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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.

Keywords: Cyflumetofen, various crops, acaricide, MRL, consumer risk assessment

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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 method, 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.

Sufficiently validated analytical methods are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in the 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
Enforcement residue definition: cyflumetofen				
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
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/EEC[1] 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 approved[2] for the use as an acaricide on 1 June 2013, with conditions for approval of plant protection products introduced in 2019[3] 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),

[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).

[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_{90} 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 nutmeal 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 nutmeal (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 nutmeal (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.[6] 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.

[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 spinaches) 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 *in vitro*, but was concluded 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.[7] 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

[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

TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WHO	World Health Organization

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

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate	Unit		
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	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate	Unit		
Peaches	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	
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	BBCH13–89	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	

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate	Unit		
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_{50}: 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

Primary crops (available studies)	**Crop groups**	**Crops**	**Applications**	**Sampling (DAT)**	**Comment/Source**
	Fruit crops	Apple	Foliar, 1 × 600 g/ha	Fruit: 1, 7, 30 Leaf: 7, 30	Radiolabelled active substance: [^{14}C- butylphenyl] and [^{14}C-trifluoromethyl phenyl] cyflumetofen (EFSA, 2012)
		Mandarin	Foliar, 1 × 600 g/ha	Fruit: 1, 7, 30 Leaf: 1, 7, 14	
		Eggplant	Foliar, 1 × 600 g/ha	Fruit: 1, 7, 14 Leaf: 14	
	Root crops	–	–	–	–
	Leafy crops	–	–	–	–
	Cereals/grass	–	–	–	–
	Pulses/ oilseeds	–	–	–	–
	Miscellaneous	–	–	–	–
Rotational crops (available studies)	**Crop groups**	**Crops**	**Application**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Radish	Bare soil, 1 × 400 g/ha	30, 120, 365	Not triggered (DT_{90} < 100 days) Radiolabelled active substance: [^{14}C- butylphenyl] and [^{14}C-trifluoromethyl phenyl] cyflumetofen (EFSA, 2012)
	Leafy crops	Lettuce	Bare soil, 1 × 400 g/ha	30, 120, 365	
	Cereal (small grain)	Wheat	Bare soil, 1 × 400 g/ha	30, 120, 365	
	Other	–	–	–	

Processed commodities (hydrolysis study)	**Conditions**	**Stable?**	**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)	Yes	Radiolabelled active substance: [^{14}C- butylphenyl] and [^{14}C-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?	No	EFSA (2012)
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?	Yes (pasteurisation) No (baking, brewing/ boiling and sterilisation	Netherlands (2016)
Plant residue definition for monitoring (RD-Mo)	Fruit crops: Cyflumetofen (sum of isomers) Processed commodities: Open	
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 nutmeal	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[a]	Residue levels observed in the supervised residue trials[b] (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[c] (mg/kg)	STMR[d] (mg/kg)	CF[e]
Oranges Lemons, Mandarins	SEU	**Mo:** 0.05, 0.07, 0.07, 0.08, 0.08, 0.10, 0.10, 0.11, 0.12, 0.13, 0.14, 0.16, 0.21, 0.22, 0.27, 0.27 **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	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 B-1 (whole fruit, pulp): 16 × < 0.01 mg/kg	0.5	**Mo:** 0.27 **RA:** 0.29	**Mo:** 0.12 **RA:** 0.14	1.20
Apricots, Peaches	SEU	**Mo:** < 0.01, 0.03, 0.07, 0.08, 0.10, 0.11, 0.12, 0.13 **RA:** 0.03, 0.06, 0.09, 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 **RA:** 0.03, 0.07, 0.08, 0.08, 0.08, 0.09, 0.12, 0.12	Residue trials on tomatoes compliant with GAP. Highest value 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
	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 **RA:** 0.04, 0.05, 0.07, 0.08, 0.10, 0.11, 0.15, 0.15, 0.15, 0.18, 0.18, 0.31	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 **RA:** 0.08, 0.09, 0.11, 0.17, 0.12, 0.17, 0.18, 0.26	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	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 **RA:** 4.2, 8.5, 8.7, 14.59	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

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?	No (cyflumetofen, B-1) Yes (TFA)	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)
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered (cyflumetofen, B-1) Yes (TFA), according to metabolism studies	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

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

B.2.2.3. Processing factors

Processed commodity	Number of valid studies[a]	Processing Factor (PF)		CF_P[b]	Comment/Source
		Individual values	Median PF		
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[c] Field trial data (Netherlands, 2016)
Orange, pulp	4	< 0.05; < 0.05; 0.05; 0.07	< 0.05	–	Tentative[c] Processing study data (Netherlands, 2016)
Orange, juice (pasteurised)	4	< 0.05; 0.07; 0.08; 0.10	0.08	.	Tentative[c] (Netherlands, 2016
	2	< 0.02, < 0.08	< 0.05	–	Tentative[c] (FAO, 2014)
Orange, pomace wet	4	0.08, 0.11, 0.14, 0.14	0.13	–	Tentative[c] (Netherlands, 2016
Orange, dried pulp	4	1.09, 1.20, 1.21, 1.40	1.21	–	Tentative[c] (Netherlands, 2016
	2	0.44, 0.58	0.51	–	Tentative[c] (FAO, 2014)
Orange, oil essence (pressing extract)	4	134, 136, 178, 217	157	–	Tentative[c] (Netherlands, 2016
	2	102, 137	120	–	Tentative[c] (FAO, 2014)
Orange, marmalade	4	0.39, 0.43, 0.65, 0.65	0.54	–	Tentative[c] (Netherlands, 2016
	2	0.03, < 0.08	0.06	–	Tentative[c] (FAO, 2014)
Orange, molasses	2	< 0.02, < 0.08	< 0.05	–	Tentative[c] (FAO, 2014)
Orange, meal	2	0.43, 0.46	0.45	–	Tentative[c] (FAO, 2014)
Apple, juice (pasteurised)	6	< 0.04, < 0.07, 0.07, < 0.10, < 0.13, < 0.17	0.09	–	Tentative[c] (Netherlands, 2016)
	2	0.20, 0.27	0.24	–	Tentative[c] (FAO, 2014)
Apple, canned (boiled, pasteurised)	6	0.08, < 0.13, 0.13, 0.15, 0.16, < 0.17	0.14	–	Tentative[c] (Netherlands, 2016)
	2	0.04, 0.18	0.11	–	Tentative[c] (FAO, 2014)

Processed commodity	Number of valid studies[a]	Processing Factor (PF)		CF_P[b]	Comment/Source
		Individual values	Median PF		
Apple, dried	6	3.25, 4.14, 5.17, 5.20, 7.30, 7.33	5.19	–	Tentative[c] (Netherlands, 2016)
	2	0.17, 0.83	0.50	–	Tentative[c] (FAO, 2014)
Apple, wet pomace	6	2.68, 3.13, 3.17, 3.31, 3.33, 4.70	3.24	–	Tentative[c] (Netherlands, 2016)
	2	0.94, 1.59	1.27	–	Tentative[c] (FAO, 2014)
Apple, sauce (pasteurised)	6	< 0.13, 0.17, 0.45, 0.60, 0.65, 1.70	0.53	–	Tentative[c] (Netherlands, 2016)
	2	2.54, 2.91	2.73	–	Tentative[c] (FAO, 2014)
Apple, syrup	6	0.03, 0.05, < 0.07, < 0.10, < 0.13, < 0.17	0.09	–	Tentative[c] (Netherlands, 2016)
Peach, juice (pasteurised)	3	0.44, 1.42, 1.71	1.42	–	Tentative[c] (Netherlands, 2016)
Peach, dried	3	6.63, 7.85, 20.87	7.85	–	Tentative[c] (Netherlands, 2016)
Peach, canned (pasteurised)	3	< 0.04, < 0.06, < 00.08	< 0.06	–	Tentative[c] (Netherlands, 2016)
Peach, jam (cooked, pasteurised)	3	0.11, 012, 0.24	0.12	–	Tentative[c] (Netherlands, 2016)
Strawberry, canned (pasteurised)	4	0.23, 0.35, 0.37, 0.71	0.36	–	Tentative[c] (Netherlands, 2016)
Strawberry, jam (cooked)	4	0.11, 0.16, 0.40, 0.46	0.28	–	Tentative[c] (Netherlands, 2016)
Tomato, juice (raw)	4	0.03, 0.14, 0.14, 0.86,	0.14	–	Tentative[c] (Netherlands, 2016)
	2	< 0.06, 0.20	0.13	–	Tentative[c] (FAO, 2014)
Tomato, peeled	4	< 0.03, < 0.05, 0.06, < 0.07	0.06	–	Tentative[c] (Netherlands, 2016)
	2	< 0.04, < 0.06	< 0.05	–	Tentative[c] (FAO, 2014)
Tomato, canned (peeled, sterilised)	4	< 0.02, < 0.03, < 0.05, 0.19	< 0.04	–	Tentative[c] (Netherlands, 2016)
	2	0.04, 0.20	0.12	–	Tentative[c] (FAO, 2014)
Tomato, puree (pasteurised)	4	0.18, 0.25, 0.28, 0.93	0.27	–	Tentative[c] (Netherlands, 2016)
	2	0.30, 0.88	0.59	–	Tentative[c] (FAO, 2014)
Tomato, paste	4	0.18, 0.21, 0.25, 0.86	0.23	–	Tentative[c] (Netherlands, 2016)
	2	0.20, 0.40	0.3	–	Tentative[c] (FAO, 2014)
Tomato, ketchup (pasteurised)	4	0.09, 0.12, 0.15, 0.44	0.14	–	Tentative[c] (Netherlands, 2016)
Hop, dried cones	4	3.6, 3.8, 5.4, 5.4	4.60	–	Tentative[c] Field trial data (Netherlands, 2016)
Hop, dried cones	2	0.96, 1.00	0.98	–	Tentative[c] Processing study data (Netherlands, 2016)
Hop, extract	2	2.67, 2.75	2.71	–	Tentative[c] (Netherlands, 2016)
Hop, beer	2	< 0.0005, < 0.0022	< 0.0014	–	Tentative[c] (Netherlands, 2016)
Hop, brewer's yeast	2	< 0.0005, < 0.0022	0.0014	–	Tentative[c] (Netherlands, 2016)

Processed commodity	Number of valid studies[a]	Processing Factor (PF)		CF_P[b]	Comment/Source
		Individual values	Median PF		
Hop, draft	2	0.02, 0.05	0.04	–	Tentative[c] (Netherlands, 2016)

PF: processing factor.
(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Conversion factor for risk assessment in the processed commodity was not calculated, pending final decision on the residue definition for risk assessment in processed products.
(c): Tentative PFs were derived assuming that the residue definition for enforcement in primary crops and processed products is cyflumetofen parent compound only.

B.3. Residues in livestock

Calculations performed with Animal Model 2017[8] (OECD, 2013).

Relevant groups (sub groups)	Dietary burden expressed in				Most critical sub group[a]	Most critical commodity[b]	Trigger exceeded (Y/N)	Previous assessment (FAO, 2014)
	mg/kg bw per day		mg/kg DM					mg/kg DM
	Median	Maximum	Median	Maximum				Max burden
Cattle (all)	0.001	0.001	0.04	0.04	Cattle (dairy)	Citrus, dried pulp	N	0.934[c]
Cattle (dairy only)	0.001	0.001	0.04	0.04	Cattle (dairy)	Citrus, dried pulp	N	0.934[c]
Sheep (all)	–	–	–	–	–	–	N	–
Sheep (ewe only)	–	–	–	–	–	–	N	–
Swine (all)	0.001	0.001	0.03	0.03	Swine (breeding)	Citrus, dried pulp	N	–
Poultry (all)	–	–	–	–	–	–	N	–
Poultry (layer only)	–	–	–	–	–	–	N	–
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).

[8] 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 Mandarins: 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.

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.

B.5. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: cyflumetofen				
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

Code[(a)]	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

Cyflumetofen

LOQs (mg/kg) range from:	0.01	to:	0.01
Toxicological reference values			
ADI (mg/kg bw/day):	0.17	ARfD (mg/kg bw):	not necessary
Source of ADI:	COM	Source of ARfD:	COM
Year of evaluation:	2019	Year of evaluation:	2019

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	2%	NL toddler	3.42	0.9%	Apples	0.4%	Pears	0.4%	Milk: Cattle		2%
	2%	DE child	2.86	1%	Apples	0.2%	Table grapes	0.1%	Milk: Cattle		2%
	1%	NL child	1.76	0.5%	Apples	0.1%	Milk: Cattle	0.1%	Table grapes		1%
	0.7%	GEMS/Food G06	1.23	0.3%	Tomatoes	0.1%	Table grapes	0.1%	Aubergines/egg plants		0.7%
	0.7%	RO general	1.18	0.2%	Wine grapes	0.1%	Tomatoes	0.1%	Apples		0.7%
	0.6%	FR toddler 2 3 yr	1.03	0.3%	Apples	0.2%	Milk: Cattle	0.0%	Tomatoes		0.6%
	0.6%	DE women 14-50 yr	1.03	0.2%	Apples	0.1%	Wine grapes	0.1%	Milk: Cattle		0.6%
	0.6%	DE general	1.00	0.2%	Apples	0.1%	Wine grapes	0.1%	Milk: Cattle		0.6%
	0.6%	PT general	1.00	0.3%	Wine grapes	0.1%	Apples	0.1%	Tomatoes		0.6%
	0.6%	FR child 3 15 yr	0.99	0.1%	Apples	0.1%	Milk: Cattle	0.1%	Tomatoes		0.6%
	0.6%	DK child	0.99	0.2%	Apples	0.1%	Cucumbers	0.1%	Milk: Cattle		0.6%
	0.5%	GEMS/Food G07	0.91	0.2%	Wine grapes	0.1%	Apples	0.1%	Tomatoes		0.5%
	0.5%	IE adult	0.87	0.2%	Wine grapes	0.1%	Aubergines/egg plants	0.1%	Apples		0.5%
	0.5%	GEMS/Food G11	0.87	0.1%	Wine grapes	0.1%	Apples	0.1%	Tomatoes		0.5%
	0.5%	FR adult	0.87	0.3%	Wine grapes	0.1%	Apples	0.0%	Tomatoes		0.5%
	0.5%	GEMS/Food G15	0.86	0.1%	Wine grapes	0.1%	Tomatoes	0.1%	Apples		0.5%
	0.5%	GEMS/Food G08	0.84	0.1%	Wine grapes	0.1%	Apples	0.1%	Tomatoes		0.5%
	0.5%	UK infant	0.81	0.2%	Milk: Cattle	0.1%	Apples	0.0%	Tomatoes		0.5%
	0.4%	UK toddler	0.74	0.1%	Apples	0.1%	Milk: Cattle	0.0%	Tomatoes		0.4%
	0.4%	GEMS/Food G10	0.71	0.1%	Tomatoes	0.1%	Apples	0.1%	Wine grapes		0.4%
	0.4%	NL general	0.65	0.1%	Apples	0.1%	Wine grapes	0.0%	Milk: Cattle		0.4%
	0.4%	DK adult	0.63	0.1%	Wine grapes	0.1%	Apples	0.0%	Tomatoes		0.4%
	0.4%	ES child	0.63	0.1%	Apples	0.1%	Tomatoes	0.1%	Milk: Cattle		0.4%
	0.4%	SE general	0.62	0.1%	Apples	0.1%	Milk: Cattle	0.1%	Tomatoes		0.4%
	0.3%	PL general	0.54	0.2%	Apples	0.1%	Tomatoes	0.0%	Table grapes		0.3%
	0.3%	FI 3 yr	0.53	0.1%	Cucumbers	0.1%	Apples	0.0%	Tomatoes		0.3%
	0.3%	ES adult	0.52	0.1%	Apples	0.1%	Tomatoes	0.1%	Wine grapes		0.3%
	0.3%	IT toddler	0.52	0.1%	Tomatoes	0.1%	Apples	0.0%	Pears		0.3%
	0.3%	FR infant	0.52	0.1%	Apples	0.1%	Milk: Cattle	0.0%	Strawberries		0.3%
	0.3%	UK adult	0.51	0.1%	Wine grapes	0.0%	Apples	0.0%	Tomatoes		0.3%
	0.3%	UK vegetarian	0.50	0.1%	Wine grapes	0.0%	Apples	0.0%	Tomatoes		0.3%
	0.3%	LT adult	0.50	0.2%	Apples	0.0%	Tomatoes	0.0%	Cucumbers		0.3%
	0.3%	IT adult	0.45	0.1%	Tomatoes	0.1%	Apples	0.0%	Aubergines/egg plants		0.3%
	0.2%	FI 6 yr	0.38	0.1%	Cucumbers	0.0%	Apples	0.0%	Tomatoes		0.2%
	0.2%	FI adult	0.35	0.0%	Apples	0.0%	Tomatoes	0.0%	Wine grapes		0.2%
	0.1%	IE child	0.12	0.0%	Apples	0.0%	Milk: Cattle	0.0%	Table grapes		0.1%

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.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

Show results for all crops

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): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

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): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							

Conclusion:

- Trifluoracetic acid

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

trifluoroacetic acid (TFA)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.05	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	
Year of evaluation:	2017	Year of evaluation:	

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	9%	NL toddler	4.54	2%	Apples	1%	Maize/corn	0.9%	Bananas		9%
	6%	GEMS/Food G06	3.10	1%	Wheat	1%	Tomatoes	0.4%	Soyabeans		6%
	6%	DE child	3.04	2%	Apples	0.8%	Wheat	0.6%	Oranges		6%
	5%	GEMS/Food G10	2.37	1%	Soyabeans	0.8%	Wheat	0.4%	Tomatoes		5%
	5%	GEMS/Food G11	2.28	1%	Soyabeans	0.7%	Wheat	0.3%	Tomatoes		5%
	5%	NL child	2.27	0.9%	Apples	0.8%	Wheat	0.3%	Bananas		5%
	4%	GEMS/Food G15	2.21	0.9%	Wheat	0.6%	Soyabeans	0.4%	Tomatoes		4%
	4%	GEMS/Food G08	2.18	0.8%	Wheat	0.6%	Soyabeans	0.4%	Tomatoes		4%
	4%	GEMS/Food G07	2.06	0.8%	Wheat	0.6%	Soyabeans	0.3%	Tomatoes		4%
	4%	DK child	2.02	1%	Rye	0.9%	Wheat	0.5%	Cucumbers		4%
	4%	RO general	1.97	1%	Wheat	0.6%	Tomatoes	0.5%	Head cabbages		4%
	4%	IE adult	1.91	0.5%	Wheat	0.3%	Melons	0.2%	Wine grapes		4%
	4%	FR child 3 15 yr	1.88	0.9%	Wheat	0.5%	Oranges	0.3%	Apples		4%
	3%	IT toddler	1.63	1%	Wheat	0.5%	Tomatoes	0.3%	Other cereals		3%
	3%	PT general	1.55	0.8%	Wheat	0.4%	Wine grapes	0.3%	Tomatoes		3%
	3%	SE general	1.54	0.6%	Wheat	0.3%	Bananas	0.2%	Tomatoes		3%
	3%	FR toddler 2 3 yr	1.52	0.6%	Wheat	0.5%	Apples	0.3%	Beans (with pods)		3%
	3%	ES child	1.52	0.9%	Wheat	0.3%	Oranges	0.3%	Tomatoes		3%
	3%	UK toddler	1.42	0.8%	Wheat	0.3%	Oranges	0.3%	Apples		3%
	3%	DE women 14-50 yr	1.34	0.4%	Wheat	0.4%	Apples	0.3%	Oranges		3%
	3%	UK infant	1.31	0.5%	Wheat	0.3%	Apples	0.2%	Bananas		3%
	3%	DE general	1.28	0.4%	Apples	0.4%	Wheat	0.3%	Oranges		3%
	3%	IT adult	1.26	0.8%	Wheat	0.4%	Tomatoes	0.1%	Other cereals		3%
	2%	NL general	1.18	0.4%	Wheat	0.2%	Apples	0.2%	Oranges		2%
	2%	FI 3 yr	1.15	0.3%	Cucumbers	0.2%	Wheat	0.2%	Bananas		2%
	2%	FI adult	1.12	1%	Coffee beans	0.2%	Tomatoes	0.1%	Rye		2%
	2%	ES adult	1.11	0.5%	Wheat	0.2%	Tomatoes	0.2%	Oranges		2%
	2%	FR adult	1.05	0.4%	Wheat	0.4%	Wine grapes	0.1%	Tomatoes		2%
	2%	UK vegetarian	0.90	0.4%	Wheat	0.2%	Tomatoes	0.1%	Oranges		2%
	2%	FI 6 yr	0.90	0.2%	Cucumbers	0.2%	Wheat	0.2%	Potatoes		2%
	2%	LT adult	0.78	0.3%	Apples	0.2%	Rye	0.2%	Wheat		2%
	2%	FR infant	0.78	0.3%	Apples	0.2%	Beans (with pods)	0.2%	Wheat		2%
	1%	DK adult	0.72	0.2%	Wheat	0.2%	Tomatoes	0.2%	Apples		1%
	1%	UK adult	0.70	0.3%	Wheat	0.2%	Wine grapes	0.1%	Tomatoes		1%
	1%	PL general	0.64	0.3%	Apples	0.3%	Tomatoes	0.1%	Potatoes		1%
	0.6%	IE child	0.28	0.2%	Wheat	0.1%	Rice	0.1%	Apples		0.6%

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.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

Show results for all crops

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): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

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): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							

Conclusion:

Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition Sum of cyflumetofen (sum of isomers) and metabolite B-1 expressed as cyflumetofen (provisional)				
Citrus, dried pulp	0.17	STMR × PF (1.21)	0.17	STMR × PF (1.21)

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	
			Input value (mg/kg)	Comment[a]	Input value (mg/kg)	Comment
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		

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
Other farmed animals: Edible offal (other than liver and kidney)	0.02	FAO (2014)	0.01	STMR-RAC		
Other farmed animals: Other products	0.01	FAO (2014)	0.01	STMR-RAC		
Milk: Cattle	0.01	FAO (2014)	0.01	STMR-RAC		
Milk: Sheep	0.01	FAO (2014)	0.01	STMR-RAC		
Milk: Goat	0.01	FAO (2014)	0.01	STMR-RAC		
Milk: Horse	0.01	FAO (2014)	0.01	STMR-RAC		
Milk: Others	0.01	FAO (2014)	0.01	STMR-RAC		
Honey	0.05	Default value[b]	0.05	MRL (LOQ)		

STMR-RAC: 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).

Trifluoracetic acid (TFA)

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	n/a	EFSA (2014)	0.08	STMR	Acute risk assessment not performed since ARfD unnecessary	
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		

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
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	
			Input value (mg/kg)	Comment[a]	Input value (mg/kg)	Comment
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)]	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	
			Input value (mg/kg)	Comment[a]	Input value (mg/kg)	Comment
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[(a)]	Input value (mg/kg)	Comment
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		
Linseeds	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		

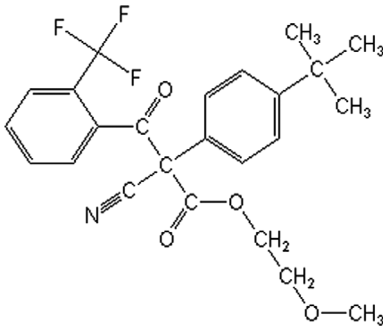
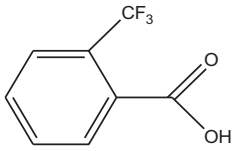
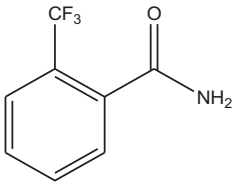
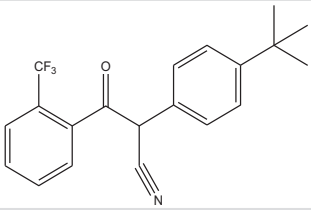
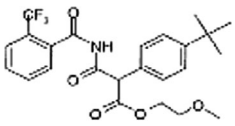
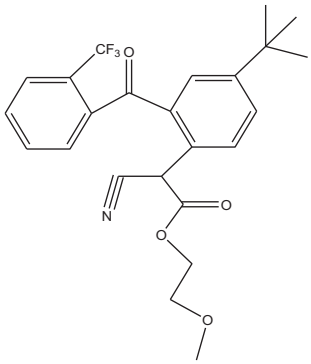
Commodity	Existing/ Proposed MRL (mg/kg)	Source/ type of MRL	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment[(a)]	Input value (mg/kg)	Comment
Wheat	n/a	Netherlands (2016)	0.099	HR-ROT crop		
Other cereals	n/a	Netherlands (2016)	0.099	HR-ROT crop		
Tea (dried leaves of *Camellia 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		

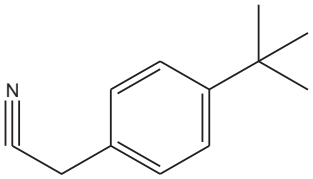
Commodity	Existing/ Proposed MRL (mg/kg)	Source/ type of MRL	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment[(a)]	Input value (mg/kg)	Comment
Vanilla pods	n/a	EFSA (2014)	0.01	STMR		
Tamarind	n/a	EFSA (2014)	0.01	STMR		
Other spices (fruits)	n/a	EFSA (2014)	0.01	STMR		
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 FC(F)(F)c1ccccc1C(=O)NC(=O)C(C#N)(c1ccc(cc1)C(C)(C)C)C(=O)OCCOC RAZUBFCBBHISOG-UHFFFAOYSA-N	
B-1	α,α,α-trifluoro-o-toluic acid FC(F)(F)c1ccccc1C(=O)O FBRJYBGLCHWYOE-UHFFFAOYSA-N	
B-3	2-(trifluoromethyl)benzamide FC(F)(F)c1ccccc1C(N)=O QBAYIBZITZBSFO-UHFFFAOYSA-N	
AB-1	3-oxo-2-phenyl-3-[2-(trifluoromethyl)phenyl] propanenitrile FC(F)(F)c1ccccc1C(=O)C(C#N)c1ccccc1 WTSIEPMTPQJZRF-UHFFFAOYSA-N	
AB-6	2-methoxyethyl 2-(4-tert-butylphenyl)-3-oxo-3-[2-(trifluoromethyl)benzamido]propanoate FC(F)(F)c1ccccc1C(=O)NC(=O)C(c1ccc(cc1)C(C)(C)C)C(=O)OCCOC RKBXBKGAVYGWOD-UHFFFAOYSA-N	
AB-7	2-methoxyethyl {4-tert-butyl-2-[2-(trifluoromethyl)benzoyl] phenyl}(cyano)acetate FC(F)(F)c1ccccc1C(=O)c1cc(ccc1C(C#N)C(=O)OCCOC)C(C)(C)C.c1ccccc1 HNUXNCYDRMUIPU-UHFFFAOYSA-N	

Code/ trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
A-2	(4-tert-butylphenyl)acetonitrile CC(C)(C)c1ccc(CC#N)cc1 FGFFQKZKAJOZKS-UHFFFAOYSA-N	
TFA	Trifluoroacetic acid FC(F)(F)C(=O)O DTQVDTLACAAQTR-UHFFFAOYSA-N	CF_3COOH

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).