REASONED OPINION

APPROVED: 27 August 2021

doi: 10.2903/j.efsa.2021.6837

Review of the existing maximum residue levels for Beta-cyfluthrin and Cyfluthrin 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 substances Beta-cyfluthrin and Cyfluthrin. Although these active substances are no longer authorised for use on edible crops within the European Union, MRLs were established by the Codex Alimentarius Commission (codex maximum residue limits (CXLs)) and import tolerances were reported by Member States (including the supporting residues data). Based on the assessment of the available data, EFSA assessed the CXLs and import tolerances requested, and a consumer risk assessment was carried out. All CXLs were found to be sufficiently supported by data, whereas some import tolerances were not supported by adequate data. Hence, the consumer risk assessment is considered indicative only and further consideration by risk managers is needed. Apart from a possible acute risk to consumers for a CXL higher than the existing MRL, no risk to consumers was identified

Keywords: Beta-cyfluthrin, Cyfluthrin, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, insecticide, acaricide

Requestor: European Commission

Question number: EFSA-Q-2008-498; EFSA-Q-2008-518

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Declarations of interest: The declarations of interest of all scientific experts active in EFSA's work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch.

Acknowledgement: EFSA wishes to thank the rapporteur Member State, Germany, for the preparatory work and Stathis Anagnos, Laszlo Bura, Andrea Mioč, Marta Szot, Aikaterini Vlachou for the support provided to this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Bellisai G, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Giner G, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Ruocco S, Santos M, Scarlato AP, Theobald A, Vagenende B and Verani A, 2021. Reasoned Opinion on the review of the existing maximum residue levels for Beta-cyfluthrin and Cyfluthrin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2021;19 (9):6837, 46 pp. https://doi.org/10.2903/j.efsa.2021.6837

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.

Summary

Beta-cyfluthrin and Cyfluthrin were both included in Annex I to Council Directive 91/414/EEC on 11 April 2003 by Commission Directive 2003/31/EC, and have been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011.

As both active substances were approved before 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 those active substances in compliance with Article 12(2) of the aforementioned regulation.

As the basis for the MRL review, on 15 September 2020, EFSA initiated the collection of data for the two active substances. Considering that both active substances are no longer approved in the European Union, Member States and the UK were invited to submit by 15 October 2020 only the Good Agricultural Practices (GAPs) for import tolerances in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State, Germany, to identify the critical GAPs in the format of a specific GAP overview file.

GAPs on import tolerances were reported by Member States on beta-cyfluthrin. No uses were reported by Member States on Cyfluthrin.

Subsequently, Member States and the UK were requested to provide residue data supporting the critical GAPs for beta-cyfluthrin, within a period of 1 month, by 14 January 2021.

On the basis of all the data submitted by Member States and the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked the RMS to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report, together with Pesticide Residues Intake Model (PRIMo) calculations were provided by the RMS to EFSA on 19 March 2021. 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 in the framework of Directive 91/414/EEC and the MRLs established by the Codex Alimentarius Commission, EFSA prepared in July 2021 a draft reasoned opinion, which was circulated to Member States and the EURLs for consultation via a written procedure. Comments received by 04 August 2021 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of cyfluthrin (sum of isomers) in plant was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definitions for enforcement and risk assessment can be proposed as **cyfluthrin, including other mixtures of constituent isomers (sum of isomers)**. This residue definition is 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, the LOQ of 0.01 mg/kg is achievable by using the Quick, Easy, Cheap, Effective, Rugged and Safe (QuEChERS) method in routine analyses.

Available residue trials data were considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for wheat and barley where tentative MRLs are derived.

Beta-cyfluthrin 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. Although the calculated dietary burdens for all groups of livestock were found to be below 0.1 mg/kg dry matter (DM), the trigger value of 0.004 mg/kg body weight (bw) per day was slightly exceeded in poultry. However, considering that the major contributor of the dietary burden for poultry is derived from a more critical GAP trial, the dietary burden is expected to be overestimated. Overall, the dietary burden is considered not to trigger further investigation of residues. As livestock are not significantly exposed to cyfluthrin residues, the setting of MRLs for commodities of animal origin is not necessary.

The residue definition both for risk assessment and monitoring for commodities of animal origin set during the peer review as **cyfluthrin, including other mixtures of constituent isomers (sum of isomers)** is applicable.

An analytical method using the multiresidue method DFG S19 with GC-ECD was fully validated for the determination of cyfluthrin, including other mixtures of constituent isomers (sum of isomers) in all

animal tissues, milk and eggs, with an LOQ of 0.01 mg/kg. According to the EURLs cyfluthrin, including other mixtures of constituent isomers (sum of isomers) can be monitored in muscle, liver, milk honey and eggs with an LOQ of 0.01 mg/kg.

Cyfluthrin is also registered for use as a veterinary product in the EU. Within this scope, MRLs for cyfluthrin (sum of isomers) in products of bovine and ovine origin are established. These MRLs are covered in the pesticide legislation.

Information on residue levels in pollen and in bee products for human consumption is not available, however, considering that uses in Europe are not authorised residues in pollen and in bee products are not expected.

Chronic and acute 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) (GEMS/Food G11 diet) and the highest acute exposure amounted to 20% of the acute reference dose (ARfD) (oranges).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for cyfluthrin (sum of isomers). Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out and exceedance of the ARfD was identified for the existing CXL in cauliflower (633%). Excluding this CXL from the calculation, the highest chronic exposure represented 12% of the ADI (Dutch toddler) and the highest acute exposure amounted to 83% of the ARfD (pears).

In addition, MRLs in milk from the veterinary use (bovine and ovine), which were higher than the relevant CXLs, were also included in the calculations. The highest chronic exposure represented 18% of the ADI (Dutch toddler) and the highest acute exposure amounted to 83% of the ARfD (pears).

According to the internationally agreed methodology, the uses under consideration will not result in consumer intake exceeding the ARfD. However, EFSA noted a narrow safety margin. Hence, if residues of cyfluthrin occur in pears, sweet peppers/bell peppers, tomatoes and apples at the derived MRL value, the dietary exposure of certain consumers may exceed the ARfD under certain conditions (i.e. consumption of a large portion of the product without washing/peeling/processing, which would lead to a reduction of the residues in the product). Risk managers should decide whether the safety margin of the exposure assessment based on the highest residue is sufficient, considering that residues in individual units/lot consumed at or above the proposed MRL might occur.

EFSA emphasises that the above assessment does not consider the possible impact of plant and livestock metabolism on the isomer ratio of cyfluthrin and further investigation on this matter would in principle be required. Beta-cyfluthrin and cyfluthrin consist of a mixture of isomers (four pairs of diastereomers, eight enantiomers) differing only in their isomeric composition. As following application of beta-cyfluthrin, isomerisation occurs reaching an equilibrium of isomeric pairs equal to the composition of cyfluthrin, and for both isomeric compositions, it was concluded that the two substances have similar toxicological profiles, no major change in the isomer ratio in the final residue is expected that would be of concern for the authorised uses in the framework of this review. Nonetheless, this conclusion does not consider any possible preferential degradation at the enantiomeric level, as no information is available, and this may lead to additional uncertainty.

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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(2) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide by 1 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC[2] before 2 September 2008.

Beta-cyfluthrin was included in Annex I to Directive 91/414/EEC on 11 April 2003 by Commission Directive 2003/31/EC[3] which has been deemed to be approved under Regulation (EC) No 1107/2009[4], in accordance with Commission Implementing Regulation (EU) No 540/2011[5], as amended by Commission Implementing Regulation (EU) No 541/2011[6] Beta cyfluthrin is no longer approved since 20 January 2021 according to Commission Implementing Regulation (EU) 2020/892[7].

Cyfluthrin was included in Annex I to Directive 91/414/EEC on 11 April 2003 by Commission Directive 2003/31/EC which has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. Cyfluthrin is no longer approved since 30 April 2014 according to Commission Regulation (EU) No 460/2014[8].

In 2020, EFSA initiated the review of all existing MRLs for both active substances.

By way of background information, **beta-cyfluthrin** was evaluated by Germany, designated as rapporteur Member State (RMS) in the framework of Directive 91/414/EEC. The conclusion on the peer review of the pesticide risk assessment of the active substance beta-cyfluthrin is available (EFSA, 2020).

By way of background information, **cyfluthrin** was evaluated by Germany, designated as rapporteur Member State (RMS) in the framework of Directive 91/414/EEC. As EFSA was not yet involved in the peer review of cyfluthrin, an EFSA conclusion on this active substance is not available.

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;

[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 Directive 2003/31/EC of 11 April 2003 amending Council Directive 91/414/EEC to include 2,4-DB, beta-cyfluthrin, cyfluthrin, iprodione, linuron, maleic hydrazide and pendimethalin as active substances (Text with EEA relevance). OJ L 101, 23.4.2003, p. 0003–0009.

[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) 2020/892 of 29 June 2020 concerning the non-renewal of the approval of the active substance beta-cyfluthrin, 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 206, 30.6.2020, p. 5–7.

[8] Commission Regulation (EU) No 460/2014 of 5 May 2014 amending Regulation (EU) No 823/2012 as regards the expiry date of the approval of the active substance cyfluthrin. OJ L 133, 6.5.2014, p. 51–52.

- 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 September 2020, EFSA initiated the collection of data for both **beta-cyfluthrin** and **cyfluthrin**.

In a first step, Member States and UK[9] were invited to submit by 15 October 2020 their Good Agricultural Practices (GAPs) for import tolerances only, in view of the withdrawal of authorisations for both active substances, in a standardised way, in the format of specific GAP forms. In the framework of this consultation, no GAP or IT were reported by MSs or the UK for **cyfluthrin** and three Member States provided feedback on import tolerances of **beta-cyfluthrin**.

Based on the GAP data submitted, the designated RMS, Germany, 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 14 January 2021.

On the basis of all the data submitted by Member States and the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked Germany to complete the PROFile and to prepare a supporting evaluation report only for beta-cyfluthrin. The PROFile and the supporting evaluation report, together with the Pesticide Residues Intake Model (PRIMo) calculations, were submitted to EFSA on 19 March 2021. 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 June 2021 a draft reasoned opinion, which was circulated to Member States and the EURLs for commenting via a written procedure. All comments received by 04 August 2021 were considered by EFSA during the finalisation of the reasoned opinion.

The **evaluation report** submitted by the RMS (Germany, 2021), 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, 2021) 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, 2021a) and the **Member States consultation report** (EFSA, 2021b). 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 and import tolerances 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 substances and their use pattern

Beta-cyfluthrin is the ISO common name for the reaction mixture comprising the enantiomeric pair *(R)*-α-cyano-4-fluoro-3-phenoxybenzyl (1*S*,3*S*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-4-fluoro-3-phenoxybenzyl (1*R*,3*R*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate in ratio 1:2 with the enantiomeric pair (*R*)-α-cyano-4-fluoro-3-phenoxybenzyl (1*S*,3*R*)-3-(2,2-

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

dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-4-fluoro-3-phenoxybenzyl (1*R*,3*S*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (IUPAC). It is noted that the unresolved isomeric mixture of this substance has the ISO common name cyfluthrin.

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

Cyfluthrin is authorised for use in veterinary medicinal products for bovine and ovine and MRLs are set in Regulation (EU) No 37/2010[10]. Cyfluthrin is approved for use in biocidal products of product-type 18 (insecticides, acaricides and products to control other arthropods) according to Commission Implementing Regulation (EU) 2016/1937[11].

The EU MRLs for beta-cyfluthrin are established in Annexes II and IIIB of Regulation (EC) No 396/2005. Codex maximum residue limits (CXLs) for cyfluthrin/beta-cyfluthrin 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	Regulation (EU) No 893/2010[(a)]	Various crops (EFSA 2010)
Implementation of CAC 2013	Regulation (EU) No 491/2014[(b)]	Various crops (EFSA 2013a): soya bean, fat (mammals)
MRL application	Regulation (EU) No 737/2014[(c)]	Artichokes (EFSA 2013b)
MRL application	Regulation (EU) 2016/1902[(d)]	Various cereals (EFSA 2016)

(a): Commission Regulation (EU) No 893/2010 of 8 October 2010 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 acequinocyl, bentazone, carbendazim, cyfluthrin, fenamidone, fenazaquin, flonicamid, flutriafol, imidacloprid, ioxynil, metconazole, prothioconazole, tebufenozide and thiophanate-methyl in or on certain products. OJ L 266, 9.10.2010, p. 10–38.

(b): Commission Regulation (EU) No 491/2014 of 5 May 2014 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for ametoctradin, azoxystrobin, cycloxydim, cyfluthrin, dinotefuran, fenbuconazole, fenvalerate, fludioxonil, fluopyram, flutriafol, fluxapyroxad, glufosinate-ammonium, imidacloprid, indoxacarb, MCPA, methoxyfenozide, penthiopyrad, spinetoram and trifloxystrobin in or on certain products. OJ L 146, 16.5.2014, p. 1–91.

(c): Commission Regulation (EU) No 737/2014 of 24 June 2014 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2-phenylphenol, chlormequat, cyflufenamid, cyfluthrin, dicamba, fluopicolide, flutriafol, fosetyl, indoxacarb, isoprothiolane, mandipropamid, metaldehyde, metconazole, phosmet, picloram, propyzamide, pyriproxyfen, saflufenacil, spinosad and trifloxystrobin in or on certain products. OJ L 202, 10.7.2014, p. 1–63.

(d): Commission Regulation (EU) 2016/1902 of 27 October 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 acetamiprid, ametoctradin, azoxystrobin, cyfluthrin, difluoroacetic acid, dimethomorph, fenpyrazamine, flonicamid, fluazinam, fludioxonil, flupyradifurone, flutriafol, fluxapyroxad, metconazole, proquinazid, prothioconazole, pyriproxyfen, spirodiclofen and trifloxystrobin in or on certain products. OJ L 298, 4.11.2016, p. 1–60.

For the purpose of this MRL review, all the uses of beta-cyfluthrin currently authorised in third countries 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 beta-cyfluthrin and cyfluthrin are given in Appendix A.

Assessment

EFSA has based its assessment on the following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (Germany, 2021);
- the renewal assessment report (RAR) prepared under Commission Regulation (EU) No 1141/2010 as amended by Commission Implementing Regulation (EU) No 380/2013 (Germany, 2017);
- the conclusion on the peer review of the pesticide risk assessment of the active substance beta-cyfluthrin (EFSA, 2020);

[10] Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. OJ L 15, 20.1.2010, p. 1–72.

[11] Commission Implementing Regulation (EU) 2016/1937 of 4 November 2016 approving cyfluthrin as an existing active substance for use in biocidal products of product-type 18. OJ L 299, 5.11.2016, p. 51–53.

- the review report on beta-cyfluthrin (European Commission, 2002);
- the Joint Meeting on Pesticide residues (JMPR) Evaluation report (FAO, 2007);
- the previous reasoned opinions on cyfluthrin and beta-cyfluthrin (EFSA, 2010, 2013a,b, 2016).

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[12] 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; EFSA, 2019a,b).

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

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of beta-cyfluthrin and cyfluthrin was recently assessed in the framework of the peer review for the renewal of beta-cyfluthrin (EFSA, 2020). The studies conducted with either isomeric composition were considered to cover both active substances. The metabolism of these active substances was investigated following foliar treatment in fruit crops (tomato and apple), root crops (potato and sugar beet), cereals (wheat) and pulses/oilseeds (soybean and cotton), and after seed treatment in sugar beet. The radiolabelling was on the fluorophenyl-UL-^{14}C, cyclopropyl-^{14}C or phenyl-UL-^{14}C position of the molecules (see Appendix B.1.1).

Parent was the major component of residues, constituting over 50% total radioactive residue (TRR) in all plant parts and growth stages investigated following foliar applications. Several metabolites were identified, but none exceeded 10% of the TRR. Despite the shortcomings of some studies, altogether the peer review has concluded that they are suitable to elucidate the metabolism in plants (EFSA, 2020).

The seed treatment of sugar beets resulted in extensive metabolism. Pending the label, either conjugates (up to 80% TRR) were detected in root and leaves at maturity or parent constituted the predominant residue in roots (43% TRR).

Overall, the metabolism is considered similar in all crop groups.

1.1.2. Nature of residues in rotational crops

Since the present assessment is limited to import tolerances of beta-cyfluthrin, only the investigation of the nature of residues in rotational crops is not required. It is noted that studies investigating the nature of residues in rotational crops was considered in previous reasoned opinions and during the peer review (EFSA, 2010, 2013a,b, 2016, 2020; Germany, 2021).

1.1.3. Nature of residues in processed commodities

Studies investigating the nature of residues in processed commodities were assessed (EFSA, 2016, 2020), although these studies are not required as the water solubility of (beta-)cyfluthrin is below 0.01 mg/L. Studies were conducted with radiolabelled fluorophenyl-UL-^{14}C simulating representative hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6). Beta-cyfluthrin was stable to hydrolysis under standard conditions of pasteurisation and baking/brewing/boiling, while degradation to two metabolites and a very polar fraction occurred under sterilisation. Given the low water solubility of the parent, the identification attempts were deemed to be sufficient during the peer review (EFSA, 2020).

1.1.4. Methods of analysis in plants

During the peer review, the multiresidue method DFG S19 using gas chromatography with mass spectroscopy (GC-MS) was fully validated in all commodity groups (EFSA, 2020). The method is

[12] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

considered suitable for enforcing cyfluthrin, including other mixtures of constituent isomers (sum of isomers) with LOQs of 0.01 mg/kg in high water, high oil, high acid content and dry commodities. According to the EURL, cyfluthrin, including other mixtures of constituent isomers (sum of isomers) 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, 2021). In addition, the EURLs provided a link to a report on the differences and similarities between isomers in their instrumental response (EFSA, 2021b).

1.1.5. Stability of residues in plants

The storage stability of cyfluthrin, including other mixtures of constituent isomers, was investigated in the framework of the peer review (EFSA, 2020).

In high water content commodities, the storage stability for cyfluthrin was demonstrated for at least 13 months, except for tomatoes and sugarcanes where it was demonstrated for 20 months when stored at –23°C. For high starch/dry content commodities, the available studies demonstrated diverging storage stability periods, ranging from 1 month (potato tuber) to 13 months (maize grain), and up to 25 months (wheat grain). In addition, for high acid (orange) and high oil content (maize oil) matrices stored at –23°C storage stability periods of 25 months and 30 months, respectively, were tentatively proposed, pending further validation data for the method used in the study (EFSA, 2020). Actually, in these studies, a low uncorrected recovery was observed in some samples taken after 13 and 20 months of storage for oranges, and 2, 3 and 7 months for maize oil, while all recoveries were above 70% in samples taken at 25 months and 20 months, respectively. Since the degradation observed after 13 and 20 months for high acid and between 2 and 7 months for high oil matrices could be linked to the analytical method used and considering that samples from citrus fruits were stored for a maximum of 19 months, whereas samples from soybeans for a maximum of 10 months in the framework of this review, the validation of the aforementioned analytical method for high acid and high oil matrices is considered only desirable. In addition, storage stability was demonstrated for 20 months for peanut shells (EFSA, 2020).

1.1.6. Proposed residue definitions

The metabolism of cyfluthrin and beta-cyfluthrin was similar in all crops assessed. Considering its low water solubility, processing is not expected to modify the nature of residues.

Cyfluthrin (sum of isomers) is found to be a sufficient marker in all crops and no major metabolites were identified. Therefore, the residue definition for enforcement and risk assessment proposed by the peer review as **cyfluthrin, including other mixtures of constituent isomers (sum of isomers)** is considered still valid. The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical and is in common to the active substance cyfluthrin and beta-cyfluthrin. Hence, it applies irrespective of whether cyfluthrin or beta-cyfluthrin is used on plants.

An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in all four main plant matrices is available (EFSA, 2020). According to the EURLs, the LOQ of 0.01 mg/kg is achievable by using the QuEChERS method in routine analyses (EURLs, 2021).

In addition, EFSA emphasises that the above studies do not investigate the possible impact of plant metabolism on the isomer ratio of cyfluthrin (sum of isomers) and further investigation on this matter would in principle be required. Beta-cyfluthrin and cyfluthrin consist of a mixture of isomers (four pairs of diastereomers, eight enantiomers) differing only in their isomeric composition. No information is available on the toxicity of the individual isomers. Studies are available with either cyfluthrin or beta-cyfluthrin, and isomerisation of beta-cyfluthrin starts immediately upon application on plants reaching an equilibrium of isomeric pairs equal to the composition of cyfluthrin (EFSA, 2020). Based on similar toxicity observed in acute and short-term studies carried out according to either isomeric specifications, it was concluded that the two substances have similar toxicological profiles (EFSA, 2020). Therefore, the studies conducted with either isomeric composition covers both substances. Considering all the information available, no major change in the isomer ratio in the final residue is expected that would be of concern for the authorised uses in the framework of this review. Nonetheless, this conclusion does not consider any possible preferential degradation at the enantiomeric level, as no information is available and this may lead to additional uncertainty.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of beta-cyfluthrin residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Germany, 2021) as well as the residue trials evaluated in the framework of a previous MRL application (EFSA, 2016). All residue trial samples considered in this framework were stored in compliance with the conditions for which storage stability of residues was demonstrated. Decline of residues during storage of the trial samples is therefore not expected.

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

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

- Barley, wheat grain: Although tentative MRL and risk assessment values can be derived from the northern European outdoor residue trials that have been performed according to a more critical GAP, eight trials compliant with the import tolerance GAPs are still required.

1.2.2. Magnitude of residues in rotational crops

Since the present assessment is limited to import tolerances only the investigation of the magnitude of residues in rotational crops is not required. Nonetheless, it is noted that studies investigating the magnitude in rotational crops (carrots, lettuce and wheat) are available and were assessed in the framework of the peer-review (EFSA, 2020).

1.2.3. Magnitude of residues in processed commodities

The effect of industrial processing and/or household preparation was assessed on studies conducted on tomatoes and oranges (EFSA, 2020; Germany, 2021). An overview of all available processing studies is available in Appendix B.1.2.3. Robust processing factors (fully supported by data) could be derived for canned tomato, raw tomato puree and juice and peeled oranges and orange juice.

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 barley and wheat where tentative MRLs are derived.

2. Residues in livestock

Beta-cyfluthrin is authorised for use on citrus fruits, wheat and barley 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.1.

Although the calculated dietary burdens for all groups of livestock were found to be below 0.1 mg/kg dry matter (DM), the trigger value of 0.004 mg/kg bw per day was slightly exceeded in poultry. However, considering that the major contributor of the dietary burden is Brewer's grain (dried) derived from a more critical GAP on a tentative basis (see Appendix B.1.2.1) the dietary burden is expected to be overestimated. Overall, further investigation of residues is not considered necessary. As livestock are not significantly exposed to cyfluthrin residues, the setting of MRLs for commodities of animal origin is not necessary.

It is noted that metabolism studies for poultry, ruminants and fish and feeding studies with poultry and cows were available and evaluated during the peer review of the renewal of the approval (EFSA, 2020). The residue definition both for risk assessment and monitoring for commodities of animal origin

set as **cyfluthrin, including other mixtures of constituent isomers (sum of isomers)** during the peer review is applicable.

An analytical method using the multiresidue method DFG S19 with GC-ECD was fully validated for the determination of cyfluthrin, including other mixtures of constituent isomers (sum of isomers) in all animal tissues, milk and eggs, with an LOQ of 0.01 mg/kg (EFSA, 2020).

According to the EURLs, cyfluthrin, including other mixtures of constituent isomers (sum of isomers), can be monitored in muscle, liver, milk honey and eggs with an LOQ of 0.01 mg/kg. In muscle, liver, honey and eggs even lower levels, were successfully validated (EURLs, 2021).

Information on residue levels in pollen and in bee products for human consumption is not available, however, considering that uses in Europe are not authorised residues in pollen and in bee products are not expected.

3. Consumer risk assessment

In the framework of this review, only the uses of beta-cyfluthrin reported by the RMS in Appendix A were considered; however, the use of cyfluthrin/beta-cyfluthrin was previously also assessed by the JMPR (FAO, 2007, 2012). The CXLs, resulting from these assessments 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. In addition to existing CXLs, veterinary MRLs were also set and considered in the present assessment.

3.1. Consumer risk assessment without consideration of the existing CXLs and veterinary MRLs

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019a). 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 values for cyfluthrin (sum of isomers) (European Commission, 2002). The highest chronic exposure was calculated for GEMS/Food G11 diet, representing 1% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for oranges, representing 20% of the ARfD. Although uncertainties remain due to the data gap identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumer's health.

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. An overview of the input values used for this exposure calculation is also provided in Appendix D.3.

Chronic and acute exposure calculations were also performed using revision 3.1 of the EFSA PRIMo and the exposure values calculated were compared with the toxicological reference values derived for cyfluthrin (sum of isomers). The highest chronic exposure was calculated for the Dutch toddler, representing 13% of the ADI. With regard to the acute exposure, however, an exceedance of the ARfD was identified for boiled cauliflower, representing 633% of the ARfD. A second exposure calculation was therefore performed, excluding the CXL for this crop. According to the results of this second calculation, the highest chronic exposure declined to 12% of the ADI for the Dutch toddler; the highest acute exposure is then calculated for pears, representing 83% of the ARfD.

Based on these calculations, EFSA concludes that the CXLs for cyfluthrin are not of concern for European consumers, except for the CXLs on cauliflower where a potential risk to consumers was identified and no further refinements of the risk assessment were possible. EFSA notes that, although according to the internationally agreed methodology for acute risk assessment, which is based on the highest residue found in the supervised field trials no acute consumer intake concerns were identified, for the uses on pears, sweet peppers/bell peppers, tomatoes and apples, the safety margin for acute exposure is narrow. If these crops contain residues at the derived new MRLs (0.1 mg/kg; 0.2 mg/kg;

0.1 mg/kg; 0.2 mg/kg, respectively), an exceedance of the ARfD cannot be excluded as the calculated acute exposure accounts for 138%; 119%, 116% and 108%, respectively.

3.3. Consumer risk assessment with further consideration of the existing veterinary MRLs

MRLs for cyfluthrin in products of animal origin, resulting from the use of cyfluthrin as a veterinary drug in bovine and ovine livestock, are also established in the framework of Regulation (EU) No 37/2010 (EMEA, 1997). The residue definition for veterinary use is the mixture of the isomers (8 enantiomers), covering all mixtures of constituents. The MRLs from the veterinary use were included in the calculations of the consumer exposure by comparing them to the CXLs and selecting the higher value. The CXLs for bovine and ovine fat are significantly higher than the veterinary MRLs for these commodities, whereas are the same for muscle, liver and kidney. These veterinary MRLs are therefore deemed covered by the previous risk assessment (see Section 3.2). No veterinary MRLs are set for swine, equine or poultry. For milk, the veterinary MRL of 0.02 mg/kg is higher than the CXL. Therefore, EFSA performed additional chronic and acute exposure calculations including the veterinary MRL for this animal commodity. An overview of the input values used for this exposure calculation is also provided in Appendix D.4.

Chronic and acute exposure calculations were also performed using revision 3.1 of the EFSA PRIMo and the exposure values calculated were compared with the toxicological reference values derived for cyfluthrin (sum of isomers). The highest chronic exposure was calculated for the Dutch toddler, representing 18% of the ADI, and the highest acute exposure remained the same, for pears, representing 83% of the ARfD. These calculations indicate that the uses assessed under this review, including the CXL and the MRLs based on the veterinary use, result in a consumer exposure lower than the toxicological reference values. Therefore, these uses are unlikely to pose a risk to consumer's health.

EFSA emphasises that the above assessment does not consider the possible impact of plant and livestock metabolism on the isomer ratio of cyfluthrin and further investigation on this matter would in principle be required. Beta-cyfluthrin and cyfluthrin consist of a mixture of isomers (eight enantiomers) differing only in their isomeric composition. No information is available on the toxicity of the individual isomers. Studies are available with either cyfluthrin or beta-cyfluthrin, and isomerisation of beta-cyfluthrin starts immediately upon application on plants reaching an equilibrium of isomeric pairs equal to the composition of cyfluthrin (EFSA, 2020). In animal tissues, the *cis:trans* ratio of cyfluthrin residues was unchanged or slightly changed (EMEA, 2000). Based on similar toxicity observed in acute and short-term studies carried out according to both isomeric specifications, it was concluded that the two substances have similar toxicological profiles (EFSA, 2020). Considering the above, in particular the equilibrium of isomers and the similar toxicity of different compositions, the potential change in isomer ratios in the final residue is not expected to be major, nor to be of concern for the authorised uses in the framework of this review. Nonetheless, this conclusion does not consider any possible preferential degradation at the enantiomeric level, as no information is available, and this may lead to additional uncertainty.

Conclusions

The metabolism of cyfluthrin (sum of isomers) in plant was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definitions for enforcement and risk assessment can be proposed as **cyfluthrin, including other mixtures of constituent isomers (sum of isomers)**. This residue definition is 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, the LOQ of 0.01 mg/kg is achievable by using the QuEChERS method in routine analyses.

Available residue trials data were considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for wheat and barley where tentative MRLs are derived.

Beta-cyfluthrin 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. Although the calculated dietary burdens for all groups of livestock were found to be below 0.1 mg/kg dry matter (DM), the trigger value of 0.004 mg/kg bw per day was slightly exceeded in

poultry. However, considering that the major contributor of the dietary burden for poultry is derived from a more critical GAP, the dietary burden is expected to be overestimated. Overall, the dietary burden is considered not to trigger further investigation of residues. As livestock are not significantly exposed to cyfluthrin residues, the setting of MRLs for commodities of animal origin is not necessary.

The residue definition both for risk assessment and monitoring for commodities of animal origin set during the peer review as **cyfluthrin, including other mixtures of constituent isomers (sum of isomers)** is applicable.

An analytical method using the multiresidue method DFG S19 with GC-ECD was fully validated for the determination of cyfluthrin, including other mixtures of constituent isomers (sum of isomers) in all animal tissues, milk and eggs, with an LOQ of 0.01 mg/kg. According to the EURLs, cyfluthrin, including other mixtures of constituent isomers (sum of isomers), can be monitored in muscle, liver, milk honey and eggs with an LOQ of 0.01 mg/kg.

Cyfluthrin is also registered for use as a veterinary product in the EU. Within this scope, MRLs for cyfluthrin (sum of isomers) in products of bovine and ovine origin are established. These MRLs are covered in the pesticide legislation.

Information on residue levels in pollen and in bee products for human consumption is not available, however, considering that uses in Europe are not authorised residues in pollen and in bee products are not expected.

Chronic and acute 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 (GEMS/Food G11 diet) and the highest acute exposure amounted to 20% of the ARfD (oranges).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for cyfluthrin (sum of isomers). Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out and exceedance of the ARfD was identified for the existing CXL in cauliflower (633%). Excluding this CXL from the calculation, the highest chronic exposure represented 12% of the ADI (Dutch toddler) and the highest acute exposure amounted to 83% of the ARfD (pears).

In addition, MRLs in milk from the veterinary use (bovine and ovine), which were higher than the relevant CXLs, were also included in the calculations. The highest chronic exposure represented 18% of the ADI (Dutch toddler) and the highest acute exposure amounted to 83% of the ARfD (pears).

According to the internationally agreed methodology, the uses under consideration will not result in consumer intake exceeding the ARfD. However, EFSA noted a narrow safety margin. Hence, if residues of cyfluthrin occur in pears, sweet peppers/bell peppers, tomatoes and apples at the derived MRL value, the dietary exposure of certain consumers may exceed the ARfD under certain conditions (i.e. consumption of a large portion of the product without washing/peeling/processing, which would lead to a reduction of the residues in the product). Risk managers should decide whether the safety margin of the exposure assessment based on the highest residue is sufficient, considering that residues in individual units/lot consumed at or above the proposed MRL might occur.

EFSA emphasises that the above assessment does not consider the possible impact of plant and livestock metabolism on the isomer ratio of cyfluthrin and further investigation on this matter would in principle be required. Beta-cyfluthrin and cyfluthrin consist of a mixture of isomers (four pairs of diastereomers, eight enantiomers) differing only in their isomeric composition. As following application of beta-cyfluthrin isomerisation occurs, reaching an equilibrium of isomeric pairs equal to the composition of cyfluthrin, and for both isomeric compositions, it was concluded that the two substances have similar toxicological profiles, no major change in the isomer ratio in the final residue is expected that would be of concern for the authorised uses in the framework of this review. Nonetheless, this conclusion does not consider any possible preferential degradation at the enantiomeric level, as no information is available, and this may lead to additional uncertainty.

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:

- residue trials supporting the import tolerance GAPs on wheat and barley.

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

- validation of the analytical method used in the storage stability studies for high acid and high oil content matrices.

Table 2: Summary table

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition: cyfluthrin, including other mixtures of constituent isomers (sum of isomers)[(F)]					
110010	Grapefruit	0.02*	0.3	0.3	Recommended[(a)]
110020	Oranges	0.02*	0.3	0.3	Recommended[(a)]
110030	Lemons	0.02*	0.3	0.3	Recommended[(a)]
110040	Limes	0.02*	0.3	0.3	Recommended[(a)]
110050	Mandarins	0.02*	0.3	0.3	Recommended[(a)]
130010	Apples	0.2	0.1	0.1	Recommended[(b)]
130020	Pears	0.2	0.1	0.1	Recommended[(b)]
211000	Potatoes	0.04	0.01*	0.01*	Recommended[(b)]
231010	Tomatoes	0.05	0.2	0.2	Recommended[(b)]
231020	Peppers	0.3	0.2	0.2	Recommended[(b)]
231030	Aubergines (egg plants)	0.1	0.2	0.2	Recommended[(b)]
241020	Cauliflower	0.05	2	–	Further consideration needed[(c)]
242020	Head cabbage	0.3	0.08	0.08	Recommended[(b)]
401060	Rape seed	0.05	0.07	0.07	Recommended[(b)]
401070	Soya bean	0.03	0.03	0.03	Recommended[(a)]
401090	Cotton seed	0.02*	0.7	0.7	Recommended[(b)]
500010	Barley grain	0.3	–	0.3	Further consideration needed[(d)] data gap #1
500090	Wheat grain	0.04	–	0.04	Further consideration needed[(d)] data gap #1
820000	Spices (fruits and berries)	0.1*	0.03	0.03	Recommended[(b)]
840000	Spices (roots and rhizome)	0.1*	0.05	0.05	Recommended[(b)]
1011010	Swine meat	0.05	0.01	0.01	Recommended[(b)]
1011020	Swine fat (free of lean meat)	0.2	0.2	0.2	Recommended[(b)]
1011030	Swine liver	0.05	0.02	0.02	Recommended[(b)]
1011040	Swine kidney	0.05	0.02	0.02	Recommended[(b)]
1012010	Bovine meat	0.05	0.01	0.01	Recommended[(b)]
1012020	Bovine fat	0.2	0.2	0.2	Recommended[(e)]
1012030	Bovine liver	0.05	0.02	0.02	Recommended[(e)]
1012040	Bovine kidney	0.05	0.02	0.02	Recommended[(e)]
1013010	Sheep meat	0.05	0.01	0.01	Recommended[(e)]
1013020	Sheep fat	0.2	0.2	0.2	Recommended[(e)]
1013030	Sheep liver	0.05	0.02	0.02	Recommended[(e)]
1013040	Sheep kidney	0.05	0.02	0.02	Recommended[(e)]
1014010	Goat meat	0.05	0.01	0.01	Recommended[(e)]
1014020	Goat fat	0.2	0.2	0.2	Recommended[(e)]
1014030	Goat liver	0.05	0.02	0.02	Recommended[(e)]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
1014040	Goat kidney	0.05	0.02	0.02	Recommended[(e)]
1015010	Horse meat	0.05	0.01	0.01	Recommended[(b)]
1015020	Horse fat	0.2	0.2	0.2	Recommended[(b)]
1015030	Horse liver	0.05	0.02	0.02	Recommended[(b)]
1015040	Horse kidney	0.05	0.02	0.02	Recommended[(b)]
1016010	Poultry meat	0.05	0.01*	0.01*	Recommended[(b)]
1016020	Poultry fat	0.05	0.01*	0.01*	Recommended[(b)]
1016030	Poultry liver	0.05	0.01*	0.01*	Recommended[(b)]
1020010	Cattle milk	0.02*	0.01	0.02	Recommended[(f)]
1020020	Sheep milk	0.02*	0.01	0.02	Recommended[(f)]
1020030	Goat milk	0.02*	0.01	0.02	Recommended[(f)]
1020040	Horse milk	0.02*	0.01	0.01	Recommended[(b)]
1030000	Birds' eggs	0.02*	0.01*	0.01*	Recommended[(b)]
–	Other commodities of plant and/or animal origin	See Reg. 1902/2016	–	–	Further consideration needed[(g)]

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.
(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): There are no relevant authorisations or import tolerances reported at EU level; CXL is supported by data but a risk to consumers cannot be excluded. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-VI in Appendix E).
(d): 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).
(e): 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. Derived MRL covers the veterinary use of cyfluthrin.
(f): MRL is derived from the veterinary use of cyfluthrin, which is supported by data and for which no risk to consumers is identified; no exposure of livestock is expected from the GAPs evaluated at EU level; existing CXL is covered by the recommended MRL.
(g): 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
CCPR	Codex Committee on Pesticide Residues
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
EMA	European Medicines Agency (former EMEA)
EMS	evaluating Member State
EURLs	European Union Reference Laboratories for Pesticide Residues (former CRLs)
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC	gas chromatography
GC-ECD	gas chromatography with electron capture detector
GC-MS	gas chromatography with mass spectrometry
GC-MS/MS	gas chromatography with tandem mass spectrometry
GLP	Good Laboratory Practice
GS	growth stage
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry

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
NESTI	national estimated short-term 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
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
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
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. Import tolerance

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]
				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	US	F	Chewing and sucking insects	EC	129.4 g/L	Foliar treatment – spraying		1	–	–	–	56 g a.i./ha	0
Oranges	US	F	Chewing and sucking insects	EC	129.4 g/L	Foliar treatment – spraying		1	–	–	–	56 g a.i./ha	0
Lemons	US	F	Chewing and sucking insects	EC	129.4 g/L	Foliar treatment – spraying		1	–	–	–	56 g a.i./ha	0
Limes	US	F	Chewing and sucking insects	EC	129.4 g/L	Foliar treatment – spraying		1	–	–	–	56 g a.i./ha	0
Mandarins	US	F	Chewing and sucking insects	EC	129.4 g/L	Foliar treatment – spraying		1	–	–	–	56 g a.i./ha	0
Soybeans	US	F	Chewing and sucking insects	EC	129.4 g/L	Foliar treatment – spraying		1–4	7	–	–	25 g a.i./ha	21
Barley	UA	F	Chewing and sucking insects	SC	12.5 g/L	Foliar treatment – spraying		1–2	N.r.	–	–	6.25 g a.i./ha	30
Wheat	UA	F	Chewing and sucking insects	SC	12.5 g/L	Foliar treatment – spraying		1–2	n.r.	–	–	6.25 g a.i./ha	30

MS: Member State. a.s.: active substance; N.r.: not reported.
(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.

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 spraying: 1 × 0.3 g a.s./L + wetting agent	0, 7, 14, 21, 28	Radiolabelled active substance: phenyl-UL-^{14}C-cyfluthrin; Non-GLP-study, not complying with OECD 501 (EFSA, 2020).
		Tomato	Brushing	1, 5, 7, 9, 14, 21, 28, 35 (fruits); 14, 21, 28 (leaves)	Fluorophenyl-UL-^{14}C-cyfluthrin; Non-GLP-study, not complying with OECD 501 (EFSA, 2020).
	Root crops	Potato	Foliar spraying: 1 × 100 g a.s./ha	0, 42, 52, 80, 98	Radiolabelled active substance: phenyl-UL-^{14}C-cyfluthrin; Non-GLP-study, not complying with OECD 501 (EFSA, 2020).
		Sugar beet	Seed treatment	112–197 days after sowing	[Fluorophenyl-UL-14C] beta-cyfluthrin and [Cyclopropyl-14C] beta-cyfluthrin; GLP-study, complying with OECD 501 (EFSA, 2020).
	Cereals/ grass	Wheat	Foliar spraying: 3 × 100 g a.s./ha	1, 21 (BBCH 14–16)	[Phenyl-UL-^{14}C]cyfluthrin
				1	[Cyclopropyl-^{14}C]cyfluthrin;
			4 × 100 g a.s./ha, 7 days interval		Non-GLP-study, not complying with OECD 501 (EFSA, 2020).
	Pulses/ oilseeds	Soya bean	Foliar spraying: 1 × 100 g a.s./ha; BBCH 60–61	4, 19, 33, 48, 62, 84 and 88	[Phenyl-UL-^{14}C]cyfluthrin; Non-GLP-study, not complying with OECD 501 (EFSA, 2020).
		Cotton	Foliar spraying: 1 × 100 g a.s./ha	Foliar spraying, Cotton boll spraying	[Fluorophenyl-UL-^{14}C]cyfluthrin; Non-GLP-study, not complying with OECD 501 (EFSA, 2020).
Rotational crops	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Red beet (root, leaf)	Bare soil: 988 g a.s./ha	36, 121, 285	Limited efforts to identify the nature of residues in harvested crop (and soil) samples. Indications for incorporation of radioactivity into natural plant constituents. (EFSA, 2020)
	Leafy crops	Kale	Bare soil: 988 g a.s./ha	36, 121, 285	
	Cereal (small grain)	Wheat (head, stalk foliage)	Bare soil: 988 g a.s./ha	36, 121, 285	

Processed commodities (hydrolysis study)	**Conditions**	**Stable?**	**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)	Yes	EFSA (2020)
	Baking, brewing and boiling (60 min, 100°C, pH 5)	Yes	EFSA (2020)
	Sterilisation (20 min, 120°C, pH 6)	No	Parent (12.1%); FPB acid (4.9%), FPB aldehyde (33.6% AR); and a very polar fraction (21.9%) (EFSA, 2020)

Can a general residue definition be proposed for primary crops?	Yes	–
Rotational crop and primary crop metabolism similar?	Not applicable	Only import tolerances assessed, as no longer authorised in Europe. Identification and characterisation of the residues in the confined rotational crop studies assessed during the renewal of beta-cyfluthrin were considered not sufficient (EFSA, 2020).
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	Due to the low solubility of cyfluthrin hydrolysis study simulating processing is not required. However, a study was provided, which demonstrated that except for sterilisation, cyfluthrin remained stable (EFSA, 2020).
Plant residue definition for monitoring (RD-Mo)	Cyfluthrin, including other mixtures of constituent isomers (sum of isomers)	
Plant residue definition for risk assessment (RD-RA)	Cyfluthrin, including other mixtures of constituent isomers (sum of isomers)	
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)	Matrices with high water content, high oil content, high acid content and dry matrices: GC-MS multi residue method DFG S19 (with ions m/z 226, 206, 199 validated for confirmation); ILV available; applicable for all matrix groups, LOQ = 0.01 mg/kg (EFSA, 2020). Both cyfluthrin (sum of isomers) and beta-cyfluthrin (which constitutes a fraction of cyfluthrin) 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, 2021).	

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; LOQ: limit of quantification; ILV: independent laboratory validation.

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**	**Comment/Source**
				Value	**Unit**		
	High water content	Whole group except: Tomato sugarcane	–23	13 20 20	Months	cyfluthrin	EFSA (2020)
	High starch content/dry	Potato tuber Wheat grain Maize grain	–23	1 25 13	Months	cyfluthrin	EFSA (2020)
	High acid content	Orange	–23	≤ 25	Months	Cyfluthrin	Germany (2021) Deficiency of the analytical method validation highlighted (EFSA, 2020). Validation of analytical method desirable.
	High oil content/ Processed products	Maize oil	–23	≤ 30	Months	cyfluthrin	
	Others	Peanut shells	–23	20	Months	cyfluthrin	EFSA (2020)

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[(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)
Citrus fruits	Import (US)	Oranges: 0.01; 5 × 0.02; 0.03; 2 × 0.04; 0.06; 0.2; 0.3 grapefruits: 2 × 0.01; 3 × 0.02; 0.03; 0.05 lemons: 2 × 0.02; 3 × 0.03; 0.04; 0.05	Trials on oranges, grapefruits, lemons compliant with the GAP (Germany, 2021). Extrapolation to citrus fruits possible. MRL_{OECD} = 0.3	0.30	0.30	0.03
Soybeans	Import (US)	12 × < 0.01; 3 × 0.01; 4 × 0.02	Trials on soybeans compliant with the GAP (Germany, 2021). MRL_{OECD} = 0.03	0.03	0.02	0.01
Barley grains	Import (UA)	2 × < 0.02; 0.03; 0.04; 0.05; 2 × 0.07; 0.08; 0.16	Trials on barley and oat performed in NEU according to a more critical GAP (2 × 12.5 g a.s./ha, PHI 21 d) (EFSA, 2016). MRL_{OECD} = 0.23	0.30 (tentative)[(d)]	0.16	0.05
Wheat grains	Import (UA)	4 × < 0.01; 2 × 0.01; 2 × < 0.02; 0.02	Trials on wheat performed in NEU according to a more critical GAP (2 × 12.5 g a.s./ha or 2 × 25 g a.s./ha, PHI 21 d) (EFSA, 2016). MRL_{OECD} = 0.03	0.04 (tentative)[(d)]	0.02	0.01

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, EU: indoor EU trials, 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): MRL is tentative since all trials are conducted in NEU, according to a more critical GAP.

B.1.2.2. Residues in rotational crops

a) Overall summary

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Not triggered	No use authorised in Europe.
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	–

B.1.2.3. Processing factors

Processed commodity	Number of valid studies[a]	Processing Factor (PF)		Comment/Source
		Individual values	Median PF	
Oranges, peeled	5	3 × < 0.05; 0.06; < 0.13	< 0.05	Extrapolation to citrus fruits possible. Germany (2021)
Oranges, juice	5	2 × 0.16; < 0.19; < 0.33; < 0.39	< 0.2	Extrapolation to citrus fruits possible. Germany (2021)
Canned tomatoes	2	0.05; 0.12	0.08	EFSA (2020)
Tomato juice (raw)	2	0.45; 0.12	0.3	EFSA, (2020)
Tomato puree (raw)	2	0.82; 0.47	0.6	EFSA (2020)

PF: Processing factor (=Residue level in processed commodity expressed according to RD-Mo/Residue level in raw commodity expressed according to RD-Mo).
(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

B.2. Residues in livestock

Relevant groups (sub groups)	Dietary burden expressed in				Most critical sub group[a]	Most critical commodity[b]	Trigger exceeded (Y/N)	Comments
	mg/kg bw per day		mg/kg DM					
	Median	Maximum	Median	Maximum				
Cattle (all diets)	0.003	0.003	0.08	0.08	Dairy cattle	Citrus, dried pulp	No	–
Cattle (dairy only)	0.003	0.003	0.08	0.08	Dairy cattle	Citrus, dried pulp	No	–
Sheep (all diets)	0.003	0.003	0.07	0.08	Lamb	Wheat, milled by–pdts	No	–
Sheep (ewe only)	0.002	0.003	0.05	0.08	Ram/Ewe	Brewer's grain, dried	No	–
Swine (all diets)	0.002	0.002	0.09	0.09	Swine (breeding)	Citrus, dried pulp	No	–

Relevant groups (sub groups)	Dietary burden expressed in				Most critical sub group[a]	Most critical commodity[b]	Trigger exceeded (Y/N)	Comments
	mg/kg bw per day		mg/kg DM					
	Median	Maximum	Median	Maximum				
Poultry (all diets)	0.005	0.005	0.07	0.07	Poultry layer	Brewer's grain, dried	No	Triggered according to new data requirement, and trigger not exceeded according to old data requirement. The trials in grain are performed according to more critical GAP; therefore, residues are expected to be overestimated.
Poultry (layer only)	0.005	0.005	0.07	0.07	Poultry layer	Brewer's grain, dried	No	Triggered according to new data requirement, and trigger not exceeded according to old data requirement. The trials in grain are performed according to more critical GAP; therefore, residues are expected to be overestimated.
Fish	–	–	–	–	–	–	–	–

(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	5 3,000	5 1	Non-GLP study, not complying with OECD 503 with [phenyl-U-^{14}C]cyfluthrin (EFSA, 2020)
	Lactating ruminants	0.5; 0.5; 0.11, 1	5; 5; 7	Non-GLP study, not complying with OECD 503 with [phenyl-U-^{14}C]cyfluthrin; GLP study, not complying with OECD 503 with [phenyl-U-^{14}C]cyfluthrin; GLP study, complying with OECD 503 with [cyclopropane-1-^{14}C]beta-cyfluthrin (EFSA, 2020)
	Fish	11.7 mg/kg DM 10.6 mg/kg DM	14	With [cyclopropane-1-14C]beta-cyfluthrin [fluorophenyl-UL-14C]beta-cyfluthrin GLP-study, complying with SANCO/11187/2013 rev. 3 (EFSA, 2020)

Time needed to reach a plateau concentration in milk and eggs (days)	Milk: 2–3 days	EFSA (2020)
	Eggs: >96 hours	EFSA (2020)
Metabolism in rat and ruminant similar	Yes	EFSA (2020)
Can a general residue definition be proposed for animals?	Yes	Residue definitions do not need to be derived as significant exposure is not expected according to the authorised uses. Residue definitions proposed during the renewal are reported (EFSA, 2020).
Animal residue definition for monitoring (RD-Mo)	Cyfluthrin, including other mixtures of constituent isomers (sum of isomers)	
Animal residue definition for risk assessment (RD-RA)	Cyfluthrin, including other mixtures of constituent isomers (sum of isomers)	
Fat soluble residues	Yes	EFSA (2020)
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)	Multi-residue method DFG S19 GC-ECD applicable for all matrix groups with ILV available; confirmatory analysis by GC-ECD, LOQ = 0.01 mg/kg (EFSA, 2020). Both cyfluthrin and beta-cyfluthrin (which constitutes a fraction of cyfluthrin) can be monitored in muscle, liver, milk honey and eggs with an LOQ of 0.01 mg/kg (EURLS, 2021).	

B.2.1.2. Stability of residues in livestock

Not relevant, as residues are not expected at significant levels in animal commodities.

B.2.2. Magnitude of residues in livestock

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

Residue definitions, MRLs and input values do not need to be derived as significant exposure is not expected according to the authorised uses.

B.3. Consumer risk assessment

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

ARfD	0.01 mg/kg bw (EC, 2020)
Highest IESTI, according to EFSA PRIMo (rev.3.1)	**Scenario EU:** Oranges: 20% of ARfD
NESTI (% ARfD)	Not assessed in this review.
Assumptions made for the calculations	**Scenario EU:** The calculation is based on the highest residue levels expected in raw agricultural commodities, except for citrus fruits were the derived peeling factor was applied.

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

ADI	0.01 mg/kg bw per day (EC, 2020)
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)	**Scenario EU:** 1% ADI (GEMS/Food G11)
NEDI (% ADI)	Not assessed in this review.
Assumptions made for the calculations	**Scenario EU:** The calculation is based on the median residue levels derived for raw agricultural commodities, except for citrus fruits where the peeling factor was also applied. 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.

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

ARfD	0.01 mg/kg bw (EC, 2020)
Highest IESTI, according to EFSA PRIMo (rev.3.1)	**Scenario CX1:** Cauliflower (boiled): 633% of ARfD **Scenario CX2:** Pears: 83% of ARfD
NESTI (% ARfD)	Not assessed in this review.
Assumptions made for the calculations	**Scenario CX1:** For those commodities having a CXL higher than the EU MRL proposal, highest residue levels applied in the EU scenario were replaced by the highest residue levels derived by JMPR, except for bulk commodities for which the median residue levels were applied. Considering that CXLs for meat were expressed on a fat basis, EFSA re-calculated the corresponding highest residue levels for meat. **Scenario CX2:** The same calculation as in scenario CX1, except cauliflower resulting from the CXL of concern was disregarded.

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

ADI	0.01 mg/kg bw per day (EC, 2020)
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)	**Scenario CX1:** 13 % ADI (NL toddler) **Scenario CX2:** 12% ADI (NL toddler)
NEDI (% ADI)	Not assessed in this review.
Assumptions made for the calculations	**Scenario CX1:** 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. Considering that CXLs for meat were expressed on a fat basis, EFSA re-calculated the corresponding highest residue levels for meat. **Scenario CX2:** The same calculation as in scenario CX1, except cauliflower resulting from the CXL of concern was disregarded.

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.3.3. Consumer risk assessment with further consideration of the existing veterinary MRLs

ARfD	0.01 mg/kg bw (EC, 2020)
Highest IESTI, according to EFSA PRIMo (rev.3.1)	**Scenario Vet:** Pears: 83% of ARfD
NESTI (% ARfD)	Not assessed in this review.
Assumptions made for the calculations	**Scenario Vet:** The same calculation as in scenario CX2, except for those livestock commodities having a veterinary MRL higher than the respective CXL, the residue levels applied in the CX2 scenarios were replaced by the veterinary MRL.

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

ADI	0.01 mg/kg bw per day (EC, 2020)
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)	**Scenario Vet:** 18% ADI (NL toddler)
NEDI (% ADI)	Not assessed in this review.
Assumptions made for the calculations	**Scenario Vet:** The same calculation as in scenario CX2, except for those livestock commodities having a veterinary MRL higher than the respective CXL, median residue levels applied in the CX2 scenarios were replaced by the veterinary MRL.

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
Enforcement residue definition: cyfluthrin, including other mixtures of constituent isomers (sum of isomers)[(F)]					
110010	Grapefruit	0.02*	0.3	0.3	Recommended[(a)]
110020	Oranges	0.02*	0.3	0.3	Recommended[(a)]
110030	Lemons	0.02*	0.3	0.3	Recommended[(a)]
110040	Limes	0.02*	0.3	0.3	Recommended[(a)]
110050	Mandarins	0.02*	0.3	0.3	Recommended[(a)]
130010	Apples	0.2	0.1	0.1	Recommended[(b)]
130020	Pears	0.2	0.1	0.1	Recommended[(b)]
211000	Potatoes	0.04	0.01*	0.01*	Recommended[(b)]
231010	Tomatoes	0.05	0.2	0.2	Recommended[(b)]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
231020	Peppers	0.3	0.2	0.2	Recommended[(b)]
231030	Aubergines (egg plants)	0.1	0.2	0.2	Recommended[(b)]
241020	Cauliflower	0.05	2	–	Further consideration needed[(c)]
242020	Head cabbage	0.3	0.08	0.08	Recommended[(b)]
401060	Rape seed	0.05	0.07	0.07	Recommended[(b)]
401070	Soya bean	0.03	0.03	0.03	Recommended[(a)]
401090	Cotton seed	0.02*	0.7	0.7	Recommended[(b)]
500010	Barley grain	0.3	–	0.3	Further consideration needed[(d)] data gap #1
500090	Wheat grain	0.04	–	0.04	Further consideration needed[(d)] data gap #1
820000	Spices (fruits and berries)	0.1*	0.03	0.03	Recommended[(b)]
840000	Spices (roots and rhizome)	0.1*	0.05	0.05	Recommended[(b)]
1011010	Swine meat	0.05	0.01	0.01	Recommended[(b)]
1011020	Swine fat (free of lean meat)	0.2	0.2	0.2	Recommended[(b)]
1011030	Swine liver	0.05	0.02	0.02	Recommended[(b)]
1011040	Swine kidney	0.05	0.02	0.02	Recommended[(b)]
1012010	Bovine meat	0.05	0.01	0.01	Recommended[(e)]
1012020	Bovine fat	0.2	0.2	0.2	Recommended[(e)]
1012030	Bovine liver	0.05	0.02	0.02	Recommended[(e)]
1012040	Bovine kidney	0.05	0.02	0.02	Recommended[(e)]
1013010	Sheep meat	0.05	0.01	0.01	Recommended[(e)]
1013020	Sheep fat	0.2	0.2	0.2	Recommended[(e)]
1013030	Sheep liver	0.05	0.02	0.02	Recommended[(e)]
1013040	Sheep kidney	0.05	0.02	0.02	Recommended[(e)]
1014010	Goat meat	0.05	0.01	0.01	Recommended[(e)]
1014020	Goat fat	0.2	0.2	0.2	Recommended[(e)]
1014030	Goat liver	0.05	0.02	0.02	Recommended[(e)]
1014040	Goat kidney	0.05	0.02	0.02	Recommended[(e)]
1015010	Horse meat	0.05	0.01	0.01	Recommended[(b)]
1015020	Horse fat	0.2	0.2	0.2	Recommended[(b)]
1015030	Horse liver	0.05	0.02	0.02	Recommended[(b)]
1015040	Horse kidney	0.05	0.02	0.02	Recommended[(b)]
1016010	Poultry meat	0.05	0.01*	0.01*	Recommended[(b)]
1016020	Poultry fat	0.05	0.01*	0.01*	Recommended[(b)]
1016030	Poultry liver	0.05	0.01*	0.01*	Recommended[(b)]
1020010	Cattle milk	0.02*	0.01	0.02	Recommended[(f)]
1020020	Sheep milk	0.02*	0.01	0.02	Recommended[(f)]
1020030	Goat milk	0.02*	0.01	0.02	Recommended[(f)]
1020040	Horse milk	0.02*	0.01	0.01	Recommended[(b)]
1030000	Birds' eggs	0.02*	0.01*	0.01*	Recommended[(b)]
–	Other commodities of plant and/or animal origin	See Reg. 1902/2016	–	–	Further consideration needed[(g)]

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.
(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): There are no relevant authorisations or import tolerances reported at EU level; CXL is supported by data but a risk to consumers cannot be excluded. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-VI in Appendix E).
(d): 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).
(e): 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. Derived MRL covers the veterinary use of cyfluthrin.
(f): MRL is derived from the veterinary use of cyfluthrin, which is supported by data and for which no risk to consumers is identified; no exposure of livestock is expected from the GAPs evaluated at EU level; existing CXL is covered by the recommended MRL.
(g): 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; 2021/01/06

Beta Cyfluthrin

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw per day):	0.01	ARfD (mg/kg bw):	0.01
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2020	Year of evaluation:	2020

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 : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)	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)
	1%	GEMS/Food G11	0.11	0.4%	Barley	0.4%	Soyabeans	0.4%	Wheat		1%
	1%	GEMS/Food G08	0.11	0.4%	Barley	0.4%	Wheat	0.2%	Soyabeans		1%
	1%	GEMS/Food G10	0.10	0.4%	Wheat	0.3%	Soyabeans	0.3%	Barley		1%
	1%	GEMS/Food G15	0.10	0.5%	Wheat	0.4%	Barley	0.2%	Soyabeans		1%
	0.9%	GEMS/Food G07	0.09	0.4%	Wheat	0.3%	Barley	0.2%	Soyabeans		0.9%
	0.9%	GEMS/Food G06	0.09	0.7%	Wheat	0.1%	Soyabeans	0.0%	Barley		0.9%
	0.7%	IT toddler	0.07	0.7%	Wheat	0.0%	Oranges	0.0%	Barley		0.7%
	0.5%	NL toddler	0.05	0.4%	Wheat	0.1%	Barley	0.0%	Oranges		0.5%
	0.5%	FR child 3 15 yr	0.05	0.5%	Wheat	0.0%	Oranges	0.0%	Barley		0.5%
	0.5%	RO general	0.05	0.5%	Wheat	0.0%	Oranges	0.0%	Grapefruits		0.5%
	0.5%	ES adult	0.05	0.2%	Barley	0.2%	Wheat	0.0%	Oranges		0.5%
	0.5%	DE child	0.05	0.4%	Wheat	0.1%	Oranges	0.0%	Mandarins		0.5%
	0.5%	ES child	0.05	0.4%	Wheat	0.0%	Oranges	0.0%	Mandarins		0.5%
	0.5%	DE general	0.05	0.3%	Barley	0.2%	Wheat	0.0%	Oranges		0.5%
	0.5%	NL child	0.05	0.4%	Wheat	0.0%	Soyabeans	0.0%	Oranges		0.5%
	0.4%	PT general	0.04	0.4%	Wheat	0.0%	Soyabeans	0.0%	Barley		0.4%
	0.4%	DK child	0.04	0.4%	Wheat	0.0%	Oranges	0.0%	Mandarins		0.4%
	0.4%	UK toddler	0.04	0.4%	Wheat	0.0%	Oranges	0.0%	Barley		0.4%
	0.4%	IT adult	0.04	0.4%	Wheat	0.0%	Oranges	0.0%	Barley		0.4%
	0.4%	NL general	0.04	0.2%	Wheat	0.1%	Barley	0.0%	Oranges		0.4%
	0.3%	FR toddler 2 3 yr	0.03	0.3%	Wheat	0.0%	Oranges	0.0%	Mandarins		0.3%
	0.3%	DE women 14-50 yr	0.03	0.2%	Wheat	0.1%	Barley	0.0%	Oranges		0.3%
	0.3%	SE general	0.03	0.3%	Wheat	0.0%	Oranges	0.0%	Mandarins		0.3%
	0.3%	UK infant	0.03	0.3%	Wheat	0.0%	Oranges	0.0%	Grapefruits		0.3%
	0.3%	IE adult	0.03	0.2%	Wheat	0.0%	Oranges	0.0%	Grapefruits		0.3%
	0.2%	FR adult	0.02	0.2%	Wheat	0.0%	Oranges	0.0%	Soyabeans		0.2%
	0.2%	UK vegetarian	0.02	0.2%	Wheat	0.0%	Oranges	0.0%	Barley		0.2%
	0.2%	UK adult	0.02	0.2%	Wheat	0.0%	Barley	0.0%	Oranges		0.2%
	0.2%	FI 3 yr	0.02	0.1%	Wheat	0.0%	Barley	0.0%	Mandarins		0.2%
	0.1%	LT adult	0.01	0.1%	Wheat	0.0%	Barley	0.0%	Oranges		0.1%
	0.1%	FI 6 yr	0.01	0.1%	Wheat	0.0%	Barley	0.0%	Mandarins		0.1%
	0.1%	IE child	0.01	0.1%	Wheat	0.0%	Barley	0.0%	Oranges		0.1%
	0.1%	DK adult	0.01	0.1%	Wheat	0.0%	Oranges	0.0%	Mandarins		0.1%
	0.1%	FR infant	0.01	0.1%	Wheat	0.0%	Oranges	0.0%	Mandarins		0.1%
	0.1%	FI adult	0.01	0.0%	Wheat	0.0%	Barley	0.0%	Oranges		0.1%
	0.0%	PL general	0.00	0.0%	Lemons	0.0%	Mandarins	0.0%	Oranges		0.0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of beta Cyfluthrin is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
20%	Oranges	0.3/0.02	2.0
12%	Grapefruits	0.3/0.02	1.2
9%	Mandarins	0.3/0.02	0.89
5%	Lemons	0.3/0.02	0.51
3%	Limes	0.3/0.02	0.30
3%	Barley	0.3/0.05	0.28
1%	Wheat	0.04/0.01	0.14
0.2%	Soyabeans	0.03/0.01	0.02

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
5%	Oranges	0.3/0.02	0.46
3%	Mandarins	0.3/0.02	0.27
3%	Grapefruits	0.3/0.02	0.27
2%	Barley	0.3/0.05	0.24
1%	Lemons	0.3/0.02	0.13
1%	Limes	0.3/0.02	0.11
0.8%	Wheat	0.04/0.01	0.08
0.6%	Soyabeans	0.03/0.01	0.06

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): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
3%	Oranges/juice	0.3/0.01	0.30
2%	Barley/cooked	0.3/0.05	0.18
1%	Wheat/milling (flour)	0.04/0.01	0.12
0.9%	Barley/milling (flour)	0.3/0.05	0.09
0.8%	Lemons/jam	0.3/0.03	0.08
0.6%	Wheat/milling (wholemeal)-baking	0.04/0.01	0.06
0.4%	Soyabeans/soya drink	0.03/0.01	0.04
0.1%	Soyabeans/boiled	0.03/0	0.01
0.0%	Limes/juice	0.3/0.03	0.00

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
4%	Barley/beer	0.3/0.01	0.36
0.8%	Oranges/juice	0.3/0.01	0.08
0.6%	Grapefruits/juice	0.3/0.01	0.06
0.5%	Lemons/juice	0.3/0.03	0.05
0.4%	Wheat/bread/pizza	0.04/0.01	0.04
0.4%	Wheat/pasta	0.04/0.01	0.04
0.3%	Wheat/bread (wholemeal)	0.04/0.01	0.03

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of beta Cyfluthrin is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

- PRIMo(CX1)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Beta Cyfluthrin

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

Toxicological reference values

ADI (mg/kg bw per day):	0.01	ARfD (mg/kg bw):	0.01
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2020	Year of evaluation:	2020

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 : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)	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)
	13%	NL toddler	1.32	6%	Milk: Cattle	2%	Apples	1%	Cauliflowers	0.1%	13%
	7%	DE child	0.69	2%	Apples	2%	Milk: Cattle	0.7%	Tomatoes	0.2%	7%
	6%	NL child	0.63	2%	Milk: Cattle	1%	Apples	0.4%	Wheat	0.1%	6%
	6%	UK infant	0.62	4%	Milk: Cattle	0.6%	Cauliflowers	0.3%	Potatoes	0.2%	6%
	6%	FR toddler 2 3 yr	0.58	3%	Milk: Cattle	0.6%	Apples	0.6%	Cauliflowers	0.1%	6%
	5%	FR child 3 15 yr	0.54	2%	Milk: Cattle	0.6%	Tomatoes	0.5%	Cauliflowers	0.2%	5%
	5%	GEMS/Food G06	0.52	3%	Tomatoes	0.7%	Wheat	0.3%	Cotton seeds	0.1%	5%
	5%	RO general	0.48	1%	Tomatoes	1%	Milk: Cattle	0.5%	Wheat	0.1%	5%
	5%	GEMS/Food G15	0.47	0.8%	Tomatoes	0.7%	Milk: Cattle	0.5%	Wheat	0.1%	5%
	5%	GEMS/Food G08	0.46	0.8%	Tomatoes	0.6%	Milk: Cattle	0.4%	Barley	0.1%	5%
	4%	GEMS/Food G11	0.45	0.8%	Milk: Cattle	0.6%	Tomatoes	0.4%	Potatoes	0.1%	4%
	4%	UK toddler	0.44	2%	Milk: Cattle	0.4%	Tomatoes	0.4%	Wheat	0.1%	4%
	4%	GEMS/Food G07	0.44	0.8%	Tomatoes	0.6%	Milk: Cattle	0.4%	Wheat	0.1%	4%
	4%	SE general	0.43	1%	Milk: Cattle	1.0%	Bovine: Muscle/meat	0.5%	Tomatoes	0.1%	4%
	4%	GEMS/Food G10	0.42	1.0%	Tomatoes	0.5%	Milk: Cattle	0.4%	Wheat	0.1%	4%
	4%	DK child	0.41	1%	Milk: Cattle	0.5%	Swine: Muscle/meat	0.5%	Apples	0.1%	4%
	4%	ES child	0.40	1%	Milk: Cattle	0.7%	Tomatoes	0.4%	Wheat	0.2%	4%
	4%	DE general	0.37	1%	Milk: Cattle	0.5%	Apples	0.5%	Tomatoes	0.1%	4%
	4%	DE women 14-50 yr	0.36	1%	Milk: Cattle	0.5%	Tomatoes	0.5%	Apples	0.1%	4%
	3%	FR infant	0.33	2%	Milk: Cattle	0.6%	Cauliflowers	0.3%	Apples	0.0%	3%
	3%	NL general	0.32	0.8%	Milk: Cattle	0.5%	Cauliflowers	0.3%	Tomatoes	0.1%	3%
	3%	ES adult	0.26	0.5%	Tomatoes	0.5%	Milk: Cattle	0.2%	Barley	0.1%	3%
	2%	IE adult	0.24	0.4%	Milk: Cattle	0.4%	Cauliflowers	0.3%	Tomatoes	0.1%	2%
	2%	IT toddler	0.22	1.0%	Tomatoes	0.7%	Wheat	0.2%	Apples		2%
	2%	LT adult	0.22	0.4%	Tomatoes	0.4%	Milk: Cattle	0.4%	Apples	0.1%	2%
	2%	DK adult	0.21	0.5%	Milk: Cattle	0.4%	Tomatoes	0.2%	Swine: Muscle/meat	0.1%	2%
	2%	PT general	0.20	0.6%	Tomatoes	0.5%	Potatoes	0.4%	Wheat		2%
	2%	FR adult	0.20	0.4%	Milk: Cattle	0.3%	Cauliflowers	0.3%	Tomatoes	0.1%	2%
	2%	PL general	0.17	0.6%	Tomatoes	0.4%	Apples	0.3%	Potatoes		2%
	2%	IT adult	0.17	0.8%	Tomatoes	0.4%	Wheat	0.2%	Apples		2%
	2%	UK vegetarian	0.17	0.4%	Tomatoes	0.3%	Milk: Cattle	0.3%	Cauliflowers	0.0%	2%
	2%	FI 3 yr	0.16	0.5%	Potatoes	0.4%	Tomatoes	0.2%	Cauliflowers		2%
	1%	UK adult	0.15	0.3%	Tomatoes	0.3%	Milk: Cattle	0.2%	Wheat	0.1%	1%
	1%	FI 6 yr	0.12	0.4%	Potatoes	0.3%	Tomatoes	0.1%	Apples		1%
	0.9%	IE child	0.09	0.4%	Milk: Cattle	0.1%	Wheat	0.1%	Swine: Fat tissue	0.0%	0.9%
	0.8%	FI adult	0.08	0.4%	Tomatoes	0.1%	Potatoes	0.1%	Apples		0.8%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of beta Cyfluthrin is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 1

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
527%	Cauliflowers	2/0.91	53
83%	Pears	0.1/0.06	8.3
71%	Sweet peppers/bell peppers	0.2/0.12	7.1
65%	Apples	0.1/0.06	6.5
58%	Tomatoes	0.2/0.1	5.8
30%	Aubergines/egg plants	0.2/0.12	3.0
22%	Head cabbages	0.08/0.05	2.2
20%	Oranges	0.3/0.02	2.0
15%	Potatoes	0.01/0.01	1.5
12%	Milk: Cattle	0.01/0.01	1.2
12%	Grapefruits	0.3/0.02	1.2
9%	Mandarins	0.3/0.02	0.89
5%	Lemons	0.3/0.02	0.51
5%	Swine: Muscle/meat	0.01/0.04	0.48
3%	Bovine: Fat tissue	0.2/0.16	0.33

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): 1

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
211%	Cauliflowers	2/0.91	21
32%	Aubergines/egg plants	0.2/0.12	3.2
21%	Head cabbages	0.08/0.05	2.1
20%	Sweet peppers/bell peppers	0.2/0.12	2.0
18%	Pears	0.1/0.06	1.8
17%	Apples	0.1/0.06	1.7
16%	Tomatoes	0.2/0.1	1.6
5%	Oranges	0.3/0.02	0.46
4%	Milk: Cattle	0.01/0.01	0.39
3%	Swine: Fat tissue	0.2/0.16	0.32
3%	Potatoes	0.01/0.01	0.30
3%	Mandarins	0.3/0.02	0.27
3%	Grapefruits	0.3/0.02	0.27
2%	Barley	0.3/0.05	0.24
2%	Bovine: Muscle	0.01/0.04	0.23

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 1

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 1

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
633%	Cauliflowers/boiled	2/0.91	63
13%	Tomatoes/juice	0.2/0.07	1.3
11%	Apples/juice	0.1/0.02	1.1
9%	Potatoes/fried	0.01/0.01	0.93
7%	Tomatoes/sauce/puree	0.2/0.07	0.67
7%	Pears/juice	0.1/0.02	0.65
6%	Potatoes/dried (flakes)	0.01/0.05	0.59
3%	Oranges/juice	0.3/0.01	0.30
2%	Barley/cooked	0.3/0.05	0.18
1%	Wheat/milling (flour)	0.04/0.01	0.12
0.9%	Barley/milling (flour)	0.3/0.05	0.09
0.8%	Lemons/jam	0.3/0.03	0.08
0.6%	Head cabbages/canned	0.08/0.01	0.06
0.6%	Wheat/milling (wholemeal)-baking	0.04/0.01	0.06
0.4%	Soyabeans/soya drink	0.03/0.01	0.04

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 1

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
379%	Cauliflowers/boiled	2/0.91	38
7%	Apples/juice	0.1/0.02	0.67
6%	Tomatoes/sauce/puree	0.2/0.07	0.57
4%	Barley/beer	0.3/0.01	0.36
0.9%	Head cabbages/canned	0.08/0.01	0.09
0.8%	Oranges/juice	0.3/0.01	0.08
0.8%	Potatoes/chips	0.01/0.01	0.08
0.6%	Grapefruits/juice	0.3/0.01	0.06
0.6%	Potatoes/dried (flakes)	0.01/0.05	0.06
0.5%	Lemons/juice	0.3/0.03	0.05
0.4%	Wheat/bread/pizza	0.04/0.01	0.04
0.4%	Wheat/pasta	0.04/0.01	0.04
0.3%	Wheat/bread (wholemeal)	0.04/0.01	0.03

Conclusion:
The estimated short term intake (IESTI) exceeded the toxicological reference value for 1 commodities.

For processed commodities, the toxicological reference value was exceeded in one or several cases.

- PRIMo(CX2)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Beta Cyfluthrin

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

Toxicological reference values

ADI (mg/kg bw per day):	0.01	ARfD (mg/kg bw):	0.01
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2020	Year of evaluation:	2020

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 : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)	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)
	12%	NL toddler	1.17	6%	Milk: Cattle	2%	Apples	0.9%	Pears	0.1%	12%
	7%	DE child	0.66	2%	Apples	2%	Milk: Cattle	0.7%	Tomatoes	0.2%	7%
	6%	NL child	0.60	2%	Milk: Cattle	1%	Apples	0.4%	Wheat	0.1%	6%
	6%	UK infant	0.56	4%	Milk: Cattle	0.3%	Potatoes	0.3%	Apples	0.2%	6%
	5%	FR toddler 2 3 yr	0.52	3%	Milk: Cattle	0.6%	Apples	0.3%	Tomatoes	0.1%	5%
	5%	GEMS/Food G06	0.51	3%	Tomatoes	0.7%	Wheat	0.3%	Cotton seeds	0.1%	5%
	5%	FR child 3 15 yr	0.49	2%	Milk: Cattle	0.6%	Tomatoes	0.5%	Wheat	0.2%	5%
	5%	RO general	0.47	1%	Tomatoes	1%	Milk: Cattle	0.5%	Wheat	0.1%	5%
	5%	GEMS/Food G15	0.46	0.8%	Tomatoes	0.7%	Milk: Cattle	0.5%	Wheat	0.1%	5%
	4%	GEMS/Food G08	0.44	0.8%	Tomatoes	0.6%	Milk: Cattle	0.4%	Barley	0.1%	4%
	4%	GEMS/Food G11	0.43	0.8%	Milk: Cattle	0.6%	Tomatoes	0.4%	Potatoes	0.1%	4%
	4%	GEMS/Food G07	0.42	0.8%	Tomatoes	0.6%	Milk: Cattle	0.4%	Wheat	0.1%	4%
	4%	UK toddler	0.42	2%	Milk: Cattle	0.4%	Tomatoes	0.4%	Wheat	0.1%	4%
	4%	GEMS/Food G10	0.41	1.0%	Tomatoes	0.5%	Milk: Cattle	0.4%	Wheat	0.1%	4%
	4%	SE general	0.41	1%	Milk: Cattle	1.0%	Bovine: Muscle/meat	0.5%	Tomatoes	0.1%	4%
	4%	DK child	0.40	1%	Milk: Cattle	0.5%	Swine: Muscle/meat	0.5%	Apples	0.1%	4%
	4%	ES child	0.39	1%	Milk: Cattle	0.7%	Tomatoes	0.4%	Wheat	0.2%	4%
	3%	DE general	0.34	1%	Milk: Cattle	0.5%	Apples	0.5%	Tomatoes	0.1%	3%
	3%	DE women 14-50 yr	0.33	1%	Milk: Cattle	0.5%	Tomatoes	0.5%	Apples	0.1%	3%
	3%	NL general	0.27	0.8%	Milk: Cattle	0.3%	Tomatoes	0.3%	Apples	0.1%	3%
	3%	FR infant	0.26	2%	Milk: Cattle	0.3%	Apples	0.2%	Potatoes	0.0%	3%
	2%	ES adult	0.25	0.5%	Tomatoes	0.5%	Milk: Cattle	0.2%	Barley	0.1%	2%
	2%	LT adult	0.22	0.4%	Tomatoes	0.4%	Milk: Cattle	0.4%	Apples	0.1%	2%
	2%	IT toddler	0.21	1.0%	Tomatoes	0.7%	Wheat	0.2%	Apples		2%
	2%	DK adult	0.20	0.5%	Milk: Cattle	0.4%	Tomatoes	0.2%	Swine: Muscle/meat	0.1%	2%
	2%	IE adult	0.20	0.4%	Milk: Cattle	0.3%	Tomatoes	0.2%	Wheat	0.1%	2%
	2%	PT general	0.20	0.6%	Tomatoes	0.5%	Potatoes	0.4%	Wheat		2%
	2%	FR adult	0.17	0.4%	Milk: Cattle	0.3%	Tomatoes	0.2%	Wheat	0.1%	2%
	2%	IT adult	0.16	0.8%	Tomatoes	0.4%	Wheat	0.2%	Apples		2%
	2%	PL general	0.15	0.6%	Tomatoes	0.4%	Apples	0.3%	Potatoes		2%
	1%	UK vegetarian	0.14	0.4%	Tomatoes	0.3%	Milk: Cattle	0.2%	Wheat	0.0%	1%
	1%	FI 3 yr	0.14	0.5%	Potatoes	0.4%	Tomatoes	0.2%	Apples		1%
	1%	UK adult	0.13	0.3%	Tomatoes	0.3%	Milk: Cattle	0.2%	Wheat	0.1%	1%
	1%	FI 6 yr	0.11	0.4%	Potatoes	0.3%	Tomatoes	0.1%	Apples		1%
	0.8%	IE child	0.08	0.4%	Milk: Cattle	0.1%	Wheat	0.1%	Swine: Fat tissue	0.0%	0.8%
	0.7%	FI adult	0.07	0.4%	Tomatoes	0.1%	Potatoes	0.1%	Apples		0.7%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of beta Cyfluthrin is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
83%	Pears	0.1/0.06	8.3
71%	Sweet peppers/bell peppers	0.2/0.12	7.1
65%	Apples	0.1/0.06	6.5
58%	Tomatoes	0.2/0.1	5.8
30%	Aubergines/egg plants	0.2/0.12	3.0
22%	Head cabbages	0.08/0.05	2.2
20%	Oranges	0.3/0.02	2.0
15%	Potatoes	0.01/0.01	1.5
12%	Milk: Cattle	0.01/0.01	1.2
12%	Grapefruits	0.3/0.02	1.2
9%	Mandarins	0.3/0.02	0.89
5%	Lemons	0.3/0.02	0.51
5%	Swine: Muscle/meat	0.01/0.04	0.48
3%	Bovine: Fat tissue	0.2/0.16	0.33
3%	Limes	0.3/0.02	0.30

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
32%	Aubergines/egg plants	0.2/0.12	3.2
21%	Head cabbages	0.08/0.05	2.1
20%	Sweet peppers/bell peppers	0.2/0.12	2.0
18%	Pears	0.1/0.06	1.8
17%	Apples	0.1/0.06	1.7
16%	Tomatoes	0.2/0.1	1.6
5%	Oranges	0.3/0.02	0.46
4%	Milk: Cattle	0.01/0.01	0.39
3%	Swine: Fat tissue	0.2/0.16	0.32
3%	Potatoes	0.01/0.01	0.30
3%	Mandarins	0.3/0.02	0.27
3%	Grapefruits	0.3/0.02	0.27
2%	Barley	0.3/0.05	0.24
2%	Bovine: Muscle	0.01/0.04	0.23
2%	Swine: Muscle/meat	0.01/0.04	0.19

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): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
13%	Tomatoes/juice	0.2/0.07	1.3
11%	Apples/juice	0.1/0.02	1.1
9%	Potatoes/fried	0.01/0.01	0.93
7%	Tomatoes/sauce/puree	0.2/0.07	0.67
7%	Pears/juice	0.1/0.02	0.65
6%	Potatoes/dried (flakes)	0.01/0.05	0.59
3%	Oranges/juice	0.3/0.01	0.30
2%	Barley/cooked	0.3/0.05	0.18
1%	Wheat/milling (flour)	0.04/0.01	0.12
0.9%	Barley/milling (flour)	0.3/0.05	0.09
0.8%	Lemons/jam	0.3/0.03	0.08
0.6%	Head cabbages/canned	0.08/0.01	0.06
0.6%	Wheat/milling (wholemeal)-baking	0.04/0.01	0.06
0.4%	Soyabeans/soya drink	0.03/0.01	0.04
0.3%	Rapeseeds/oils	0.07/0.1	0.03

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
7%	Apples/juice	0.1/0.02	0.67
6%	Tomatoes/sauce/puree	0.2/0.07	0.57
4%	Barley/beer	0.3/0.01	0.36
0.9%	Head cabbages/canned	0.08/0.01	0.09
0.8%	Oranges/juice	0.3/0.01	0.08
0.8%	Potatoes/chips	0.01/0.01	0.08
0.6%	Grapefruits/juice	0.3/0.01	0.06
0.6%	Potatoes/dried (flakes)	0.01/0.05	0.06
0.5%	Lemons/juice	0.3/0.03	0.05
0.4%	Wheat/bread/pizza	0.04/0.01	0.04
0.4%	Wheat/pasta	0.04/0.01	0.04
0.3%	Wheat/bread (wholemeal)	0.04/0.01	0.03

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of beta Cyfluthrin is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

- PRIMo(veterinary)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Beta Cyfluthrin

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

Toxicological reference values

ADI (mg/kg bw per day):	0.01	ARfD (mg/kg bw):	0.01
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2020	Year of evaluation:	2020

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)	18%	NL toddler	1.77	12%	Milk: Cattle	2%	Apples	0.9%	Pears	0.1%	18%
	9%	UK infant	0.94	8%	Milk: Cattle	0.3%	Potatoes	0.3%	Apples	0.2%	9%
	9%	DE child	0.86	4%	Milk: Cattle	2%	Apples	0.7%	Tomatoes	0.2%	9%
	8%	NL child	0.84	5%	Milk: Cattle	1%	Apples	0.4%	Wheat	0.1%	8%
	8%	FR toddler 2 3 yr	0.82	6%	Milk: Cattle	0.6%	Apples	0.3%	Tomatoes	0.1%	8%
	7%	FR child 3 15 yr	0.72	5%	Milk: Cattle	0.6%	Tomatoes	0.5%	Wheat	0.2%	7%
	6%	UK toddler	0.62	4%	Milk: Cattle	0.4%	Tomatoes	0.4%	Wheat	0.1%	6%
	6%	RO general	0.59	2%	Milk: Cattle	1%	Tomatoes	0.5%	Wheat	0.1%	6%
	5%	GEMS/Food G06	0.54	3%	Tomatoes	0.7%	Wheat	0.5%	Milk: Cattle	0.1%	5%
	5%	SE general	0.53	2%	Milk: Cattle	1.0%	Bovine: Muscle/meat	0.5%	Tomatoes	0.1%	5%
	5%	GEMS/Food G15	0.53	1%	Milk: Cattle	0.8%	Tomatoes	0.5%	Wheat	0.1%	5%
	5%	DK child	0.53	3%	Milk: Cattle	0.5%	Swine: Muscle/meat	0.5%	Apples	0.1%	5%
	5%	ES child	0.51	2%	Milk: Cattle	0.7%	Tomatoes	0.4%	Wheat	0.2%	5%
	5%	GEMS/Food G11	0.50	2%	Milk: Cattle	0.6%	Tomatoes	0.4%	Potatoes	0.1%	5%
	5%	GEMS/Food G08	0.49	1%	Milk: Cattle	0.8%	Tomatoes	0.4%	Barley	0.1%	5%
	5%	GEMS/Food G07	0.49	1%	Milk: Cattle	0.8%	Tomatoes	0.4%	Wheat	0.1%	5%
	5%	GEMS/Food G10	0.47	1%	Milk: Cattle	1.0%	Tomatoes	0.4%	Wheat	0.1%	5%
	5%	DE general	0.46	2%	Milk: Cattle	0.5%	Apples	0.5%	Tomatoes	0.1%	5%
	5%	DE women 14-50 yr	0.45	2%	Milk: Cattle	0.5%	Tomatoes	0.5%	Apples	0.1%	5%
	4%	FR infant	0.43	3%	Milk: Cattle	0.3%	Apples	0.2%	Potatoes	0.0%	4%
	4%	NL general	0.36	2%	Milk: Cattle	0.3%	Tomatoes	0.3%	Apples	0.1%	4%
	3%	ES adult	0.30	1.0%	Milk: Cattle	0.5%	Tomatoes	0.2%	Barley	0.1%	3%
	3%	LT adult	0.26	0.8%	Milk: Cattle	0.4%	Tomatoes	0.4%	Apples	0.1%	3%
	3%	DK adult	0.26	1%	Milk: Cattle	0.4%	Tomatoes	0.2%	Swine: Muscle/meat	0.1%	3%
	2%	IE adult	0.24	0.9%	Milk: Cattle	0.3%	Tomatoes	0.2%	Wheat	0.1%	2%
	2%	FR adult	0.22	0.9%	Milk: Cattle	0.3%	Tomatoes	0.2%	Wheat	0.1%	2%
	2%	IT toddler	0.21	1.0%	Tomatoes	0.7%	Wheat	0.2%	Apples		2%
	2%	PT general	0.20	0.6%	Tomatoes	0.5%	Potatoes	0.4%	Wheat		2%
	2%	UK vegetarian	0.17	0.7%	Milk: Cattle	0.4%	Tomatoes	0.2%	Wheat	0.0%	2%
	2%	IT adult	0.16	0.8%	Tomatoes	0.4%	Wheat	0.2%	Apples		2%
	2%	UK adult	0.16	0.6%	Milk: Cattle	0.3%	Tomatoes	0.2%	Wheat	0.1%	2%
	2%	PL general	0.15	0.6%	Tomatoes	0.4%	Apples	0.3%	Potatoes		2%
	1%	FI 3 yr	0.14	0.5%	Potatoes	0.4%	Tomatoes	0.2%	Apples		1%
	1%	IE child	0.12	0.7%	Milk: Cattle	0.1%	Wheat	0.1%	Swine: Fat tissue	0.0%	1%
	1%	FI 6 yr	0.11	0.4%	Potatoes	0.3%	Tomatoes	0.1%	Apples		1%
	0.7%	FI adult	0.07	0.4%	Tomatoes	0.1%	Potatoes	0.1%	Apples		0.7%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of beta Cyfluthrin is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
83%	Pears	0.1/0.06	8.3
71%	Sweet peppers/bell peppers	0.2/0.12	7.1
65%	Apples	0.1/0.06	6.5
58%	Tomatoes	0.2/0.1	5.8
30%	Aubergines/egg plants	0.2/0.12	3.0
25%	Milk: Cattle	0.02/0.02	2.5
22%	Head cabbages	0.08/0.05	2.2
20%	Oranges	0.3/0.02	2.0
15%	Potatoes	0.01/0.01	1.5
12%	Grapefruits	0.3/0.02	1.2
9%	Mandarins	0.3/0.02	0.89
5%	Lemons	0.3/0.02	0.51
5%	Swine: Muscle/meat	0.01/0.04	0.48
5%	Milk: Goat	0.02/0.02	0.48
3%	Bovine: Fat tissue	0.2/0.16	0.33

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
32%	Aubergines/egg plants	0.2/0.12	3.2
21%	Head cabbages	0.08/0.05	2.1
20%	Sweet peppers/bell peppers	0.2/0.12	2.0
18%	Pears	0.1/0.06	1.8
17%	Apples	0.1/0.06	1.7
16%	Tomatoes	0.2/0.1	1.6
8%	Milk: Cattle	0.02/0.02	0.77
5%	Oranges	0.3/0.02	0.46
4%	Milk: Goat	0.02/0.02	0.37
3%	Swine: Fat tissue	0.2/0.16	0.32
3%	Milk: Sheep	0.02/0.02	0.30
3%	Potatoes	0.01/0.01	0.30
3%	Mandarins	0.3/0.02	0.27
3%	Grapefruits	0.3/0.02	0.27
2%	Barley	0.3/0.05	0.24

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): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
13%	Tomatoes/juice	0.2/0.07	1.3
11%	Apples/juice	0.1/0.02	1.1
9%	Potatoes/fried	0.01/0.01	0.93
7%	Tomatoes/sauce/puree	0.2/0.07	0.67
7%	Pears/juice	0.1/0.02	0.65
6%	Potatoes/dried (flakes)	0.01/0.05	0.59
3%	Oranges/juice	0.3/0.01	0.30
2%	Barley/cooked	0.3/0.05	0.18
1%	Wheat/milling (flour)	0.04/0.01	0.12
0.9%	Barley/milling (flour)	0.3/0.05	0.09
0.8%	Lemons/jam	0.3/0.03	0.08
0.6%	Head cabbages/canned	0.08/0.01	0.06
0.6%	Wheat/milling (wholemeal)-baking	0.04/0.01	0.06
0.4%	Soyabeans/soya drink	0.03/0.01	0.04
0.3%	Rapeseeds/oils	0.07/0.1	0.03

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
7%	Apples/juice	0.1/0.02	0.67
6%	Tomatoes/sauce/puree	0.2/0.07	0.57
4%	Barley/beer	0.3/0.01	0.36
0.9%	Head cabbages/canned	0.08/0.01	0.09
0.8%	Oranges/juice	0.3/0.01	0.08
0.8%	Potatoes/chips	0.01/0.01	0.08
0.6%	Grapefruits/juice	0.3/0.01	0.06
0.6%	Potatoes/dried (flakes)	0.01/0.05	0.06
0.5%	Lemons/juice	0.3/0.03	0.05
0.4%	Wheat/bread/pizza	0.04/0.01	0.04
0.4%	Wheat/pasta	0.04/0.01	0.04
0.3%	Wheat/bread (wholemeal)	0.04/0.01	0.03

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of beta Cyfluthrin is unlikely to present a public health risk.

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

Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: cyfluthrin, including other mixtures of constituent isomers (sum of isomers)				
Citrus, dried pulp[(a)]	0.28	STMR × default PF (10)	0.28	STMR × default PF (10)
Soybean, seed	0.01*	STMR	0.01*	STMR
Soybean, meal[(a)]	0.01	STMR × default PF (1.3)	0.01	STMR × default PF (1.3)
Soybean, hulls[(a)]	0.13	STMR × default PF (13)	0.13	STMR × default PF (13)
Barley, grain	0.05	STMR	0.05	STMR
Brewer's grain, dried[(a)]	0.17	STMR × default PF (3.3)	0.17	STMR × default PF (3.3)
Triticale, grain	0.01	STMR	0.01	STMR
Wheat, grain	0.01	STMR	0.01	STMR
Wheat, distiller's grain (dry)[(a)]	0.03	STMR × default PF (3.3)	0.03	STMR × default PF (3.3)
Wheat gluten, meal[(a)]	0.02	STMR × default PF (1.8)	0.02	STMR × default PF (1.8)
Wheat, milled by-pdts[(a)]	0.07	STMR × default PF (7)	0.07	STMR × default PF (7)

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
*: Indicates that the input value is proposed at the limit of quantification.
(a): In the absence of processing factors supported by data, default processing factors were included in the calculation to consider the potential concentration of residues in these commodities.

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: cyfluthrin, including other mixtures of constituent isomers (sum of isomers)				
Citrus fruits	0.001	STMR × PF (0.05)	0.015	HR × PF (0.05)
Soybeans	0.01*	STMR	0.01*	STMR
Barley	0.05	STMR (tentative)	0.05	STMR (tentative)
Wheat	0.01	STMR (tentative)	0.01	STMR (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		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: cyfluthrin, including other mixtures of constituent isomers (sum of isomers)				
Citrus fruits	0.001	STMR × PF (0.05)	0.015	HR × PF (0.05)
Apples	0.02	STMR (CXL)	0.06	HR (CXL)
Pears	0.02	STMR (CXL)	0.06	HR (CXL)
Potatoes	0.01	STMR (CXL)	0.01	HR (CXL)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Tomatoes	0.07	STMR (CXL)	0.1	HR (CXL)
Sweet peppers/bell peppers	0.06	STMR (CXL)	0.12	HR (CXL)
Aubergines/egg plants	0.05	STMR (CXL)	0.12	HR (CXL)
Cauliflowers	0.24/–[(a)]	STMR (CXL)/–	0.91/–[(a)]	HR (CXL)/–
Head cabbages	0.01	STMR (CXL)	0.05	HR (CXL)
Rapeseeds/canola seeds	0.05	STMR (CXL)	0.05	HR (CXL)
Soybeans	0.01	STMR	0.01	STMR
Cotton seeds	0.1	STMR (CXL)	0.52	HR (CXL)
Barley	0.05	STMR (tentative)	0.05	STMR (tentative)
Wheat	0.01	STMR (tentative)	0.01	STMR (tentative)
Swine meat	0.022	0.8 × STMR (CXL) muscle + 0.2 × STMR (CXL) fat	0.01	0.8 × HR (CXL) muscle + 0.2 × HR (CXL) fat
Swine fat	0.07	STMR (CXL)	0.01	HR (CXL)
Swine liver	0.005	STMR (CXL)	0.04	HR (CXL)
Swine kidney	0.005	STMR (CXL)	0.16	HR (CXL)
Bovine and equine meat	0.022	0.8 × STMR (CXL) muscle + 0.2 × STMR (CXL) fat	0.01	0.8 × HR (CXL) muscle + 0.2 × HR (CXL) fat
Bovine and equine fat	0.07	STMR (CXL)	0.01	HR (CXL)
Bovine and equine liver	0.005	STMR (CXL)	0.04	HR (CXL)
Bovine and equine kidney	0.005	STMR (CXL)	0.16	HR (CXL)
Sheep and goat meat	0.022	0.8 × STMR (CXL) muscle + 0.2 × STMR (CXL) fat	0.01	0.8 × HR (CXL) muscle + 0.2 × HR (CXL) fat
Sheep and goat fat	0.07	STMR (CXL)	0.01	HR (CXL)
Sheep and goat liver	0.005	STMR (CXL)	0.04	HR (CXL)
Sheep and goat kidney	0.005	STMR (CXL)	0.16	HR (CXL)
Poultry meat	0.01*	0.8 × STMR (CXL) muscle + 0.2 × STMR (CXL) fat	0.01*	0.8 × HR (CXL) muscle + 0.2 × HR (CXL) fat
Poultry fat	0.01*	STMR (CXL)	0.01*	HR (CXL)
Poultry liver	0.01*	STMR (CXL)	0.01*	HR (CXL)
Cattle and horse milk	0.01	STMR (CXL)	0.01	STMR (CXL)
Sheep and goat milk	0.01	STMR (CXL)	0.01	STMR (CXL)
Birds eggs	0.01*	STMR (CXL)	0.01*	HR (CXL)

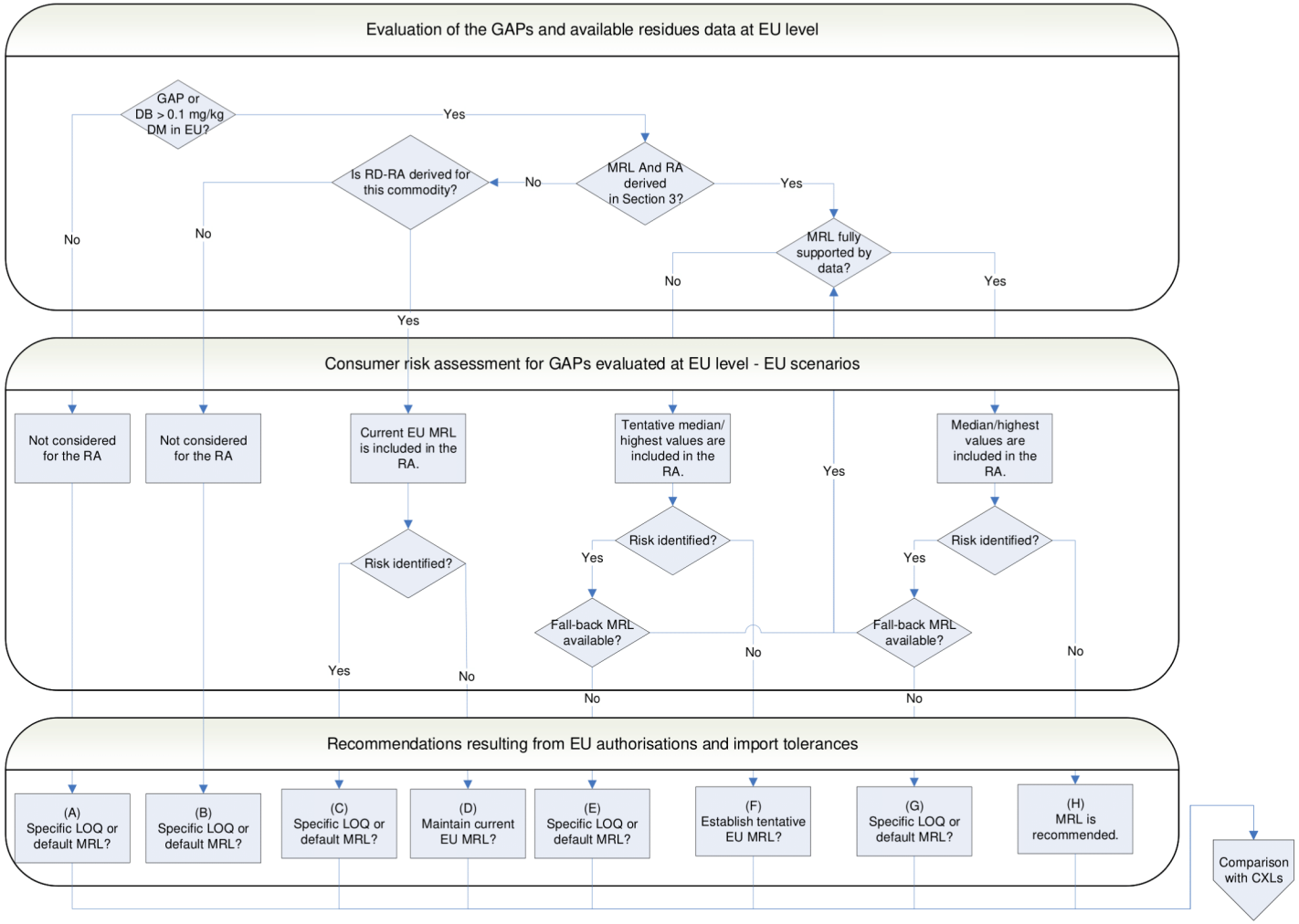
*: Indicates that the input value is proposed at the limit of quantification.
(a): No input value considered due to acute concern identified for the CXL.

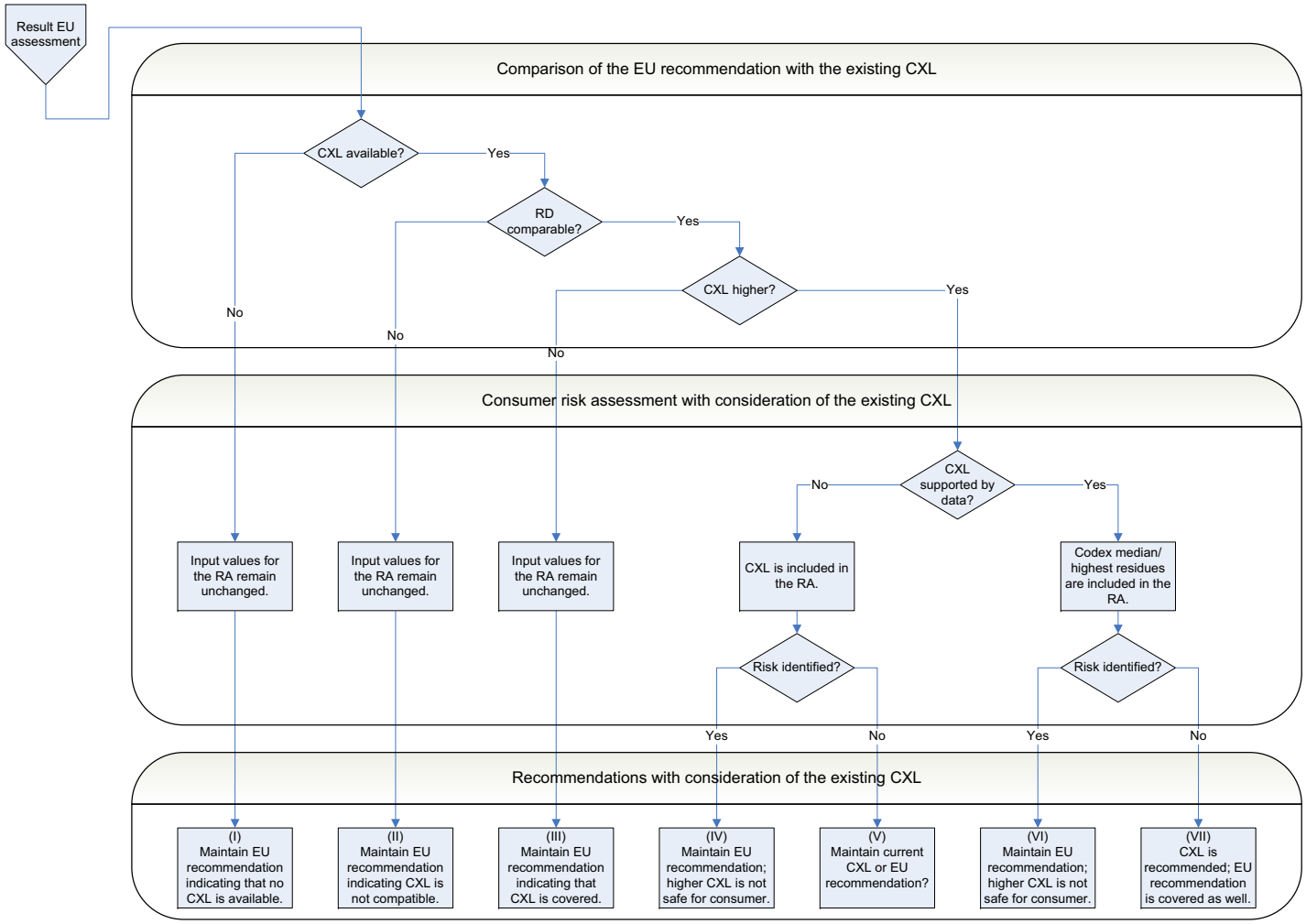
D.4. Consumer risk assessment with consideration of the existing CXLs and veterinary MRLs

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: cyfluthrin, including other mixtures of constituent isomers (sum of isomers)				
Citrus fruits	0.001	STMR × PF (0.05)	0.015	HR × PF (0.05)
Apples	0.02	STMR (CXL)	0.06	HR (CXL)
Pears	0.02	STMR (CXL)	0.06	HR (CXL)
Potatoes	0.01	STMR (CXL)	0.01	HR (CXL)
Tomatoes	0.07	STMR (CXL)	0.1	HR (CXL)
Sweet peppers/bell peppers	0.06	STMR (CXL)	0.12	HR (CXL)
Aubergines/egg plants	0.05	STMR (CXL)	0.12	HR (CXL)
Head cabbages	0.01	STMR (CXL)	0.05	HR (CXL)
Rapeseeds/canola seeds	0.05	STMR (CXL)	0.05	HR (CXL)
Soybeans	0.01	STMR	0.01	STMR
Cotton seeds	0.1	STMR (CXL)	0.52	HR (CXL)
Barley	0.05	STMR (tentative)	0.05	STMR (tentative)
Wheat	0.01	STMR (tentative)	0.01	STMR (tentative)
Swine meat	0.022	0.8 × STMR (CXL) muscle + 0.2 × STMR (CXL) fat	0.01	0.8 × HR (CXL) muscle + 0.2 × HR (CXL) fat
Swine fat	0.07	STMR (CXL)	0.01	HR (CXL)
Swine liver	0.005	STMR (CXL)	0.04	HR (CXL)
Swine kidney	0.005	STMR (CXL)	0.16	HR (CXL)
Bovine and equine meat	0.022	0.8 × STMR (CXL) muscle + 0.2 × STMR (CXL) fat	0.01	0.8 × HR (CXL) muscle + 0.2 × HR (CXL) fat
Bovine and equine fat	0.07	STMR (CXL)	0.01	HR (CXL)
Bovine and equine liver	0.005	STMR (CXL)	0.04	HR (CXL)
Bovine and equine kidney	0.005	STMR (CXL)	0.16	HR (CXL)
Sheep and goat meat	0.022	0.8 × STMR (CXL) muscle+ 0.2 × STMR (CXL) fat	0.01	0.8 × HR (CXL) muscle+ 0.2 × HR (CXL) fat
Sheep and goat fat	0.07	STMR (CXL)	0.01	HR (CXL)
Sheep and goat liver	0.005	STMR (CXL)	0.04	HR (CXL)
Sheep and goat kidney	0.005	STMR (CXL)	0.16	HR (CXL)
Poultry meat	0.01*	0.8 × STMR (CXL) muscle + 0.2 × STMR (CXL) fat	0.01*	0.8 × HR (CXL) muscle + 0.2 × HR (CXL) fat
Poultry fat	0.01*	STMR (CXL)	0.01*	HR (CXL)
Poultry liver	0.01*	STMR (CXL)	0.01*	HR (CXL)
Cattle, sheep and goat milk	0.02	MRL (veterinary)	0.02	MRL (veterinary)
Horse milk	0.01	STMR (CXL)	0.01	STMR (CXL)
Birds eggs	0.01*	STMR (CXL)	0.01*	HR (CXL)

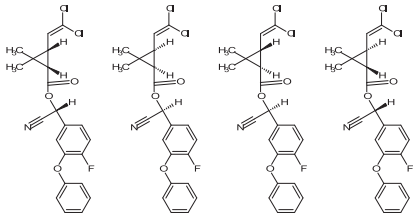
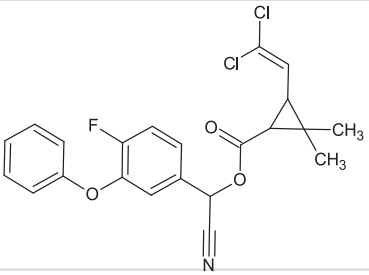
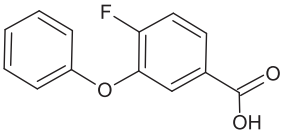
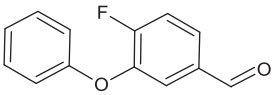
*: Indicates that the input value is proposed at the limit of quantification.

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]
beta-cyfluthrin	reaction mixture comprising the enantiomeric pair *(R)*-α-cyano-4-fluoro-3-phenoxybenzyl (1*S*,3*S*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and *(S)*-α-cyano-4-fluoro-3-phenoxybenzyl (1*R*,3*R*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate in ratio 1:2 with the enantiomeric pair *(R)*-α-cyano-4-fluoro-3-phenoxybenzyl (1*S*,3*R*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and *(S)*-α-cyano-4-fluoro-3-phenoxybenzyl (1*R*,3*S*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate Cl\C(Cl)=C/[C@@H]1[C@@H](C(=O)O[C@H](C#N)c2ccc(F)c(Oc3ccccc3)c2)C1(C)C.Fc1ccc(cc1Oc1ccccc1)[C@H](C#N)OC(=O)[C@H]1[C@H](/C=C(/Cl)Cl)C1(C)C.Cl\C(Cl)=C/[C@H]1[C@@H](C(=O)O[C@H](C#N)c2ccc(F)c(Oc3ccccc3)c2)C1(C)C.Fc1ccc(cc1Oc1ccccc1)[C@H](C#N)OC(=O)[C@H]1[C@@H](/C=C(/Cl)Cl)C1(C)C MUAQRFLDMBWWOD-XWJCWIGJSA-N	
cyfluthrin	(*RS*)-α-cyano-4-fluoro-3-phenoxybenzyl (1*RS*,3*RS*;1*RS*,3*SR*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate Cl\C(Cl)=C/C1C(C(=O)OC(C#N)c2ccc(F)c(Oc3ccccc3)c2)C1(C)C QQODLKZGRKWIFG-UHFFFAOYSA-N	
FPB acid	4-fluoro-3-phenoxybenzoic acid O=C(O)c1cc(Oc2ccccc2)c(F)cc1 VLXNXMTVRWIUJZ-UHFFFAOYSA-N	
FPB aldehyde	4-fluoro-3-phenoxybenzaldehyde O=Cc1cc(Oc2ccccc2)c(F)cc1 JDICMOLUAHZVDS-UHFFFAOYSA-N	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): ACD/Name 2017.2.1 ACD/Labs 2017 Release (File version N40E41, Build 96719, 6 September 2017).
(b): ACD/ChemSketch 2017.2.1 ACD/Labs 2017 Release (File version C40H41, Build 99535, 14 February 2018).