Modification of the existing maximum residue levels for cyflumetofen in various crops

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Abstract
In accordance with Article 6 of Regulation (EC) No 396/2005, the applicants BASF Agro B.V. (represented by OAT Agrio Co. Ltd.) and Certis Europe B.V. submitted separate requests to the competent national authority in the Netherlands to modify the existing maximum residue levels (MRLs) for the active substance cyflumetofen in various crops. The data submitted in support of the requests were found to be sufficient to derive MRL proposals for citrus fruits, apricots, peaches, tomatoes, aubergines, cucumbers and hops. Adequate analytical methods for enforcement are available to control the residues of cyflumetofen on the fruit commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg and on hops at the LOQ of 0.1 mg/kg. Based on the risk assessment results, EFSA concluded that the long-term intake of residues resulting from the use of cyflumetofen according to the reported agricultural practices is unlikely to present a risk to consumer health.

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, BASF Agro B.V. (represented by OAT Agrio Co. Ltd.) submitted an application to the competent national authority in the Netherlands (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance cyflumetofen in various crops. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 2 August 2016. To accommodate for the intended European Union (EU) uses of cyflumetofen, the EMS proposed to raise the existing MRLs from 0.3 to 0.5 mg/kg for citrus fruits and 0.4 mg/kg for tomatoes and to set MRLs of 0.3 mg/kg for apricots and peaches, 0.4 for aubergines and 30 mg/kg for hops. EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps or points which needed further clarification, which were requested from the EMS. On 20 August 2020 and 25 November 2020, the EMS submitted the requested information in revised versions of the evaluation report (Netherlands, 2016), which replaced the previously submitted evaluation report.

Moreover, in accordance with Article 6 of Regulation (EC) No 396/2005, Certis Europe B.V. submitted an application to the competent national authority in the Netherlands (EMS) to modify the existing MRL for the active substance cyflumetofen in cucumbers. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 11 September 2020. To accommodate for the intended indoor uses of cyflumetofen, the EMS proposed to set an MRL of 0.5 mg/kg for cucumbers. EFSA identified points which needed further clarification, which were requested from the EMS. EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. On 25 November 2020, the EMS submitted the requested clarifications in a revised evaluation report (Netherlands, 2020), which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional data provided by the EMS in the framework of these applications, the following conclusions are derived.

The metabolism of cyflumetofen following foliar application was investigated in crops belonging to the group of fruit crops. Studies investigating the effect of processing on the nature of cyflumetofen (hydrolysis studies) demonstrated that the active substance remained stable under pasteurisation, partially degraded under cooking/boiling/baking and almost completely degraded under sterilisation conditions into metabolites B-1, AB-1 and A-2. In rotational crops, cyflumetofen was not found and the major residue identified in rotated crops was trifluoroacetic acid (TFA), which is considered as toxicologically relevant and occurs in plants after the use of other pesticides as well.

Based on the metabolic pattern identified in metabolism studies, the toxicological significance of metabolites and the capability of enforcement analytical methods, the residue definition for enforcement as ‘cyflumetofen (sum of isomers)’ and the provisional residue definition for risk assessment as ‘sum of cyflumetofen (sum of isomers) and B-1, expressed as cyflumetofen’ was set for fruit crops during the EU pesticides peer review. The current enforcement residue definition in Regulation (EC) No 396/2005 is comparable, missing only detail on the sum of isomers. These residue definitions are restricted to primary fruit crops and applicable to the intended uses on fruit crops. For the intended use on hops (representing leafy crop group), EFSA agreed with the EMS proposal to apply the same residue definitions as proposed for fruits crops considering the results of metabolism in the fruit leaves.

The toxicological relevance of processing degradation products AB-1 and A-2 has been assessed in the framework of one of these applications. The data indicated that the toxicity of AB-1 is covered by the parent compound, whereas A-2 was considered as unlikely to be genotoxic in vitro but with a chronic toxicity qualitatively different than the parent compound. Based on the results of an oral chronic toxicity study in rats with A-2 and applying an uncertainty factor of 1,800, a specific acceptable daily intake (ADI) of 0.0036 mg/kg body weight (bw) per day was set.

Based on the toxicity assessment, the EMS proposed to apply in processed commodities the same residue definitions as for primary crops, because the sum of cyflumetofen and metabolite B-1 in the commodities prior to processing was never lower than the sum of cyflumetofen and the metabolites observed in products which undergo heat treatment. EFSA is of the opinion that the residue definition for processed products should be established in the context of Article 12 of Regulation (EC) No 396/2005, where a comprehensive assessment of all authorised uses of cyflumetofen is performed and Member States are consulted.
Sufficiency validated analytical methods are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in the fruit crops assessed and at or above 0.1 mg/kg in hops (LOQ).

The available residue trials are sufficient to derive MRL proposals for citrus fruits, apricots, peaches, tomatoes, aubergines, cucumbers and hops.

Several studies investigating the magnitude of cyflumetofen residues in processed commodities of oranges, apples, peaches, strawberries, tomatoes and hops were provided. Overall, a dilution of residues was observed in processed products such as juice, canned fruits, marmalade/jam, syrup, beer, whereas concentration occurred in fruit pomace, oils, extracts and dried products. Pending a final decision on the residue definition for enforcement, the derived processing factors are not proposed for inclusion in Annex VI of Regulation (EC) No 396/2005. It is noted that the samples of processed products were not analysed for all the degradation products observed in the standard hydrolysis studies. However, considering that the total theoretical maximum daily intake (TMDI) for cyflumetofen is below 10% of the ADI, further studies are not deemed to be necessary. The peeling factor of 0.17 was derived from the residue trials on citrus fruits.

The occurrence of cyflumetofen residues in rotational crops was investigated in the framework of the current assessment. Based on the available information on the nature and magnitude of residues, EFSA concluded that residues of cyflumetofen are not likely to occur in rotational/succeeding crops provided that the active substance is used according to the intended Good Agricultural Practice (GAP). It is, however, noted that significant residues of TFA in rotational crops cannot be excluded after the use of cyflumetofen and other active substances containing a trifluoromethyl moiety. Although not specific to cyflumetofen metabolism, this compound accumulates in soil, therefore Member States should consider the need to set specific risk mitigation measures to avoid the presence of TFA in rotational crops.

As the by-product citrus dried pulp is used as feed product, a potential carry-over into food of animal origin was assessed. Since the calculated dietary burdens for the relevant groups of livestock were found to be below the trigger value of 0.1 mg/kg dry matter (DM), further investigation of the nature and magnitude of residues as well as the modification of the existing MRLs in products of animal origin is not necessary.

The toxicological profile of cyflumetofen was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.17 mg/kg bw per day. An acute reference dose (ARfD) was deemed unnecessary. The toxicological reference values of the parent cyflumetofen are applicable to the metabolite B-1, which is included in the provisional residue definition for risk assessment of fruit crops.

The consumer risk assessments were performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The short-term exposure was not conducted as the setting of an ARfD was considered unnecessary. The chronic exposure for cyflumetofen was calculated using the median residue levels according to risk assessment for the crops under consideration and for the Codex residue limit (CXL) implemented in the EU legislation. The default MRL value of 0.05 mg/kg was used for honey. The crops for which no MRL was set in the legislation were excluded from the calculation. No long-term consumer intake concern was identified for any of the European diets incorporated in the EFSA PRIMo. The total chronic intake accounted for a maximum of 2% of the ADI (NL toddler diet); the contribution of the residues in the evaluated crops accounted for maximum of 0.27% of ADI (tomatoes).

A toxicological reference value (ADI) has been set for TFA in a previous EFSA conclusion and a risk assessment regarding the overall exposure to metabolite TFA from different sources was performed in a previous EFSA opinion. EFSA updated these calculations taking into consideration the contribution of TFA measured in the rotational crop metabolism studies conducted with cyflumetofen and using PRIMo 3.1 consumption data. Due to the lack of reliable information on TFA concentrations in rotated crops after the use of cyflumetofen according to the intended GAPs, the calculations are indicative and affected by uncertainties. Nevertheless, a consumer concern was not identified. The total chronic intake accounted for a maximum of 9% of the ADI (NL toddler diet). The short-term exposure for TFA was not conducted as no ARfD was set for this metabolite.

EFSA concluded that the proposed use of cyflumetofen on the crops under evaluation will not result in a consumer exposure exceeding the toxicological reference values of cyflumetofen and therefore is unlikely to pose a risk to consumers' health. The indicative dietary exposure assessment indicated that the potential contribution of TFA residues expected in crops grown in rotation after the use of cyflumetofen on the relevant crops under assessment to the overall TFA exposure is low.
The review of the existing MRLs in accordance with Article 12 of Regulation (EC) No 396/2005 is not yet finalised, and therefore, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the MRL review.

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

| Code\(^{(a)}\) | Commodity            | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|-------------|----------------------|------------------------|-------------------------|---------------------------------------------------------------------------------------|
| 0110000     | Citrus fruits        | 0.3                    | 0.5                     | The submitted data on oranges, lemons, and mandarins are sufficient to derive an MRL proposal by extrapolation for the SEU use on citrus fruits. Risk for consumers unlikely |
| 0140010     | Apricots             | –                      | 0.3                     | The submitted data on apricots and peaches are sufficient to derive an MRL proposal by extrapolation for the SEU use on apricots. Risk for consumers unlikely |
| 0140030     | Peaches              | –                      | 0.3                     | The submitted data on apricots and peaches are sufficient to derive an MRL proposal by extrapolation for the SEU use on peaches. Risk for consumers unlikely |
| 0231010     | Tomatoes             | 0.3                    | 0.4                     | The submitted data on tomatoes are sufficient to derive an MRL proposal for both the SEU and indoor uses. The MRL proposal reflects the more critical residue situation of the indoor use. Risk for consumers unlikely |
| 0231030     | Aubergines/eggplants | –                      | 0.4                     | The submitted data on tomatoes are sufficient to derive MRL proposals by extrapolation for both the SEU and indoor uses on aubergines. The MRL proposal reflects the more critical residue situation of the indoor use. Risk for consumers unlikely |
| 0232010     | Cucumbers            | –                      | 0.4                     | The submitted data on cucumbers are sufficient to derive an MRL proposal for the SEU use. Risk for consumers unlikely |
| 0700000     | Hops                 | –                      | 30                      | The submitted data on hops are sufficient to derive an MRL proposal for the NEU use. Risk for consumers unlikely |

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

\(^{(a)}\): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
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Assessment

The European Food Safety Authority (EFSA) received two separate applications to modify the existing maximum residue levels (MRLs) for cyflumetofen in various crops. The detailed description of the intended European Union (EU) uses of cyflumetofen, which are the basis for these MRL applications, is reported in Appendix A.

Cyflumetofen is the ISO common name for 2-methoxyethyl 2-(4-tert-butylphenyl)-2-cyano-3-oxo-3-[2-( trifluoromethyl)benzamido]propanoate (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Cyflumetofen was evaluated in the framework of Council Directive 91/414/EEC1 with the Netherlands designated as rapporteur Member State (RMS) for the representative uses as an acaricide on ornamental crops, nursery trees, perennial ornamentals and public greens. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (2012). Cyflumetofen was approved2 for the use as an acaricide on 1 June 2013, with conditions for approval of plant protection products introduced in 20193 following the assessment of the confirmatory data (EFSA, 2016).

The renewal of approval of the active substance in accordance with Regulation (EC) No 1107/2009 is ongoing and therefore the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the renewal.

The EU MRLs for cyflumetofen are established in Annex III of Regulation (EC) No 396/2005. They represent the Codex MRLs implemented in the EU MRL legislation (FAO, 2014; EFSA, 2015a). The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has not yet been completed.

In accordance with Article 6 of Regulation (EC) No 396/2005, BASF Agro B.V. (represented by OAT Agrio Co. Ltd.) submitted an application to the competent national authority in the Netherlands (evaluating Member State, EMS) to modify the existing MRLs for the active substance cyflumetofen in citrus fruits, apricots, peaches, tomatoes, aubergines and hops. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 2 August 2016. To accommodate for the intended uses of cyflumetofen, the EMS proposed to raise the existing MRLs from 0.3 to 0.5 mg/kg for citrus fruits and 0.4 mg/kg for tomatoes and to set MRLs of 0.3 mg/kg for apricots and peaches (including nectarines), 0.4 mg/kg for aubergines and 30 mg/kg for hops. Since, according to the EMS, the intended uses on pome fruits and strawberries do not trigger a change of the existing MRLs, they were not further considered in this opinion. EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps or points which needed further clarification, which were requested from the EMS. On 20 August 2020 and 25 November 2020, the EMS submitted the requested information in revised versions of the evaluation report (Netherlands, 2016), which replaced the previously submitted evaluation report.

Moreover, in accordance with Article 6 of Regulation (EC) No 396/2005, Certis Europe B.V. submitted an application to the competent national authority in the Netherlands (EMS) to modify the existing MRL for the active substance cyflumetofen in cucumbers. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 11 September 2020. To accommodate for the intended EU indoor uses of cyflumetofen, the EMS proposed to set an MRL of 0.5 mg/kg for cucumbers. EFSA identified points which needed further clarification, which were requested from the EMS. EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. On 25 November 2020, the EMS submitted the requested clarification in a revised evaluation report (Netherlands, 2020), which replaced the previously submitted evaluation report.

For reasons of efficiency, EFSA assessed both MRL requests in one reasoned opinion. EFSA based its assessment on the evaluation reports submitted by the EMS (Netherlands, 2016, 2020), the draft assessment report (DAR) and its addendum (Netherlands, 2010, 2011) prepared under Council Directive 91/414/EEC, the Commission review report on cyflumetofen (European Commission, 2019),

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1 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
2 Commission Implementing Regulation (EU) No 22/2013 of 15 January 2013 approving the active substance cyflumetofen, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 11, 16.1.2013, p. 8–11.
3 Specific provision introduced in the implementing regulation: ‘Plant protection products containing cyflumetofen shall only be authorised for uses where the level of metabolite B-3 in groundwater is expected to be below 0.1 µg/L.’
the conclusions on the peer review of the pesticide risk assessment of the active substance cyflumetofen and on its confirmatory data (EFSA, 2012, 2016) and the scientific report prepared in support to the assessment of the Codex residue limits (CXLs) (EFSA, 2015a).

For these applications, the data requirements established in Regulation (EU) No 544/2011\(^4\) and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011\(^5\).

As the review of the existing MRLs under Article 12 of Regulation (EC) No 396/2005 is not yet finalised, the conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the MRL review.

A selected list of end points of the studies assessed by EFSA in the framework of these MRL applications, including the end points of relevant studies assessed previously, is presented in Appendix B.

The evaluation reports submitted by the EMS (Netherlands, 2016, 2020) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. **Mammalian toxicity**

   The toxicological assessment of cyflumetofen was peer reviewed by EFSA (2012). Its toxicological reference values are summarised in Appendix B.1.

   In the framework of one of the two applications, additional data were provided for metabolites AB-6, A-2 and AB-1 (Netherlands, 2016). The following assessment considered both the additional data and studies available during the peer review (EFSA, 2012).

   Metabolite AB-6 is not a major rat metabolite. It is considered unlikely to be genotoxic in vitro. Regarding the general toxicity, AB-6 is of low acute oral toxicity to rats but additional studies were not provided. Therefore, no conclusion can be drawn on general toxicity of metabolite AB-6.

   Metabolite A-2 is not a major rat metabolite. It is considered unlikely to be genotoxic in vitro. For the general toxicity, based on 28-day oral studies in rat, metabolite A-2 is considered qualitatively different than the parent compound and therefore in the framework of the current assessment, specific reference values are set, i.e. acceptable daily intake (ADI) of 0.0036 mg/kg body weight (bw) per day was derived from a 28-day study in rats (with an additional uncertainty factor of 6 for the extrapolation to chronic exposure and an additional uncertainty factor of 3 for uncertainties for reproductive toxicity) based on a no observed adverse effect level (NOAEL) of 6.5 mg/kg bw per day for findings in liver and testes. An acute reference dose (ARfD) was not set and not considered necessary.

   Metabolite AB-1 can be considered a major rat metabolite and therefore covered by the toxicological reference values of the parent compound.

   The toxicological profile of plant metabolite B-1 (included in the risk assessment residue definition in fruits crops) was assessed in the framework of the EU pesticides peer review (EFSA, 2012). It was concluded that the toxicological reference values set for the parent are also applicable to metabolite B-1.

   The toxicological profile of the common metabolite trifluoroacetic acid (TFA) was peer reviewed by EFSA (2017). Its toxicological reference values are summarised in Appendix B.1.

2. **Residues in plants**

   2.1. **Nature of residues and methods of analysis in plants**

   2.1.1. **Nature of residues in primary crops**

   The metabolism of cyflumetofen in primary crops was investigated in fruit crops following a foliar application in the framework of the EU pesticides peer review (EFSA, 2012).

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\(^4\) Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

\(^5\) Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
The major part of the radioactive residues remained on the surface of the fruits and on the leaves and was easily removed by solvent rinses. Cyflumetofen metabolism was limited and the active substance was the predominant residue on fruits (67% to 44% total radioactive residue (TRR)) and leaves (87% to 81% TRR). Several metabolites were recovered, none exceeding 10% TRR, except the metabolite B-1 (free and conjugated). In eggplant fruits, B-1 was at similar levels and proportions as cyflumetofen. The EU pesticides peer review concluded that in fruit crops the relevant compounds for the risk assessment are parent cyflumetofen and its metabolite B-1, considering that B-1 (free and conjugated) was detected in eggplant fruit at similar levels and proportions as cyflumetofen (EFSA, 2012).

For the intended use on hops (representing leafy crop group), a metabolism study in leafy crops is not available and would in principle be required. EFSA agreed with the proposal of the EMS to consider the results of the metabolism studies in mandarins, apples and, in particular, in eggplants. The metabolism of cyflumetofen has been elucidated in leaves of these crops and the results could be used to reflect the possible metabolic pattern in hops. The metabolic pattern identified in eggplant leaves (at preharvest interval (PHI) 14 days relevant for hops) was qualitatively comparable with the metabolic pattern in the fruits, but quantitatively different: the metabolite AB-6 exceeded the 10% TRR (butylphenyl-label study) in leaves. This metabolite was also found in the samples from the residue trials on hops (up to 0.26 mg/kg), thus giving an indication that metabolism data in eggplant leaves could be used to address the metabolism of cyflumetofen in hops. The new toxicity studies provided under the current assessment (see Section 1) indicated that metabolite AB-6 is of no genotoxic concern in vitro, but they were insufficient to conclude on the general toxicity of this compound. The relevance of the metabolite AB-6 shall be considered when setting the risk assessment residue definition for cyflumetofen in leafy crops based on the results of specific metabolism studies in a representative crop of this crop group.

It was noted that in the metabolism studies, the possible changes in the stereochemistry of the active substance was not investigated and a data gap was identified by EFSA (2012).

For the crops under assessment, EFSA concluded that the metabolic behaviour is addressed.

2.1.2. Nature of residues in rotational crops

According to the soil degradation studies evaluated in the framework of the peer review, accumulation in soil of cyflumetofen is not expected. The DT$_{50}$ value for cyflumetofen and its main soil metabolites B-1, AB-1 and B-3 in laboratory studies is almost below the trigger value of 100 days in different types of soils (EFSA, 2012). Nonetheless, a confined rotational crop metabolism study with the active substance applied once at 400 g/ha to bare soil (1N the critical seasonal intended application rate on the annual crops under consideration) was assessed by the EMS (Netherlands, 2016, 2020). The only relevant metabolite formed in rotational crops (lettuces, radishes, wheat) was TFA, which was not identified in primary crop metabolism in fruit crops. Highest residues were observed in radish tops (0.16 mg eq/kg, PBI 30 days) and wheat chaff (1.61 mg eq/kg, PBI 30 days). TFA is very persistent in soil (DT$_{50}$ > 1,000 days (EFSA, 2017)) and is a common plant/soil metabolite to other active substances.

For the proposed uses assessed in these applications, no further information is required.

2.1.3. Nature of residues in processed commodities

The effect of processing on the nature of cyflumetofen under standard hydrolytic conditions representing pasteurisation, boiling/baking/brewing and sterilisation was assessed by the EMS in the framework of one of these two applications (Netherlands, 2016). These studies showed that cyflumetofen remained stable under pasteurisation, degraded partially under cooking/boiling/baking and almost completely under sterilisation conditions into metabolites B-1, AB-1 and A-2. Under standard boiling/baking/brewing conditions (60 min, 100°C, pH 5) and under sterilisation conditions (20 min, 120°C, pH 6) a cyflumetofen conversion of 40% and 49% to form metabolite AB-1 and of 53% and 44% to form metabolite A-2 was observed, respectively (butylphenyl-label study). Metabolite B-1 was the major degradation product (up to 73% AR, sterilisation conditions) in the benzoyl-labelled study.

The toxicological relevance of the metabolite B-1 was assessed in the framework of the EU pesticides peer review (EFSA, 2012) and of metabolites AB-1 and A-2 in the evaluation report of one of the two MRL applications (Netherlands, 2016). Results of the toxicological assessment are reported in Section 1.

For the proposed uses assessed in these applications, no further information is required.
2.1.4. Methods of analysis in plants

Methods to quantify residues of cyflumetofen by liquid chromatography with tandem mass spectrometry (LC-MS/MS) monitoring two ion transitions were proposed for enforcement purpose (Netherlands, 2016, 2020). The methods were sufficiently validated in terms of specificity, linearity, precision, accuracy at or above the limit of quantification (LOQ) of 0.01 mg/kg in high water (tomato) and high acid (orange) matrices.

The results of the validation of the LC-MS/MS method in hops (dried cones as well as green cones) at or above the LOQ of 0.1 mg/kg and independent laboratory validations (ILV) of the proposed enforcement methods for matrices with a high water content, high acid content and for hops were provided.

EFSA concludes that for the crops under assessment (matrices with high acid and high-water content) and for hops, sufficiently validated analytical methods are available to quantify residues of cyflumetofen according to the established residue definition.

2.1.5. Storage stability of residues in plants

The storage stability of cyflumetofen and the metabolite B-1 in plants stored under deep freeze conditions was assessed in the framework of the current MRL applications (Netherlands, 2016, 2020).

The freezer storage stability was investigated in almond nut meal representative for the high oil content commodities, apple fruits (and juice) representative for the high water content fruit commodities, lettuces representative for the high water content leafy crops, radish roots representative for the high water/high starch content commodities and orange fruits (and juice) representative for high acid content commodities. Data were also provided for orange oil. Samples of each plant matrix were fortified separately with the test item at a level of 0.1 mg/kg each and stored frozen (−20°C to −10°C) for up to 910 days (30 months).

Cyflumetofen showed to be stable for at least 25 months in almond nut meal (high oil content), in apple fruits (high water content) and apple juice (processed products), in orange fruits (high acid content) and orange juice and oil (processed products), 3 months in lettuces (high water content) and radish roots (high water/high starch content).

Storage stability data on metabolite B-1 were more difficult to assess. Using procedural recovery values to adjust measured amounts, storage stability of metabolite B-1 can be claimed for 22–30 months in the different matrices tested. However, the approach is not appropriate.

The uncorrected recovery data showed a large variation among sampling time points and matrices. Values were often below 70% at different dates (but with no clear trend, so the findings were ‘random’). Already at time point zero, low recovery values were observed in both the stored commodities (high water/high acid content matrices: 60–84%; high oil content matrix: 68%) and freshly spiked samples (high water/high acid content matrices: 65–90%; high oil content matrix: 82%).

To allow appropriate interpretation of the findings with regard to possible residue decline, applicant provided a graphical presentation of the recoveries of metabolite B-1 in stored commodities (Netherlands, 2016). This graph was used to determine the percentage reduction of residues at any point in time by means of data interpolation starting from day zero as 100% (European Commission, 1997f). Despite some variability, no large fluctuation attributable to the residue decline was overall observed during the storage period.

Considering the available data in the light of the interpolation method, residues of metabolite B-1 showed to be stable for 22 months in apple fruit and juice (high water content), about 30 months in orange fruit and juice (high acid content) and about 30 months in almond nut meal (high oil content matrix). For lettuces and orange oils, the data were inconclusive.

Applicant provided also the results of storage stability for the metabolites AB-6 and AB-7, which are not currently considered in the residue definition for risk assessment but were analysed for in the residue and processing trials. These data were not further assessed by EFSA. On the contrary, storage stability for the major degradation product in hydrolysis studies (A-2) was not provided despite the fact that the compound was analysed in the submitted processing studies on apples and peaches. Therefore, such studies would be required to confirm the validity of the results from processing studies if the compound is included in the residue definition for risk assessment of processed products.
2.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and degradation products and the capability of enforcement analytical method, the following residue definitions were proposed for fruit crops in the EU pesticides peer review (EFSA, 2012):

- Residue definition for enforcement: cyflumetofen (sum of isomers)
  The residue definition for enforcement currently set under Regulation (EC) No 396/2005 is comparable even though the detail about the sum of isomers of cyflumetofen is not specified.

- Residue definition for risk assessment: Sum of cyflumetofen (sum of isomers) and metabolite B-1 expressed as cyflumetofen (provisional).

The residue definition for enforcement and risk assessment are restricted to primary fruit crops and applicable to the intended uses on fruit crops under consideration. In order to address the data gap related to the lack of metabolism studies with leafy crops (relevant for the intended use on hops), EFSA considered the data in leaves from fruit metabolism studies. Metabolite AB-6 was observed in relevant concentrations and its presence is confirmed in the residue trials on hops. However, considering the dilution of residues expected after processing of hops into beer, EFSA agreed with the EMS proposal to apply the same residue definitions as proposed for fruits crops, also for hops. If in future additional uses on leafy crops are intended to be authorised, the submission of a metabolism study in a crop belonging to the crop category of leafy crops is required. Based on its relevance in the metabolism study, general toxicological information on AB-6 may be required.

In rotational crops, TFA is the main metabolite, resulting from an extensive metabolism of cyflumetofen in soil. However, a separate residue definition for cyflumetofen in rotational crops, including TFA, cannot be considered because this compound is a transformation product common to other pesticides and an environmental contaminant.

Standard hydrolysis studies showed a progressive degradation of cyflumetofen to B-1 and a few compounds (AB-1 and A-2), for which the toxicological relevance has been assessed in studies submitted in the framework of one of current applications (see Section 1). The EMS proposed for processed products to apply the same residue definition as for primary fruit crops, because the sum of cyflumetofen and metabolites B-1 in the commodities prior to be processed was never lower than the sum of cyflumetofen and the metabolites observed in products which undergo heat treatment (Netherlands, 2016). EFSA is of the opinion that the residue definition for processed products should be established in the context of Article 12 of Regulation (EC) No 396/2005 where a comprehensive assessment of all authorised uses of cyflumetofen is performed and Member States are consulted.

2.2. Magnitude of residues in plants

2.2.1. Magnitude of residues in primary crops

In support of both MRL applications, the applicants submitted residue trials performed on oranges, lemons, mandarins, apricots, peaches, tomatoes, hops and cucumbers. The samples were analysed for the parent compound and for the metabolite B-1, currently included in the risk assessment residue definition for fruit crops. Before summing up, the residues of the metabolite B-1 were recalculated to express them as cyflumetofen equivalent by a molecular weight conversion factor of 2.35. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Netherlands, 2016, 2020). The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

The residues levels in the supervised residue trials submitted are reported in Appendix B.2.2.1.

**Citrus fruits**

Sixteen GAP-compliant residue trials on oranges (8 trials), lemons (4 trials) and mandarins (4 trials) performed in southern Europe (SEU) over two growing seasons were submitted and support the proposed extrapolation to the whole group of citrus fruits (European Commission, 2017). Samples were analysed for residues in peel and pulp. The data are sufficient to derive an MRL proposal of 0.5 mg/kg for the intended SEU use.

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6 Conversion factor obtained based on molecular weight (MW) ratio (cyflumetofen: B-1) (447.45:190.12).
**Apricots, peaches**

Eight GAP-compliant residue trials on apricots (4 trials) and peaches (4 trials) performed in the SEU over two growing seasons were submitted and support the proposed extrapolation to peaches and apricots (European Commission, 2017). The data are sufficient to derive an MRL proposal of 0.3 mg/kg for the intended SEU use.

**Tomatoes, aubergines**

Eight GAP-compliant residue trials on tomatoes performed in the SEU and twelve GAP-compliant residue trials conducted indoor in the EU over two growing seasons were submitted and support the intended outdoor (SEU) and indoor use on tomatoes. The SEU and indoor datasets fulfil the requirements for the extrapolation from tomatoes to aubergines (European Commission, 2017).

Since producing a more critical residue situation, the MRL proposal of 0.4 mg/kg and risk assessment values were proposed based on the indoor use on tomatoes and was extrapolated to aubergines.

**Hops**

Four GAP-compliant residue trials on hops support the intended northern Europe (NEU) use on hops and allow to derive an MRL proposal of 30 mg/kg. The intended SEU use is not supported by data.

**Cucumbers**

Eight GAP-compliant residue trials on cucumbers conducted indoor in the EU over one growing season support the intended indoor use. Since all trials were conducted at application rates which do not deviate more than the allowed 25% tolerance, EFSA did not considered necessary to use the proportionality approach (although proposed by the EMS) to scale residues at the nominal application rate. An MRL proposal of 0.4 mg/kg is derived.

The technical guidelines for determining the magnitude of pesticide residues in honey and setting MRLs in honey (European Commission, 2018) applies to the MRL applications submitted after 1 January 2020. The MRL application on cucumbers qualifies for the assessment of residues in honey as submitted on 5 May 2020 and since cucumber is listed as a melliferous crop according to the guideline. EMS provided a justification not to assess residues in honey following the indoor use of cyflumetofen in cucumbers (Netherlands, 2020). EFSA acknowledged the argumentation of the EMS and applicant that parthenocarpic (seedless) cucumber varieties do not need pollination for fruit development but noted that the intended indoor application on cucumbers is with no specific variety, thus, bees can be used for pollination purposes. At the current stage, EFSA cannot estimate what is the proportion of honey produced from greenhouse pollinator honeybees to the overall honey production and thus what would be the magnitude of cyflumetofen residues expected in honey. Considering the arguments of the applicant, the knowledge that cyflumetofen does not have translaminar or systemic activity (FAO, 2014) and noting that not only honey producing bees but also bumblebees are significant cucumber pollinators in greenhouses (thus reducing the share of honey produced by greenhouse honeybees), EFSA agrees with the EMS that the likelihood that honey produced from indoor cucumber pollination, will contribute significantly to the overall honey consumption is very low and therefore the assessment of cyflumetofen residues in honey can be neglected.

### 2.2.2. Magnitude of residues in rotational crops

Cyflumetofen is intended for use in certain crops (cucumber, tomato, aubergine) which may be grown in rotation. The possible transfer of residues to rotated crops has been assessed in limited rotational crop field studies submitted with the current MRL applications (Netherlands, 2016, 2020). The available studies demonstrated that no quantifiable residues (above LOQ of 0.01 mg/kg) are expected in succeeding crops (wheat, carrots, broccoli and spinach) planted in soil treated at 400 g/ha (1N the total maximum application rate for the intended crops). Samples from these studies were not analysed for TFA, which is noted as a shortcoming of the available studies, since the TFA is the main residue in rotational crops.

Based on the available information and considering that TFA is highly persistent in soil, possible uptake of TFA in rotational crops cannot be excluded and risk mitigation measures at national level may be considered for plant protection products.
2.2.3. Magnitude of residues in processed commodities

The results of specific processing studies on oranges, apples, peaches, strawberries, tomatoes and hops were provided (Netherlands, 2016). The studies were carried out at exaggerate treatment rates (3N the intended rate on the crop under assessment) investigating the effect of pasteurisation, boiling and brewing on the magnitude of cyflumetofen residues. All samples were analysed for parent cyflumetofen and metabolite B-1 and AB-6. Results give evidence of dilution of cyflumetofen residues in processed products such as juice, canned fruits, marmalade/jam, syrup, beer. The metabolites B-1 and AB-6 were measured in fruit pomace, extracts and dried products (i.e. dried fruit and pulp). Assuming the same residue definition for enforcement for primary fruit crops (raw agricultural commodities) is set for processed products, processing factors were derived for cyflumetofen. An overview of these tentative processing factors is presented in Appendix B.2.2.3. For complete information, the table includes also the processing factors which were derive by JMPR (FAO, 2014).

In two additional studies on apples and three processing studies on peaches, samples were analysed for metabolite A-2. In the apples studies conducted at the nominal application rate, this metabolite was not found (< LOQ of 0.01 mg/kg) in any processed products. In the peach studies conducted at exaggerate rate (3N), it was only found in two wet pomace samples (up to 0.018 mg/kg) and in one dried fruit sample (0.036 mg/kg). It should be noted that the results from these studies are not fully supported by the storage stability. Samples were stored for a period (up to 73 day for apples and 152 days for peaches) exceeding maximum of 30 days for not presenting storage stability data. Moreover, in none of the submitted processing studies the metabolite AB-1 was tested.

Considering the low contribution of residues in the crops under assessment to the total consumer exposure to cyflumetofen residues (TMDI is largely below the 10% of the ADI) and that the toxicity of the metabolites B-1 and AB-1 is covered by the parent compound, further studies on the crops under consideration are not triggered at this stage. Metabolite A-2, which was largely formed under boiling/sterilisation conditions in the hydrolysis studies, has no genotoxicity potential considered to be more toxic than the parent compound (see Section 1). Considering the actual intended application rates of cyflumetofen, the potential A-2 residues in processed products will not raise any consumer intake concerns. The need for additional processing studies addressing the magnitude of residues in processed commodities and fully covered by storage stability should be reconsidered depending on the final decision on the residue definitions for processed products.

2.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for the uses under evaluation (see Appendix B.2.2). The following MRL values are proposed: 0.3 mg/kg for apricots and peaches, 0.4 mg/kg for tomatoes, aubergines and cucumbers, 0.5 mg/kg for citrus fruits and 30 mg/kg for hops.

In Section 4, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

3. Residues in livestock

The by-product citrus dried pulp may be fed to cattle and pigs. Hence, it was necessary to perform dietary burden calculations for livestock to estimate whether the intended use of cyflumetofen in citrus fruits would have an impact on the livestock exposure and subsequent residues in food of animal origin (European Commission, 1996). EFSA calculated the animal dietary burdens for different groups of livestock using the animal feedstuff Table reported in the OECD guidance No 64 – Series on Pesticides No 32 and Series on Pesticides No 73 (OECD, 2009, 2013) and the animal model developed by EFSA.

The input values for the exposure calculations based on the EU uses of cyflumetofen are presented in Appendix D.1. The processing factor of 1.21 tentatively derived under the current assessment (Appendix B.2.2.3) for cyflumetofen in orange dried pulp was used in the calculation to take into

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7 EFSA did not considered the residues on apple wet pomace in the calculations. Thus, because a change of the existing MRL is not requested and the residues expected in this by-product from the EU use are assumed to be covered in the dietary burden calculations performed by JMPR by a most critical use in the US (FAO, 2014). It is noted that the EMS considered in the dietary burden calculation the EU use on apples, the tentatively derived processing factor of 3.2 for wet pomace and the tentatively derived conversion factor for risk assessment of 1.05, assuming the same residue definition for risk assessment (sum of cyflumetofen and B-1, expressed as cyflumetofen) applies to processed products (Netherlands, 2016).
consideration possible concentration of residues. Pending a final decision on the residue definitions in processed products, the calculation shall be considered as indicative.

The results of the dietary burden calculations are presented in Section B.3. The exposure of livestock species did not exceed the trigger value of 0.1 mg/kg DM in cattle and swine and further investigation of the nature and magnitude of residues are not necessary. In addition, the existing MRLs in commodities of swine, ruminants, equine and other farmed animals reflect the CXLs, which were derived on a basis of significantly higher livestock dietary burdens as calculated by the JMPR in 2014 (FAO, 2014; EFSA, 2015a). Therefore, a change of the existing MRLs in products of animal origin is not required.

3.1. Nature of residues and methods of analysis in livestock

For animal commodities, no residue definitions have been derived in the framework of the EU pesticides peer review considering that representative uses were not of food/feed producing crops (EFSA, 2012). In the framework of the assessment of the implementation of CXLs into the EU legislation, EFSA proposed to take over in the EU legislation the CXLs set by the JMPR for edible tissues and milk of mammalians according to the residue definitions derived by JMPR. The residue definition for enforcement and risk assessment set by JMPR is the ‘sum of cyflumetofen and metabolite B-1, expressed as cyflumetofen’ (EFSA, 2015a). Thus, the existing MRLs for products of animal origin in the EU legislation correspond to the sum of cyflumetofen and metabolite B-1, expressed as cyflumetofen. In the framework of one of the two MRL applications, the results of two metabolism studies conducted in lactating goats and validation data for an enforcement analytical method to determine cyflumetofen and metabolite B-1 in animal matrices were provided (Netherlands, 2016). Since a change of the existing MRLs in products of animal origin is not required, EFSA did not assess the submitted data in this opinion.

4. Consumer risk assessment

EFSA performed two separate consumer risk assessments, one for cyflumetofen and one for TFA. Revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo) was used. This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population (EFSA, 2018, 2019b).

The ADI value of 0.17 of mg/kg bw day for cyflumetofen used in the risk assessment was derived in the framework of the EU pesticides peer review. The setting of an ARfD was deemed as unnecessary (European Commission, 2019). The toxicological reference values of the parent cyflumetofen are applicable to the metabolite B-1 (EFSA, 2012). An ADI value has been established for TFA during the EU peer review of the active substance flurtamone (EFSA, 2017). TFA is expected to be found in primary and rotational crops after the use of several active substances used in plant protection products and in rotational crops after the use of cyflumetofen.

Consumer risk assessment for cyflumetofen

For the chronic exposure, EFSA used the supervised trial median residues (STMR) derived from the residue trials under assessment and the STMRs corresponding to the CXLs implemented in the EU legislation (FAO, 2014). The peeling factor of 0.17 derived from the residue trials was used for citrus fruits and the default MRL value of 0.05 mg/kg for honey. For the remaining commodities of plant and animal origin, the EU MRLs for cyflumetofen are not set nor a default value is reported in the Regulation. These commodities were excluded from the exposure calculation.

The short-term exposure was not conducted as not necessary. The input values used in the dietary exposure calculation are summarised in Appendix D.2.

No long-term consumer intake concern was identified for any of the European diets incorporated in the EFSA PRIMO. The total chronic intake accounted for a maximum of 2% of the ADI (NL toddler diet); the contribution of the residues in the evaluated crops accounted for max. 0.27% of ADI (tomatoes).

An uncertainty with regard to the consumer exposure assessment is related to the possible preferential metabolism of each enantiomer of cyflumetofen in plants and animal commodities, which was not investigated. For the intended uses assessed in this MRL application, according to the exposure calculation, there is a sufficient margin of safety to the toxicological reference values to cover the uncertainty related to this data gap.
Consumer risk assessment for trifluoroacetic acid

The risk assessment regarding the overall exposure to the metabolite TFA was performed in a previous EFSA reasoned opinion (EFSA, 2014). In this opinion, the exposure calculations considered the TFA concentrations resulting from the use of pesticides which are possible sources of TFA and from environmental contamination. There is no need any longer to conduct the acute exposure calculations for TFA as an ARfD is deemed unnecessary (EFSA, 2017).

It was not possible to realistically assess the exposure of TFA resulting from the uptake of rotational crops after the use of cyflumetofen in the non-permanent crops under assessment because the compound was not analysed in the rotational crop field studies submitted. EFSA considered instead the results from the rotational crop metabolism studies after bare soil application (results at PBI 30 days). Results of these rotational crop metabolism studies with cyflumetofen were used to update the indicative chronic consumer risk assessment for TFA performed in 2014 considering the data available for TFA from residues in primary and rotational crops resulting from the use of pesticides which were mentioned in the EFSA conclusions as possible sources of TFA and food from environment contaminations. The MRL review concluded that the potential contribution of TFA resulting from the application of fluazinam and fluometuron according to the authorised uses was deemed covered by this previous 2014 assessment and an update was not necessary (EFSA, 2015b, 2019a). When higher, the HR from the studies with cyflumetofen was used to replace the STMRs previously used in the calculations. PRIMo rev. 3.1 consumption data were also used. This approach is quite conservative because used the highest instead of the median residue values and affected by uncertainty. The input values used in the dietary exposure calculation are summarised in Appendix D.2.

No long-term consumer intake concern was identified for any of the European diets incorporated in the EFSA PRIMo. The total chronic intake accounted for a maximum of 9% of the ADI (NL toddler diet); the crop which contributed the most to the overall exposure to TFA among the crops under assessment was tomato (1.14% of ADI). The short-term exposure for TFA was not conducted as an ARfD is deemed unnecessary.

For further details on the exposure calculations, a screenshot of the Report sheets of the PRIMo for cyflumetofen and for trifluoroacetic acid is presented in Appendix C.

5. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for citrus fruits, apricots, peaches, tomatoes, aubergines, cucumbers and hops.

EFSA concluded that the proposed use of cyflumetofen on the crops under evaluation will not result in a consumer exposure exceeding the toxicological reference values of cyflumetofen and therefore is unlikely to pose a risk to consumers' health. The indicative dietary exposure assessment indicated that the potential contribution of TFA residues expected in crops grown in rotation after the use of cyflumetofen on the relevant crops under assessment to the overall TFA exposure is low.

The review of the existing MRLs in accordance with Article 12 of Regulation (EC) No 396/2005 is not yet finalised, and therefore, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the MRL review.

The MRL recommendations are summarised in Appendix B.5.

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Abbreviations

a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CF conversion factor for enforcement to risk assessment residue definition
CXL Codex maximum residue limit
DAR draft assessment report
DAT days after treatment
DM dry matter
DT$_{90}$ period required for 90% dissipation (define method of estimation)
EMS evaluating Member State
eq residue expressed as a.s. equivalent
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
HR highest residue
IEDI international estimated daily intake
ILV independent laboratory validation
InChiKey International Chemical Identifier Key
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
JMPR Joint FAO/WHO Meeting on Pesticide Residues
LC-MS/MS liquid chromatography with tandem mass spectrometry detector
LOQ limit of quantification
MRL maximum residue level
MS Member States
MW molecular weight
NEU northern Europe
NOAEL no observed adverse effect level
OECD Organisation for Economic Co-operation and Development
PBI plant-back interval
PeF peeling factor
PF processing factor
PHI preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
RA risk assessment
RAC raw agricultural commodity
RD residue definition
RMS rapporteur Member State
SANCO Directorate-General for Health and Consumers
SC suspension concentrate
SEU southern Europe
STMR supervised trials median residue
TFA trifluoroacetic acid
| Acronym | Definition                      |
|---------|---------------------------------|
| TMDI    | theoretical maximum daily intake|
| TRR     | total radioactive residue        |
| WHO     | World Health Organization        |
## Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F, G or T | NEU, SEU, MS or country | Pests or group of pests controlled | Preparation Type | Conc. a.s. | Method kind | Range of growth stages & season | Number min–max | Interval between application (min) | g a.s./hl min–max | Water L/ha min–max | Rate | Unit | PHI (days) | Remarks |
|-----------------------|-------------------------|----------|-------------------------|----------------------------------|------------------|-----------|-------------|-------------------------------|---------------|-----------------------------|----------------|----------------|------|------|---------|---------|
| Grapefruits SEU F    | Panonychus citri, Tetranychus urticae Tetranychus sp. | Foliar treatment – broadcast spraying | BBCH 11–85 | 2 | 10–14 | 2,000 | 200 | g a.i/ha | 7 |
| Oranges SEU F        | Panonychus citri, Tetranychus urticae Tetranychus sp. | Foliar treatment – broadcast spraying | BBCH 11–85 | 2 | 10–14 | 2,000 | 200 | g a.i/ha | 7 |
| Lemons SEU F         | Panonychus citri, Tetranychus urticae Tetranychus sp. | Foliar treatment – broadcast spraying | BBCH 11–85 | 2 | 10–14 | 2,000 | 200 | g a.i/ha | 7 |
| Limes SEU F          | Panonychus citri, Tetranychus urticae Tetranychus sp. | Foliar treatment – broadcast spraying | BBCH 11–85 | 2 | 10–14 | 2,000 | 200 | g a.i/ha | 7 |
| Mandarins SEU F      | Panonychus citri, Tetranychus urticae Tetranychus sp. | Foliar treatment – broadcast spraying | BBCH 11–85 | 2 | 10–14 | 2,000 | 200 | g a.i/ha | 7 |
| Other Citrus SEU F   | Panonychus citri, Tetranychus urticae Tetranychus sp. | Foliar treatment – broadcast spraying | BBCH 11–85 | 2 | 10–14 | 2,000 | 200 | g a.i/ha | 7 |
| Apricots SEU F       | Panonychus ulmi, Tetranychus urticae Tetranychus sp. | Foliar treatment – broadcast spraying | BBCH 11–85 | 2 | 10–14 | 1,200 | 200 | g a.i/ha | 7 |
| Crop and/or situation | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|-----------------------------------|-------------|-------------|------------------------------|------------|---------|
| NEU, SEU, MS or country | F | Panonychus ulmi, Tetranychus urticae Tetranychus sp. | Foliar treatment – broadcast spraying | BBCH 11–85 | 2 | 10–14 | 1,200 | 200 | g a.i/ha | 7 |
| Hops | NEU | F | Tetranychus urticae Tetranychus sp. | Foliar treatment – broadcast spraying | BBCH 15–79 | 2 | 10–14 | 3,300 | 200 | g a.i/ha | 14 |
| Tomatoes | SEU | F | Tetranychus urticae Tetranychus sp. | Foliar treatment – broadcast spraying | BBCH 13–89 | 2 | 10–14 | 2,000 | 200 | g a.i/ha | 1 |
| Cherry tomatoes | SEU | F | Tetranychus urticae Tetranychus sp. | Foliar treatment – broadcast spraying | BBCH 13–89 | 2 | 10–14 | 2,000 | 200 | g a.i/ha | 1 |
| Aubergines/egg plants | SEU | F | Tetranychus urticae Tetranychus sp. | Foliar treatment – broadcast spraying | BBCH 13–89 | 2 | 10–14 | 2,000 | 200 | g a.i/ha | 1 |
| Tomatoes | EU | G | Tetranychus urticae Tetranychus sp. | Foliar treatment – broadcast spraying | BBCH 13–89 | 2 | 10–14 | 2,000 | 200 | g a.i/ha | 1 |
| Cherry tomatoes | EU | G | Tetranychus urticae Tetranychus sp. | Foliar treatment – broadcast spraying | BBCH 13–89 | 2 | 10–14 | 2,000 | 200 | g a.i/ha | 1 |
### Table: Pesticide Application Data

| Crop and/or situation | NEU, SEU, MS or country | Pests or group of pests controlled | Preparation | Method kind | Range of growth stages & season | Number min – max | Interval between application (min) | g a.s./hL min – max | Water L/ha min – max | Rate | Unit | PHI (days)(d) | Remarks |
|-----------------------|-------------------------|-----------------------------------|-------------|-------------|---------------------------------|-----------------|----------------------------------|-------------------|-------------------|------|------|-------------|---------|
| Aubergines/egg plants | EU                      | G Tetranychus urticae, Tetranychus sp. | Foliar treatment – broadcast spraying | BBCH 13–89 | 2 | 10–14 | 2,000 | 200 g a.i/ha | 1 |
| Cucumbers             | EU                      | G Spider mites | SC 200 g/L | Foliar treatment – broadcast spraying | BBCH 11–89 | 1–2 | 7 | 200–1,500 | 300 g a.i/ha | 1 |

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

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

(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI: minimum preharvest interval.
Appendix B – List of end points

B.1. Mammalian toxicity

Other toxicological studies

Studies performed on metabolites

| Metabolite A-2: | Genotoxicity: |
|----------------|-------------|
| In vitro Ames test: negative |
| In vitro micronucleus assay: negative |
| Unlikely to be genotoxic in vitro |

- General toxicity:
  - 28-day study in the rat, NOAEL = 6.5 mg/kg bw per day for finding in liver and testes. (Netherlands, 2016)

| Metabolite AB-1 (major metabolite) |
|-----------------------------------|
| Major metabolite, covered by the parent compound (Netherlands, 2010) |

| Metabolite AB-6: | Genotoxicity: |
|----------------|-------------|
| In vitro Ames test: negative |
| In vitro gene mutation assay: negative |
| In vitro chromosome aberration assay: negative |
| In vitro micronucleus test in human lymphocytes: negative |
| Unlikely to be genotoxic in vitro |

- General toxicity:
  - Acute oral toxicity in mice, LD$_{50}$: $>2000$ mg/kg bw (F)
  - No conclusion can be drawn on general toxicity. (Netherlands, 2016)

Summary

| Cyflumetofen | Value (mg/kg bw per day) | Study | Uncertainty factor |
|--------------|--------------------------|-------|-------------------|
| Acceptable daily intake (ADI) (a), (b) | 0.17 | 90-day and 2-year rat studies | 100 |
| Acute reference dose (ARfD) (a), (b) | | Not allocated, not necessary |

(a) European Commission (2019).
(b) Applicable to AB-1 (Netherlands, 2010) and B-1 (EFSA, 2012).
### Metabolite TFA

| Value (mg/kg bw per day) | Study | Uncertainty factor |
|-------------------------|-------|-------------------|
| Acceptable daily intake (ADI) (a) | 0.05 | 90-day rat study | 200 (b) |
| Acute Reference Dose (ARfD) (a) | Not allocated, not necessary | |

(a) EFSA (2017).
(b) Increased UF for the extrapolation from subchronic to chronic.

### Metabolite A-2

| Value (mg/kg bw per day) | Study | Uncertainty factor |
|-------------------------|-------|-------------------|
| Acceptable Daily Intake (ADI). | 0.0036 | 28-day rat study | 1,800 (a) |
| Acute Reference Dose (ARfD). | Not allocated, not necessary | |

(a) Additional UF of 6 for the extrapolation to chronic exposure and additional uncertainty factor of 3 for uncertainties for reprotoxicity.

NOAEL: no observed adverse effect level; bw: body weight; LD<sub>50</sub>: lethal dose, median.

### B.2. Residues in plants

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

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

| Crop groups | Crops | Applications | Sampling (DAT) | Comment/Source |
|-------------|-------|--------------|----------------|----------------|
| Primary crops (available studies) | | | | |
| | Fruit crops | Apple | Foliar, 1 x 600 g/ha | Fruit: 1, 7, 30 Leaf: 7, 30 | Radiolabelled active substance: [14C-butylyphenyl] and [14C-trifluoromethyl phenyl] cyflumetofen (EFSA, 2012) |
| | | Mandarin | Foliar, 1 x 600 g/ha | Fruit: 1, 7, 30 Leaf: 1, 7, 14 | |
| | | Eggplant | Foliar, 1 x 600 g/ha | Fruit: 1, 7, 14 Leaf: 14 | |
| | Root crops | – | – | – | |
| | Leafy crops | – | – | – | |
| | Cereals/grass | – | – | – | |
| | Pulses/ oilseeds | – | – | – | |
| | Miscellaneous | – | – | – | |
| Rotational crops (available studies) | | | | |
| | Root/tuber crops | Radish | Bare soil, 1 x 400 g/ha | 30, 120, 365 | Not triggered (DT<sub>90</sub> < 100 days) Radiolabelled active substance: [14C-butylyphenyl] and [14C-trifluoromethyl phenyl] cyflumetofen (EFSA, 2012) |
| | Leafy crops | Lettuce | Bare soil, 1 x 400 g/ha | 30, 120, 365 | |
| | Cereal (small grain) | Wheat | Bare soil, 1 x 400 g/ha | 30, 120, 365 | |
### Processed Commodities (Hydrolysis Study)

| Conditions                               | Stable? | Comment/Source                                  |
|------------------------------------------|---------|-------------------------------------------------|
| Pasteurisation (20 min, 90°C, pH 4)      | Yes     | Radiolabelled active substance: [14C-butylphenyl] and [14C-trifluoromethyl phenyl] cyflumetofen (Netherlands, 2016) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | No      |                                                  |
| Sterilisation (20 min, 120°C, pH 6)      | No      |                                                  |
| Other processing conditions               | –       | –                                               |

### Can a General Residue Definition be Proposed for Primary Crops?

| Rotational crop and primary crop metabolism similar? |
|------------------------------------------------------|
| No (fruit crops)                                     |
| TFA was present in rotational crops according to metabolism studies but not identified in primary crop metabolism in fruit crops |

### Residue Pattern in Processed Commodities Similar to Residue Pattern in Raw Commodities?

| Plant residue definition for monitoring (RD-Mo)             |
|-------------------------------------------------------------|
| Fruit crops: Cyflumetofen (sum of isomers)                  |
| Processed commodities: Open                                 |
| Netherlands (2016)                                         |

### Plant Residue Definition for Risk Assessment (RD-RA)

| Fruit crops: Sum of cyflumetofen (sum of isomers) and metabolite B-1 expressed as cyflumetofen (provisional) (EFSA, 2012) |
| Processed commodities: Open                                 |

### Methods of Analysis for Monitoring of Residues (Analytical Technique, Crop Groups, LOQs)

| Matrices with high water content, high acid content: LC–MS/MS, LOQ 0.01 mg/kg (method D1003) |
| Confirmatory method and ILV available                        |
| Hops: LC–MS/MS, LOQ 0.1 mg/kg (method D1003)                  |
| Confirmatory method and ILV available                         |
| (Netherlands, 2016)                                         |

DAT: days after treatment; PBI: plant-back interval; MRL: maximum residue level; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.
## B.2.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C)\(^{(a)}\) | Stability (days) | Comment/Source |
|-----------------------------------|----------|-----------|-----------------|-----------------|----------------|
|                                   |          |           |                 | Cyflumetofen    | B-1\(^{(b)}\)  |                 |
| High water content                | Apple    | FS        | 750             | 683             | Netherlands (2016) |
|                                  | Lettuce  | FS        | 91              | Inconclusive    | Netherlands (2016) |
| High water/starch content         | Radish root | FS   | 91              | 648             | Netherlands (2016) |
| High oil content                  | Almond nutmealf | FS | 765             | 910             | Netherlands (2016) |
| High acid content                 | Orange  | FS        | 743             | 888             | Netherlands (2016) |
| Processed products                | Apple juice | FS   | 765             | 679             | Netherlands (2016) |
|                                  | Orange juice | FS | 765             | 910             | Netherlands (2016) |
|                                  | Orange oil | FS      | 770             | 89              | Netherlands (2016) |

\(^{(a)}\): FS: frozen storage conditions of the studies, reported as between -20 and -10°C.

\(^{(b)}\): Metabolite B-1: (uncorrected) recoveries showed a large variation among sampling time points and matrices, dropping below 70% at certain sampling times during the storage period of the studies. Despite some variability, the graphical presentation of the recoveries according to current guidance (European Commission, 1997f) showed no large fluctuation attributable of the residue decline.
## B.2.2. Magnitude of residues in plants

### B.2.2.1. Summary of residues data from the supervised residue trials

| Commodity | Region/Indoor | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR(c) (mg/kg) | STMR(d) (mg/kg) | CF(e) |
|-----------|---------------|---------------------------------------------------------------|----------------|------------------------|--------------|----------------|-------|
| Oranges   | SEU           | **Mo:** 0.05, 0.07, 0.07, 0.08, 0.08, 0.10, 0.10, 0.11, 0.12, 0.13, 0.14, 0.15, 0.16, 0.21, 0.22, 0.27, 0.27, 0.24, 0.29, 0.29 | Residue trials on oranges (8), lemons (4), mandarins (4) compliant with GAP. Highest values measured at a longer PHI of 13–14 days (underlined). Extrapolation to citrus fruits possible. RA pulp: 7 < 0.03; 4 < 0.04; 3 < 0.05; 0.08; 0.09 | 0.5 | Mo: 0.27 | RA: 0.29 | Mo: 0.12 | RA: 0.14 | 1.20 |
| Lemons, Mandarins |                     | **RA:** 0.08, 0.09, 0.10, 0.10, 0.11, 0.12, 0.12, 0.13, 0.14, 0.15, 0.16, 0.18, 0.23, 0.24, 0.29, 0.29 | | | | | |
| Apricots, Peaches | SEU | **Mo:** < 0.01, 0.03, 0.07, 0.08, 0.10, 0.11, 0.12, 0.13, 0.14, 0.15 | Residue trials on apricots (4) and peaches (4) compliant with GAP. B-1: 8 < 0.01 mg/kg Extrapolation to apricots and peaches possible | 0.3 | Mo: 0.13 | RA: 0.15 | Mo: 0.09 | RA: 0.12 | 1.26 |
| Tomatoes | SEU | **Mo:** 0.01, 0.04, 0.05, 0.05, 0.06, 0.06, 0.09, 0.09, 0.09, 0.11, 0.12, 0.13, 0.14, 0.15 | Residue trials on tomatoes compliant with GAP. Highest values measured at a longer PHI of 4 days (underlined). B-1: 8 < 0.01 mg/kg Extrapolation to aubergines possible | 0.2 | Mo: 0.09 | RA: 0.12 | Mo: 0.06 | RA: 0.08 | 1.43 |
| Tomatoes | EU | **Mo:** 0.02, 0.03, 0.05, 0.05, 0.08, 0.09, 0.13, 0.13, 0.13, 0.16, 0.16, 0.27 | Residue trials on tomatoes compliant with GAP. Highest values measured at a longer PHI of 2–4 days or 7–8 days (underlined). B-1: 11 × < 0.01; 0.019 mg/kg Extrapolation to aubergines possible | 0.4 | Mo: 0.27 | RA: 0.31 | Mo: 0.11 | RA: 0.13 | 1.22 |
| Cucumbers | EU | **Mo:** 0.06; 0.07; 0.09; 0.10; 0.10 0.15; 0.16; 0.24 | Residue trials on cucumbers compliant with the GAP. Highest values measured at a longer PHI of 2–3 days (underlined). B-1: 4 0.01; 3 0.01; 0.03 Extrapolation to aubergines possible | 0.4 | Mo: 0.24 | RA: 0.26 | Mo: 0.10 | RA: 0.15 | 1.22 |
| Hops | NEU | **Mo:** 3.6; 7.6; 8.0; 14.00 | Residue trials on hops compliant with GAP. B-1: 0.25, 0.26, 0.27, 0.39 mg/kg | 30 | Mo: 14.00 | RA: 14.59 | Mo: 7.80 | RA: 8.60 | 1.10 |
| Cucumbers | EU | **RA:** 4.2, 8.5, 8.7, 14.59 | | | | | |

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Individual results according to the residue definition for enforcement (cyflumetofen, sum of isomers) reported in ascending order and related values according to the residue definition for risk assessment (sum of cyflumetofen (sum of isomers) and metabolite B-1 expressed as cyflumetofen) in the corresponding sample. Residues of B-1 were multiplied by the CF for risk assessment of 2.35 prior to be summed up.
(c): Highest residue. The highest residue for enforcement (Mo) and risk assessment (RA) refers to the whole commodity and not to the edible portion.
(d): Supervised trials median residue. The median residue for enforcement (Mo) risk assessment (RA) refers to the whole commodity and not to the edible portion.
(e): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
B.2.2.2. Residues in rotational crops

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

| Residues Expected | Summary |
|-------------------|---------|
| No (cyflumetofen, B-1) | Cyflumetofen was not recovered and B-1 at trace level. In all tested crops and at all plant back intervals, TFA residue levels were measured. Maximum levels at PHI 30 d: 0.075 mg eq/kg in immature lettuces; 0.065 mg eq/kg in mature lettuces; 0.021 mg eq/kg in radish tops; 0.159 mg eq/kg in radish roots; 0.099 mg eq/kg in wheat grain; 0.498 mg eq/kg in wheat straw; 0.641 mg eq/kg in wheat hay (Netherlands, 2016) |
| Yes (TFA) | |

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

| Residues Expected | Summary |
|-------------------|---------|
| Not triggered (cyflumetofen, B-1) | Residues of cyflumetofen, B-1 all below the LOQ (<0.01 mg/kg) in wheat, carrots, broccoli and spinaches already at PBI 30 days. Samples not analysed for TFA |
| Yes (TFA), according to metabolism studies | |

LOQ: limit of quantification; PBI: plant-back interval; TFA: trifluoroacetic acid.

B.2.2.3. Processing factors

| Processed commodity | Number of valid studies | Processing Factor (PF) | CFp | Comment/Source |
|---------------------|-------------------------|------------------------|-----|---------------|
| Citrus, pulp        | 16                      | < 0.04, < 0.08, < 0.08, < 0.09, 0.09, < 0.12, 0.14, < 0.15, 0.18, < 0.19, 0.22, 0.24, 0.25, 0.27, 0.39, 0.62 | 0.17 | Tentative (Netherlands, 2016) |
| Orange, pulp        | 4                       | < 0.05; < 0.05; 0.05; 0.07 | < 0.05 | Tentative (Netherlands, 2016) |
| Orange, juice (pasteurised) | 4 | < 0.05; 0.07; 0.08; 0.10 | 0.08 | Tentative (Netherlands, 2016) |
| Orange, pomace wet | 2                       | < 0.02, < 0.08 | < 0.05 | Tentative (FAO, 2014) |
| Orange, dried pulp  | 4                       | 1.09, 1.20, 1.21, 1.40 | 1.21 | Tentative (Netherlands, 2016) |
| Orange, oil essence (pressing extract) | 4 | 134, 136, 178, 217 | 157 | Tentative (Netherlands, 2016) |
| Orange, marmalade   | 4                       | 0.39, 0.43, 0.65, 0.65 | 0.54 | Tentative (Netherlands, 2016) |
| Orange, molasses    | 2                       | < 0.03, < 0.08 | 0.06 | Tentative (FAO, 2014) |
| Apple, juice (pasteurised) | 2 | < 0.02, < 0.08 | < 0.05 | Tentative (FAO, 2014) |
| Apple, meal         | 2                       | 0.43, 0.46 | 0.45 | Tentative (FAO, 2014) |
| Apple, canned (boiled, pasteurised) | 6 | < 0.04, < 0.07, 0.07, < 0.10, 0.13, < 0.17 | 0.09 | Tentative (Netherlands, 2016) |
|                     | 2                       | 0.20, 0.27 | 0.24 | Tentative (FAO, 2014) |
|                     | 6                       | 0.08, 0.13, 0.13, 0.15, 0.16, < 0.17 | 0.14 | Tentative (Netherlands, 2016) |
|                     | 2                       | 0.04, 0.18 | 0.11 | Tentative (FAO, 2014) |
| Processed commodity                  | Number of valid studies | Processing Factor (PF) | CF<sub>P</sub> | Comment/Source                                  |
|-------------------------------------|-------------------------|------------------------|----------------|-----------------------------------------------|
|                                     | Individual values       | Median PF              |                |                                               |
| Apple, dried                        | 6                       | 3.25, 4.14, 5.17, 5.20, 7.30, 7.33 | 5.19           | Tentative<sup>(c)</sup> (Netherlands, 2016)   |
|                                     |                         | 0.17, 0.83             | 0.50           | Tentative<sup>(c)</sup> (FAO, 2014)           |
| Apple, wet pomace                   | 6                       | 2.68, 3.13, 3.17, 3.31, 3.33, 4.70 | 3.24           | Tentative<sup>(c)</sup> (Netherlands, 2016)   |
|                                     |                         | 0.94, 1.59             | 1.27           | Tentative<sup>(c)</sup> (FAO, 2014)           |
| Apple, sauce (pasteurised)          | 6                       | < 0.13, 0.17, 0.45, 0.60, 0.65, 1.70 | 0.53           | Tentative<sup>(c)</sup> (Netherlands, 2016)   |
|                                     |                         | 2.54, 2.91             | 2.73           | Tentative<sup>(c)</sup> (FAO, 2014)           |
| Apple, syrup                        | 6                       | 0.03, 0.05, < 0.07, < 0.10, < 0.13, < 0.17 | 0.09           | Tentative<sup>(c)</sup> (Netherlands, 2016)   |
| Peach, juice (pasteurised)          | 3                       | 0.44, 1.42, 1.71       | 1.42           | Tentative<sup>(c)</sup> (Netherlands, 2016)   |
| Peach, dried                        | 3                       | 6.63, 7.85, 20.87      | 7.85           | Tentative<sup>(c)</sup> (Netherlands, 2016)   |
| Peach, canned (pasteurised)         | 3                       | < 0.04, < 0.06, < 0.08 | < 0.06         | Tentative<sup>(c)</sup> (Netherlands, 2016)   |
| Peach, jam (cooked, pasteurised)    | 3                       | 0.11, 012, 0.24        | 0.12           | Tentative<sup>(c)</sup> (Netherlands, 2016)   |
| Strawberry, canned (pasteurised)    | 4                       | 0.23, 0.35, 0.37, 0.71 | 0.36           | Tentative<sup>(c)</sup> (Netherlands, 2016)   |
| Strawberry, jam (cooked)            | 4                       | 0.11, 0.16, 0.40, 0.46 | 0.28           | Tentative<sup>(c)</sup> (Netherlands, 2016)   |
| Tomato, juice (raw)                 | 4                       | 0.03, 0.14, 0.14, 0.86, < 0.07 | 0.14           | Tentative<sup>(c)</sup> (Netherlands, 2016)   |
| Tomato, peeled                      | 4                       | < 0.03, < 0.05, < 0.06, < 0.07 | 0.06           | Tentative<sup>(c)</sup> (Netherlands, 2016)   |
| Tomato, canned (peeled, sterilised) | 4                       | < 0.04, < 0.06         | < 0.05         | Tentative<sup>(c)</sup> (FAO, 2014)           |
| Tomato, puree (pasteurised)         | 4                       | < 0.02, < 0.03, < 0.05, < 0.19 | < 0.04         | Tentative<sup>(c)</sup> (Netherlands, 2016)   |
| Tomato, paste                       | 4                       | 0.18, 0.25, 0.28, 0.93 | 0.27           | Tentative<sup>(c)</sup> (Netherlands, 2016)   |
| Tomato, ketchup (pasteurised)       | 4                       | 0.18, 0.21, 0.25, 0.86 | 0.23           | Tentative<sup>(c)</sup> (Netherlands, 2016)   |
| Hop, dried cones                    | 4                       | 3.6, 3.8, 5.4, 5.4     | 4.60           | Tentative<sup>(c)</sup> Field trial data (Netherlands, 2016) |
| Hop, dried cones                    | 2                       | 0.96, 1.00             | 0.98           | Tentative<sup>(c)</sup> Processing study data (Netherlands, 2016) |
| Hop, extract                        | 2                       | 2.67, 2.75             | 2.71           | Tentative<sup>(c)</sup> (Netherlands, 2016)   |
| Hop, beer                           | 2                       | < 0.0005, < 0.0022     | < 0.0014       | Tentative<sup>(c)</sup> (Netherlands, 2016)   |
| Hop, brewer's yeast                 | 2                       | < 0.0005, < 0.0022     | 0.0014         | Tentative<sup>(c)</sup> (Netherlands, 2016)   |
### B.3. Residues in livestock

Calculations performed with Animal Model 2017\(^8\) (OECD, 2013).

| Relevant groups (sub groups) | Dietary burden expressed in | Most critical commodity\(^b\) | Trigger exceeded (Y/N) | Previous assessment (FAO, 2014) mg/kg DM |
|-----------------------------|-----------------------------|-----------------------------|------------------------|-----------------------------------------|
|                             | Median bw per day | Maximum | Median | Maximum |                                      | Max burden |
| Cattle (all)                | 0.001             | 0.01    | 0.04   | 0.04    | Cattle (dairy)                        | N           | 0.934\(^c\) |
| Cattle (dairy only)         | 0.001             | 0.01    | 0.04   | 0.04    | Cattle (dairy)                        | N           | 0.934\(^c\) |
| Sheep (all)                 | –                 | –       | –      | –       | –                                     | –           | –          |
| Sheep (ewe only)            | –                 | –       | –      | –       | –                                     | –           | –          |
| Swine (all)                 | 0.001             | 0.001   | 0.03   | 0.03    | Swine (breeding)                      | N           | –          |
| Poultry (all)               | –                 | –       | –      | –       | –                                     | –           | –          |
| Poultry (layer only)        | –                 | –       | –      | –       | –                                     | –           | –          |
| Fish                        | n/a               | –       | –      | –       | –                                     | –           | –          |

bw: body weight; DM: dry matter; n/a: not applicable.

(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’.

(c): The highest dietary burden expressed in mg/kg DM resulted from the Australian animal diet (FAO, 2014).

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\(^8\) [https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en](https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en)
B.4. Consumer risk assessment

Cyflumetofen

Acute consumer risk assessment not relevant since no ARfD has been considered necessary.

| ADI | 0.17 mg/kg bw per day (European Commission, 2019) |
|-----|---------------------------------------------------|
| Highest IEDI, according to EFSA PRIMo | 2% ADI (NL toddler diet) |

Contribution of crops assessed:
- Grapefruits: 0.01% of ADI
- Oranges: 0.06% of ADI
- Lemons: 0.01% of ADI
- Limes: 0.00% of ADI
- Mandarins: 0.01% of ADI
- Apricots: 0.03% of ADI
- Peaches: 0.03% of ADI
- Tomatoes: 0.27% of ADI
- Aubergines/egg plants: 0.08% of ADI
- Cucumbers: 0.14% of ADI
- Hops (dried): 0.03% of ADI

Assumptions made for the calculations

The calculation is based on the median residue levels derived for raw agricultural commodities from the submitted residue trials on the crops under assessment and for the CXLs implemented in the EU legislation (FAO, 2014). The peeling factor of 0.17 derived from the residue trials was used for citrus fruits. The default LOQ value of 0.05 mg/kg was used for honey.

For the remaining commodities of plant and animal origin, EU MRLs for cyflumetofen are not set nor a default value is reported in the Regulation. These commodities were excluded from the exposure calculation.

Calculations performed with PRIMo revision 3.1.
Trifluoracetic acid (TFA)

Acute consumer risk assessment not relevant since no ARfD has been considered necessary.

| ADI | 0.05 mg/kg bw per day (EFSA, 2017) |
| --- | --------------------------------- |
| Highest IEDI, according to EFSA PRIMo | 9% ADI (NL toddler diet) |
| Contribution of crops assessed: |  |
| Grapefruits: | 0.64% of ADI |
| Oranges: | 0.06% of ADI |
| Lemons: | 0.01% of ADI |
| Limes: | 0.13% of ADI |
| Mandarin: | 0.01% of ADI |
| Apricots: | 0.06% of ADI |
| Peaches: | 0.06% of ADI |
| Tomatoes: | 1.14% of ADI |
| Aubergines/egg plants: | 0.11% of ADI |
| Cucumbers: | 0.52% of ADI |
| Hops (dried): | 0.0001% of ADI |

Assumptions made for the calculations

The calculation is based on the median residue levels derived in the framework of a previous EFSA opinion (EFSA, 2014) and the highest residues measured in the rotational crop studies with cyflumetofen (Netherlands, 2016) on radish roots for the groups of root and tuber vegetables and bulb vegetables, on radish tops for the groups of fruiting vegetables, Brassica vegetables, leafy vegetables and stem vegetables, and on wheat grain for cereals and coffee.

Calculations performed with PRIMo revision 3.1.

B.5. Recommended MRLs

| Code(a) | Commodity             | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------------------|-------------------------|-------------------------|-----------------------|
| 0110000 | Citrus fruits         | 0.3                     | 0.5                     | The submitted data on oranges, lemons, and mandarins are sufficient to derive an MRL proposal by extrapolation for the SEU use on citrus fruits. Risk for consumers unlikely |
| 0140010 | Apricots              | –                       | 0.3                     | The submitted data on apricots and peaches are sufficient to derive an MRL proposal by extrapolation for the SEU use on apricots. Risk for consumers unlikely |
| 0140030 | Peaches               | –                       | 0.3                     | The submitted data on apricots and peaches are sufficient to derive an MRL proposal by extrapolation for the SEU use on peaches. Risk for consumers unlikely |
| 0231010 | Tomatoes              | 0.3                     | 0.4                     | The submitted data on tomatoes are sufficient to derive an MRL proposals for both the SEU and indoor uses. The MRL proposal reflects the more critical residue situation of the indoor use. Risk for consumers unlikely |
| 0231030 | Aubergines/eggplants  | –                       | 0.4                     | The submitted data on tomatoes are sufficient to derive MRL proposals by extrapolation for both the SEU and indoor uses on aubergines. The MRL proposal reflects the more critical residue situation of the indoor use. Risk for consumers unlikely |

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

Agricultural enforcement residue definitions: cyflumetofen

www.efsa.europa.eu/efsajournal 32 EFSA Journal 2021;19(2):6373
| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|------------------|-----------|------------------------|-------------------------|------------------------|
| 0232010          | Cucumbers | –                      | 0.4                     | The submitted data on cucumbers are sufficient to derive an MRL proposal for the SEU use. Risk for consumers unlikely |
| 0700000          | Hops      | –                      | 30                      | The submitted data on hops are sufficient to derive an MRL proposal for the NEU use. Risk for consumers unlikely |

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

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
### Appendix C – Pesticide Residue Intake Model (PRIMo)

#### Cyflumetofen

**European Food Safety Authority**

**EFSA PRIMo revision 3.1; 2019/03/19**

**Conclusion:**

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of Cyflumetofen is unlikely to present a public health concern.

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**Input values**

**Details – chronic risk assessment**

**Details – acute risk assessment**

**Supplementary results – chronic risk assessment**

**Details – acute risk assessment/children**

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**MODIFICATION OF THE EXISTING MRLs FOR CYFLUMETOFEN IN VARIOUS CROPS**

**Source of ADIs**

EFSA PRIMo revision 3.1; 2019/03/19

**Comments:**

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

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### Normal mode

#### Chronic risk assessment: JMPR methodology (IEDI/TMDI)

**Exposure resulting from**

**No of diets exceeding the ADI : ---**

**Commodity/MS diet (µg/kg per day)**

| Commodity/MS diet | No of diets exceeding the ADI | % of ADI | % of ADI | % of ADI |
|-------------------|------------------------------|----------|----------|----------|
| Apples            | 2%                           | 3.42     | 0.9%     | 0.4%     |
| Milk: Cattle      | 2%                           |          |          |          |

| Commodity/MS diet | No of diets exceeding the ADI | % of ADI | % of ADI | % of ADI |
|-------------------|------------------------------|----------|----------|----------|
| Apples            | 2%                           | 2.86     | 1%       | 0.4%     |
| Milk: Cattle      | 2%                           |          |          |          |

| Commodity/MS diet | No of diets exceeding the ADI | % of ADI | % of ADI | % of ADI |
|-------------------|------------------------------|----------|----------|----------|
| Apples            | 2%                           | 1.76     | 0.3%     | 0.1%     |
| Milk: Cattle      | 2%                           |          |          |          |

| Commodity/MS diet | No of diets exceeding the ADI | % of ADI | % of ADI | % of ADI |
|-------------------|------------------------------|----------|----------|----------|
| Apples            | 2%                           | 1.32     | 0.1%     | 0.1%     |
| Milk: Cattle      | 2%                           |          |          |          |

| Commodity/MS diet | No of diets exceeding the ADI | % of ADI | % of ADI | % of ADI |
|-------------------|------------------------------|----------|----------|----------|
| Apples            | 2%                           | 0.45     | 0.2%     | 0.1%     |
| Milk: Cattle      | 2%                           |          |          |          |

| Commodity/MS diet | No of diets exceeding the ADI | % of ADI | % of ADI | % of ADI |
|-------------------|------------------------------|----------|----------|----------|
| Apples            | 2%                           | 0.35     | 0.1%     | 0.1%     |
| Milk: Cattle      | 2%                           |          |          |          |

| Commodity/MS diet | No of diets exceeding the ADI | % of ADI | % of ADI | % of ADI |
|-------------------|------------------------------|----------|----------|----------|
| Apples            | 2%                           | 0.30     | 0.1%     | 0.1%     |
| Milk: Cattle      | 2%                           |          |          |          |

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**Calculated exposure (% of ADI)**

| Commodity/MS diet | Exposure resulting from (µg/kg per day) | % of ADI | % of ADI | % of ADI |
|-------------------|----------------------------------------|----------|----------|----------|
| Apples            | 2%                                     | 3.42     | 0.9%     | 0.4%     |
| Milk: Cattle      | 2%                                     |          |          |          |

| Commodity/MS diet | Exposure resulting from (µg/kg per day) | % of ADI | % of ADI | % of ADI |
|-------------------|----------------------------------------|----------|----------|----------|
| Apples            | 2%                                     | 2.86     | 1%       | 0.4%     |
| Milk: Cattle      | 2%                                     |          |          |          |

| Commodity/MS diet | Exposure resulting from (µg/kg per day) | % of ADI | % of ADI | % of ADI |
|-------------------|----------------------------------------|----------|----------|----------|
| Apples            | 2%                                     | 1.76     | 0.3%     | 0.1%     |
| Milk: Cattle      | 2%                                     |          |          |          |

| Commodity/MS diet | Exposure resulting from (µg/kg per day) | % of ADI | % of ADI | % of ADI |
|-------------------|----------------------------------------|----------|----------|----------|
| Apples            | 2%                                     | 1.32     | 0.1%     | 0.1%     |
| Milk: Cattle      | 2%                                     |          |          |          |

| Commodity/MS diet | Exposure resulting from (µg/kg per day) | % of ADI | % of ADI | % of ADI |
|-------------------|----------------------------------------|----------|----------|----------|
| Apples            | 2%                                     | 0.45     | 0.2%     | 0.1%     |
| Milk: Cattle      | 2%                                     |          |          |          |

| Commodity/MS diet | Exposure resulting from (µg/kg per day) | % of ADI | % of ADI | % of ADI |
|-------------------|----------------------------------------|----------|----------|----------|
| Apples            | 2%                                     | 0.35     | 0.1%     | 0.1%     |
| Milk: Cattle      | 2%                                     |          |          |          |

| Commodity/MS diet | Exposure resulting from (µg/kg per day) | % of ADI | % of ADI | % of ADI |
|-------------------|----------------------------------------|----------|----------|----------|
| Apples            | 2%                                     | 0.30     | 0.1%     | 0.1%     |
| Milk: Cattle      | 2%                                     |          |          |          |

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**Year of evaluation:** 2019

**EFSA PRIMo revision 3.1; 2019/03/19**

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**急速化後の既存MRLsに対するシフルメトフェンの各種検査の適用**

**ソースのADIs**

EFSA PRIMo revision 3.1; 2019/03/19

**コメント:**

慢性リスク評価: JMPR方式（IEDI/TMDI）
As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

### Conclusion:

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

| Details – acute risk assessment/children | Details – acute risk assessment/children |
|------------------------------------------|------------------------------------------|
| **Unprocessed commodities**              | **Processed commodities**                |
| Results for children                     | Results for children                     |
| No. of commodities for which ARfD/ADI is exceeded (IESTI): | No. of processed commodities for which ARfD/ADI is exceeded (IESTI): |
| IESTI                                    | IESTI                                    |
| Highest % of ARfD/ADI Commodities        | MRL/input for RA (mg/kg) Exposure        |
|                                        | Highest % of ARfD/ADI Commodities        | MRL/input for RA (mg/kg) Exposure        |
|                                        | Exposure (µg/kg bw)                      | Exposure (µg/kg bw)                      |

Expand/collapse list

Show results for all crops

| Results for children                     | Results for adults                     |
| No. of processed commodities for which ARfD/ADI is exceeded (IESTI): | No. of processed commodities for which ARfD/ADI is exceeded (IESTI): |
| IESTI                                    | IESTI                                    |
| Highest % of ARfD/ADI Processed commodi | MRL/input for RA (mg/kg) Exposure        |
|                                        | Highest % of ARfD/ADI Processed commodi |
|                                        | Exposure (µg/kg bw)                      | Exposure (µg/kg bw)                      |

Expand/collapse list

**Conclusion:**

Details – acute risk assessment/children

Details – acute risk assessment/children
### Trifluoroacetic acid

**trifluoroacetic acid (TFA)**

#### Toxicological reference values

| ADI (mg/kg bw/day) | ARfD (mg/kg bw) | Source of ADI | Source of ARfD | Year of evaluation |
|--------------------|-----------------|--------------|----------------|-------------------|
| 0.05               |                  | EFSA         | EFSA PRIMo revision 3.1; 2019/03/19 | 2017              |

#### Calculated exposure (% of ADI)

| Commodity/group of commodities | Exposure resulting from | MRLs set at the LOQ (in % of ADI) | commodities not under assessment (in % of ADI) |
|--------------------------------|-------------------------|-----------------------------------|-----------------------------------------------|
| Bananas                        | 9% 4.54                 | 2% 1% 0.9%                        |                                               |
| Soyabeans                      | 6% 3.10                 | 1% 1% 0.4%                        |                                               |
| Oranges                        | 6% 3.04                 | 2% 0.8%                           |                                               |
| Tomatoes                       | 5% 2.37                 | 1% 0.8%                           |                                               |
| Tomatoes                       | 5% 2.28                 | 0.9% 0.8%                         |                                               |
| Bananas                        | 5% 2.27                 | 0.9% 0.8%                         |                                               |
| Tomatoes                       | 4% 2.21                 | 0.9% 0.6%                         |                                               |
| Tomatoes                       | 4% 2.18                 | 0.8% 0.6%                         |                                               |
| Tomatoes                       | 4% 2.06                 | 0.8% 0.3%                         |                                               |
| Tomatoes                       | 4% 2.02                 | 1% 0.9%                           |                                               |
| Tomatoes                       | 4% 1.97                 | 1% 0.6%                           |                                               |
| Tomatoes                       | 4% 1.91                 | 0.5% 0.3%                         |                                               |
| Tomatoes                       | 4% 1.88                 | 0.9% 0.5%                         |                                               |
| Tomatoes                       | 4% 1.85                 | 0.4% 0.4%                         |                                               |
| Tomatoes                       | 4% 1.81                 | 0.3% 0.4%                         |                                               |
| Tomatoes                       | 4% 1.78                 | 0.2% 0.4%                         |                                               |
| Tomatoes                       | 4% 1.75                 | 0.1% 0.4%                         |                                               |
| Tomatoes                       | 4% 1.72                 | 0.1% 0.4%                         |                                               |
| Tomatoes                       | 4% 1.70                 | 0.1% 0.2%                         |                                               |
| Tomatoes                       | 4% 1.68                 | 0.1% 0.2%                         |                                               |
| Tomatoes                       | 4% 1.65                 | 0.1% 0.2%                         |                                               |
| Tomatoes                       | 4% 1.63                 | 0.1% 0.2%                         |                                               |
| Tomatoes                       | 4% 1.61                 | 0.1% 0.2%                         |                                               |
| Tomatoes                       | 4% 1.58                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.56                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.54                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.52                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.50                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.48                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.46                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.44                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.42                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.40                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.38                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.36                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.34                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.32                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.30                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.28                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.26                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.24                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.22                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.20                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.18                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.16                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.14                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.12                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.10                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.08                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.06                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.04                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 1.02                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.99                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.97                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.95                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.93                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.90                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.88                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.85                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.82                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.79                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.76                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.73                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.70                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.67                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.64                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.61                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.58                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.54                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.51                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.48                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.44                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.41                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.37                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.34                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.30                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.27                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.24                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.20                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.17                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.14                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.10                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.06                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.02                 | 0.1% 0.1%                         |                                               |
| Tomatoes                       | 4% 0.00                 | 0.1% 0.1%                         |                                               |

**Conclusion:**

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of trifluoroacetic acid (TFA) is unlikely to present a public health concern.
As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

### Show results for all crops

|                      | Highest % of ARfD/ADI | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|----------------------|------------------------|--------------------------|---------------------|------------------------|--------------------------|---------------------|
| **Unprocessed commodities** |                        |                          |                     |                        |                          |                     |
| Results for children | No of commodities for which ARfD/ADI is exceeded (IESTI): |                      |                     |                        |                          |                     |
| Results for adults   | No of commodities for which ARfD/ADI is exceeded (IESTI): |                      |                     |                        |                          |                     |
| **Processed commodities** |                        |                          |                     |                        |                          |                     |
| Results for children | No of processed commodities for which ARfD/ADI is exceeded (IESTI): |                      |                     |                        |                          |                     |
| Results for adults   | No of processed commodities for which ARfD/ADI is exceeded (IESTI): |                      |                     |                        |                          |                     |

**Conclusion:**

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation).
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                |
| Citrus, dried pulp   | 0.17                  | STMR × PF (1.21)       |

Risk assessment residue definition: Sum of cyflumetofen (sum of isomers) and metabolite B-1 expressed as cyflumetofen (provisional)

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

D.2. Consumer risk assessment

Cyflumetofen

| Commodity             | Existing/Proposed MRL (mg/kg) | Source/type of MRL | Chronic risk assessment | Acute risk assessment |
|-----------------------|------------------------------|--------------------|-------------------------|-----------------------|
|                      | Input value (mg/kg)          | Comment(a)         | Input value (mg/kg)     | Comment               |
| Grapefruits           | 0.5                          | Intended           | 0.02                    | STMR-RAC × PeF(a)     | Acute risk assessment not performed since ARfD unnecessary |
| Oranges               | 0.5                          | Intended           | 0.02                    | STMR-RAC × PeF(a)     |                                      |
| Lemons                | 0.5                          | Intended           | 0.02                    | STMR-RAC × PeF(a)     |                                      |
| Limes                 | 0.5                          | Intended           | 0.02                    | STMR-RAC × PeF(a)     |                                      |
| Mandarins             | 0.5                          | Intended           | 0.02                    | STMR-RAC × PeF(a)     |                                      |
| Other citrus fruit    | 0.5                          | Intended           | 0.02                    | STMR-RAC × PeF(a)     |                                      |
| Almonds               | 0.01                         | FAO (2014)         | 0.01                    | STMR-RAC              |                                      |
| Brazil nuts           | 0.01                         | FAO (2014)         | 0.01                    | STMR-RAC              |                                      |
| Cashew nuts           | 0.01                         | FAO (2014)         | 0.01                    | STMR-RAC              |                                      |
| Chestnuts             | 0.01                         | FAO (2014)         | 0.01                    | STMR-RAC              |                                      |
| Coconuts              | 0.01                         | FAO (2014)         | 0.01                    | STMR-RAC              |                                      |
| Hazelnuts             | 0.01                         | FAO (2014)         | 0.01                    | STMR-RAC              |                                      |
| Macadamia             | 0.01                         | FAO (2014)         | 0.01                    | STMR-RAC              |                                      |
| Pecans                | 0.01                         | FAO (2014)         | 0.01                    | STMR-RAC              |                                      |
| Pine nut kernels      | 0.01                         | FAO (2014)         | 0.01                    | STMR-RAC              |                                      |
| Pistachios            | 0.01                         | FAO (2014)         | 0.01                    | STMR-RAC              |                                      |
| Walnuts               | 0.01                         | FAO (2014)         | 0.01                    | STMR-RAC              |                                      |
| Other tree nuts       | 0.01                         | FAO (2014)         | 0.01                    | STMR-RAC              |                                      |
| Apples                | 0.4                          | FAO (2014)         | 0.14                    | STMR-RAC              |                                      |
| Pears                 | 0.4                          | FAO (2014)         | 0.14                    | STMR-RAC              |                                      |
| Quinces               | 0.4                          | FAO (2014)         | 0.14                    | STMR-RAC              |                                      |
| Medlar                | 0.4                          | FAO (2014)         | 0.14                    | STMR-RAC              |                                      |
| Loquats/J. medlars    | 0.4                          | FAO (2014)         | 0.14                    | STMR-RAC              |                                      |
| Other pome fruit      | 0.4                          | FAO (2014)         | 0.14                    | STMR-RAC              |                                      |
| Apricots              | 0.3                          | Intended           | 0.12                    | STMR-RAC              |                                      |
| Peaches               | 0.3                          | Intended           | 0.12                    | STMR-RAC              |                                      |
| Table grapes          | 0.6                          | FAO (2014)         | 0.22                    | STMR-RAC              |                                      |
| Wine grapes           | 0.6                          | FAO (2014)         | 0.22                    | STMR-RAC              |                                      |
| Strawberries          | 0.6                          | FAO (2014)         | 0.18                    | STMR-RAC              |                                      |
| Azarole/Mediterranean medlar | 0.4 | FAO (2014) | 0.14 | STMR-RAC |
| Commodity                  | Existing/Proposed MRL (mg/kg) | Source/type of MRL | Chronic risk assessment | Acute risk assessment |
|---------------------------|------------------------------|-------------------|------------------------|------------------------|
| Kaki/Japanese persimmons | 0.4                          | FAO (2014)        | 0.14                   | STMR-RAC               |
| Tomatoes                  | 0.4                          | Intended          | 0.13                   | STMR-RAC               |
| Cucumbers                 | 0.4                          | Intended          | 0.15                   | STMR-RAC               |
| Hops (dried)              | 30                           | Intended          | 8.6                    | STMR-RAC               |
| Swine: Muscle/meat        | 0.01                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Swine: Fat tissue         | 0.01                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Swine: Liver              | 0.02                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Swine: Kidney             | 0.02                         | FAO (2014)        | 0.008                  | STMR-RAC               |
| Swine: Edible offal       | 0.02                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Swine: Other products     | 0.01                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Bovine: Muscle/meat       | 0.01                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Bovine: Fat tissue        | 0.01                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Bovine: Liver             | 0.02                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Bovine: Kidney            | 0.02                         | FAO (2014)        | 0.008                  | STMR-RAC               |
| Bovine: Edible offal      | 0.02                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Bovine: Other products    | 0.01                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Sheep: Muscle/meat        | 0.01                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Sheep: Fat tissue         | 0.01                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Sheep: Liver              | 0.02                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Sheep: Kidney             | 0.02                         | FAO (2014)        | 0.008                  | STMR-RAC               |
| Sheep: Edible offal       | 0.02                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Sheep: Other products     | 0.01                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Goat: Muscle/meat         | 0.01                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Goat: Fat tissue          | 0.01                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Goat: Liver               | 0.02                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Goat: Kidney              | 0.02                         | FAO (2014)        | 0.008                  | STMR-RAC               |
| Goat: Edible offal        | 0.02                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Goat: Other products      | 0.01                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Equine: Muscle/meat       | 0.01                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Equine: Fat tissue        | 0.01                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Equine: Liver             | 0.02                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Equine: Kidney            | 0.02                         | FAO (2014)        | 0.008                  | STMR-RAC               |
| Equine: Edible offal      | 0.02                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Equine: Other products    | 0.01                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Other farmed animals:     |                              |                   |                        |                        |
| Muscle/meat               | 0.01                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Other farmed animals:     |                              |                   |                        |                        |
| Fat tissue                | 0.01                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Other farmed animals:     |                              |                   |                        |                        |
| Liver                     | 0.02                         | FAO (2014)        | 0.01                   | STMR-RAC               |
| Other farmed animals:     |                              |                   |                        |                        |
| Kidney                    | 0.02                         | FAO (2014)        | 0.008                  | STMR-RAC               |
## Trifluoracetic acid (TFA)

| Commodity                  | Existing/Proposed MRL (mg/kg) | Source/type of MRL | Chronic risk assessment | Acute risk assessment |
|----------------------------|-------------------------------|--------------------|-------------------------|------------------------|
| Grapefruits                | n/a                           | EFSA (2014)        | 0.08                    | STMR                   |
| Oranges                    | n/a                           | EFSA (2014)        | 0.08                    | STMR                   |
| Lemons                     | n/a                           | EFSA (2014)        | 0.08                    | STMR                   |
| Limes                      | n/a                           | EFSA (2014)        | 0.08                    | STMR                   |
| Mandarins                  | n/a                           | EFSA (2014)        | 0.08                    | STMR                   |
| Other citrus fruit         | n/a                           | EFSA (2014)        | 0.08                    | STMR                   |
| Almonds                    | n/a                           | EFSA (2014)        | 0.08                    | STMR                   |
| Brazil nuts                | n/a                           | EFSA (2014)        | 0.08                    | STMR                   |
| Cashew nuts                | n/a                           | EFSA (2014)        | 0.08                    | STMR                   |
| Chestnuts                  | n/a                           | EFSA (2014)        | 0.08                    | STMR                   |
| Coconuts                   | n/a                           | EFSA (2014)        | 0.08                    | STMR                   |
| Hazelnuts/cobnuts          | n/a                           | EFSA (2014)        | 0.08                    | STMR                   |
| Macadamia                  | n/a                           | EFSA (2014)        | 0.08                    | STMR                   |
| Pecans                     | n/a                           | EFSA (2014)        | 0.08                    | STMR                   |
| Pine nut kernels           | n/a                           | EFSA (2014)        | 0.08                    | STMR                   |
| Pistachios                 | n/a                           | EFSA (2014)        | 0.08                    | STMR                   |
| Walnuts                    | n/a                           | EFSA (2014)        | 0.08                    | STMR                   |
| Other tree nuts            | n/a                           | EFSA (2014)        | 0.08                    | STMR                   |
| Apples                     | n/a                           | EFSA (2014)        | 0.08                    | STMR                   |
| Pears                      | n/a                           | EFSA (2014)        | 0.08                    | STMR                   |
| Quinces                    | n/a                           | EFSA (2014)        | 0.08                    | STMR                   |
| Medlar                     | n/a                           | EFSA (2014)        | 0.08                    | STMR                   |
| Loquats/Japanese medlars    | n/a                           | EFSA (2014)        | 0.08                    | STMR                   |

STMR: supervised trials median residue in raw agricultural commodity; PeF: peeling factor; MRL: maximum residue level; LOQ: limit of quantification.

(a): A peeling factor of 0.17 derived from residue trial data was applied.

(b): In the absence of a specific LOQ in honey for the active substance under consideration, the default value of 0.05 mg/kg was used (European Commission, 2018.).
| Commodity                        | Existing/Proposed MRL (mg/kg) | Source/type of MRL | Chronic risk assessment | Acute risk assessment |
|---------------------------------|-------------------------------|--------------------|-------------------------|-----------------------|
|                                 |                               |                    | Input value (mg/kg)     | Comment(a)            |
|                                 |                               |                    |                         |                       |
| Other pome fruit                | n/a                           | EFSA (2014)        | 0.08                    | STMR                  |
| Apricots                        | n/a                           | EFSA (2014)        | 0.08                    | STMR                  |
| Cherries (sweet)                | n/a                           | EFSA (2014)        | 0.08                    | STMR                  |
| Peaches                         | n/a                           | EFSA (2014)        | 0.08                    | STMR                  |
| Plums                           | n/a                           | EFSA (2014)        | 0.08                    | STMR                  |
| Other stone fruit               | n/a                           | EFSA (2014)        | 0.08                    | STMR                  |
| Table grapes                    | n/a                           | EFSA (2014)        | 0.08                    | STMR                  |
| Wine grapes                     | n/a                           | EFSA (2014)        | 0.08                    | STMR                  |
| Strawberries                    | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Blackberries                    | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Dewberries                      | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Raspberries (red and yellow)    | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Other cane fruit                | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Blueberries                     | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Cranberries                     | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Currants (red, black and white) | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Gooseberries (green, red and yellow) | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Rose hips                       | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Mulberries (black and white)    | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Azarole/Mediterranean medlar    | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Elderberries                    | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Other small fruit and berries   | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Dates                           | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Figs                            | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Table olives                    | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Kumquats                        | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Carambolas                      | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Kaki/Japanese persimmons        | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Jambuls/jambolans               | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Other miscellaneous fruit (edible peel) | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Kiwi fruits (green, red, yellow)| n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Litchis/lychees                 | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Passion fruits/ maracujas       | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Prickly pears/cactus fruits     | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Star apples                     | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Commodity | Existing/Proposed MRL (mg/kg) | Source/type of MRL | Chronic risk assessment | Acute risk assessment |
|-----------|------------------------------|--------------------|------------------------|----------------------|
| American persimmon/Virginia kaki | n/a | EFSA (2014) | 0.01 | STMR |
| Other miscellaneous fruit (inedible peel, small) | n/a | EFSA (2014) | 0.01 | STMR |
| Avocados | n/a | EFSA (2014) | 0.01 | STMR |
| Bananas | n/a | EFSA (2014) | 0.08 | STMR |
| Mangoes | n/a | EFSA (2014) | 0.08 | STMR |
| Papayas | n/a | EFSA (2014) | 0.01 | STMR |
| Granate apples/pomegranates | n/a | EFSA (2014) | 0.01 | STMR |
| Cherimoyas | n/a | EFSA (2014) | 0.01 | STMR |
| Guavas | n/a | EFSA (2014) | 0.01 | STMR |
| Pineapples | n/a | EFSA (2014) | 0.01 | STMR |
| Breadfruits | n/a | EFSA (2014) | 0.01 | STMR |
| Durians | n/a | EFSA (2014) | 0.01 | STMR |
| Soursops/guanabanas | n/a | EFSA (2014) | 0.01 | STMR |
| Other miscellaneous fruit (inedible peel, large) | n/a | EFSA (2014) | 0.01 | STMR |
| Potatoes | n/a | Netherlands (2016) | 0.021 | HR-ROT crop |
| Cassava roots/manioc | n/a | Netherlands (2016) | 0.021 | HR-ROT crop |
| Sweet potatoes | n/a | Netherlands (2016) | 0.021 | HR-ROT crop |
| Yams | n/a | Netherlands (2016) | 0.021 | HR-ROT crop |
| Arrowroots | n/a | Netherlands (2016) | 0.021 | HR-ROT crop |
| Other tropical root and tuber vegetables | n/a | Netherlands (2016) | 0.021 | HR-ROT crop |
| Beetroots | n/a | Netherlands (2016) | 0.021 | HR-ROT crop |
| Carrots | n/a | Netherlands (2016) | 0.021 | HR-ROT crop |
| Celeriacs/turnip-rooted celeries | n/a | Netherlands (2016) | 0.021 | HR-ROT crop |
| Horseradishes | n/a | Netherlands (2016) | 0.021 | HR-ROT crop |
| Jerusalem artichokes | n/a | Netherlands (2016) | 0.021 | HR-ROT crop |
| Parsnips | n/a | Netherlands (2016) | 0.021 | HR-ROT crop |
| Parsley roots/Hamburg roots parsley | n/a | Netherlands (2016) | 0.021 | HR-ROT crop |
| Radishes | n/a | Netherlands (2016) | 0.021 | HR-ROT crop |
| Commodity                        | Existing/Proposed MRL (mg/kg) | Source/type of MRL | Chronic risk assessment | Acute risk assessment |
|---------------------------------|-------------------------------|--------------------|------------------------|-----------------------|
|                                 |                               |                    | Input value (mg/kg)    | Comment(a)            |
|                                 |                               |                    | Comment                | Input value (mg/kg)   |
|                                 |                               |                    |                        | Comment              |
| Salsifies n/a                   |                               | Netherlands (2016)  | 0.021                  | HR-ROT crop          |
| Swedes/rutabagas n/a           |                               | Netherlands (2016)  | 0.021                  | HR-ROT crop          |
| Turnips n/a                    |                               | Netherlands (2016)  | 0.021                  | HR-ROT crop          |
| Other root and tuber vegetables n/a | Netherlands (2016)  |                      | 0.021                  | HR-ROT crop          |
| Garlic n/a                     |                               | Netherlands (2016)  | 0.021                  | HR-ROT crop          |
| Onions n/a                     |                               | Netherlands (2016)  | 0.021                  | HR-ROT crop          |
| Shallots n/a                   |                               | Netherlands (2016)  | 0.021                  | HR-ROT crop          |
| Spring onions/green onions and Welsh onions n/a | Netherlands (2016)  |                      | 0.021                  | HR-ROT crop          |
| Other bulb vegetables n/a       |                               | Netherlands (2016)  | 0.021                  | HR-ROT crop          |
| Tomatoes n/a                   |                               | Netherlands (2016)  | 0.159                  | HR-ROT crop          |
| Sweet peppers/bell peppers n/a |                               | Netherlands (2016)  | 0.159                  | HR-ROT crop          |
| Aubergines/egg plants n/a      |                               | Netherlands (2016)  | 0.159                  | HR-ROT crop          |
| Okra/lady's fingers n/a        |                               | Netherlands (2016)  | 0.159                  | HR-ROT crop          |
| Other solanacea n/a            |                               | Netherlands (2016)  | 0.159                  | HR-ROT crop          |
| Cucumbers n/a                  |                               | Netherlands (2016)  | 0.159                  | HR-ROT crop          |
| Gherkins n/a                   |                               | Netherlands (2016)  | 0.159                  | HR-ROT crop          |
| Courgettes n/a                 |                               | Netherlands (2016)  | 0.159                  | HR-ROT crop          |
| Other cucurbits - edible peel n/a | Netherlands (2016)  |                      | 0.159                  | HR-ROT crop          |
| Melons n/a                     |                               | Netherlands (2016)  | 0.159                  | HR-ROT crop          |
| Pumpkins n/a                   |                               | Netherlands (2016)  | 0.159                  | HR-ROT crop          |
| Watermelons n/a                |                               | Netherlands (2016)  | 0.159                  | HR-ROT crop          |
| Other cucurbits - inedible peel n/a | Netherlands (2016)  |                      | 0.159                  | HR-ROT crop          |
| Broccoli n/a                   |                               | Netherlands (2016)  | 0.159                  | HR-ROT crop          |
| Cauliflowers n/a               |                               | Netherlands (2016)  | 0.159                  | HR-ROT crop          |
| Other flowering brassica n/a   |                               | Netherlands (2016)  | 0.159                  | HR-ROT crop          |
| Commodity                          | Existing/ Proposed MRL (mg/kg) | Source/ type of MRL | Chronic risk assessment | Acute risk assessment |
|-----------------------------------|-------------------------------|---------------------|-------------------------|-----------------------|
| Brussels sprouts                  | n/a                           | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Head cabbages                     | n/a                           | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Other head brassica               | n/a                           | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Chinese cabbages/ pe-tsai         | n/a                           | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Kales                             | n/a                           | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Other leafy brassica              | n/a                           | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Kohlrabies                        | n/a                           | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Lamb's lettuce/corn salads        | n/a                           | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Lettuces                          | n/a                           | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Escaroles/broad-leaved endives    | n/a                           | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Cress and other sprouts and shoots| n/a                           | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Land cress                        | n/a                           | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Roman rocket/rucola               | n/a                           | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Red mustards                      | n/a                           | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Baby leaf crops (including brassica species) | n/a                        | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Other lettuce and other salad plants| n/a                        | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Spinaches                         | n/a                           | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Purslanes                         | n/a                           | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Chards/beet leaves                | n/a                           | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Other spinach and similar         | n/a                           | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Grape leaves and similar species  | n/a                           | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Watercress                        | n/a                           | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Witloofs/Belgian endives          | n/a                           | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Chervil                           | n/a                           | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Chives                            | n/a                           | Netherlands (2016)  | 0.159                   | HR-ROT crop           |
| Commodity                        | Existing/Proposed MRL (mg/kg) | Source/type of MRL | Chronic risk assessment | Acute risk assessment |
|---------------------------------|------------------------------|--------------------|-------------------------|-----------------------|
|                                 |                              |                    | Input value (mg/kg)     | Comment(a)           | Input value (mg/kg) |
|                                 |                              |                    |                         |                       | Comment            |
| Celery leaves                   | n/a                          | Netherlands (2016) | 0.159                   | HR-ROT crop          |                    |
| Parsley                         | n/a                          | Netherlands (2016) | 0.159                   | HR-ROT crop          |                    |
| Sage                            | n/a                          | Netherlands (2016) | 0.159                   | HR-ROT crop          |                    |
| Rosemary                        | n/a                          | Netherlands (2016) | 0.159                   | HR-ROT crop          |                    |
| Thyme                           | n/a                          | Netherlands (2016) | 0.159                   | HR-ROT crop          |                    |
| Basil and edible flowers        | n/a                          | Netherlands (2016) | 0.159                   | HR-ROT crop          |                    |
| Laurel/bay leaves               | n/a                          | Netherlands (2016) | 0.159                   | HR-ROT crop          |                    |
| Tarragon                        | n/a                          | Netherlands (2016) | 0.159                   | HR-ROT crop          |                    |
| Other herbs                     | n/a                          | Netherlands (2016) | 0.159                   | HR-ROT crop          |                    |
| Beans (with pods)               | n/a                          | EFSA (2014)        | 0.165                   | STMR                 |                    |
| Beans (without pods)            | n/a                          | EFSA (2014)        | 0.165                   | STMR                 |                    |
| Peas (with pods)                | n/a                          | EFSA (2014)        | 0.165                   | STMR                 |                    |
| Peas (without pods)             | n/a                          | EFSA (2014)        | 0.165                   | STMR                 |                    |
| Lentils (fresh)                 | n/a                          | EFSA (2014)        | 0.165                   | STMR                 |                    |
| Other legume vegetables (fresh) | n/a                          | EFSA (2014)        | 0.165                   | STMR                 |                    |
| Asparagus                       | n/a                          | Netherlands (2016) | 0.159                   | HR-ROT crop          |                    |
| Cardoons                        | n/a                          | Netherlands (2016) | 0.159                   | HR-ROT crop          |                    |
| Celeries                        | n/a                          | Netherlands (2016) | 0.159                   | HR-ROT crop          |                    |
| Florence fennels                | n/a                          | Netherlands (2016) | 0.159                   | HR-ROT crop          |                    |
| Globe artichokes                | n/a                          | Netherlands (2016) | 0.159                   | HR-ROT crop          |                    |
| Leeks                           | n/a                          | Netherlands (2016) | 0.159                   | HR-ROT crop          |                    |
| Rhubarbs                        | n/a                          | Netherlands (2016) | 0.159                   | HR-ROT crop          |                    |
| Bamboo shoots                   | n/a                          | Netherlands (2016) | 0.159                   | HR-ROT crop          |                    |
| Palm hearts                     | n/a                          | Netherlands (2016) | 0.159                   | HR-ROT crop          |                    |
| Other stem vegetables           | n/a                          | Netherlands (2016) | 0.159                   | HR-ROT crop          |                    |
| Cultivated fungi                | n/a                          | EFSA (2014)        | 0.01                    | STMR                 |                    |
| Wild fungi                      | n/a                          | EFSA (2014)        | 0.01                    | STMR                 |                    |
| Mosses and lichens              | n/a                          | EFSA (2014)        | 0.01                    | STMR                 |                    |
| Commodity                        | Existing/Proposed MRL (mg/kg) | Source/type of MRL | Chronic risk assessment | Acute risk assessment |
|---------------------------------|-------------------------------|--------------------|-------------------------|-----------------------|
|                                 |                               |                    | Input value (mg/kg)     | Comment               |
|                                 |                               |                    | Comment (a)             |                       |
|                                 |                               |                    |                         |                       |
| Algae and prokaryotes organisms | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Beans                           | n/a                           | EFSA (2014)        | 0.165                   | STMR                  |
| Lentils                         | n/a                           | EFSA (2014)        | 0.165                   | STMR                  |
| Peas                            | n/a                           | EFSA (2014)        | 0.165                   | STMR                  |
| Lupins/lupini beans             | n/a                           | EFSA (2014)        | 0.165                   | STMR                  |
| Other pulses                    | n/a                           | EFSA (2014)        | 0.165                   | STMR                  |
| Linseed                         | n/a                           | EFSA (2014)        | 0.068                   | STMR                  |
| Peanuts/groundnuts              | n/a                           | EFSA (2014)        | 0.068                   | STMR                  |
| Poppy seeds                     | n/a                           | EFSA (2014)        | 0.068                   | STMR                  |
| Sesame seeds                    | n/a                           | EFSA (2014)        | 0.068                   | STMR                  |
| Sunflower seeds                 | n/a                           | EFSA (2014)        | 0.068                   | STMR                  |
| Rapeseeds/canola seeds          | n/a                           | EFSA (2014)        | 0.068                   | STMR                  |
| Soya beans                      | n/a                           | EFSA (2014)        | 0.165                   | STMR                  |
| Mustard seeds                   | n/a                           | EFSA (2014)        | 0.068                   | STMR                  |
| Cotton seeds                    | n/a                           | EFSA (2014)        | 0.068                   | STMR                  |
| Pumpkin seeds                   | n/a                           | EFSA (2014)        | 0.068                   | STMR                  |
| Safflower seeds                 | n/a                           | EFSA (2014)        | 0.068                   | STMR                  |
| Borage seeds                    | n/a                           | EFSA (2014)        | 0.068                   | STMR                  |
| Gold of pleasure seeds          | n/a                           | EFSA (2014)        | 0.068                   | STMR                  |
| Hemp seeds                      | n/a                           | EFSA (2014)        | 0.068                   | STMR                  |
| Castor beans                    | n/a                           | EFSA (2014)        | 0.068                   | STMR                  |
| Other oilseeds                  | n/a                           | EFSA (2014)        | 0.068                   | STMR                  |
| Olives for oil production       | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Oil palm kernels                | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Oil palm fruits                 | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Kapok                            | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Other oilfruit                  | n/a                           | EFSA (2014)        | 0.01                    | STMR                  |
| Barley                          | n/a                           | Netherlands (2016) | 0.099                   | HR-ROT crop           |
| Buckwheat and other pseudo-cereals | n/a                           | Netherlands (2016) | 0.099                   | HR-ROT crop           |
| Maize/corn                      | n/a                           | Netherlands (2016) | 0.099                   | HR-ROT crop           |
| Common millet/proso millet      | n/a                           | Netherlands (2016) | 0.099                   | HR-ROT crop           |
| Oat                             | n/a                           | Netherlands (2016) | 0.099                   | HR-ROT crop           |
| Rice                            | n/a                           | Netherlands (2016) | 0.099                   | HR-ROT crop           |
| Rye                             | n/a                           | Netherlands (2016) | 0.099                   | HR-ROT crop           |
| Sorghum                         | n/a                           | Netherlands (2016) | 0.099                   | HR-ROT crop           |
| Commodity                              | Existing/Proposed MRL (mg/kg) | Source/type of MRL | Chronic risk assessment | Acute risk assessment |
|----------------------------------------|------------------------------|--------------------|-------------------------|-----------------------|
|                                       |                              |                    | Input value (mg/kg)     | Comment(a)            |
| Wheat                                 | n/a                          | Netherlands (2016) | 0.099                   | HR-ROT crop           |
| Other cereals                         | n/a                          | Netherlands (2016) | 0.099                   | HR-ROT crop           |
| Tea (dried leaves of *Camellia sinensis*) | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Coffee beans                          | n/a                          | Netherlands (2016) | 0.099                   | HR-ROT crop           |
| Chamomile                             | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Hibiscus/roselle                      | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Rose                                  | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Jasmine                               | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Lime/linden                           | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Other herbal infusions (dried flowers) | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Strawberry leaves                     | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Rooibos                               | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Mate/maté                            | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Other herbal infusions (dried leaves) | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Valerian root                         | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Ginseng root                          | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Other herbal infusions (dried roots)  | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Cocoa beans                           | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Carobs/Saint John’s bread             | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| HOPS (dried)                          | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Anise/aniseed                         | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Black caraway/black cumin             | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Celery seed                           | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Coriander seed                        | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Cumin seed                            | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Dill seed                             | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Fennel seed                           | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Fenugreek                             | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Nutmeg                                | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Other spices (seeds)                  | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Allspice/pimento                      | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Sichuan pepper                        | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Caraway                               | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Cardamom                              | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Juniper berry                         | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Peppercorn (black, green and white)   | n/a                          | EFSA (2014)        | 0.01                    | STMR                  |
| Commodity                        | Existing/Proposed MRL (mg/kg) | Source/type of MRL | Chronic risk assessment | Input value (mg/kg) | Comment(a) | Acute risk assessment | Input value (mg/kg) | Comment |
|---------------------------------|-------------------------------|--------------------|-------------------------|---------------------|------------|----------------------|---------------------|---------|
| Vanilla pods                    | n/a                           | EFSA (2014)        |                         | 0.01                | STMR       |                      |                     |         |
| Tamarind                        | n/a                           | EFSA (2014)        |                         | 0.01                | STMR       |                      |                     |         |
| Other spices (fruits)           | n/a                           | EFSA (2014)        |                         | 0.01                | STMR       |                      |                     |         |
| Cinnamon                        | n/a                           | EFSA (2014)        |                         | 0.01                | STMR       |                      |                     |         |
| Other spices (bark)             | n/a                           | EFSA (2014)        |                         | 0.01                | STMR       |                      |                     |         |
| Liquorice                       | n/a                           | EFSA (2014)        |                         | 0.01                | STMR       |                      |                     |         |
| Ginger                          | n/a                           | EFSA (2014)        |                         | 0.01                | STMR       |                      |                     |         |
| Turmeric/curcuma                | n/a                           | EFSA (2014)        |                         | 0.01                | STMR       |                      |                     |         |
| Horseradish, root spices        | n/a                           | EFSA (2014)        |                         | 0.01                | STMR       |                      |                     |         |
| Other spices (roots)            | n/a                           | EFSA (2014)        |                         | 0.01                | STMR       |                      |                     |         |
| Cloves                          | n/a                           | EFSA (2014)        |                         | 0.01                | STMR       |                      |                     |         |
| Capers                          | n/a                           | EFSA (2014)        |                         | 0.01                | STMR       |                      |                     |         |
| Other spices (buds)             | n/a                           | EFSA (2014)        |                         | 0.01                | STMR       |                      |                     |         |
| Saffron                         | n/a                           | EFSA (2014)        |                         | 0.01                | STMR       |                      |                     |         |
| Other spices (flower stigma)    | n/a                           | EFSA (2014)        |                         | 0.01                | STMR       |                      |                     |         |
| Mace                            | n/a                           | EFSA (2014)        |                         | 0.01                | STMR       |                      |                     |         |
| Other spices (aril)             | n/a                           | EFSA (2014)        |                         | 0.01                | STMR       |                      |                     |         |
| Sugar beet roots                | n/a                           | EFSA (2014)        |                         | 0.01                | STMR       |                      |                     |         |
| Sugar canes                     | n/a                           | EFSA (2014)        |                         | 0.01                | STMR       |                      |                     |         |
| Chicory roots                   | n/a                           | EFSA (2014)        |                         | 0.01                | STMR       |                      |                     |         |
| Other sugar plants              | n/a                           | EFSA (2014)        |                         | 0.01                | STMR       |                      |                     |         |

n/a: not applicable (no MRLs are set for TFA). STMR: supervised trials median residue derived; HR-ROT crop: highest residue measured in rotational metabolism studies with cyflumetofen.

(a): STMR as derived in a previous EFSA assessment considering the highest TFA median residue in primary and rotational crops resulting from the use of pesticides which were mentioned in the EFSA conclusions as possible sources of TFA (fluazinam, trifloxystrobin, fluometuron) and from food environmental contamination (EFSA, 2014), replaced, if higher, with the highest residue measured in the rotational crops metabolism studies with cyflumetofen assessed in these applications (Netherlands, 2016).
### Appendix E – Used compound codes

| Code/trivial name(a) | IUPAC name/SMILES notation/InChiKey(b) | Structural formula(c) |
|---------------------|---------------------------------------|-----------------------|
| **Cyflumetofen**    | 2-methoxyethyl 2-(4-tert-butylphenyl)-2-cyano-3-oxo-3-[2-(trifluoromethyl)benzamido]propanoate | ![Structural formula](image1.png) |
|                     | FC(F)(F)c1cccc1C(=O)NC(=O)C(C#N)(c1ccc(cc1)C(C)(C)C)C(=O)OCCOC |                       |
|                     | RAZUBFCBHSOG-UHFFFAOYSA-N |                       |
| **B-1**             | α,α,α-trifluoro-o-toluic acid | ![Structural formula](image2.png) |
|                     | FC(F)(F)c1cccc1C(=O)O |                       |
|                     | FBRJYBGLCHWYOE-UHFFFAOYSA-N |                       |
| **B-3**             | 2-(trifluoromethyl)benzamide | ![Structural formula](image3.png) |
|                     | FC(F)(F)c1cccc1C(N)=O |                       |
|                     | QBAYIBZITZBSFO-UHFFFAOYSA-N |                       |
| **AB-1**            | 3-oxo-2-phenyl-3-[2-(trifluoromethyl)phenyl]propanenitrile | ![Structural formula](image4.png) |
|                     | FC(F)(F)c1cccc1C(=O)C(C#N)c1cccc1 |                       |
|                     | WTSIEPMTQJZRF-UHFFFAOYSA-N |                       |
| **AB-6**            | 2-methoxyethyl 2-(4-tert-butylphenyl)-3-oxo-3-[2-(trifluoromethyl)benzamido]propanoate | ![Structural formula](image5.png) |
|                     | FC(F)(F)c1cccc1C(=O)NC(=O)C(c1ccc(cc1)C(C)(C)C)(C)(C)c1cccc1 |                       |
|                     | RKBXBGAVYGWOD-UHFFFAOYSA-N |                       |
| **AB-7**            | 2-methoxyethyl 4-[4-tert-butyl-2-[2-(trifluoromethyl)benzoyl]phenyl](cyano)acetate | ![Structural formula](image6.png) |
|                     | FC(F)(F)c1cccc1C(=O)c1cc(cc1C(C#N)C(=O)OCCOC)(C)(C)c1cccc1 |                       |
|                     | HNUXNCYDRMUIPU-UHFFFAOYSA-N |                       |
| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-----------------------------|---------------------------------------------|----------------------|
| A-2                         | (4-tert-butylphenyl)acetonitrile<br>CC(C)(C)c1ccc(CC#N)cc1<br>FGFFQKZKAJOZKS-UHFFFAOYSA-N | ![Structural formula](image) |
| TFA                         | Trifluoroacetic acid<br>FC(F)(F)=O<br>DTQVDTLACAAQTR-UHFFFAOYSA-N | CF<sub>3</sub>COOH |

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

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2019.1.3 ACD/Labs 2019 Release (File version N05E41, Build 111418, 3 September 2019).
(c): ACD/ChemSketch 2019.1.3 ACD/Labs 2019 Release (File version C05H41, Build 111302, 27 August 2019).