 0.03*       | Recommended<sup>(a)</sup>          |
| 1013010     | Sheep muscle | 0.03*                   | 0.03*       | Recommended<sup>(a)</sup>          |
| 1013020     | Sheep fat tissue | 0.03*                   | 0.03*       | Recommended<sup>(a)</sup>          |
| 1013030     | Sheep liver | 0.03*                   | 0.03*       | Recommended<sup>(a)</sup>          |
| 1013040     | Sheep kidney | 0.03*                   | 0.03*       | Recommended<sup>(a)</sup>          |
| 1014010     | Goat muscle | 0.03*                   | 0.03*       | Recommended<sup>(a)</sup>          |
| Code number | Commodity                  | Existing EU MRL (mg/kg) | Outcome of the review                  |
|-------------|---------------------------|-------------------------|---------------------------------------|
|             |                           | MRL (mg/kg)             | Comment                               |
| 1014020     | Goat fat tissue           | 0.03*                   | Recommended (a)                       |
| 1014030     | Goat liver                | 0.03*                   | Recommended (a)                       |
| 1014040     | Goat kidney               | 0.03*                   | Recommended (a)                       |
| 1015010     | Equine muscle             | 0.03*                   | Recommended (a)                       |
| 1015020     | Equine fat tissue         | 0.03*                   | Recommended (a)                       |
| 1015030     | Equine liver              | 0.03*                   | Recommended (a)                       |
| 1015040     | Equine kidney             | 0.03*                   | Recommended (a)                       |
| 1016010     | Poultry muscle            | 0.03*                   | Further consideration needed (b)      |
| 1016020     | Poultry fat tissue        | 0.03*                   | Further consideration needed (b)      |
| 1016030     | Poultry liver             | 0.03*                   | Further consideration needed (b)      |
| 1020010     | Cattle milk               | 0.03*                   | Recommended (a)                       |
| 1020020     | Sheep milk                | 0.03*                   | Recommended (a)                       |
| 1020030     | Goat milk                 | 0.03*                   | Recommended (a)                       |
| 1020040     | Horse milk                | 0.03*                   | Recommended (a)                       |
| 1030000     | Birds eggs                | 0.03*                   | Further consideration needed (b)      |
|             | Other commodities of plant and/or animal origin | See Reg. (EU) 2017/171 | – Further consideration needed (d) |

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix E).
(b): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination C-I in Appendix E).
(c): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers is identified; no CXL is available (combination E-I in Appendix E).
(d): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).
## Appendix C – Pesticide Residue Intake Model (PRIMo)

### Cyflufenamid

| Status of the active substance: | Approved |
|--------------------------------|----------|
| Code no. | Proposed LOQ |
| LOQ (mg/kg bw): | Proposed LOQ |

### Toxicological end points

| ADI (mg/kg bw per day): | 0.04 |
|------------------------|------|
| ARfD (mg/kg bw): | 0.05 |
| Source of ADI: | EFSA |
| Source of ARfD: | EFSA |
| Year of evaluation: | 2009 |
| Year of evaluation: | 2009 |

### Year of evaluation:

**2009**

### Chronic risk assessment – refined calculations

| TMDI values in % of ADI | Commodity/group of commodities | MS Diet to % of ADI | Commodity/group of commodities | MS Diet to % of ADI | Commodity/group of commodities | MS Diet to % of ADI |
|-------------------------|--------------------------------|---------------------|--------------------------------|---------------------|--------------------------------|---------------------|
| 3.6 FR toddler          | Milk and cream                 | 0.1                 | Wheat                          | 0.1                | Birds’ eggs                    | 0.1                 |
| 3.2 NL child            | Milk and cream                 | 0.1                 | Wheat                          | 0.1                | Birds’ eggs                    | 0.1                 |
| 2.3 FR infant           | Milk and cream                 | 0.2                 | Apples                         | 0.2                | Wheat                          | 0.2                 |
| 2.3 FR infant           | Milk and cream                 | 0.2                 | Apples                         | 0.2                | Wheat                          | 0.2                 |
| 2.0 UK Toddler          | Milk and cream                 | 0.2                 | Wheat                          | 0.1                | Birds’ eggs                    | 0.1                 |
| 1.8 DK child            | Milk and cream                 | 0.3                 | Wheat                          | 0.2                | Rye                            | 0.2                 |
| 1.6 ES child            | Milk and cream                 | 0.2                 | Wheat                          | 0.1                | Birds’ eggs                    | 0.1                 |
| 1.6 WHO Cluster diet B  | Wheat                          | 0.2                 | Milk and cream                 | 0.2                | Tomatoes                       | 0.2                 |
| 1.4 SE general population 90th percentile | Milk and cream | 0.2 | Wheat | 0.1 | Tomatoes | 0.1 |
| 1.1 WHO cluster diet D  | Milk and cream                 | 0.3                 | Wheat                          | 0.1                | Tomatoes                       | 0.1                 |
| 1.0 IE adult            | Milk and cream                 | 0.1                 | Maze                           | 0.1                | Maze                           | 0.1                 |
| 1.0 WHO cluster diet E  | Milk and cream                 | 0.2                 | Wheat                          | 0.1                | Birds’ eggs                    | 0.1                 |
| 0.9 WHO regional European diet | Milk and cream | 0.1 | Wheat | 0.1 | Bovine: Meat | 0.1 |
| 0.9 NL general          | Milk and cream                 | 0.1                 | Wheat                          | 0.1                | Bovine: Meat                    | 0.1                 |
| 0.9 WHO Cluster diet F  | Milk and cream                 | 0.2                 | Wheat                          | 0.1                | Bovine: Meat                    | 0.1                 |
| 0.8 ES adult            | Milk and cream                 | 0.1                 | Wheat                          | 0.1                | Bovine: Meat                    | 0.1                 |
| 0.8 FR all population   | Milk and cream                 | 0.2                 | Milk and cream                 | 0.2                | Wheat                          | 0.2                 |
| 0.8 DK adult            | Milk and cream                 | 0.1                 | Wheat                          | 0.1                | Wine grapes                     | 0.1                 |
| 0.6 LT adult            | Milk and cream                 | 0.1                 | Wheat                          | 0.1                | Apples                         | 0.1                 |
| 0.6 FI adult            | Milk and cream                 | 0.0                 | Wheat                          | 0.0                | Rye                            | 0.0                 |
| 0.6 PT General population | Wheat | 0.2 | Wheat | 0.2 | Thomatoes | 0.2 |
| 0.5 UK vegetarian       | Milk and cream                 | 0.1                 | Wheat                          | 0.1                | Wine grapes                     | 0.1                 |
| 0.5 IT kid/toddler      | Milk and cream                 | 0.1                 | Tomatoes                       | 0.0                | Apples                         | 0.0                 |
| 0.5 UK Adult            | Milk and cream                 | 0.1                 | Wheat                          | 0.1                | Wine grapes                     | 0.1                 |
| 0.4 IT adult            | Milk and cream                 | 0.1                 | Tomatoes                       | 0.0                | Apples                         | 0.0                 |
| 0.2 PL general population | Milk and cream | 0.0 | Wheat | 0.0 | Table grapes | 0.0 |

### Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs 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

The acute risk assessment is based on the ARID.

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 lead to an exposure equivalent to 100% of the ARID.

| No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): |
|------------------------------------------------------------|------------------------------------------------------------|
| Highest % of ARfD/ADI Commodity | pTMRL/threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodity | pTMRL/threshold MRL (mg/kg) |
| 15.7 | Table grapes | 0.12/- | 15.7 | Table grapes | 0.12/- |
| 9.1 | Melons | 0.0299/- | 9.1 | Melons | 0.0299/- |
| 7.5 | Milk and milk products: | 0.03/- | 7.5 | Milk and milk products: | 0.03/- |
| 7.3 | Watermelons | 0.0299/- | 7.3 | Watermelons | 0.0299/- |
| 6.9 | Apples | 0.035/- | 5.1 | Apples | 0.035/- |

### No of critical MRLs (IESTI 1):

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.

### No of critical MRLs (IESTI 2):

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

## Acute risk assessment/adults/general population – refined calculations

Conclusion:

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

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 lead to an exposure equivalent to 100% of the ARID.

| No of commodities for which ARfD/ADI is exceeded: | No of commodities for which ARfD/ADI is exceeded: |
|------------------------------------------------|------------------------------------------------|
| Highest % of ARfD/ADI Processed commodity | pTMRL/threshold MRL (mg/kg) | Highest % of ARfD/ADI Processed commodity | pTMRL/threshold MRL (mg/kg) |
| 7.9 | Grape juice | 0.12/- | 0.9 | Wine | 0.12/- |
| 3.6 | Apple juice | 0.035/- | 0.5 | Apple juice | 0.035/- |
| 1.2 | Pear juice | 0.035/- | 0.2 | Bread/pizza | 0.02/- |
| 1.1 | Peach juice | 0.03/- | 0.1 | Peach preserved with 0.03/- |
| 1.0 | Tomato juice | 0.03/- | 0.1 | Tomato (preserved) 0.03/- |

### No of critical MRLs (IESTI 1):

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.

### No of critical MRLs (IESTI 2):

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

**Footnotes:**

1. *) The results of the IESTI calculations are reported for at least 5 commodities. If the ARID is exceeded for more than 5 commodities, all IESTI values > 90% of ARD are reported.
2. **) pTMRL: provisional temporary MRL.
3. ***) pTMRL: provisional temporary MRL for unprocessed commodity.

### Conclusion:

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 D – Input values for the exposure calculations

#### D.1. Livestock dietary burden calculations

| Feed commodity                  | Median dietary burden | Maximum dietary burden |
|---------------------------------|-----------------------|------------------------|
|                                 | Input value (mg/kg)   | Comment                | Input value (mg/kg) | Comment |
| Apple, pomace, wet              | 0.08                  | STMR × default PF (5)(a) | 0.08 | STMR × default PF (5)(a) |
| Barley, grain                   | 0.02                  | STMR                   | 0.02 | STMR |
| Brewer’s grain, dried           | 0.07                  | STMR × default PF (3.3)(a) | 0.07 | STMR × default PF (3.3)(a) |
| Oat, grain                      | 0.02                  | STMR                   | 0.02 | STMR |
| Rye, grain                      | 0.02                  | STMR                   | 0.02 | STMR |
| Triticale, grain                | 0.02                  | STMR                   | 0.02 | STMR |
| Wheat, grain                    | 0.02                  | STMR                   | 0.02 | STMR |
| Wheat, distiller’s grain (dry)  | 0.07                  | STMR × default PF (3.3)(a) | 0.07 | STMR × default PF (3.3)(a) |
| Wheat gluten, meal              | 0.04                  | STMR × default PF (1.8)(a) | 0.04 | STMR × default PF (1.8)(a) |
| Wheat, milled by-products       | 0.14                  | STMR × default PF (7)(a) | 0.14 | STMR × default PF (7)(a) |
| Barley, straw                   | 0.21                  | STMR                   | 0.54 | HR |
| Oat, straw                      | 0.21                  | STMR                   | 0.54 | HR |
| Rye, straw                      | 0.20                  | STMR                   | 0.56 | HR |
| Triticale, straw                | 0.20                  | STMR                   | 0.56 | HR |
| Wheat, straw                    | 0.20                  | STMR                   | 0.56 | HR |

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

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.

(a): In the absence of processing factors supported by data, default the processing factor of was included in the calculation to consider the potential concentration of residues in these commodities.

#### D.2. Consumer risk assessment

| Commodity            | Chronic risk assessment | Acute risk assessment |
|----------------------|-------------------------|-----------------------|
|                      | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment |
| Pome fruits          | 0.02                    | STMR                  | 0.04 | HR |
| Apricots and peaches | 0.02                    | STMR                  | 0.03 | HR |
| Cherries (sweet)     | 0.04                    | STMR                  | 0.05 | HR |
| Plums                | 0.02                    | STMR                  | 0.03 | HR |
| Table and wine grapes| 0.03                    | STMR                  | 0.12 | HR |
| Strawberries         | 0.02                    | STMR                  | 0.03 | HR |
| Tomatoes             | 0.02                    | STMR                  | 0.03 | HR |
| Sweet peppers/bell peppers | 0.02 | STMR | 0.03 | HR |
| Aubergines/eggplants | 0.02                    | STMR                  | 0.02 | HR |
| Cucumbers, gherkins and courgettes | 0.02 | STMR | 0.04 | HR |
| Melons and pumpkins  | 0.02                    | STMR                  | 0.03 | HR |
| Watermelons          | 0.02                    | STMR                  | 0.03 | HR |
| Globe artichokes     | 0.02                    | STMR                  | 0.02 | HR |

**Risk assessment residue definition for plant commodities:** sum of cyflufenamid (Z-isomer) and its E-isomer.
| Commodity                                                                 | Chronic risk assessment | Acute risk assessment |
|---------------------------------------------------------------------------|-------------------------|-----------------------|
| Barley, oat grains, buckwheat and other pseudo-cereal grains             | 0.02 STMR               | 0.07 HR               |
| Maize/corn grains                                                        | 0.02 EU MRL             | 0.02 EU MRL           |
| Common millet/proso millet grains                                        | 0.02 EU MRL             | 0.02 EU MRL           |
| Rice grains                                                               | 0.02 EU MRL             | 0.02 EU MRL           |
| Sorghum grains                                                            | 0.02 EU MRL             | 0.02 EU MRL           |
| Wheat and rye grains                                                      | 0.02 STMR               | 0.02 HR               |

**Risk assessment residue definition for animal commodities**: Sum of cyflufenamid (Z-isomer), its E-isomer and metabolite 149-F1, expressed as cyflufenamid.

| Commodity                          | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
|------------------------------------|---------------------|---------|---------------------|---------|
| Bovine and equine meat            | 0.03*               | STMR    | 0.03*               | 0.8 × HR muscle + 0.2 × HR fat |
| Bovine and equine fat             | 0.03*               | STMR    | 0.03*               | HR      |
| Bovine and equine liver           | 0.03*               | STMR    | 0.03*               | HR      |
| Bovine and equine kidney          | 0.03*               | STMR    | 0.03*               | HR      |
| Sheep and goat meat               | 0.03*               | STMR    | 0.03*               | 0.8 × HR muscle + 0.2 × HR fat |
| Sheep and goat fat                | 0.03*               | STMR    | 0.03*               | HR      |
| Sheep and goat liver              | 0.03*               | STMR    | 0.03*               | HR      |
| Sheep and goat kidney             | 0.03*               | STMR    | 0.03*               | HR      |
| Poultry meat                       | 0.03*               | EU MRL  | 0.03*               | EU MRL  |
| Poultry fat                        | 0.03*               | EU MRL  | 0.03*               | EU MRL  |
| Poultry liver                      | 0.03*               | EU MRL  | 0.03*               | EU MRL  |
| Cattle and horse milk             | 0.03*               | STMR    | 0.03*               | HR      |
| Sheep and goat milk               | 0.03*               | STMR    | 0.03*               | HR      |
| Birds eggs                         | 0.03*               | EU MRL  | 0.03*               | EU MRL  |

STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level.

*: Indicates that the input value is proposed at the limit of quantification.
Appendix E – Decision tree for deriving MRL recommendations

**Evaluation of the GAPs and available residues data at EU level**

- GAP of D8 > 0.1 mg/kg DM in EU?
  - Yes
  - MRL derived in Section 3?
    - Yes
    - MRL fully supported by data?
      - Yes
      - MRL is recommended.
      - No
      - MRL is not considered for the RA.
    - No
    - Risk identified?
      - Yes
      - Fall-back MRL available?
        - Yes
        - MRL is recommended.
        - No
        - MRL is not considered for the RA.
      - No
      - Not considered for the RA.
  - No
  - MRL derived in Section 3?
    - Yes
    - MRL fully supported by data?
      - Yes
      - MRL is recommended.
      - No
      - MRL is not considered for the RA.
    - No
    - Risk identified?
      - Yes
      - Fall-back MRL available?
        - Yes
        - MRL is recommended.
        - No
        - MRL is not considered for the RA.
      - No
      - Not considered for the RA.

**Consumer risk assessment for GAPs evaluated at EU level – EU scenarios**

- Not considered for the RA.
- Current EU MRL is included in the RA.
- Tentative median/highest values are included in the RA.
- Median/highest values are included in the RA.
- Risk identified?
  - Yes
    - Fall-back MRL available?
      - Yes
      - MRL is recommended.
      - No
      - Not considered for the RA.
    - No
      - Not considered for the RA.
  - No
    - Not considered for the RA.

**Recommendations resulting from EU authorisations and import tolerances**

- (A) Specific LOQ or default MRL?
- (B) Specific LOQ or default MRL?
- (C) Maintain current EU MRL?
- (D) Specific LOQ or default MRL?
- (E) Establish tentative EU MRL?
- (F) Specific LOQ or default MRL?
- (G) MRL is recommended.

Comparison with CXLs
## Appendix F – 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-[(cyclopropylmethoxyiminoo)-2,3-difluoro-6-(trifluoromethyl)benzyl]-2-phenylacetamide | ![Structural formula for Cyflufenamid 149-(Z)-FB](https://example.com/cyflufenamid_149_Z_FB.png) |
|                              | FC(F)(F)c1ccc(F)c(C)(\=O)C1ccc1c1ccc1c1cc1-N\ OCC1CC1 | |
|                              | ACMXQHFNODYQAT-TWGOAJXNA-N                       | ![Structural formula for Cyflufenamid 149-(Z)-FB](https://example.com/cyflufenamid_149_Z_FB.png) |
| 149-(E)-FB                   | (E)-N-[(cyclopropylmethoxyiminoo)-2,3-difluoro-6-(trifluoromethyl)benzyl]-2-phenylacetamide | ![Structural formula for Cyflufenamid 149-(E)-FB](https://example.com/cyflufenamid_149_E_FB.png) |
|                              | FC(F)(F)c1ccc(F)c1C(\=O)C1ccc1c1ccc1c1cc1-N\ OCC1CC1 | |
|                              | ACMXQHFNODYQAT-UHFFFAOYSA-N                     | ![Structural formula for Cyflufenamid 149-(E)-FB](https://example.com/cyflufenamid_149_E_FB.png) |
| 149-F-α-OH-B                 | (2RS)-N-[(cyclopropylmethoxyiminoo)[2,3-difluoro-6-(trifluoromethyl)phenyl]methyl]-2-hydroxy-2-phenylacetamide | ![Structural formula for Cyflufenamid 149-F-α-OH-B](https://example.com/cyflufenamid_149_F_alpha_OH_B.png) |
|                              | FC(F)(F)c1ccc(F)c1C(\=O)C(O)c1ccc1c1ccc1c1cc1-N\ OCC1CC1 | |
|                              | LDHBGNVGBDQQB-UHFFFAOYSA-N                     | ![Structural formula for Cyflufenamid 149-F-α-OH-B](https://example.com/cyflufenamid_149_F_alpha_OH_B.png) |
| 149-F-2-OH-B                 | N-[(Z)-[(cyclopropylmethoxyiminoo)[2,3-difluoro-6-(trifluoromethyl)phenyl]methyl]-2-(2-hydroxyphenyl) acetamide | ![Structural formula for Cyflufenamid 149-F-2-OH-B](https://example.com/cyflufenamid_149_F_2_OH_B.png) |
|                              | FC(F)(F)c1ccc(F)c1C(\=O)C1(cc1)cc1-N\ OCC1CC1 | |
|                              | ASPKDUOKRHTRE-UHFFFAOYSA-N                     | ![Structural formula for Cyflufenamid 149-F-2-OH-B](https://example.com/cyflufenamid_149_F_2_OH_B.png) |
| 149-F-4-OH-B                 | N-[(Z)-[(cyclopropylmethoxyiminoo)[2,3-difluoro-6-(trifluoromethyl)phenyl]methyl]-2-(4-hydroxyphenyl) acetamide | ![Structural formula for Cyflufenamid 149-F-4-OH-B](https://example.com/cyflufenamid_149_F_4_OH_B.png) |
|                              | FC(F)(F)c1ccc(F)c1C(\=O)C1(O)C(c1ccc1cc1)-N\ OCC1CC1 | |
|                              | UGYDAQRGWGVUNH-UHFFFAOYSA-N                    | ![Structural formula for Cyflufenamid 149-F-4-OH-B](https://example.com/cyflufenamid_149_F_4_OH_B.png) |

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<sup>(a)</sup> Code/trivial name

<sup>(b)</sup> IUPAC name/SMILES notation/InChiKey

<sup>(c)</sup> Structural formula
| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-------------------------|-----------------------------------------------|----------------------------------|
| 149-F                  | \(N'\)-(cyclopropylmethoxy)-2,3-difluoro-6-\(\text{tri}-\text{fluoro}-\text{methyl})\)benzene-1-carboximidamide <br> \(N/\text{C}\{=\text{N}\}\text{OCC1CC1}c1c(c(cc(c1F)c1F)C(F)F \text{GATGRGDKTXMNK-UHFFFAOYSA-N} \) | ![Structural formula for 149-F](image) |
| 149-F4B-Glu           | 1-O-\((Z)-[\text{2,3-difluoro-6-}(\text{tri}-\text{fluoro}-\text{methyl})\)phenyl][2-phenylacetamido)methylidene\)-amino-o-glucopyranose <br> \(\text{FC(F)}(\text{F})\text{c1ccc(c(F)}(\text{F})\text{c1C}(=\text{N})\text{OCC10(C[@H][CO]})[\text{C[[@H][O][C[[@H][O][C[[@H][O][C[[@H][O]}[C[[@H][O]}[C[[@H][O]}[C[[@H][O]}\text{NC}(=\text{O})\text{C1cccc1} \text{XTGJAPBYZAGYQV-CFVPOCXSA-N} \) | ![Structural formula for 149-F4B-Glu](image) |
| 149-F-4-OH-B-Glu     | \(N'\)-(\text{Z})-\{(\text{cyclopropylmethoxy})\text{imino}]\text{[2,3-difluoro-6-}(\text{tri}-\text{fluoro}-\text{methyl})\)phenyl\}-\text{2-[4-\text{o-glucopyranosyl}oxy]phenyl}acetamide <br> \(\text{FC(F)}(\text{F})\text{c1ccc(F)}c(F)c1C(=\text{N})\text{OCC10(C[[@H][CO][C[[@H][O][C[[@H][O][C[[@H][O][C[[@H][O]}[C[[@H][O]}\text{NC}(=\text{O})\text{C1cccc1} \text{RAFWPYBEVSIFJC-ZVWDNCMFSAN} \) | ![Structural formula for 149-F-4-OH-B-Glu](image) |
| 149-F1                | 2,3-difluoro-6-(\text{tri}-\text{fluoro}-\text{methyl})\)benzene-1-carboximidamide <br> \(\text{Fc1c(C}(=\text{N})\text{N)c}(ccc1F)\text{C(F)}(\text{F})\text{F} \text{JYSBNJJWTHMPOC-UHFFFAOYSA-N} \) | ![Structural formula for 149-F1](image) |
| 149-F6                | 2,3-difluoro-6-(\text{tri}-\text{fluoro}-\text{methyl})\)benzamide <br> \(\text{Fc1c(C(N)=O}c(ccc1F)\text{C(F)}(\text{F})\text{F} \text{GGCPJJFCTISPMQ-UHFFFAOYSA-N} \) | ![Structural formula for 149-F6](image) |
| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-------------------------------|-----------------------------------------------|---------------------------------|
| 149-F11                       | 3-(((Z)-[[((cyclopropylmethoxy)imino][2,3-difluoro-6-( trifluoromethyl)phenyl]methyl) amino)-3-oxopropanoic acid FC(F)(F)c1ccc(F)c(F)c1C(\NC(=O)CC(=O)O)=N | ![Structural formula](image) |
|                               | FC(F)(F)c1ccc(F)c(F)c1C(\NC(=O)CC(=O)O)=N | WPVGLSIJMFFSGB-UHFFFAOYSA-N     |

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

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).
(c): ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).