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

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Abstract
In compliance with Article 43 of Regulation (EC) No 396/2005, the European Food Safety Authority (EFSA) received from the European Commission a mandate to provide its reasoned opinion on the existing maximum residue levels (MRLs) for lambda-cyhalothrin which might lead to consumers intake concerns on the basis of the new toxicological reference values for gamma-cyhalothrin and of the data currently available to EFSA for lambda-cyhalothrin. In order to identify the MRLs of potential concern that require a more detailed assessment, EFSA performed a conservative risk assessment screening taking into account the crops for which MRLs were proposed in the framework of the Article 12 and the Article 43 of Regulation (EC) No 396/2005 reflecting the use of lambda-cyhalothrin and the new toxicological reference values for gamma-cyhalothrin.

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Keywords: lambda-cyhalothrin, gamma-cyhalothrin, Regulation (EC) No 396/2005, consumer risk assessment, pyrethroid, insecticide

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Summary

Lambda-cyhalothrin was included in Annex I to Directive 91/414/EEC on 1 January 2002 by Commission Directive 2000/80/EC, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. The European Food Safety Authority (EFSA) published a reasoned opinion on the review of the existing maximum residue levels (MRLs) for lambda-cyhalothrin in compliance with Article 12(2) of Regulation (EC) No 396/2005 on 24 January 2014. In the same period, lambda-cyhalothrin was evaluated for renewal of approval. The conclusion on the peer review of the pesticide risk assessment of the active substance was published shortly after the MRL review has been completed. In this conclusion, the lowering of the toxicological reference values was proposed. On 9 January 2015, EFSA received a mandate from the European Commission in accordance with Article 43 of Regulation (EC) No 396/2005 to revise the assessment of lambda-cyhalothrin taking into consideration the new toxicological reference values as noted by the Standing Committee on Plants, Animals, Food and Feed and the new data presented by Italy. EFSA published its reasoned opinion on the revision of the existing MRLs for lambdacyphalothrin on 2 December 2015. In EFSA assessments, the residue definition proposed for enforcement and risk assessment is ‘lambda-cyhalothrin (fat soluble)’, which is a 1:1 mixture of two of the four components of cyhalothrin, the $R,S$- and the $S,R$-isomers. The two isomers are not distinguishable with laboratory methods and the isomer $S,R$ alone constitutes the substance gamma-cyhalothrin.

Gamma-cyhalothrin is a new active substance that was approved on 1 April 2015 under Regulation (EC) No 1107/2009 by Commission Implementing Regulation (EU) No 1334/2014. EFSA published its conclusion on the peer review of the pesticide risk assessment of the active substance gamma-cyhalothrin on 11 February 2014. Considering that confirmatory data addressing data gaps identified in the peer review are currently being evaluated by the rapporteur Member State (RMS) (United Kingdom), the review of the existing MRLs for gamma-cyhalothrin in compliance with Article 12(2) of Regulation (EC) No 396/2005, has been postponed. Following the approval of gamma cyhalothrin in 2015, Member States have authorised uses for gamma-cyhalothrin. Lower toxicological reference values were derived for this active substance compared to lambda-cyhalothrin and the MRLs that will be established should be safe in respect of the use of gamma-cyhalothrin as active substance.

In compliance with Article 43 of Regulation (EC) No 396/2005, EFSA received from the European Commission a mandate to provide its reasoned opinion on the existing MRLs for lambda-cyhalothrin which might lead to consumers intake concerns on the basis of the lower toxicological reference values for gamma-cyhalothrin and of the data currently available to EFSA for lambda-cyhalothrin.

For this assessment, EFSA mainly relied on its previous reasoned opinions for lambda-cyhalothrin and its conclusions on the peer review of gamma- and lambda-cyhalothrin. The additional information provided by the European Union Reference Laboratories (EURLs) and by France during the Member State consultation was also considered. Furthermore, the residue data available in the recent JMPR Evaluation report and supporting the CXLs for cardamom legally implemented in the European Union (EU) legislation after the previous EFSA assessment on lambda-cyhalothrin under Article 43 of Regulation (EC) No 396/2005, were also considered.

In order to identify the MRLs of potential concern that require a more detailed assessment, both chronic and acute intake calculations were performed with revision 2 of the EFSA Pesticide Residues Intake Model by considering the MRLs and risk assessment values identified as safe in the previous EFSA assessment on lambda-cyhalothrin and the lower toxicological reference values for gamma-cyhalothrin. The MRL for cardamom legally implemented in the EU legislation after the previous EFSA assessment on lambda-cyhalothrin, were also included in the calculation.

Based on these theoretical calculations, EFSA identified 21 commodities that required a more detailed assessment in the framework of this mandate, as for these commodities a potential intake concern could not be excluded if the residues in these commodities would consist only of the more toxic gamma-cyhalothrin.

EFSA collected good agricultural practices (GAPs) and residue trials supporting the existing uses for gamma-cyhalothrin for the concerned commodities through a Member State consultation. Six commodities for which the potential acute intake concern is linked to the existing CXLs (i.e. bovine fat, aubergines, swine meat, plums, onions and swine fat) were not included in the request since the proposed lambda-cyhalothrin MRLs are not based on EU uses.
According to the information submitted to EFSA, among the different commodities possibly of concern, gamma-cyhalothrin is authorised for use on table grapes only. For the notified GAP of gamma-cyhalothrin in table grapes, residue trials performed in southern European Union (SEU) were submitted; all trials were overdosed compared to the authorised GAP (performed with six applications at 9-11 g/ha instead of three applications at 6 g/ha) allowing to derive only tentative MRL and risk assessment values.

A restricted acute and chronic risk assessment for lambda-cyhalothrin was then calculated on the basis of the risk assessment performed by EFSA in 2015, including the tentative risk assessment values for table grapes reflecting the gamma-cyhalothrin use and the relative potency factor for gamma-cyhalothrin (relative potency factor = 2). Based on this tentative risk assessment, chronic and acute intake concerns were not identified.

It is noted that this assessment does not replace the full MRL review for all authorised uses of gamma-cyhalothrin; as soon as the confirmatory data identified in the framework of the peer review have been provided, a full MRL review in accordance with Article 12(2) of Regulation (EC) No 396/2005 needs to be performed.
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1. **Introduction**

1.1. **Background and Terms of Reference as provided by the requestor**

On 2 December 2015, the European Food Safety Authority (EFSA) published its reasoned opinion on the revision of the existing maximum residue levels (MRLs) for lambda-cyhalothrin (EFSA, 2015).

The residue definition of the substance for enforcement and risk assessment proposed in the EFSA document is ‘lambda-cyhalothrin (fat soluble)’, which is a 1:1 mixture of two of the four components of cyhalothrin, the \( R,S \)- and the \( S,R \)-isomers. The two isomers are not distinguishable with laboratory methods and the isomer \( S,R \) alone constitutes the substance gamma-cyhalothrin.

This means that the proposed residue definition for lambda-cyhalothrin, if accepted, will also cover the substance gamma-cyhalothrin. Following the approval of gamma-cyhalothrin in 2015, Member States have authorised uses for gamma-cyhalothrin. Lower toxicological reference values were derived for this active substance compared to lambda-cyhalothrin and the MRLs that will be established should be safe in respect of the use of gamma-cyhalothrin as active substance.

Following discussions between the Commission services and EFSA experts, it was agreed that the full review under Article 12(2) of Regulation (EC) No 396/2005\(^1\) will only be carried out once the outstanding confirmatory data identified in the peer review of gamma-cyhalothrin (EFSA, 2014b) are available. A preliminary risk assessment provided by EFSA experts indicated that if gamma-cyhalothrin was used at levels equivalent to lambda-cyhalothrin uses, there could be an intake concern for some commodities, since the toxicological reference values are lower for gamma-cyhalothrin.

It is likely that the good agricultural practices (GAPs) authorised for gamma-cyhalothrin are used at lower application rates and that lower MRLs would be needed to cover these uses. However, this assumption should be confirmed by assessing the existing uses on gamma-cyhalothrin relevant for the concerned commodities.

As a pragmatic approach and in order to enable the European Commission to propose appropriate MRLs without undue delay, EFSA was requested to deliver a reasoned opinion in accordance with Article 43 of Regulation (EC) No 396/2005 on gamma-cyhalothrin uses relevant for the concerned commodities.

This opinion should present both sets of MRLs: those derived from existing GAPs of lambda-cyhalothrin, as well as possible fall-back GAPs [see previous reasoned opinion on lambda-cyhalothrin (EFSA, 2015)] and those derived from existing GAPs for gamma-cyhalothrin on the crops for which a concern was identified in the preliminary risk assessment, as well as possible fall-back GAPs.

Where the GAPs for lambda- and gamma-cyhalothrin result in different MRLs derived for the same commodity when using the OECD calculator, this should be flagged and left for consideration of risk managers. It would also be helpful to highlight which MRLs and fall-back MRLs for lambda-cyhalothrin could be of concern, if exposure was calculated with existing uses for lambda-cyhalothrin and the lower toxicological reference values for gamma-cyhalothrin (e.g. in case of possible misuse).

In order to have the necessary data, EFSA should invite Member States to submit all the GAPs on the crops for which a concern was identified in the preliminary risk assessment related to gamma-cyhalothrin containing plant protection products which have been authorised or are under assessment for being authorised.

On the basis of the submitted GAPs, EFSA should identify the critical GAPs and assess whether the critical GAPs for gamma-cyhalothrin will lead to gamma-cyhalothrin residues in food or feed that may lead to consumer intake risks. If the critical GAPs cause consumer health risks, possible fall-back GAPs for gamma-cyhalothrin should be assessed. The European Commission shared all relevant information with EFSA.

1.2. **Interpretation of the Terms of Reference**

In the letter accepting the mandate, EFSA outlined how the Terms of Reference provided by the requestor will be addressed. The methodology is described in detail in Section 2.2.

\(^1\) Regulation (EC) No 396/2005 of the 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.
1.3. Regulatory information on the active substances lambda-cyhalothrin and gamma-cyhalothrin

1.3.1. Lambda-cyhalothrin

Lambda-cyhalothrin is the ISO common name for the 1:1 mixture of (R)-a-cyano-3-phenoxybenzyl (1S,3S)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (S)-a-cyano-3-phenoxybenzyl (1R,3R)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate (IUPAC). The molecular structure can be found in Appendix D.

Lambda-cyhalothrin was included in Annex I to Directive 91/414/EEC on 1 January 2002 by Commission Directive 2000/80/EC, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011.

In 2014, EFSA published a reasoned opinion on the review of the existing MRLs for lambda-cyhalothrin in compliance with Article 12(2) of Regulation (EC) No 396/2005 (EFSA, 2014a).

In the same period, lambda-cyhalothrin was evaluated for renewal of approval. The conclusion on the peer review of the pesticide risk assessment of the active substance was published shortly after the MRL review has been completed (EFSA, 2014c). In this conclusion, the lowering of the toxicological reference values [acceptable daily intake (ADI) and acute reference dose (ARfD)] was proposed (see Table 1).

On 9 January 2015, EFSA received a mandate from the European Commission in accordance with Article 43 of Regulation (EC) No 396/2005 to revise the assessment of lambda-cyhalothrin taking into consideration the new toxicological reference values as noted by the Standing Committee on Plants, Animals, Food and Feed (European Commission, 2015) and the new data presented by Italy. EFSA published its reasoned opinion on the revision of the review of the existing MRLs for lambda-cyhalothrin on 2 December 2015 (EFSA, 2015). The recommended amendments of the existing European Union (EU) MRLs have not yet been legally implemented. Following the adoption of CXLs by the Codex Alimentarius Commission in July 2016, a new MRL for cardamom was recently legally implemented by means of Commission Regulation (EU) No 2017/626.

The residue definition for enforcement and risk assessment in plant and livestock has been proposed as lambda-cyhalothrin (EFSA, 2014c). The current enforcement residue definition in Regulation (EC) No 396/2005 is lambda-cyhalothrin.

1.3.2. Gamma-cyhalothrin

Gamma-cyhalothrin is the ISO common name for (S)-a-cyano-3-phenoxybenzyl (1R,3R)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate (IUPAC), representing the isomer S,R contained in lambda-cyhalothrin. The molecular structure can be found in Appendix D.

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2 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 9.8.1991, p. 1–32, as last amended.

3 Commission Directive 2000/80/EC of 4 December 2000 amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market, so as to consolidate that Annex and include a further active substance (lambda-cyhalothrin). OJ L 309, 9.12.2000, p. 14–23.

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 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, difenconazole, ethephon, fluometuron, flutriafol, fluopyram, imazapic, imazapyr, lambda-cyhalothrin, mesotrione, profenofos, procymidine, pyrimethanil, spirotetramat, tebuconazole, triadimefon and trifloxystrobin in or on certain products. OJ L 96, 7.4.2017, p. 1–43.
Gamma-cyhalothrin is a new active substance that was approved on 1 April 2015 under Regulation (EC) No 1107/2009 by Commission Implementing Regulation (EU) No 1334/2014. EFSA published its conclusion on the peer review of the pesticide risk assessment of the active substance gamma-cyhalothrin on 11 February 2014 (EFSA, 2014b).

Considering that confirmatory data addressing data gaps identified in the peer review are currently being evaluated by the rapporteur Member State (RMS) (United Kingdom), the review of the existing MRLs for gamma-cyhalothrin in compliance with Article 12(2) of Regulation (EC) No 396/2005, has been postponed.

The EU MRLs for gamma-cyhalothrin are currently set at the default MRL of 0.01 mg/kg according to Article 18(1)(b) of the Regulation (EC) No 396/2005. It should be highlighted that analytical methods that would routinely allow the enforcement of a residue definition of gamma-cyhalothrin are currently unavailable (see Section 1.3.4).

Following approval of gamma-cyhalothrin, authorisations for gamma-cyhalothrin were granted by several EU Member States. Since the new uses for gamma-cyhalothrin did not require an amendment of the legal limits set for lambda-cyhalothrin, MRL applications in accordance with Article 6 of Regulation (EC) No 396/2005 were not considered necessary by the Member States granting the authorisations.

1.3.3. Toxicological reference values for lambda-cyhalothrin and gamma-cyhalothrin

The mammalian toxicology of lambda-cyhalothrin was discussed together with gamma-cyhalothrin at the Pesticides Peer Review Experts Meeting 108 in November 2013. Under the peer review, it was concluded that gamma-cyhalothrin (primarily a single isomer) is the biologically most active isomer of cyhalothrin (which is constituted by four isomers) and lambda-cyhalothrin (which is constituted by two isomers), representing the toxicologically active component of cyhalothrin’s isomers. Moreover, toxicokinetics and metabolism of gamma-cyhalothrin, cyhalothrin and lambda-cyhalothrin were considered unlikely to be different (EFSA, 2014b).

Based on the available toxicity studies, the following toxicological reference values were derived by EFSA during the peer reviews (see Table 1).

**Table 1:** Overview of the toxicological reference values

| Source | Year | Value          | Study                                      | Uncertainty factor |
|--------|------|----------------|--------------------------------------------|--------------------|
| **Lambda-cyhalothrin** |      |                |                                            |                    |
| ADI    | EFSA | 2014c         | 0.0025 mg/kg bw per day                    | Multigeneration study in rat (performed with cyhalothrin) | 200<sup>a</sup> |
| ARFD   | EFSA | 2014c         | 0.005 mg/kg bw                            | 1-year study in dog (performed with lambda-cyhalothrin) | 100                |
| **Gamma-cyhalothrin** |      |                |                                            |                    |
| ADI    | EFSA | 2014b         | 0.0012 mg/kg bw per day                    | Multigeneration study in rat (performed with cyhalothrin) | 400<sup>b</sup> |
| ARFD   | EFSA | 2014b         | 0.0025 mg/kg bw                            | 1-year study in dog (performed with lambda-cyhalothrin) | 200<sup>c</sup> |

ADI: acceptable daily intake; ARFD: acute reference dose; bw: body weight.

(a): Additional uncertainty factor of 2 to convert from cyhalothrin to lambda-cyhalothrin.

(b): Additional uncertainty factor of 4 to convert from cyhalothrin to gamma-cyhalothrin.

(c): Additional uncertainty factor of 2 to convert from lambda- to gamma-cyhalothrin.

Thus, on the basis of the assessment, a relative potency factor of 2 can be used for acute and chronic risk assessment to take into account the hazard contribution of gamma-cyhalothrin to lambda-cyhalothrin.

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<sup>a</sup> 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.
1.3.4. Analytical methods for enforcement of MRLs for lambda-cyhalothrin and gamma-cyhalothrin

Analytical methods are available to enforce the current residue definition set for lambda-cyhalothrin; the Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) multiresidue method [gas chromatography–mass spectrometry (GC–MS)] and the multiresidue method using liquid chromatography–tandem mass spectrometry (LC–MS/MS) were considered sufficiently validated for plant commodities at the limit of quantification (LOQ) of 0.01 mg/kg in each commodity group and the multi-residue method DFG S19 (GC–MS) was considered appropriate for monitoring lambda-cyhalothrin in animal commodities with a LOQ of 0.01 mg/kg in muscle, liver, kidney, fat, milk and eggs (EFSA, 2014c).

For gamma-cyhalothrin, several analytical methods were proposed for monitoring residues in commodities of plant and animal origin. A multiresidue method DFG S19 [gas chromatography with electron capture detector (GC-ECD) and GC–MS or gas chromatography with tandem mass spectrometry (GC–MS/MS)] with a LOQ of 0.01 mg/kg was considered sufficiently validated in each plant commodity group. The multiresidue method DFG S19 (LC–MS/MS) was considered appropriate for monitoring in food and feed of animal origin with a LOQ of 0.01 mg/kg in muscle, liver, kidney, fat, milk and eggs. However, the analytical methods proposed are not specific for gamma-cyhalothrin; they do not allow distinguishing between gamma-cyhalothrin (1R, cis, Z,S enantiomer alone) and lambda-cyhalothrin. For this reason, the peer review suggested to define the residue for monitoring in plants and animal commodities as sum of gamma-cyhalothrin and its enantiomer (any ratio of constituent enantiomers of lambda-cyhalothrin) (EFSA, 2014b).

It is noted that, according to the applicant for gamma-cyhalothrin, a normal phase high-performance liquid chromatography with ultraviolet detection (HPLC-UV) (225 nm) method, using a chiral o-phenylglycine column, is available. If it is decided to amend the residue definition for monitoring, covering only gamma-cyhalothrin, method validation data could be provided (EFSA, 2014b).

According to the information received in the framework of this focussed assessment by the European Union Reference Laboratories (EURLs), in routine laboratories lambda-cyhalothrin is typically analysed using GC-based methods in high water content, high acid content, high oil content and dry commodities with an LOQ of 0.01 mg/kg. Validation data generated by EURLs indicate that lambda-cyhalothrin can be enforced in commodities of animal origin (validated in muscle and eggs) with an LOQ of 0.005 mg/kg. In milk, however, the validation at 0.005 mg/kg and 0.1 mg/kg failed. Therefore, no LOQ could be proposed by the EURLs for this commodity group for the time being (EURLs, 2017).

No validation data on gamma-cyhalothrin is available to the EURLs, neither in commodities of plant origin nor in commodities of animal origin. Moreover, EURLs confirmed that lambda- and gamma-cyhalothrin cannot be measured separately using standard GC columns used in routine laboratories (EURLs, 2017).

Additional information was reported by the EURLs:

- Lambda-cyhalothrin gives normally one peak in GC with a small second peak being formed due to isomerisation within the GC (ranging between 2% and 20% depending on matrix and instrument conditions).
- Gamma-cyhalothrin gives one peak in GC with a small second peak being formed due to isomerisation within the GC (ranging between 2% and 20% depending on matrix and instrument conditions).
- Lambda-cyhalothrin and gamma-cyhalothrin show similar behaviour during GC analysis. They both can be used as analytical standards for each other. Using matrix-matched procedures quantification gives acceptable results even if only evaluating the main peak and neglecting the smaller second peak formed within the GC.
- Cyhalothrin⁹ gives two peaks in GC (separating the two enantiomeric pairs of the diastereomers). Both peaks show similar peak areas.
- Residues of cyhalothrin can be distinguished from lambda- and/or gamma-cyhalothrin, as cyhalothrin gives two peaks.

⁹ Cyhalothrin, a mixture of 2 enantiomeric pairs of diastereoisomers ([1R,cis,Z,S'], [1S,cis,Z,R'], [1R,cis,Z,R'] and [1S,cis,Z,S']) in a similar proportion (25:25:25:25), is no longer approved in the EU.
2. Data and methodologies

2.1. Data

EFSA has based its assessment on the previous reasoned opinion on the revision of the review of the existing MRLs for lambda-cyhalothrin under Art. 43 (EFSA, 2015), the conclusion on the peer review of the pesticide risk assessment of gamma-cyhalothrin (EFSA, 2014b), the conclusion on the peer review of the pesticide risk assessment of lambda-cyhalothrin (EFSA, 2014c) and the evaluation reports submitted during the consultations of Member States in the framework of this Art. 43 assessment (EURLs, 2017; France, 2017; Italy, 2017). Furthermore, the residue data available in the recent JMPR report (FAO, 2015), supporting the CXL for cardamom legally implemented in the EU legislation after the previous EFSA assessment on lambda-cyhalothrin under Article 43 of Regulation (EC) No 396/2005, were also considered.

2.2. Methodology

In order to address the Terms of Reference, EFSA proposed in its acceptance letter to use the following approach which can be outlined in four subsequent assessment steps:

- **Step 1** – Screening for MRLs that should be further assessed in view of potential consumer health risks: With a risk assessment screening, commodities were identified for which the lambda-cyhalothrin MRLs proposed by EFSA in the most recent assessment of lambda-cyhalothrin (EFSA, 2015) may not be sufficiently protective for EU consumers, if the residues would consist of the more toxic gamma-cyhalothrin. The CXL for cardamom taken over in the EU legislation by Regulation (EU) No 2017/626 was included as well. For this risk assessment, screening EFSA used the toxicological reference values derived for gamma-cyhalothrin and the MRLs and risk assessment values derived for lambda-cyhalothrin.

- **Step 2** – Collection of existing GAPs for gamma-cyhalothrin: The results of the risk assessment screening were circulated to all Member States on 9 February 2017, who were invited to submit to EFSA all existing GAPs for gamma-cyhalothrin and the supporting residue trials on the crops for which a potential concern was identified with the risk assessment screening described in Step 1. In addition, Member States were asked to inform EFSA on ongoing authorisation processes related to the commodities concerned. Member States were granted a 6 weeks period for this consultation.

- **Step 3** – Restricted risk assessment for lambda-cyhalothrin (considering authorised uses of gamma-cyhalothrin and the higher potency of gamma-cyhalothrin): On the basis of the submitted GAPs and supporting residue trials, EFSA assessed whether the critical GAPs for gamma-cyhalothrin lead to residues in food or feed that may lead to consumer intake risks. For this restricted risk assessment, EFSA included in the risk assessment performed under the previous assessment on lambda-cyhalothrin, MRLs and risk assessment values derived from the existing GAPs for gamma-cyhalothrin collected under step 2.

- **Step 4** – If relevant, identification of alternative GAPs for gamma-cyhalothrin: Less critical GAPs for gamma-cyhalothrin should be identified (fall-back GAPs) if the restricted risk assessment for the gamma-cyhalothrin uses described under step 3 lead to an exceedance of the toxicological reference value of gamma-cyhalothrin. For the fall-back GAPs, the supporting residue data should be assessed to derive the respective MRL proposals and risk assessment values.

Based on the data received from the Member States, EFSA was asked to prepare two lists of MRLs:

1) MRLs for lambda-cyhalothrin derived from the uses of lambda-cyhalothrin and including the CXLs, highlighting those MRLs that would pose a consumer health risk if the residues were related to the more toxic gamma-cyhalothrin. This list comprises the commodities identified in the risk assessment screening described under step 1.

2) MRLs for lambda-cyhalothrin reflecting the existing uses of gamma-cyhalothrin that do not pose a consumer health concern. This list of MRLs should be based on the assessment described in steps 2, 3 and 4.

It is noted that the assessment has been focussing only on the uses of gamma-cyhalothrin possibly of concern according to the risk assessment screening. All other gamma-cyhalothrin uses and the related MRLs for plant and animal commodities will be assessed under the framework of the MRL
review under Article 12(2) of the Regulation (EC) No 396/2005 once the assessment of the outstanding confirmatory data on gamma-cyhalothrin is available.

The draft reasoned opinion was shared on 7 June 2017 with the European Commission in order to allow a first discussion in the Standing Committee on Pesticides Residues on 12–13 June 2017. The comments received from Member States on the draft reasoned opinion were also reported in the Member State consultation report (EFSA, 2017) and considered for the finalisation of the reasoned opinion.

3. Assessment

3.1. Screening for MRLs to be assessed in view of potential consumer health risks

In order to identify the MRLs of potential concern that require a more detailed assessment, both chronic and acute intake calculations were performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo) (EFSA, 2007) by considering the MRLs and risk assessment values identified as safe in the previous EFSA assessment on lambda-cyhalothrin (EFSA, 2015) and the lower toxicological reference values for gamma-cyhalothrin (EFSA, 2014b). The MRL for cardamom legally implemented in the EU legislation after the previous EFSA assessment on lambda-cyhalothrin, were also included in the calculation.

Based on these theoretical calculations, EFSA identified 21 commodities that required a more detailed assessment in the framework of this mandate, as for these commodities a potential intake concern could not be excluded if the residues in these commodities would consist only of the more toxic gamma-cyhalothrin. An overview of these commodities with potential concern is presented in Table 2. It is noted that for six of the 21 commodities listed in Table 2 the risk assessment values were related to CXLs assessed by EFSA in 2015.

Apart from the acute intake calculations, EFSA also calculated the residue concentration that would lead to an intake equivalent to 100% of the ARfD (threshold level).

It should be stressed that the results presented in Table 2 do not contradict the previous EFSA risk assessment performed for lambda-cyhalothrin (EFSA, 2015). If the residues consist of lambda-cyhalothrin, the expected exposure would not exceed the toxicological reference values applicable for lambda-cyhalothrin. Detailed results of this calculation are also reported in Section E.1 in Appendix E.

Table 2: Commodities identified with risk assessment screening to be further assessed under the current mandate

| Commodity         | Input value considered in the risk assessment; source of the input values (mg/kg) | Acute intake (mg/kg) | Threshold level (mg/kg)(a) | Acute intake (mg/kg)(a) | Threshold level (mg/kg)(a) |
|-------------------|----------------------------------------------------------------------------------|----------------------|---------------------------|------------------------|---------------------------|
| Spinnach          | 0.22 (HR, EU GAP)                                                               | 199                  | 0.11                      | 79                     | –                         |
| Apples            | 0.05 (HR, EU GAP)                                                               | 196                  | 0.02                      | 45                     | –                         |
| Chinese cabbage   | 0.13 (HR, EU GAP)                                                               | 193                  | 0.06                      | 186                    | 0.07                      |
| Head cabbage      | 0.09 (HR, EU GAP)                                                               | 190                  | 0.04                      | 114                    | 0.07                      |
| Cauliflower       | 0.07 (HR, EU GAP)                                                               | 185                  | 0.03                      | 89                     | –                         |
| Pears             | 0.05 (HR, EU GAP)                                                               | 182                  | 0.02                      | 43                     | –                         |
| Bovine: Fat       | 2.2 (HR, CXL)                                                                   | 182                  | 1.2                       | 59                     | –                         |
| Aubergines (egg plants) | 0.18 (HR, CXL)                                                                 | 180                  | 0.1                       | 179                    | 0.1                       |
Regarding the chronic calculations, the highest theoretical intake was calculated for Dutch children, representing 120% of the ADI and the main contributing crops already being listed in Table 2. Regarding all other MRLs and risk assessment values derived for lambda-cyhalothrin (including the new MRL for cardamom), acute intake calculations were below the ARfD (the highest being calculated for watermelons and representing 98% of the ARfD) and their contributions to the chronic exposure were found to be minor. These MRLs are therefore not considered to be of concern for European consumers and further action is not required pending the complete review of gamma-cyhalothrin under Article 12 (2) of Regulation (EC) No 396/2005.

### 3.2. Collection of existing GAPs for gamma-cyhalothrin

In the framework of a Member State consultation, EFSA collected GAPs and residue trials supporting the existing uses for gamma-cyhalothrin for the concerned commodities listed in Table 2; the six commodities for which the potential acute intake concern is linked to the existing CXLs (i.e. bovine fat, aubergines, swine meat, plums, onions and swine fat) were not included in the request since the proposed lambda-cyhalothrin MRLs are not based on EU uses.

By 23 March 2017, only one Member State reported gamma-cyhalothrin GAPs for one of the commodities under consideration, i.e. table grapes. According to the information submitted to EFSA, gamma-cyhalothrin is authorised for use on table grapes in France only. The detailed GAP is provided in Section A.2 in Appendix A. Thus, for table grapes a restricted risk assessment was considered necessary in the next step (see Section 3.3).

For none of the other commodities identified in the risk assessment screening (Table 2), GAP information was submitted. Assuming that the information provided to EFSA as regards the authorised

| Commodity                        | Input value considered in the risk assessment; source of the input values (mg/kg) | Children | Adults |
|----------------------------------|---------------------------------------------------------------------------------|----------|--------|
|                                  | Acute intake (% ARfD) | Threshold level (mg/kg)(a) | Acute intake (% ARfD) | Threshold level (mg/kg)(a) |
| Swine: Meat                     | 0.52 (HR, CXL)          | 177 | 0.29 | 104 | 0.5 |
| Onions                           | 0.11 (HR, CXL)          | 175 | 0.06 | 65  | –   |
| Peaches                          | 0.07 (HR, CXL)          | 166 | 0.04 | 49  | –   |
| Broccoli                         | 0.07 (HR, EU GAP)       | 163 | 0.04 | 60  | –   |
| Peppers                          | 0.06 (HR, EU GAP)       | 151 | 0.03 | 39  | –   |
| Plums                            | 0.1 (HR, EU GAP)        | 136 | 0.07 | 38  | –   |
| Table grapes                     | 0.05 (HR, CXL)          | 131 | 0.03 | 64  | –   |
| Scarole (broad-leaf endive)      | 0.035 (HR, EU GAP)      | 122 | 0.02 | 12  | –   |
| Melons                           | 0.02 (HR, EU GAP)       | 121 | 0.01 | 32  | –   |
| Tomatoes                         | 0.05 (HR, EU GAP)       | 116 | 0.04 | 30  | –   |
| Wild fungi                       | 0.23 (HR, EU GAP)       | 116 | 0.19 | 92  | –   |
| Courgettes                       | 0.06 (HR, EU GAP)       | 112 | 0.05 | 65  | –   |
| Swine: Fat free of lean meat     | 2.2 (HR, CXL)           | 110 | 1.99 | 126 | 1.75 |

ARfD: acute reference dose; HR: highest residue; GAP: good agricultural practice; CXL: codex maximum residue limit.

(a): Value is derived by inverse modelling where the residue concentration is calculated that would lead to an intake calculation equivalent to 100% of the ARfD.
uses and uses that are currently under the authorisation process for gamma-cyhalothrin is complete, the existing MRLs for lambda-cyhalothrin (reflecting the use of lambda-cyhalothrin only) are not likely to pose a consumer health risk. However, in case of misuses of gamma-cyhalothrin, leading to gamma-cyhalothrin residues above the threshold residue concentration reported in Table 2, a consumer health risk cannot be excluded.

3.3. Restricted risk assessment for lambda-cyhalothrin (considering authorised use for gamma-cyhalothrin)

3.3.1. Acute risk assessment

For the notified GAP of gamma-cyhalothrin in table grapes, residue trials performed in southern European Union (SEU) were submitted; all trials were overdosed compared to the authorised GAP, being performed with six applications at 9–11 g/ha instead of three applications at 6 g/ha. The residue data submitted by France are summarised in Appendix B. No residue trials performed in northern European Union (NEU) are available.10

Considering the lack of residue trials matching the approved use, only a tentative MRL proposal and risk assessment values could be derived for the SEU use of gamma-cyhalothrin (MRL of 0.02 mg/kg; highest residue (HR) and supervised trials median residue (STMR) values of 0.02 mg/kg and 0.01 mg/kg, respectively).

A full data set compliant with the GAP needs to be provided. It is proposed to address this data gap under the Article 12 review of gamma-cyhalothrin.

The acute intake calculation based on the above mentioned residue data are summarised in Table 3. Based on the tentative risk assessment no exceedance of the ARfD was identified.

Table 3: Tentative acute risk assessment for lambda-cyhalothrin based on the reported existing EU uses for gamma-cyhalothrin

| Commodity       | Input value considered in the risk assessment (mg/kg) | Children | Adults |
|-----------------|------------------------------------------------------|----------|--------|
| Table grapes    | 0.04 (HR gamma-cyhalothrin × potency factor of 2), SEU GAP | 52%      | 25%    |

ARfD: acute reference dose; HR: highest residue; SEU: southern European Union; GAP: good agricultural practice.

3.3.2. Chronic risk assessment

The tentative chronic risk assessment for lambda-cyhalothrin was calculated on the basis of the risk assessment performed by EFSA in 2015 (EFSA, 2015), including the STMR for table grapes reflecting the gamma-cyhalothrin use and the relative potency factor for gamma-cyhalothrin (relative potency factor = 2). The input values are summarised in Appendix C. According to this calculation, no chronic intake concern was identified. The detailed results of the restricted risk assessment are reported in Section E.2 in Appendix E.

3.4. Identification of alternative GAPs for gamma-cyhalothrin

This step outlined in the proposed methodology (see Section 2.2) was not required. No alternative GAPs for gamma-cyhalothrin had to be identified since the risk assessment performed under Section 3.3 did not exceed the toxicological reference values.

Conclusions and recommendations

The European Commission asked EFSA to review the MRL proposals for lambda-cyhalothrin derived in 2015 (EFSA, 2015) in view of potential consumer health risks, taking into account that:
• currently no validated analytical methods are available to distinguish between the more toxic residues of gamma-cyhalothrin and the residues of lambda-cyhalothrin that include residue components of reported lower toxicity (less active isomers),
• Member States have granted authorisations for uses of gamma-cyhalothrin that would not require higher legal limits than the MRLs proposed for lambda-cyhalothrin.

In total, 21 commodities were identified for which a short-term consumer health risk cannot be excluded if the food products comply with the proposed lambda-cyhalothrin MRLs derived in 2015, but contain residues of the more toxic gamma-cyhalothrin (see Table 4). Thus, uses of the more toxic active substance gamma-cyhalothrin leading to residues not exceeding the proposed MRLs for lambda-cyhalothrin could result in consumer health risks, lacking specific analytical methods.

**Table 4:** MRL proposals for lambda-cyhalothrin derived from the uses of lambda-cyhalothrin (including the CXLs) that would pose a consumer health risk in case the commodity contains gamma-cyhalothrin residues compliant with the proposed MRL, but at or above the threshold residue concentration (Summary Table 1)

| Code number | Product       | MRL proposal for lambda-cyhalothrin (EFSA, 2015) (mg/kg) | Threshold residue concentration (mg/kg) | Comment                                                                                                                                                                                                                                                                                                                                 |
|-------------|---------------|----------------------------------------------------------|----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 130010      | Apples        | 0.08                                                     | 0.02                                   | The proposed MRL is related to a NEU outdoor GAP of lambda-cyhalothrin (HR 0.05 mg/kg, STMR 0.02 mg/kg)<br>No GAP for gamma-cyhalothrin was reported to EFSA                                                                                                                                                                                                                     |
| 130020      | Pears         | 0.08                                                     | 0.02                                   | The proposed MRL is related to a NEU outdoor GAP of lambda-cyhalothrin (HR 0.05 mg/kg, STMR 0.02 mg/kg)<br>No GAP for gamma-cyhalothrin was reported to EFSA                                                                                                                                                                                                                     |
| 140030      | Peaches       | 0.15                                                     | 0.04                                   | The proposed MRL is related to a SEU outdoor GAP of lambda-cyhalothrin (HR 0.07 mg/kg, STMR 0.03 mg/kg)<br>No GAP for gamma-cyhalothrin was reported to EFSA                                                                                                                                                                                                                     |
| 140040      | Plums         | 0.2                                                      | 0.07                                   | The proposed MRL is related to a CXL (HR 0.1 mg/kg, STMR 0.02 mg/kg)<br>An alternative MRL proposal (fall-back MRL) of 0.06 mg/kg was derived by EFSA (2015), reflecting the most critical EU use (outdoor, NEU; HR 0.04 mg/kg, STMR 0.01 mg/kg)<br>No GAP for gamma-cyhalothrin was reported to EFSA                                                                                                                                                                    |
| 151010      | Table grapes  | 0.08                                                     | 0.03                                   | The proposed MRL is related to a SEU outdoor GAP of lambda-cyhalothrin (HR 0.07 mg/kg, STMR 0.03 mg/kg)<br>An authorisation for gamma-cyhalothrin in France was reported<br>The MRL proposal related to the approved French GAP is reported in Table 5                                                                                                                                                              |
| 220020      | Onions        | 0.2                                                      | 0.06                                   | The proposed MRL is related to a CXL (HR 0.11 mg/kg, STMR 0.05 mg/kg)<br>An alternative MRL proposal (fall-back MRL) of 0.06 mg/kg was derived by EFSA (2015), reflecting the most critical EU use (outdoor, NEU; HR 0.04 mg/kg, STMR 0.01 mg/kg)<br>No GAP for gamma-cyhalothrin was reported to EFSA                                                                                                                                                                    |
### Focussed MRL review of lambda-cyhalothrin

| Code number | Product      | MRL proposal for lambda-cyhalothrin (EFSA, 2015) (mg/kg) | Threshold residue concentration (mg/kg) | Comment                                                                                                                                                                                                 |
|------------|--------------|---------------------------------------------------------|-----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 231010     | Tomatoes     | 0.07                                                    | 0.04                                    | The proposed MRL is related to an indoor GAP of lambda-cyhalothrin (HR 0.05 mg/kg, STMR 0.02 mg/kg) No GAP for gamma-cyhalothrin was reported to EFSA                                                                 |
| 231020     | Peppers      | 0.1                                                     | 0.03                                    | The proposed MRL is related to a SEU outdoor GAP of lambda-cyhalothrin (HR 0.06 mg/kg, STMR 0.02 mg/kg) No GAP for gamma-cyhalothrin was reported to EFSA                                                                  |
| 231030     | Aubergines   | 0.3                                                     | 0.1                                     | The proposed MRL is related to a CXL (HR 0.18 mg/kg, STMR 0.03 mg/kg) An alternative MRL proposal (fall-back MRL) of 0.03 mg/kg was derived by EFSA (2015), reflecting the most critical EU use (indoor use, HR 0.02 mg/kg, STMR 0.01 mg/kg) No GAP for gamma-cyhalothrin was reported to EFSA |
| 232030     | Courgettes   | 0.15                                                    | 0.05                                    | The proposed MRL is related to a NEU outdoor GAP of lambda-cyhalothrin (HR 0.06 mg/kg, STMR 0.04 mg/kg) No GAP for gamma-cyhalothrin was reported to EFSA                                                                 |
| 233010     | Melons       | 0.06                                                    | 0.01                                    | The proposed MRL is related to a SEU outdoor GAP of lambda-cyhalothrin (HR 0.02 mg/kg, STMR 0.005 mg/kg, for the peeled product [peeling factor 0.5]) No GAP for gamma-cyhalothrin was reported to EFSA |
| 241010     | Broccoli     | 0.1                                                     | 0.04                                    | The proposed MRL is related to a NEU outdoor GAP of lambda-cyhalothrin (HR 0.07 mg/kg, STMR 0.02 mg/kg) No GAP for gamma-cyhalothrin was reported to EFSA                                                                  |
| 241020     | Cauliflower  | 0.1                                                     | 0.03                                    | The proposed MRL is related to a NEU outdoor GAP of lambda-cyhalothrin (HR 0.07 mg/kg, STMR 0.02 mg/kg) No GAP for gamma-cyhalothrin was reported to EFSA                                                                  |
| 242020     | Head cabbage | 0.15                                                    | 0.04                                    | The proposed MRL is related to a NEU outdoor GAP of lambda-cyhalothrin (HR 0.09 mg/kg, STMR 0.03 mg/kg) No GAP for gamma-cyhalothrin was reported to EFSA                                                                  |
| 243010     | Chinese cabbages | 0.3                                                  | 0.06                                    | The proposed MRL is related to a SEU outdoor GAP of lambda-cyhalothrin (HR 0.13 mg/kg, STMR 0.08 mg/kg) No GAP for gamma-cyhalothrin was reported to EFSA                                                                  |
| 251030     | Scarole      | 0.07                                                    | 0.02                                    | The proposed MRL is related to a NEU outdoor GAP of lambda-cyhalothrin (HR 0.04 mg/kg, STMR 0.02 mg/kg) No GAP for gamma-cyhalothrin was reported to EFSA                                                                  |
According to the information provided by Member States, gamma-cyhalothrin has been authorised for use only on one of the commodities under consideration, i.e. table grapes. For the approved use of gamma-cyhalothrin in table grapes, a tentative MRL proposal for lambda-cyhalothrin was derived (Table 5). The residue data supporting the use did not match with the GAP, but were all overdosed. Therefore the derived MRL and risk assessment values should be considered only tentative and should be confirmed by the following data:

- Full data set compliant with the SEU outdoor GAP for gamma-cyhalothrin on table grapes.

It is proposed to address the above mentioned data gap in the framework of the Article 12 review for gamma-cyhalothrin.

| Code number | Product          | MRL proposal for lambda-cyhalothrin (EFSA, 2015) (mg/kg) | Threshold residue concentration (mg/kg) | Comment                                                                                                                                                                                                 |
|-------------|------------------|---------------------------------------------------------|----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 252010      | Spinach          | 0.6                                                     | 0.11                                   | The proposed MRL is related to a SEU outdoor GAP of lambda-cyhalothrin (HR 0.22 mg/kg, STMR 0.2 mg/kg) No GAP for gamma-cyhalothrin was reported to EFSA                                                                 |
| 280020      | Wild fungi       | 0.5                                                     | 0.19                                   | The proposed MRL is related to a NEU outdoor GAP of lambda-cyhalothrin (HR 0.23 mg/kg, STMR 0.17 mg/kg) No GAP for gamma-cyhalothrin was reported to EFSA                                                                 |
| 1011010     | Swine muscle     | 0.15                                                    |                                        | The proposed MRL is related to a CXL (HR 0.52 mg/kg, STMR 0.23 mg/kg for meat) Considering only EU uses for feed commodities, an alternative MRL proposal (fall-back MRL) of 0.01 mg/kg was derived by EFSA (2015) (HR 0.07 mg/kg, STMR 0.03 mg/kg for meat) |
| 1011020     | Swine fat        | 3                                                       | 1.75                                   | The proposed MRL is related to a CXL (HR 2.2 mg/kg, STMR 1.0 mg/kg) Considering only EU uses for feed commodities, an alternative MRL proposal (fall-back MRL) of 0.3 mg/kg was derived by EFSA (2015) (HR 0.29 mg/kg, STMR 0.09 mg/kg) |
| 1012020     | Bovine fat       | 3                                                       | 1.2                                    | The proposed MRL is related to a CXL (HR 2.2 mg/kg, STMR 1.0 mg/kg) Considering only EU uses for feed commodities, an alternative MRL proposal (fall-back MRL) of 0.3 mg/kg was derived by EFSA (2015) (HR 0.71 mg/kg, STMR 0.21 mg/kg) |

MRL: maximum residue level; NEU: northern European Union; GAP: good agricultural practice; HR: highest residue; STMR: supervised trials median residue; SEU: southern European Union; CXL: codex maximum residue limit.
It is noted that the risk assessment performed in this reasoned opinion was focussed on the 21 products that were identified by the risk assessment screening. Thus, this assessment does not replace the full MRL review for all authorised uses of gamma-cyhalothrin; as soon as the confirmatory data identified in the framework of the peer review have been provided, a full MRL review in accordance with Article 12(2) of Regulation (EC) No 396/2005 needs to be performed.

Based on the focussed MRL review requested under the current mandate, EFSA derives the following conclusions.

- The information presented in this reasoned opinion should support risk management decision on the setting of sufficiently protective MRLs for lambda-cyhalothrin, complementing the previous assessments of EFSA performed in 2015 (EFSA, 2015).

EFSA recommends that:

- validated analytical methods should be developed that allow the discrimination between the more toxic gamma-cyhalothrin and the less toxic lambda-cyhalothrin. If a residue definition comprises different active substances with significantly different toxicological properties (e.g. the residue definition for lambda-cyhalothrin which covers also gamma-cyhalothrin), an unequivocal risk assessment is possible only if the individual components can be quantified separately. Lacking specific analytical enforcement methods, misuses of the more toxic active substance cannot be detected, if the gamma-cyhalothrin residues do not exceed the legal limits set on the basis of lambda-cyhalothrin. A possible risk management option is the setting of MRLs for lambda-cyhalothrin at a lower level (below the threshold residue concentration calculated by inverse modelling).

- Provided specific analytical methods are available for gamma-cyhalothrin, the default MRLs for gamma-cyhalothrin (Article 18(b)) should be replaced by gamma-cyhalothrin MRLs that reflect both, the authorised use of gamma- and lambda-cyhalothrin. These specific MRL proposals should be derived in the framework of the MRL review, taking into account uses of gamma- and lambda-cyhalothrin.

- Before granting authorisations for plant protection products containing gamma-cyhalothrin, a specific risk assessment for gamma-cyhalothrin needs to be performed. The fact that the intended uses for gamma-cyhalothrin do not lead to residues above the lambda-cyhalothrin MRLs is not sufficient to demonstrate the absence of a consumer health concern.

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Abbreviations

- a.i.: active ingredient
- ADI: acceptable daily intake
- ARfD: acute reference dose
- BBCH: growth stages of mono- and dicotyledonous plants
- bw: body weight
- CIPAC: Collaborative International Pesticide Analytical Council
- CS: capsule suspension
- CXL: codex maximum residue limit
- EC: emulsiﬁable concentrate
- EURLs: EU Reference Laboratories (former CRLs)
- FAO: Food and Agriculture Organisation of the United Nations
- GAP: good agricultural practice
- GC-ECD: gas chromatography with electron capture detector
- GC-MS: gas chromatography with mass spectrometry
- GC-MS/MS: gas chromatography with tandem mass spectrometry
- HPLC-UVD: high performance liquid chromatography with ultra-violet detector
- HR: highest residue
- ISO: International Organisation for Standardization
- IUPAC: International Union of Pure and Applied Chemistry
- JMPR: Joint FAO/WHO Meeting on Pesticide Residues
- LOQ: limit of quantification
- MRL: maximum residue level
- MS: Member States
- NEU: northern European Union
- OECD: Organisation for Economic Co-operation and Development
- PHI: pre-harvest interval
- PRIMo: (EFSA) Pesticide Residues Intake Model
| Acronym | Definition |
|---------|------------|
| QuEChERS | Quick, Easy, Cheap, Effective, Rugged, and Safe |
| RMS | rapporteur Member State |
| SC | suspension concentrate |
| SEU | southern European Union |
| SMILES | simplified molecular-input line-entry system |
| STMR | supervised trials median residue |
| WG | water-dispersible granule |
| WHO | World Health Organization |
Appendix A – Overview of GAPs

A.1. GAPs on lambda-cyhalothrin for which a risk to consumer cannot be excluded in cases of misuses of gamma-cyhalothrin

| Crop | Region | Member state or country | Pest controlled | Formulation | Method | Growth stage | Application | PHI or waiting period (days) | Comments (max. 250 characters) |
|------|--------|------------------------|-----------------|-------------|--------|--------------|-------------|-------------------------------|-------------------------------|
| Apples | NEU Outdoor | HU | Aphids, caterpillars | CS | 50 g/L | Foliar treatment – spraying | 1 2 8 15 g a.i./ha | 3 |
| Pears | NEU Outdoor | HU | Aphids, caterpillars | CS | 50 g/L | Foliar treatment – spraying | 1 2 8 15 g a.i./ha | 3 |
| Courgettes | NEU Outdoor | BE | Aphids, caterpillars | EC | 50 g/L | Foliar treatment – spraying | 1 2 10 g a.i./ha | 7 |
| Broccoli | NEU Outdoor | FR | Aphids | CS | 50 g/L | Foliar treatment – spraying | 1 2 10 g a.i./ha | 7 |
| Cauliflower | NEU Outdoor | FR | Aphids | CS | 50 g/L | Foliar treatment – spraying | 1 2 10 g a.i./ha | 7 |
| Head Cabbage | NEU Outdoor | BE | Aphids, Noctuidae | CS | 100 g/L | Foliar treatment – spraying | 1 2 12.5 g a.i./ha | 7 |
| Scarole (Broad-Leaf Endive) | NEU Outdoor | AT, BE | Aphids, Noctuidae | CS | 50 g/L | Foliar treatment – spraying | 11 1 2 12 7.5 g a.i./ha | 7 |
| Crop                          | Region | Pest controlled | Formulation | Application |
|------------------------------|--------|-----------------|-------------|-------------|
| **Critical outdoor GAPs for Northern Europe** |        |                 | Type | Content | Method | Growth stage | Number | Interval (days) | Rate | PHI or waiting period (days) | Comments (max. 250 characters) |
| Wild Fungi                   | NEU    | DE              | WG 50 g/kg | Foliar treatment – general (see also comment field) | 1 | 7.5 g a.i./ha | n.a. |

| Crop                          | Region | Pest controlled | Formulation | Application |
|------------------------------|--------|-----------------|-------------|-------------|
| **Critical outdoor GAPs for Southern Europe** |        |                 | Type | Content | Method | Growth stage | Number | Interval (days) | Rate | PHI or waiting period (days) | Comments (max. 250 characters) |
| Peaches                      | SEU    | Aphids, Caterpillars | WG 50 g/kg | Foliar treatment – spraying | 1 | 2 | 14 | 17.5 g a.i./ha | 7 |
| Table Grapes                 | SEU    | Aphids, Caterpillars | WG 50 g/kg | Foliar treatment – spraying | 1 | 2 | 7.5 | 20 g a.i./ha | 7 |
| Peppers                      | SEU    | Aphids | WG 50 g/kg | Foliar treatment – spraying | 1 | 2 | 12 | 20 g a.i./ha | 3 |
| Melons                       | SEU    | Aphids | WG 50 g/kg | Foliar treatment – spraying | 1 | 2 | 12 | 20 g a.i./ha | 3 |
### Critical Indoor GAPs for Northern and Southern Europe (incl. post-harvest treatments)

| Crop | Region | Pest controlled | Formulation | Application | PHI or waiting period (days) | Comments (max. 250 characters) |
|------|--------|-----------------|-------------|-------------|-------------------------------|--------------------------------|
| Tomatoes | EU Indoor FR | Aphids, Noctuidae | CS 50 g/L Foliar treatment – spraying | 81 2 10 20 g a.i./ha | 3 |

GAP: good agricultural practice; BBCH: growth stages of mono- and dicotyledonous plants; PHI: preharvest interval; NEU: northern European Union; SEU: southern European Union; CS: capsule suspension; EC: emulsifiable concentrate; WG: water-dispersible granule; a.i.: active ingredient.

### A.2. Existing GAPs on gamma-cyhalothrin relevant for the MRL possibly of concern

| Crop | Region | Pest controlled | Formulation | Application | PHI or waiting period (days) | Comments (max. 250 characters) |
|------|--------|-----------------|-------------|-------------|-------------------------------|--------------------------------|
| Table grapes | SEU Outdoor FR | Aphids, caterpillars | CS 60 g/L Foliar treatment – spraying | 73 85 1 3 14 6 g a.i./ha | 10 |

GAP: good agricultural practice; BBCH: growth stages of mono- and dicotyledonous plants; PHI: preharvest interval; SEU: southern European Union; CS: capsule suspension; a.i.: active ingredient.
Appendix B – Summary of residues data from the supervised residue trials for gamma-cyhalothrin

| Crop       | Region/Indoor\(^{(a)}\) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg)\(^{(b)}\) | STMR (mg/kg)\(^{(c)}\) |
|------------|--------------------------|-------------------------------------------------------------------------------------------------|---------------------------------------------|-----------------------|---------------------|---------------------|
| Table grapes | SEU                      | \(7 \times < 0.01, 6 \times 0.01, 0.02\)                                                      | Trials on grapes overdosed (performed at \(6 \times 9-11\) g/ha instead of \(3 \times 6\) g/ha) (France, 2017) used to derive a tentative MRL. MRL\(^{OECD}\): 0.02 | 0.02                  | 0.02                | 0.01                |

MRL: maximum residue level; GAP: good agricultural practice; OECD: Organisation for Economic Co-operation and Development.

* 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, Indoor: indoor EU trials or Country code: if non-EU trials.

\(^{(b)}\): Highest residue.

\(^{(c)}\): Supervised trials median residue.
### Appendix C – Input values for the risk assessment

| Commodity | Chronic risk assessment | Acute risk assessment |
|-----------|-------------------------|-----------------------|
|           | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Risk assessment residue definition: lambda-cyhalothrin |                      |                       |                      |                       |
| Table grapes | 0.01 STMR (EFSA, 2015) | (risk assessment screening, Section 3.1) | 0.05 HR (EFSA, 2015) | (risk assessment screening, Section 3.1) |
|            | 0.02 STMR (gamma-cyhalothrin) × potency factor of 2 (risk assessment Section 3.3) | 0.04 HR (gamma-cyhalothrin) × potency factor of 2 (risk assessment Section 3.3) |                      |                       |
| Other commodities of plant and animal origin | See Appendix C.3 EFSA, 2015 |                       |                      |                       |

STMR: supervised trials median residue; HR: highest residue.
### Appendix D – Used compound codes

| Code/trivial name       | Chemical name/SMILES notation                                                                 | Structural formula |
|-------------------------|-----------------------------------------------------------------------------------------------|-------------------|
| lambda-Cyhalothrin     | A 1:1 mixture of: (R)-α-cyano-3-phenoxybenzyl (1S,3S)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate or a 1:1 mixture of: (R)-α-cyano-3-phenoxybenzyl (1S)-cis-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (S)-α-cyano-3-phenoxybenzyl (1R)-cis-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate | ![Formula](image1.png) |
| gamma-Cyhalothrin      | (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-dimethylcyclopropanecarboxylate | ![Formula](image2.png) |
| Cyhalothrin            | (RS)-α-Cyano-3-phenoxybenzyl (1RS,3RS)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate or (RS)-α-Cyano-3-phenoxybenzyl (1RS)-cis-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate | ![Formula](image3.png) |

SMILES: simplified molecular-input line-entry system.

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Appendix E – Results from the risk assessment

E.1. Screening risk assessment

| Lambda- and gamma-cyhalothrin | Status of the active substance: | Proposed LOQ | Source of ADI | Source of ARfD |
|-------------------------------|--------------------------------|--------------|---------------|---------------|
| ADI (mg/kg bw per day)        | 0.0012                         |              | EFSA          | EFSA          |
| LOQ (mg/kg bw)                | 0.0025                         |              |               |               |

| Code no. | LOQ (mg/kg bw) | ADI (mg/kg bw per day) | ARfD (mg/kg bw) | Year of evaluation | Source of ADI |
|----------|----------------|------------------------|-----------------|--------------------|---------------|
|          |                |                        |                 |                    |               |

Higher calculated TMDI values in % of ADI (minimum – maximum)

| Commodity/ group of commodities | MS Diets |
|---------------------------------|----------|
| 120.1 NL child                  | 25.8     |
| 111.0 WHO Cluster diet B        | 17.6     |
| 94.1 FR toddler                 | 33.0     |
| 79.2 DE child                   | 20.1     |
| 74.4 WHO regional European diet | 24.2     |
| 74.7 WHO diaster dist E         | 144.4    |
| 71.3 IE adult                   | 1.10     |
| 68.2 UK infant                  | 32.3     |
| 60.2 FR infant                  | 21.4     |
| 59.9 WHO Cluster diet F         | 23.3     |
| 59.5 UK Toddler                 | 18.1     |
| 52.7 NL general                 | 17.8     |
| 52.0 E child                    | 13.7     |
| 50.0 WHO diaster dist D         | 6.3      |
| 47.0 LT adult                   | 18.5     |
| 39.0 DK child                   | 10.5     |
| 38.3 SE general population      | 10.3     |
| 31.9 FR all population          | 6.7      |
| 30.5 PT General population      | 4.4      |
| 24.6 UK vegetarian              | 4.1      |
| 23.0 UK Adult                   | 4.5      |
| 20.7 IT kids toddler            | 5.5      |
| 20.5 DK adult                   | 4.5      |
| 19.2 IT adult                   | 3.4      |
| 15.6 PL adult                   | 4.7      |
| 14.7 PL general population      | 3.4      |

Conclusion:
The estimated Theoretical Maximum Daily intakes based on MS and WHO diets and pTMRs were in the range of 14.7% to 120% of the ADI.
For 2 diets, the ADI is exceeded. Further refinements of the dietary intake estimates have not been performed. A public health risk cannot be excluded at the moment.

Scenario performed considering EU uses and CXLs for lambda-cyhalothrin and the toxicological reference values derived for gamma-cyhalothrin.

Chronic risk assessment – refined calculations

| Commodity/ group of commodities | MS Diets |
|---------------------------------|----------|
| 120.1 NL child                  | 25.8     |
| 111.0 WHO Cluster diet B        | 17.6     |
| 94.1 FR toddler                 | 33.0     |
| 79.2 DE child                   | 20.1     |
| 74.4 WHO regional European diet | 24.2     |
| 74.7 WHO diaster dist E         | 144.4    |
| 71.3 IE adult                   | 1.10     |
| 68.2 UK infant                  | 32.3     |
| 60.2 FR infant                  | 21.4     |
| 59.9 WHO Cluster diet F         | 23.3     |
| 59.5 UK Toddler                 | 18.1     |
| 52.7 NL general                 | 17.8     |
| 52.0 E child                    | 13.7     |
| 50.0 WHO diaster dist D         | 6.3      |
| 47.0 LT adult                   | 18.5     |
| 39.0 DK child                   | 10.5     |
| 38.3 SE general population      | 10.3     |
| 31.9 FR all population          | 6.7      |
| 30.5 PT General population      | 4.4      |
| 24.6 UK vegetarian              | 4.1      |
| 23.0 UK Adult                   | 4.5      |
| 20.7 IT kids toddler            | 5.5      |
| 20.5 DK adult                   | 4.5      |
| 19.2 IT adult                   | 3.4      |
| 15.6 PL adult                   | 4.7      |
| 14.7 PL general population      | 3.4      |

Conclusion:
The estimated Theoretical Maximum Daily intakes based on MS and WHO diets and pTMRs were in the range of 14.7% to 120% of the ADI.
For 2 diets, the ADI is exceeded. Further refinements of the dietary intake estimates have not been performed. A public health risk cannot be excluded at the moment.
The acute risk assessment is based on the ARfD.

For each commodity, calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS, with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

No of critical MRLs (IESTI 1): 21

No of critical MRLs (IESTI 2): 18

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The acute risk assessment/children – refined calculations

 acute risk assessment/adults/general population – refined calculations

The estimated short-term intake (IESTI 1) exceeded the ARfD/ADI for 21 commodities.

For processed commodities, the ARfD/ADI was exceeded in one or several cases.

For lambda- and gamma-cyhalothrin, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No of commodities for which ARfD/ADI is exceeded (IESTI 1): 21

No of commodities for which ARfD/ADI is exceeded (IESTI 2): 18

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Focussed MRL review of lambda-cyhalothrin

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E.2. Restricted risk assessment considering authorised use for gamma-cyhalothrin

**Table: Lambda-cyhalothrin**

| Code no. | LOQ (mg/kg) | Proposed LOQ | LOQ (mg/kg) |
|----------|-------------|--------------|-------------|
|          |             |              | 0.0005      |

**Toxicological and points**

| ADI (mg/kg bw per day) | 0.0025 | 0.0025 |
|------------------------|--------|--------|
| Source of ADI           | EFSA   | EFSA   |
| Year of evaluation      | 2014   | 2014   |

**Chronic risk assessment – refined calculations**

| Commodity/group of commodities | Highest calculated TMDI values (%) of ADI |
|---------------------------------|------------------------------------------|
|                                 | MS Diet                                  |
|                                 | 57.6 NL child                            |
|                                 | 53.3 WHO Cluster diet E                  |
|                                 | 46.2 FR toddler                          |
|                                 | 38.0 DE child                            |
|                                 | 37.6 ES child                            |
|                                 | 36.7 WHO regional European diet          |
|                                 | 35.8 WHO cluster diet E                 |
|                                 | 34.2 IE adult                            |
|                                 | 32.7 UK infant                           |
|                                 | 29.9 FR infant                           |
|                                 | 28.8 WHO Cluster diet F                 |
|                                 | 28.5 UK Toddler                          |
|                                 | 25.3 NL general                          |
|                                 | 24.9 ES adult                            |
|                                 | 24.0 WHO cluster diet D                 |
|                                 | 22.5 LT adult                            |
|                                 | 18.7 DK child                            |
|                                 | 16.4 SE general population 90th percentile |
|                                 | 15.3 FR adult population                 |
|                                 | 12.7 PT General population               |
|                                 | 11.8 UK general population               |
|                                 | 11.0 UK Adult                            |
|                                 | 10.0 IT Mediterranean                     |
|                                 | 9.9 DK adult                             |
|                                 | 8.7 IT adult                             |
|                                 | 7.5 FI adult                             |
|                                 | 7.1 PL general population                 |

**Highest contributor to MS diet (%) of ADI**

- **1st contributor**
  - NL child: 14.3 Swine: Meat
  - WHO Cluster diet E: 8.4 Olives for oil production
  - FR toddler: 15.8 Milk and cream
  - DE child: 9.7 Apples
  - ES child: 11.4 Swine: Meat
  - WHO regional European diet: 11.6 Swine: Meat
  - WHO cluster diet E: 6.9 Swine: Fat free of lean meat
  - IE adult: 5.3 Tea (dried leaves and stalks)
  - UK infant: 15.5 Milk and cream
  - FR infant: 10.3 Milk and cream
  - WHO Cluster diet F: 10.7 Swine: Meat
  - UK Toddler: 9.1 Sugar beet (root)
  - NL general: 8.5 Swine: Meat
  - ES adult: 6.6 Swine: Meat
  - WHO cluster diet D: 3.0 Swine: Fat free of lean meat
  - LT adult: 5.3 Swine: Meat
  - DK child: 5.1 Milk and cream
  - SE general population 90th percentile: 5.0 Milk and cream
  - FR adult population: 3.2 Wine grapes
  - PT General population: 2.1 Potatoes
  - UK general population: 2.0 Tea (dried leaves and stalks)
  - UK Adult: 2.2 Tea (dried leaves and stalks)
  - IT Mediterranean: 2.7 Wheat
  - DK adult: 2.1 Milk and cream
  - IT adult: 1.7 Wheat
  - FI adult: 2.3 Milk and cream
  - PL general population: 1.6 Apples

**2nd contributor to MS diet (%) of ADI**

- NL child: 11.7 Milk and cream
- WHO Cluster diet E: 7.1 Swine: Meat
- FR toddler: 5.5 Milk and cream
- DE child: 5.7 Milk and cream
- ES child: 5.0 Milk and cream
- WHO regional European diet: 4.9 Swine: Fat free of lean meat
- IE adult: 4.5 Barley
- UK infant: 4.0 Sugar beet (root)
- FR infant: 3.7 Beans (with pods)
- WHO Cluster diet F: 2.2 Barley
- UK Toddler: 2.2 Barley
- NL general: 1.6 Milk and cream
- ES adult: 1.6 Milk and cream
- WHO cluster diet D: 2.6 Swine: Fat free of lean meat
- LT adult: 2.2 Milk and cream
- SE general population 90th percentile: 1.7 Barley
- FR adult population: 2.7 Swine: Meat
- PT General population: 2.0 Wine grapes
- UK general population: 1.6 Sugar beet (root)
- UK Adult: 1.6 Sugar beet (root)
- IT Mediterranean: 1.1 Tomatoes
- DK adult: 1.1 Tomatoes
- IT adult: 0.9 Tomatoes
- FI adult: 0.6 Tea (dried leaves and stalks)
- PL general population: 1.4 Potatoes

**3rd contributor to MS diet (%) of ADI**

- NL child: 5.1 Apples
- WHO Cluster diet E: 4.9 Beans (with pods)
- FR toddler: 4.2 Barley
- DE child: 3.3 Swine: Fat free of lean meat
- ES child: 2.8 Barley
- WHO regional European diet: 2.1 Bovine: Meat
- IE adult: 1.8 Swine: Fat free of lean meat
- UK infant: 2.3 Tea (dried leaves and stalks)
- FR infant: 3.5 Spinach
- WHO Cluster diet F: 1.8 Swine: Fat free of lean meat
- UK Toddler: 1.6 Wheat
- NL general: 1.4 Bovine: Meat
- ES adult: 1.6 Milk and cream
- WHO cluster diet D: 2.0 Milk and cream
- LT adult: 1.6 Milk and cream
- SE general population 90th percentile: 1.7 Potatoes
- FR adult population: 1.3 Milk and cream
- PT General population: 1.6 Wheat
- UK general population: 1.3 Milk and cream
- UK Adult: 1.2 Milk and cream
- IT Mediterranean: 0.7 Apples
- DK adult: 1.1 Bovine: Meat
- IT adult: 0.7 Spinach
- FI adult: 0.5 Potatoes
- PL general population: 0.7 Tomatoes

**Conclusion:**

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Lambda-cyhalothrin is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available, an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002) for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residual level which would lead to an exposure equivalent to 100% of the ARfD.

![Table](image)

- **Threshold MRL**: the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

**Conclusion:**

For lambda-cyhalothrin, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

See also [www.efsa.europa.eu/efsajournal 29 EFSA Journal 2017;15(7):4930](www.efsa.europa.eu/efsajournal 29 EFSA Journal 2017;15(7):4930) for further details.