REASONED OPINION

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

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Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance cyflumetofen. To assess the occurrence of cyflumetofen residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Commission Regulation (EU) No 188/2011 and the MRLs established by the Codex Alimentarius Commission as well as European authorisations reported by Member States and the UK. Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was missing. Hence, the consumer risk assessment is considered indicative only and some MRL proposals derived by EFSA still require further consideration by risk managers.

Keywords: cyflumetofen, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, acaricide

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Summary

Cyflumetofen was approved on 01 June 2013 by means of Commission Implementing Regulation (EU) No 22/2013 in the framework of Regulation (EC) No 1107/2009, as amended by Commission Implementing Regulations (EU) No 540/2011 and 541/2011. On 30 April 2019 conditions of approval of the active substance cyflumetofen were amended by the Commission Implementing Regulation (EU) No 2019/716.

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

As the basis for the MRL review, on 15 June 2020, EFSA initiated the collection of data for this active substance. In a first step, Member States and the UK were invited to submit by 15 July 2020 their national Good Agricultural Practices (GAPs) that are authorised nationally and the GAPs in non-EU countries for which import tolerances are authorised in a standardised way in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State, Spain, to identify the critical GAPs in the format of a specific GAP overview file. Subsequently, Member States were requested to provide residue data supporting the critical GAPs, within a period of 1 month, by 30 September 2020. On the basis of all the data submitted by Member States and by the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked the rapporteur Member State (RMS) to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report, together with Pesticide Residues Intake Model (PRIMo) calculations and an updated GAP overview file were provided by the RMS to EFSA on 15 December 2020. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Based on the information provided by the RMS, Member States and the EURLs, and taking into account the conclusions derived by EFSA in the framework of Commission Regulation (EU) No 188/2011 and the MRLs established by the Codex Alimentarius Commission, EFSA prepared in May 2021 a draft reasoned opinion, which was circulated to Member States and EURLs for consultation via a written procedure. Comments received by 10 June 2021 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of cyflumetofen in plants was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement can be proposed as cyflumetofen (sum of isomers) and for risk assessment as sum of cyflumetofen (sum of isomers) and 2-(trifluoromethyl)benzoic acid (metabolite B-1), expressed as cyflumetofen. These residue definitions are also applicable to processed commodities. Fully validated analytical methods are available for the enforcement of the proposed residue definition in all major matrices at the limit of quantification (LOQ) of 0.01 mg/kg. According to the EURLs, this LOQ is achievable in routine analyses.

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for cherries, plums, cane fruits and other small fruits and berries for which additional trials are required.

Robust processing factors could be derived for processed commodities from oranges, apples, peaches, strawberries, tomatoes and hops.

Cyflumetofen is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. The dietary burdens calculated for beef cattle were found to marginally exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues was therefore assessed in this group of livestock. Based on the metabolism study in lactating goats, the residue definition for enforcement is proposed as 2-(trifluoromethyl)benzoic acid (metabolite B-1), expressed as cyflumetofen.

An analytical method using LC-MS/MS was fully validated for the determination of 2-(trifluoromethyl)benzoic acid (metabolite B-1), expressed as cyflumetofen in all animal tissues, milk and eggs, with a LOQ of 0.02 mg/kg. However, the independent laboratory validation (ILV) of the method is still required.

According to the EURLs, an LOQ of 0.01 mg/kg 2-(trifluoromethyl)benzoic acid is deemed achievable for routine analysis in milk and liver.

For risk assessment, the residue definition for animals is proposed as the sum of cyflumetofen (sum of isomers) and 2-(trifluoromethyl)benzoic acid (metabolite B-1), expressed as cyflumetofen.

MRLs and risk assessment values for the relevant ruminant commodities can be established at the LOQ level.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMo. The highest chronic exposure represented 1% of the acceptable daily intake (ADI) (German child). Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance.

Apart from the MRLs evaluated in the framework of this review, internationally recommended code maximum residue limits (CXLs) have also been established for cyflumetofen. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out, the highest chronic exposure represented 2% of the ADI (Dutch toddler).

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Background

Regulation (EC) No 396/2005[1] (hereinafter referred to as 'the Regulation') establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC[2] a reasoned opinion on the review of the existing MRLs for that active substance. As cyflumetofen was approved on 01 June 2013 by means of Commission Implementing Regulation (EU) No 22/2013[3] in the framework of Regulation (EC) No 1107/2009[4] as implemented by Commission Implementing Regulations (EU) No 540/2011[5] and 541/2011[6], EFSA initiated the review of all existing MRLs for that active substance.

By way of background information, cyflumetofen was evaluated by the Netherlands, designated as rapporteur Member State (RMS) in the framework of Regulation (EC) No 1107/2009 as amended by Commission Implementing Regulations (EU) No 540/2011 and 541/2011. Subsequently, a peer review on the initial evaluation of the RMS was conducted by EFSA, leading to the conclusions as set out in the EFSA scientific output (EFSA, 2012).

The approval of cyflumetofen has been restricted in 2019[7] to uses where the level of metabolite B3 in groundwater is expected to be below 0.1 μg/L, following the assessment of the confirmatory data (EFSA, 2016).

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

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

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

As the basis for the MRL review, on 15 June 2020 EFSA initiated the collection of data for this active substance. In a first step, Member States and the UK[8] were invited to submit by 15 July 2020

[1] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

[2] 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. Repealed by Regulation (EC) No 1107/2009.

[3] 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.

[4] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

[5] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.

[6] Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187–188.

[7] Commission Implementing Regulation (EU) 2019/716 of 30 April 2019 amending Implementing Regulations (EU) No 22/2013 and (EU) No 540/2011 as regards the conditions of approval of the active substance cyflumetofen. OJ L 122, 10.5.2019, p. 39–43.

[8] The United Kingdom withdrew from EU on 1 February 2020. In accordance with the Agreement on the Withdrawal of the UK from the EU, and with the established transition period, the EU requirements on data reporting also apply to the UK data collected until 31 December 2020.

their Good Agricultural Practices (GAPs) that are authorised nationally, in a standardised way, in the format of specific GAP forms. In the framework of this consultation 16 Member States and the UK provided feedback on their national authorisations of cyflumetofen. Based on the GAP data submitted, the designated RMS Spain was asked to identify the critical GAPs to be further considered in the assessment, in the format of a specific GAP overview file. Subsequently, in a second step, Member States and the UK were requested to provide residue data supporting the critical GAPs by 30 September 2020.

On the basis of all the data submitted by Member States, the UK and the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked Spain to complete the PROFile and to prepare a supporting evaluation report. The PROFile and the supporting evaluation report, together with the Pesticide Residues Intake Model (PRIMo) calculations and an updated GAP overview file, were submitted to EFSA on 15 December 2020. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Considering all the available information and taking into account the MRLs established by the Codex Alimentarius Commission (CAC) (i.e. codex maximum residue limit; CXLs), EFSA prepared in May 2021 a draft reasoned opinion, which was circulated to Member States and EURLs for commenting via a written procedure. All comments received by 10 June 2021 were considered by EFSA during the finalisation of the reasoned opinion.

The **evaluation report** submitted by the RMS (Spain, 2020), taking into account also the information provided by Member States and the UK during the collection of data, and the **EURLs report on analytical methods** (EURLs, 2020) are considered as main supporting documents to this reasoned opinion and, thus, made publicly available.

In addition, further supporting documents to this reasoned opinion are the **completeness check report** (EFSA, 2021b) and the **Member States consultation report** (EFSA, 2021c). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Furthermore, the exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (**PRIMo**) and the **PROFile** as well as the **GAP overview file** listing all authorised uses are key supporting documents and made publicly available as background documents to this reasoned opinion. A screenshot of the report sheet of the PRIMo is presented in Appendix C.

Terms of Reference

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

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

The active substance and its use pattern

Cyflumetofen is the ISO common name for 2-methoxyethyl (*RS*)-2-(4-tert-butylphenyl)-2-cyano-3-oxo-3-(α,α,α -trifluoro-o-tolyl)propionate (IUPAC).

The chemical structure of the active substance and its main metabolites are reported in Appendix F.

The EU MRLs for cyflumetofen are established in Annexes IIIA of Regulation (EC) No 396/2005. Codex maximum residue limits (CXLs) for cyflumetofen were also established by the Codex Alimentarius Commission (CAC). An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below (Table 1).

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

Procedure	Legal implementation	Remarks
MRL application	Commission Regulation (EU) 2021/1098(1)	Citrus fruits, apricots, peaches, tomatoes, aubergines/eggplants, cucumbers, hops (EFSA, 2021a)
Implementation of CAC 2015	Commission Regulation (EU) 2016/567(2)	Citrus fruit, pome fruits, grapes, strawberries, Azaroles/ Mediterranean medlars, Kaki/Japanese persimmons, tomatoes, liver (swine, bovine, sheep, goat, equine and other farmed terrestrial animals), kidney (swine, bovine, sheep, goat, equine and other farmed terrestrial animals), edible offals (swine, bovine, sheep, goat, equine and other farmed terrestrial animals) (EFSA, 2015)

(1): Commission Regulation (EU) 2021/1098 of 2 July 2021 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 24-epibrassinolide, Allium cepa L. bulb extract, cyflumetofen, fludioxonil, fluroxypyr, sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate in or on certain products. OJ L 238, 6.7.2021, p. 5–28.

(2): Commission Regulation (EU) 2016/567 of 6 April 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorantraniliprole, cyflumetofen, cyprodinil, dimethomorph, dithiocarbamates, fenamidone, fluopyram, flutolanil, imazamox, metrafenone, myclobutanil, propiconazole, sedaxane and spirodiclofen in or on certain products. OJ L 100, 15.4.2016, p. 1–60.

For the purpose of this MRL review, all the uses of cyflumetofen currently authorised within the EU as submitted by the Member States during the GAP collection, have been reported by the RMS in the GAP overview file. The critical GAPs identified in the GAP overview file were then summarised in the PROFile and considered in the assessment. The details of the authorised critical GAP for cyflumetofen are given in Appendix A. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

Assessment

EFSA has based its assessment on the following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (Spain, 2020);
- the draft assessment report (DAR) and its addendum prepared under Council Directive 91/414/EEC (Netherlands, 2010, 2011);
- the conclusion on the peer review of the pesticide risk assessment of the active substance cyflumetofen (EFSA, 2012);
- the conclusion on the peer review of the pesticide risk assessment for the active substance cyflumetofen in light of confirmatory data (EFSA, 2016);
- the final review report on cyflumetofen (European commission, 2019);
- the Joint Meeting on Pesticide residues (JMPR) Evaluation report (FAO, 2014a,b);
- the previous reasoned opinion on cyflumetofen (EFSA, 2021a).

The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011[9] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013).

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

[9] 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, 11.06.2011, p. 127–175.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of cyflumetofen was investigated after foliar treatment in fruits (mandarin, apple and eggplant) (Netherlands, 2011) and assessed in the framework of the peer-review (EFSA, 2012). The studies were conducted with a single foliar application of ^{14}C-cyflumetofen, either labelled on the *tert* -butyl phenyl ring or the trifluoromethyl phenyl ring at a dose of 600 g a.s./ha.

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. Metabolism was limited, with cyflumetofen constituting the major component of the total radioactive residues (TRR) ranging from 67% to 84% TRR and 77–87% TRR 7 days after application, and 44–65% TRR and 44–81% TRR after 30 days on fruits and leaves, respectively. Although several metabolites were identified, only 2-(trifluoromethyl)benzoic acid (metabolite B-1), free and conjugated) was detected above 10% TRR (up to 15% and 16% TRR, free and conjugated, respectively, in eggplant fruits) and AB-6 at 10% TRR in eggplant leaves.

There are no metabolism studies available for leafy crops that would in principle be required for a use on hops. Nonetheless, a possible metabolic pattern comparable to that observed in fruit crops was proposed and considered sufficient to address the metabolism of cyflumetofen for an intended use on hops (EFSA, 2021a). Considerations were based on the metabolic pattern observed, in particular in eggplant leaves, at PHI 14 days relevant for the intended use, combined with the results of the residue trials on hops. EFSA emphasises that these considerations are valid only for the use on hops and are not considered sufficient to cover all leafy vegetables.

1.1.2. Nature of residues in rotational crops

Cyflumetofen is authorised on crops that may be grown in rotation. According to the soil degradation laboratory studies the DT_{90} value for cyflumetofen and its main soil metabolites AB-1 and B-3 is below the trigger value of 100 days, whereas the DT_{90} value of metabolite B-1 is up to 120 days (EFSA, 2012).

A confined rotational crop metabolism study is available for this review (Spain, 2020) that was assessed in the framework of an MRL application (EFSA, 2021a). ^{14}C-cyflumetofen, either labelled on the *tert*-butyl phenyl ring or the trifluoromethyl phenyl ring, was applied once at 400 g/ha to bare soil covering the authorised uses assessed. Crops (lettuces, radishes, spring wheat) were planted at nominal plant back intervals (PBI) of 30, 120 and 365 days after treatment (DAT).

The total radioactive residues in the edible parts of the rotational crops at harvest and at all plant back intervals were up to 0.06 mg/kg in lettuce, up to 0.03 mg/kg and 0.14 mg/kg in radish roots and tops, and up to 0.17 mg/kg, 0.64 mg/kg and 0.48 mg/kg in wheat grain, hay and straw, respectively, at the PBI of 30 days. Residues in all crops declined over time, with higher TRRs present in case of the benzyl label.

The only major radioactive residue, identified in all crop matrices, was trifluoroacetic acid (TFA). Highest levels of TFA were detected in radish tops (0.16 mg eq/kg, PBI 30 days) and wheat hay (0.64 mg eq/kg, PBI 30 days). All other metabolites, including metabolite B-1, were below < 0.01 mg/kg.

TFA was not identified in the primary crop metabolism in fruit crops, nor was it identified as a significant soil metabolite during the peer review (EFSA, 2012). It can be formed from the parent compound cyflumetofen by degradation in the soil and uptake by the plants or from metabolite B-1 (Spain, 2020). Furthermore, TFA is very persistent in soil (DT_{50} > 1,000 days (EFSA, 2017) and occurs ubiquitously in the environment from a variety of other sources.

1.1.3. Nature of residues in processed commodities

Studies investigating the nature of residues in processed commodities are available for this review (Spain, 2020) that were also assessed in the framework of an MRL application (EFSA, 2021a). Studies were conducted with cyflumetofen radiolabelled on the butylphenyl ring or the trifluoromethyl phenyl ring. 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 (see Appendix B.1.1.1). In the study using the butylphenyl-label, under standard boiling/ baking/brewing conditions (60 min. 100°C, pH 5) and under sterilisation conditions (20 min. 120°C, pH 6)

40% and 49% of cyflumetofen degraded to metabolite AB-1 and 53% and 44% to metabolite A-2, respectively. Metabolite B-1 was the major degradation product (up to 75.3% AR, sterilisation conditions) in the trifluoromethyl phenyl ring labelled study.

1.1.4. Methods of analysis in plants

Validated methods to quantify residues of cyflumetofen by liquid chromatography with tandem mass spectrometry (LC-MS/MS) monitoring two ion transitions are available with a limit of quantification (LOQ) of 0.01 mg/kg in high water- (tomato, lettuce, lentils), high acid- (orange), high oil content (soybean seed), dry (dry bean, wheat and rice grain) and specific (raisins, hops, orange oil, straw) matrices. The analytical methods were assessed in the framework of zonal registration of products (Spain, 2020) and in a previous MRL application (EFSA, 2021a). The primary methods are supported by independent laboratory validations (ILV) for high water, high acid content, dry matrices as well as for hops (Spain, 2020; EFSA, 2021a).

According to the EURLs, cyflumetofen can be monitored in high water content, high acid content, dry and high oil content commodities with an LOQ of 0.01 mg/kg (EURLs, 2020).

1.1.5. Stability of residues in plants

The storage stability of cyflumetofen and its metabolite B-1 was investigated in the framework of an MRL application (Netherlands, 2016; EFSA, 2021a). The storage stability of cyflumetofen was demonstrated for at least 25 months in wheat grains (high starch content), 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) when stored frozen (–20°C to –10°C).

Regarding the storage stability of metabolite B-1, several deficiencies were observed in the studies. Uncorrected recovery data showed a large variation among sampling time points and matrices, with low recoveries observed also at time point zero and in freshly spiked samples. Uncorrected recoveries dropped below 70% at certain sampling times during the storage period of the studies. However, despite the variability, the graphical presentation of the recoveries according to current guidance (European Commission, 1997f) showed no large fluctuation attributable of the residue decline. Based on the available data and the interpolation method, residues of metabolite B-1 were considered stable for 22 months in wheat grains (high starch content), apple fruit and juice (high water content), about 30 months in orange fruit and juice (high acid content) and 30 months in almond nutmeal (high oil content matrix). For lettuces and orange oils the data were inconclusive (EFSA, 2021a).

It is noted that no specific study is available for the storage stability of A-2 or AB-1. For these metabolites, this data will only be required pending the requirement of further processing studies in the future.

1.1.6. Proposed residue definitions

The metabolism of cyflumetofen was assessed following foliar treatment in fruit crops.

Considering the results of both the metabolism studies and the magnitude of residues in primary and rotational crops, the parent compound was found to be a sufficient marker and the residue definition for enforcement is proposed as cyflumetofen (sum of isomers). This residue definition is limited to fruit crops and to the use on hops.

An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in all matrices is available (Spain, 2020; EFSA, 2021a). According to the EURLs the LOQ of 0.01 in all 4 major matrices is achievable in routine analyses (EURLs, 2020).

TFA is the only major metabolite relevant for rotational crops. It is formed by the extensive metabolism of cyflumetofen in soil and was not identified in the metabolism of primary crops. It is a common metabolite found ubiquitously in the environment from various sources. Overall, considering the results of the rotational crop confined studies and an updated indicative risk assessment of TFA (EFSA, 2021a) it can be concluded that for the authorised uses of cyflumetofen, consumers are not expected to be exposed to significant residues of this metabolite and therefore a separate residue definition for risk assessment for rotational crops is not deemed necessary. In case of further uses, the need to consider TFA may need to be reviewed.

Metabolite B-1 is a major metabolite formed in rats following oral ingestion and was considered covered by the toxicological profile of the parent compound (EFSA, 2012).

The toxicological relevance of processing degradation products AB-1 and A-2 has been assessed in the framework of an MRL application (EFSA, 2021a). 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 28-day toxicity study 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 for A-2. An acute reference dose (ARfD) was not set and not considered necessary.

As metabolite B-1 is a major metabolite in fruit crops, a minor metabolite in rotational crops and a main degradation product during processing, the residue definition for risk assessment is proposed to be the sum of cyflumetofen (sum of isomers) and 2-(trifluoromethyl)benzoic acid (metabolite B-1), expressed as cyflumetofen.

Standard hydrolysis studies showed a progressive degradation of cyflumetofen to metabolite AB-1 that is further degraded to metabolite B-1, and A-2. However, in the various processing studies, major degradation of parent to metabolites B-1 and A-2 was not observed (Appendix B.1.2.3). There are no data on the occurrence of AB-1 in processing studies. A-2 was analysed for in peach and apple processed commodities. Metabolite B-1 was analysed in apple, peach, strawberry, tomato and citrus processing studies. An additional risk assessment residue definition for processed products is not deemed necessary for the current uses, as based on the available studies formation of A-2 is expected to be low, and lower than B-1; metabolite B-1 was present at significantly lower levels than cyflumetofen in processed products, if at all (except in dried citrus fruits); exposure to cyflumetofen residues is low (up to 2% of ADI) and in view of the toxicity profiles of A-2 and AB-1 (see above), the residue definition for plants is proposed to be applicable also for processed products considering the current uses. In case further uses are authorised in the future, the need to consider AB-1 and/or A-2 in the residue definition may need to be reviewed.

In addition, EFSA emphasises that the above studies do not investigate the possible impact of plant metabolism on the isomer ratio of cyflumetofen and further investigation on this matter would in principle be required. However, in view of the large margin of safety in the exposure calculation, the potential change in isomer ratios in the final residue is not expected to be of concern for the authorised use in the framework of this review. In case future uses of active substance would lead to a higher consumer exposure, further information regarding the impact of plant metabolism on the isomer ratio might be required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of cyflumetofen residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Spain, 2020), as well as the residue trials evaluated in the framework of a previous MRL application (EFSA, 2021a). All residue trial samples considered in this framework were stored in compliance with the conditions for which storage stability of residues was demonstrated, except for a few trials on strawberries. Out of thirteen trials in strawberries, in four trials samples were stored for a longer period than the demonstrated storage stability period. However, as results were in the same range as in the other trials, and disregarding them would lead to a lower MRL, the trials were considered acceptable. Decline of residues during storage of the trial samples is therefore not expected.

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

Available residue trials are sufficient to derive (tentative) MRLs and risk assessment values for all crops under assessment, taking note of the following considerations:

- Cherries, plums, cane fruits and other small fruits and berries: Although no trials are available, as the application is done after harvest, and considering the properties of the a.s. and the results of the metabolism studies, residues are not expected in the edible part of the crop and the MRL can be proposed at the LOQ. Nonetheless, two trials compliant with the northern outdoor GAPs and two trials compliant with the indoor GAPs are required.
- Apricots and peaches: Although no residue trial supporting the northern outdoor GAP and indoor GAP is available, as residues are not expected according to the condition of use, and the southern GAP is clearly more critical, further trials are not required.

1.2.2. Magnitude of residues in rotational crops

A field rotational crop study was available for this review (Spain, 2020) that was assessed in the framework of zonal registration of products and in a previous MRL application (EFSA, 2021a). Cyflumetofen was applied to bare soil at 400 g a.s./ha covering the authorised uses. Leafy vegetables (spinach, broccoli), root crops (carrots) and cereals (wheat) were planted at the nominal plant back intervals of 30, 120 and 365 days after treatment. Residues of cyflumetofen and its metabolites AB-6 and B-1 were analysed for. These were all below the LOQ of 0.01 mg/kg at all plant-back intervals, in all crop parts. It is noted that samples were not analysed for TFA, the common metabolite that may be taken up in rotational crops. Nevertheless, levels of TFA from the confined rotational crops can be relied upon and no additional trials analysing for this metabolite are required.

Based on the studies, it can be concluded that apart from TFA, cyflumetofen residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that cyflumetofen is applied in compliance with the GAPs reported in Appendix A.

1.2.3. Magnitude of residues in processed commodities

The effect of industrial processing and/or household preparation was assessed in studies conducted on oranges, apples, peaches, strawberries, tomatoes and hops and evaluated during a previous MRL assessment (Netherlands, 2016; Spain, 2020; EFSA, 2021a). An overview of the available processing studies is presented in Appendix B.1.2.3. Robust processing factors (fully supported by data) could be derived for processed orange commodities (pulp, juice, marmalade, dried pulp, wet pomace), processed apple commodities (juice, dried fruit, dry and wet pomace), processed peach commodities (juice, canned fruit, jam, dried fruit), processed strawberries (jam, canned fruits), processed tomatoes (peeled and canned, paste, ketchup, juice), processed hop commodities (dried cones, hop extract, beer, brewer's yeast).

AB-1 was not analysed in the processing studies, whereas the presence of metabolite A-2 was investigated only in processed apple and peach products. After processing, A-2 was not detected (< 0.01 mg/kg) in processed products from apple (juice, dried fruit, dry and wet pomace) or peaches (canned fruit, juice and jam), except at low levels in dried peaches (< 0.01–0.036 mg/kg) (see Appendix B.1.2.3).

Based on the results of the standard hydrolysis studies (see Appendix B.1.1.1), the levels of metabolite B-1 are expected to be at the same level or higher in processed products compared to A-2. This is also supported by the findings of the available processing studies (Appendix B.1.2.3). Therefore, although the storage stability of A-2 was not investigated leading to additional uncertainty, the levels of metabolite B-1 observed in the processed commodities indicate that the levels of A-2 are also expected to be low.

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

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for cherries, plums, cane fruits and other small fruits and berries for which additional trials are required.

2. Residues in livestock

Cyflumetofen is authorised for use on pome fruits, and registration of authorisation is ongoing for citrus fruits that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D. The dietary burdens calculated for beef cattle were found to marginally exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues was therefore assessed in this group of livestock.

A study investigating the metabolism of cyflumetofen residues in lactating goats is available for the current review (Spain, 2020). Cyflumetofen, radiolabelled in the benzoyl ring or in the *tert*-butylphenyl ring of the molecule was administered at a rate of 0.27–0.30 mg/kg for 12 days or at a rate of 0.43–0.48 mg/kg for 10 days, respectively.

The studies indicate that the majority of cyflumetofen, 78.5–89.6% of the total administered radioactivity, is rapidly excreted. Highest residue levels were found in liver (0.29–0.40 mg eq./kg) and kidney (0.17–0.19 mg eq./kg) whilst limited transfer was observed in fat and muscle (≤ 0.03 mg eq./kg). In milk low proportions, 0.03–0.14% or 0.008–0.19 mg/kg, of the administered dose were found.

In the study using the benzoyl label, parent cyflumetofen in edible tissues was only identified in fat (21.0% TRR) but at low concentration of < 0.003 mg/kg. The predominant metabolite was 2-(trifluoromethyl)benzoic acid (metabolite B-1) accounting in tissues for 21–53.9% of the TRR and in milk for 4.5% TRR (0.13 mg/kg in liver, 0.1 mg/kg in kidney, < 0.01 mg/kg in muscle, fat and milk). In the study using the butylphenyl-label, cyflumetofen and its metabolites were all < 0.01 mg/kg.

EFSA concludes that the metabolism of cyflumetofen in livestock is adequately elucidated, and metabolite B-1 is the most relevant component of the residues in livestock commodities.

As cyflumetofen is not present in most matrices, whereas metabolite B-1 was found to be a sufficient marker in livestock commodities, the residue definition for enforcement is proposed as 2-(trifluoromethyl)benzoic acid (metabolite B-1), expressed as cyflumetofen.

It is noted that the existing residue definition is the same as for plants, i.e. cyflumetofen (sum of isomers).

An analytical method using LC-MS/MS, assessed in the framework of a zonal registration of products (Spain, 2020), was fully validated for the determination of 2-(trifluoromethyl)benzoic acid (metabolite B-1) in all animal tissues, milk and eggs, with a LOQ of 0.01 mg/kg. As the residue definition is expressed as cyflumetofen, the LOQ has been recalculated and is equivalent to 0.02 mg/kg 2-(trifluoromethyl)benzoic acid, expressed as cyflumetofen. However, the ILV of the method is still required.

During the data collection, the EURLs reported that the LOQ of 0.01 mg/kg for cyflumetofen in milk is achievable (EURLs, 2020). Moreover, in line with the proposed new residue definition, during the Member States consultation the EURLs reported that an LOQ of 0.01 mg/kg 2-(trifluoromethyl)benzoic acid is deemed achievable for routine analysis in milk and liver (EFSA, 2021a).

Storage stability data for animal commodities is not available and is not required.

For risk assessment, the residue definition is proposed as the sum of cyflumetofen (sum of isomers) and 2-(trifluoromethyl)benzoic acid (metabolite B-1), expressed as cyflumetofen.

Based on the metabolism study using the benzoyl label (performed at ~ 150N rate compared to the maximum dietary burden) it can be concluded that residues of cyflumetofen are not expected in cattle tissues. MRLs and risk assessment values for the relevant commodities in ruminants can be established at the LOQ level. These MRLs are all tentative due to the data gap on the analytical methods (ILV). For all other animal products, the derivation of residue definitions, risk assessment values and MRLs are not required.

3. Consumer risk assessment

In the framework of this review, only the uses of cyflumetofen reported by the RMS in Appendix A were considered; however, the use of cyflumetofen was previously also assessed by the JMPR (FAO, 2014a,b). The CXLs, resulting from this assessment by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. To facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs.

It is noted that while the residue definitions for plants derived by JMPR and at EU level are the same, the enforcement residue definition for animal commodities derived by JMPR includes also cyflumetofen, besides metabolite B-1. Despite the wider definition compared to the one proposed by EFSA, the residue definition can be considered comparable as parent is not expected to be present at significant levels in animal commodities, and the residue definition is proposed to be expressed as cyflumetofen. The risk assessment residue definition for animal commodities is the same.

3.1. Consumer risk assessment without consideration of the existing CXLs

Chronic exposure calculations for all crops reported in the framework of this review were performed using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for those

commodities where a (tentative) MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). All input values included in the exposure calculations are summarised in Appendix D.2.

The exposure values calculated were compared with the toxicological reference value for cyflumetofen, derived by EFSA (EFSA, 2012). The highest chronic exposure was calculated for the German child, representing 1% of the acceptable daily intake (ADI). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance. Although uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumer's health.

In addition, it is highlighted that an updated indicative risk assessment of TFA that considered its potential uptake following the use of cyflumetofen and from other sources was carried out in a recent reasoned opinion concluding that no chronic intake concern is expected (EFSA, 2021a). This conclusion is still valid for the uses assessed in the current review.

3.2. Consumer risk assessment with consideration of the existing CXLs

To include the CXLs in the calculations of the consumer exposure, CXLs were compared with the EU MRL proposals in compliance with Appendix E and all data relevant to the consumer exposure assessment have been collected from JMPR evaluations. For livestock commodities, the CXL of 0.01* mg/kg was rounded up to the LOQ of 0.02* mg/kg which was derived at EU level for enforcement of this matrix. An overview of the input values used for this exposure calculation is also provided in Appendix D.3.

Chronic exposure calculations were also performed using revision 3.1 of the EFSA PRIMo and the exposure values calculated were compared with the toxicological reference value derived for cyflumetofen. The highest chronic exposure was calculated for the Dutch toddler, representing 2% of the ADI. Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance. Although minor uncertainties remain due to the data gap identified on the analytical methods for animal commodities applicable for these CXLs (ILV missing), the exposure calculation did not indicate a risk to consumers.

In addition, EFSA emphasises that the assessment does not investigate the possible impact of plant and animal metabolism on the isomer ratio of cyflumetofen and further investigation on this matter would in principle be required. However, in view of the large margin of safety in the exposure calculation, the potential change in isomer ratios in the final residue is not expected to be of concern for the authorised use in the framework of this review. In case future uses of active substance would lead to a higher consumer exposure, further information regarding the impact of metabolism on the isomer ratio might be required.

Conclusions

The metabolism of cyflumetofen in plant was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement can be proposed as cyflumetofen (sum of isomers) and for risk assessment as sum of cyflumetofen (sum of isomers) and 2-(trifluoromethyl)benzoic acid (metabolite B-1), expressed as cyflumetofen. These residue definitions are also applicable to processed commodities. Fully validated analytical methods are available for the enforcement of the proposed residue definition in all major matrices at the LOQ of 0.01 mg/kg. According to the EURLs this LOQ is achievable in routine analyses.

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for cherries, plums, cane fruits and other small fruits and berries for which additional trials are required.

Robust processing factors could be derived for processed commodities from oranges, apples, peaches, strawberries, tomatoes and hops.

Cyflumetofen is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. The dietary burdens calculated for beef cattle were found to marginally exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues was therefore assessed in this group of livestock. Based on the metabolism study in lactating goats, the residue definition for enforcement is proposed as 2-(trifluoromethyl)benzoic acid (metabolite B-1), expressed as cyflumetofen.

An analytical method using LC-MS/MS was fully validated for the determination of 2-(trifluoromethyl)benzoic acid (metabolite B-1), expressed as cyflumetofen in all animal tissues, milk and eggs, with a LOQ of 0.02 mg/kg. However, the ILV of the method is still required.

According to the EURLs an LOQ of 0.01 mg/kg 2-(trifluoromethyl)benzoic acid is deemed achievable for routine analysis in milk and liver.

For risk assessment, the residue definition for animals is proposed as the sum of cyflumetofen (sum of isomers) and 2-(trifluoromethyl)benzoic acid (metabolite B-1), expressed as cyflumetofen.

MRLs and risk assessment values for the relevant ruminant commodities can be established at the LOQ of 0.02 mg/kg 2-(trifluoromethyl)benzoic acid, expressed as cyflumetofen.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMo. The highest chronic exposure represented 1 % of the ADI (German child). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for cyflumetofen. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out, the highest chronic exposure represented 2 % of the ADI (Dutch toddler).

Recommendations

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

1) 2 additional residue trials on cherries, plums, cane fruits and other small fruits and berries (except azaroles).
2) ILV of the analytical method for enforcement in animal commodities.

In addition, EFSA highlights that the proposed residue definition for enforcement in commodities of animal products is overlapping with the residue definition for enforcement for flutolanil in commodities of animal origin, which has been established for flutolanil as: *Flutolanil and metabolites containing the 2-(trifluoromethyl)benzoic acid moiety, expressed as flutolanil*. However, as according to the metabolism study with flutolanil under evaluation in the framework of the renewal (Netherlands, 2018) free 2-(trifluoromethyl)benzoic acid is not formed at significant levels in livestock following flutolanil use, the use of flutolanil is not expected to impact the MRLs proposed for cyflumetofen. Residues resulting from the use of cyflumetofen are not expected to trigger the need to modify the existing MRLs for flutolanil.

Table 2: Summary table

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment #data gap
Enforcement residue definition (existing): cyflumetofen (sum of isomers) **Enforcement residue definition (proposed):** cyflumetofen (sum of isomers)					
110000	Citrus fruits	0.5	0.3	0.5	Recommended[(a)]
120000	Tree nuts	0.01*	0.01*	0.01*	Recommended[(b)]
130000	Pome fruits	0.4	0.4	0.4	Recommended[(c)]
140010	Apricots	0.3	–	0.3	Recommended[(d)]
140020	Cherries	–	–	0.01*	Further consideration needed[(e)] #1
140030	Peaches	0.3	–	0.3	Recommended[(d)]
140040	Plums	–	–	0.01*	Further consideration needed[(e)] #1
151010	Table grapes	0.6	0.6	0.6	Recommended[(b)]
151020	Wine grapes	0.6	0.6	0.6	Recommended[(b)]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment #data gap
152000	Strawberries	0.6	0.6	0.6	Recommended[(a)]
153010	Blackberries	–	–	0.01*	Further consideration needed[(e)] #1
153020	Dewberries	–	–	0.01*	Further consideration needed[(e)] #1
153030	Raspberries	–	–	0.01*	Further consideration needed[(e)] #1
154010	Blueberries	–	–	0.01*	Further consideration needed[(e)] #1
154020	Cranberries	–	–	0.01*	Further consideration needed[(e)] #1
154030	Currants (red, black and white)	–	–	0.01*	Further consideration needed[(e)] #1
154040	Gooseberries	–	–	0.01*	Further consideration needed[(e)] #1
154050	Rose hips	–	–	0.01*	Further consideration needed[(e)] #1
154060	Mulberries	–	–	0.01*	Further consideration needed[(e)] #1
154070	Azarole (mediterranean medlar)	0.4	0.4	0.4	Recommended[(f)]
154080	Elderberries	–	–	0.01*	Further consideration needed[(e)] #1
161060	Persimmon	0.4	0.4	0.4	Recommended[(b)]
231010	Tomatoes	0.4	0.3	0.4	Recommended[(a)]
231030	Aubergines (egg plants)	0.4	–	0.4	Recommended[(d)]
232010	Cucumbers	0.4	–	0.4	Recommended[(d)]
700000	Hops	30	–	30	Recommended[(d)]
Enforcement residue definition (existing): cyflumetofen (sum of isomers) **Enforcement residue definition (proposed):** 2-(trifluoromethyl)benzoic acid (metabolite B-1), expressed as cyflumetofen					
1011010	Swine meat	0.01*	0.02*,[(1)]	0.02*	Further consideration needed[(g)] #2
1011020	Swine fat	0.01*	0.02*,[(1)]	0.02*	Further consideration needed[(g)] #2
1011030	Swine liver	0.02	0.02	0.02	Further consideration needed[(g)] #2
1011040	Swine kidney	0.02	0.02	0.02	Further consideration needed[(g)] #2
1012010	Bovine meat	0.01*	0.02*,[(1)]	0.02*	Further consideration needed[(h)] #2
1012020	Bovine fat	0.01*	0.02*,[(1)]	0.02*	Further consideration needed[(h)] #2
1012030	Bovine liver	0.02	0.02	0.02*	Further consideration needed[(h)] #2
1012040	Bovine kidney	0.02	0.02	0.02*	Further consideration needed[(h)] #2
1013010	Sheep meat	0.01*	0.02*,[(1)]	0.02*	Further consideration needed[(g)] #2
1013020	Sheep fat	0.01*	0.02*,[(1)]	0.02*	Further consideration needed[(g)] #2
1013030	Sheep liver	0.02	0.02	0.02	Further consideration needed[(g)] #2
1013040	Sheep kidney	0.02	0.02	0.02	Further consideration needed[(g)] #2
1014010	Goat meat	0.01*	0.02*,[(1)]	0.02*	Further consideration needed[(g)] #2
1014020	Goat fat	0.01*	0.02*,[(1)]	0.02*	Further consideration needed[(g)] #2
1014030	Goat liver	0.02	0.02	0.02	Further consideration needed[(g)] #2
1014040	Goat kidney	0.02	0.02	0.02	Further consideration needed[(g)] #2
1015010	Horse meat	0.01*	0.02*,[(1)]	0.02*	Further consideration needed[(h)] #2
1015020	Horse fat	0.01*	0.02*,[(1)]	0.02*	Further consideration needed[(h)] #2
1015030	Horse liver	0.02	0.02	0.02*	Further consideration needed[(h)] #2
1015040	Horse kidney	0.02	0.02	0.02*	Further consideration needed[(h)] #2
1020010	Cattle milk	0.01*	0.02*,[(1)]	0.02*	Further consideration needed[(g)] #2
1020020	Sheep milk	0.01*	0.02*,[(1)]	0.02*	Further consideration needed[(g)] #2
1020030	Goat milk	0.01*	0.02*,[(1)]	0.02*	Further consideration needed[(g)] #2
1020040	Horse milk	0.01*	0.02*,[(1)]	0.02*	Further consideration needed[(g)] #2

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment #data gap
–	Other commodities of plant and/or animal origin	See Reg. 2021/1098	–	–	Further consideration needed(i)

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(F): The residue definition is fat soluble.
(1): CXL of 0.01* mg/kg was rounded up to the LOQ of 0.02* mg/kg which was derived at EU level for enforcement of this matrix.
(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination H-III in Appendix E).
(b): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix E).
(c): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination H-VII in Appendix E).
(d): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination H-I in Appendix E).
(e): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination F-I in Appendix E).
(f): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower tentative MRL (combination F-VII in Appendix E).
(g): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified (assuming the existing residue definition); there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix E).
(h): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); existing CXL is covered by the tentative MRL (combination F-III in Appendix E).
(i): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).

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Abbreviations

a.i.	active ingredient
a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIRCA	(EU) Communication & Information Resource Centre Administrator
CS	capsule suspension
CV	coefficient of variation (relative standard deviation)
CXL	codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DB	dietary burden
DM	dry matter
DS	powder for dry seed treatment
DT_{90}	period required for 90% dissipation (define method of estimation)
EC	emulsifiable concentrate
EDI	estimated daily intake
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EURLs	European Union Reference Laboratories for Pesticide Residues (former CRLs)
FAO	Food and Agriculture Organization of the United Nations
FID	flame ionisation detector
GAP	Good Agricultural Practice
GC	gas chromatography
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography with mass spectrometry
GC-MS/MS	gas chromatography with tandem mass spectrometry
GS	growth stage
HPLC	high-performance liquid chromatography
HPLC-MS	high-performance liquid chromatography with mass spectrometry
HPLC-MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
ILV	independent laboratory validation
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues).
LC	liquid chromatography
LC–MS/MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
Mo	monitoring

MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEDI	national estimated daily intake
NTMDI	national theoretical maximum daily intake
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
RA	risk assessment
RD	residue definition
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern European Union
SMILES	simplified molecular-input line-entry system
SL	soluble concentrate
SP	water soluble powder
STMR	supervised trials median residue
TFA	trifluoroacetic acid
TAR	total applied radioactivity
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UV	ultraviolet (detector)
WHO	World Health Organization

Appendix A – Summary of authorised uses considered for the review of MRLs

A.1. Authorised outdoor uses in northern EU

Crop and/or situation	MS or country	F 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 and season[c]	Number min–max	Interval between application (min)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Apples	NL	F	Mites	SC	200 g/L	Foliar treatment	11–85	2	10	–	–	200 g a.i./ha	14	
Apricots	NL	F	Mites	SC	200 g/L	Foliar treatment	90–93	2	7	–	–	200 g a.i./ha	n.r.	
Cherries	NL	F	Mites	SC	200 g/L	Foliar treatment	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Peaches	NL	F	Mites	SC	200 g/L	Foliar treatment	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Plums	NL	F	Mites	SC	200 g/L	Foliar treatment	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Blackberries	NL	F	Mites	SC	200 g/L	Foliar treatment	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Dewberries	NL	F	Mites	SC	200 g/L	Foliar treatment	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Raspberries	NL	F	Mites	SC	200 g/L	Foliar treatment	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Blueberries	NL	F	Mites	SC	200 g/L	Foliar treatment	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Cranberries	NL	F	Mites	SC	200 g/L	Foliar treatment	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Currants	NL	F	Mites	SC	200 g/L	Foliar treatment	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Gooseberries	NL	F	Mites	SC	200 g/L	Foliar treatment	90–93	2	7	–	–	240 g a.i./ha	n.r.	

Crop and/or situation	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 and season[c]	Number min–max	Interval between application (min)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Rose hips	NL	F	Mites	SC	200 g/L	Foliar treatment	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Mulberries	NL	F	Mites	SC	200 g/L	Foliar treatment	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Azaroles	NL	F	Mites	SC	200 g/L	Foliar treatment	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Elderberries	NL	F	Mites	SC	200 g/L	Foliar treatment	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Hops	NL[e]	F		SC	200 g/L	Foliar treatment – spraying	15–79	2	10	–	–	200 g a.i./ha	14	Based on EFSA (2021a)

MS: Member State.
(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.
(c): Catalogue of pesticide formulation types and international coding system. 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.
(e): NL is reported here as the EMS of the MRL application recently assessed by EFSA (EFSA, 2021a).

A.2. Authorised outdoor uses in southern EU

Crop and/or situation	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 and season[c]	Number min–max	Interval between application (min)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Grapefruits	NL[e]	F	*Panonychus citri, Tetranychus urticae, Tetranychus sp*	SC	200 g/L	Foliar treatment – spraying	11–85	2	10	–	–	200 g a.i./ha	7	Based on EFSA (2021a)
Oranges	NL[e]	F		SC	200 g/L	Foliar treatment	11–85	2	10	–	–	200 g a.i./ha	7	
Lemons	NL[e]	F		SC	200 g/L	Foliar treatment	11–85	2	10	–	–	200 g a.i./ha	7	
Limes	NL[e]	F		SC	200 g/L	Foliar treatment	11–85	2	10	–	–	200 g a.i./ha	7	
Mandarins	NL[e]	F		SC	200 g/L	Foliar treatment	11–85	2	10	–	–	200 g a.i./ha	7	
Apples	BG, ES	F	Mites	SC	200 g/L	Foliar treatment	11–85	2	10	–	–	200 g a.i./ha	7	
Pears	BG, ES	F	Mites	SC	200 g/L	Foliar treatment	11–85	2	10	–	–	200 g a.i./ha	7	
Quinces	BG, ES	F	Mites	SC	200 g/L	Foliar treatment	11–85	2	10	–	–	200 g a.i./ha	7	
Medlars	BG, ES	F	Mites	SC	200 g/L	Foliar treatment	11–85	2	10	–	–	200 g a.i./ha	7	
Loquats	BG, ES	F	Mites	SC	200 g/L	Foliar treatment	11–85	2	10	–	–	200 g a.i./ha	7	
Apricots	NL[e]	F		SC	200 g/L	Foliar treatment	11–85	2		–	–	200 g a.i./ha	7	Based on EFSA (2021a)
Peaches	NL[e]	F		SC	200 g/L	Foliar treatment	11–85	2		–	–	200 g a.i./ha	7	Based on EFSA (2021a)
Tomatoes	BG	F	Mites	SC	200 g/L	Foliar treatment	11–89	2	10	–	–	200 g a.i./ha	1	

Crop and/or situation	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 and season[c]	Number min–max	Interval between application (min)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Aubergines	NL[e]	F		SC	200 g/L	Foliar treatment – spraying	13–89	2	10	–	–	200 g a.i./ha	1	Based on EFSA (2021a)

MS: Member State.
(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.
(c): Catalogue of pesticide formulation types and international coding system. 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.
(e): NL is reported here as the EMS of the MRL application recently assessed by EFSA (EFSA, 2021a).

A.3. Authorised indoor uses in EU

Crop and/or situation	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 and season[c]	Number min–max	Interval between application (min)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Apricots	NL	I	Mites	SC	200 g/L	Foliar treatment – spraying	90–93	2	7	–	–	200 g a.i./ha	n.r.	
Cherries	NL	I	Mites	SC	200 g/L	Foliar treatment – spraying	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Peaches	NL	I	Mites	SC	200 g/L	Foliar treatment – spraying	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Plums	NL	I	Mites	SC	200 g/L	Foliar treatment – spraying	90–93	2	7	–	–	240 g a.i./ha	n.r.	

Crop and/or situation	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 and season[c]	Number min–max	Interval between application (min)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Strawberries	BE, BG, CZ, DE, NL, PL	I	Mites	SC	201 g/L	Foliar treatment – spraying	13–89	2	10	–	–	200 g a.i./ha	1	
Blackberries	NL, BE	I	Mites	SC	200 g/L	Foliar treatment – spraying	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Dewberries	NL	I	Mites	SC	200 g/L	Foliar treatment – spraying	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Raspberries	NL, BE	I	Mites	SC	200 g/L	Foliar treatment – spraying	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Blueberries	NL, BE	I	Mites	SC	200 g/L	Foliar treatment – spraying	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Cranberries	NL, BE	I	Mites	SC	200 g/L	Foliar treatment – spraying	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Currants	NL, BE	I	Mites	SC	200 g/L	Foliar treatment – spraying	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Gooseberries	NL, BE	I	Mites	SC	200 g/L	Foliar treatment – spraying	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Rose hips	NL	I	Mites	SC	200 g/L	Foliar treatment – spraying	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Mulberries	NL	I	Mites	SC	200 g/L	Foliar treatment – spraying	90–93	2	7	–	–	240 g a.i./ha	n.r.	

Crop and/or situation	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 and season[c]	Number min–max	Interval between application (min)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Azaroles	NL	I	Mites	SC	200 g/L	Foliar treatment – spraying	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Elderberries	NL	I	Mites	SC	200 g/L	Foliar treatment – spraying	90–93	2	7	–	–	240 g a.i./ha	n.r.	
Tomatoes	NL[e]	I	Mites	SC	200 g/L	Foliar treatment – spraying	13–89	2	10	–	–	200 g a.i./ha	1	
Aubergines	NL[e]	I	Mites	SC	200 g/L	Foliar treatment – spraying	13–89	2		–	–	200 g a.i./ha	1	Based on EFSA (2021a)
Cucumbers	NL[e]	I	Mites	SC	200 g/L	Foliar treatment – spraying	11–89	2	7	–	–	300 g a.i./ha	1	Based on EFSA (2021a)

MS: Member State; n.r.: not relevant.
(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.
(c): Catalogue of pesticide formulation types and international coding system. 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.
(e): NL is reported here as the EMS of the MRL application recently assessed by EFSA (EFSA, 2021a).

Appendix B – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and methods of analysis in plants

B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling (DAT)**	**Comment/Source**
	Fruit crops	Apple	Foliar, 1 × 600 g/ha	Fruit: 1, 7, 30 Leaf: 7, 30	Radiolabelled active substance: [^{14}C- butylphenyl] or [^{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	
	Leafy crops	–	–	–	Data on leaves in fruit crop metabolism studies considered sufficient to cover the use on hops (EFSA, 2021a).
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Radish	Bare soil, 1 × 400 g/ha	30, 120, 365	Cyflumetofen and metabolites (AB-1, B-3) DT_{90} < 100 days; B-1 DT_{90} max 120 days. Radiolabelled active substance: [^{14}C- butylphenyl] or [^{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	

Processed commodities (hydrolysis study)	**Conditions**	**Stable?**	**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)	Yes	[^{14}C-trifluoromethyl phenyl]/[^{14}C- butylphenyl] labelled: Cyflumetofen 70.9% TRR/69.3% TRR AB-1: 4.2% TRR/39.9% TRR B-1: 23.2% TRR/not relevant for label A-2: not relevant for label/14.3% TRR (Spain, 2020; EFSA, 2021a)
	Baking, brewing and boiling (60 min, 100°C, pH 5)	No	[^{14}C-trifluoromethyl phenyl]/[^{14}C- butylphenyl] labelled: Cyflumetofen 17.9% TRR/5% TRR AB-1: 31.7% TRR/39.9% TRR B-1: 58.7% TRR/not relevant for label A-2: not relevant for label/52.9% TRR (Spain, 2020; EFSA, 2021a)
	Sterilisation (20 min, 120°C, pH 6)	No	[^{14}C-trifluoromethyl phenyl]/[^{14}C- butylphenyl] labelled: Cyflumetofen: not found/not found AB-1: 38.8% TRR/49.1% TRR B-1: 75.3% TRR/not relevant for label A-2: not relevant for label/44.4% TRR (Spain, 2020; EFSA, 2021a)
	Other processing conditions	–	–

Can a general residue definition be proposed for primary crops?	No	Metabolism studies only in fruits, with foliar treatment available.
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. TFA is a common metabolite, found ubiquitously in the environment from various sources (other pesticides, environmental contaminant). Considering the results from the rotational crop confined studies, for the authorised uses of cyflumetofen, consumers are not expected to be exposed to significant residues of this metabolite and therefore there is no need to include it in the residue definition for risk assessment.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes (pasteurisation) No (baking, brewing/ boiling and sterilisation	Cyflumetofen is progressively degraded to B-1, AB-1 and A-2. Nonetheless, considering that B-1 is a major metabolite in both the RAC and in the processed commodities, and considering that the consumer exposure to cyflumetofen residues is low, the potential formation of AB-1 and A-2 in processed products is not expected to be of concern for the consumers. Therefore, for the authorised uses a separate residue definition for processed products is not deemed necessary. In case of further uses, the need to consider AB-1 and/or A-2 may need to be reviewed.
Plant residue definition for monitoring (RD-Mo)	Fruits, hops: cyflumetofen (sum of isomers)	
Plant residue definition for risk assessment (RD-RA)	Fruits, hops: sum of cyflumetofen (sum of isomers) and 2-(trifluoromethyl)benzoic acid (metabolite B-1), expressed as cyflumetofen	
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)	Matrices with high water content, high acid content, high oil content and dry: LC-MS/MS, LOQ 0.01 mg/kg Confirmatory method and ILV available. Hops: LC-MS/MS, LOQ 0.1 mg/kg Confirmatory method and ILV available. (EFSA, 2021a) According to the EURLs, cyflumetofen can be monitored in high water content, high acid content, dry and high fat content commodities with an LOQ of 0.01 mg/kg (EURLs, 2020).	

a.i.: active ingredient; DAT: days after treatment; PBI: plant-back interval; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.1.1.2. Stability of residues in plants

Plant products (available studies)	Category	Commodity	T (°C)[a]	Stability (months)		Comment/Source
				Cyflumetofen	Metabolite B-1[b]	
	High water content	Apple	FS	25	25	EFSA (2021a)
		Lettuce	FS	3	Inconclusive	EFSA (2021a)
		Radish root	FS	3	21	EFSA (2021a)
	High starch content	Wheat grains	FS	25	22	Netherlands (2016), Spain (2020)
	High oil content	Almond nutmeal	FS	25	30	EFSA (2021a)
	High acid content	Orange	FS	25	30	EFSA (2021a)
	Processed products	Apple juice	FS	25	25	EFSA (2021a)
		Orange juice	FS	25	30	EFSA (2021a)
		Orange oil	FS	25	Inconclusive	EFSA (2021a)

(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 (EFSA, 2021a).

B.1.2. Magnitude of residues in plants

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

Commodity	Region/ Indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CF[d]
Citrus fruits	SEU	Oranges: **Mo:** 0.05; 0.07; 0.08; 0.10; 0.11; 0.14; 0.27; 0.27 **RA:** 0.08; 0.10; 0.10; 0.12; 0.13; 0.16; 0.29; 0.29 Lemons: **Mo:** 0.07; 0.12; 0.13; 0.21 **RA:** 0.09; 0.14; 0.15; 0.23 Mandarins: **Mo:** 0.08; 0.10; 0.16; 0.22 **RA:** 0.11; 0.12; 0.18; 0.24	Residue trials on oranges, lemons, mandarins compliant with GAP. Extrapolation to citrus fruits possible (EFSA, 2021a). MRL_{OECD} = 0.42	0.5	0.27	0.12	1.2

Commodity	Region/ Indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CF[d]
Apples	NEU	Apples: **Mo:** 0.03; 0.05; 0.11; 0.15 **RA:** 0.05; 0.08; 0.13; 0.17 Pears: **Mo:** 0.02; 0.03; 0.08; 0.09 **RA:** 0.04; 0.06; 0.1; 0.11	Residue trials on pears and on apples compliant with the GAP (Spain, 2020). MRL_{OECD} = 0.25	0.3	0.15	0.06	1.4
Pome fruits	SEU	Apples: **Mo:** 0.03; 0.04; 0.06; 0.08 **RA:** 0.06; 0.06; 0.08; 0.10 Pears: **Mo:** 0.02; 0.03; 0.05; 0.07 **RA:** 0.05; 0.06; 0.07; 0.09	Residue trials on pears and on apples compliant with the GAP. Extrapolation to pome fruits possible (Spain, 2020). MRL_{OECD} = 0.14	0.15	0.08	0.04	1.6
Apricots, peaches	NEU	–	No residue trials available. Since the application is done after harvest, and considering the properties of the a.s. and the results of the metabolism studies, residues are not expected in the edible part of the crop and the MRL can be proposed at the LOQ (Spain, 2020). Additional trials not required, as the SEU GAP is clearly more critical.	0.01*	0.01	0.01	1[e]
	SEU	Apricots: **Mo**: < 0.01; 0.08; 0.11; 0.12 **RA:** 0.03; 0.11; 0.13; 0.14 Peaches: **Mo**: 0.03; 0.07; 0.10; 0.13 **RA:** 0.06; 0.09; 0.12; 0.15	Residue trials on apricots and peaches compliant with GAP (EFSA, 2021a). Extrapolation to apricots and peaches possible. MRL_{OECD} = 0.25	0.3	0.13	0.09	1.2

Commodity	Region/ Indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CF[d]
	EU	–	No residue trials available. Since the application is done after harvest, and considering the properties of the a.s. and the results of the metabolism studies, residues are not expected in the edible part of the crop and the MRL can be proposed at the LOQ (Spain, 2020). Additional trials not required, as the SEU GAP is clearly more critical.	0.01*	0.01	0.01	1[e]
Cherries, plums, cane fruits and other small fruits and berries	NEU	–	No residue trials available. Since the application is done after harvest, and considering the properties of the a.s. and the results of the metabolism studies, residues are not expected in the edible part of the crop and the MRL can be proposed at the LOQ (Spain, 2020).	0.01* (tentative)[f]	0.01	0.01	1[e]
	EU	–	No residue trials available. Since the application is done after harvest, and considering the properties of the a.s. and the results of the metabolism studies, residues are not expected in the edible part of the crop and the MRL can be proposed at the LOQ (Spain, 2020).	0.01* (tentative)[f]	0.01	0.01	1[e]
Strawberries	EU	**Mo:** 0.07; 0.08; 0.11; 0.11[g]; 0.12; 0.12; 0.12[g]; 0.13; 0.13; 0.14[g]; 0.15[g]; 0.2; 0.45 **RA**: 0.09; 010; 0.13; 0.14; 0.15; 0.15; 0.15; 0.15; 0.16; 0.17; 0.21; 0.22; 0.47	Residue trials on strawberries compliant with the GAP (Spain, 2020). MRL_{OECD} = 0.53	0.6	0.45	0.12	1.3
Tomatoes Aubergines/eggplants	SEU	Mo: 0.06; 0.06; 0.05; 0.05; 0.09; 0.09; 0.04; 0.01 RA: 0.09; 0.08; 0.08; 0.08; 0.12; 0.12; 0.07; 0.04	Residue trials on tomatoes compliant with GAP (EFSA, 2021a). Extrapolation to aubergines possible. MRL_{OECD} = 0.17	0.2	0.09	0.06	1.4

Commodity	Region/ Indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CF[d]
	EU	Mo: 0.02; 0.03; 0.05; 0.05; 0.08; 0.09; 4 × 0.13; 0.16; 0.27 RA: 0.04; 0.05; 0.07; 0.1; 0.11; 0.114; 4 × 0.15; 0.18; 0.29	Residue trials on tomatoes compliant with GAP (EFSA, 2021a). Highest values measured at a longer PHI of 2–4 days or 7–8 days. MRL_{OECD} = 0.38	0.4	0.27	0.11	1.3
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 (EFSA, 2021a). MRL_{OECD} = 0.36	0.4	0.24	0.10	1.2
Hops	NEU	Mo: 3.6; 7.6; 8.0; 14 RA: 4.2; 8.5; 8.7; 14.6	Residue trials on hops compliant with the GAP (EFSA, 2021a). MRL_{OECD} = 25.45	30	14.00	7.80	1.1

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level; Mo: residue levels expressed according to the monitoring residue definition; RA: residue levels expressed according to risk assessment residue definition.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
(e): Since parent and metabolite are expected to remain below the LOQ a CF of 1 is proposed.
(f): MRL proposal is tentative because additional trials are required.
(g): Samples stored up to 841 days, which is outside of the demonstrated storage stability period, considered acceptable since the results are in the same range as residue values from samples stored according to the demonstrated storage stability.

B.1.2.2. Residues in rotational crops

a) Overall summary

Residues in rotational and succeeding crops expected based on confined rotational crop study?	No (cyflumetofen, metabolite B-1) Yes (TFA)	Cyflumetofen was not recovered and metabolite 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 (EFSA, 2021a; Spain, 2020)
Residues in rotational and succeeding crops expected based on field rotational crop study?	No (cyflumetofen, metabolite B-1) Inconclusive for TFA	Residues of cyflumetofen, metabolite B-1 all below the LOQ (<0.01 mg/kg) in wheat, carrots, broccoli and spinaches. Samples not analysed for TFA. However, as TFA is a common metabolite, and considering the results of the rotational crop confined studies it can be concluded that for the authorised uses of cyflumetofen, consumers are not expected to be exposed to significant residues of this metabolite. Therefore, additional trials analysing for this metabolite are not required.

B.1.2.3. 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	1	EFSA (2021a) B-1: < 0.01 mg/kg in processed commodity
Oranges, pulp	4	< 0.05; < 0.05; 0.05; 0.07	0.05	1	EFSA (2021a), Spain (2020) B-1: < 0.01 mg/kg in processed commodity
Oranges, juice	4	< 0.05; 0.07; 0.08; 0.1	0.08	1.1	EFSA (2021a), Spain (2020) B-1: < 0.01–0.01 mg/kg in processed commodity
Orange, dried pulp	4	1.09; 1.2; 1.21; 1.4	1.2	3	EFSA (2021a), Spain (2020) B-1: 0.17–0.36 mg/kg in processed commodity

Processed commodity	Number of valid studies[a]	Processing Factor (PF)		CF_P[b]	Comment/Source
		Individual values	Median PF		
Oranges, wet pomace	4	0.08; 0.11; 0.14; 0.14	0.13	1	EFSA (2021a); Spain (2020) B-1: < 0.01 mg/kg in processed commodity
Oranges, marmalade	4	0.4; 0.4; 0.65; 0.65	0.5	1	EFSA (2021a); Spain (2020) B-1: < 0.01 mg/kg in processed commodity
Apples, juice	4	< 0.04; < 0.07; 0.07; < 0.10	0.07	1.1	EFSA (2021a), Spain (2020), Netherlands (2016) Residues in the processed commodity: B-1: < 0.01 mg/kg A-2: < 0.01 mg/kg
Apples, dried	6	3.25, 4.14, 5.17, 5.20, 7.30, 7.33	5.2	1.1	EFSA (2021a), Spain (2020), Netherlands (2016) Residues in the processed commodity: B-1: 0.01–0.03 mg/kg A-2: < 0.01 mg/kg
Apples, dry pomace	4	13.5; 14; 16.8; 30	15	1	Spain (2020), Netherlands (2016) Residues in the processed commodity: B-1: 0.03–0.06 mg/kg A-2: < 0.01 mg/kg
Apples, wet pomace	6	2.68, 3.13, 3.17, 3.31, 3.33, 4.70	3.3	1	EFSA (2021a), Spain (2020), Netherlands (2016) B-1: < 0.01–0.01 mg/kg in processed commodity A-2: < 0.01 mg/kg
Peaches, juice	3	0.4; 1.4; 1.7	1.4	1.1	EFSA (2021a), Spain (2020) Residues in the processed commodity: B-1: 0.011–0.019 mg/kg A-2: < 0.01 mg/kg
Peaches, canned	3	< 0.04; < 0.06; < 0.08	< 0.06	1	EFSA (2021a), Spain (2020) Residues in the processed commodity: B-1: < 0.01 mg/kg A-2: < 0.01 mg/kg
Peaches, jam	3	0.1; 0.1; 0.2	0.1	1	EFSA (2021a), Spain (2020) Residues in the processed commodity: B-1: < 0.01–0.014 mg/kg A-2: < 0.01 mg/kg
Peaches, dried fruit	3	6.6; 7.85; 20.9	7.85	1.3	EFSA (2021a), Spain (2020) Residues in the processed commodity: B-1: 0.12–0.46 mg/kg A-2: < 0.01–0.036 mg/kg

Processed commodity	Number of valid studies[a]	Processing Factor (PF)		CF_P[b]	Comment/Source
		Individual values	Median PF		
Strawberries, jam	4	0.11; 0.16; 0.40; 0.46	0.28	1	EFSA (2021a), Spain (2020) B-1: < 0.01–0.01 mg/kg in processed commodity
Strawberries, canned	4	0.23; 0.35; 0.37; 0.71	0.36	1	EFSA (2021a), Spain (2020) B-1: < 0.01–0.02 mg/kg in processed commodity
Tomatoes, peeled and canned (sterilised)	4	< 0.02; < 0.03; < 0.05; 0.19	< 0.04	1	EFSA (2021a), Spain (2020) B-1: < 0.01 mg/kg in processed commodity
Tomatoes, paste	4	0.18; 0.25; 0.28; 0.93	0.27	1	EFSA (2021a), Spain (2020) B-1: 0.01–0.04 mg/kg in processed commodity
Tomatoes, ketchup (pasteurised)	4	0.09; 0.12; 0.15; 0.44	0.14	1	EFSA (2021a), Spain (2020) B-1: < 0.01–0.03 mg/kg in processed commodity
Tomatoes, juice	4	0.03; 0.14; 0.14; 0.86	0.14	1	EFSA (2021a), Spain (2020) B-1: < 0.01–0.02 mg/kg in processed commodity
Hop, dried cones	4	3.6, 3.8, 5.4, 5.4	4.6	1.1	Field trial data, EFSA (2021a) B-1: 0.26–1.8 mg/kg in dried cones
Hop, dried cones	2	0.96, 1.00	0.98	1.3	Processing study data, EFSA (2021a) B-1: 1.1; 1.7 mg/kg in dried cones
Hop, extract	2	2.67, 2.75,	2.7	2	EFSA (2021a) B-1: 7.8–11 mg/kg in processed commodity
Hop, beer	2	< 0.0005, < 0.002	< 0.001	1	EFSA (2021a) B-1: < 0.01–0.02 mg/kg in processed commodity
Hop, brewer's yeast	2	< 0.0005, < 0.002	< 0.001	1	EFSA (2021a) B-1: 0.03–0.05 mg/kg in processed commodity

PF: Processing factor (=Residue level in processed commodity expressed according to RD-Mo/Residue level in raw commodity expressed according to RD-Mo); CF_P: Conversion factor for risk assessment in processed commodity (=Residue level in processed commodity expressed according to RD-RA/Residue level in processed commodity expressed according to RD-Mo).
(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Median of the individual conversion factors for each processing residues trial.

B.2. Residues in livestock

Relevant groups (subgroups)	Dietary burden expressed in				Most critical subgroup[a]	Most critical commodity[b]	Trigger exceeded (Y/N)	Comments
	mg/kg bw per day		mg/kg DM					
	Median	Maximum	Median	Maximum				
Cattle (all)	0.003	0.003	0.11	0.11	Beef cattle	Apple pomace, wet	Yes	–
Cattle (dairy only)	0.002	0.002	0.05	0.05	Dairy cattle	Apple pomace, wet	No	–
Sheep (all)	0.002	0.002	0.05	0.05	Lamb	Apple pomace, wet	No	–
Sheep (ewe only)	0.002	0.002	0.05	0.05	Ram/Ewe	Apple pomace, wet	No	–
Swine (all)	0.001	0.001	0.02	0.02	Swine (breeding)	Citrus dried pulp	No	–
Poultry (all)	–	–	–	–	–	–	No	–
Poultry (layer only)	–	–	–	–	–	–	No	–

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

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

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

Livestock (available studies)	Animal	Dose (mg/kg bw per day)	Duration (days)	Comment/Source
	Laying hen	–	–	Not triggered, not required.
	Lactating ruminants	0.27–0.48	10–12	Goat; [^{14}C- butylphenyl] or [^{14}C-trifluoromethyl phenyl] cyflumetofen (Spain, 2020)

Time needed to reach a plateau concentration in milk and eggs (days)	Milk: 4	Only low proportions of the administered dose were found.
	Eggs:-	Not triggered, not required.
Metabolism in rat and ruminant similar	yes	
Can a general residue definition be proposed for animals?	not applicable	No study on poultry available or required.
Animal residue definition for monitoring (RD-Mo)	2-(trifluoromethyl)benzoic acid (metabolite B-1), expressed as cyflumetofen	
Animal residue definition for risk assessment (RD-RA)	Sum of cyflumetofen (sum of isomers) and 2-(trifluoromethyl)benzoic acid (metabolite B-1), expressed as cyflumetofen	
Fat soluble residues	No	No accumulation in fat observed.
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)	Muscle, fat, liver, milk and eggs: HPLC-MS/MS, LOQ of B-1 is 0.01 mg/kg; B-1 recalculated, as cyflumetofen: 0.02 mg/kg. Confirmatory method available ILV not available (data gap) (Spain, 2020) The EURLs indicated that the same LOQ is deemed achievable for routine analyses in milk and liver (EFSA, 2021c).	

B.2.1.2. Stability of residues in livestock

Not available, not required.

B.2.2. Magnitude of residues in livestock

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

Calculations performed with Animal model 2017[10]

Animal commodity	Residues at the closest feeding level (mg/kg)		Estimated value at 1N		MRL proposal (mg/kg)	CF[(c)]
	Mean	Highest	$STMR_{Mo}$[(a)] (mg/kg)	HR_{Mo}[(b)] (mg/kg)		
Cattle (all) – Closest feeding level (0.43 mg/kg bw; × ~ 150 rate)[(d)]						
Muscle	0.005	0.005	0.02	0.02	0.02* (tentative)[(e)]	1[(f)]
Fat	0.006	0.006	0.02	0.02	0.02* (tentative)[(e)]	1[(f)]
Liver	0.125	0.125	0.02	0.02	0.02* (tentative)[(e)]	1[(f)]
Kidney	0.102	0.102	0.02	0.02	0.02* (tentative)[(e)]	1[(f)]
Cattle (dairy only), sheep, swine, poultry – residue definitions, MRLs and input values do not need to be derived as no significant exposure is expected according to the authorised uses						

n.a.: not applicable; n.r. : not reported.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): Median residues expressed according to the residue definition for monitoring, considering the LOQ achievable for enforcement.
(b): Highest residues expressed according to the residue definition for monitoring, considering the LOQ achievable for enforcement.
(c): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
(d): The results of the metabolism study performed with ^{14}C-trifluoromethyl phenyl label were considered.
(e): The MRL is tentative because of data gap on the analytical method for enforcement (ILV).
(f): CF is proposed as 1, as no residues are expected for parent and metabolite.

B.3. Consumer risk assessment

B.3.1. Consumer risk assessment without consideration of the existing CXLs

Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not considered necessary.

ADI	0.17 mg/kg bw per day (European Commission, 2019)
TMDI according to EFSA PRIMo	Not assessed in this review.
NTMDI, according to (to be specified)	Not assessed in this review.
Highest IEDI, according to EFSA PRIMo (rev.3.1)	1 % ADI (German child)
NEDI (% ADI)	Not assessed in this review.
Assumptions made for the calculations	The calculation is based on the median residue levels derived for raw agricultural commodities, multiplied by the conversion factor for risk assessment. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation.

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

[10] https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en

Consumer exposure assessment through drinking water resulting from groundwater metabolite(s) according to SANCO/221/2000 rev.10 Final (25/2/2003)

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

B.3.2. Consumer risk assessment with consideration of the existing CXLs

Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not considered necessary.

ADI	0.17 mg/kg bw per day (European Commission, 2019)
TMDI according to EFSA PRIMo	Not assessed in this review.
NTMDI, according to (to be specified)	Not assessed in this review.
Highest IEDI, according to EFSA PRIMo (rev.3.1)	2 % ADI (Dutch toddler)
NEDI (% ADI)	Not assessed in this review.
Assumptions made for the calculations	For those commodities having a CXL higher than the respective EU MRL proposal, median residue levels applied in the EU scenarios were replaced by the median residue levels derived by JMPR. For livestock the CXLs were recalculated in line with the LOQ for enforcement available in the current review.

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

B.4. Proposed MRLs

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment #data gap
Enforcement residue definition (existing): cyflumetofen (sum of isomers) **Enforcement residue definition (proposed):** cyflumetofen (sum of isomers)					
110000	Citrus fruits	0.5	0.3	0.5	Recommended[a]
120000	Tree nuts	0.01*	0.01*	0.01*	Recommended[b]
130000	Pome fruits	0.4	0.4	0.4	Recommended[c]
140010	Apricots	0.3	–	0.3	Recommended[d]
140020	Cherries	–	–	0.01*	Further consideration needed[e] #1
140030	Peaches	0.3	–	0.3	Recommended[d]
140040	Plums	–	–	0.01*	Further consideration needed[e] #1
151010	Table grapes	0.6	0.6	0.6	Recommended[b]
151020	Wine grapes	0.6	0.6	0.6	Recommended[b]
152000	Strawberries	0.6	0.6	0.6	Recommended[a]
153010	Blackberries	–	–	0.01*	Further consideration needed[e] #1
153020	Dewberries	–	–	0.01*	Further consideration needed[e] #1
153030	Raspberries	–	–	0.01*	Further consideration needed[e] #1
154010	Blueberries	–	–	0.01*	Further consideration needed[e] #1
154020	Cranberries	–	–	0.01*	Further consideration needed[e] #1

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment #data gap
154030	Currants (red, black and white)	–	–	0.01*	Further consideration needed[e] #1
154040	Gooseberries	–	–	0.01*	Further consideration needed[e] #1
154050	Rose hips	–	–	0.01*	Further consideration needed[e] #1
154060	Mulberries	–	–	0.01*	Further consideration needed[e] #1
154070	Azarole (mediterranean medlar)	0.4	0.4	0.4	Recommended[f]
154080	Elderberries	–	–	0.01*	Further consideration needed[e] #1
161060	Persimmon	0.4	0.4	0.4	Recommended[b]
231010	Tomatoes	0.4	0.3	0.4	Recommended[a]
231030	Aubergines (egg plants)	0.4	–	0.4	Recommended[d]
232010	Cucumbers	0.4	–	0.4	Recommended[d]
700000	Hops	30	–	30	Recommended[d]
Enforcement residue definition (existing): cyflumetofen (sum of isomers) **Enforcement residue definition (proposed):** 2-(trifluoromethyl)benzoic acid (metabolite B-1), expressed as cyflumetofen					
1011010	Swine meat	0.01*	0.02*,(1)	0.02*	Further consideration needed[g] #2
1011020	Swine fat	0.01*	0.02*,(1)	0.02*	Further consideration needed[g] #2
1011030	Swine liver	0.02	0.02	0.02	Further consideration needed[g] #2
1011040	Swine kidney	0.02	0.02	0.02	Further consideration needed[g] #2
1012010	Bovine meat	0.01*	0.02*,(1)	0.02*	Further consideration needed[h] #2
1012020	Bovine fat	0.01*	0.02*,(1)	0.02*	Further consideration needed[h] #2
1012030	Bovine liver	0.02	0.02	0.02*	Further consideration needed[h] #2
1012040	Bovine kidney	0.02	0.02	0.02*	Further consideration needed[h] #2
1013010	Sheep meat	0.01*	0.02*,(1)	0.02*	Further consideration needed[g] #2
1013020	Sheep fat	0.01*	0.02*,(1)	0.02*	Further consideration needed[g] #2
1013030	Sheep liver	0.02	0.02	0.02	Further consideration needed[g] #2
1013040	Sheep kidney	0.02	0.02	0.02	Further consideration needed[g] #2
1014010	Goat meat	0.01*	0.02*,(1)	0.02*	Further consideration needed[g] #2
1014020	Goat fat	0.01*	0.02*,(1)	0.02*	Further consideration needed[g] #2
1014030	Goat liver	0.02	0.02	0.02	Further consideration needed[g] #2
1014040	Goat kidney	0.02	0.02	0.02	Further consideration needed[g] #2
1015010	Horse meat	0.01*	0.02*,(1)	0.02*	Further consideration needed[h] #2
1015020	Horse fat	0.01*	0.02*,(1)	0.02*	Further consideration needed[h] #2
1015030	Horse liver	0.02	0.02	0.02*	Further consideration needed[h] #2
1015040	Horse kidney	0.02	0.02	0.02*	Further consideration needed[h] #2
1020010	Cattle milk	0.01*	0.02*,(1)	0.02*	Further consideration needed[g] #2
1020020	Sheep milk	0.01*	0.02*,(1)	0.02*	Further consideration needed[g] #2
1020030	Goat milk	0.01*	0.02*,(1)	0.02*	Further consideration needed[g] #2
1020040	Horse milk	0.01*	0.02*,(1)	0.02*	Further consideration needed[g] #2
–	Other commodities of plant and/or animal origin	See Reg. 2021/1098	–	–	Further consideration needed[i]

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(F): The residue definition is fat soluble.
(1): CXL of 0.01* mg/kg was rounded up to the LOQ of 0.02* mg/kg which was derived at EU level for enforcement of this matrix.
(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination H-III in Appendix E).
(b): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix E).

(c): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination H-VII in Appendix E).
(d): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination H-I in Appendix E).
(e): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination F-I in Appendix E).
(f): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower tentative MRL (combination F-VII in Appendix E).
(g): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified (assuming the existing residue definition); there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix E).
(h): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); existing CXL is covered by the tentative MRL (combination F-III in Appendix E).
(i): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).

Appendix C – Pesticide Residue Intake Model (PRIMo)

- PRIMo(EU)

European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Cyflumetofen

LOQs (mg/kg) range from: 0.01 to: 0.02

Toxicological reference values

ADI (mg/kg bw per day):	0.17	ARfD (mg/kg bw):	not necessary
Source of ADI:	Reg. (EU) No	Source of ARfD:	Reg. (EU) No 2019/716
Year of evaluation:		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	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)	1%	DE child	2.34	0.7%	Apples	0.3%	Oranges	0.1%	Tomatoes		1%
	1%	NL toddler	2.07	0.6%	Apples	0.2%	Oranges	0.2%	Pears		1%
	0.7%	NL child	1.22	0.3%	Apples	0.1%	Oranges	0.1%	Tomatoes		0.7%
	0.6%	GEMS/Food G06	1.07	0.3%	Tomatoes	0.1%	Oranges	0.1%	Apples		0.6%
	0.5%	FR child 3 15 yr	0.92	0.3%	Oranges	0.1%	Apples	0.1%	Tomatoes		0.5%
	0.5%	FR toddler 2 3 yr	0.80	0.2%	Apples	0.1%	Oranges	0.1%	Mandarins		0.5%
	0.5%	DE women 14-50 yr	0.80	0.2%	Apples	0.2%	Oranges	0.1%	Tomatoes		0.5%
	0.4%	DE general	0.74	0.1%	Apples	0.1%	Oranges	0.1%	Tomatoes		0.4%
	0.4%	ES child	0.69	0.2%	Oranges	0.1%	Tomatoes	0.1%	Apples		0.4%
	0.4%	UK toddler	0.67	0.2%	Oranges	0.1%	Apples	0.1%	Tomatoes		0.4%
	0.4%	DK child	0.66	0.1%	Apples	0.1%	Cucumbers	0.0%	Tomatoes		0.4%
	0.4%	GEMS/Food G10	0.64	0.1%	Tomatoes	0.1%	Oranges	0.0%	Apples		0.4%
	0.4%	SE general	0.62	0.1%	Tomatoes	0.1%	Apples	0.1%	Oranges		0.4%
	0.4%	GEMS/Food G07	0.61	0.1%	Oranges	0.1%	Tomatoes	0.1%	Apples		0.4%
	0.4%	RO general	0.61	0.2%	Tomatoes	0.1%	Apples	0.0%	Oranges		0.4%
	0.4%	IE adult	0.61	0.1%	Oranges	0.1%	Grapefruits	0.0%	Apples		0.4%
	0.3%	GEMS/Food G11	0.58	0.1%	Apples	0.1%	Tomatoes	0.1%	Oranges		0.3%
	0.3%	GEMS/Food G15	0.53	0.1%	Tomatoes	0.1%	Apples	0.1%	Oranges		0.3%
	0.3%	GEMS/Food G08	0.53	0.1%	Tomatoes	0.1%	Apples	0.0%	Oranges		0.3%
	0.3%	IT toddler	0.52	0.1%	Tomatoes	0.1%	Apples	0.0%	Oranges		0.3%
	0.3%	UK infant	0.49	0.1%	Oranges	0.1%	Apples	0.0%	Tomatoes		0.3%
	0.3%	ES adult	0.48	0.1%	Oranges	0.1%	Tomatoes	0.0%	Apples		0.3%
	0.3%	FI 3 yr	0.47	0.1%	Cucumbers	0.1%	Apples	0.1%	Tomatoes		0.3%
	0.3%	NL general	0.45	0.1%	Apples	0.1%	Oranges	0.0%	Tomatoes		0.3%
	0.3%	IT adult	0.43	0.1%	Tomatoes	0.0%	Apples	0.0%	Oranges		0.3%
	0.2%	PT general	0.42	0.1%	Tomatoes	0.1%	Apples	0.0%	Oranges		0.2%
	0.2%	PL general	0.40	0.1%	Apples	0.1%	Tomatoes	0.0%	Pears		0.2%
	0.2%	LT adult	0.37	0.1%	Apples	0.1%	Tomatoes	0.0%	Cucumbers		0.2%
	0.2%	UK vegetarian	0.36	0.1%	Oranges	0.1%	Tomatoes	0.0%	Apples		0.2%
	0.2%	FI 6 yr	0.35	0.1%	Cucumbers	0.0%	Tomatoes	0.0%	Apples		0.2%
	0.2%	FR adult	0.32	0.0%	Oranges	0.0%	Apples	0.0%	Tomatoes		0.2%
	0.2%	UK adult	0.30	0.0%	Oranges	0.0%	Tomatoes	0.0%	HOPS (dried)		0.2%
	0.2%	DK adult	0.30	0.1%	Apples	0.0%	Tomatoes	0.0%	Cucumbers		0.2%
	0.2%	FI adult	0.30	0.1%	Tomatoes	0.0%	Apples	0.0%	Oranges		0.2%
	0.2%	FR infant	0.30	0.1%	Apples	0.0%	Oranges	0.0%	Strawberries		0.2%
	0.0%	IE child	0.06	0.0%	Apples	0.0%	Oranges	0.0%	Tomatoes		0.0%

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:

- PRIMo(CXL)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Cyflumetofen

LOQs (mg/kg) range from: 0.01 to: 0.02

Toxicological reference values

ADI (mg/kg bw per day):	0.17	ARfD (mg/kg bw):	not necessary
Source of ADI:	Reg. (EU) No	Source of ARfD:	Reg. (EU) No 2019/716
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	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)	2%	NL toddler	3.87	0.7%	Milk: Cattle	0.7%	Apples	0.3%	Pears		2%
	2%	DE child	3.15	0.8%	Apples	0.3%	Oranges	0.2%	Milk: Cattle		2%
	1%	NL child	2.04	0.4%	Apples	0.3%	Milk: Cattle	0.1%	Table grapes		1%
	0.9%	FR child 3 15 yr	1.58	0.3%	Oranges	0.3%	Milk: Cattle	0.1%	Apples		0.9%
	0.9%	FR toddler 2 3 yr	1.50	0.3%	Milk: Cattle	0.2%	Apples	0.1%	Oranges		0.9%
	0.8%	GEMS/Food G06	1.37	0.3%	Tomatoes	0.1%	Table grapes	0.1%	Oranges		0.8%
	0.8%	DE women 14-50 yr	1.32	0.2%	Apples	0.2%	Oranges	0.1%	Milk: Cattle		0.8%
	0.8%	UK infant	1.30	0.5%	Milk: Cattle	0.1%	Oranges	0.1%	Apples		0.8%
	0.7%	DE general	1.26	0.2%	Apples	0.1%	Milk: Cattle	0.1%	Oranges		0.7%
	0.7%	RO general	1.25	0.2%	Wine grapes	0.2%	Tomatoes	0.1%	Milk: Cattle		0.7%
	0.7%	UK toddler	1.16	0.2%	Milk: Cattle	0.2%	Oranges	0.1%	Apples		0.7%
	0.7%	GEMS/Food G07	1.14	0.2%	Wine grapes	0.1%	Oranges	0.1%	Tomatoes		0.7%
	0.6%	GEMS/Food G11	1.07	0.1%	Wine grapes	0.1%	Apples	0.1%	Milk: Cattle		0.6%
	0.6%	DK child	1.05	0.2%	Apples	0.1%	Milk: Cattle	0.1%	Cucumbers		0.6%
	0.6%	IE adult	1.04	0.1%	Wine grapes	0.1%	Oranges	0.1%	Grapefruits		0.6%
	0.6%	ES child	1.01	0.2%	Oranges	0.1%	Milk: Cattle	0.1%	Tomatoes		0.6%
	0.6%	GEMS/Food G15	1.00	0.1%	Wine grapes	0.1%	Tomatoes	0.1%	Milk: Cattle		0.6%
	0.6%	PT general	0.97	0.3%	Wine grapes	0.1%	Tomatoes	0.1%	Apples		0.6%
	0.6%	GEMS/Food G08	0.97	0.1%	Wine grapes	0.1%	Tomatoes	0.1%	Apples		0.6%
	0.5%	GEMS/Food G10	0.92	0.1%	Tomatoes	0.1%	Oranges	0.1%	Milk: Cattle		0.5%
	0.5%	FR adult	0.90	0.3%	Wine grapes	0.1%	Milk: Cattle	0.0%	Apples		0.5%
	0.5%	SE general	0.89	0.1%	Milk: Cattle	0.1%	Tomatoes	0.1%	Apples		0.5%
	0.5%	NL general	0.83	0.1%	Milk: Cattle	0.1%	Apples	0.1%	Oranges		0.5%
	0.4%	ES adult	0.71	0.1%	Oranges	0.1%	Tomatoes	0.1%	Milk: Cattle		0.4%
	0.4%	FR infant	0.67	0.2%	Milk: Cattle	0.1%	Apples	0.0%	Oranges		0.4%
	0.4%	DK adult	0.66	0.1%	Wine grapes	0.1%	Milk: Cattle	0.1%	Apples		0.4%
	0.4%	UK vegetarian	0.61	0.1%	Wine grapes	0.1%	Oranges	0.1%	Tomatoes		0.4%
	0.3%	UK adult	0.58	0.1%	Wine grapes	0.0%	Oranges	0.0%	Tomatoes		0.3%
	0.3%	IT toddler	0.56	0.1%	Tomatoes	0.1%	Apples	0.0%	Oranges		0.3%
	0.3%	FI 3 yr	0.53	0.1%	Cucumbers	0.1%	Apples	0.1%	Tomatoes		0.3%
	0.3%	LT adult	0.50	0.1%	Apples	0.1%	Tomatoes	0.0%	Milk: Cattle		0.3%
	0.3%	PL general	0.50	0.1%	Apples	0.1%	Tomatoes	0.0%	Table grapes		0.3%
	0.3%	IT adult	0.47	0.1%	Tomatoes	0.1%	Apples	0.0%	Oranges		0.3%
	0.2%	FI 6 yr	0.39	0.1%	Cucumbers	0.0%	Tomatoes	0.0%	Apples		0.2%
	0.2%	FI adult	0.38	0.1%	Tomatoes	0.0%	Apples	0.0%	Wine grapes		0.2%
	0.1%	IE child	0.16	0.0%	Milk: Cattle	0.0%	Apples	0.0%	Oranges		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:

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 2- (trifluoromethyl)benzoic acid (metabolite B-1), expressed as cyflumetofen				
Citrus fruits, dried pulp	0.14	$STMR_{Mo} \times CF_p$ (3) × PF (1.2)	0.14	$STMR_{Mo} \times CF_p$ (3) × PF (1.2)
Apple, pomace, wet	0.21	$STMR_{Mo} \times CF_p$(1) × PF (3.3)	0.21	$STMR_{Mo} \times CF_p$(1) × PF (3.3)

STMR: supervised trials median residue; HR: highest residue; PF: processing factor; CFp: Conversion factor for risk assessment in processed commodity.
*: Indicates that the input value is proposed at the limit of quantification.

D.2. Consumer risk assessment without consideration of the existing CXLs

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of cyflumetofen (sum of isomers) and 2- (trifluoromethyl)benzoic acid (metabolite B-1), expressed as cyflumetofen		
Citrus fruits	0.14	$STMR_{Mo} \times CF$ (1.2)
Pome fruits, azaroles/Mediterranean medlars, kaki/Japanese persimmons	0.1	$STMR_{Mo} \times CF$ (1.6)
Apricots	0.09	$STMR_{Mo} \times CF$ (1)
Cherries (sweet)	0.01*	$STMR_{Mo} \times CF$ (1) (tentative)
Peaches	0.09	$STMR_{Mo} \times CF$ (1)
Plums	0.01*	$STMR_{Mo} \times CF$ (1) (tentative)
Strawberries	0.15	$STMR_{Mo} \times CF$ (1.3)
Cane fruits, and other small fruits and berries	0.01*	$STMR_{Mo} \times CF$ (1) (tentative)
Tomatoes	0.16	$STMR_{Mo} \times CF$ (1.4)
Aubergines/eggplants	0.16	$STMR_{Mo} \times CF$ (1.4)
Cucumbers	0.12	$STMR_{Mo} \times CF$ (1.2)
Hops	8.6	$STMR_{Mo} \times CF$ (1.1)
Bovine and equine meat	0.02*	$STMR_{Mo} \times CF$ (1) (tentative)
Bovine and equine fat	0.02*	$STMR_{Mo} \times CF$ (1) (tentative)
Bovine and equine liver	0.02*	$STMR_{Mo} \times CF$ (1) (tentative)
Bovine and equine kidney	0.02*	$STMR_{Mo} \times CF$ (1) (tentative)

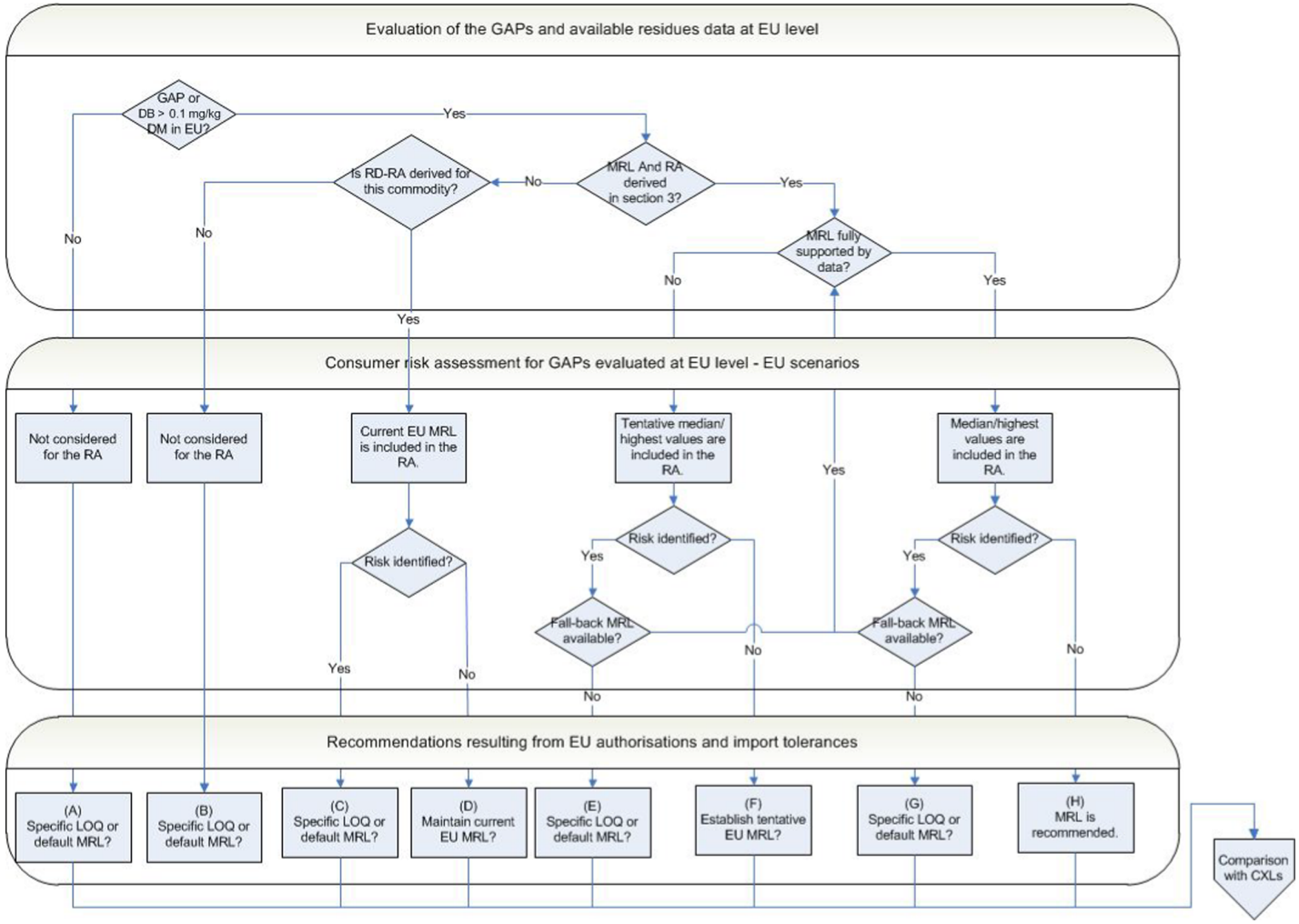
*: Indicates that the input value is proposed at the limit of quantification.

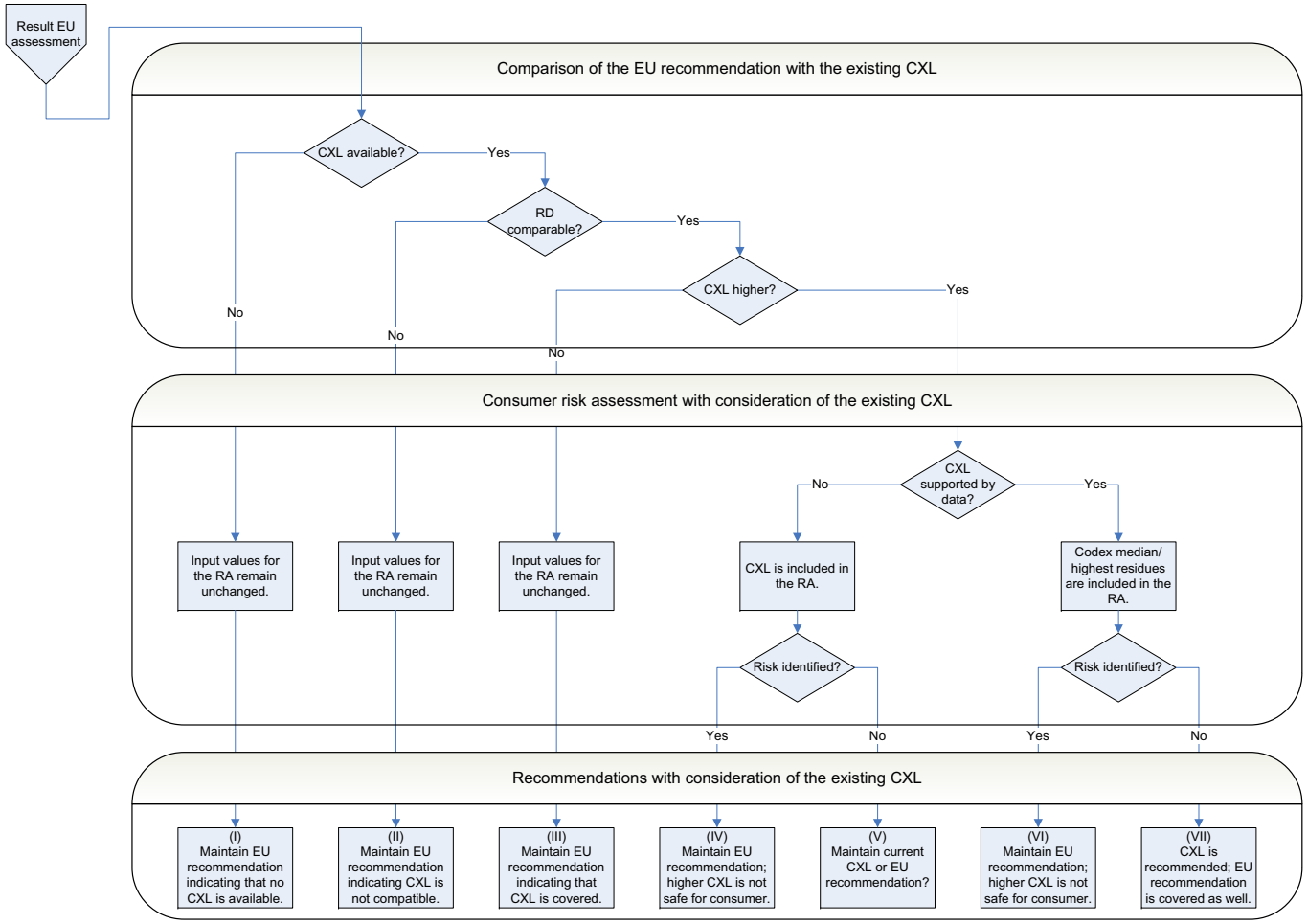
D.3. Consumer risk assessment with consideration of the existing CXLs

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of cyflumetofen (sum of isomers) and 2- (trifluoromethyl)benzoic acid (metabolite B-1), expressed as cyflumetofen		
Citrus fruits	0.14	$STMR_{Mo}$ × CF (1.2)
Tree nuts	0.01*	$STMR_{Mo}$ (CXL) × CF (1)
Pome fruits	0.11	$STMR_{Mo}$ (CXL) × CF (1.2)
Apricots	0.09	$STMR_{Mo}$ × CF (1)
Cherries (sweet)	0.01*	$STMR_{Mo}$ × CF (1) (tentative)
Peaches	0.09	$STMR_{Mo}$ × CF (1)
Plums	0.01*	$STMR_{Mo}$ × CF (1) (tentative)
Table and wine grapes	0.19	$STMR_{Mo}$ (CXL) × CF (1.2)
Strawberries	0.15	$STMR_{Mo}$ × CF (1.3)
Cane fruits, and other small fruits and berries	0.01*	$STMR_{Mo}$ × CF (1) (tentative)
Tomatoes	0.16	$STMR_{Mo}$ × CF (1.4)
Aubergines/eggplants	0.16	$STMR_{Mo}$ × CF (1.4)
Cucumbers	0.12	$STMR_{Mo}$ × CF (1.2)
Hops	8.6	$STMR_{Mo}$ × CF (1.1)
Bovine and equine meat	0.02*	$STMR_{Mo}$ × × CF (1) (tentative)
Bovine and equine fat	0.02*	$STMR_{Mo}$ × CF (1) (tentative)
Bovine and equine liver	0.02*	$STMR_{Mo}$ × CF (1) (tentative)
Bovine and equine kidney	0.02*	$STMR_{Mo}$ × CF (1) (tentative)
Swine, sheep and goat meat	0.02*	$STMR_{Mo}$ (CXL) × CF (1) muscle (tentative)
Swine, sheep and goat fat	0.02*	$STMR_{Mo}$ (CXL) × CF (1) (tentative)
Swine, sheep and goat kidney	0.02*	$STMR_{Mo}$ (CXL) × CF (1) (tentative)
Swine, sheep and goat liver	0.02*	$STMR_{Mo}$ (CXL) × CF (1) (tentative)
Cattle, horse, sheep and goat milk	0.02*	$STMR_{Mo}$ (CXL) × CF (1) (tentative)

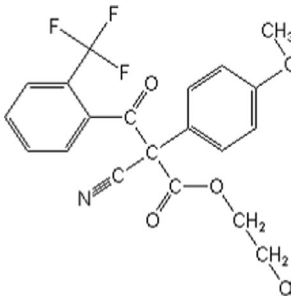
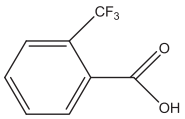
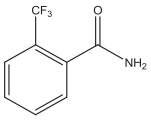
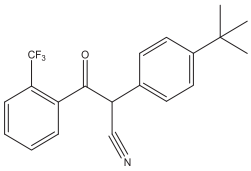
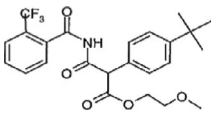
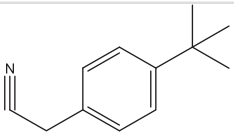
*: Indicates that the input value is proposed at the limit of quantification.

Appendix E – Decision tree for deriving MRL recommendations




Result EU assessment
Comparison of the EU recommendation with the existing CXL
CXL available?
Yes
No
RD comparable?
Yes
No
CXL higher?
Yes
No
Consumer risk assessment with consideration of the existing CXL
CXL supported by data?
No
Yes
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
CXL is included in the RA.
Codex median/ highest residues are included in the RA.
Risk identified?
Risk identified?
Yes
No
Yes
No
Recommendations with consideration of the existing CXL
(I) Maintain EU recommendation indicating that no CXL is available.
(II) Maintain EU recommendation indicating CXL is not compatible.
(III) Maintain EU recommendation indicating that CXL is covered.
(IV) Maintain EU recommendation; higher CXL is not safe for consumer.
(V) Maintain current CXL or EU recommendation?
(VI) Maintain EU recommendation; higher CXL is not safe for consumer.
(VII) CXL is recommended; EU recommendation is covered as well.

Appendix F – Used compound codes

Code/trivial name	IUPAC name/SMILES notation/InChiKey[a]	Structural formula[b]
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	
2-(trifluoromethyl) benzoic acid B1	2-(trifluoromethyl)benzoic acid a,a,a-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	
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): ACD/Name 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116563, 15 June 2020).
(b): ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C25H41, Build 121153, 22 March 2021).