Evaluation of confirmatory data following the Article 12 MRL review and setting of import tolerances for bifenthrin in maize grain and sweet corn

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Abstract

The applicant FMC Agricultural Solutions A/S submitted a request to the competent national authority in Belgium to evaluate the confirmatory data that were identified in the framework of the maximum residue level (MRL) review under Article 12 of Regulation (EC) No 396/2005 as not available. To address the data gaps, a new storage stability study was submitted and information on an analytical method for determination of bifenthrin in eggs was made available. The data gaps were sufficiently addressed. The new information provided, did not require a revision of the existing MRLs. In addition, in accordance with Article 6 of Regulation (EC) No 396/2005, the applicant submitted a request to set import tolerances for bifenthrin in sweet corn and maize grain. The data submitted in support of the request were found to be sufficient to derive an MRL proposal for maize grain only. For sweet corn, data gaps were identified which precluded the derivation of an MRL proposal. Adequate analytical methods for enforcement are available to control the residues of bifenthrin (sum of isomers) in plant matrices under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg and in animal matrices. EFSA concluded that the short-term and long-term intake of residues resulting from the uses of bifenthrin according to the reported agricultural practices is unlikely to present a risk to consumer health. The risk assessment is affected by additional non-standard uncertainty related to the expiry of EU authorisation for a number of crops for which previously EU MRLs were established, and which are still included in the risk assessment.

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Keywords: bifenthrin, maize grain and sweet corn, confirmatory data, import tolerance, pesticide, MRL review, risk assessment

Requestor: European Commission

Question numbers: EFSA-Q-2019-00400 and EFSA-Q-2019-00800

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Acknowledgements: EFSA wishes to thank: Stathis Anagnos, Laszlo Bura, Viktorija Krivova, Silvia Ruocco and Viktor Toth for the support provided to this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Anastassiadou M, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Scarlato AP, Theobald A, Vagenende B and Verani A, 2020. Reasoned Opinion on the evaluation of confirmatory data following the Article 12 MRL review and setting of import tolerances for bifenthrin in maize grain and sweet corn. EFSA Journal 2020;18(12):6361, 37 pp. https://doi.org/10.2903/j.efsa.2020.6361

ISSN: 1831-4732

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Summary

In 2015, when the European Food Safety Authority (EFSA) reviewed the existing maximum residue levels (MRLs) for bifenthrin according to Article 12 of Regulation (EC) No 396/2005, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified. The following data gaps were noted:

1) fully validated analytical methods for enforcement of bifenthrin (sum of isomers) in eggs;
2) storage stability studies for bifenthrin in acidic commodities;
3) residue trials supporting the authorisations on apples, pears, cherries, peaches, plums, strawberries, currants, garlic, cucumbers, courgettes, melons, watermelons, fresh beans (with and without pods) and fresh peas (with and without pods).

Following the MRL review, the existing MRLs have been modified in the MRL legislation by Commission Regulation (EU) No 2017/170. Tentative MRL proposals have been implemented, including footnotes related to data gaps 1 and 2 indicating the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRL by 3 February 2019.

The footnote related to data gap number 3 has not been included in the MRL regulation (Commission Regulation (EU) No 2017/170), because risk managers decided to decrease the existing EU MRLs to the limit of determination (0.01 mg/kg) for nearly all of the commodities affected by data gap number 3, i.e. crops not supported by any residue trial data, namely for apples, pears, cherries, peaches, plums, currants, garlic, cucumbers, courgettes, melons, watermelons, beans with pods, beans without pods, peas with pods and peas without pods. As a consequence of the lowering of the MRLs to the limit of quantification (LOQ), the previously authorised uses of plant protection products containing bifenthrin had to be revoked for the crops concerned.

For strawberries, a risk management decision was taken to set the EU MRL tentatively at the level of the existing Codex limit (CXL), although the CXL was not supported by data; however, since the exposure calculation did not indicate a consumer health concern for European consumers (when using the toxicological reference values agreed in the EU) (EFSA, 2015) and considering that at Codex level the assessment of an alternative Good Agricultural Practice (GAP) was assessed by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), the CXL was found acceptable to be implemented temporarily in the European Union (EU) legislation.

For strawberries and the other acidic commodities of plant origin for which the EU MRL has been tentatively set at the level of the corresponding existing CXL (i.e. for citrus fruits, blackberries, dewberries, raspberries, other cane fruits), a footnote was included in Reg. (EU) No 2017/170 referring to the data gap number 2.

In 2016, the process of renewal of the approval of the active substance bifenthrin in accordance with the provisions of Regulation (EC) No 1107/2009 was initiated by submission of an application for renewal by the applicant FMC Agricultural Solutions A/S. On 5 October 2018, the applicant confirmed that they no longer support the renewal of bifenthrin. Consequently, the EU approval of bifenthrin expired on 31 July 2019 (Regulation (EU) No 2019/324).

Following the non-renewal of the approval, the authorisations of plant protection products containing bifenthrin expired and the EU uses became obsolete. A review of the existing EU MRLs in the light of the changed EU situation has not yet been performed.

In accordance with the agreed procedure set out in the working document SANTE/10235/2016, FMC Agricultural Solutions A/S submitted an application to the competent national authority in Belgium (rapporteur Member State, RMS) to evaluate the confirmatory data identified during the MRL review. The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to the European Food Safety Authority EFSA on 20 June 2019.

Furthermore, in July 2019, the applicant FMC Agricultural Solutions A/S submitted an application for the modification of the existing MRLs and setting of import tolerances for bifenthrin on sweet corn and maize grain.

To address the data gap number 2 identified in the framework of the MRL review, the applicant provided a new frozen storage stability study on oranges and in processed orange products. The data demonstrated that bifenthrin was stable in oranges and processed commodities (dried pulp, juice and oil) over the storage period tested, i.e. 18 months at -18°C. EFSA concluded that the data gap identified in the framework of the MRL review was addressed.
To address the data gap number 1 related to the analytical method for eggs, in particular related to its validation to demonstrate linear response of the electron capture detector (ECD) used in the gas chromatography (GC) method, the applicant provided no new validation data. However, the evaluating Member State (EMS) is of the opinion that validation of the formerly used GC-ECD method is no longer relevant as this methodology is not considered any longer state-of-the-art and therefore unlikely to be used for routine enforcement.

The EMS noted that the multi-residue QuEChERS method in combination with gas chromatography with mass spectrometry (GC–MS) detection is applicable for determination of bifenthrin residues in eggs. This method has been successfully validated for this purpose (LOQ in eggs: 0.01 mg/kg) (CEN, 2008). However, an independent laboratory validation (ILV) would be considered as desirable. EFSA concluded that considering that the method is accepted by CEN and that according to the feeding studies in poultry residues in eggs are unlikely to occur at levels greater than 0.01 mg/kg, this is a minor deficiency.

It can be concluded that the confirmatory data and related two footnotes in the MRL implementing legislation (Regulation (EU) No 2017/170) are sufficiently addressed and that the footnotes can be deleted.

For the use on maize grain and sweet corn, the metabolic behaviour in primary crops is sufficiently addressed and rotational crop assessments are not relevant for an import tolerance. Concerning processed commodities, further data are not considered necessary because residues of bifenthrin in the raw agricultural commodities under consideration (sweet corn and maize grain) are not expected to exceed 0.1 mg/kg.

The previously derived residue definitions for monitoring and risk assessment (bifenthrin (sum of isomers)) are still applicable.

The available data are sufficient to derive an MRL proposal as well as risk assessment values for maize grain at the limit of quantification of 0.05 mg/kg. For sweet corn the submitted residue trials were not representative for the GAP and therefore a modification of the existing MRL is not sufficiently supported.

Sufficiently validated methods are available to enforce bifenthrin in animal commodities with an LOQ of 0.05 mg/kg in muscle and fat and an LOQ of 0.01 mg/kg in milk, kidney, liver and eggs.

EFSA updated the previous risk assessment with the new data submitted under the import tolerance application. In addition, the risk assessment values for CXLs that were taken over in the EU MRL legislation by Commission Reg. (EU) No 2018/687 (CXLs for grapes, blueberries, peas with pods and peas without pods) were included in the risk assessment. The commodities, for which due to the lack of residue data MRLs were lowered to the LOQ in Regulation (EU) 2017/170 and consequently authorisations had to be withdrawn, were not included in the exposure calculation.

For the risk assessment of bifenthrin, EFSA used the toxicological reference values (acceptable daily intake (ADI) and acute reference dose (ARfD)) for bifenthrin derived in the framework of the peer review process (EFSA, 2011) and implemented in the Regulation (EU) No 2018/291. The calculations were performed using revision 3.1 of the EFSA PRIMo.

For maize grain the estimated short-term exposure did not exceed the ARfD of bifenthrin (1% of ARfD). Considering all crops included in the confirmatory data assessment of bifenthrin, the highest ARfD was observed for sweet peppers/bell peppers with 61% of ARfD.

The estimated long-term dietary intake related to the crops under assessment accounted for maximum 42% of the ADI (NL toddler). The contribution of the import tolerance for maize grain to the overall long-term exposure is 2.35% of the ADI (NL toddler).

EFSA concluded that the long-term intake of residues of bifenthrin resulting from the prior to the non-renewal decision existing uses and from the authorised use on maize grain in the USA is unlikely to present a risk to consumer health.

The current risk assessment is affected by an additional uncertainty related to the expiry of EU authorisation for a number of crops for which previously EU MRLs were established and which are still included in the risk assessment.

The summary table below provides an overview of the assessment of confirmatory data and the recommended MRL modifications to Regulation (EU) No 396/2005 relating to the application for import tolerances in maize grain and sweet corn.
### Existing enforcement residue definition for plants and animals: Bifenthrin (sum of isomers)\(^{(f)}\)

| Code\(^{(a)}\) | Commodity | Existing MRL\(^{(b)}\) | Proposed MRL | Conclusion/recommendation |
|--------------|------------|------------------------|--------------|---------------------------|
| 0110000      | Citrus fruits | 0.05 (ft 1) | 0.05         | The existing MRL is based on the existing CXL set by Codex Alimentarius Commission (CAC) in 2011. The data gap identified by EFSA concerning storage stability has been addressed. |
| 0110010      | Grapefruits | 0.05 (ft 1) | 0.05         | Further risk management considerations required |
| 0110020      | Oranges     | 0.05 (ft 1) | 0.05         | The data gap identified by EFSA concerning storage stability has been addressed. EFSA recommends further risk management discussions whether the existing EU MRL which is based on a CXL should be maintained, taking into account the assessment history in Codex: In 1992, JMPR assessed the use of bifenthrin in strawberries and derived a Codex MRL proposal. JMPR noted that the residue trials did not fully reflect the reported GAP for bifenthrin; additional data on strawberries reflecting the GAP which allows multiple applications would be desirable. In 1995, the CXL for strawberries was adopted, despite the data gaps. In the framework of the periodic review in 2010, JMPR recommended the withdrawal of the existing CXL, since a GAP supporting the CXL of 1 mg/kg was not provided. In this periodic review, JMPR assessed a new GAP for strawberries; however, since the expected exposure exceeded the ARfD, CCPR decided to maintain the old CXL, awaiting the submission of an alternative GAP. In 2019, JMPR assessed an alternative GAP and again an exceedance of the ARfD was identified. Taking into account that JMPR has never received information on a GAP matching the residue trials which were used to derive the existing CXL of 1 mg/kg, and that no alternative GAP has been provided within the last 10 years which would allow to establish a CXL which does not pose a consumer health risk, further risk management considerations are required whether the existing EU MRL should be reconsidered. |
| 0110030      | Lemons      | 0.05 (ft 1) | 0.05         | |
| 0110040      | Limes       | 0.05 (ft 1) | 0.05         | |
| 0110050      | Mandarins   | 0.05 (ft 1) | 0.05         | |
| 0110990      | Others      | 0.05 (ft 1) | 0.05         | |
| 0152000      | Strawberries | 1 (ft 1)    | 1            | The existing MRL is based on the CXL derived in 2011 for blackberries, dewberries and raspberries. The data gap identified by EFSA concerning storage stability has been addressed. |
| 0153000      | Others      | 1 (ft 1)    | 1            | |
| 0153010      | Blackberries | 1 (ft 1)    | 1            | |
| 0153020      | Dewberries  | 1 (ft 1)    | 1            | |
| 0153030      | Raspberries (red and yellow) | 1 (ft 1) | 1 | |
| 0153990      | Others      | 1 (ft 1)    | 1            | |

\(^{(a)}\) Code

\(^{(b)}\) Commodity

\(^{(c)}\) Existing MRL

\(^{(f)}\) Proposed MRL

\(^{(g)}\) Conclusion/recommendation
| Code<sup>(a)</sup> | Commodity       | Existing MRL<sup>(b)</sup> | Proposed MRL | Conclusion/recommendation                                                                                                                                                                                                                                                                                                                                 |
|------------------|-----------------|-----------------------------|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1030000          | Birds eggs      | 0.01 (Ft 2)                 | 0.01*        | The requested validation data for the analytical methods have not been provided. However, a CEN method is available for products of animal origin (including eggs), which was sufficiently validated for quantifying bifenthrin (sum of isomers) residues at or above the LOQ of 0.01 mg/kg. For the CEN method, a full validation by an independent laboratory would be desirable. However, considering that the method is accepted by CEN and that according to the feeding studies in poultry residues in eggs are unlikely to occur at levels greater than 0.01 mg/kg, this is considered a minor deficiency |
| 1030010          | Chicken         | 0.01*                       |              |                                                                                                                                                                                                                                                                                                                                                                                     |
| 1030020          | Duck            | 0.01*                       |              |                                                                                                                                                                                                                                                                                                                                                                                     |
| 1030030          | Geese           | 0.01*                       |              |                                                                                                                                                                                                                                                                                                                                                                                     |
| 1030040          | Quail           | 0.01*                       |              |                                                                                                                                                                                                                                                                                                                                                                                     |
| 1030990          | Others          | 0.01*                       |              |                                                                                                                                                                                                                                                                                                                                                                                     |

**Import tolerance application**

| Code<sup>(a)</sup> | Commodity       | Existing MRL<sup>(b)</sup> | Proposed MRL | Conclusion/recommendation                                                                                                                                                                                                                                                                                                                                 |
|------------------|-----------------|-----------------------------|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0500030          | Maize grain     | 0.05*                       | 0.05*        | Label information for the USA was provided. The submitted data are sufficient to derive an import tolerance based on the foliar use. Risk for consumers unlikely. Bifenthrin MRL in the USA of 0.05 mg/kg is in place                                                                                                                                         |
| 0234000          | Sweet corn      | 0.01*                       | No proposal  | Label information for the USA was provided. No GAP-compliant trials were provided. Bifenthrin MRL in the USA of 0.05 mg/kg is in place                                                                                                                                                                                                                        |

MRL: maximum residue limit; CXL: Codex maximum residue limit; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; ARfD: acute reference dose; CCPR: Codex Committee on Pesticide Residues; GAP: Good Agricultural Practice; CEN: European Committee for Standardisation; LOQ: limit of quantification.

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): Existing EU MRL and corresponding footnote on confirmatory data.
(F): Fat-soluble.

Ft 1: The European Food Safety Authority identified some information on storage stability as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 3 February 2019, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 2).

Ft 2: The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 3 February 2019, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 1).
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Evaluation of confirmatory data and setting of import tolerances for bifenthrin

Assessment

The review of existing maximum residue levels (MRLs) for the active substance bifenthrin according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed in 2015 (EFSA, 2015). European Food Safety Authority (EFSA) identified some information as unavailable (data gaps) and derived tentative MRLs for those uses not fully supported by data but for which no risk to consumers was identified.

Following the review of existing MRLs, the legal limits have been modified by Commission Regulation (EU) No 2017/170², including footnotes for tentative MRLs that specified the type of information that was identified as missing. Any party having an interest in maintaining the proposed tentative MRL was requested to address the confirmatory data by 3 February 2019.

In accordance with the specific provisions set out in the working document of the European Commission SANTE/10235/2016 (European Commission, 2016) the applicant, FMC Agricultural Solutions A/S, submitted an application to the competent national authority in Belgium (designated rapporteur Member State, RMS) to evaluate the confirmatory data identified during the MRL review. To address the data gaps identified by EFSA, the applicant provided a new storage stability study for matrices with high acidity and information on an analytical method for determination of bifenthrin in eggs.

The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA on 20 June 2019 (Belgium, 2019a). EFSA assessed the application as requested by the European Commission in accordance with Article 9 of Regulation (EC) No 396/2005. EFSA based its assessment on the evaluation report submitted by the RMS (Belgium, 2019a) and the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2015).

In accordance with Article 6 of Regulation (EC) No 396/2005, FMC Agricultural Solutions A/S also submitted an application to the competent national authority in Belgium (evaluating Member State, EMS) to set import tolerances for the active substance bifenthrin in sweet corn and maize grain. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 11 December 2019. The EMS proposed to establish MRLs for maize grain imported from USA at the level of 0.05 mg/kg. For sweet corn, the EMS concluded that due to insufficient data provided by the applicant a modification of the existing European Union (EU) MRL currently set at the limit of quantification (0.01 mg/kg) is not recommended.

EFSA based its assessment of the import tolerance request on the evaluation report submitted by the EMS (Belgium, 2019b), the draft assessment report (DAR) and its addendum (France, 2005, 2008) prepared under Council Directive 91/414/EEC, the Commission review report on bifenthrin (European Commission, 2018), the conclusion on the peer review of the pesticide risk assessment of the active substance bifenthrin (EFSA, 2011).

For these applications, the data requirements established in Regulation (EU) No 544/2011³ and the guidance documents applicable at the date of implementation of the confirmatory data requirements by Regulation (EU) No 2017/170 or the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011⁴.

An updated list of end points, including the end points of relevant studies assessed in this assessment is presented in Appendix B.

The evaluation reports submitted by the EMS (Belgium, 2019a,b) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMO) are considered as supporting documents to

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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.
2 Commission Regulation (EU) 2017/170 of 30 January 2017 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenthrin, carbetamide, cinidion-ethyl, fenpropimorph and triflusulfuron in or on certain products C/2017/0387 OJ L 30, 3.2.2017, p. 1–44.
3 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
4 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.
this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. **Residues in plants**

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

1.1.1. **Nature of residues in primary crops**

Not relevant for the confirmatory data assessment.

**Import tolerance application** on maize grain and sweet corn:

The metabolism of bifenthrin in primary crops belonging to the group of fruit crops, cereals/grass, pulses/oilseeds has been investigated in the framework of the EU pesticides peer review and MRL review (EFSA, 2011, 2015).

In the crops tested, parent compound was the main residue, representing approximately 72–98% of the total radioactive residues (TRRs) and the metabolic pathway was similar in all crops. No significant cis-trans isomerisation was observed during the peer review (EFSA, 2011).

For the use on maize grain and sweet corn, the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. **Nature of residues in rotational crops**

Not relevant for the current assessments of the confirmatory data and the application for the import tolerance on maize grain and sweet corn.

1.1.3. **Nature of residues in processed commodities**

No confirmatory data on the nature of residues were requested in the framework of the MRL review, although a minor deficiency was identified regarding the lack of information on the effect of sterilisation (EFSA, 2015). The applicant resubmitted the study which had already been evaluated during the peer review and the MRL review (EFSA, 2011, 2015). Hence, no new information is available.

With regard to the application for an import tolerance for sweet corn and maize grain, the EMS explained that further data are not necessary, taking also into account that residues of bifenthrin in the raw agricultural commodities under consideration (sweet corn and maize grain) are not expected to exceed 0.1 mg/kg (i.e. trigger value according to data requirements under Regulation (EU) No 544/2011).

It is acknowledged that for the previously assessed uses sterilisation was considered not a relevant process; for the import tolerance request a hydrolysis study is not triggered due to the low residues. Therefore, for the current assessment, the available data are considered sufficient to derive a conclusion on the residue definition for processed products. However, if in the future new MRL applications will be submitted, data on the effect of sterilisation on the nature of residues would be required.

1.1.4. **Methods of analysis in plants**

Not relevant for the confirmatory data assessment.

Analytical methods for the determination of bifenthrin residues were assessed during the EU pesticides peer review and MRL review (EFSA, 2011, 2015). No additional data were submitted with this import tolerance application (Belgium, 2019b).

The methods are sufficiently validated for residues of bifenthrin in the crops under consideration. The methods allow quantifying residues at or above the limit of quantification (LOQ) of 0.01 mg/kg for bifenthrin (sum of isomers) in crops belonging to the group of dry (high starch) commodities.
1.1.5. Storage stability of residues in plants

In the context of the confirmatory data assessment, the applicant provided a new storage stability study on frozen oranges and in processed orange products to address data gap number 2.\(^5\)

According to the EMS, the study is valid. The data demonstrated that bifenthrin is stable in oranges and processed commodities (dried pulp, juice and oil) over the storage period tested, i.e. 18 months at \(-18^\circ\)C (Belgium, 2019a).

EFSA concluded that the data gap identified in the framework of the MRL review is addressed.

With regard to the application for an import tolerance on sweet corn and maize grain, storage stability studies were provided for maize grain and processed maize products (flour, meal, starch and dry milled refined deodorised oil) which demonstrated stability for the storage period of approximately 13 months at \(-18^\circ\)C (Belgium, 2019b) (see Table B.1.1.2).

1.1.6. Proposed residue definitions

The previously derived residue definitions are still applicable (EFSA, 2011).

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

Not relevant for the confirmatory data assessment.

In support of the import tolerance application, the applicant submitted residue trials performed in sweet corn and maize grain. The samples were analysed for bifenthrin according to the residue definitions for enforcement and risk assessment. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose. The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

Maize grain

Good Agricultural Practice (GAP) USA: Foliar, 6 × 112.5 g/ha (maximum seasonal application rate of 225 g/ha), interval not specified, preharvest interval (PHI) 30 days (Belgium, 2019b).

The applicant provided in total 30 supervised residue trials on maize grain conducted in the USA in the growing seasons in 1984 (12 trials), in 1986 (6 trials), in 1987 and in 1988 (12 trials), and 2 decline trials performed in 2002. The trials were performed with multiple foliar applications with total application rates ranging from 336 g/ha to 1,659 g/ha; in some trials additional in-furrow applications at planting were performed.

In order to derive the MRL proposal, the EMS recommended to select only those trials where the last application was at least 112 g/ha with sampling taking place around the PHI of 30 days (29–38 days). Although the eight selected trials were overdosed in terms of the seasonal application rate compared to the US GAP, they were found acceptable because in none of the residue trials detectable/quantifiable residues were found (limit of detection (LOD) 0.01 mg/kg, LOQ 0.05 mg/kg) (Belgium, 2019b).

EFSA agrees with the EMS that the available residue data are sufficient to support an import tolerance (Belgium, 2019b). EFSA suggests setting the MRL at the level of 0.05 mg/kg in maize grain, which is equivalent to the limit of quantification achieved with the analytical methods used in the residue trials (see also the risk assessment results for this crop reported in section 3). According to EFSA, the data do not provide evidence that the existing EU MRL which is set at the LOQ of 0.05 mg/kg has to be modified.

GAP USA: Soil treatment at sowing, 1 × 112.5 g/ha, PHI 30 days (Belgium, 2019b).

The EMS considered that this GAP is less critical than the GAP on foliar application above (Belgium, 2019b) and would therefore not be relevant for setting an import tolerance. Two decline trials were performed with in-furrow application of 112 g a.s./ha at sowing, followed by four broadcast foliar spray applications of 56 g a.s./ha (equivalent to 336 g a.s./ha/season). Grain was harvested after 1, 3, 7 and 15 days after the last treatment. There were no detectable residues of bifenthrin reported (LOD = 0.01 mg/kg; LOQ = 0.05 mg/kg) in any of the grain samples. Although the trials do not match the GAP exactly, since additional treatments were performed after sowing, the trials confirm the assumption that no residues are expected.

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5 Storage stability studies for bifenthrin in acidic commodities.
The applicant provided information on the registered label in the USA supporting the current MRL application. The tolerance for maize grain established in the USA is 0.05 mg/kg.

**Sweet corn**

GAP USA: 6 × 112.5 g/ha, interval not specified, PHI 1 day (Belgium, 2019b).

The applicant provided in total 14 supervised residue trials on maize conducted in the USA in 1996 (one trial was deleted from the study, due to application and sampling errors) and one decline trial performed in 1998. In the valid 13 trials from the 1996 growing season, sweet corn was treated with two foliar applications at 90 g a.s./ha followed by one application at 45 g a.s./ha (3–4 days interval between the applications), with sampling of sweet corn ear samples 1 day after last treatment.

The decline trial was performed with two foliar applications of 90 g a.s./ha and one application at 45 g a.s./ha with 3–4 days interval between applications (equivalent to a total seasonal application of 225 g a.s./ha). Sweet corn ear samples were sampled at 0, 1, 3 and 7 days after last treatment. In none of the trials, residues were detectable/quantifiable (LOD of 0.01 mg/kg; LOQ of 0.05 mg/kg) (Belgium, 2019b).

The EMS noted that since the last application in the trial was performed at a lower application rate of 45 g a.s./ha compared to the application rate specified in the GAP (i.e. 1,12.5 g a.s./ha), the trials are not GAP compliant, considering that with the short PHI the last treatment is expected to have the major impact on the residue levels in the harvested product. The results cannot be scaled up because the results were below the LOQ. Consequently, no MRL can be derived based on the available trials and a modification of the current EU MRL for sweet corn of 0.01 mg/kg (at the LOQ) is not recommended (Belgium, 2019b).

EFSA agrees with this assessment and notes that the EMS has informed the applicant about the negative outcome of the evaluation. No further supporting data were provided by the applicant in this respect.

The applicant provided information on the registered label in the USA supporting the current MRL application and on the US tolerance for sweet corn which is established at the level of 0.05 mg/kg.6

GAP USA: Foliar, 1 × 112.5 g/ha, interval not specified, PHI 30 days (Belgium, 2019b).

This US GAP consisting of in-furrow treatment at planting is deemed less critical than the GAP on foliar application (Belgium, 2019b). According to the EMS, no GAP-compliant trials were provided to support this GAP. Consequently, no MRL proposal can be derived for this commodity.

1.2.2. Magnitude of residues in rotational crops

Not relevant for the assessment of confirmatory data and the application for the import tolerance on maize grain and sweet corn.

1.2.3. Magnitude of residues in processed commodities

Not relevant for the assessment of confirmatory data.

In the framework of the import tolerance application, two studies investigating the transfer of bifenthrin residues into processed maize products following dry and wet milling were provided (Belgium, 2019b). The EMS noted that the studies were previously evaluated by JMPR (FAO, 2011).

From the dry milling process tentative processing factors of 2.9 and 1.1 for hulls and flour, respectively were derived. The studies investigating the wet milling process, gave an indication that bifenthrin residues increase in crude oil, refined oil, hulls and refined bleached oil factors (processing factors of 1.9, 2.3, 1.5 and 2.0, respectively). For all other products (flour, meal starch, germs, small, medium and large grits, expeller press cake, solvent extraction press cake, refined bleached deodorised oil), bifenthrin residues were lower in the processed products compared to the raw agricultural commodity (see Table B.1.2.3).

Since all processing factors are based on a single study, they are considered as indicative and are not recommended for inclusion in Annex VI of Regulation (EC) No 396/2005.

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6 [www.ecfr.gov/cgi-bin/text-idx?SID=a3b649316cccb17c31211db2edd81f789&mc=true&node=pt40.24.180&rgn=div5#se40.26.180_1442](www.ecfr.gov/cgi-bin/text-idx?SID=a3b649316cccb17c31211db2edd81f789&mc=true&node=pt40.24.180&rgn=div5#se40.26.180_1442)
1.2.4. Proposed MRLs

For the import tolerance application for maize grain, the available data are considered sufficient to derive an MRL proposal as well as risk assessment values for maize grain at the limit of quantification of 0.05 mg/kg. For sweet corn the submitted residue trials were not representative for the GAP and therefore no modification of the existing MRL is proposed (see Appendix B.1.2.1).

In Section 3, EFSA assessed whether residues on maize grain resulting from the uses authorised in the USA for maize grain are likely to pose a consumer health risk.

The assessment of the confirmatory data did not trigger a modification of the existing MRLs.

2. Residues in livestock

In the framework of the MRL review, a tentative estimation of the livestock dietary burden was performed; in the absence of residue trials for most feed items such as potatoes and fruit pomace, the dietary burden calculation took into account only animal intake of residues via rape seed meal. Therefore, the calculated dietary burden was likely to underestimate the actual livestock intake (EFSA, 2015).

The confirmatory data assessed in this evaluation do not have an impact on pesticide residues expected in livestock.

For the import tolerance request, the dietary burden calculation was updated, including the expected residues in maize grain and maize by-products.7 EFSA assumed that in maize by-products the residues will not increase compared to maize grain, taking into account the results of processing studies and the residue trials which give an indication of a no-residue situation. Since for sweet corn no MRL proposal could be derived it has not been considered further (see Section 1.2.1) (Belgium, 2019b). The dietary burden calculation is indicative and affected by a number of non-standard uncertainties: the EU regulatory background has changed due to the expiry of the approval. Hence, for a number of feed products for which previously EU uses were authorised (e.g. citrus, potatoes, carrots, swedes, turnips, cabbages, beans, peas, lupins, rapeseed, soybean and cotton) the EU authorisations expired. However, imported feed items complying with the current EU MRL might still enter the feed chain and contribute to the dietary burden. As no residue data are available for these crops that would allow to estimate the residue levels in feed, EFSA performed a calculation based on rapeseed and maize only, similar to the approach taken in the MRL review. Even if the calculation does not reflect the worst-case situation, it allows a comparison with the previously calculated indicative dietary burden (based on rape seed only).

The results of the dietary burden calculation are presented in Appendix B.2. In the table additional information was included, i.e. the dietary burden calculated in the EFSA MRL review and since the current MRLs for animal products are based on Codex MRLs, EFSA also included the dietary burden derived by JMPR (FAO, 2011).

The calculations show a slight increase in the dietary burden, when maize and maize by-products are included, compared to the dietary burden derived by EFSA in 2015. However, the dietary burden is still below the trigger value. Comparing the results with the calculations obtained by JMPR, the EU results are significantly lower. Hence, a modification of the existing EU MRLs for bifenthrin (the existing EU MRLs for animal products except poultry are based on Codex MRLs) is currently not indicated.

Considering that the dietary burden calculations are indicative, and contribution of other crops cannot be fully excluded, the residue situation for animal products should be further investigated.

2.1. Nature of residues and methods of analysis in livestock

No new information was provided on the nature of residues in livestock.

With regard to the method of analysis, in the framework of the MRL review, EFSA identified a data gap related to the analytical method for eggs,8 in particular EFSA noted in its assessment (EFSA, 2015) that validation data were insufficient to demonstrate linear response of the electron capture detector (ECD) use in the gas chromatography (GC) method. The applicant provided no new validation data to address the data gap number 1 and re-submitted the previously evaluated study report describing independent laboratory validation of the analytical method for eggs. Therefore, the EMS assessed the same study again and came to the same conclusion as the MRL review (Belgium, 2019a). However,

7 Import is related to maize grain and not maize forage and maize stover which were therefore not considered. Consequently, only maize grain and derived processed commodities are considered in the framework of this application.

8 Data gap number 1: Fully validated analytical methods for enforcement of bifenthrin (sum of isomers) in eggs.
the EMS is of the opinion that validation of the formerly used GC-ECD method is no longer relevant as this methodology is not considered any longer state-of-the-art and therefore unlikely to be used for routine enforcement.

The EMS noted that the multi-residue QuEChERS method in combination with gas chromatography with mass spectrometry (GC–MS) is applicable for determination of bifenthrin residues in eggs. This method has been successfully validated for this purpose (LOQ in eggs: 0.01 mg/kg) (CEN, 2008). However, there is only limited evidence on independent laboratory validation (ILV). An independent ILV would therefore be considered desirable.

EFSA concluded that the data gap identified in the framework of the MRL review was not fully addressed; according to the EU guidance document (European Commission, 2010b) a full validation by an independent laboratory would be desirable. However, considering that the method is accepted by CEN and that according to the feeding studies in poultry residues in eggs are unlikely to occur at levels greater than 0.01 mg/kg, this is considered a minor deficiency and data gap number 1 is considered addressed.

2.2. Magnitude of residues in livestock

Feeding studies with lactating cows and laying hens were assessed previously (EFSA, 2011, 2015). EFSA derived MRL values for commodities of animal origin (pig, ruminant and poultry) which were all at the LOQ.

The MRL of 0.01 mg/kg (at the LOQ) for bird eggs was considered tentative, because of outstanding requirements for a fully validated method (EFSA, 2015). The updated dietary burden calculation confirmed the previous MRLs.

EFSA is of the opinion that the data/information submitted in support of the application for assessment of confirmatory data gives sufficient evidence to delete the footnote related to data gap number 1 (see Section 2.2).

3. Consumer risk assessment

The submitted confirmatory data do not directly impact the previous risk assessment performed in the framework of the MRL review (EFSA, 2015) and therefore most of the previously used input values were taken over; however, the input values for commodities, for which due to the lack of residue data MRLs were lowered to the LOQ in Regulation (EU) 2017/170 and consequently authorisations had to be withdrawn, were not included in the exposure calculation.

EFSA now updated the previous risk assessment with the new data submitted under the import tolerance application. In addition, the risk assessment values for CXLs that were taken over in the EU MRL legislation by Commission Reg. (EU) No 2018/687 (CXLs for grapes, blueberries, peas with pods and peas without pods) were included in the risk assessment.

For the risk assessment of bifenthrin, EFSA used the toxicological reference values (acceptable daily intake (ADI) and acute reference dose (ARfD)) for bifenthrin derived in the framework of the peer review process reviewed by risk managers (European Commission, 2018) and implemented in the European Regulation. The calculations were performed using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019).

For maize grain, the estimated short-term exposure did not exceed the ARfD of bifenthrin (1% of ARfD). Among the crops for which currently MRLs are set in the EU legislation, the highest exposure was observed for sweet peppers/bell peppers accounting for 61% of the ARfD.

The estimated long-term dietary intake related to the crops under assessment accounted for maximum 42% of the ADI (NL toddler). The ADI for the import tolerance for maize grain is 2.35% for NL toddler.

The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is presented in more detail in Appendix B.3. EFSA concluded that the long-term intake of residues of bifenthrin resulting from the existing and the authorised use is unlikely to present a risk to consumer health.

It is noted that in 2015, for a number of commodities, the EU MRLs were derived for uses of bifenthrin authorised in the EU. Following the expiry of the approval for bifenthrin, these EU uses became obsolete and for most of these commodities, the existing MRLs should be lowered to the LOQ, provided that no import tolerances are requested. In the current risk assessment, the commodities, on
which EU uses were previously authorised, are still reflected with the respective input values derived by EFSA in 2015, because the presence of bifenthrin residues in some imported products cannot be excluded. The current risk assessment is therefore affected by an additional uncertainty.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

4. Conclusion and Recommendations

To address data gap number 2 identified in the framework of the MRL review, the applicant provided a new frozen storage stability study on oranges and in processed orange products. The data demonstrated that bifenthrin was stable in oranges and processed commodities (dried pulp, juice and oil) over the storage period tested, i.e. 18 months at –18°C. EFSA concluded that the data gap number 2 identified in the framework of the MRL review was addressed.

To address data gap number 1 related to the analytical method for eggs, in particular related to its validation to demonstrate linear response of the ECD used in the GC method, the applicant provided no new validation data. However, the EMS is of the opinion that validation of the formerly used GC-ECD method is no longer relevant as this methodology is not considered any longer state-of-the-art and therefore unlikely to be used for routine enforcement.

The EMS noted that the multi-residue QuEChERS method in combination with GC-MS detection is applicable for determination of bifenthrin residues in eggs. This method has been successfully validated for this purpose (LOQ in eggs: 0.01 mg/kg) (CEN, 2008). However, an ILV would be considered as desirable. EFSA concluded that considering that the method is accepted by CEN and that according to the feeding studies in poultry residues in eggs are unlikely to occur at levels greater than 0.01 mg/kg this is considered a minor deficiency.

It can be concluded that the confirmatory data and related two footnotes in the MRL implementing legislation are sufficiently addressed and that the footnotes can be deleted. For the use on maize grain and sweet corn, the metabolic behaviour in primary crops is sufficiently addressed and rotational crop assessments are not relevant for the import tolerance. Concerning processed commodities, further data are not considered necessary because residues of bifenthrin in the raw agricultural commodities under consideration (sweet corn and maize grain) are not expected to exceed 0.1 mg/kg.

The previously derived residue definitions for monitoring and risk assessment (bifenthrin (sum of isomers)) are still applicable.

For the application regarding an import tolerance for maize grain, the available data are sufficient to derive an MRL proposal as well as risk assessment values for maize grain at the LOQ of 0.05 mg/kg. For sweet corn, the submitted residue trials were not representative for the GAP and therefore a modification of the existing MRL is not sufficiently supported.

Sufficiently validated methods are available to enforce bifenthrin in animal commodities with an LOQ of 0.05 mg/kg in muscle and fat and an LOQ of 0.01 mg/kg in milk, kidney, liver and eggs.

EFSA updated the previous risk assessment with the new data submitted under the import tolerance application. In addition, the risk assessment values for CXLs that were taken over in the EU MRL legislation by Commission Reg. (EU) No 2018/687 (CXLs for grapes, blueberries, peas with pods and peas without pods) were included in the risk assessment. The commodities, for which due to the lack of residue data MRLs were lowered to the LOQ in Regulation (EU) 2017/170 and consequently authorisations had to be withdrawn, were not included in the exposure calculation.

For the risk assessment of bifenthrin EFSA used the toxicological reference values (ADI and ARfD) for bifenthrin derived in the framework of the peer review process (EFSA, 2011) and implemented in the European Regulation. The calculations were performed using revision 3.1 of the EFSA PRIMo.

For maize grain, the estimated short-term exposure did not exceed the ARfD of bifenthrin (1% of ARfD). Considering all crops included in the confirmatory data assessment of bifenthrin, the highest ARfD was observed for sweet peppers/bell peppers with 61% of ARfD.

The estimated long-term dietary intake related to the crops under assessment accounted for maximum 42% of the ADI (NL toddler). The ADI for the import tolerance for maize grain is 2.35% for NL toddler.

EFSA concluded that the long-term intake of residues of bifenthrin resulting from the prior to the non-renewal decision existing uses and from the authorised use on maize grain in the USA is unlikely to present a risk to consumer health.
The current risk assessment is affected by an additional uncertainty related to the expiry of EU authorisation for a number of crops for which previously EU MRLs were established and which are still included in the risk assessment.

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Abbreviations

a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CAC Codex Alimentarius Commission
CCPR Codex Committee on Pesticide Residues
CF conversion factor for enforcement to risk assessment residue definition
cGAP critical GAP
CXL Codex maximum residue limit
DAR draft assessment report
DAT days after treatment
EC emulsifiable concentrate
ECD electron capture detector
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
GC gas chromatography
GC-ECD gas chromatography with electron capture detector
GC-MS gas chromatography with mass spectrometry
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
InChiKey International Chemical Identifier Key
ISO International Organization for Standardization
IUPAC International Union of Pure and Applied Chemistry
JMPR Joint FAO/WHO Meeting on Pesticide Residues
LOD limit of detection
LOQ limit of quantification
MRL maximum residue level
MS Member States
NEU northern Europe
OECD Organisation for Economic Co-operation and Development
PBI plant-back interval
PF processing factor
PHI preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA risk assessment
| Abbreviation | Description |
|--------------|-------------|
| RAC          | raw agricultural commodity |
| RD           | residue definition |
| RMS          | rapporteur Member State |
| SEU          | southern Europe |
| STMR         | supervised trials median residue |
| TRR          | total radioactive residue |
| WHO          | World Health Organization |
## Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F, G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|-------------------------|-------------|-----------------------------------|-------------|----------------|-----------------------------|--------------|---------|
|                       |                         |             |                                   | Type(b) | Conc. a.s. | Method kind | Range of growth stages & season(c) | Number min-max | Interval between application (min) | g a.s./hL max | Water L/ha (min) | Rate | Unit |               |               |                     |
| Sweet corn            | USA                     | F           | Rootworm larvae, Cutworm grubs, seed corn beetle | EC 240 g/L | Soil treatment – general (see also comment field) | BBCH 00 | 1 | – | 30 | 67.50–112.50 | g a.s./ha | 30 | Maximum rate at plant use is 112.5 g a.s./ha (0.0023–0.0046 lb a.s. per 1000 linear feet of row; for row spacings of 40–30 inches, this corresponds to 0.060–0.080 pounds a.s./acre; (max. 0.1 lb a.s./acre per season)) |
| Sweet corn            | USA                     | F           | Biting and sucking insects, mites | EC 240 g/L | Foliar treatment – broadcast spraying | 1–6 | Not specified | 100 | 37.00–112.50 | g a.s./ha | 1 | Maximum season rate is 225 g a.s./ha (0.033–0.10 lb a.s./acre (max. 0.2 lb a.s./acre per season)) |
| Crop and/or situation | NEU, SEU, MS or country | F, G or I(\(a\)) | Crops and pests controlled | Preparation | Application | Application rate per treatment | Remarks |
|-----------------------|--------------------------|------------------|-----------------------------|-------------|-----------------|-------------------------------|---------|
|                       |                          |                  |                             | Type(\(b\)) | Conc. a.s. | Method kind | Range of growth stages & season(\(c\)) | Number min-max | Interval between application (min) | g a.s./hL min-max | Water L/ha (min) | Rate Unit | PHI (days)(\(d\)) | |
| Maize/ corn           | USA                      | F                | Rootworm larvae, cutworm grubs, seed corn beetle | EC          | 240 g/L   | Soil treatment – general (see also comment field) | BBCH 00 1 | – | 30 | 67.50–112.50 | g a.s./ha | 30 | Maximum rate at plant use is 112.5 g a.s./ha (0.0023–0.0046 lb a.s. per 1000 linear feet of row; for row spacings of 40–30 inches, this corresponds to 0.060–0.080 pounds a.s./acre; (max. 0.1 lb a.s./acre per season)) |
| Maize/ corn           | USA                      | F                | Biting and sucking insects, Mites | EC          | 240 g/L   | Foliar treatment – broadcast spraying | 1–6 Not specified | 100 | 37.00–112.50 | g a.s./ha | 30 | Maximum season rate is 225 g a.s./ha (0.033–0.10 lb a.s./acre (max. 0.2 lb a.s./acre per season)) |

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; EC: emulsifiable concentrate.

(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 methods of analysis in plants

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

| Primary crops (available studies) | Crop groups | Crop(s) | Applications | Sampling (DAT) | Comment/Source |
|----------------------------------|-------------|---------|--------------|----------------|----------------|
| Fruit crops                      | Apple       | Foliar spray, field: 3 × 48 g/L | 0, 7, 14, 21 | Phenyl 14C-bifenthrin (France, 2008) |
|                                  |             | Foliar direct on leaf, field: 12, 24 g/L | 0, 7, 14, 21, 28(a) | Phenyl 14C-bifenthrin was pipetted on apples and leaves; (a)Sampling of leaves only (France, 2008) |
|                                  |             | Foliar direct on leaf, field: 12, 24 g/L | 0, 7, 14, 21, 28(a) | Cyclopropyl 14C-bifenthrin was pipetted on apples and leaves; (a)Sampling of leaves only (France, 2008) |
| Cereals/ grass                   | Maize       | Foliar direct on leaf, glasshouse: 1(b) × 0.53 kg a.s./ha | 0, 7, 14, 21, 30 | Phenyl 14C-bifenthrin; (b)The number of applications were not clearly specified in the DAR (France, 2008) |
|                                  |             | Foliar direct on leaf, glasshouse: 1(b) × 0.53 kg a.s./ha | Maturation (grain-stage) |  |
|                                  |             | Soil treatment, glasshouse: 1(b) × 2.26 kg a.s./ha | Silage stage and maturity (grain-stage) |  |
|                                  |             | Foliar direct on leaf, glasshouse: 1(b) × 0.53 kg a.s./ha | 0, 7, 14, 21, 30 | Cyclopropyl 14C-bifenthrin; (b)The number of applications were not clearly specified in the DAR (France, 2008) |
|                                  |             | Foliar direct on leaf, glasshouse: 1(b) × 0.53 kg a.s./ha | Maturity (grain-stage) |  |
|                                  |             | Soil treatment, glasshouse: 1(b) × 2.26 kg a.s./ha | Silage stage and maturity (grain-stage) |  |
|                                  |             | Foliar, glasshouse: 1 × 0.56 kg a.s./ha | 29, 77 | Phenyl 14C-bifenthrin (EFSA, 2015) |
| Pulses/oilseeds                 | Cotton      | Foliar direct, glasshouse: 1 × 25 to 37 µg/leaf | 0, 14, 28 | Phenyl 14C-bifenthrin and Cyclopropyl 13C-bifenthrin were pipetted on leaves (France, 2008) |
|                                  |             | Soil treatment, glasshouse: 1 × 2.5 kg a.s./ha | 0, 14, 28 | Phenyl 14C-bifenthrin and Cyclopropyl 14C-bifenthrin was applied to soil surface (France, 2008) |
### Rotational crops (available studies)

| Crop groups   | Crop(s)       | Application(s)          | PBI (DAT)  | Comment/Source                                                      |
|---------------|---------------|-------------------------|------------|-------------------------------------------------------------------|
| Root/tuber crops | Sugar beet    | Soil, 1 × 0.56 kg a.s./ha | 30, 60, 120 | Phenyl 14C- bifenthrin, glasshouse (EFSA, 2011)                   |
|               |               | Soil, 1 × 0.56 kg a.s./ha |            | Cyclopropyl 14C- bifenthrin, glasshouse (EFSA, 2011)               |
| Leafy crops   | Lettuce       | Soil, 1 × 0.56 kg a.s./ha | 30, 60, 120 | Phenyl 14C- bifenthrin, glasshouse (EFSA, 2011)                   |
|               |               | Soil, 1 × 0.56 kg a.s./ha |            | Cyclopropyl 14C- bifenthrin, glasshouse (EFSA, 2011)               |
| Cereal (small grain) | Wheat     | Soil, 1 × 0.56 kg a.s./ha | 30, 60, 120, 210 and 365 | Phenyl 14C- bifenthrin, glasshouse (EFSA, 2011)                   |
|               |               | Soil, 1 × 0.56 kg a.s./ha |            | Cyclopropyl 14C- bifenthrin, glasshouse (EFSA, 2011)               |

### Processed commodities (hydrolysis study)

| Conditions                                           | Stable? | Comment/Source                                                      |
|------------------------------------------------------|---------|-------------------------------------------------------------------|
| Pasteurisation (20 min, 90°C, pH 4)                  | Yes     | EFSA (2011)                                                       |
| Baking, brewing and boiling (60 min, 100°C, pH 5)    | Yes     | EFSA (2011)                                                       |
| Sterilisation (20 min, 120°C, pH 6)                  | No      | Lack of information on sterilisation was considered a minor deficiency, considering the authorised uses assessed in the MRL review (EFSA, 2015) |
| Other processing conditions                         | -       | -                                                                |

Can a general residue definition be proposed for primary crops? Yes EFSA (2011)
Rotational crop and primary crop metabolism similar? Yes EFSA (2011)
Residue pattern in processed commodities similar to residue pattern in raw commodities? Yes For pasteurisation/baking, brewing and boiling (EFSA, 2011)
Inconclusive For sterilisation (EFSA, 2011)
Plant residue definition for monitoring (RD-Mo) Bifenthrin (sum of isomers)
Plant residue definition for risk assessment (RD-RA) Bifenthrin (sum of isomers)
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs) Matrices with high water content, high oil content and dry matrices: Analytical method (DFG S-19) using GC-ECD, confirmed by GC–MS for bifenthrin, LOQ 0.01 mg/kg. Confirmatory method available. ILV available. (France, 2008, 2010)

DAT: days after treatment; PBI: plant-back interval; a.s.: active substance; MRL: maximum residue level; LOQ: limit of quantification; GC-ECD: gas chromatography with electron capture detector; GC–MS: gas chromatography with mass spectrometry; ILV: independent laboratory validation.
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category               | Commodity          | T (°C) | Stability period Value | Compounds covered | Comment/Source                                                                 |
|-----------------------------------|------------------------|--------------------|--------|------------------------|-------------------|--------------------------------------------------------------------------------|
|                                    | High water content     | Apples             | –18    | 49 Months              | Bifenthrin        | The studies were evaluated during the peer review (EFSA, 2011)                |
|                                    |                        | Potato tuber       | –18    | 6 Months               | Bifenthrin        |                                                                                  |
|                                    |                        | Lettuce            | –18    | 36 Months              | Bifenthrin        |                                                                                  |
|                                    | High oil content       | Pecan nuts         | –18    | 36 Months              | Bifenthrin        |                                                                                  |
|                                    |                        | Cotton seeds       | –18    | 24 Months              | Bifenthrin        |                                                                                  |
|                                    | High protein content   | Dry peas           | –18    | 15 Months              | Bifenthrin        |                                                                                  |
|                                    | Dry/High starch        | Maize grain        | –18    | 34 Months              | Bifenthrin        |                                                                                  |
|                                    | High acid content      | Orange, whole fruit| –18    | 18 Months              | Bifenthrin        | Belgium (2019a)                                                                |
| processed products Others          | Processed potato       | –18                | 6 Months | Bifenthrin              | The studies were evaluated during the peer review (EFSA, 2011) |
| Others                            | Maize silage           | –18                | 49 Months | Bifenthrin              |                    |
|                                    | Maize stover           | –18                | 49 Months | Bifenthrin              |                    |
|                                    | Maize flour            | –18                | 396 Days | Bifenthrin              | Stability of maize corn during the storage interval of 391 days, where the other commodities were stored for 396 days (Belgium, 2019b) |
|                                    | Maize meal             | –18                | 396 Days | Bifenthrin              |                    |
|                                    | Maize starch           | –18                | 396 Days | Bifenthrin              |                    |
|                                    | Maize dry milled refined deodorised oil | –18 | 396 Days | Bifenthrin              |                    |
|                                    | Orange, juice          | –18                | 18 Months | Bifenthrin              | Belgium (2019a)   |
|                                    | Orange, pulp           | –18                | 18 Months | Bifenthrin              |                    |
|                                    | Orange, oil            | –18                | 18 Months | Bifenthrin              |                    |
### B.1.2. Magnitude of residues in plants

#### B.1.2.1. Summary of residues data from the supervised residue trials

| Commodity       | Region/Indoor\(^{(a)}\) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR\(^{(b)}\) (mg/kg) | STMR\(^{(c)}\) (mg/kg) | CF\(^{(d)}\) |
|-----------------|--------------------------|---------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|-----------------------|------------------------|------------|
| Maize grain     | **Outdoor GAP USA** (Foliar, 6 × 112.5 g/ha, PHI 30 days) | 8 × < 0.05                                                     | Residue trials on maize grain compliant with GAP (Belgium, 2019b)              | 0.05                   | 0.05                  | 0.05                   | 1          |
|                 | **Outdoor GAP USA** (Soil treatment, 1 × 112.5 g/ha, PHI 30 days) | 2 × < 0.05                                                     | Decline trials on maize grain performed with one in-furrow application of 112 g a.s./ha at sowing, followed by four broadcast foliar spray applications of 56 g a.s./ha (Belgium, 2019b) | –                     | –                     | –                      | 1          |
| Sweet corn      | **Outdoor GAP USA** (Foliar, 6 × 112.5 g/ha, PHI 1 day) | –                                                             | No GAP-compliant residue trials on sweet corn are available and are required A modification of the current EU MRL for sweet corn of 0.01* mg/kg is not recommended (Belgium, 2019b) | –                     | –                     | –                      | 1          |
|                 | **Outdoor GAP USA** (Soil treatment, 1 × 112.5 g/ha, PHI 30 days) | –                                                             | –                                                                              | –                     | –                     | –                      | 1          |

MRL: maximum residue level; GAP: Good Agricultural Practice; a.s.: active substance; PHI: preharvest interval.

*: 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. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.

\(^{(c)}\): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.

\(^{(d)}\): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
### B.1.2.2. Residues in rotational crops

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | Not triggered | After application of bifenthrin on cereals according to the notified cGAP, no residues above 0.01 mg/kg are expected in parts of rotational crops intended for human consumption (EFSA, 2015). Not relevant for import tolerance application |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | Not triggered | Not relevant for import tolerance application |

cGAP: critical God Agricultural Practice.

### B.1.2.3. Processing factors

| Processed commodity | Number of valid studies(a) | Processing Factor (PF) | CFP(b) | Comment/Source |
|---------------------|---------------------------|------------------------|--------|----------------|
| Maize, coarse meal (dry milling) | 1 | 0.3 | 1 | Tentative(c) Study report P-2281 (Belgium, 2019b) |
| Maize, flour (dry milling I) | 1 | 1.1 | 1 | Tentative(c) Study report P-2281 (Belgium, 2019b) |
| Maize, medium grits (dry milling I) | 1 | < 1 | < 1 | Tentative(c) No concentration because residue was < 0.01 mg/kg. Study report P-2281 (Belgium, 2019b) |
| Maize, crude oil (dry milling I) | 1 | 0.8 | 1 | Tentative(c) Study report P-2281 (Belgium, 2019b) |
| Maize, refined oil (dry milling I) | 1 | 0.9 | 1 | Tentative(c) Study report P-2281 (Belgium, 2019b) |
| Maize, starch (wet milling I) | 1 | < 1 | < 1 | Tentative(c) No concentration because residue was < 0.01 mg/kg. Study report P-2281 (Belgium, 2019b) |
| Maize, crude oil (wet milling I) | 1 | 1.9 | 1 | Tentative(c) Study report P-2281 (Belgium, 2019b) |
| Maize, refined oil (wet milling I) | 1 | 2.3 | 1 | Tentative(c) Study report P-2281 (Belgium, 2019b) |
| Maize, large grits (dry milling II) | 1 | < 1 | < 1 | Tentative(c) No concentration because residue was < 0.01 mg/kg. Study report P-2300 (Belgium, 2019b) |
| Maize, small grits (dry milling II) | 1 | < 1 | < 1 | Tentative(c) No concentration because residue was < 0.01 mg/kg. Study report P-2300 (Belgium, 2019b) |
| Maize, meal (dry milling II) | 1 | 0.5 | 1 | Tentative(c) Study report P-2300 (Belgium, 2019b) |
| Maize, expeller (dry milling II) | 1 | < 1 | < 1 | Tentative(c) No concentration because residue was < 0.01 mg/kg. Study report P-2300 (Belgium, 2019b) |
## B.2. Residues in livestock

Dietary burden calculation according to OECD (2013).

| Relevant groups (sub groups) | Dietary burden (DB) expressed in mg/kg bw per day | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) | EFSA (2015) Max. DB (mg/kg DM)(c) | FAO (2011) Max. DB (ppm) |
|-----------------------------|---------------------------------------------------|---------------------------|---------------------------|------------------------|---------------------------------|--------------------------|
| Cattle (all)                | 0.002 0.002 0.08 0.08                              | Dairy cattle              | Corn, field; gluten feed | No                     | 0.007                           | 8.258                    |
| Cattle (dairy only)         | 0.002 0.002 0.05 0.05                              | Dairy cattle              | Corn, field; gluten feed | No                     | 0.007                           | 7.413                    |
| Sheep (all)                 | 0.002 0.002 0.05 0.05                              | Lamb                      | Corn, field; gluten feed | No                     | –                               | –                        |
| Sheep (ewe only)            | 0.002 0.002 0.05 0.05                              | Ram/Ewe                   | Corn, field; gluten feed | No                     | –                               | –                        |
| Swine (all)                 | 0.002 0.002 0.06 0.06                              | Swine (finishing)         | Corn, field; milled by-products | No                     | –                               | –                        |
| Poultry (all)               | 0.004 0.004 0.06 0.06                              | Turkey                    | Corn, field; milled by-products | No                     | 0.002                           | 0.426                    |

10 The calculations were calculated according to EC guidance document 1996 (European Commission, 1996).
| Relevant groups (sub groups) | Dietary burden (DB) expressed in | Most critical subgroup | Most critical commodity | EFSA (2015) Max. DB (mg/kg DM) | FAO (2011) Max. DB (ppm) |
|-----------------------------|----------------------------------|------------------------|------------------------|------------------------------|--------------------------|
|                             | mg/kg bw per day | mg/kg DM | Median Max. | Median Max. | (Y/N) |                           |
| Poultry (layer only)        | 0.004              | 0.004     | 0.06        | 0.06          | No  | 0.002                      | 1.967                    |
| Corn, field; milled by-products |

Fish: not performed

bw: body weight; DM: dry matter.
(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                    | 2.3              | 7                       | 14C-phenyl-labelled bifenthrin, two animals (EFSA, 2015) |
|                               | 2.3              | 7                       | 14C-cyclopropyl-labelled bifenthrin, two animals (EFSA, 2015) |
| Lactating ruminants           | 2.0              | 10                      | Lactating goats (20 animals), 14C-phenyl-labelled bifenthrin (EFSA, 2015) |
|                               | 2.0              | 10                      | Lactating goats (20 animals), 14C-cyclopropyl-labelled bifenthrin (EFSA, 2015) |

Time needed to reach a plateau concentration in milk and eggs (days)

|                          | Milk             | 4 days (EFSA, 2015) |
|--------------------------|------------------|---------------------|
|                          | Eggs             | 8 days (EFSA, 2015) |

Metabolism in rat and ruminant similar

Yes
Can a general residue definition be proposed for animals?

**Yes**

**Animal residue definition for monitoring (RD-Mo)**

Bifenthrin (sum of isomers)

**Animal residue definition for risk assessment (RD-RA)**

Bifenthrin (sum of isomers)

**Fat soluble residues**

**Yes**

**EFSA (2015)**

**Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs)**

GC–ECD method (DFG S-19), confirmatory method GC–MS and its ILV for food of animal origin with an LOQ of 0.05 mg/kg in muscle and fat and an LOQ of 0.01 mg/kg in milk, kidney and liver (France, 2008; EFSA, 2011). Insufficient validation for eggs (linearity) (EFSA, 2015).

QuEChERS method: tandem mass spectrometry with positive electron ionisation, GC–MS; LOQ of 0.01 mg/kg to enforce bifenthrin (sum of isomers) in eggs (CEN, 2008). An independent ILV would be desirable.

**bw**: body weight; **GC–ECD**: gas chromatography with electron capture detector; **GC–MS**: gas chromatography with mass spectrometry; **LOQ**: limit of quantification; **QuEChERS**: Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method); **ILV**: independent laboratory validation.

### B.2.1.2. Stability of residues in livestock

| Animal Products (available studies) | Animal | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|------------------------------------|--------|-----------|--------|------------------|-------------------|---------------|
|                                    | Cow    | Muscle    | –18    | 36 Months        | Bifenthrin parent | EFSA (2011)   |
|                                    | Fat    | –18       | 36     | Months           | Bifenthrin parent | EFSA (2011)   |
|                                    | Liver  | –18       | 36     | Months           | Bifenthrin parent | EFSA (2011)   |
|                                    | Kidney | –18       | 36     | Months           | Bifenthrin parent | EFSA (2011)   |
|                                    | Milk   | –18       | 36     | Months           | Bifenthrin parent | EFSA (2011)   |
| Poultry                            | Eggs   | –18       | 36     | Months           | Bifenthrin parent | EFSA (2011)   |

### B.3. Consumer risk assessment

**ARfD**

0.03 mg/kg bw (European Commission, 2018)

**Highest IESTI, according to EFSA PRIMo**

Crop under assessment:

Maize grain: 1% of ARfD

Previously assessed uses:

Highest result for sweet pepper/bell pepper: 61% of ARfD

**Assumptions made for the calculations**

The calculation was performed for maize grain and the existing EU MRLs, considering the respective input values derived in the current or in previous assessments.

The calculation was performed with PRIMo rev. 3.1.
High contribution among other commodities assessed previously:
Milk cattle: 21% of ADI
Wheat: 7% of ADI

Assumptions made for the calculations
The exposure calculation took into account maize grain (import tolerance request under assessment) and the previously assessed uses, except the commodities where the EU MRLs have been lowered to the LOQ in 2017. The calculation was performed with PRIMO rev. 3.1.

ADI
0.015 mg/kg bw per day (European Commission, 2018)

Highest IEDI, according to EFSA PRIMO
42% ADI (NL toddler)
Contribution of crop under assessment
Maize grain: 2.35% of ADI (NL toddler)

B.4. Recommended MRLs

| Code (a) | Commodity | Existing MRL (b) | Proposed MRL | Conclusion/recommendation |
|---------|-----------|-----------------|--------------|----------------------------|
| 0110000 | Citrus fruits | 0.05 (ft 1) | 0.05 | The existing MRL is based on the existing CXL set by Codex Alimentarius Commission (CAC) in 2011. The data gap identified by EFSA concerning storage stability has been addressed |
| 0110100 | Grapefruits | | | |
| 0110200 | Oranges | | | |
| 0110300 | Lemons | | | |
| 0110400 | Limes | | | |
| 0110500 | Mandarins | | | |
| 0110990 | Others | | | |
| 0152000 | Strawberries | 1 (ft 1) | Further risk management considerations required | The data gap identified by EFSA concerning storage stability has been addressed. EFSA recommends further risk management discussions whether the existing EU MRL which is based on a CXL should be maintained, taking into account the assessment history in Codex: In 1992, JMPR assessed the use of bifenthrin in strawberries and derived a Codex MRL proposal. JMPR noted that the residue trials did not fully reflect the reported GAP for bifenthrin; additional data on strawberries reflecting the GAP which allows multiple applications would be desirable. In 1995, the CXL for strawberries was adopted, despite the data gaps. In the framework of the periodic review in 2010, JMPR recommended the withdrawal of the existing CXL, since a GAP supporting the CXL of 1 mg/kg was not provided. In this periodic review, JMPR assessed a new GAP for strawberries; however, since the expected exposure exceeded the ARFD, CCPR decided to maintain the old CXL, awaiting the submission of an alternative GAP. In 2019, JMPR assessed an alternative GAP and again an exceedance of the ARFD was identified.|

ARID: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMO: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; LOQ: limit of quantification.
Taking into account that JMPR has never received information on a GAP matching the residue trials which were used to derive the existing CXL of 1 mg/kg, and that no alternative GAP has been provided within the last 10 years which would allow to establish a CXL which does not pose a consumer health risk, further risk management considerations are required whether the existing EU MRL should be reconsidered.

The requested validation data for the analytical methods have not been provided. However, a CEN method is available for products of animal origin (including eggs), which was sufficiently validated for quantifying bifenthrin (sum of isomers) residues at or above the LOQ of 0.01 mg/kg.

For the CEN method, a full validation by an independent laboratory would be desirable. However, considering that the method is accepted by CEN and that according to the feeding studies in poultry residues in eggs are unlikely to occur at levels greater than 0.01 mg/kg, this is considered a minor deficiency.

Label information for the USA was provided. The submitted data are sufficient to derive an import tolerance based on the foliar use. Risk for consumers unlikely. Bifenthrin MRL in the USA of 0.05 mg/kg is in place.

Label information for the USA was provided. No GAP compliant trials were provided. Bifenthrin MRL in the USA of 0.05 mg/kg is in place.

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**Evaluation of confirmatory data and setting of import tolerances for bifenthrin**

| Code(a) | Commodity | Existing MRL(b) | Proposed MRL | Conclusion/recommendation |
|---------|------------|----------------|--------------|---------------------------|
| 0153000 | Cane fruits | 1 (ft 1) | 1 | The existing MRL is based on the CXL derived in 2011 for blackberries, dewberries and raspberries. The data gap identified by EFSA concerning storage stability has been addressed. |
| 0153010 | Blackberries | 1 | | |
| 0153020 | Dewberries | 1 | | |
| 0153030 | Raspberries (red and yellow) | 0.01 (ft 2) | 0.01* | The requested validation data for the analytical methods have not been provided. However, a CEN method is available for products of animal origin (including eggs), which was sufficiently validated for quantifying bifenthrin (sum of isomers) residues at or above the LOQ of 0.01 mg/kg. For the CEN method, a full validation by an independent laboratory would be desirable. However, considering that the method is accepted by CEN and that according to the feeding studies in poultry residues in eggs are unlikely to occur at levels greater than 0.01 mg/kg, this is considered a minor deficiency. |
| 0153990 | Others | | | |
| 1030000 | Birds eggs | 0.01* | | |
| 1030010 | Chicken | | | |
| 1030020 | Duck | | | |
| 1030030 | Geese | | | |
| 1030040 | Quail | | | |
| 1030990 | Others | | | |

### Import tolerance application

| Code(a) | Commodity | Existing MRL(b) | Proposed MRL | Conclusion/recommendation |
|---------|------------|----------------|--------------|---------------------------|
| 0500030 | Maize grain | 0.05* | 0.05* | Label information for the USA was provided. The submitted data are sufficient to derive an import tolerance based on the foliar use. Risk for consumers unlikely. Bifenthrin MRL in the USA of 0.05 mg/kg is in place. |
| 0234000 | Sweet corn | 0.01* | No proposal | Label information for the USA was provided. No GAP compliant trials were provided. Bifenthrin MRL in the USA of 0.05 mg/kg is in place. |

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**Notes:**

- **MRL:** maximum residue limit; CXL: Codex maximum residue limit; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; CCPR: Codex Committee on Pesticide Residues; GAP: Good Agricultural Practice; CEN: European Committee for Standardisation; LOQ: limit of quantification; ARfD: acute reference dose.
- **:** Indicates that the MRL is set at the limit of analytical quantification (LOQ).
- **(a):** Commodity code number according to Annex I of Regulation (EC) No 396/2005.
- **(b):** Existing EU MRL and corresponding footnote on confirmatory data.
- **(F):** Fat-soluble.
- **ft 1:** The European Food Safety Authority identified some information on storage stability as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 3 February 2019, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 2).
- **ft 2:** The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 3 February 2019, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 1).
### Evaluation of confirmatory data and setting of import tolerances for bifenthrin

#### Appendix C – Pesticide Residue Intake Model (PRIMo)

**Bifenthrin (F)**

| Commodity | Calculated exposure (µg/kg bw per day) | Highest contributor to Calendar Year diet (as % of ADI) | Community | Highest contributor to MS diet (as % of ADI) | Community |
|-----------|---------------------------------------|-------------------------------------------------------|-----------|--------------------------------------------|-----------|
| Wheat     | 2.97                                  | Wheat                                                | 3%        | Wheat                                      | 3%        |
| Milk: Cattle | 2.38                                  | Wheat                                                | 3%        | Milk: Cattle                               | 3%        |
| Bovine: Muscle/meat | 2.20                                  | Wheat                                                | 3%        | Bovine: Muscle/meat                        | 3%        |
| Strawberries | 2.04                                  | Strawberry                                            | 3%        | Strawberries                               | 3%        |
| Tomatoes  | 2.01                                  | Tomato                                               | 3%        | Tomatoes                                   | 3%        |
| Soyabeans | 1.88                                  | Soyabeans                                             | 3%        | Soyabeans                                  | 3%        |
| Potatoes  | 1.72                                  | Potato                                               | 3%        | Potatoes                                   | 3%        |
| Head cabbages | 1.49                                  | Head cabbage                                          | 3%        | Head cabbage                               | 3%        |
| Cabbage   | 1.44                                  | Cabbage                                              | 3%        | Cabbage                                    | 3%        |
| Tomatoes  | 1.43                                  | Tomato                                               | 3%        | Tomato                                     | 3%        |
| Potatoes  | 1.27                                  | Potato                                               | 3%        | Potato                                     | 3%        |
| head cabbages | 1.23                                  | head cabbage                                          | 3%        | head cabbage                               | 3%        |
| Cabbage   | 1.19                                  | Cabbage                                              | 3%        | Cabbage                                    | 3%        |
| Tomatoes  | 1.15                                  | Tomato                                               | 3%        | Tomato                                     | 3%        |
| Potatoes  | 1.12                                  | Potato                                               | 3%        | Potato                                     | 3%        |
| head cabbages | 1.10                                  | head cabbage                                          | 3%        | head cabbage                               | 3%        |
| Cabbage   | 1.07                                  | Cabbage                                              | 3%        | Cabbage                                    | 3%        |
| Tomatoes  | 1.05                                  | Tomato                                               | 3%        | Tomato                                     | 3%        |
| Potatoes  | 1.01                                  | Potato                                               | 3%        | Potato                                     | 3%        |
| head cabbages | 0.90                                  | head cabbage                                          | 3%        | head cabbage                               | 3%        |
| Cabbage   | 0.85                                  | Cabbage                                              | 3%        | Cabbage                                    | 3%        |
| Tomatoes  | 0.81                                  | Tomato                                               | 3%        | Tomato                                     | 3%        |
| Potatoes  | 0.76                                  | Potato                                               | 3%        | Potato                                     | 3%        |
| head cabbages | 0.71                                  | head cabbage                                          | 3%        | head cabbage                               | 3%        |
| Cabbage   | 0.66                                  | Cabbage                                              | 3%        | Cabbage                                    | 3%        |
| Tomatoes  | 0.62                                  | Tomato                                               | 3%        | Tomato                                     | 3%        |
| Potatoes  | 0.59                                  | Potato                                               | 3%        | Potato                                     | 3%        |
| head cabbages | 0.55                                  | head cabbage                                          | 3%        | head cabbage                               | 3%        |
| Cabbage   | 0.51                                  | Cabbage                                              | 3%        | Cabbage                                    | 3%        |
| Tomatoes  | 0.48                                  | Tomato                                               | 3%        | Tomato                                     | 3%        |
| Potatoes  | 0.45                                  | Potato                                               | 3%        | Potato                                     | 3%        |
| head cabbages | 0.41                                  | head cabbage                                          | 3%        | head cabbage                               | 3%        |
| Cabbage   | 0.38                                  | Cabbage                                              | 3%        | Cabbage                                    | 3%        |
| Tomatoes  | 0.35                                  | Tomato                                               | 3%        | Tomato                                     | 3%        |
| Potatoes  | 0.32                                  | Potato                                               | 3%        | Potato                                     | 3%        |
| head cabbages | 0.29                                  | head cabbage                                          | 3%        | head cabbage                               | 3%        |
| Cabbage   | 0.26                                  | Cabbage                                              | 3%        | Cabbage                                    | 3%        |
| Tomatoes  | 0.24                                  | Tomato                                               | 3%        | Tomato                                     | 3%        |
| Potatoes  | 0.21                                  | Potato                                               | 3%        | Potato                                     | 3%        |
| head cabbages | 0.18                                  | head cabbage                                          | 3%        | head cabbage                               | 3%        |
| Cabbage   | 0.16                                  | Cabbage                                              | 3%        | Cabbage                                    | 3%        |
| Tomatoes  | 0.14                                  | Tomato                                               | 3%        | Tomato                                     | 3%        |
| Potatoes  | 0.12                                  | Potato                                               | 3%        | Potato                                     | 3%        |
| head cabbages | 0.10                                  | head cabbage                                          | 3%        | head cabbage                               | 3%        |
| Cabbage   | 0.08                                  | Cabbage                                              | 3%        | Cabbage                                    | 3%        |
| Tomatoes  | 0.06                                  | Tomato                                               | 3%        | Tomato                                     | 3%        |
| Potatoes  | 0.04                                  | Potato                                               | 3%        | Potato                                     | 3%        |
| head cabbages | 0.02                                  | head cabbage                                          | 3%        | head cabbage                               | 3%        |
| Cabbage   | 0.00                                  | Cabbage                                              | 3%        | Cabbage                                    | 3%        |
| Tomatoes  | 0.00                                  | Tomato                                               | 3%        | Tomato                                     | 3%        |
| Potatoes  | 0.00                                  | Potato                                               | 3%        | Potato                                     | 3%        |

**Conclusion:**

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Bifenthrin (F) is unlikely to present a public health concern.
### Evaluation of confirmatory data and setting of import tolerances for bifenthrin

**Acute risk assessment/children**

- Details – acute risk assessment/children

**Acute risk assessment/adults/general population**

- Details – acute risk assessment/adults

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#### Show results for all crops

| Commodities                  | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | IESTI | Highest % of ARfD/ADI | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | IESTI | Highest % of ARfD/ADI |
|------------------------------|--------------------------|---------------------|-------|-----------------------|--------------------------|---------------------|-------|-----------------------|
| Sweet peppers/bell peppers  | 0.50/0.31                | 18                  | 61%   | 0.5%                  |                          |                     |       |                       |
| Strawberries                 | 1/1                      | 16                  | 54%   | 1%                    |                          |                     |       |                       |
| Cauliflowewrs               | 0.40/0.19                | 11                  | 37%   | 27%                   |                          |                     |       |                       |
| Tabe grapes                  | 0.30/0.14                | 10                  | 34%   | 17%                   |                          |                     |       |                       |
| Kohrabies                    | 0.40/0.19                | 9.9                 | 33%   | 16%                   |                          |                     |       |                       |
| Blueberries                  | 3/16/0.95                | 9.5                 | 32%   | 15%                   |                          |                     |       |                       |
| Tomatoes                     | 0.30/0.15                | 8.7                 | 29%   | 15%                   |                          |                     |       |                       |
| Head cabbages               | 0.40/0.19                | 8.4                 | 28%   | 14%                   |                          |                     |       |                       |
| Tea (dried leaves of)        | 0.17/0.80                | 8.0                 | 27%   | 13%                   |                          |                     |       |                       |
| Broccoli                     | 0.40/0.19                | 7.9                 | 26%   | 11%                   |                          |                     |       |                       |
| Potatoes                     | 0.05/0.05                | 7.7                 | 26%   | 9%                    |                          |                     |       |                       |
| Oranges                      | 0.05/0.05                | 6.6                 | 22%   | 9%                    |                          |                     |       |                       |
| Milk: Cow                    | 0.20/0.05                | 6.6                 | 19%   | 9%                    |                          |                     |       |                       |
| Sweet: Muscle/meat           | 0.20/0.46                | 5.6                 | 19%   | 9%                    |                          |                     |       |                       |
| Blackberries                 | 1.5/1                   | 5.5                 | 18%   | 9%                    |                          |                     |       |                       |
| Raspberries (red and)        | 1/0.1                   | 4.7                 | 16%   | 8%                    |                          |                     |       |                       |
| Peas (with pods)             | 0.9/0.5                 | 4.1                 | 14%   | 7%                    |                          |                     |       |                       |
| Boivne: Fat tissue           | 3/1.9                   | 4.0                 | 13%   | 7%                    |                          |                     |       |                       |
| Grapefruits                  | 0.05/0.05               | 3.9                 | 12%   | 7%                    |                          |                     |       |                       |
| Wheat                        | 0.5/0.25                 | 3.6                 | 11%   | 7%                    |                          |                     |       |                       |
| Boivne: Muscle/meat          | 0.20/0.46               | 3.3                 | 11%   | 6%                    |                          |                     |       |                       |
| Swine: Fat tissue            | 3/1.9                   | 3.2                 | 11%   | 6%                    |                          |                     |       |                       |
| Carrots                      | 0.05/0.05               | 3.2                 | 10%   | 6%                    |                          |                     |       |                       |
| Mandarins                    | 0.05/0.05               | 3.0                 | 10%   | 5%                    |                          |                     |       |                       |
| Beetroots                    | 0.05/0.05               | 2.9                 | 10%   | 5%                    |                          |                     |       |                       |
| Swine: Muscle/meat           | 0.20/0.46               | 2.5                 | 8%    | 3%                    |                          |                     |       |                       |
| Aubergines/egg plants        | 0.15/0.1                | 2.5                 | 8%    | 3%                    |                          |                     |       |                       |
| Papayas                      | 0.40/0.05               | 1.9                 | 6%    | 3%                    |                          |                     |       |                       |
| Parsnips                     | 0.05/0.05               | 1.8                 | 6%    | 3%                    |                          |                     |       |                       |
| Turnips                      | 0.05/0.05               | 1.8                 | 6%    | 3%                    |                          |                     |       |                       |
| Lemons                       | 0.05/0.05               | 1.8                 | 6%    | 3%                    |                          |                     |       |                       |
| Brussels sprouts             | 0.40/0.19               | 1.6                 | 5%    | 3%                    |                          |                     |       |                       |
| Yams                         | 0.05/0.05               | 1.6                 | 5%    | 3%                    |                          |                     |       |                       |
| Salafes                      | 0.05/0.05               | 1.6                 | 5%    | 2%                    |                          |                     |       |                       |
| Bananas                      | 0.1/0.01                | 1.4                 | 5%    | 2%                    |                          |                     |       |                       |
| Bovine: Liver                | 0.20/0.17               | 1.3                 | 4%    | 2%                    |                          |                     |       |                       |
| Wine grapes                  | 0.5/0.05                | 1.3                 | 4%    | 2%                    |                          |                     |       |                       |
| Mangoes                      | 0.5/0.02                | 1.3                 | 4%    | 2%                    |                          |                     |       |                       |
| Milk: Goat                   | 0.20/0.05               | 1.3                 | 4%    | 2%                    |                          |                     |       |                       |
| Radishes                     | 0.05/0.05               | 1.2                 | 4%    | 2%                    |                          |                     |       |                       |
| Pours: Muscle                | 0.05/0.05               | 1.0                 | 3%    | 2%                    |                          |                     |       |                       |
| Limes                        | 0.30/0.05               | 0.9                 | 3%    | 2%                    |                          |                     |       |                       |
| Beans                        | 0.30/0.05               | 0.9                 | 3%    | 2%                    |                          |                     |       |                       |
| Potleys: Muscle/meat         | 0.05/0.05               | 0.85                | 3%    | 2%                    |                          |                     |       |                       |
| Coconuts                     | 0.05/0.05               | 0.72                | 2%    | 2%                    |                          |                     |       |                       |
| Bovine: Kidney               | 0.20/0.17               | 0.62                | 2%    | 2%                    |                          |                     |       |                       |
| Peas (without pods)          | 0.05/0.05               | 0.41                | 1%    | 1%                    |                          |                     |       |                       |
| Cassova roots/manioc         | 0.05/0.05               | 0.40                | 1%    | 1%                    |                          |                     |       |                       |
| Celeries                     | 0.05/0.05               | 0.37                | 1%    | 1%                    |                          |                     |       |                       |
| Maize/com                    | 0.05/0.05               | 0.34                | 1%    | 1%                    |                          |                     |       |                       |
| Lentis                       | 0.30/0.05               | 0.33                | 1%    | 1%                    |                          |                     |       |                       |
| Peas                         | 0.30/0.05               | 0.33                | 1%    | 1%                    |                          |                     |       |                       |
| Pistaschi                    | 0.05/0.05               | 0.29                | 1%    | 1%                    |                          |                     |       |                       |
| Sweet potatoes               | 0.05/0.05               | 0.26                | 0.9%  | 1%                    |                          |                     |       |                       |
| HOPS (dried)                 | 0.05/0.05               | 0.23                | 0.8%  | 1%                    |                          |                     |       |                       |
| Parsley roots/Hamburg        | 0.05/0.05               | 0.22                | 0.7%  | 1%                    |                          |                     |       |                       |
| Chestnuts                    | 0.05/0.05               | 0.21                | 0.7%  | 1%                    |                          |                     |       |                       |
| Swine: Kidney                | 0.20/0.17               | 0.20                | 0.7%  | 1%                    |                          |                     |       |                       |
| Milk: Sheep                  | 0.20/0.05               | 0.19                | 0.6%  | 1%                    |                          |                     |       |                       |
| Walnuts                      | 0.05/0.05               | 0.17                | 0.5%  | 1%                    |                          |                     |       |                       |
| Hazelnuts/coanuts            | 0.05/0.05               | 0.16                | 0.5%  | 1%                    |                          |                     |       |                       |
| Almonds                      | 0.05/0.05               | 0.14                | 0.5%  | 1%                    |                          |                     |       |                       |
| Pecans                       | 0.05/0.05               | 0.14                | 0.5%  | 1%                    |                          |                     |       |                       |
### Evaluation of confirmatory data and setting of import tolerances for bifenthrin

| Processed commodities            | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Processed commodities            | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|----------------------------------|--------------------------|---------------------|----------------------------------|--------------------------|---------------------|
| Broccoli/boiled                 | 0.4/0.19                 | 15                  | Cauliflowers/boiled              | 0.4/0.19                 | 15                  |
| Potatoes/fried                   | 0.05/0.05                | 4.7                 | Potatoes/dried (flakes)          | 0.05/0.23                | 3.0                 |
| Raspberries/ juice               | 1.0/2.9                  | 3.4                 | Orange/ juice                    | 0.05/0.05                | 2.6                 |
| Wheat/milling (flour)            | 0.5/0.25                 | 3.0                 | Peas (with pods)/boiled          | 0.9/0.5                  | 1.7                 |
| Potato/s/bread                   | 0.05/0.05                | 2.5                 | Wine grapes/wine                 | 0.3/0.14                 | 1.3                 |
| Turnips/boiled                   | 0.05/0.05                | 2.5                 | Head cabbages/canned             | 0.4/0.12                 | 1.1                 |
| Parsnips/boiled                  | 0.05/0.05                | 2.5                 | Wheat/bread/pizza                | 0.5/0.25                 | 1.1                 |
| Sweet potatoes/boiled            | 0.05/0.05                | 2.5                 | Tea (dried leaves of)            | 0.3/0.05                 | 1.1                 |
| Beetroot/boiled                  | 0.05/0.05                | 2.2                 | Turnips/boiled                   | 0.5/0.05                 | 0.95                |
| Brussels sprouts/boiled          | 0.4/0.19                 | 1.9                 | Parsnips/boiled                  | 0.5/0.05                 | 1.1                 |
| Tea (dried leaves of Camelli)    | 0.3/0.05                 | 1.8                 | Cassava roots/boiled             | 0.5/0.05                 | 0.95                |
| Carrots/ juice                   | 0.05/0.05                | 1.8                 | Celeriacs/boiled                 | 0.5/0.05                 | 0.91                |

### Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Bifenthrin (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

| Feed commodity | Median dietary burden | Maximum dietary burden |
|----------------|-----------------------|------------------------|
|                | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| **Risk assessment residue definition:** bifenthrin (sum of isomers) |
| Rapeseed | 0.02 | STMR × PF default<sup>a</sup> (EFSA, 2015) | 0.02 | STMR × PF default<sup>a</sup> (EFSA, 2015) |
| Corn (field/pop) grain<sup>b</sup> | 0.05 | STMR | 0.05 | STMR |
| Corn (field), milled by-product<sup>b</sup> | 0.05 | STMR | 0.05 | STMR |
| Corn (field), hominy meal<sup>b</sup> | 0.05 | STMR | 0.05 | STMR |
| Corn (field), gluten feed<sup>b</sup> | 0.05 | STMR | 0.05 | STMR |
| Corn (field), gluten meal<sup>b</sup> | 0.05 | STMR | 0.05 | STMR |
| Distiller's grain, dried<sup>b</sup> | 0.05 | STMR | 0.05 | STMR |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.

<sup>a</sup>: For rape seed a default processing factors of 2 was included in the calculation to consider the potential concentration of residues in these commodities (EFSA, 2015).

<sup>b</sup>: For corn grain, corn milled-by-products, corn hominy meal, corn gluten feed, corn gluten meal and distiller's grain (dried) no default processing factor was applied because bifenthrin residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.

### D.2. Consumer risk assessment

| Commodity | Existing/Proposed MRL (mg/kg) | Source/type of MRL | Chronic risk assessment<sup>a</sup> | Acute risk assessment<sup>b</sup> |
|-----------|-------------------------------|--------------------|------------------------------------|-----------------------------------|
|           |                               |                    | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Grapefruits | 0.05  | EFSA (2015) | 0.05 | STMR-RAC | 0.05 | MRL |
| Oranges   | 0.05  | EFSA (2015) | 0.05 | STMR-RAC | 0.05 | LOQ |
| Lemons    | 0.05  | EFSA (2015) | 0.05 | STMR-RAC | 0.05 | LOQ |
| Limes     | 0.05  | EFSA (2015) | 0.05 | STMR-RAC | 0.05 | LOQ |
| Mandarins | 0.05  | EFSA (2015) | 0.05 | STMR-RAC | 0.05 | LOQ |
| Other citrus fruit | 0.05 | EFSA (2015) | 0.05 | STMR-RAC | – | – |
| Almonds   | 0.05  | EFSA (2015) | 0.05 | STMR-RAC | 0.05 | LOQ |
| Brazil nuts | 0.05 | EFSA (2015) | 0.05 | STMR-RAC | 0.05 | LOQ |
| Cashew nuts | 0.05 | EFSA (2015) | 0.05 | STMR-RAC | 0.05 | LOQ |
| Chestnuts | 0.05  | EFSA (2015) | 0.05 | STMR-RAC | 0.05 | LOQ |
| Coconuts  | 0.05  | EFSA (2015) | 0.05 | STMR-RAC | 0.05 | LOQ |
| Hazelnuts/cobnuts | 0.05 | EFSA (2015) | 0.05 | STMR-RAC | 0.05 | LOQ |
| Macadamia | 0.05  | EFSA (2015) | 0.05 | STMR-RAC | 0.05 | LOQ |
| Pecans    | 0.05  | EFSA (2015) | 0.05 | STMR-RAC | 0.05 | LOQ |
| Pine nut kernels | 0.05 | EFSA (2015) | 0.05 | STMR-RAC | 0.05 | LOQ |
| Pistachios | 0.05 | EFSA (2015) | 0.05 | STMR-RAC | 0.05 | LOQ |
| Walnuts   | 0.05  | EFSA (2015) | 0.05 | STMR-RAC | 0.05 | LOQ |
| Other tree nuts | 0.05 | EFSA (2015) | 0.05 | STMR-RAC | – | – |
| Table grapes | 0.3  | CXL (FAO, 2016) | 0.06 | STMR-RAC | 0.14 | HR-RAC |
| Wine grapes | 0.3   | CXL adopted (FAO, 2016) | 0.06 | STMR-RAC | 0.14 | HR-RAC |
| Strawberries | 1   | EU MRL | 1 | STMR-RAC | 1 | HR-RAC |
| Blackberries | 1  | CXL (FAO, 2011) | 0.29 | STMR-RAC | 0.51 | HR-RAC |
| Commodity                      | Existing/Proposed MRL (mg/kg) | Source/type of MRL | Chronic risk assessment\(^{(a)}\) | Input value (mg/kg) | Comment | Acute risk assessment\(^{(b)}\) | Input value (mg/kg) | Comment |
|-------------------------------|-------------------------------|--------------------|-----------------------------------|---------------------|---------|---------------------------------|---------------------|---------|
| Dewberries                    | 1                             | CXL (FAO, 2011)    | STMR-RAC                          | 1                   |         | HR-RAC                          |                     |         |
| Raspberries (red and yellow)  | 1                             | CXL (FAO, 2011)    | STMR-RAC                          | 1                   |         | HR-RAC                          |                     |         |
| Other cane fruit              | 1                             | EFSA (2015)        | STMR-RAC                          | –                   | –       | –                               | –                   | –       |
| Blueberries                   | 3                             | CXL (FAO, 2016)    | STMR-RAC                          | 0.67                |         | HR-RAC                          | 1.6                 |         |
| Bananas                       | 0.1                           | EFSA (2015)        | STMR-RAC                          | 0.01                |         | HR-RAC                          | 0.015               |         |
| Mangoes                       | 0.5                           | EFSA (2015)        | STMR-RAC                          | 0.01                |         | HR-RAC                          | 0.016               |         |
| Papayas                       | 0.4                           | EFSA (2015)        | STMR-RAC                          | 0.023               |         | HR-RAC                          | 0.045               |         |
| Potatoes                      | 0.05                          | EFSA (2015)        | STMR-RAC                          | 0.05                |         | LOQ                             |                     |         |
| Cassava roots/manioc          | 0.05                          | EFSA (2015)        | STMR-RAC                          | 0.05                |         | LOQ                             |                     |         |
| Sweet potatoes                | 0.05                          | EFSA (2015)        | STMR-RAC                          | 0.05                |         | LOQ                             |                     |         |
| Yams                          | 0.05                          | EFSA (2015)        | STMR-RAC                          | 0.05                |         | LOQ                             |                     |         |
| Arrowroots                    | 0.05                          | EFSA (2015)        | STMR-RAC                          | 0.05                |         | LOQ                             |                     |         |
| Other tropical root and tuber vegetables | 0.05 | EFSA (2015) | STMR-RAC                          | 0.05                |         | –                               | –                   | –       |
| Beetroots                     | 0.05                          | EFSA (2015)        | STMR-RAC                          | 0.05                |         | LOQ                             |                     |         |
| Carrots                       | 0.05                          | EFSA (2015)        | STMR-RAC                          | 0.05                |         | LOQ                             |                     |         |
| Celeriacs/turnip rooted celeries | 0.05 | EFSA (2015) | STMR-RAC                          | 0.05                |         | LOQ                             |                     |         |
| Horseradishes                 | 0.05                          | EFSA (2015)        | STMR-RAC                          | 0.05                |         | LOQ                             |                     |         |
| Jerusalem artichokes          | 0.05                          | EFSA (2015)        | STMR-RAC                          | 0.05                |         | LOQ                             |                     |         |
| Parsnips                      | 0.05                          | EFSA (2015)        | STMR-RAC                          | 0.05                |         | LOQ                             |                     |         |
| Parsley roots/Hamburg roots parsley | 0.05 | EFSA (2015) | STMR-RAC                          | 0.05                |         | LOQ                             |                     |         |
| Radishes                      | 0.05                          | EFSA (2015)        | STMR-RAC                          | 0.05                |         | LOQ                             |                     |         |
| Salsifies                     | 0.05                          | EFSA (2015)        | STMR-RAC                          | 0.05                |         | LOQ                             |                     |         |
| Swedes/rutabagas              | 0.05                          | EFSA (2015)        | STMR-RAC                          | 0.05                |         | LOQ                             |                     |         |
| Turnips                       | 0.05                          | EFSA (2015)        | STMR-RAC                          | 0.05                |         | LOQ                             |                     |         |
| Other root and tuber vegetables | 0.05 | EFSA (2015) | STMR-RAC                          | 0.05                |         | –                               | –                   | –       |
| Tomatoes                      | 0.3                           | CXL (FAO, 2011)    | STMR-RAC                          | 0.06                |         | HR-RAC                          | 0.15                |         |
| Sweet peppers/bell peppers    | 0.5                           | CXL (FAO, 2011)    | STMR-RAC                          | 0.14                |         | HR-RAC                          | 0.31                |         |
| Aubergines/egg plants         | 0.3                           | CXL (FAO, 2011)    | STMR-RAC                          | 0.05                |         | HR-RAC                          | 0.1                 |         |
| Okra/lady’s fingers           | 0.2                           | CXL (FAO, 2011)    | STMR-RAC                          | 0.07                |         | HR-RAC                          | 0.11                |         |
| Broccoli                      | 0.4                           | EFSA (2015)        | STMR-RAC                          | 0.12                |         | HR-RAC                          | 0.19                |         |
| Cauliflowers                  | 0.4                           | EFSA (2015)        | STMR-RAC                          | 0.12                |         | HR-RAC                          | 0.19                |         |
| Other flowering brassica      | 0.4                           | EFSA (2015)        | STMR-RAC                          | 0.12                |         | –                               | –                   | –       |
| Brussels sprouts              | 0.4                           | EFSA (2015)        | STMR-RAC                          | 0.12                |         | HR-RAC                          | 0.19                |         |
| Head cabbages                 | 0.4                           | EFSA (2015)        | STMR-RAC                          | 0.12                |         | HR-RAC                          | 0.19                |         |
| Commodity                  | Existing/Proposed MRL (mg/kg) | Source/type of MRL | Chronic risk assessment\(^{(a)}\) | Acute risk assessment\(^{(b)}\) |
|---------------------------|-----------------------------|-------------------|---------------------------------|-------------------------------|
|                           |                             |                   | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Other head brassica       | 0.4                         | EFSA (2015)       | 0.12               | STMR-RAC | –                  | – |
| Kohlrabies                | 0.4                         | EFSA (2015)       | 0.12               | STMR-RAC | 0.19               | HR-RAC |
| Baby leaf crops (including brassica species) | 4                           | EFSA (2015)       | 1.75               | STMR-RAC | 2.3                | HR-RAC |
| Peas (with pods)          | 0.9                         | CXL (FAO, 2016)   | 0.23               | STMR-RAC | 0.5                | HR-RAC |
| Peas (without pods)       | 0.05                        | EFSA (2015)       | 0.05               | STMR-RAC | 0.05               | LOQ |
| Celeries                  | 0.01                        | EFSA (2015)       | 0.01               | STMR-RAC | 0.01               | LOQ |
| Beans                     | 0.3                         | EFSA (2015)       | 0.05               | STMR-RAC | 0.05               | STMR-RAC |
| Lentils                   | 0.3                         | EFSA (2015)       | 0.05               | STMR-RAC | 0.05               | STMR-RAC |
| Peas                      | 0.3                         | EFSA (2015)       | 0.05               | STMR-RAC | 0.05               | STMR-RAC |
| Lupins/lupini beans       | 0.3                         | EFSA (2015)       | 0.05               | STMR-RAC | 0.05               | STMR-RAC |
| Other pulses              | 0.3                         | EFSA (2015)       | 0.05               | STMR-RAC | –                  | – |
| Rapeseyes/canola seeds    | 0.05                        | EFSA (2015)       | 0.05               | STMR-RAC | 0.05               | STMR-RAC |
| Soya beans                | 0.3                         | EFSA (2015)       | 0.05               | STMR-RAC | 0.05               | STMR-RAC |
| Cotton seeds              | 0.5                         | CXL (FAO, 2011)   | 0.05               | STMR-RAC | 0.05               | STMR-RAC |
| Barley                    | 0.05                        | EFSA (2015)       | 0.01               | STMR-RAC | 0.01               | STMR-RAC |
| Maize/corn                | 0.05                        | EFSA (2015)       | 0.05               | STMR-RAC | 0.05               | STMR-RAC |
| Wheat                     | 0.5                         | EFSA (2015)       | 0.25               | STMR-RAC | 0.25               | STMR-RAC |
| Tea (dried leaves of Camellia sinensis) | 30                         | EFSA (2015)       | 5.2                | STMR-RAC | 5.2                | STMR-RAC |
| HOPS (dried)              | 20                          | EFSA (2015)       | 1.9                | STMR-RAC | 5.4                | HR-RAC |
| Allspice/pimento          | 0.03                        | EFSA (2015)       | 0.03               | STMR-RAC | 0.03               | HR-RAC |
| Sichuan pepper            | 0.03                        | EFSA (2015)       | 0.03               | STMR-RAC | 0.03               | HR-RAC |
| Caraway                   | 0.03                        | EFSA (2015)       | 0.03               | STMR-RAC | 0.03               | HR-RAC |
| Cardamom                  | 0.03                        | EFSA (2015)       | 0.03               | STMR-RAC | 0.03               | HR-RAC |
| Juniper berry             | 0.03                        | EFSA (2015)       | 0.03               | STMR-RAC | 0.03               | HR-RAC |
| Peppercorn (black, green and white) | 0.03                        | EFSA (2015)       | 0.03               | STMR-RAC | 0.03               | HR-RAC |
| Vanilla pods              | 0.03                        | EFSA (2015)       | 0.03               | STMR-RAC | 0.03               | HR-RAC |
| Tamarind                  | 0.03                        | EFSA (2015)       | 0.03               | STMR-RAC | 0.03               | HR-RAC |
| Other spices (fruits)     | 0.03                        | EFSA (2015)       | 0.03               | STMR-RAC | –                  | – |
| Liquorice                 | 0.05                        | EFSA (2015)       | 0.05               | STMR-RAC | 0.05               | HR-RAC |
| Ginger                    | 0.05                        | EFSA (2015)       | 0.05               | STMR-RAC | 0.05               | STMR-RAC |
| Turmeric/curcuma          | 0.05                        | EFSA (2015)       | 0.05               | STMR-RAC | 0.05               | HR-RAC |
| Horseradish, root spices  | 0.35                        | EFSA (2015)       | 0.05               | STMR-RAC | 0.05               | HR-RAC |
| Other spices (roots)      | 0.05                        | EFSA (2015)       | 0.05               | STMR-RAC | –                  | – |
| Commodity         | Existing/Proposed MRL (mg/kg) | Source/type of MRL | Chronic risk assessment<sup>(a)</sup> | Acute risk assessment<sup>(b)</sup> |
|------------------|------------------------------|--------------------|----------------------------------------|-------------------------------------|
|                  |                              |                    | Input value (mg/kg) | Comment      | Input value (mg/kg) | Comment      |
| Swine: Muscle/meat<sup>(c)</sup> | 0.2                          | EFSA (2015)        | 0.174                    | STMR-RAC  | 0.463                | HR-RAC      |
| Swine: Fat tissue | 3                            | EFSA (2015)        | 0.59                     | STMR-RAC  | 1.9                  | HR-RAC      |
| Swine: Liver      | 0.2                          | EFSA (2015)        | 0.07                     | STMR-RAC  | 0.165                | HR-RAC      |
| Swine: Kidney     | 0.2                          | EFSA (2015)        | 0.07                     | STMR-RAC  | 0.165                | HR-RAC      |
| Bovine: Muscle/meat<sup>(c)</sup> | 0.2                          | EFSA (2015)        | 0.174                    | STMR-RAC  | 0.463                | HR-RAC      |
| Bovine: Fat tissue | 3                            | EFSA (2015)        | 0.59                     | STMR-RAC  | 1.9                  | HR-RAC      |
| Bovine: Liver     | 0.2                          | EFSA (2015)        | 0.07                     | STMR-RAC  | 0.165                | HR-RAC      |
| Bovine: Kidney    | 0.2                          | EFSA (2015)        | 0.07                     | STMR-RAC  | 0.165                | HR-RAC      |
| Sheep: Muscle/meat<sup>(c)</sup> | 0.2                          | EFSA (2015)        | 0.174                    | STMR-RAC  | 0.463                | HR-RAC      |
| Sheep: Fat tissue | 3                            | EFSA (2015)        | 0.59                     | STMR-RAC  | 1.9                  | HR-RAC      |
| Sheep: Liver      | 0.2                          | EFSA (2015)        | 0.07                     | STMR-RAC  | 0.165                | HR-RAC      |
| Sheep: Kidney     | 0.2                          | EFSA (2015)        | 0.07                     | STMR-RAC  | 0.165                | HR-RAC      |
| Goat: Muscle/meat<sup>(c)</sup> | 0.2                          | EFSA (2015)        | 0.174                    | STMR-RAC  | 0.463                | HR-RAC      |
| Goat: Fat tissue  | 3                            | EFSA (2015)        | 0.59                     | STMR-RAC  | 1.9                  | HR-RAC      |
| Goat: Liver       | 0.2                          | EFSA (2015)        | 0.07                     | STMR-RAC  | 0.165                | HR-RAC      |
| Goat: Kidney      | 0.2                          | EFSA (2015)        | 0.07                     | STMR-RAC  | 0.165                | HR-RAC      |
| Poultry: Muscle/meat<sup>(c)</sup> | 0.05                          | EFSA (2015)        | 0.05                     | STMR-RAC  | 0.05                 | HR-RAC      |
| Poultry: Fat tissue | 0.05                        | EFSA (2015)        | 0.05                     | STMR-RAC  | 0.05                 | HR-RAC      |
| Poultry: Liver    | 0.01                         | EFSA (2015)        | 0.01                     | STMR-RAC  | 0.01                 | HR-RAC      |
| Milk: Cattle      | 0.2                          | CXL (FAO, 2011)    | 0.053                    | STMR-RAC  | 0.053                | STMR-RAC    |
| Milk: Sheep       | 0.2                          | CXL (FAO, 2011)    | 0.053                    | STMR-RAC  | 0.053                | STMR-RAC    |
| Milk: Goat        | 0.2                          | CXL (FAO, 2011)    | 0.053                    | STMR-RAC  | 0.053                | STMR-RAC    |
| Milk: Horse       | 0.2                          | CXL (FAO, 2011)    | 0.053                    | STMR-RAC  | 0.053                | STMR-RAC    |
| Milk: Others      | 0.2                          | CXL (FAO, 2011)    | 0.053                    | STMR-RAC  | 0.053                | STMR-RAC    |
| Eggs: Chicken     | 0.01                         | EFSA (2015)        | 0.01                     | STMR-RAC  | 0.01                 | HR-RAC      |
| Eggs: Duck        | 0.01                         | EFSA (2015)        | 0.01                     | STMR-RAC  | 0.01                 | HR-RAC      |
| Eggs: Goose       | 0.01                         | EFSA (2015)        | 0.01                     | STMR-RAC  | 0.01                 | HR-RAC      |
| Eggs: Quail       | 0.01                         | EFSA (2015)        | 0.01                     | STMR-RAC  | 0.01                 | HR-RAC      |
| Eggs: Others      | 0.01                         | EFSA (2015)        | 0.01                     | STMR-RAC  | –                    | –           |
| Other crops/commodities | – | – | – | – | – | – |

MRL: maximum residue limit; CXL: Codex maximum residue limit; STMR-RAC: supervised trials median residue in raw agricultural commodity; LOQ: limit of quantification; HR-RAC: highest residue in raw agricultural commodity.

(a): Refined calculation mode.
(b): Assessment of all crops.
(c): Consumption figures in the EFSA PRIMO are expressed as meat. Since the a.s. is a fat-soluble pesticide, STMR and HR residue values were calculated considering a 80%/90% muscle and 20%/10% fat content for mammal/poultry meat respectively (FAO, 2016).
## Appendix E – Used compound codes

| Code/trivial name | IUPAC name/SMILES notation/InChiKey<sup>(a)</sup> | Structural formula<sup>(b)</sup> |
|-------------------|-------------------------------------------------|----------------------------------|
| bifenthrin        | 2-methylbiphenyl-3-ylmethyl \((1RS,3RS)-3-(Z)-2\text{-chl}oro3,3,3\text{-trifluoroprop-1-enyl})-2,2\text{-dimethylcyclopropanecarboxylate} \quad \text{or} \quad 2\text{-methylbiphenyl-3-ylmethyl (1RS)-cis-3-(Z)-2\text{-chl}oro3,3,3\text{-trifluoroprop-1-enyl})-2,2\text{-dimethylcyclopropanecarboxylate} \quad \text{OMFRMAHOULISGP-UHFFFAOYSA-N} |

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

<sup>(a)</sup> ACD/Name 2019.1.3 ACD/Labs 2019 Release (File version N05E41, Build 111418, 3 September 2019).

<sup>(b)</sup> ACD/ChemSketch 2019.1.3 ACD/Labs 2019 Release (File version C05H41, Build 111302, 27 August 2019).