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REASONED OPINION

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

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Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance gamma-cyhalothrin. To assess the occurrence of gamma-cyhalothrin residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Commission Regulation (EU) No 188/2011, as well as the European authorisations reported by Member States (including the supporting residues data) in the framework of this review. Based on the assessment of the available data, MRL proposals were derived, and a consumer risk assessment was carried out. Although no risk to consumers was identified, some information required by the regulatory framework was missing. The residue definition for monitoring (lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R, S and S, R isomers)) covers both lambda- and gamma-cyhalothrin. Appropriate enantioselective techniques, which are not commonly used in routine analysis, are required to differentiate gamma-cyhalothrin residues from lambda-cyhalothrin. According to the available data, it is expected that the MRLs currently set in Regulation (EC) No 396/2005 will cover the uses of gamma-cyhalothrin assessed in the present review. Therefore, risk managers can consider maintaining the existing EU MRLs.

KEYWORDS

consumer risk assessment, gamma-cyhalothrin, insecticide, MRL review, pyrethroids, Regulation (EC) No 396/2005

CONTENTS

SUMMARY

Gamma-cyhalothrin was approved on 1 April 2015 by means of Commission Implementing Regulation (EU) No 1334/2014 in the framework of Regulation (EC) No 1107/2009 as implemented by Commission Implementing Regulations (EU) No 540/2011 and 541/2011.

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

As the basis for the MRL review, on 16 January 2023, EFSA initiated the collection of data for this active substance. In a first step, Member States and the United Kingdom (UK) were invited to submit by 13 February 2023 their national good agricultural practices (GAPs) that are authorised nationally and the GAPs in non-EU countries for which import tolerances are authorised, in the format of specific GAP forms, allowing the designated rapporteur Member State Germany (DE) to identify the critical GAPs in the format of a specific GAP overview file. Subsequently, Member States and the UK were requested to provide residue data supporting the critical GAPs, within a period of 1 month, by 18 May 2023. Under the same timeframe, the EU Reference Laboratories for Pesticides Residues (EURLs) were asked to provide information on the analytical methods for enforcement used in routine analysis. On the basis of all the data submitted by Member States and the EURLs, EFSA asked the rapporteur Member State (RMS) to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report, together with Pesticide Residues Intake Model (PRIMo) calculations were provided by the RMS to EFSA on 17 July 2023. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise, including the clarifications provided by the RMS, was compiled in the completeness check report.

Based on the information provided by the RMS, Member States and the EURLs, and taking into account the conclusions derived by EFSA in the framework of Commission Regulation (EU) No 188/2011, EFSA prepared in December 2023 a draft reasoned opinion, which was circulated to Member States and the EURLs for consultation via a written procedure. Comments received by 31 January 2024 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of gamma-cyhalothrin in plant was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement can be proposed as *lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers)* and for risk assessment *sum of gamma-cyhalothrin and CPCA* (Cyclopropyl carboxylic acid)*, expressed as gamma-cyhalothrin*. For processed commodities, the residue definition for risk assessment is only tentative, pending investigation on the toxicological properties of PBAld (3-phenoxybenzaldehyde) and gamma lactone that may be formed in processed commodities under hydrolytic conditions representative of sterilisation. Nevertheless, since most of the commodities under assessment are not expected to undergo sterilisation during processing and considering that according to the available trials low residues are expected in raw commodities relevant for human consumption when gamma-cyhalothrin is used according to the authorised uses, the data gap for additional toxicological information on gamma-lactone and PBAld is not considered relevant for the uses assessed in this review. Fully validated analytical methods are available for the enforcement of the proposed residue definition in all major matrices at the limit of quantification (LOQ) of 0.01 mg/kg. According to the EURLs, this LOQ is achievable in routine analyses.

Available residue trial data were considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for brussels sprouts, head cabbages and beans (with pods), peas (with pods), sugar beet and fodder beet tops where tentative MRLs are derived, and for sunflower seed and pea vines for which data were not sufficient to derive MRL proposals and risk assessment values.

Gamma-cyhalothrin is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. The dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. The behaviour of residues was therefore assessed in all commodities of animal origin.

Residues of gamma-cyhalothrin in livestock were investigated relying on lambda-cyhalothrin livestock metabolism and feeding data since bridging of the data was considered acceptable during the peer review of gamma-cyhalothrin. According to the results of these studies, the residue definition for enforcement is proposed as *Lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers)*, while for risk assessment in all animal commodities is proposed as *sum of gamma-cyhalothrin and CPCA expressed as gamma-cyhalothrin*. An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in all animal matrices is available. According to the EURLs, this LOQ is achievable in routine analyses.

Livestock feeding studies on lactating cow were used to derive MRL and risk assessment values in milk and tissues of ruminants. Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs. For poultry, the available metabolism study is sufficient to conclude that residue levels would remain below the enforcement LOQ of 0.01 mg/kg in muscle, fat, liver and eggs.

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. For sunflower seeds where data were insufficient to derive a MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure represented 52% of the acceptable daily intake (ADI) (Dutch toddler) and the highest acute exposure amounted to 97% of the acute reference dose (ARfD) (head cabbage).

BACKGROUND

Regulation (EC) No 396/2005[1] (hereinafter referred to as 'the Regulation') establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Council Directive 91/414/EEC[2] a reasoned opinion on the review of the existing MRLs for that active substance.

As gamma-cyhalothrin was approved on 1 April 2015 by means of Commission Implementing Regulation (EU) No 1334/2014[3] in the framework of Regulation (EC) No 1107/2009[4] as implemented by Commission Implementing Regulations (EU) No 540/2011[5] and 541/2011,[6] EFSA initiated the review of all existing MRLs for that active substance.

By way of background information, gamma-cyhalothrin was evaluated by UK, designated as rapporteur Member State (RMS), as a new active substance, in the framework of Council Directive 91/414/EEC. In accordance with Article 11(6) of Commission Regulation (EU) No 188/2011,[7] additional information was requested from the applicant. The RMS's evaluation of the additional information was provided in the format of an updated DAR, which was received on 13 September 2012. Subsequently, a peer review on the initial evaluation of the RMS was conducted by EFSA, leading to the conclusions as set out in the EFSA scientific output (EFSA, 2014a). According to the provisions of the approval regulation, confirmatory information was requested, among others, as regards the toxicity profile of the metabolites Cyclopropyl carboxylic acid (CPCA), 3-phenoxybenzoic acid (PBA) and 3-(4-hydroxyphenoxy)benzoic acid PBA(OH), to be submitted by 31 March 2017. The confirmatory information requested was submitted and the toxicity profiles of the metabolites were evaluated and concluded (EFSA, 2019; EFSA PPR Panel, 2022).

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

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

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

As the basis for the MRL review, on 16 January 2023, EFSA initiated the collection of data for gamma-cyhalothrin. In a first step, Member States and UK[8] were invited to submit by 13 February 2023 their good agricultural practices (GAPs) that are authorised nationally and the GAPs in non-EU countries for which import tolerances (IT) are authorised, in the format of specific GAP forms. In the framework of this consultation, 10 Member States provided feedback on their national authorisations of gamma-cyhalothrin. 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 were requested to provide residue data supporting the critical GAPs by 18 May 2023. Under the same timeframe, the EU Reference Laboratories for Pesticides Residues (EURLs) were asked to provide information on the analytical methods for enforcement used in routine analysis.

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

[2]Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32. Repealed by Regulation (EC) No 1107/2009.

[3]Commission Implementing Regulation (EU) No 1334/2014 of 16 December 2014 approving the active substance gamma-cyhalothrin, 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 and allowing Member States to extend provisional authorisations granted for that active substance. OJ L 360, 17.12.2014, p. 1–5.

[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 Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ No L 53, 26.2.2011, p. 51–55.

[8]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 in particular with the Windsor Framework, the EU requirements on data reporting are also applicable to NI.

On the basis of all the data submitted by Member States and the EURLs, EFSA asked Germany to complete the PROFile and to prepare a supporting evaluation report. The PROFile and the supporting evaluation report, together with the Pesticide Residues Intake Model (PRIMo) calculations, were submitted to EFSA on 17 July 2023. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS was compiled in the completeness check report.

Considering all the available information, EFSA prepared in December 2023 a draft reasoned opinion, which was circulated to Member States and the EURLs for commenting via a written procedure. All comments received by 31 January 2024 were evaluated and considered by EFSA during the finalisation of the reasoned opinion.

The **evaluation report** submitted by the RMS (Germany, 2023), taking into account also the information provided by Member States and during the collection of data, and the **EURLs report on analytical methods** (EURLs, 2023) 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, 2023) and the **Member States consultation report** (EFSA, 2024). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Furthermore, the exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (**PRIMo**) and the **PROFile** as well as the **GAP overview file** listing all authorised uses are key supporting documents and made publicly available as background documents to this reasoned opinion.[9] A screenshot of the report sheet of the PRIMo is presented in Appendix C. According to the information received by the RMS, existing MRLs currently set in the Regulation and based on the uses of lambda-cyhalothrin, cover as well uses of gamma-cyhalothrin authorised in third countries. Considering that lambda- and gamma-cyhalothrin share the same residue definition and that, during enforcement, it is not possible to distinguish between the two active substances, these uses were not further considered in the assessment. For information only, a separate file listing third country uses reported is also made available.

Terms of Reference

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

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

The active substance and its use pattern

Gamma-cyhalothrin[10] is the ISO common name for (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate or (S)-α-cyano-3-phenoxybenzyl (1R)-cis-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropane-carboxylate (IUPAC).

It should be noted that gamma-cyhalothrin is one of the isomers forming the substances which have their own ISO common name lambda-cyhalothrin and cyhalothrin.

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

Cyhalothrin (sum of isomers) is authorised for use in veterinary medicinal products for cattle (fat, kidney and milk) and MRLs are set in Regulation (EU) No 37/2010.[11] These veterinary MRLs were already considered in the revised MRL review of lambda-cyhalothrin (EFSA, 2015) and are not considered further in this review.

The EU MRLs for gamma-cyhalothrin are established in Annexes II of Regulation (EC) No 396/2005 as lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R, S and S, R isomers). Codex maximum residue limits (CXLs) are established for cyhalothrin (includes lambda-cyhalothrin), but none of the existing CXLs is based on the uses of gamma-cyhalothrin. These CXLs were already considered in the revised MRL review of lambda-cyhalothrin (EFSA, 2015) and are not considered further in this assessment. An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below (Table 1).

[9]Background documents to this reasoned opinion are published on the OpenEFSA portal and are available at the following link: https://open.efsa.europa.eu/study-inventory/EFSA-Q-2015-00071

[10]It should be noted that *gamma-cyhalothrin* is identified as a *pesticide active substance* that meets the definition of per- and polyfluoroalkyl substances (PFAS) based on its chemical structure (https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas).

[11]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.

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

Procedure	Legal implementation	Remarks
MRL applications on lambda-cyhalothrin in globe artichokes and currants and implementation of CXLs for lambda-cyhalothrin adopted by the Codex Alimentarius commission (CAC) in 2009	Regulation (EC) No 459/2010[a]	Several commodities (EFSA, 2009a, 2009b; FAO, 2009a, 2009b)
MRL application on lambda-cyhalothrin	Regulation (EU) No 834/2013[b]	Azarole and persimmon (EFSA, 2013
Implementation of CXLs for lambda-cyhalothrin adopted by the CAC in 2016	Regulation (EU) No 2017/626[c]	Cardamom (EFSA, 2016)
Revised MRL review on lambda-cyhalothrin and focussed review of the existing maximum residue levels for lambda-cyhalothrin in light of the unspecific residue definition and the existing good agricultural practices for the substance gamma-cyhalothrin	Regulation (EU) No 2018/960[d]	Several commodities of plant and animal origin (EFSA, 2015, 2017)
Implementation of CXLs for lambda-cyhalothrin adopted by the CAC in 2009	Regulation (EU) No 2019/50[e]	Rye (FAO, 2009a, 2009b)
MRL application on lambda-cyhalothrin and implementation of CXLs for lambda-cyhalothrin adopted by the CAC in 2009	Regulation (EU) 2019/1015[f]	Celeries, Florence fennels, rice (EFSA, 2019). Sunflower seeds, soyabeans (FAO, 2009a, 2009b)
MRL application on lambda-cyhalothrin	Reg. (EU) 2021/590[g]	Seed and fruit spices (EFSA, 2020)
MRL application on lambda-cyhalothrin	Not yet legally implemented	Import tolerance in avocado (EFSA, 2023)

[a]Commission Regulation (EU) No 459/2010 of 27 May 2010 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for certain pesticides in or on certain products. OJ L 129, 28.5.2010, p. 3–49.

[b]Commission Regulation (EU) No 834/2013 of 30 August 2013 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, bixafen, diazinon, difenoconazole, etoxazole, fenhexamid, fludioxonil, isopyrazam, lambda-cyhalothrin, profenofos and prothioconazole in or on certain products OJ L 233, 31.8.2013, p. 11–42.

[c]Commission Regulation (EU) 2017/626 of 31 March 2017 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, cyantraniliprole, cypermethrin, cyprodinil, difenoconazole, ethephon, fluopyram, flutriafol, fluxapyroxad, imazapic, imazapyr, lambda-cyhalothrin, mesotrione, profenofos, propiconazole, pyrimethanil, spirotetramat, tebuconazole, triazophos and trifloxystrobin in or on certain products OJ L 96, 7.4.2017, p. 1–43.

[d]Commission Regulation (EU) 2018/960 of 5 July 2018 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 lambda-cyhalothrin in or on certain products. OJ L 169, 6.7.2018, p. 27–50.

[e]Commission Regulation (EU) 2019/50 of 11 January 2019 amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorantraniliprole, clomazone, cyclaniliprole, fenazaquin, fenpicoxamid, fluoxastrobin, lambda-cyhalothrin, mepiquat, onion oil, thiacloprid and valifenalate in or on certain products. OJ L 10, 14.1.2019, p. 8–59.

[f]Commission Regulation (EU) 2019/1015 of 20 June 2019 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aminopyralid, captan, cyazofamid, flutianil, kresoxim-methyl, lambda-cyhalothrin, mandipropamid, pyraclostrobin, spiromesifen, spirotetramat, teflubenzuron and tetraconazole in or on certain products. OJ L 165, 21.6.2019, p. 23–64.

[g]Commission Regulation (EU) 2021/590 of 12 April 2021 amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aclonifen, boscalid, cow milk, etofenprox, ferric pyrophosphate, L-cysteine, lambda-cyhalothrin, maleic hydrazide, mefentrifluconazole, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate and triclopyr in or on certain products. OJ L 125, 13.4.2021, p. 15–41.

For the purpose of this MRL review, all the uses of gamma-cyhalothrin currently authorised within the EU as submitted by the Member States during the GAP collection have been reported by the RMS in the GAP overview file. The critical GAPs identified in the GAP overview file were then summarised in the PROFile and considered in the assessment. The details of the authorised critical GAPs for gamma-cyhalothrin considered in this review are given in Appendix A. Although uses of gamma-cyhalothrin are registered in several non-EU countries, considering that lambda- and gamma-cyhalothrin share the same residue definition and that, during enforcement, it is not possible to distinguish between the two active substances, these uses were not further considered in the assessment.

Assessment

EFSA has based its assessment on the following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (Germany, 2023);
- the draft assessment report (DAR) prepared under Council Directive 91/414/EEC (UK, 2008) and its addendum prepared under Regulation (EU) No 188/2011 (UK, 2014) for gamma-cyhalothrin;
- the renewal assessment report (RAR) prepared under Regulation (EC) 1107/2009 (Sweden, 2013) and its addendum (Sweden, 2014) for lambda-cyhalothrin;
- the conclusion on the peer review of the pesticide risk assessment of the active substance gamma-cyhalothrin (EFSA, 2014a);

- the conclusion on the peer review of the pesticide risk assessment of the active substance lambda-cyhalothrin (EFSA, 2014b);
- the technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for gamma-cyhalothrin in light of confirmatory data (EFSA, 2019);
- the PPR Panel opinion on toxicity of pyrethroid common metabolites (EFSA PPR Panel, 2022);
- the EFSA statement on the review of the residue definitions for risk assessment of pyrethroids forming common metabolites (EFSA, 2023a);
- the Article 43 assessment on the revision of the review of the existing maximum residue levels for the active substance lambda-cyhalothrin (EFSA, 2015).

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, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2010, 2023a, 2023b, 2023c; OECD, 2011, 2013).

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

1 | RESIDUES IN PLANTS

1.1 | Nature of residues and methods of analysis in plants

1.1.1 | Nature of residues in primary crops

The metabolism in primary crops was investigated with gamma-cyhalothrin in cereals (wheat) and fruit (grapes), and with the racemate lambda-cyhalothrin in pulses and oilseeds (soya and cotton), in cereals (wheat), fruit (tomato, apple) and leafy vegetables (cabbage) in the framework of the peer review for gamma-cyhalothrin (EFSA, 2014a) and the revision of MRL review for lambda-cyhalothrin (EFSA, 2015). Both active substances were radiolabelled in the cyclopropyl ring and in the phenoxyphenyl ring.

Parent was the predominant compound of the total residues in all the crops investigated, ranging between 37% and 95% of the total radioactive residues (TRR). Cyclopropyl carboxylic acid (CPCA) was identified as a significant metabolite in soya bean and cotton leaves and in grapes. Whereas parent remained the major component in cotton leaves and soybean leaves, contributing to 37% TRR and 52% TRR, CPCA was present at 17.6% TRR and at 25.3% TRR, respectively. In grapes, 10 days after the last foliar application (DALA) of gamma-cyhalothrin, CPCA was present at 12.5% TRR whereas the parent constituted 73.2% of the TRR. CPCA was not a major contributor of the residue in any other case, being present at up to 6% of the TRR.

The common pyrethroid metabolites, 3-phenoxybenzoic acid (PBA) and its hydroxy-derivative 3-(4-hydroxyphenoxy) benzoic acid (PBA(OH)) ranged between 0.1% and 7% TRR and 0.2%–10% TRR, with highest contribution found in wheat hay and straw in the study conducted with gamma-cyhalothrin having shorter DALA periods.

Based on the metabolism data for gamma-cyhalothrin and lambda-cyhalothrin, similar pathways were concluded for both compounds by the peer review (EFSA, 2014a). The metabolic pathway is similar in all crops under evaluation.

With respect to isomerisation, the conversion of gamma-cyhalothrin to the epimer was investigated in cereals and was found to be not significant (max. 4%) (EFSA, 2014a). For lambda-cyhalothrin, from residue trials on wheat, tomatoes and plums evaluated during the peer review for renewal, a slight isomeric conversion was observed (< 10% TRR) which was considered of low concern (EFSA, 2015). Chiral analysis of the enantiomers of lambda-cyhalothrin were also conducted on kale, lettuce and apple residue samples showing that the initial 1:1 enantiomeric ratio was maintained in each crop at harvest, indicating no preferential degradation/conversion between the two enantiomers of lambda-cyhalothrin. Significant conversion of lambda-cyhalothrin versus the other cyhalothrin isomers was observed in cotton leaves only (EFSA, 2015).

1.1.2 | Nature of residues in rotational crops

All crops under consideration may be grown in rotation. According to the soil degradation studies evaluated in the framework of the peer review for gamma-cyhalothrin, the DT_{50} value is up to 33 days under laboratory conditions (EFSA, 2014a), from which the calculated DT_{90} value of gamma-cyhalothrin is higher than the trigger value of 100 days. Therefore, the nature of the residues in rotational crops needs to be investigated.

There are no studies conducted with gamma-cyhalothrin. However, studies performed with lambda-cyhalothrin were considered acceptable by the peer review on gamma-cyhalothrin (EFSA, 2014a). Confined rotational crop studies conducted with cyclopropyl- and phenoxyphenyl-labelled lambda-cyhalothrin at a dose rate of 0.47 kg a.s./ha in rotational

[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.

wheat, lettuce and carrots was evaluated in the framework of the peer review for lambda-cyhalothrin (EFSA, 2014b). Accordingly, the total radioactive residues were significantly higher in rotational crops conducted with the cyclopropyl labelling, indicating a preferential uptake of metabolites containing the cyclopropyl moiety. Metabolite CPCA was the major compound of the total residues in carrot root (up to 52% TRR, 0.022 mg/kg at 60 days plant back interval [PBI]), carrot leaves (40.7%, 0.026 mg/kg at 60 days PBI), lettuce (61% TRR, 0.032 at 30 days PBI) and wheat straw (34% TRR, 0.289 mg/kg at 30 days PBI) (United Kingdom, 2014). The parent compound was either not detected or present at a negligible proportion (< 1% TRR) in wheat straw only. No metabolites identification was conducted in wheat grain.

1.1.3 | Nature of residues in processed commodities

There were no studies investigating the nature of residues of gamma-cyhalothrin in processed commodities available; however, the study conducted with radiolabelled lambda-cyhalothrin was considered acceptable in the framework of the peer review of gamma-cyhalothrin (EFSA, 2014b) and is reported for this review.

Accordingly, lambda-cyhalothrin remained stable under hydrolytic conditions representative of pasteurisation and baking, brewing and boiling (82%–91% TRR), while a significant degradation occurred at sterilisation by hydrolytic cleavage of the parent molecule into CPCA (cyclopropyl label specific) (59% TRR), the common metabolite 3-phenoxybenzaldehyde (PBAld) (phenyl label specific) (63% TRR) and gamma-lactone (15% TRR).

1.1.4 | Analytical methods for enforcement purposes in plant commodities

In the framework of the peer review of lambda-cyhalothrin, a multiresidue QuEChERS method using GC–MS was validated for the determination of lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S, R isomers) in high water content (lettuce), high acid content (whole orange), high oil content (oilseed rape) and dry commodities (wheat grain) (EFSA, 2014b) with LOQ of 0.01 mg/kg. Sufficient confirmation and independent laboratory validation (ILV) were available. Extraction efficiency was addressed in high water content commodities (soya bean leaves) (Germany, 2023). In the framework of this review, uses on commodities belonging to high oil content and dry matrices were reported, but extraction efficiency on these matrices was not demonstrated according to the requirements of the extraction efficiency Guidance, SANTE 2017/10632-rev. 5 (European Commission, 2023c). The lack of these data introduces uncertainty to the present assessment.

During the completeness check, the EURLs provided multiresidue quick, easy, cheap, effective, rugged and safe (QuEChERS) and QuOil methods, using GC-MS/MS for the routine analysis of the four main plant matrices and black tea with LOQ of 0.01 mg/kg.

Lambda-cyhalothrin is a 1:1 mixture of the RS and SR isomers, while gamma-cyhalothrin is constituted only by the SR-isomer. Gamma-cyhalothrin separates from the RS-enantiomer using appropriate enantioselective LC techniques. A chiral LC-MS/MS method was reported by EURLs with satisfactory recovery and repeatability in cucumber, orange juice, wheat flour, sunflower seed oil and infant formula (EURLs, 2019, 2023).

1.1.5 | Stability of residues in plants

The storage stability of gamma-cyhalothrin was investigated in the framework of the peer review for gamma-cyhalothrin (EFSA, 2014a) in high water content (broccoli, tomato, field peas), high oil content (cotton seeds), dry (wheat grain) and processed (grape wine, corn oil) commodities stored at –20°C, demonstrating that gamma-cyhalothrin is stable for 12 months. Additional studies investigating the storage stability of lambda-cyhalothrin (includes gamma-cyhalothrin) were reported in the framework of the revised MRL review (EFSA, 2015). Lambda-cyhalothrin was shown to be stable for 26 months in high water, high oil content and dry commodities when stored at –18°C (EFSA, 2015). Conclusion on the stability of lambda-cyhalothrin can be extrapolated to gamma cyhalothrin.

1.1.6 | Proposed residue definitions

Based on the metabolic pattern observed in primary and rotational crops, the metabolism of gamma-cyhalothrin and lambda-cyhalothrin was similar in all crops assessed. Processing of gamma-cyhalothrin is not expected to modify the nature of residues except under sterilising conditions.

As the parent compound was found to be a sufficient marker in the metabolism studies, and considering that enantioselective analytical methods are required to differentiate between lambda and gamma-cyhalothrin, the current residue definition for enforcement *as lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers)* is considered to be still valid for the current assessment.

In the primary crop metabolism studies, unchanged parent was always the main constituent of the residues (24%–98% TRR), while CPCA was also detected above 10% TRR in pulses and oilseed leaves (24%–27% TRR) and in grapes (13% TRR). CPCA

was also a major metabolite in the edible parts of the rotational crops (34%–61% TRR) and was formed at significant levels (59% TRR) in hydrolysis studies simulating sterilisation. According to the confirmatory data assessment, CPCA is unlikely to be genotoxic, and being a major metabolite in the rat metabolism, it was considered covered by the toxicological profile of the parent compound (EFSA, 2019). With respect to the common pyrethroid metabolites 3-PBA and 4-OH-PBA, it is proposed not to include these compounds in the residue definition for risk assessment of gamma-cyhalothrin based on the previous assessment on their toxicological profile (EFSA PPR Panel, 2022). Therefore, the residue definition for risk assessment for raw and processed commodities is proposed to be the *sum of gamma-cyhalothrin and CPCA, expressed as gamma-cyhalothrin*.

For processed commodities, considering that no information is available on the toxicological profile of gamma-lactone, that the toxicological information of 3-phenoxybenzaldehyde (PBAld) is not complete (EFSA, 2023), and that only limited information on their magnitude in processed commodities (see Section 1.2.3) is available, the proposed residue definition for risk assessment is tentative only. Nevertheless since most of the commodities under assessment are not expected to undergo sterilisation during processing[13] and considering that according to the available trials, low residues are expected in raw commodities relevant for human consumption when gamma-cyhalothrin is used according to the authorised uses (max 0.055 mg/kg in head cabbages from trials performed according to a more critical GAP, see Appendix B.1.2.1), the data gap for additional toxicological information on gamma-lactone and PBAld is not considered relevant for the uses assessed in this review.

An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in the four main plant matrix groups is available. According to the EURLs, the LOQ of 0.01 is achievable by using multiresidue methods in routine analyses. It is noted that the analytical standard for gamma-cyhalothrin is commercially available (EURLs, 2023).

1.2 | Magnitude of residues in plants

1.2.1 | Magnitude of residues in primary crops

To assess the magnitude of gamma-cyhalothrin residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Germany, 2023), as well as the residue trials evaluated in the framework of the peer review of gamma-cyhalothrin (EFSA, 2014a, 2019). Some trials were conducted using lambda-cyhalothrin and were assessed earlier by EFSA (EFSA, 2015). Since lambda-cyhalothrin also includes gamma-cyhalothrin and assuming that the metabolism is similar for both lambda- and gamma-cyhalothrin, these trials were considered (tentatively) acceptable to support the gamma-cyhalothrin uses. 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 were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2023b).

Residue trials are not available or not sufficient to support the authorisations on sunflower seeds and pea vines. Therefore, MRL and risk assessment values could not be derived for these crops and the following data gaps were identified:

- Sunflower seed: Although in the available trials residues were < LOQ, based on the results from trials on other oilseeds is not possible to conclude that residues will remain below the LOQ. Therefore, six additional trials compliant with the northern outdoor GAP are required.
- Pea vines: Four trials compliant with the northern outdoor GAP are required.

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

- Brussels sprouts: Although tentative MRL and risk assessment values can be derived from the trials conducted with lambda-cyhalothrin according to a more critical GAP, four trials performed according to the northern outdoor GAP are still required.
- Head cabbages: Tentative MRL and risk assessment values were derived based on trials performed with lambda-cyhalothrin according to a more critical GAP (both number and rate of application more critical), with results of the trials adjusted to consider only the gamma-cyhalothrin portion in lambda-cyhalothrin (1:1 ratio).[14] Nevertheless, eight trials performed according to the northern outdoor GAP are still required.
- Peas (with pods): Although tentative MRL and risk assessment values can be derived from the trials conducted according to a more critical GAP, four trials performed according to the northern outdoor GAP are still required.
- Beans (with pods): Although tentative MRL and risk assessment values can be derived from the trials conducted according to a more critical GAP, eight trials performed according to the northern outdoor GAP are still required.

[13] A significant degradation of gamma cyhalothrin into gamma-lactone and PBAld was only observed under hydrolytic conditions representative of sterilisation (see Section 1.1.3).

[14] Since an acute risk was identified when considering the available trials performed with lambda-cyhalothrin reflecting more critical use conditions, a factor of 0.5 has been applied to have a more realistic estimation of the MRL and the risk assessment values expected according to the use of gamma-cyhalothrin (EFSA, 2023b).

- Peas (without pods): The number of residue trials supporting the northern outdoor GAP is not compliant with the data requirements for this crop. However, the reduced number of residue trials conducted according to a more critical GAP is considered acceptable in this case because all results were below the LOQ and a no residues situation is expected. Further residue trials are therefore not required.
- Peas, beans (dry): The number of residue trials supporting the GAP is not compliant with the data requirements for this crop. However, the reduced number of residue trials conducted using lambda-cyhalothrin according to a more critical GAP is considered acceptable in this case because all results were below the LOQ and a no residue situation is expected. Further residue trials are therefore not required.
- Rapeseeds/canola seeds, poppy seeds, mustard seeds: Trials conducted with five to seven applications instead of two, with the last applications within 25% of the cGAP are deemed acceptable, as residues are at or below 0.01 mg/kg and the earlier applications are not expected to contribute to the final residue. Further residue trials are therefore not required.
- Barley, oat, wheat, rye: Trials conducted with three instead of two applications are acceptable as the first application is not expected to contribute to the final residue. Further residue trials are therefore not required.
- Beetroots, sugar beet roots and fodder beet roots: The number of residue trials supporting the GAP is not compliant with the data requirements for this crop. However, the reduced number of residue trials conducted with lambda-cyhalothrin according to a more critical GAP is considered acceptable in this case because all results were below the LOQ. Further residue trials are therefore not required.
- Sugar beet tops and fodder beet: Although tentative MRL and risk assessment values can be derived from the trials conducted with lambda-cyhalothrin according to a more critical GAP, four trials performed according to the northern outdoor GAP are still required.

Metabolite CPCA was not analysed in any of the trials. In case residues of gamma-cyhalothrin were close to/at or below the LOQ of 0.01 mg/kg (potatoes, Brussels sprouts, beans with pods, peas with pods, peas without pods, dry peas, rapeseeds, poppy seeds, mustard seeds, cereals grain, sugar beet roots, beetroots, fodder beet roots) as in the metabolism studies the level of parent was always higher than the level of the metabolite, it is assumed that CPCA will not be present at significant levels and a conversion factor (CF) of 1 was considered to recalculate residues according to the residue definition for risk assessment. In the other cases (head cabbages, cereal straw, sugar beet tops and fodder beet tops), metabolism studies on cabbages and wheat were considered to derive CF from enforcement to risk assessment and residue trials analysing for metabolite CPCA are in principle still required to confirm these conversion factors. Nevertheless, considering that, in the metabolism studies, CPCA was a minor metabolite and that for Brussels sprouts, head cabbages, sugar beet tops and fodder beet tops, residue from trials performed according to a more critical GAP were included in the exposure calculations, this data gap is not expected to have a significant impact on the risk assessment. Therefore, additional trials analysing for metabolite CPCA are only desirable.

1.2.2 | Magnitude of residues in rotational crops

Based on the confined rotational crop metabolism studies conducted with lambda-cyhalothrin at 0.47 kg/ha bare soil treatment (47N compared to the maximum total application rate of gamma-cyhalothrin according to the authorised EU uses), it can be concluded that no significant residue levels (< 0.01 mg/kg) in the edible parts of the rotated crops are expected, provided that gamma cyhalothrin is applied in compliance with the GAPs reported in Appendix A.

This conclusion is confirmed by rotational crop field trials conducted on radish/turnip, lettuce/spinach, barley/wheat, alfalfa and mustard leaves following harvest of a treated primary crop (cotton) at a total dose rate of 0.5 kg a.s./ha which resulted in residues of lambda-cyhalothrin and CPCA below the LOQ in the edible parts at 30 and 60 days plant back intervals (EFSA, 2015).

1.2.3 | Magnitude of residues in processed commodities

No processing studies conducted with gamma-cyhalothrin are available. As lambda- and gamma- cyhalothrin share the same residue definition and the isomeric composition is not expected to impact on the effect of processing, the processing factors derived for lambda-cyhalothrin may apply to gamma-cyhalothrin residues. Acceptable processing studies submitted in the framework of the renewal for lambda cyhalothrin demonstrated that, in processed tomatoes and beans with pods (including sterilised canned products), the levels of gamma-lactone, CPCA and PBAld were below the LOQ (< 0.01 mg/kg) (EFSA, 2014b; Sweden, 2014). 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 sunflower seeds and pea vines for which data were not sufficient to derive MRL and risk

assessment values. For brussels sprouts, head cabbages, beans (with pods), peas (with pods) only tentative MRLs are derived, pending submission of additional trials.

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

2 | RESIDUES IN LIVESTOCK

Gamma-cyhalothrin is authorised for use on potatoes, head cabbages, sunflower seeds, cereals, sugar and fodder beet, peas that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D. The dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues was therefore assessed in all commodities of animal origin.

It is highlighted that for pea vines and sunflower seeds, sufficient residue data were not available. The animal intake of gamma-cyhalothrin residues via these commodities has therefore not been assessed and may have been underestimated. However, this is not expected to have a significant impact on the calculated dietary burden considering that for other feed items (fodder beet tops, sugar beet tops) residue from trials performed according to a more critical GAP were included in the calculations.

2.1 | Nature of residues and methods of analysis in livestock

Metabolism studies with gamma-cyhalothrin in livestock are not available. However, bridging from metabolism studies conducted in goat and poultry using lambda-cyhalothrin was considered acceptable in the peer review for gamma-cyhalothrin (EFSA, 2014a). According to these studies, parent was the predominant compound in all tissues, except in liver and kidney, where, depending on the labelling, metabolites CPCA or PBA are the predominant compounds of the total residues. A change in the ratio of enantiomers within the cis B pair of diastereoisomers (lambda-cyhalothrin) was observed in milk, muscle and fat. However, this was considered not relevant for lambda-cyhalothrin (EFSA, 2015), and the same conclusion is applicable for gamma-cyhalothrin.

In addition, in the framework of the peer review, livestock feeding studies for lambda-cyhalothrin in cows and, for both lambda-cyhalothrin and gamma-cyhalothrin in poultry were investigated. In poultry feeding studies, residues of lambda-cyhalothrin were higher (up to 2-fold) than those found for gamma-cyhalothrin at the same dose level, suggesting that the enantiomer 1R, cis, Z-S* (gamma-cyhalothrin) may be metabolised more rapidly than the enantiomer 1S, cis, Z-R*, also present in lambda-cyhalothrin (EFSA, 2014a).

Based on the livestock studies and considering that enantioselective analytical methods are required to differentiate between lambda and gamma-cyhalothrin, the current residue definition for enforcement as *lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers)* is considered still applicable for the current assessment.

As CPCA is covered by the toxicological profile of the parent compound (EFSA, 2019), the residue definition for risk assessment in all animal commodities is proposed as *sum of gamma-cyhalothrin and CPCA, expressed as gamma-cyhalothrin*. With respect to the common pyrethroid metabolites 3-PBA, based on the previous assessment on its toxicological profile (EFSA PPR Panel, 2022), it is proposed not to include this compound in the residue definition for risk assessment of gamma-cyhalothrin.

The general metabolic pathways in rodents and ruminants were found to be comparable. The metabolic pattern in ruminants can therefore be extrapolated to pigs.

A multiresidue DFG S19 analytical method using LC-MS/MS was sufficiently validated and peer reviewed for the determination of lambda-cyhalothrin (includes gamma-) in all animal tissues, milk and eggs, with an LOQ of 0.01 mg/kg. Sufficient confirmation and ILV data were available (EFSA, 2014b). No information on extraction efficiency according to the requirements of the extraction efficiency Guidance, SANTE 2017/10632 was available for any animal matrix, which is source of uncertainty in the present assessment.

The storage stability of lambda-cyhalothrin was demonstrated for a period of 3 months at –18°C in muscle, fat, liver, kidney, eggs and 4 months in milk, whereas for CPCA, it ranged between 36 and 43 months (EFSA, 2015).

According to the EURLs, the LOQ of 0.01 mg/kg is achievable in eggs, liver, milk, and dairy products by multiresidue methods in routine analysis. A chiral LC–MS/MS method was reported by EURLs with satisfactory recovery and repeatability in liver and milk. It is noted that the analytical standard for gamma-cyhalothrin is commercially available (EURLs, 2023).

2.2 | Magnitude of residues in livestock

In the framework of the peer review for gamma-cyhalothrin, the use of lambda-cyhalothrin livestock metabolism and feeding data to support gamma-cyhalothrin was considered acceptable (EFSA, 2014a). Therefore, in the framework of the current assessment, the same studies were relied upon as in the MRL review for lambda-cyhalothrin (EFSA, 2015) to derive MRL and risk assessment values in milk and tissues of ruminants and swine. In an additional feeding study with lactating cows

performed at 20N rate compared to the maximum dietary burden, residues of CPCA were below 0.01 mg/kg (Sweden, 2013), and therefore, residues of CPCA are not expected in any of the tissues or milk based on the livestock exposure expected from the gamma-cyhalothrin uses under assessment. For poultry, the available metabolism study (performed at 70N rate compared to the maximum dietary burden) is sufficient to conclude that residue levels would remain below the enforcement LOQ of 0.01 mg/kg in muscle, fat, liver and eggs. The storage period of the samples from the livestock feeding studies was covered by the conditions for which storage stability was demonstrated thus decline of residues during storage of the trial samples is not expected.

3 | CONSUMER RISK ASSESSMENT

In the framework of this review, only the uses of gamma-cyhalothrin reported by the RMS in Appendix A were considered. The EU and Codex MRLs established based on lambda-cyhalothrin uses and the veterinary MRLs based on the use of cyhalothrin were already assessed by EFSA in the framework of the revised MRL review (EFSA, 2015) and are, therefore, not part of the current review.

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, 2019b). 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, 2009a, 2009b). For those commodities where data were insufficient to derive an MRL in Section 1 (sunflower seeds), EFSA considered the existing EU MRL for an indicative calculation. All input values included in the exposure calculations are summarised in Appendix D.

The exposure values calculated were compared with the toxicological reference values for gamma-cyhalothrin, derived by EFSA (EFSA, 2014a). The highest chronic exposure was calculated for the Dutch toddler, representing 52% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for head cabbage, representing 97% of the ARfD. Although uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumer's health.

Since the risk assessment was performed considering the toxicological reference values for gamma-cyhalothrin, representing the toxicologically active component of cyhalothrin's isomers, a possible change in the isomer ratio in the final residue, is not expected to be of concern for the authorised uses reported in the framework of this review (EFSA, 2019).

CONCLUSIONS

The metabolism of gamma-cyhalothrin in plant was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement can be proposed as *lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers)* and for risk assessment as *sum of gamma-cyhalothrin and CPCA, expressed as gamma-cyhalothrin*. For processed commodities, the residue definition for risk assessment is only tentative, pending investigation on the toxicological properties of PBAld and gamma lactone that may be formed in processed commodities under hydrolytic conditions representative of sterilisation. Nevertheless, since most of the commodities under assessment are not expected to undergo sterilisation during processing and considering that, according to the available trials, low residues are expected in raw commodities relevant for human consumption when gamma-cyhalothrin is used according to the authorised uses, the data gap for additional toxicological information on gamma-lactone and PBAld is not considered relevant for the uses assessed in this review. Fully validated analytical methods are available for the enforcement of the proposed residue definition in all major matrices at the LOQ of 0.01 mg/kg. According to the EURLs, this LOQ is achievable in routine analyses.

Available residue trials data were considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for brussels sprouts, head cabbages and beans (with pods), peas (with pods), sugar beet and fodder beet tops where tentative MRLs are derived, and for sunflower seed and pea vines for which data were not sufficient to derive MRL proposals and risk assessment values.

Gamma-cyhalothrin is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. The dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues was therefore assessed in all commodities of animal origin.

Residues of gamma-cyhalothrin in livestock were investigated relying on lambda-cyhalothrin livestock metabolism and feeding data. According to the results of these studies, the residue definition for enforcement is proposed as *Lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers)*, while for risk assessment in all animal commodities is proposed as *sum of gamma-cyhalothrin and CPCA expressed as gamma-cyhalothrin*. An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in all animal matrices is available. According to the EURLs, this LOQ is achievable in routine analyses.

Livestock feeding studies on lactating cow were used to derive MRL and risk assessment values in milk and tissues of ruminants. Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants

were relied upon to derive the MRL and risk assessment values in pigs. For poultry, the available metabolism study is sufficient to conclude that residue levels would remain below the enforcement LOQ of 0.01 mg/kg in muscle, fat, liver and eggs.

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. For sunflower seeds where data were insufficient to derive a MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure represented 52% of the ADI (Dutch toddler) and the highest acute exposure amounted to 97% of the ARfD (head cabbage).

Recommendations

The residue definition for monitoring covers both lambda- and gamma-cyhalothrin. Lambda-cyhalothrin is a 1:1 mixture of the RS and SR isomers, while gamma-cyhalothrin is constituted only by the SR-isomer. Appropriate enantioselective techniques, which are not commonly used in routine analysis, are required to differentiate gamma-cyhalothrin residues from lambda-cyhalothrin. MRLs derived in the present assessment are equal or lower than the MRLs based on the uses of lambda-cyhalothrin currently set in the Regulation (see Table 2). Therefore, it is expected that the existing MRLs will cover the uses of gamma-cyhalothrin assessed in the present review. Thus, risk managers can consider maintaining the existing EU MRLs, noting that the data gaps identified by EFSA for lambda-cyhalothrin and currently in the Regulation are still considered applicable, except for the toxicological profiles of metabolites CPCA and PBA, PB-OH which have been meanwhile addressed in previous EFSA outputs.

Based on the uses of gamma-cyhalothrin evaluated, EFSA identified the following data gaps which are not expected to impact on the validity of the proposed MRLs (which are all based on lambda-cyhalothrin and veterinary uses) but which might have an impact on national authorisations for gamma-cyhalothrin:

- additional residue trials supporting the northern outdoor GAP for gamma-cyhalothrin on brussels sprouts, head cabbages, beans (with pods), peas (with pods), sunflowers seeds, sugar beet tops, fodder beet tops and pea vines.

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

TABLE 2 Summary table.

Code number	Commodity	Existing EU MRL (based on lambda-cyhalothrin uses and vet uses) (mg/kg)	Derived MRL (based on gamma-cyhalothrin uses) (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition: lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers)[F]					
211000	Potatoes	0.01*	0.01*	0.01*	Risk managers can consider maintaining the existing EU MRL[a]
213010	Beetroot	0.04	0.01*	0.04	Risk managers can consider maintaining the existing EU MRL[b]
242010	Brussels sprouts	0.04	0.04	0.04	Risk managers can consider maintaining the existing EU MRL[c]
242020	Head cabbage	0.15	0.09	0.15	Risk managers can consider maintaining the existing EU MRL[d]
260010	Beans (fresh, with pods)	0.4	0.03	0.4	Risk managers can consider maintaining the existing EU MRL[d]
260030	Peas (fresh, with pods)	0.2	0.03	0.2	Risk managers can consider maintaining the existing EU MRL[d]
260040	Peas (fresh, without pods)	0.2	0.01*	0.2	Risk managers can consider maintaining the existing EU MRL[b]
300010	Beans (dry)	0.05	0.01*	0.05	Risk managers can consider maintaining the existing EU MRL[b]
300030	Peas (dry)	0.05	0.01*	0.05	Risk managers can consider maintaining the existing EU MRL[b]
401030	Poppy seed	0.2	0.015	0.2	Risk managers can consider maintaining the existing EU MRL[b]
401050	Sunflower seed	0.2	0.2	0.2	Risk managers can consider maintaining the existing EU MRL[e]
401060	Rape seed	0.2	0.015	0.2	Risk managers can consider maintaining the existing EU MRL[b]

(Continues)

TABLE 2 (Continued)

Code number	Commodity	Existing EU MRL (based on lambda-cyhalothrin uses and vet uses) (mg/kg)	Derived MRL (based on gamma-cyhalothrin uses) (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
401080	Mustard seed	0.2	0.015	0.2	Risk managers can consider maintaining the existing EU MRL[b]
500010	Barley grain	0.5	0.05	0.5	Risk managers can consider maintaining the existing EU MRL[b]
500050	Oats grain	0.3	0.05	0.3	Risk managers can consider maintaining the existing EU MRL[b]
500070	Rye grain	0.05	0.015	0.05	Risk managers can consider maintaining the existing EU MRL[b]
500090	Wheat grain	0.05	0.015	0.05	Risk managers can consider maintaining the existing EU MRL[b]
900010	Sugar beet (root)	0.01*	0.01*	0.01*	Risk managers can consider maintaining the existing EU MRL[a]
1011010	Swine meat	0.15	0.01*	0.15	Risk managers can consider maintaining the existing EU MRL[b]
1011020	Swine fat (free of lean meat)	3	0.09	3	Risk managers can consider maintaining the existing EU MRL[b]
1011030	Swine liver	0.05	0.01*	0.05	Risk managers can consider maintaining the existing EU MRL[b]
1011040	Swine kidney	0.2	0.01*	0.2	Risk managers can consider maintaining the existing EU MRL[b]
1012010	Bovine meat	0.02	0.01*	0.02	Risk managers can consider maintaining the existing EU MRL[b]
1012020	Bovine fat	3	0.3	3	Risk managers can consider maintaining the existing EU MRL[f]
1012030	Bovine liver	0.05	0.015	0.05	Risk managers can consider maintaining the existing EU MRL[b]
1012040	Bovine kidney	0.2	0.01*	0.2	Risk managers can consider maintaining the existing EU MRL[f]
1013010	Sheep meat	0.02	0.01*	0.02	Risk managers can consider maintaining the existing EU MRL[b]
1013020	Sheep fat	3	0.3	3	Risk managers can consider maintaining the existing EU MRL[b]
1013030	Sheep liver	0.05	0.015	0.05	Risk managers can consider maintaining the existing EU MRL[b]
1013040	Sheep kidney	0.2	0.01*	0.2	Risk managers can consider maintaining the existing EU MRL[b]
1014010	Goat meat	0.15	0.01*	0.15	Risk managers can consider maintaining the existing EU MRL[b]
1014020	Goat fat	3	0.3	3	Risk managers can consider maintaining the existing EU MRL[b]
1014030	Goat liver	0.05	0.015	0.05	Risk managers can consider maintaining the existing EU MRL[b]
1014040	Goat kidney	0.2	0.01*	0.2	Risk managers can consider maintaining the existing EU MRL[b]
1015010	Horse meat	0.02	0.01*	0.02	Risk managers can consider maintaining the existing EU MRL[b]
1015020	Horse fat	3	0.3	3	Risk managers can consider maintaining the existing EU MRL[b]
1015030	Horse liver	0.05	0.015	0.05	Risk managers can consider maintaining the existing EU MRL[b]
1015040	Horse kidney	0.2	0.01*	0.2	Risk managers can consider maintaining the existing EU MRL[b]
1016000	Poultry	0.01*	0.01*	0.01*	Risk managers can consider maintaining the existing EU MRL[a]

TABLE 2 (Continued)

Code number	Commodity	Existing EU MRL (based on lambda-cyhalothrin uses and vet uses) (mg/kg)	Derived MRL (based on gamma-cyhalothrin uses) (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
1020010	Cattle milk	0.02	0.01*	0.02	Risk managers can consider maintaining the existing EU MRL[g]
1020020	Sheep milk	0.02	0.01*	0.02	Risk managers can consider maintaining the existing EU MRL[a]
1020030	Goat milk	0.02	0.01*	0.02	Risk managers can consider maintaining the existing EU MRL[b]
1020040	Horse milk	0.02	0.01*	0.02	Risk managers can consider maintaining the existing EU MRL[b]
1030000	Eggs	0.01*	0.01*	0.01*	Risk managers can consider maintaining the existing EU MRL[a]
–	Other commodities of plant and/or animal origin	See Reg. 590/2021	–	–	Risk managers can consider maintaining the existing EU MRL[h]

Abbreviations: CXL, codex maximum residue limit; MRL, maximum residue level.

*Indicates that the MRL is set at the limit of quantification.

[F]The residue definition is fat soluble.

[a]The existing use of gamma-cyhalothrin, which is fully supported by data and for which no risk for consumers was identified, leads to an MRL of 0.01 mg/kg which is equal to the existing EU MRL.

[b]The existing use of gamma-cyhalothrin, which is fully supported by data and for which no risk for consumers was identified, leads to an MRL lower than the existing EU MRL.

[c]The existing use of gamma-cyhalothrin, which not is fully supported by data but for which no risk for consumers was identified, leads to a tentative overestimated MRL equal to the existing EU MRL.

[d]The existing use of gamma-cyhalothrin, which not is fully supported by data but for which no risk for consumers was identified, leads to a tentative MRL lower than the existing EU MRL.

[e]The existing use of gamma-cyhalothrin is not supported by sufficient data, but no risk for consumers was identified for the existing EU MRL.

[f]The existing use of gamma-cyhalothrin, which is fully supported by data and for which no risk for consumers was identified, leads to an MRL lower than the existing EU MRL. The existing EU MRL covers as well the veterinary MRL set under Regulation No 37/2010.

[g]The existing use of gamma-cyhalothrin, which is fully supported by data and for which no risk for consumers was identified, leads to an MRL lower than the existing EU MRL. An higher MRL is set in Regulation No 37/2010 for cattle milk but an acute exceedance cannot be excluded for this veterinary MRL (EFSA, 2015).

[h]There are no relevant authorisations or import tolerances reported at EU level for gamma-cyhalothrin.

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
BVL	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany
bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CCPR	Codex Committee on Pesticide Residues
CEN	European Committee for Standardization (Comité Européen de Normalisation)
CF	conversion factor for enforcement residue definition to risk assessment residue definition
cGAP	critical GAP
CIPAC	Collaborative International Pesticide Analytical Council
CIRCA	(EU) Communication & Information Resource Centre Administrator
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
CS	capsule suspension
CV	coefficient of variation (relative standard deviation)
CXL	codex maximum residue limit
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DB	dietary burden
DM	dry matter
DP	dustable powder

DS	powder for dry seed treatment
DT_{90}	period required for 90% dissipation (define method of estimation)
DTU	Danish Technical University
dw	dry weight
EC	emulsifiable concentrate
EC	European Commission
ECD	electron capture detector
EDI	estimated daily intake
EMA	European Medicines Agency (former EMEA)
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
ESI	electrospray ionisation
EURLs	European Union Reference Laboratories for Pesticide Residues (former CRLs)
FAO	Food and Agriculture Organisation of the United Nations
FID	flame ionisation detector
FLD	fluorescence detector
FPD	flame photometric detector
GAP	Good Agricultural Practice
GC	gas chromatography
GC-ECD	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-FPD	gas chromatography with flame photometric detector
GC–MS	gas chromatography with mass spectrometry
GC–MS/MS	gas chromatography with tandem mass spectrometry
GC-NPD	gas chromatography with nitrogen/phosphorous detector
GCPF	Global Crop Protection Federation (formerly International Group of National Associations of Manufacturers of Agrochemical Products; GIFAP)
GLP	Good Laboratory Practice
GR	granule
GS	growth stage
HPLC	high performance liquid chromatography
HPLC-MS	high performance liquid chromatography with mass spectrometry
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HPLC-UVD	high performance liquid chromatography with ultra-violet detector
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
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
NEU	Northern Europe
NPD	nitrogen/phosphorous detector
NTMDI	national theoretical maximum daily intake
OECD	Organisation for Economic Co-operation and Development
PAFF	Standing Committee on Plants, Animals, Food and Feed
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)
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate

SEU	southern European
SMILES	simplified molecular-input line-entry system
SG	water soluble granule
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
WHO	World Health Organization
YF	yield factor

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CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

European Commission.

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APPENDIX A

Summary of authorised uses considered for the review of MRLs

A.1 | AUTHORISED OUTDOOR USES IN NORTHERN EU

				Preparation		Application				Application rate per treatment				
Crop and/or situation	MS or country	F, G or I[a]	European Food Safety Authority	Type[b]	Conc. a.s.	Method kind	Range of growth stages and season[c]	Number Min-max	Interval between application (min)	a.s./hL Min–max	Water L/ha Min–max	Rate and unit	PHI (days)[d]	Remarks
Potatoes	BE	F	Colorado beetle	CS	60 g/L	Foliar treatment – broadcast spraying		1		–	–	4.5 g a.i./ha	7	
Beetroots	LT	F	Pegomya hyoscyami, Aphis fabae, Myzus persicae, Chaetocnema concinna, Silpha undata, Blitophaga opaca	CS	60 g/L	Foliar treatment – broadcast spraying	13–43	1		–	–	3.6 g a.i./ha	10	
Brussels sprouts	LT	F	Pieris rapae	CS	60 g/L	Foliar treatment – broadcast spraying	12–79	1		–	–	4.8 g a.i./ha	7	General GAP for head brassicas
Head cabbages	LT	F	Pieris rapae	CS	60 g/L	Foliar treatment – broadcast spraying	12–79	1		–	–	4.8 g a.i./ha	7	General GAP for head brassicas
Beans (with pods)	FI	F	Aphids	CS	60 g/L	Foliar treatment – broadcast spraying	12–29	1		–	–	3.6 g a.i./ha	14	
Peas (with pods)	FI	F	Aphids	CS	60 g/L	Foliar treatment – broadcast spraying	12–29	1		–	–	3.6 g a.i./ha	14	
Peas (without pods)	SE	F	Insects	CS	60 g/L	Foliar treatment – broadcast spraying	10–69	1		–	–	3.6 g a.i./ha	14	
Beans (dry)	LT	F	Cydia nigricana, Acyrthosiphon pisum, Sitona lineatus	CS	60 g/L	Foliar treatment – broadcast spraying	10–69	1		–	–	3.6 g a.i./ha	14	Most critical GAP with treatment up to BBCH 77 with 7 day PHI, is not supported with residue data

(Continues)

(Continued)

				Preparation		Application				Application rate per treatment				
Crop and/or situation	MS or country	F, G or I[a]	European Food Safety Authority	Type[b]	Conc. a.s.	Method kind	Range of growth stages and season[c]	Number Min-max	Interval between application (min)	a.s./hL Min–max	Water L/ha Min–max	Rate and unit	PHI (days)[d]	Remarks
Peas (dry)	CZ	F	Insect pests	CS	60 g/L	Foliar treatment – broadcast spraying		1–2		–	–	4.8 g a.i./ha	14	
Poppy seeds	CZ	F	Insect pests	CS	60 g/L	Foliar treatment – broadcast spraying		1–2		–	–	4.8 g a.i./ha	28	
Sunflower seeds	HU	F	Miroidea sp., Aphids	CS	60 g/L	Foliar treatment – broadcast spraying	14–69	2	10	–	–	4.8 g a.i./ha	28	
Rapeseeds	AT	F	1APHIF, Aphididae	CS	60 g/L	Foliar treatment – general (see also comment field)		2		–	–	5 g a.i./ha	28	Early summer, after flowering, after reaching thresholds or after warning service appeal
Mustard seeds	CZ	F	Insect pests	CS	60 g/L	Foliar treatment – broadcast spraying		1–2		–	–	4.8 g a.i./ha	28	Application according to infestation
Barley	CZ	F	Aphids	CS	60 g/L	Foliar treatment – broadcast spraying		1–2		–	–	4.8 g a.i./ha	28	Application according to infestation
Oat	CZ	F	Ahids	CS	60 g/L	Foliar treatment – broadcast spraying		1–2		–	–	4.8 g a.i./ha	28	Application according to infestation
Rye	CZ	F	Aphids	CS	60 g/L	Foliar treatment – broadcast spraying		1–2		–	–	4.8 g a.i./ha	28	Application according to infestation
Wheat	CZ	F	Aphids	CS	60 g/L	Foliar treatment – broadcast spraying		1–2		–	–	4.8 g a.i./ha	28	Application according to infestation
Sugar beets	CZ	F	Aphids	CS	60 g/L	Foliar treatment – broadcast spraying		1–2		–	–	4.8 g a.i./ha	28	Application according to infestation

(Continued)

				Preparation		Application				Application rate per treatment				
Crop and/or situation	MS or country	F, G or I[a]	European Food Safety Authority	Type[b]	Conc. a.s.	Method kind	Range of growth stages and season[c]	Number Min-max	Interval between application (min)	a.s./hL Min–max	Water L/ha Min–max	Rate and unit	PHI (days)[d]	Remarks
Peas (for forage)	IE	F		CS	60 g/L	Foliar treatment – broadcast spraying	n.a. to 69	1–3		–	–	3 g a.i./ha	n.a.	GAP unclear. Latest growth stage for forage use is flat-pod stage at end of flowering or close after. This GS also represents the max. BBCH for treatment. Harvest close to treatment requires information on pre-harvest intervals
Fodder beets	CZ	F	Aphids	CS	60 g/L	Foliar treatment – broadcast spraying		1–2		–	–	4.8 g a.i./ha	28	Application according to infestation

Abbreviation: MS, Member State.

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

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

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

[d]PHI – minimum preharvest interval.

APPENDIX B

List of end points

B.1 | RESIDUES IN PLANTS

B.1.1 | Nature of residues and analytical methods for enforcement purposes in plant commodities

B.1.1.1 | Metabolism studies, analytical methods and residue definitions in plants

Primary crops (available studies)	Crop groups	Crop(s)	Application(s)	Sampling (DAT)	Comment/Source
	Fruit crops	Grape	4×0.1 kg/ha	14 after 2 application; 3, 7, 10 after last treatment	Gamma-cyhalothrin, Cyclopropyl and phenoxyphenyl ring-labelled [14C] gamma-cyhalothrin (EFSA, 2014a)
		Apples	Spotting on fruits, 33 µg per apple	0, 7, 14, 28, 56	Lambda-cyhalothrin, (EFSA, 2015)
		Tomatoes	Foliar, 4×0.1 kg a.s./ha	3	Lambda-cyhalothrin, (EFSA, 2015)
	Leafy crops	Cabbage	Spotting on leaves, 26 µg per leaf	14, 28, 35, 42, 49	Lambda-cyhalothrin, (EFSA, 2015)
			Foliar, 4–8×0.055 kg a.s./ha	7	Lambda-cyhalothrin, (EFSA, 2015)
	Cereals/grass	Wheat	Foliar, 5×0.0435 kg a.s./ha	T1+9 (forage), T4+7 (hay), T5+28 (straw, grain)	Gamma-cyhalothrin (EFSA, 2014a)
			Foliar, 2×0.224 kg a.s./ha	14, 85, 30	Lambda-cyhalothrin, (EFSA, 2015)
	Pulses/oilseeds	Soybean	Foliar, 2×0.02 kg a.s./ha	39, 51	Lambda-cyhalothrin, (EFSA, 2015)
		Cotton	Foliar, 3×0.066 kg a.s./ha	30, 50	
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Carrots	Bare soil, 470 g a.s./ha	30, 60, 120	Lambda-cyhalothrin, (EFSA, 2014b)
			Bare soil, 110 g a.s./ha	30, 120	
	Leafy crops	Lettuce	Bare soil, 470 g a.s./ha	30, 60, 120	
			Bare soil, 110 g a.s./ha	30, 120	
	Cereal (small grain)	Wheat	Bare soil, 470 g a.s./ha	30, 60, 120	
			Bare soil, 110 g a.s./ha	30, 120	
Processed commodities (hydrolysis study)	**Conditions**		**Stable?**		**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)		Yes		EFSA (2014b)
	Baking, brewing and boiling (60 min, 100°C, pH 5)		Yes		EFSA (2014b)
	Sterilisation (20 min, 120°C, pH 6)		No		Extensive degradation of lambda-cyhalothrin into metabolites CPCA (59% TRR), PBAld (63% TRR) and gamma-lactone (15% TRR) (EFSA, 2014a)

Can a general residue definition be proposed for primary crops?	yes	
Rotational crop and primary crop metabolism similar?	yes	CPCA identified as main compound of the residues.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes, except for sterilisation	Yes, for pasteurization, brewing and boiling. Extensive degradation of the parent during sterilization.
Plant residue definition for monitoring (RD-Mo)	lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers)	
Plant residue definition for risk assessment (RD-RA)	Sum of gamma-cyhalothrin and CPCA, expressed as gamma-cyhalothrin (tentative for processed commodities as for PBA(Ald) and gamma-lactone, additional toxicological data are missing). Data gap not relevant for the existing uses of gamma-cyhalothrin since most of the commodities under assessment are not expected to undergo sterilization and considering that low residues are expected in raw commodities relevant for human consumption (see Appendix B.1.2.1).	
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)	Lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers) in high water content, high acid content, high oil content and dry commodities (EFSA, 2014b): • Multi-residue QuEChERS (GC-MS) • LOQ: 0.01 mg/kg • Confirmation by validation of two additional fragment ions • ILV available for high water content and dry commodities (sufficient for the four plant matrix groups) • Multiresidue QuEChERS and QuOil methods (GC-MS/MS) with LOQ = 0.01 mg/kg in four main plant matrices and black tea in routine analysis. Enantioselective analysis of gamma-cyhalothrin was achieved by chiral LC-MS/MS in cucumber, orange juice, wheat flour, sunflower seed oil and infant formula (EURLs, 2019, 2023).	

DAT: days after treatment; PBI: plant-back interval; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LC–MS/MS: liquid chromatography with tandem mass spectrometry; GC–MS/MS: gas chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.1.1.2 | Stability of residues in plants

Plant products (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/Source
				Value	Unit		
	High water content	Apple, peach, sugar beet root, cabbage, potato	–18	26	Months	Lambda-cyhalothrin	EFSA (2015)
		Broccoli, tomato, field peas	–20	12	Months	Gamma-cyhalothrin	EFSA (2014a)
	High oil content	Cotton seed, rape seed	–18	26	Months	Lambda-cyhalothrin	EFSA (2015)
		Cotton seed	–20	12	Months	Gamma-cyhalothrin	EFSA (2014a)
	Dry, high starch content	Wheat grain	–18	26	Months	Lambda-cyhalothrin	EFSA (2015)
		Wheat grain	–20	12	Months	Gamma-cyhalothrin	EFSA (2014a)
	Processed products	Grape wine, corn oil	–20	12	Months	Gamma-cyhalothrin	EFSA (2014a)
	Others	Hops	–18	8	Months	Lambda-cyhalothrin	EFSA (2015)

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)	CF
Potatoes	NEU	RD Mo: 12 × < 0.01 RD RA: –	Trials on potatoes with lambda-cyhalothrin compliant with the GAP (EFSA, 2015)	0.01*	0.01	0.01	1[d]
Brussels sprouts	NEU	RD Mo: 2× 0.01; 4 × < 0.02; 2 × 0.02 RD RA: –	Trials performed with lambda-cyhalothrin according to a more critical GAP (2 × 10 g a.s./ha, PHI: 3 d) (EFSA, 2015) deemed acceptable on a tentative basis. MRL_{OECD} = 0.04	0.04 (tentative)[e]	0.02	0.02	1[d]
Head cabbages	NEU	RD Mo: 0.04; 0.05; 2 × 0.07; 0.08; 2 × 0.10; 0.11 adjusted residues by a factor of 0.5: RD Mo: 0.02; 0.025; 2 × 0.035; 0.04; 2 × 0.05; 0.055 RD RA: –	Trials performed with lambda-cyhalothrin according to a more critical GAP (2 × 12.5 g a.s./ha, PHI: 7 days) (EFSA, 2015). Results were adjusted by a factor of 0.5 considering only the proportion of gamma-cyhalothrin in lambda-cyhalothrin to derive a tentative MRL. MRL_{OECD} = 0.09	0.09 (tentative)[e]	0.055	0.04	1[f]
Beans, peas (with pods)	NEU	RD Mo: 6 × < 0.01; 2 × 0.01; 0.02 RD RA: –	Trials performed with lambda-cyhalothrin according to a more critical GAP (2 × 7.5 g a.s./ha; PHI 3 days) acceptable on a tentative basis (EFSA, 2015) MRL_{OECD} = 0.02	0.03 (tentative)[e]	0.02	0.01	1[d]
Peas (without pods)	NEU	RD Mo: 5 × < 0.01 RD RA: –	Trials performed with lambda-cyhalothrin according to a more critical GAP (2 × 7.5 g/ha; PHI 3 days), deemed acceptable, as residues are below 0.01 mg/kg (EFSA, 2015). MRL_{OECD} = 0.01	0.01*	0.01	0.01	1[d]

(Continued)

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)	CF
Peas, beans (dry)	NEU	RD Mo: 5 × < 0.01 RD RA: –	Trials performed with lambda-cyhalothrin (2 × 7.5 g/ha; PHI 3 days) according to a more critical GAP deemed acceptable as residues are below 0.01 mg/kg (EFSA, 2015). MRL_{OECD} = 0.01	0.01*	0.01	0.01	1[d]
Sunflower seeds	NEU	RD Mo: 2 × < 0.01 RD RA: –	Trials performed with lambda-cyhalothrin according to a more critical GAP (2 × 7.5 g a.s./ha, PHI: 21 days, EFSA, 2015) not sufficient for a major crop. MRL_{OECD} = –	–	–	–	–
Rapeseeds/canola seeds Poppy seeds Mustard seeds	NEU	RD Mo: 7 × < 0.01; 0.01 RD RA: –	Trials on rapeseed conducted with 5–7 applications instead of 2, with the last application within 25% of the cGAP are deemed acceptable, as residues are at or below 0.01 mg/kg (Germany, 2023). Extrapolation to poppy seeds and mustard seeds are possible. MRL_{OECD} = 0.01	0.015	0.01	0.01	1[d]
Barley grains, Oat grains	NEU	RD Mo: < 0.01; 4 × 0.01; 4 × 0.02; 0.03 RD RA: –	Trials on barley compliant with GAP or performed with 3 instead of 2 applications are acceptable as the first application is not expected to contribute to the final residue (EFSA, 2019; Germany, 2023). Extrapolation to wheat and barley is acceptable. MRL_{OECD} = 0.04	0.05	0.03	0.02	1[d]
Wheat grains, Rye grains	NEU	RD Mo: 13 × < 0.01; 0.01 RD RA: –	Trials on wheat with 3 applications instead of 2 acceptable as the first application is not expected to impact the final residue (EFSA, 2014a, 2019; Germany, 2023). MRL_{OECD} = 0.01	0.015	0.01	0.01	1[d]
Sugar beet roots Beetroots Fodder beet roots	NEU	RD Mo: 6 × < 0.01; RD RA: –	Trials on sugar beet performed with lambda-cyhalothrin according to a more critical GAP acceptable as residues are < LOQ (EFSA, 2015). Extrapolation to beet root and fodder beet root applicable. MRL_{OECD} = 0.01	0.01* (tentative for fodder beet roots)[g]	0.01	0.01	1[d]
Pea vines	NEU	–	No GAP compliant data. GAP information unclear	–	–	–	–
Barley straw Oat straw	NEU	RD Mo: 0.09; 0.11; 0.16; 0.18; 2 × 0.20; 2 × 0.26; 0.27; 2 × 0.31; 0.49 RD RA: –	Trials with 3 applications instead of 2 are acceptable as first application is not expected to contribute to the final residues (Germany, 2023). Extrapolation to oat applicable. MRL_{OECD} = 0.71	0.8 (tentative)[g]	0.49	0.23	1.12[f]

(Continues)

(Continued)

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)	CF
Wheat straw Rye straw	NEU	Mo: 0.08; 0.11; 0.12; 0.13; 2 × 0.15; 0.16; 0.19; 0.20; 2 × 0.22; 0.25; 0.31; 0.33; 0.51 RD RA: –	Trials with 3 applications instead of 2 are acceptable as first application at early stage not expected to contribute to the final residue (Germany, 2023). MRL_{OECD} = 0.65	0.7 (tentative)[g]	0.51	0.19	1.12[f]
Sugar beet tops Fodder beet tops	NEU	Mo: 0.10; 0.12; 0.13; 0.17; 0.19; 0.21 RD RA: –	Trials on sugar beet conducted with lambda-cyhalothrin according to a more critical GAP (2 × 12.5 g a.s./ha; PHI 14 days vs. 2 × 4.8 g a.s./ha; PHI 28 days) (EFSA, 2015) are tentatively acceptable. Extrapolation to fodder beet tops applicable. MRL_{OECD} = 0.46	0.5 (tentative)[e,g]	0.21	0.15	1[f]

Abbreviations: GAP, Good Agricultural Practice; Mo, residue levels expressed according to the monitoring residue definition; MRL, maximum residue level; OECD, Organisation for Economic Co-operation and Development; RA, residue levels expressed according to risk assessment residue definition.

*Indicates that the MRL is proposed at the limit of quantification.

[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]Metabolite CPCA was not analysed in any of the trials. As in the metabolism studies, the level of parent was always higher than the level of the metabolite, it is assumed that CPCA will not be present at significant levels and a conversion factor (CF) of 1 was considered to recalculate residues according to the residue definition for risk assessment.

[e]MRL is tentative because trials were performed according to a more critical GAP.

[f]Metabolite CPCA was not analysed in any of the trials. Conversion factor (CF) to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment was derived from the metabolism studies on wheat and cabbage.

[g]Tentative MRLs are derived for feed items in view of the future need to set MRLs in these commodities.

B.1.2.2 | Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	No	Based on data generated with lambda-cyhalothrin, no residues are expected in the edible parts of succeeding crops provided that gamma-cyhalothrin is applied in compliance with the GAPs reported in Appendix A. The most abundant residue in rotational wheat, lettuce and carrots was CPCA. However, considering the most cGAP (rapeseed, 2 x 5 g/ha) under assessment, residues of CPCA above 0.01 mg/kg are not expected.
Residues in rotational and succeeding crops expected based on field rotational crop study?	No	Field studies conducted with lambda-cyhalothrin confirm that no residues are expected in succeeding crops.

B.1.2.3 | Processing factors

There are no new processing factors derived specifically with gamma-cyhalothrin. The tentative processing factors established for lambda-cyhalothrin (EFSA, 2015) may be applied to gamma-cyhalothrin.

B.2 | Residues in livestock

Relevant groups (subgroups)	Dietary burden expressed in				Most critical subgroup[a]	Most critical commodity[b]	Trigger exceeded (Y/N)
	mg/kg bw per day		mg/kg DM				
	Median	Maximum	Median	Maximum			
Cattle (all)	0.011	0.015	0.35	0.47	Dairy cattle	Beet, mangel fodder	Y
Cattle (dairy only)	0.011	0.015	0.29	0.39	Dairy cattle	Beet, mangel fodder	Y
Sheep (all)	0.009	0.017	0.21	0.40	Lamb	Barley straw	Y
Sheep (ewe only)	0.007	0.013	0.21	0.40	Ram/Ewe	Barley straw	Y
Swine (all)	0.005	0.006	0.21	0.27	Swine (breeding)	Beet, mangel fodder	Y
Poultry (all)	0.004	0.007	0.06	0.10	Poultry layer	Wheat straw	Y
Poultry (layer only)	0.004	0.007	0.06	0.10	Poultry layer	Wheat straw	Y
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	2×0.68	14	[cyclopropyl-^{14}C]-lambda-cyhalothrin; [phenoxy-^{14}C]-lambda-cyhalothrin (EFSA, 2014a)
	Lactating ruminants	1×0.36	7	Goat, lambda-cyhalothrin (EFSA, 2014a)
		1×0.42	7	Cow, lambda-cyhalothrin (EFSA, 2014a)

Time needed to reach a plateau concentration in milk and eggs (days)	Milk: 4 days	-
	Eggs: 7 – 9 days	-
Metabolism in rat and ruminant similar	yes	-
Can a general residue definition be proposed for animals?	yes	-
Animal residue definition for monitoring (RD-Mo)	lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers)	
Animal residue definition for risk assessment (RD-RA)	Sum of gamma-cyhalothrin and CPCA, expressed as gamma-cyhalothrin	
Fat soluble residues	Yes	-
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)	Lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers) in muscle, liver, kidney, fat, milk and eggs (EFSA, 2014b): • Multi-residue DFG S19 (LC-MS/MS) • LOQ: 0.01 mg/kg • Confirmation by validation of one additional MRM transition • ILV available for meat and liver (sufficient for the other commodities) • Multiresidue methods (GC-MS/MS) with LOQ = 0.01 mg/kg in eggs, liver, milk, and dairy products in routine analysis. Enantioselective analysis of gamma-cyhalothrin was achieved by chiral LC-MS/MS in liver and milk (EURLs, 2023).	

B.2.1.2 | Stability of residues in livestock

Animal products (available studies)	Animal	Commodity	T (°C)	Stability period		Compounds covered	Comment/ Source
				Value	Unit		
	Poultry	Muscle	–18	3	Months	Lambda-cyhalothrin	EFSA (2015)
	Poultry	Fat	–18	3	Months	Lambda-cyhalothrin	EFSA (2015)
	Poultry	Liver	–18	3	Months	Lambda-cyhalothrin	EFSA (2015)
	–	Kidney	–18	3	Months	Lambda-cyhalothrin	EFSA (2015)
	Bovine	Milk	–18	4	Months	Lambda-cyhalothrin	EFSA (2015)
	Poultry	Eggs	–18	3	Months	Lambda-cyhalothrin	EFSA (2015)
		Milk, eggs, muscle, kidney, liver, fat		36–43	Months	CPCA	EFSA (2015)

B.2.2 | Magnitude of residues in livestock

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

Calculations performed with Animal model 2017.[15]

Animal commodity	Residues at the closest feeding level (mg/kg)		Estimated value at 1N		MRL proposal (mg/kg)	CF[c]
	Mean	Highest	$STMR_{Mo}$[a] (mg/kg)	HR_{Mo}[b] (mg/kg)		
Cattle (all) – Closest feeding level (0.0364 mg/kg bw; 2.4 N rate)[d]						
Muscle	0.01	0.01	0.003	0.004	0.01*	1.0
Fat	0.25	0.48	0.077	0.207	0.3	1.0
Liver	0.09	0.25	0.005	0.012	0.015	1.0
Kidney	0.01	0.02	0.004	0.008	0.01*	1.0
Cattle (dairy only) – Closest feeding level (0.0364 mg/kg bw; 2.4 N rate)[d]						
Milk[e]	0.02	n.a.	0.006	0.007	0.01*	1.0
Sheep (all)[f] – Closest feeding level (0.0364 mg/kg bw; 2.1 N rate)[d]						
Muscle	0.01	0.01	0.002	0.005	0.01*	1.0
Fat	0.25	0.48	0.06	0.235	0.3	1.0
Liver	0.09	0.25	0.004	0.014	0.015	1.0
Kidney	0.01	0.02	0.003	0.009	0.01	1.0
Sheep (ewe only)[f] – Closest feeding level (0.0364 mg/kg bw; 2.7 N rate)[d]						
Milk[e]	0.02	n.a.	0.003	0.007	0.01*	1.0
Swine (all)[f] – Closest feeding level (0.0364 mg/kg bw; 5.9 N rate)[d]						
Muscle	0.01	0.01	0.001	0.002	0.01*	1.0
Fat	0.25	0.48	0.03	0.085	0.09	1.0
Liver	0.09	0.25	0.002	0.005	0.01*	1.0
Kidney	0.01	0.02	0.002	0.003	0.01*	1.0
Poultry (all) – Feeding level in metabolism study (1.36 mg/kg bw; ~200 N rate)[d]						
Muscle	–	–	< 0.01	< 0.01	0.01*	1.0
Fat	–	–	< 0.01	< 0.01	0.01*	1.0
Liver	–	–	< 0.01	< 0.01	0.01*	1.0
Poultry (layer only) – Feeding level in metabolism study (1.36 mg/kg bw; ~200 N rate)[d]						
Eggs	–	–	< 0.01	< 0.01	0.01*	1.0

Abbreviation: n.a., not applicable.

*Indicates that the MRL is proposed at the limit of quantification.

[a]Median residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the median dietary burden.

[b]Highest residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the maximum dietary burden.

[c]Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

[d]Closest feeding level and N dose rate related to the maximum dietary burden.

[e]For milk, mean was derived from samplings performed from day 1 to day 30 (daily mean of 3 cows).

[f]Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.

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

B.3 | CONSUMER RISK ASSESSMENT

ARfD	0.0025 mg/kg bw (Reg. (EU) No 1334/2014)
Highest IESTI, according to EFSA PRIMo (rev.3.1)	Head cabbage: 97% of ARfD
NESTI (% ARfD)	Not assessed in this review.
Assumptions made for the calculations	The calculation is based on the highest residue levels expected in raw agricultural commodities, except for bulked commodities (cereals, milk, oilseeds, pulses) for which the derived median residue levels was considered. In the absence of sufficient residue trials, the existing EU MRL for sunflower seeds was included for the calculation.

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	0.0012 mg/kg bw per day (Reg. (EU) No 1334/2014)
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)	52% ADI (Dutch toddler) Major contributors among crops assessed: Milk: 30% of ADI Sunflower seeds: 5% of ADI Sugar beet roots: 4% of ADI
NEDI (% ADI)	Not assessed in this review.
Assumptions made for the calculations	The calculation is based on the median residue levels derived for raw agricultural commodities, except for sunflower seeds for which the existing MRL was considered. 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.

Consumer exposure assessment through drinking water resulting from groundwater metabolite(s) according to SANCO/221/2000 rev.10 Final (25/02/2003)

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

APPENDIX C

Pesticide Residue Intake Model (PRIMo)

Appendix C containing the PRIMo image of the report sheet can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2024.8758

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

gamma-cyhalothrin (F)

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

Toxicological reference values

ADI (mg/kg bw/day):	0.0012	ARfD (mg/kg bw):	0.0025
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2014	Year of evaluation:	2014

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)
	52%	NL toddler	0.63	30%	Milk: Cattle	5%	Sunflower seeds	4%	Sugar beet roots		52%
	37%	NL child	0.44	12%	Milk: Cattle	7%	Sugar beet roots	6%	Sunflower seeds		37%
	33%	RO general	0.39	11%	Sunflower seeds	6%	Milk: Cattle	5%	Head cabbages		33%
	31%	UK infant	0.37	19%	Milk: Cattle	3%	Potatoes	2%	Wheat		31%
	30%	FR child 3 15 yr	0.36	11%	Milk: Cattle	4%	Sunflower seeds	4%	Wheat		30%
	28%	FR toddler 2 3 yr	0.34	15%	Milk: Cattle	3%	Wheat	2%	Sugar beet roots		28%
	27%	GEMS/Food G15	0.33	9%	Sunflower seeds	4%	Wheat	4%	Milk: Cattle		27%
	25%	GEMS/Food G08	0.30	8%	Sunflower seeds	3%	Wheat	3%	Potatoes		25%
	24%	UK toddler	0.29	10%	Milk: Cattle	3%	Wheat	3%	Potatoes		24%
	23%	GEMS/Food G07	0.27	7%	Sunflower seeds	4%	Wheat	3%	Milk: Cattle		23%
	22%	SE general	0.27	7%	Bovine: Muscle/meat	6%	Milk: Cattle	3%	Potatoes		22%
	22%	DK child	0.26	6%	Milk: Cattle	5%	Rye	4%	Wheat		22%
	21%	DE child	0.25	10%	Milk: Cattle	4%	Wheat	2%	Potatoes		21%
	19%	ES child	0.23	6%	Milk: Cattle	4%	Wheat	2%	Bovine: Muscle/meat		19%
	19%	GEMS/Food G10	0.23	4%	Sunflower seeds	3%	Wheat	3%	Milk: Cattle		19%
	18%	NL general	0.22	4%	Milk: Cattle	3%	Sunflower seeds	2%	Sugar beet roots		18%
	18%	GEMS/Food G11	0.21	4%	Milk: Cattle	3%	Potatoes	3%	Wheat		18%
	17%	DE general	0.21	6%	Milk: Cattle	4%	Sugar beet roots	2%	Wheat		17%
	17%	DE women 14-50 yr	0.20	6%	Milk: Cattle	4%	Sugar beet roots	2%	Wheat		17%
	16%	GEMS/Food G06	0.20	6%	Wheat	4%	Sunflower seeds	2%	Potatoes		16%
	14%	FR infant	0.17	8%	Milk: Cattle	2%	Potatoes	1%	Sugar beet roots		14%
	13%	IE adult	0.16	3%	Sunflower seeds	2%	Milk: Cattle	2%	Wheat		13%
	13%	PT general	0.16	5%	Sunflower seeds	4%	Potatoes	3%	Wheat		13%
	11%	ES adult	0.13	2%	Milk: Cattle	2%	Wheat	2%	Sunflower seeds		11%
	11%	LT adult	0.13	3%	Potatoes	2%	Milk: Cattle	1%	Head cabbages		11%
	10%	FR adult	0.12	2%	Milk: Cattle	2%	Wheat	2%	Sunflower seeds		10%
	8%	DK adult	0.10	3%	Milk: Cattle	1%	Potatoes	0.9%	Wheat		8%
	7%	UK adult	0.08	1%	Milk: Cattle	1%	Wheat	1%	Potatoes		7%
	7%	FI 3 yr	0.08	4%	Potatoes	1.0%	Wheat	0.7%	Oat		7%
	7%	IT toddler	0.08	6%	Wheat	0.7%	Potatoes	0.3%	Sunflower seeds		7%
	6%	UK vegetarian	0.08	2%	Wheat	2%	Milk: Cattle	1%	Potatoes		6%
	6%	FI 6 yr	0.07	3%	Potatoes	0.8%	Wheat	0.5%	Rye		6%
	4%	IT adult	0.05	3%	Wheat	0.5%	Potatoes	0.2%	Sunflower seeds		4%
	4%	PL general	0.05	3%	Potatoes	1%	Head cabbages	0.2%	Beetroots		4%
	4%	IE child	0.05	2%	Milk: Cattle	1.0%	Wheat	0.5%	Potatoes		4%
	3%	FI adult	0.03	1.0%	Potatoes	0.6%	Rye	0.3%	Head cabbages		3%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of gamma-cyhalothrin (F) 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)
97%	Head cabbages	0.09 / 0.06	2.4
62%	Potatoes	0.01 / 0.01	1.5
30%	Milk: Cattle	0.01 / 0.01	0.75
26%	Sunflower seeds	0.2 / 0.2	0.64
23%	Beetroots	0.01 / 0.01	0.57
17%	Bovine: Fat tissue	0.3 / 0.21	0.43
13%	Bovine: Muscle/meat	0.01 / 0.04	0.32
11%	Sheep: Muscle/meat	0.01 / 0.05	0.28
11%	Equine: Muscle/meat	0.01 / 0.04	0.27
9%	Beans (with pods)	0.03 / 0.02	0.23
9%	Swine: Muscle/meat	0.01 / 0.02	0.23
7%	Beans	0.01 / 0.01	0.18
7%	Poultry: Muscle/meat	0.01 / 0.01	0.17
7%	Brussels sprouts	0.04 / 0.02	0.17
7%	Peas (with pods)	0.03 / 0.02	0.16

Expand/collapse list

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

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)
93%	Head cabbages	0.09 / 0.06	2.3
12%	Potatoes	0.01 / 0.01	0.30
10%	Bovine: Muscle	0.01 / 0.04	0.25
10%	Sheep: Muscle/meat	0.01 / 0.05	0.24
9%	Milk: Cattle	0.01 / 0.01	0.23
9%	Beetroots	0.01 / 0.01	0.23
9%	Equine: Muscle/meat	0.01 / 0.04	0.21
8%	Bovine: Fat tissue	0.3 / 0.21	0.20
8%	Sunflower seeds	0.2 / 0.2	0.20
7%	Swine: Fat tissue	0.09 / 0.09	0.17
6%	Beans (with pods)	0.03 / 0.02	0.15
5%	Brussels sprouts	0.04 / 0.02	0.12
5%	Poultry: Muscle	0.01 / 0.01	0.12
4%	Swine: Muscle/meat	0.01 / 0.02	0.09
3%	Wheat	0.02 / 0.01	0.08

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)
44%	Sugar beets (root) / sugar	0.01 / 0.12	1.1
37%	Potatoes / fried	0.01 / 0.01	0.93
24%	Potatoes / dried (flakes)	0.01 / 0.05	0.59
19%	Sunflower seeds / oils	0.2 / 0.4	0.47
18%	Beetroots / boiled	0.01 / 0.01	0.44
10%	Beans (with pods) / boiled	0.03 / 0.02	0.25
9%	Head cabbages / canned	0.09 / 0.04	0.23
8%	Brussels sprouts / boiled	0.04 / 0.02	0.20
5%	Wheat / milling (flour)	0.02 / 0.01	0.12
3%	Peas (without pods) / canned	0.01 / 0.01	0.08
3%	Peas / canned	0.01 / 0	0.07
2%	Wheat / milling (wholemeal)-baking	0.02 / 0.01	0.06
2%	Oat / boiled	0.05 / 0.02	0.05
2%	Barley / cooked	0.05 / 0.02	0.05
2%	Oat / milling (flakes)	0.05 / 0.02	0.05

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)
18%	Sugar beets (root) / sugar	0.01 / 0.12	0.44
16%	Beetroots / boiled	0.01 / 0.01	0.39
15%	Head cabbages / canned	0.09 / 0.04	0.38
4%	Barley / beer	0.05 / 0	0.11
3%	Potatoes / chips	0.01 / 0.01	0.08
3%	Beans / canned	0.01 / 0.01	0.07
3%	Peas (with pods) / boiled	0.03 / 0.02	0.07
2%	Potatoes / dried (flakes)	0.01 / 0.05	0.06
2%	Wheat / bread/pizza	0.02 / 0.01	0.04
2%	Wheat / pasta	0.02 / 0.01	0.04
1%	Wheat / bread (wholemeal)	0.02 / 0.01	0.03
1%	Peas (without pods) / boiled	0.01 / 0.01	0.03
1%	Peas / canned	0.01 / 0	0.03
0.9%	Oat / boiled	0.05 / 0.02	0.02

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of gamma-cyhalothrin (F) 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

	Median dietary burden		Maximum dietary burden	
Feed commodity	**Input value[a] (mg/kg)**	**Comment**	**Input value[a] (mg/kg)**	**Comment**
Risk assessment residue definition: sum of gamma-cyhalothrin and CPCA, expressed as gamma-cyhalothrin				
Potato, culls	0.01*	STMR × CF (1)	0.01*	HR × CF (1)
Potato, process waste	0.01*	STMR[b] × CF (1)	0.01*	STMR[b] × CF (1)
Potato, dried pulp	0.01*	STMR[b] × CF (1)	0.01*	STMR[b] × CF (1)
Cabbage, heads, leaves	0.04	STMR × CF (1)	0.06	HR × CF (1)
Bean, seed (dry)	0.01*	STMR × CF (1)	0.01*	STMR × CF (1)
Cowpea, seed	0.01*	STMR × CF (1)	0.01[a]	STMR × CF (1)
Pea (Field pea), seed (dry)	0.01*	STMR × CF (1)	0.01*	STMR × CF (1)
Canola (Rape seed), meal	0.02	STMR × PF (2)[c] × CF (1)	0.02	STMR × default PF (2)[c] × CF (1)
Rape, meal	0.02	STMR × PF (2)[c] × CF (1)	0.02	STMR × PF (2)[c] × CF (1)
Barley, grain	0.02	STMR × CF (1)	0.02	STMR × CF (1)
Brewer's grain, dried	0.05	STMR × PF (3.3)[c] × CF (1)	0.05	STMR × PF (3.3)[c] × CF (1)
Oat, grain	0.02	STMR × CF (1)	0.02	STMR × CF (1)
Rye, grain	0.01	STMR × CF (1)	0.01	STMR × CF (1)
Triticale, grain	0.01	STMR × CF (1)	0.01	STMR × CF (1)
Wheat, grain	0.01	STMR × CF (1)	0.01	STMR × CF (1)
Wheat, distiller's grain (dry)	0.03	STMR × PF (3.3)[c] × CF (1)	0.03	STMR × PF (3.3)[c] × CF (1)
Wheat gluten, meal	0.02	STMR × PF (1.8)[c] × CF (1)	0.02	STMR × PF (1.8)[c] × CF (1)
Wheat, milled by-products	0.07	STMR × PF (7)[c] × CF (1)	0.07	STMR × PF (7)[c] × CF (1)
Beet, sugar, dried pulp	0.01*	STMR[b] × CF (1)	0.01*	STMR[b] × CF (1)
Beet, sugar, ensiled pulp	0.01*	STMR[b] × CF (1)	0.01*	STMR[b] × CF (1)
Beet, sugar, molasses	0.01*	STMR[b] × CF (1)	0.01*	STMR[b] × CF (1)
Barley, straw	0.26	STMR × CF (1.12)	0.55	HR × CF (1.12)
Oat, straw	0.26	STMR × CF (1.12)	0.55	HR × CF (1.12)
Rye, straw	0.21	STMR × CF (1.12)	0.57	HR × CF (1.12)
Triticale, straw	0.21	STMR × CF (1.12)	0.57	HR × CF (1.12)
Wheat, straw	0.21	STMR × CF (1.12)	0.57	HR × CF (1.12)
Beet, mangel, roots	0.01*	STMR × CF (1)	0.01*	HR × CF (1)
Beet, mangel, tops	0.15	STMR × CF (1)	0.21	HR × CF (1)
Beet, sugar, tops	0.15	STMR × CF (1)	0.21	HR × CF (1)

Abbreviations: CF, conversion factor from enforcement to risk assessment; HR, highest residue according to the residue definition for monitoring; PF, processing factor; STMR, supervised trials median residue according to the residue definition for monitoring.

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

[a]Figures in the table are rounded to two digits, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce dietary burden calculations, the unrounded values need to be used.

[b]For potatoes and sugar beets, no default processing factor was applied because gamma-cyhalothrin is applied early in the growing season and residues are expected to be below the LOQ in the raw commodities. Concentration of residues in these commodities is therefore not expected.

[c]In the absence of processing factors supported by data, default the processing factor of was included in the calculation to consider the potential concentration of residues in these commodities.

D.2 | CONSUMER RISK ASSESSMENT

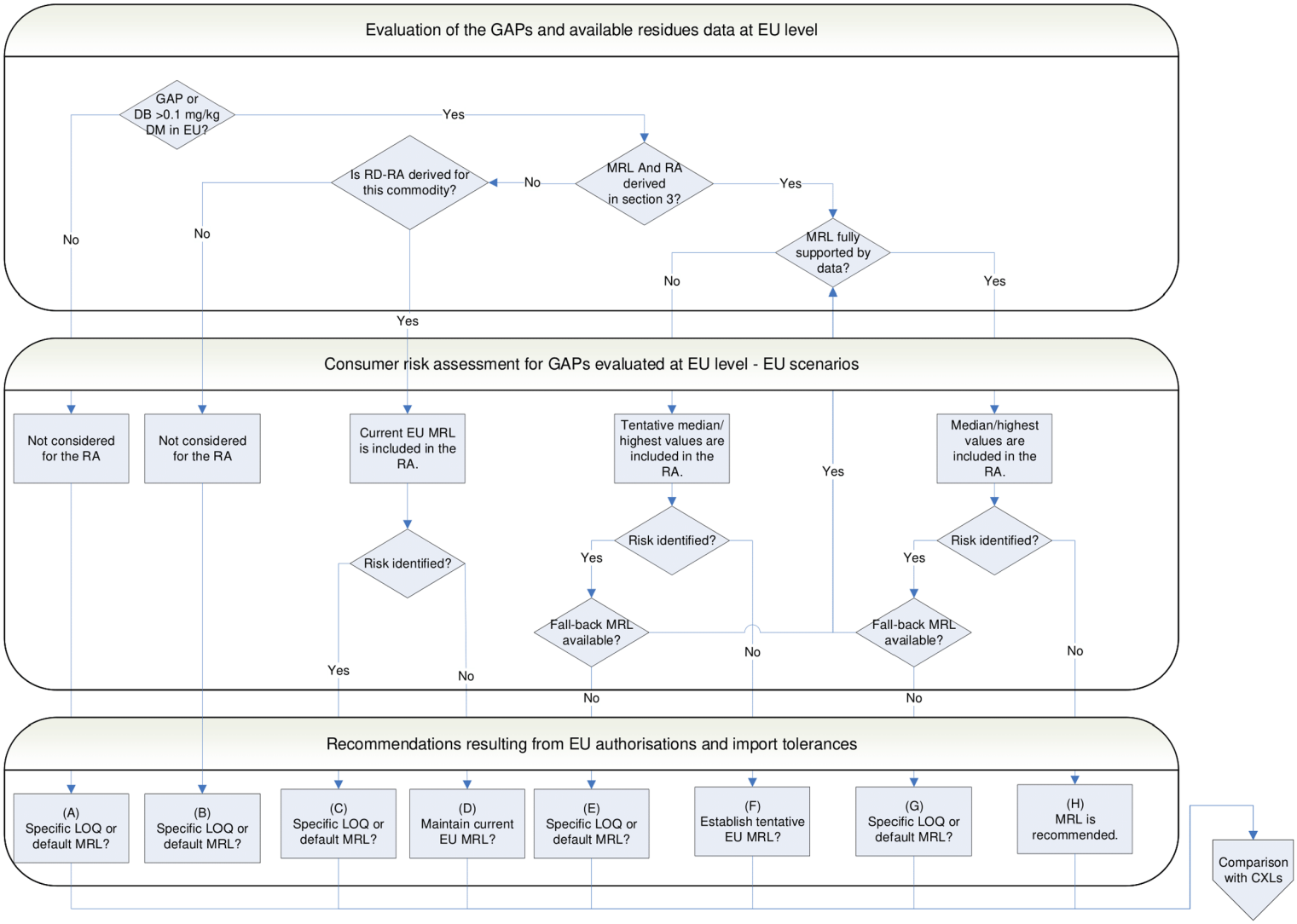
	Chronic risk assessment		Acute risk assessment	
Commodity	**Input value[a] (mg/kg)**	**Comment**	**Input value[a] (mg/kg)**	**Comment**
Risk assessment residue definition: Sum of gamma-cyhalothrin and CPCA, expressed as gamma-cyhalothrin				
Potatoes	0.01*	$STMR_{Mo}$ × CF (1)	0.01*	HR_{Mo} × CF (1)
Beetroots	0.01*	$STMR_{Mo}$ × CF (1)	0.01*	HR_{Mo} × CF (1)
Brussels sprouts	0.02	$STMR_{Mo}$ × CF (1) (tentative)	0.02	HR_{Mo} × CF (1) (tentative)
Head cabbages	0.04	$STMR_{Mo}$ × CF (1) (tentative)	0.06	HR_{Mo} × CF (1) (tentative)
Beans (with pods)	0.01	$STMR_{Mo}$ × CF (1) (tentative)	0.02	HR_{Mo} × CF (1) (tentative)
Peas (with pods)	0.01	$STMR_{Mo}$ × CF (1) (tentative)	0.02	HR_{Mo} × CF (1) (tentative)
Peas (without pods)	0.01*	$STMR_{Mo}$ × CF (1)	0.01*	HR_{Mo} × CF (1)
Beans (dry)	0.01*	$STMR_{Mo}$ × CF (1)	0.01*	$STMR_{Mo}$ × CF (1)
Peas (dry)	0.01*	$STMR_{Mo}$ × CF (1)	0.01*	$STMR_{Mo}$ × CF (1)
Poppy seeds	0.01*	$STMR_{Mo}$ × CF (1)	0.01*	$STMR_{Mo}$ × CF (1)
Sunflower seeds	0.20	EU MRL × CF (1)	0.20	EU MRL × CF (1)
Rapeseeds/canola seeds	0.01	$STMR_{Mo}$ × CF (1)	0.01	$STMR_{Mo}$ × CF (1)
Mustard seeds	0.01	$STMR_{Mo}$ × CF (1)	0.01	$STMR_{Mo}$ × CF (1)
Barley grains	0.02	$STMR_{Mo}$ × CF (1)	0.02	$STMR_{Mo}$ × CF (1)
Oat grains	0.02	$STMR_{Mo}$ × CF (1)	0.02	$STMR_{Mo}$ × CF (1)
Rye grains	0.01	$STMR_{Mo}$ × CF (1)	0.01	$STMR_{Mo}$ × CF (1)
Wheat grains	0.01	$STMR_{Mo}$ × CF (1)	0.01	$STMR_{Mo}$ × CF (1)
Sugar beet roots	0.01	$STMR_{Mo}$ × CF (1)	0.01	HR_{Mo} × CF (1)
Swine meat	0.007	0.8 × $STMR_{Mo}$ muscle + 0.2 × $STMR_{Mo}$ fat × CF (1)	0.019	0.8 × HR_{Mo} muscle + 0.2 × HR_{Mo} fat × CF (1)
Swine fat	0.033	$STMR_{Mo}$ × CF (1)	0.085	HR_{Mo} × CF (1)
Swine liver	0.002	$STMR_{Mo}$ × CF (1)	0.005	HR_{Mo} × CF (1)
Swine kidney	0.002	$STMR_{Mo}$ × CF (1)	0.003	HR_{Mo} × CF (1)
Bovine and equine meat	0.018	0.8 × $STMR_{Mo}$ muscle + 0.2 × $STMR_{Mo}$ fat × CF (1)	0.045	0.8 × HR_{Mo} muscle + 0.2 × HR_{Mo} fat × CF (1)
Bovine and equine fat	0.077	$STMR_{Mo}$ × CF (1)	0.207	HR_{Mo} × CF (1)
Bovine and equine liver	0.005	$STMR_{Mo}$ × CF (1)	0.012	HR_{Mo} × CF (1)
Bovine and equine kidney	0.004	$STMR_{Mo}$ × CF (1)	0.008	HR_{Mo} × CF (1)
Sheep and goat meat	0.014	0.8 × $STMR_{Mo}$ muscle + 0.2 × $STMR_{Mo}$ fat × CF (1)	0.051	0.8 × HR_{Mo} muscle + 0.2 × HR_{Mo} fat × CF (1)
Sheep and goat fat	0.060	$STMR_{Mo}$ × CF (1)	0.235	HR_{Mo} × CF (1)
Sheep and goat liver	0.004	$STMR_{Mo}$ × CF (1)	0.014	HR_{Mo} × CF (1)
Sheep and goat kidney	0.003	$STMR_{Mo}$ × CF (1)	0.009	HR_{Mo} × CF (1)
Poultry meat, fat, liver	0.01*	$STMR_{Mo}$ × CF (1)	0.01*	HR_{Mo} × CF (1)
Cattle and horse milk	0.006	$STMR_{Mo}$ × CF (1)	0.006	$STMR_{Mo}$ × CF (1)
Sheep and goat milk	0.003	$STMR_{Mo}$ × CF (1)	0.003	$STMR_{Mo}$ × CF (1)
Birds eggs	0.01*	$STMR_{Mo}$ × CF (1)	0.01*	HR_{Mo} × CF (1)

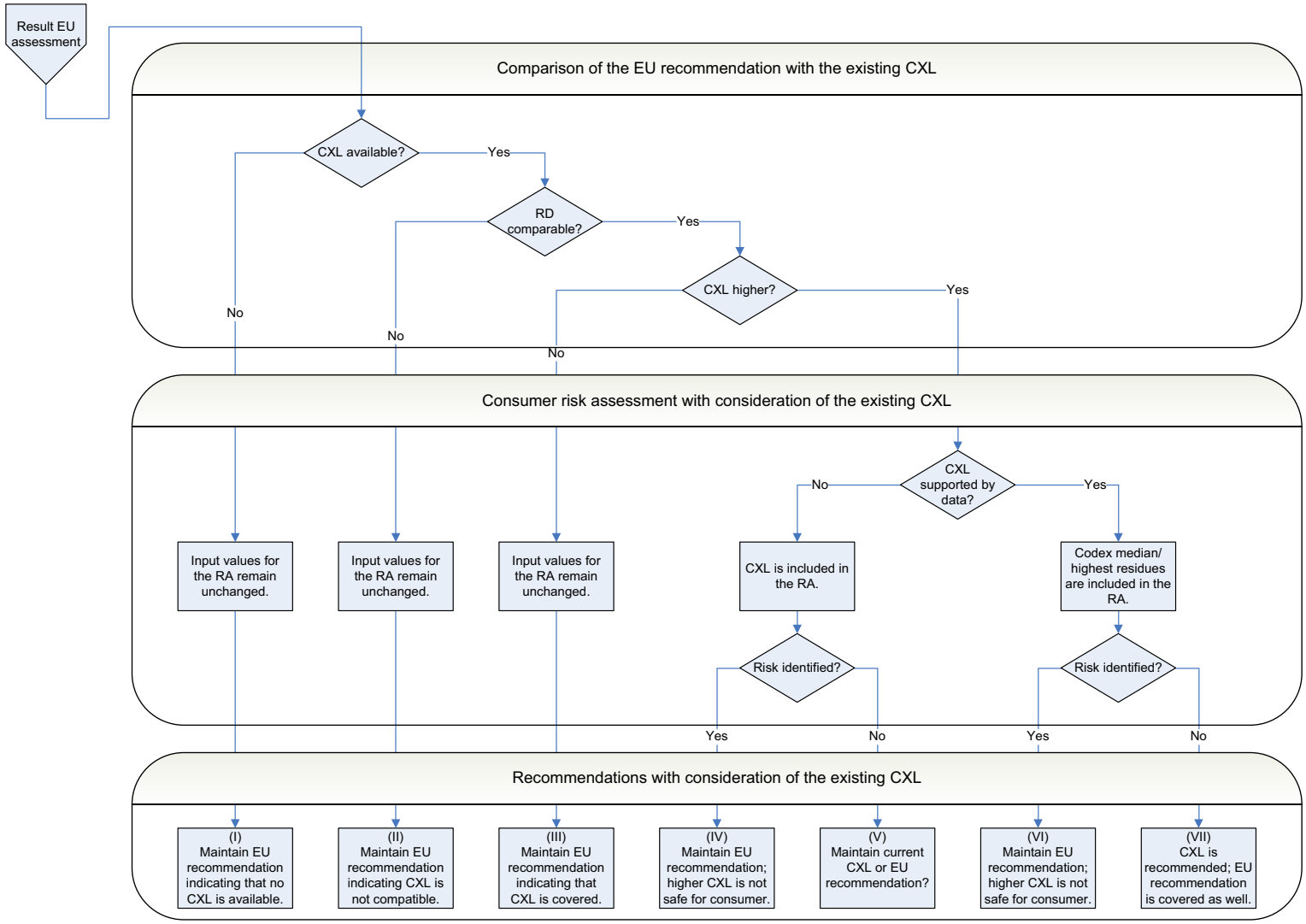
*Indicates that the input value is proposed at the limit of quantification.

[a]Figures in the table are rounded to two digits, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce a PRIMo calculation, the unrounded values need to be used.

APPENDIX E

Decision tree for deriving MRL recommendations

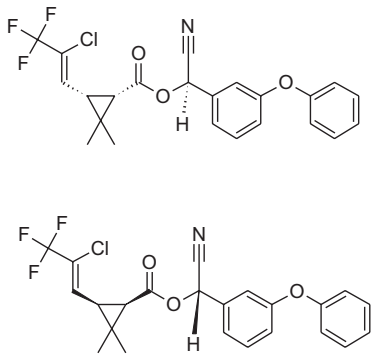
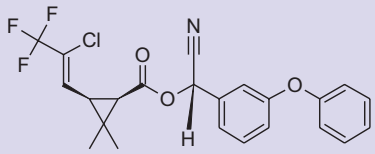
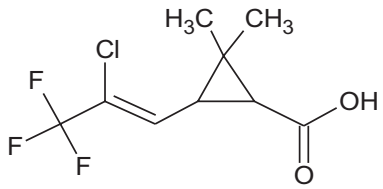
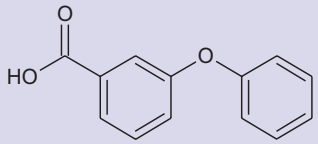
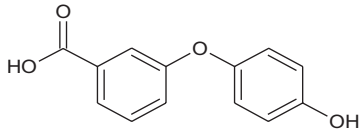
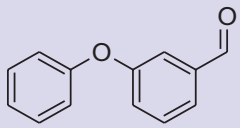



Result EU assessment
Comparison of the EU recommendation with the existing CXL
CXL available?
Yes
No
RD comparable?
Yes
No
CXL higher?
Yes
No
Consumer risk assessment with consideration of the existing CXL
CXL supported by data?
No
Yes
Input values for the RA remain unchanged.
Input values for the RA 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

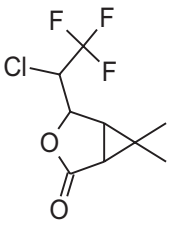
Used compound codes

It should be noted that lambda-cyhalothrin, gamma-cyhalothrin and the metabolites gamma-lactone (R947650) and CPCA a + Ib meet the definition of per- and polyfluoroalkyl substances (PFAS) based on their chemical structure (see: https://echa.europa.eu/en/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b; https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas).

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Lambda-cyhalothrin	reaction product comprising equal quantities of (R)-α-cyano-3-phenoxybenzyl (1S,3S)-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate and (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate Rothamsted-style stereodescriptors: reaction product comprising equal quantities of (R)-α-cyano-3-phenoxybenzyl (1S)-cis-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate and (S)-α-cyano-3-phenoxybenzyl (1R)-cis-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate Cl\C(=C/[C@@H]1[C@H](C(=O)O[C@@H](C#N)c2cccc(Oc3ccccc3)c2)C1(C)C)C(F)(F)F.FC(F)(F)C(/Cl)=C/[C@H]1[C@@H](C(=O)O[C@H](C#N)c2cccc(Oc3ccccc3)c2)C1(C)C BFPGVJIMBRLFIR-GUCBCRIZSA-N	
Gamma-cyhalothrin	(S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate Rothamsted-style stereodescriptors: (S)-α-cyano-3-phenoxybenzyl (1R)-cis-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate Cl\C(=C/[C@H]1[C@@H](C(=O)O[C@H](C#N)c2cccc(Oc3ccccc3)c2)C1(C)C)C(F)(F)F ZXQYGBMAQZUVMI-GCMPRSNUSA-N	
CPCA Ia + Ib	3-[(1Z)-2-chloro-3,3,3-trifluoroprop-1-en-1-yl]-2,2-dimethylcyclopropane-1-carboxylic acid SPVZAYWHHVLPBN-HYXAFXHYSA-N Cl\C(=C/C1C(C(=O)O)C1(C)C)C(F)(F)F	
PBA	3-phenoxybenzoic acid O=C(O)c1cc(Oc2ccccc2)ccc1 NXTDJHZGHOFSQG-UHFFFAOYSA-N	
PBA(OH) 4-OH-3PBA	3-(4-hydroxyphenoxy)benzoic acid O=C(O)c1cc(Oc2ccc(O)cc2)ccc1 OSGCDVKVZWMYBG-UHFFFAOYSA-N	
PBAld	3-phenoxybenzaldehyde O=Cc1cc(Oc2ccccc2)ccc1 MRLGCTNJRREZHZ-UHFFFAOYSA-N	

(Continues)

(Continued)

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Gamma-lactone (R947650)	(1RS,4RS,5SR)-4-[(1RS)-1-chloro-2,2,2-trifluoroethyl]-6,6-dimethyl-3-oxabicyclo[3.1.0]hexan-2-one (Unstated stereochemistry) CC1(C)C2C(=O)OC(C(Cl)C(F)(F)F)C21 ZSSZFVGRINYCPY-UHFFFAOYSA-N	

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

[a]The metabolite name in bold is the name used in the conclusion.

[b]ACD/Name 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 7 July 2021).

[c]ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 28 August 2021).