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Targeted review of maximum residue levels (MRLs) for bifenthrin

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Abstract

In accordance with Article 43 of Regulation (EC) 396/2005, EFSA received a request from the European Commission to review the existing maximum residue levels (MRLs) for the non-approved active substance bifenthrin in view of the possible lowering of the MRLs. EFSA investigated the origin of the current EU MRLs. For existing EU MRLs that reflect previously authorised uses in the EU, or that are based on obsolete Codex maximum residue limits, or import tolerances that are not required any longer, EFSA proposed the lowering to the limit of quantification or to an alternative MRL. EFSA performed an indicative chronic and acute dietary risk assessment for the revised list of MRLs to allow risk managers to take the appropriate decisions. For some commodities, further risk management discussions are required to decide which of the risk management options proposed by EFSA should be implemented in the EU MRL legislation.

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Keywords: consumer risk assessment, toxicological evaluation, residue definitions, MRL setting, bifenthrin, non-approved active substance

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Summary

The European Commission submitted a request to EFSA for a targeted review of maximum residue limits (MRLs) for 10 active substances no longer approved in the EU, but for which MRLs greater than the limit of quantification (LOQ) are still in place and for which Member States have identified potential consumer health risks. Separate reasoned opinions should be provided in accordance with Article 43 of Regulation (EC) 396/2005, for each of the substances included in this mandate, one of them being bifenthrin.

In accordance with the terms of reference, EFSA investigated the origin of the current EU MRLs for bifenthrin, and whether they are sufficiently substantiated. An EU MRL is considered substantiated if it is sufficiently supported by data and established for uses still authorised or based on Codex maximum residue limit (CXL) or import tolerance that are still in place and relevant. Accordingly, MRLs that were derived for previously authorised EU uses are obsolete and should be lowered to the LOQ. For those commodities for which the existing EU MRLs are based on a CXL, EFSA investigated whether the CXLs are still in place and whether they are sufficiently supported by data. Obsolete or insufficiently supported Codex MRLs are also candidates for being lowered to the LOQ. To identify possible import tolerances, EFSA consulted Member States on Good Agricultural Practices authorised in third countries that were evaluated at national level, which might justify maintaining certain MRLs as import tolerances. Following this Member State consultation, EFSA concluded that none of the existing EU MRL for bifenthrin has been established as an import tolerance. EFSA also screened the quality of the toxicological reference values (TRVs) derived at EU level and by the Joint Meeting on Pesticide residues (JMPR). As EFSA identified critical issues related to the available toxicological database, EFSA organised an expert consultation (Pesticides Peer Review Teleconference 89) to discuss the toxicological profile and the TRVs for bifenthrin.

EFSA prepared a draft reasoned opinion that was shared with Member States and the European Reference Laboratories (EURLs) for consultation via a written procedure. Comments received were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

According to the metabolism studies available and assessed both at EU level and by JMPR, the residue definition for enforcement and risk assessment, for plant and animal products, is bifenthrin (sum of isomers), the residue being fat soluble. Fully validated analytical methods are available for the enforcement of the proposed residue definition in all four main plant matrices and in food of animal origin. However, no validation data are available to monitor bifenthrin in spices, tea and hops. According to the EURLs, a QuEChERS (and QuOil) multi-residue analytical method is available with an LOQ of 0.01 mg/kg for the routine analysis of bifenthrin in high water, high acid, high oil and dry commodities. A default LOQ of 0.01 mg/kg is also deemed achievable to monitor bifenthrin in all commodities of animal origin.

EFSA identified a list of current MRLs that are not sufficiently substantiated: CXLs for strawberries, mangoes, papayas, flowering and head brassica, kohlrabies, pulses, tea and hops; EU MRLs for herbal infusions and okra. No fall-back MRLs were identified for any of these crops. Moreover, further risk management discussions are required to decide whether the existing EU MRLs for baby leaf crops, soya beans, muscle and other edible offals from swine, bovine, sheep, goat and equine should be maintained or lowered to the LOQ.

Regarding the screening of the quality of the TRVs set at EU level and of those established by the JMPR, the experts concluded that overall, the TRVs cannot be confirmed for bifenthrin since the available data do not provide sufficient evidence to exclude the genotoxicity potential of bifenthrin, the data available were insufficient compared to current standards, and uncertainty factors could not be established. Accordingly, the acceptable daily intake (ADI) and acute reference dose (ARfD) derived in 2009 at EU level do not comply with the current scientific standards. Therefore, EFSA recommends withdrawing these TRVs. The toxicological reference values derived by JMPR values suffer from the same limitations.

EFSA performed an indicative risk assessment, taking into account those existing MRLs that, according to the screening of the origin of the EU MRL, were not identified as obsolete. Chronic and acute exposure calculations were performed using revision 3.1 of Pesticide Residues Intake Model (PRIMo). Comparing to the EU TRVs derived in 2009, no exceedances were observed, and the highest chronic exposure represented 40% of the ADI (Dutch toddler).

EFSA emphasises that the risk assessment could not be finalised because the toxicological reference values are not meeting the current scientific standards. Due to the deficiencies identified regarding the toxicological studies for bifenthrin, EFSA recommends that risk managers discuss

whether all MRLs currently implemented in EU Regulation should be lowered to the respective LOQs (see Summary table).

Summary table:

Code[a]	Commodity	Existing MRL[b] (mg/kg)	Outcome of the review	
			MRL proposal (mg/kg)	Comment
Residue definition for enforcement (plants and animal products): Bifenthrin (sum of isomers)[F]				
0110000	Citrus fruits	0.05	0.05 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. However, further risk management discussions are needed to decide whether the existing MRL needs to be lowered as the risk assessment could not be finalised, lacking robust TRVs for bifenthrin (EFSA recommends withdrawing the previously derived EU TRVs, as the toxicological database does not fully comply with the current scientific standards).
0120000	Tree nuts	0.05	0.05 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
0151000	Grapes	0.3	0.3 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits. In addition, EFSA noted that the exposure resulting from residues in table grapes exceeded the ARfD derived by JMPR, noting that the toxicological database available to JMPR does not fully comply with the current scientific standards. No fall-back MRL identified.
0152000	Strawberries	1	0.01*	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.
0153000	Cane fruits	1	1 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
0154010	Blueberries	3	3 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits. In addition, EFSA noted that the exposure resulting from residues in blueberries exceeded the ARfD derived by JMPR, noting that the toxicological database available to JMPR does not fully comply with the current scientific standards. No fall-back MRL identified.
0163020	Bananas	0.1	0.1 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.

Code[(a)]	Commodity	Existing MRL[(b)] (mg/kg)	Outcome of the review	
			MRL proposal (mg/kg)	Comment
0163030	Mangoes	0.5	0.01*	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.
0163040	Papayas	0.4	0.01*	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.
0211000	Potatoes	0.05	0.05 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
0212000	Tropical roots and tuber vegetables	0.05		
0213000	Other root and tuber vegetables except sugar	0.05		
0231010	Tomatoes	0.3	0.3 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
0231020	Sweet peppers	0.5	0.5 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits. In addition, EFSA noted that the exposure resulting from residues in sweet peppers exceeded the ARfD derived by JMPR, noting that the toxicological database available to JMPR does not fully comply with the current scientific standards. No fall-back MRL identified.
0231030	Aubergines	0.3	0.3 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
0231040	Okra/lady's fingers	0.2	0.01*	The existing MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.
0241000	Flowering brassica	0.4	0.01*	The existing MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.
0242000	Head brassica	0.4		
0244000	Kohlrabies	0.4		
0251080	Baby leaf crops	4	4 or LOQ Further consideration by risk managers needed	Further risk management discussions are needed to decide whether the existing MRL is substantiated or should be lowered to the LOQ, noting that the current EU MRL is based on the CXL for radish leaves. In addition, it should be discussed whether the existing MRL needs to be lowered as the risk assessment could not be finalised, lacking robust TRVs for bifenthrin (EFSA recommended to withdraw the previously derived EU TRVs, as the toxicological database does not fully comply with the current scientific standards).

Code[(a)]	Commodity	Existing MRL[(b)] (mg/kg)	Outcome of the review	
			MRL proposal (mg/kg)	Comment
0260030	Peas (with pods)	0.9	0.9 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
0260040	Peas (without pods)	0.05	0.05* or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
0300000	Pulses	0.3	0.01*	The existing MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.
0401060	Rapeseeds/canola seeds	0.05	0.05 or LOQ Further risk management considerations required	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
0401070	Soya beans	0.3	0.3 or LOQ Further consideration by risk managers needed	Further risk management discussions are needed to decide whether the existing MRL is substantiated, noting that EU expressed a reservation for the CXL on pulses (covering soya beans), but that sufficient trials on soya beans are available. In addition, it should be discussed whether the existing MRL needs to be lowered as the risk assessment could not be finalised, lacking robust TRVs for bifenthrin (EFSA recommended to withdraw the previously derived EU TRVs, as the toxicological database does not fully comply with the current scientific standards).
0401090	Cotton seeds	0.5	0.5 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
0500090	Wheat	0.5	0.5 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
0610000	Teas	30	0.05*	The existing MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.
0630000	Herbal infusion	0.1	0.02*	The existing MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.
0700000	Hops	20	0.05*	The existing MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.
0820000	Fruit spices	0.03	0.03 or LOQ Further risk management considerations required	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.

Code[(a)]	Commodity	Existing MRL[(b)] (mg/kg)	Outcome of the review	
			MRL proposal (mg/kg)	Comment
0840000	Root and rhizome spices	0.05	0.05 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
1011010 1012010 1013010 1014010 1015010 1017010	Muscle from Swine Bovine Sheep Goat Equine Other farmed terrestrial animals	0.2	0.2 or LOQ Further consideration by risk managers needed	Further risk management discussions are needed to decide whether the existing MRL is substantiated, noting that formally no CXL is in place for muscle, and EU uses leading to the maximum dietary burden are no longer authorised. In addition, it should be discussed whether the existing MRL needs to be lowered as the risk assessment could not be finalised, lacking robust TRVs for bifenthrin (EFSA recommended to withdraw the previously derived EU TRVs, as the toxicological database does not fully comply with the current scientific standards).
1011020 1012020 1013020 1014020 1015020 1017020	Fat from Swine Bovine Sheep Goat Equine Other farmed terrestrial animals	3	3 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
1011030 1012030 1013030 1014030 1015030 1017030	Liver from Swine Bovine Sheep Goat Equine Other farmed terrestrial animals	0.2	0.2 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
1011040 1012040 1013040 1014040 1015040 1017040	Kidney from Swine Bovine Sheep Goat Equine Other farmed terrestrial animals	0.2	0.2 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
1011050 1012050 1013050 1014050 1015050 1017050	Other edible offals from Swine Bovine Sheep Goat Equine Other farmed terrestrial animals	3	0.2 or LOQ Further consideration by risk managers needed	The EU MRL was derived from the CXL for fat. Further risk management discussions are needed to decide whether a CXL of 0.2 mg/kg (Codex MRL for edible offals) would be more appropriate. In addition, it should be discussed whether the existing MRL needs to be lowered as the risk assessment could not be finalised, lacking robust TRVs for bifenthrin (EFSA recommended to withdraw the previously derived EU TRVs, as the toxicological database does not fully comply with the current scientific standards).

Code[(a)]	Commodity	Existing MRL[(b)] (mg/kg)	Outcome of the review	
			MRL proposal (mg/kg)	Comment
				EFSA noted that the exposure resulting from residues other edible offals exceeded the ARfD derived by JMPR, noting that the toxicological database available to JMPR does not fully comply with the current scientific standards. No fall-back MRL identified.
1020000	Milk	0.2	0.2 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.

MRL: maximum residue limit; CXL: Codex maximum residue limit; LOQ: limit of quantification; TRV: toxicological reference value; ARfD: acute reference dose; GAP: good agricultural practice.
*: Indicates that the MRL is set at the limit of quantification.
(F): Fat soluble.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): MRL currently set under Regulation (EC) No 2018/687.

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Background

In March 2021, a Member State submitted to the European Commission the results of a screening performed on all maximum residue levels (MRLs) of active substances used in plant protection products that are not approved in the EU. The list contained 904 substances; for 297 of them, at least one MRL was set at a level above the limit of quantification (LOQ).

For 219 of these substances, the MRLs are not related to the uses of the substances in plant protection products (e.g. MRLs reflect the use of biocides or veterinary medical products, or MRLs are set to account for their occurrence in certain food due to environmental persistence, or their natural occurrence). For the other 78 substances, the MRLs were established either based on formerly approved uses in the EU, on import tolerance requests, or on Codex maximum residue limits (CXLs).

Some of these substances were never approved in the EU, or their approval was withdrawn before 2008, and therefore they did not fall within the scope of the systematic review of all existing MRLs under Article 12 of Regulation (EC) No 396/2005[1].

A second Member State conducted additional analysis, identifying potential consumer risk for some of the MRLs set for these active substances.

Based on these analyses, the European Commission conducted a prioritisation exercise to identify substances for which existing MRLs should be reviewed with high priority. The prioritisation was also discussed and agreed with Member States during several meetings of the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF), section Phytopharmaceuticals – Pesticides residues (September 2021,[2] November 2021,[3] and February 2022[4]). The SCoPAFF agreed that 10 active substances, for which potential consumer risks were identified, should be assessed by EFSA as a priority. One of the substances identified for being assessed with high priority is bifenthrin.

The European Commission proposed to mandate EFSA to provide a targeted review of MRLs for the substances concerned without delay. Due to the urgency of the subject, EFSA was invited to consider, if appropriate, delivering a separate reasoned opinion for each of the substances included in this mandate, as to be able to start providing outcomes to the Commission as soon as possible and successively. In this reasoned opinion, EFSA covered the targeted review of the MRLs for bifenthrin.

Terms of reference (as provided by the requestor)

EFSA was requested by the European Commission, according to Article 43 of Regulation (EC) No 396/2005, to prepare a reasoned opinion on bifenthrin. In particular, the following tasks should be performed:

1) to investigate the origin of the current EU MRLs (e.g. MRL based on formerly approved uses in the EU, on import tolerance requests, or on CXLs). This analysis should allow to verify if the CXLs/import tolerances are still justified[5] and to identify MRLs that do not correspond to import tolerances or currently established CXLs (non-verified CXL/import tolerances);
2) to consult Member States on information about Good Agricultural Practices authorised in third countries and already evaluated at MS level, which might support maintaining the existing import tolerances or setting of new (lowered) import tolerances, if this is necessary in view of consumer protection;
3) to identify fall-back MRLs for MRLs that do not correspond to a verified CXLs/import tolerance; these fall-back MRLs could be either a lower import tolerance or a lower CXL established more recently. If no fall-back MRL can be identified, the MRL should be considered for lowering to the appropriate LOQ;

[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, 16.03.2005, p. 1–16.
[2] Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals – Pesticide Residues 23–24 September 2021 (https://food.ec.europa.eu/system/files/2021-10/sc_phyto_20210923_ppr_sum.pdf).
[3] Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals – Pesticide Residues 22–23 November 2021 (https://food.ec.europa.eu/system/files/2021-12/sc_phyto_20211122_ppr_sum_0.pdf).
[4] Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals – Pesticide Residues 22–23 February 2022 (https://food.ec.europa.eu/system/files/2022-08/sc_phyto_20220222_ppr_sum.pdf).
[5] A CXL is considered justified if it is still in place (i.e., if it has not been withdrawn). An import tolerance is to be considered justified if the GAP in the country of origin is still authorised and the MRL in the country of origin is established at a level corresponding to the EU MRL (taking into account the potential difference in the RDs).

4) to consult the EU Reference Laboratories (EURLs) on the LOQs achievable during routine analyses for all commodities;
5) to perform an indicative screening of the chronic and acute consumer exposure related to the existing EU MRLs reflecting the verified CXLs/import tolerances, fall-back MRLs and/or proposed revised LOQ MRLs, using the newest version of the Pesticide Residues Intake Model (PRIMo) based on the available residue definitions for risk assessment and, if not available, residue definitions for enforcement derived at EU level or by JMPR. The following scenarios should be calculated:
    a) Scenario 1:
        i) Values at the appropriate LOQ: all MRLs that are based on former EU uses and all CXLs that were revoked by the Codex Committee on Pesticide Residues (CCPR) should be lowered to the appropriate LOQ;
        ii) Non-LOQ values to be considered: CXLs that were previously taken over in EU legislation, CXLs that were covered by still existing (higher) EU MRLs to be considered at the value of the CXL, MRLs based on existing import tolerances;
    b) Scenario 2:
        i) Like scenario 1, but lowering all CXLs that were evaluated by EFSA before and including 2009[6] and all import tolerances established before and including 2007,[7] respectively, to the appropriate LOQ.
6) to derive the input values for commodities of animal origin for the consumer exposure calculation from the relevant assessment where the MRLs for animal products were derived. However, if the respective risk assessment values (HR/STMR) cannot be retrieved from the available sources, the exposure shall be calculated with the existing MRL. If the existing MRL is no longer justified and no fall-back MRL can be retrieved, the existing MRL should be considered for being lowered to the LOQ; in this case the risk assessment screening should be performed with the LOQ;
7) to examine the available information in order to screen the quality of the toxicological reference values (TRVs) set at EU level and of those established by JMPR. This screening should also consider the completeness of the set of toxicological studies used to derive the TRVs, as to assess if it would be acceptable according to the current standards. In case deficiencies are identified, these should be highlighted along with the resulting uncertainties;
8) to examine the available information in order to screen the quality of the residue definitions for risk assessment set at EU level and of those established by JMPR. In case deficiencies are identified, these should be highlighted along with the resulting uncertainties;
9) to compare the indicative chronic and acute dietary exposure to the toxicological reference values derived at EU level or, if not available, to the toxicological reference values derived by JMPR;
10) to report information on the classification of the substance under the CLP Regulation[8] and whether the active substance meets the criteria for endocrine disruptors;
11) to assess, in all cases, the contribution of MRLs at the LOQ to the exposure in all exposure scenarios;
12) to recommend MRLs that do not pose an unacceptable risk to consumers, where possible, and advise risk managers on alternative options. Where relevant, EFSA should indicate whether the achievable LOQs are sufficiently protective for consumers;
13) to share its draft reasoned opinion for consultation with Member States (MSs) and EURLs before finalising it.

EFSA accepted the mandate and to deliver its assessment by finalising separate reasoned opinions for each of the substances included in this mandate, including bifenthrin, by 22 May 2023.

[6] The first EFSA scientific report in preparation of CCPR was prepared in 2010.
[7] The first evaluations of import tolerances under Regulation (EC) No 396/2005 which fully entered into force on 1.9.2008.
[8] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.OJ L 353, 31.12.2008, p. 1.

Assessment

To address the complex Terms of Reference (ToRs), EFSA used the following approach:

- In Section 1 (Regulatory background information on bifenthrin), information on classification of the active substance under CLP regulation and on endocrine properties is reported (addressing ToR 10).
- In Section 2.1 (Nature of residues and residue definitions), a screening of the quality of residue definitions is reported (addressing ToR 8).
- In Section 2.2 (Analytical methods for MRLs enforcement), information on analytical methods for MRLs enforcement provided by the EURLs on the LOQs achievable during routine residue analysis is reported (ToR 4). In addition, EFSA summarised the information on the analytical methods assessed previously by EFSA.
- In Section 2.3 (Existing MRLs), information on the origin of the current MRL is reported in tabular format (ToR 1). In the same section, information provided by MSs on good agricultural practices (GAPs) authorised in third countries and previously evaluated in view of setting import tolerances can be found (ToR 2). This information, together with information on existing CXLs, is used to derive possible fall-back MRLs (ToR 3) that are also reported in the table if available.
- In Section 3 (Toxicological reference values), the quality of the TRVs set in the EU and by the Joint Meeting on Pesticide residues (JMPR) are assessed (ToR 7).
- In Section 4 (Consumer risk assessment), an indicative screening of the chronic and acute consumer exposure is presented (ToR 5 and 6). The dietary exposure assessment Scenario 1 is performed as requested in ToR 5 (a). Scenario 2 (ToR 5 (b)) is not relevant for the assessment of bifenthrin, as all CXLs (and IT) set in EU Regulation were implemented and evaluated by EFSA after 2009. This section also addresses ToR 11 (contribution of MRLs at the LOQ to the total exposure) and ToR 9 (comparison of the dietary exposure with the TRVs derived at EU and JMPR level). However, noting that following the experts' meeting on mammalian toxicology, EFSA proposes to withdraw the EU TRVs currently in place.
- In the Conclusions and recommendations section, EFSA presents the MRL proposals that are unlikely to pose an unacceptable risk to consumers, where possible, and the ones for which further consideration is required (ToR 12).

EFSA has based its assessment on the following documents:

- the conclusion on the peer review of the pesticide risk assessment of the active substance bifenthrin (EFSA, 2009, 2011) and respective background documents: Draft Assessment Report (DAR) and its addenda (France, 2005, 2008);
- the Reports and Evaluations of the JMPR (FAO, 1996, 2009, 2011a,b, 2015, 2016);
- the reports of the Codex Committee on Pesticide residues (CCPR, 2011, 2016, 2017, 2021);
- the previous reasoned opinions on bifenthrin (EFSA, 2015, 2020).

As requested by the terms of reference (ToR 2), Member States were invited to submit by 2 August 2022 the Good Agricultural Practices (GAPs) that are authorised in third countries and already evaluated at national level, in the format of specific GAP forms, as well as the supporting residue data, in the format of an evaluation report. In the framework of this consultation, 8 Member States (CZ, DE, ES, FI, FR, IE, IT and SE) and UK[9] provided feedback regarding bifenthrin and notified that no import tolerances were in place. The EU Reference Laboratories (EURLs) were also consulted (ToR 4) to provide an evaluation report on the availability of analytical methods for enforcement and the LOQs achievable during routine analysis in plants and animal commodities. The **EURLs report on analytical methods** (EURLs, 2022) submitted during the collection of data is considered as a main supporting document to this reasoned opinion and, thus, made publicly available. In addition, an expert consultation in the area of mammalian toxicology was conducted in September 2022; the **peer review meeting report TC 89** (EFSA, 2022) is also considered as a main supporting document.

On the basis of the data submitted by the MSs, the EURLs, the data available in the JMPR Evaluation reports and taking into account the conclusions derived by EFSA in previous opinions and

[9] The United Kingdom withdrew from EU on 1 February 2020. In accordance with the Agreement on the Withdrawal of the United Kingdom from the EU, and in particular with the Protocol on IE/NI, the EU requirements on data reporting are also applicable to NI.

the screening of the available toxicological data with regard to their completeness and quality according to current standards, EFSA prepared a draft reasoned opinion, which was circulated to Member States and EURLs for consultation via a written procedure in December 2022. Comments received by 22 December 2022 were considered during the finalisation of this reasoned opinion (ToR 13).

A further supporting document to this reasoned opinion is the **Member States consultation report** (EFSA, 2023). The exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (**PRIMo**) are also key supporting documents made publicly available as background document to this reasoned opinion.

1. Regulatory background information on bifenthrin

The key events concerning the regulatory history of bifenthrin, the background information, together with the relevant published documents are summarised in Table 1.

Table 1: Background information

Process	Status	Comments, references
Approval status	Not approved	Decision on non-inclusion of bifenthrin in Annex I of Council Directive 91/414/EEC by Decision 2009/887/EC.[(a)] Approval in 2012 by Regulation (EU) No 582/2012.[(b)] Assessment of confirmatory data leading to an amendment of the approval conditions by Regulation (EU) 2018/291.[(c)] An application to renew the approval was submitted but withdrawn in 2018. Approval expired in July 2019.
EFSA conclusion available	Yes, see comments	EFSA (2009) EFSA (2011)
MRL review performed	Yes, see comments	EFSA (2015) Legally implemented by Regulation (EU) No 2017/170[(d)]
EU MRL applications or other EU assessments	Yes, see comments	MRL application (Art. 10): Art. 12 confirmatory data (citrus fruits, strawberries, cane fruits and animal commodities) and import tolerance in sweet corn and maize grain (EFSA, 2020). Not yet legally implemented. Implementation of certain CXLs adopted by CAC 2011 following assessment by EFSA (EFSA, 2011) and discussion in CCPR 43 (2011) (i.e. CXLs for cane fruits, tomato, pepper, aubergine, cotton seeds, products of animal origin from swine, bovine, sheep and goat). Legally implemented by Regulation (EU) No 441/2012.[(e)] Implementation of CXLs adopted by CAC 2016 following assessment by EFSA (EFSA, 2015) and discussion in CCPR 48 (2016) (i.e. CXL on blueberries, grapes, peas with and without pods). Legally implemented by Regulation (EU) 2018/687.[(f)]
Classification under CLP Regulation	See comments	Carc. 2, H351 'suspected of causing cancer'; Acute Tox 3, H331 'toxic if inhaled'; Acute Tox 2, H300 'fatal if swallowed'; STOT RE 1, H372 (nervous system) 'causes damage to organs'; Skin Sens. 1B, H317 'may cause an allergic skin reaction' bifenthrin does not fall under cut off criteria (ECHA, 2011; ATP5[(g)])
Endocrine effects of a.s.	Not assessed	ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(h)]) have not been performed.
Other relevant information	–	Bifenthrin is also registered in Europe as a biocide (product-type PT08) for wood preservation. Approval in 2013 by Directive 2011/10/EU[(i)] expires 31 January 2023.

a.s: active substance; MRL: maximum residue limit; CXL: Codex maximum residue limit; CCPR: Codex Committee on Pesticide Residues; CAC: Codex Alimentarius Commission; CLP: classification, labelling and packaging; ED: endocrine disruptor; ECHA: European chemicals agency; ATP: 'adaptation to technical progress' list.

(a): Commission Decision 2009/887/EC of 30 November 2009 concerning the non-inclusion of bifenthrin in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance. C(2009) 9196. OJ L 318, 4.12.2009, p. 41–42.
(b): Commission Implementing Regulation (EU) No 582/2012 of 2 July 2012 approving the active substance bifenthrin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 173, 3.7.2012, p. 3–7.
(c): Commission Implementing Regulation (EU) 2018/291 of 26 February 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance bifenthrin. OJ L 55, 27.2.2018, p. 30–33.
(d): 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, cinidon-ethyl, fenpropimorph and triflusulfuron in or on certain products. C/2017/0387. OJ L 30, 3.2.2017, p. 1–44.
(e): Commission Regulation (EU) No 441/2012 of 24 May 2012 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate, bifenthrin, boscalid, cadusafos, chlorantraniliprole, chlorothalonil, clothianidin, cyproconazole, deltamethrin, dicamba, difenoconazole, dinocap, etoxazole, fenpyroximate, flubendiamide, fludioxonil, glyphosate, metalaxyl-M, meptyldinocap, novaluron, thiamethoxam, and triazophos in or on certain products. OJ L 135, 25.5.2012, p. 4–56.
(f): Commission Regulation (EU) 2018/687 of 4 May 2018 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acibenzolar-S-methyl, benzovindiflupyr, bifenthrin, bixafen, chlorantraniliprole, deltamethrin, flonicamid, fluazifop-P, isofetamid, metrafenone, pendimethalin and teflubenzuron in or on certain products. C/2018/2627. OJ L 121, 16.5.2018, p. 63–104.
(g): Commission Regulation (EU) No 944/2013 of 2 October 2013 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. OJ L 261, 3.10.2013, p. 5–22.
(h): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.
(i): Commission Directive 2011/10/EU of 8 February 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include bifenthrin as an active substance in Annex I. OJ L 34, 9.2.2011, p. 41–44.

2. Residue definitions and existing EU MRLs

2.1. Nature of residues and residue definitions

As requested in point 8 of the ToR, EFSA summarised in this section the information used to derive the residue definitions for plant and animal products. Table 2 covers the studies submitted in the framework of the peer review and assessed previously by EFSA to derive the EU residue definitions, as well as studies that were submitted to JMPR in the framework of the setting of CXLs (studies not assessed at EU level).

Table 2: Available metabolism studies

	Crop groups	Crop(s)	Application(s)	Sampling (DAT)	Comment/source
Primary crops	Fruit crops	Apple	Foliar (spray appl.), 3 × 48 g a.s./hL	0, 7, 14, 21	[^{14}C-phenyl]-bifenthrin (EFSA, 2011, 2015; FAO, 2011b)
			Foliar (direct appl.), 3 × 12 or 24 g a.s./hL	0, 7, 14, 21, 28	2 studies: [^{14}C-phenyl] and [^{14}C-cyclopropyl]-bifenthrin (EFSA, 2011, 2015; FAO, 2011b)
	Root crops	Potato	Indoor, 1 soil appl. (in-furrow) 0.34 kg a.s./ha (planting) + 2 foliar appl. 0.11 kg a.s./ha	At maturity, 14 DALT	2 studies: [^{14}C-phenyl] and [^{14}C-cyclopropyl]-bifenthrin (FAO, 2011b)
	Leafy crops	–	–	–	No study available but not required since the metabolism is similar in all crop groups investigated.
	Cereals/grass	Maize	Indoor leaf appl., 0.53 kg a.s./ha	0, 7, 14, 21, 30	2 studies: [^{14}C-phenyl] and [^{14}C-cyclopropyl]-bifenthrin (EFSA, 2011, 2015; FAO, 2011b)
			Indoor husk appl., 0.53 kg a.s./ha	At maturity	2 studies: [^{14}C-phenyl] and [^{14}C-cyclopropyl]-bifenthrin (EFSA, 2011, 2015; FAO, 2011b)

	Crop groups	Crop(s)	Application(s)	Sampling (DAT)	Comment/source
			Indoor, soil treatment, 2.26 kg a.s./ha	Silage and maturity	2 studies: [^{14}C-phenyl] and [^{14}C-cyclopropyl]-bifenthrin (EFSA, 2011, 2015; FAO, 2011b)
			Indoor foliar appl., 0.56 kg a.s./ha	29, 77	[^{14}C-phenyl]-bifenthrin (EFSA, 2011, 2015; FAO, 2011b)
	Pulses/ oilseeds	Cotton	Indoor leaf appl. and soil treatment, 1 × 2.5 kg a.s./ha	0, 14, 28	2 studies: [^{14}C-phenyl] and [^{14}C-cyclopropyl]-bifenthrin (EFSA, 2011, 2015; FAO, 2011b)

	Animal	Dose (mg/kg bw per day)	Duration (day)	Comment/source
Livestock	Laying hen	2	10	2 studies: [^{14}C-phenyl] and [^{14}C-cyclopropyl]-bifenthrin (EFSA, 2011, 2015; FAO, 2011b)
	Ruminant, goat	2.3	7	2 studies: [^{14}C-phenyl] and [^{14}C-cyclopropyl]-bifenthrin (EFSA, 2011, 2015; FAO, 2011b)
	Pigs	–	–	Study not required as metabolism in rat and ruminant was found to be similar (EFSA, 2011).

a.s.: active substance; DAT: days after treatment; DALT: days after last treatment; bw: body weight.

Metabolism studies on apple, cotton seeds and maize were assessed in the framework of the peer review (EFSA, 2011) and the MRL review (EFSA, 2015). As in all three categories of crops (fruits, cereals and oilseeds), unchanged parent bifenthrin was the predominant component of the residue, the residue definition for monitoring and risk assessment in plant commodities was proposed as bifenthrin (sum of isomers). It was also concluded that metabolites found in plants are covered by the toxicological profile of the parent and no significant *cis*- to *trans*-isomerisation and translocation of residues through the plant were observed in the course of the metabolism studies (EFSA, 2011). The residue definitions are applicable to all crop groups.

In addition to the metabolism studies assessed at EU level, JMPR assessed an additional study on potatoes. This additional study showed similar results with parent bifenthrin being the major compound identified (FAO, 2011a,b).

The nature of bifenthrin residues in livestock was investigated and assessed in the framework of the peer review (EFSA, 2011) and the MRL review (EFSA, 2015). In the metabolism studies with goats and laying hens, bifenthrin was identified in significant proportions in all animal matrices. Additional metabolites were determined in some matrices, however not considered toxicologically relevant to be included in the residue definition. Thus, a residue definition as bifenthrin (sum of isomers) was proposed for enforcement and risk assessment (EFSA, 2015), the residue being fat soluble. This is in line with the conclusions reached by the JMPR following the assessment of the same metabolism studies.

Table 3 summarises the residue definitions derived at EU level and by JMPR. The EU residue definitions for enforcement are the ones set in Regulation (EC) No 396/2005. EU residue definitions for risk assessment were proposed in the framework of the peer review (EFSA, 2011) and of the Article 12 review of all existing MRLs (EFSA, 2015). The same residue definitions for enforcement and risk assessment were derived by the JMPR (FAO, 2011a,b).

Table 3: Residue definitions derived at EU level and by JMPR

Type of residue definition (RD)	Commodity group	EU residue definition	JMPR residue definitions
RD for enforcement	Plant products	Bifenthrin (sum of isomers) EFSA (2011, 2015)	Bifenthrin (sum of isomers) FAO (2011a,b)
	Animal products	Bifenthrin (sum of isomers) The residue is fat soluble EFSA (2011, 2015)	Bifenthrin (sum of isomers) The residue is fat soluble FAO (2011a,b)

Type of residue definition (RD)	Commodity group	EU residue definition	JMPR residue definitions
RD for risk assessment	Plant products	Bifenthrin (sum of isomers) EFSA (2011, 2015)	Bifenthrin (sum of isomers) FAO (2011a,b)
	Animal products	Bifenthrin (sum of isomers) EFSA (2015)	Bifenthrin (sum of isomers) FAO (2011a,b)
Comments: The residue definitions are fully comparable.			

2.2. Analytical methods for MRLs enforcement

Analytical methods for the determination of bifenthrin residues were assessed in the framework of the EU pesticides peer review and the MRL review (EFSA, 2011, 2015). Sufficiently validated analytical methods are available to enforce residues of bifenthrin in all four main plant matrices with an LOQ of 0.01 mg/kg. This method is not stereoselective and therefore determines the sum of the two isomers of bifenthrin. No methods were reported to monitor bifenthrin in specific matrices, i.e. spices, tea and hops.

Bifenthrin can be enforced in food of animal origin with an LOQ of 0.05 mg/kg in muscle and fat, and with an LOQ of 0.01 mg/kg in milk, kidney and liver (EFSA, 2011, 2015). A validated analytical method for enforcement of residues in eggs was not available.

During the data collection, the EURLs provided information on QuEChERS and QuOil multi-residue analytical methods using gas chromatography with tandem mass spectrometry (GC–MS/MS) and liquid chromatography with tandem mass spectrometry (LC–MS/MS) techniques, with an LOQ of 0.01 mg/kg for the routine analysis of bifenthrin in high water, high acid, high oil and dry commodities. No data were provided regarding the possible enforcement of bifenthrin in complex matrices. According to the EURLs, bifenthrin can be monitored with a default LOQ of 0.01 mg/kg in commodities of animal origin (muscle, liver, milk, egg and honey). Based on the experience gained with these matrices, an LOQ of 0.01 mg/kg for animal fat and kidney is deemed achievable (EURLs, 2022).

Table 4 provides an overview of the available analytical methods and the LOQs at which the methods were successfully validated. It is concluded that analytical methods are available for all commodities under assessment, except for tea, hops and spices.

Table 4: Analytical methods available

Commodity group		Analytical method available	LOQ (mg/kg)	Source
Plant commodities	High water	Yes (GC-ECD)	0.01	EFSA (2011)
		Yes (QuEChERS method with GC–MS/MS)	0.01	EURLs (2022)
	High oil	Yes (GC-ECD)	0.01	EFSA (2011)
		Yes (QuEChERS and QuOil methods with GC–MS/MS)	0.01	EURLs (2022)
	High acid content	Yes (QuEChERS method with GC–MS)	0.01	EURLs (2022); EFSA (2015)
		Yes (QuEChERS method with GC–MS/MS)	0.01	EURLs (2022)
	Dry	Yes (GC-ECD)	0.01	EFSA (2011)
		Yes (QuEChERS method with GC–MS/MS and LC–MS/MS)	0.01	EURLs (2022)
	Other: wheat straw	Yes (GC–MS; ILV not available)	0.01	EFSA (2011)
	Other: difficult matrices (spices, hop, tea)	No	–	–
Animal commodities	Muscle	Yes (GC-ECD)	0.05	EFSA (2015)
		Yes (QuEChERS method with GC–MS/MS)	0.01	EURLs (2022)

Commodity group		Analytical method available	LOQ (mg/kg)	Source
	Kidney	Yes (GC-ECD)	0.01	EFSA (2015)
		Yes (QuEChERS method with GC–MS/MS)	0.01	EURLs (2022)
	Liver	Yes (GC-ECD)	0.01	EFSA (2015)
		Yes (QuEChERS method with GC–MS/MS)	0.01	EURLs (2022)
	Fat	Yes (GC-ECD)	0.05	EFSA (2015)
		Yes (QuEChERS method with GC–MS/MS)	0.01	EURLs (2022)
	Milk	Yes (GC-ECD)	0.01	EFSA (2015)
		Yes (QuEChERS method with GC–MS/MS)	0.01	EURLs (2022)
	Eggs	No	–	–
		Yes (QuEChERS method with GC–MS/MS)	0.01	EURLs (2022)
	Other: honey	Yes (QuEChERS method with GC–MS/MS)	0.01	EURLs (2022)

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

2.3. Existing MRLs

The EU MRLs for bifenthrin are established in Annex II of Regulation (EC) No 396/2005. For a number of food products, CXLs have been taken over in the EU legislation. It should be noted that in the framework of the current review, Member States did not notify import tolerances in place.

EFSA reported in Table 5, the existing EU MRLs for the respective crop/crop groups, including information on the source of the MRLs together with the relevant GAPs and the references to the assessment where the MRL proposal was derived. In response to ToR 1 which requests to provide an analysis whether the existing EU MRL, the CXL or the import tolerance established for a crop is sufficiently substantiated, EFSA applied the following criteria:

A CXL is considered substantiated if:

- it is still in place (CXL has not been withdrawn from the Codex system);
- the CXL is sufficiently supported by data;
- the enforcement residue definition is identical with the EU residue definition.

An import tolerance is considered substantiated if:

- the GAP in the country of origin is still authorised;
- the import tolerance is sufficiently supported by data;
- the MRL in the country of origin is established at a level corresponding to the EU MRL (taking into account the potential difference in the RDs);
- in case the residue definition in the country of origin is different, the import tolerance is substantiated if sufficient information is available to derive an MRL for the EU RD.

An existing EU MRLs is obsolete if:

- it is based on a previously authorised EU use;
- it is based on a previous CXL that has been revoked/withdrawn;
- it is based on an import tolerance that is no longer relevant as the use in the country of origin is not confirmed.

In order to address ToRs 3, 5 and 6, in cases where the current CXLs or import tolerances are not sufficiently substantiated, information on possible fall-back GAPs and the associated fall-back MRLs should be reported in Table. Additional considerations relevant for taking a risk management decision can be found in the last column of this table.

Table 5: Background information on current MRLs for bifenthrin established at a level above the LOQ (CXLs/import tolerances), verification whether these values are sufficiently substantiated, and possible fall-back MRLs/GAPs

Commodity	Existing MRL (mg/kg)	Source of existing MRL	cGAP for existing MRL	Existing MRL substantiated? (Y/N)[a]	Fall-back GAP[b]	Fall-back MRL[b] (mg/kg)	Comment
Citrus fruits Grapefruits, Oranges, Lemons, Limes, Mandarins	0.05	CXL (CAC, 2011)	USA: soil application, 0.11–0.56 kg a.s./ha, PHI 1 day (FAO, 2011b)	Y	n.r.	n.r.	The EU did not express a reservation in the CCPR 43/CAC in 2011. The CXL was implemented by Reg. (EU) 2017/170 in the context of the MRL review.
Tree nuts Almonds, Brazil nuts, cashew nuts, Chestnuts, Coconuts, Hazelnuts/ cobnuts, Macadamias, Pecans, Pine nut kernels, Pistachios, Walnuts	0.05	CXL (CAC, 2011)	USA: foliar spray, 0.056–0.22 kg a.s./ha, PHI 21 days for pecans and 7 days for other tree nuts (FAO, 2011b)	Y	n.r.	n.r.	The EU did not express a reservation in the CCPR 43/CAC in 2011. The CXL was implemented by Reg. (EU) 2017/170 in the context of the MRL review.
Grapes Table grapes, Wine grapes	0.3	CXL (CAC, 2016)	USA: 0.11 kg a.s./ha per season, PHI 30 days (FAO, 2016)	Y	n.r.	n.r.	The EU did not express a reservation in the CCPR 43/CAC in 2011. The CXL was implemented by Reg. (EU) No 2018/687.
Strawberries	1	CXL (CAC, 1995)	Country not reported, foliar, 2 × 0.024–0.04 kg a.s./ha, 14 days PHI (FAO, 1996)	N	No fall-back GAP identified	–	In 1995, this CXL was adopted despite several data gaps identified. In 2010, JMPR recommended the withdrawal of the CXL, as no information on a GAP matching the residue trials which were used to derive the existing CXL of 1 mg/kg were received and as no alternative GAP has been provided within the last 10 years which would allow to establish a CXL which does not pose a

Commodity	Existing MRL (mg/kg)	Source of existing MRL	cGAP for existing MRL	Existing MRL substantiated? (Y/N)[a]	Fall-back GAP[b]	Fall-back MRL[b] (mg/kg)	Comment
							consumer health risk. CXL was implemented by Reg. (EU) 2017/170 in the context of the MRL review. In 2021, CCPR52 decided to revoke this CXL (CCPR, 2021). Existing MRL is not substantiated as no EU uses and no CXL in place. No IT nor fall-back GAP identified.
Cane fruits Blackberries, Dewberries, Raspberries	1	CXL (CAC, 2011)	USA: foliar spray, 2 × 0.056–0.11 kg a.s./ha, PHI 3 days (FAO, 2011b)	Y	n.r.	n.r.	The EU did not express a reservation in the CCPR43/CAC in 2011. The CXL was implemented by Reg. (EU) 2017/170 in the context of the MRL review.
Blueberries	3	CXL (CAC, 2016)	USA: 0.11 kg a.s./ha, 7-day interval, PHI 1 day; 0.56 kg a.s./ha per season (FAO, 2016)	Y	n.r.	n.r.	The EU did not express a reservation in the CCPR43/CAC in 2011. The CXL was implemented by Reg. (EU) 2018/687.
Bananas	0.1	CXL (CAC, 2011)	Central America: tree bag with 1% bifenthrin placed on banana bunch before flowering and until harvest (FAO, 2011b)	Y	n.r.	n.r.	The EU did not express a reservation in the CCPR43/CAC in 2011. The CXL was implemented by Reg. (EU) 2017/170 in the context of the MRL review.
Mangoes	0.5	See comments	No approved use or label. The Codex MRL proposal was derived based on the requirement of appropriate control of diseases, considering results of residue trials (4 trials: foliar spray, 0.05 kg a.s./ha, PHI 7 days) (FAO, 2011b).	N	No fall-back GAP identified	–	In 2010, JMPR derived a Codex MRL proposal for mangoes, which was maintained at step 7. In 2017, CCPR49 decided to withdraw the MRL proposal due to a lack of GAP information (CCPR, 2017). The Codex MRL proposal was implemented in EU legislation by Reg. (EU) 2017/170 in the context of the MRL review. EU MRL is not substantiated as no EU uses and no CXL in place.

Commodity	Existing MRL (mg/kg)	Source of existing MRL	cGAP for existing MRL	Existing MRL substantiated? (Y/N)[a]	Fall-back GAP[b]	Fall-back MRL[b] (mg/kg)	Comment
Papayas	0.4	See comments	No approved use or label. The Codex MRL proposal was derived based on the requirement of appropriate control of diseases, considering results of residue trials (8 trials: foliar spray, 4 × 0.05 kg a.s./ha, PHI 3 days) (FAO, 2011b).	N	No fall-back GAP identified	–	In 2010, JMPR derived a Codex MRL proposal for papayas, which was maintained at step 7. In 2017, CCPR49 decided to withdraw the MRL proposal due to a lack of GAP information (CCPR, 2017). The Codex MRL proposal was implemented in EU legislation by Reg. (EU) 2017/170 in the context of the MRL review. EU MRL is not substantiated as no EU uses and no CXL in place.
Potatoes	0.05	CXL (CAC, 2011)	USA: foliar spray, 0.09–0.11 kg a.s./ha, PHI 21 days Brazil: soil treatment, 0.1 kg a.s./ha, PHI 35 days (GAPs on root and tuber vegetables) (FAO, 2011b)	Y	n.r.	n.r.	The EU did not express a reservation in the CCPR43/CAC in 2011. The CXL was implemented in EU legislation by Reg. (EU) 2017/170 in the context of the MRL review.
Tropical root and tuber vegetables: Cassava roots/ manioc, Sweet potatoes, Yams, Arrowroots, Others	0.05	CXL (CAC, 2011)	See potatoes	Y	n.r.	n.r.	See potatoes
Other root and tuber vegetables except sugarbeets: Beetroots, Carrots, Celeriacs, Horseradishes, Jerusalem artichokes, Parsnips,	0.05	CXL (CAC, 2011)	See potatoes	Y	n.r.	n.r.	See potatoes

Commodity	Existing MRL (mg/kg)	Source of existing MRL	cGAP for existing MRL	Existing MRL substantiated? (Y/N)[a]	Fall-back GAP[b]	Fall-back MRL[b] (mg/kg)	Comment
Parsley roots, Radishes, salsifies, Swedes/ rutabagas, Turnips, Others							
Tomatoes	0.3	CXL (CAC, 2011)	Mexico: foliar spray, 0.06 kg a.s./ha, PHI 1 day (FAO, 2011b)	Y	n.r.	n.r.	The EU did not express a reservation in the CCPR43/CAC in 2011. The CXL was implemented in EU legislation by Reg. (EU) 2017/170 in the context of the MRL review.
Sweet peppers	0.5	CXL (CAC, 2011)	USA: foliar spray, 0.022–0.11 kg a.s./ha, PHI 7 days (FAO, 2011b)	Y	n.r.	n.r.	The EU did not express a reservation in the CCPR43/CAC in 2011. The CXL was implemented in EU legislation by Reg. (EU) 2017/170 in the context of the MRL review.
Aubergines	0.3	CXL (CAC, 2011)	USA: foliar spray, 0.034–0.11 kg a.s./ha, PHI 7 days (FAO, 2011b)	Y	n.r.	n.r.	The EU did not express a reservation in the CCPR43/CAC in 2011. The CXL was implemented in EU legislation by Reg. (EU) 2017/170 in the context of the MRL review.
Okra/lady's fingers	0.2	See comments	No approved use or label. The Codex MRL proposal was derived based on the requirement of appropriate control of diseases, considering results of residue trials (4 trials: foliar spray, 2 × 0.05 kg a.s./ha, PHI 2 days) (FAO, 2011b).	N	no fall-back GAP identified	–	EU MRL of 0.2 mg/kg was established under Reg. (EC) 149/2008. The origin of this MRL in unknown. A Codex MRL proposal of 0.2 mg/kg was derived by JMPR in 2010, but the proposal was held at step 7. The Codex MRL proposal was implemented in EU legislation by Reg. (EU) 2017/170 in the context of the MRL review. In 2021, CCPR52, decided to withdraw the Codex MRL proposal for okra (CCPR, 2021). EU MRL is not substantiated as no EU uses and no CXL in place.

Commodity	Existing MRL (mg/kg)	Source of existing MRL	cGAP for existing MRL	Existing MRL substantiated? (Y/N)[a]	Fall-back GAP[b]	Fall-back MRL[b] (mg/kg)	Comment
Flowering brassica: Broccoli Cauliflowers Others	0.4	CXL (CAC, 2011)	USA: foliar spray, 5 × 0.034–0.11 kg a.s./ha, PHI 7 days; soil treatment, at seeding or transplant, max 0.11 kg a.s./ha (FAO, 2011b)	N	No fall-back GAP identified	–	The EU expressed a reservation in the CCPR43/CAC in 2011. The CXL was implemented in EU legislation by Reg. (EU) 2017/170 in the context of the MRL review. The existing CXL is not substantiated because the EU reservation is still valid (insufficient number of trials) (CCPR, 2011).
Head brassica: Brussels sprouts Head cabbages Others	0.4	CXL (CAC, 2011)	USA: foliar spray, 5 × 0.034–0.11 kg a.s./ha, PHI 7 days; soil treatment, at seeding or transplant, max 0.11 kg a.s./ha (FAO, 2011b)	N	No fall-back GAP identified	–	The EU expressed a reservation in the CCPR43/CAC in 2011. The CXL was implemented in EU legislation by Reg. (EU) 2017/170 in the context of the MRL review. The existing CXL is not substantiated because the EU reservation is still valid (inappropriate extrapolation) (CCPR, 2011).
Kohlrabies	0.4	CXL (CAC, 2011)	USA: foliar spray, 5 × 0.034–0.11 kg a.s./ha, PHI 7 days; soil treatment, at seeding or transplant, max 0.11 kg a.s./ha (FAO, 2011b)	N	No fall-back GAP identified	–	The EU expressed a reservation in the CCPR43/CAC in 2011. The CXL was implemented in EU legislation by Reg. (EU) 2017/170 in the context of the MRL review. The existing CXL is not substantiated because the EU reservation is still valid (inappropriate extrapolation) (CCPR, 2011).
Baby leaf crops	4	See comments	USA: foliar spray, 0.037–0.11 kg a.s./ha, PHI 7 days (GAP on brassica leafy vegetables) (FAO, 2011b).	tbd	No fall-back GAP identified	–	In Codex food classification, there is no corresponding code for baby leaf crops. The current EU MRL is based on the CXL for radish leaves. It is recommended that risk managers discuss whether this EU MRL is still substantiated, noting that radish leaves are classified under kales in Reg. (EC) 396/2005 (Annex I).
Peas (with pods)	0.9	CXL (CAC, 2016)	USA: at planting (in-furrow) and foliar, 0.11 kg a.s./ha, PHI 3 days, 0.22 kg a.s./ha	Y	n.r.	n.r.	The EU did not express a reservation in the CCPR48/CAC in 2016. The CXL was

Commodity	Existing MRL (mg/kg)	Source of existing MRL	cGAP for existing MRL	Existing MRL substantiated? (Y/N)[a]	Fall-back GAP[b]	Fall-back MRL[b] (mg/kg)	Comment
			per season (GAP on peas and beans) (FAO, 2016)				implemented in the EU legislation by Reg. (EU) 2018/687.
Peas (without pods)	0.05	CXL (CAC, 2016) See comments	USA: at planting (in-furrow) and foliar, 0.11 kg a.s./ha, PHI 3 days, 0.22 kg a.s./ha per season (GAP on peas and beans) (FAO, 2016)	Y	n.r.	n.r.	The EU did not express a reservation in the CCPR48/CAC in 2016. The CXL was implemented in the EU legislation by Reg. (EU) 2018/687. It is noted that the CXL is labelled with "*" indicating that the CXL is set at the limit of quantification. Hence, the EU MRL should be also labelled with an asterisk.
Pulses Beans, Lentils, Peas, Lupins/lupini, Beans, Others)	0.3	CXL (CAC, 2011)	USA: 0.028–0.11 kg a.s./ha, PHI 14 days (GAP on beans and peas) (FAO, 2011b)	N	No fall-back GAP identified	–	The EU expressed a reservation on this CXL in CCPR43/CAC in 2011 as the database was found inappropriate to derive the group CXL by extrapolation (9 GAP compliant trials were available for pulses but JMPR derived the CXL on trials on soya beans). The CXL was implemented in EU legislation by Reg. (EU) 2017/170 in the context of the MRL review. The existing CXL is not substantiated because the EU reservation is still valid (inappropriate extrapolation) (CCPR, 2011).
Rapeseeds/canola seeds	0.05	CXL (CAC, 2011)	USA: foliar, 0.036–0.045 kg a.s./ha, PHI 35 days (FAO, 2011b)	Y	n.r.	n.r.	The EU did not express a reservation in the CCPR43/CAC in 2011. The CXL was implemented in EU legislation by Reg. (EU) 2017/170 in the context of the MRL review.
Soya beans	0.3	CXL (CAC, 2011)	USA: 0.028–0.11 kg a.s./ha, PHI 18 days (FAO, 2011b)	tbd	No fall-back GAP identified	–	The CXL set for pulses (VD 0070) also covers soya beans. The EU expressed a reservation for the CXL on pulses in CCPR43/CAC in 2011 (see also Pulses). The CXL was implemented in EU legislation by Reg. (EU) 2017/170 in the context of the MRL review.

Commodity	Existing MRL (mg/kg)	Source of existing MRL	cGAP for existing MRL	Existing MRL substantiated? (Y/N)[a]	Fall-back GAP[b]	Fall-back MRL[b] (mg/kg)	Comment
							It is recommended that risk managers discuss whether this MRL is substantiated, considering that sufficient trials on soya beans are available.
Cotton seeds	0.5	CXL (CAC, 2011)	USA: foliar, 0.11 kg a.s./ha, PHI 14 days, 0.56 kg a.s./ha per season (FAO, 2011b)	Y	n.r.	n.r.	The EU did not express a reservation in the CCPR43/CAC in 2011. The CXL was implemented in EU legislation by Reg. (EU) 2017/170 in the context of the MRL review.
Maize/corn	0.05*	CXL (CAC, 2011)	USA: foliar, 0.11 kg a.s./ha, PHI 30 days (FAO, 2011b)	Y	USA: 1–6 × 37–112.5 g a.s./ha, PHI 30 days (EFSA, 2020)	0.05* (IT)	The EU did not express a reservation in the CCPR43/CAC in 2011. The CXL was implemented in EU legislation by Reg. (EU) 2017/170 in the context of the MRL review. The CXL is in place and considered justified. In 2020, EFSA assessed a request for an US import tolerance for maize (EFSA, 2020).
Wheat	0.5	CXL (CAC, 2011)	Brazil: grain storage, 0.0004 kg a.s./ton, 30 days withholding period (FAO, 2011b)	Y	n.r.	n.r.	Post-harvest use. The EU did not express a reservation in the CCPR43/CAC in 2011. The CXL was implemented in EU legislation by Reg. (EU) 2017/170 in the context of the MRL review.
Teas	30	CXL (CAC, 2011)	Japan: foliar, 0.08 kg a.s./ha, PHI 14 days FAO, 2011b)	N	No fall-back GAP identified	–	The EU expressed a reservation in the CCPR43/CAC in 2011. The CXL was implemented in EU legislation by Reg. (EU) 2017/170 in the context of the MRL review. The existing MRL is not substantiated because the EU reservation is still valid (insufficient number of trials) (CCPR, 2011).
Herbal infusion	0.1	EU MRL (Reg. (EU) 2017/170)	No GAP information available	N	No fall-back GAP identified	–	Taking into account comments by European stakeholder associations and trading partners, as there was no risk identified for consumers, the MRL for

Commodity	Existing MRL (mg/kg)	Source of existing MRL	cGAP for existing MRL	Existing MRL substantiated? (Y/N)[a]	Fall-back GAP[b]	Fall-back MRL[b] (mg/kg)	Comment
							herbal infusions was maintained in Regulation (EU) 2017/170 at the level of 0.1 mg/kg. A footnote was introduced to this MRL to suggest monitoring the situation for a further 3 years. As the 3 years period expired and no data were submitted to provide evidence regarding the need to maintain the EU MRL, the current MRL is not substantiated.
Hops	20	CXL (CAC, 2011)	USA: 0.056–0.11 kg a.s./ha, PHI 14 days (FAO, 2011b)	N	No fall-back GAP identified	–	The EU expressed a reservation in the CCPR43/CAC in 2011. The CXL was implemented in EU legislation by Reg. (EU) 2017/170 in the context of the MRL review. The existing MRL is not substantiated because the EU reservation is still valid (insufficient number of trials) (CCPR, 2011).
Fruit spices: Allspice/pimento Sichuan pepper Caraway Cardamom Juniper berry Peppercorn Vanilla Tamarind Others	0.03	CXL (CAC, 2011)	CXL based on monitoring data from Thailand (FAO, 2011b).	Y	n.r.	n.r.	The CXL was derived from monitoring data. As no detectable residues were found in monitoring samples, the CXL was set at the reported highest LOQ.
Root and rhizome spices: Liquorice Turmeric/ curcuma Others	0.05	CXL (CAC, 2011)	CXL based on monitoring data from Thailand (FAO, 2011b).	Y	n.r.	n.r.	The CXL was derived from monitoring data. As no detectable residues were found in monitoring samples, CXL was set at the reported highest LOQ.

Commodity	Existing MRL (mg/kg)	Source of existing MRL	cGAP for existing MRL	Existing MRL substantiated? (Y/N)[a]	Fall-back GAP[b]	Fall-back MRL[b] (mg/kg)	Comment
Animal commodities: Muscle from swine, bovine, sheep, goat, equine, other	0.2	EU MRL (Reg. (EU) 2017/170) derived from JMPR assessment	Mean/max. dietary burden (EU beef cattle): 3.35/ 8.26 ppm (FAO, 2011b)	tbd	No fall-back GAP identified	–	The CXL was based on the maximum dietary burden identified for the EU livestock diet. The EU did not express a reservation in the CCPR43/CAC in 2011 for the CXL of 2 mg/kg derived by JMPR for meat (expressed on fat basis). As no CXL was derived for muscle, the EU calculated the corresponding value for this commodity, based on feeding studies and the dietary burden calculation from JMPR. This value was implemented in EU legislation by Reg. (EU) 2017/170 in the context of the MRL review. It is recommended that risk managers discuss whether this MRL is still substantiated, as formally no CXL is in place for muscle, noting also that EU uses leading to the maximum dietary burden are no longer authorised.
Animal commodities: Fat from swine, bovine, sheep, goat, equine, other	3	CXL (CAC, 2011)	Mean/max. dietary burden (EU beef cattle): 3.35/ 8.26 ppm (FAO, 2011b)	Y	n.r.	n.r.	The EU did not express a reservation in the CCPR43/CAC in 2011. The CXL was implemented in EU legislation by Reg. (EU) 2017/170 in the context of the MRL review.
Animal commodities: Liver and kidney from swine, bovine, sheep, goat, equine, other	0.2	CXL (CAC, 2011)	Mean/max. dietary burden (EU beef cattle): 3.35/ 8.26 ppm (FAO, 2011b)	Y	n.r.	n.r.	The EU did not express a reservation in the CCPR43/CAC in 2011. The CXL was implemented in EU legislation by Reg. (EU) 2017/170 in the context of the MRL review.

Commodity	Existing MRL (mg/kg)	Source of existing MRL	cGAP for existing MRL	Existing MRL substantiated? (Y/N)[a]	Fall-back GAP[b]	Fall-back MRL[b] (mg/kg)	Comment
Animal commodities: Other edible offals from swine, bovine, sheep, goat, equine, other	3	EU MRL (Reg. (EU) 2017/170)	Mean/max. dietary burden (EU beef cattle): 3.35/ 8.26 ppm (FAO, 2011b)	tbd	No fall-back GAP identified	–	The EU MRL for these matrices was derived from the CXL for fat (which is the highest MRL for animal commodities). The MRL was implemented in EU legislation by Reg. (EU) 2017/170 in the context of the MRL review. Since the codex MRL for edible offals (liver, kidney and other edible offals) is 0.2 mg/kg, it is recommended that risk managers discuss whether a CXL of 0.2 mg/kg could be an alternative option.
Animal commodities: Milk	0.2	CXL (CAC, 2011)	Mean/max. dietary burden (EU dairy cattle): 3.21/ 7.41 ppm (FAO, 2011b)	Y	n.r.	n.r.	The EU did not express a reservation in the CCPR43/CAC in 2011. The CXL was implemented in EU legislation by Reg. (EU) 2017/170 in the context of the MRL review.

MRL: maximum residue limit; CXL: Codex maximum residue limit; IT: import tolerance; CAC: Codex Alimentarius Commission; CCPR: Codex committee on pesticide residues: GAP: good agricultural practice; cGAP: critical good agricultural practice; a.s.: active substance; PHI: pre-harvest interval; n.r.: not relevant; tbd: to be discussed; ppm: parts per million.

(a): The criteria for deciding whether the existing MRL is sufficiently substantiated can be found in the paragraphs above the table. In the last column of this table, further explanations can be found why an existing MRL is considered not substantiated.

(b): Fall-back GAP and fall-back MRL are not relevant (n.r.), if the existing MRL is substantiated.

3. Toxicological reference values

EFSA was mandated to examine the available information in order to screen the quality of the TRVs set at EU level and of those established by the JMPR and to assess the completeness of the set of toxicological studies used to derive the TRVs according to the current standards (ToR 7).

The TRVs for bifenthrin reported in Table 6 were derived by EFSA in 2009; the TRVs were formally adopted by the European Commission with the approval of bifenthrin by Regulation (EU) No 582/2012 and they were reiterated by Regulation (EU) No 2018/291. In 2009, JMPR derived an ADI and an ARfD which are reported in Table 7.

The different ARfD and ADI values derived by EFSA and JMPR can be explained by the fact that JMPR assessed an additional toxicological study that was not available to the peer review (see Table 7). In addition, different maternal and developmental no observed adverse effect levels (NOAELs) were derived in the developmental toxicity studies in rats that are also critical to the setting of these values.

Table 6: Toxicological reference values (TRVs) set at EU level

TRV	Value	Reference	Comments
ADI	0.015 mg/kg bw per day	EFSA (2009)	Based on clinical signs of neurotoxicity (tremors) in a 1-year dog, supported by developmental studies and applying an UF of 100. The ADI was formally adopted by Regulation (EU) 2018/291.
ARfD	0.03 mg/kg bw	EFSA (2009)	Based on clinical signs of neurotoxicity (tremors, and twitching) and functional observation battery effects in a 90-day rat neurotoxicity with UF of 100. The ARfD was formally adopted by Regulation (EU) 2018/291.

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight; UF: uncertainty factor.

Table 7: Toxicological reference values (TRVs) set by the JMPR

TRV	Value	Reference	Comments
ADI	0.01 mg/kg bw per day	FAO (2009)	Based on increased incidence of tremors in dams and increased foetal and litter incidences of hydroureter in a developmental toxicity study in rats and applying an UF of 100.
ARfD	0.01 mg/kg bw	FAO (2009)	Based on reduced motor activity in an acute toxicity study in male rats*, supported by the developmental toxicity study in rats and applying an UF of 100.

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight; UF: uncertainty factor.
*: Study not available to the EU peer review.

EFSA screened the completeness and the quality of the toxicological studies that were used to derive the EU and the JMPR TRVs, focussing on the question whether the studies meet current scientific standards. EFSA did not undertake a full review of the original studies, the basis of the TRV derivation was scrutinised based on the available data reported mainly in the original DAR and addenda (France, 2005, 2008).

During this scrutiny, EFSA identified critical issues related to the available toxicological database which were discussed with Member State experts in mammalian toxicology in the Pesticides Peer Review Teleconference 89 in September 2022 (EFSA, 2022).

The discussions with the Member State experts focussed on the following two critical points:

- the genotoxicity data set;
- the robustness of the available data to derive toxicological reference values, i.e. the ADI, the ARfD and respective UF.

The genotoxicity data package for bifenthrin contains studies assessing the three endpoints, i.e., gene mutation in bacterial and mammalian cells (*in vitro*), clastogenicity (*in vitro* and *in vivo*) and aneugenicity (*in vivo*).[10]

[10] See experts' consultation point 2.1 at the Pesticide Peer Review Teleconference 89 (EFSA, 2022).

The studies for gene mutation showed negative, positive and inconclusive results. The studies for clastogenicity and aneugenicity showed negative results. The large majority of the studies were conducted in the 80s and therefore conducted according to the OECD test guidelines in place at the time but updated later on following scientific and technical knowledge developments, or previously to their publication. Some of the test guidelines were deleted in the meantime (sister chromatid exchange test (TG 479), *in vitro* unscheduled DNA synthesis (UDS) assay (TG 482) used in three studies and an *in vivo* sex linked recessive lethal assay in *Drosophila melanogaster* (TG 477)) that were considered relevant and reliable at the time of the assessment to clarify the gene mutation potential of the test substance, but are not considered relevant anymore.

The reliability of the *other in vitro* studies was questioned in the experts' meeting due to significant deviations with regards to current test guidelines, such as low number of cells analysed, precipitation observed at all dose levels, different exposure conditions or solvent medium that could explain different results observed at similar concentrations in different tests. With regards to *in vivo* studies (mammalian bone marrow cytogenetic test in rats and mammalian erythrocyte micronucleus test in mice), deviations were also noted with regards to current standard, in particular proof of bone marrow exposure was not shown (lethargy and closed eyes observed are not considered as clinical signs indicating bone marrow exposure on the basis of the chemical class bifenthrin belongs to, and plasma analysis was not performed) and their negative results cannot be confirmed (EFSA Scientific Committee, 2017). This is particularly relevant to address the aneugenicity potential of bifenthrin that was not tested *in vitro*.

It was noted that, according to the current scientific standards, if a substance is tested positive in an *in vitro* gene mutation test, a suitable *in vivo* follow-up test (e.g. *in vivo* Comet assay (TG 489) or transgenic rodent somatic and germ cell gene mutation assay (TG 488)) would be requested (EFSA Scientific Committee, 2011). The experts agreed that an *in vitro* study covering mammalian gene mutation according to the most updated standard quality is not available; the *in vivo* micronucleus study is lacking proof of bone marrow exposure.

Overall, the data package available is not considered reliable. It is not possible to conclude on the genotoxicity potential of bifenthrin, in particular regarding gene mutation and aneugenicity.

With regard to the toxicological data package needed to derive an ADI and ARfD for bifenthrin according to the current data requirements,[11] the experts identified major limitations and missing data. Due to the deficiencies listed below, the experts concluded that the derivation of toxicological reference values according to current scientific standards is not possible[12]:

- According to current standards, the genotoxic potential of bifenthrin was found to be inconclusive.
- The assessment of the validity of the toxicological studies and reliability of their results is limited by the lack of details on the toxicological studies reported in the DAR (France, 2005) (e.g. that do not allow to verify the compliance of these studies with the current version of the test guidelines), and the unknown validity of the analytical methods used in feed, body fluids and tissues, air and any additional matrices used in support of the toxicity studies. These limitations imply, for instance, that it is not possible to understand the difference in NOAELs derived by the EU and the JMPR assessments, as is the case of the maternal and developmental toxicity NOAELs of a developmental toxicity study in rats (critical to the risk assessment).
- A search for published literature has not been conducted; the JMPR identified a published study (Wolansky et al., 2006) not available to the EU peer review, that was used as the basis to derive an ARfD.
- The endocrine disruptive potential of bifenthrin was not assessed according to the current ECHA/EFSA Guidance (ECHA and EFSA, 2018). It is expected that additional toxicological information would be needed to perform such an assessment.
- A comparative in vitro metabolism study performed on animal species used in pivotal studies and on human material is not available to determine the relevance of the toxicological animal data to humans and whether additional testing of potential unique human metabolites would be required.

[11] Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market OJ L 93, 3.4.2013, p. 1–84.

[12] See experts' consultation point 2.2 at the Pesticide Peer Review Teleconference 89 (EFSA, 2022).

The experts expressed concern regarding the lack of an up-to-date assessment of the developmental neurotoxicity study that is considered critical for the risk assessment of active substances belonging to the pyrethroids chemical class and for which the performing protocol has significantly evolved with time. For instance, the actual concentration of bifenthrin analysed in maternal milk could be used to establish a more robust (neurotoxicity) developmental NOAEL since the offspring were not dosed directly.

The use of an additional uncertainty factor was discussed but could not be established on the basis of deficiencies and uncertainties identified.

It was concluded that the existing toxicological reference values derived at EU level in the past cannot be confirmed for bifenthrin since its genotoxicity potential is inconclusive regarding gene mutation in mammalian cells and aneugenicity, the data available were considered insufficient when compared to current standards, and uncertainty factors could not be established.

Accordingly, considering that the ADI and ARfD derived in 2009 in the EU do not comply with the current scientific standards, EFSA would recommend their withdrawal.

The JMPR values suffer from the same limitations as it appears to be based on the same toxicological studies, at least with regards to the genotoxicity data package.

4. Consumer risk assessment

In order to address ToR 5 (a) (Scenario 1), ToR 6 and ToR 11, EFSA calculated the chronic and acute dietary exposure, based on the current residue definition for risk assessment, i.e. parent bifenthrin. Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019). All input values included in the exposure calculations are summarised in Appendix C.

As for some commodities EFSA suggested two risk management options (i.e. for baby leaf crops, soya beans, meat and other edible offals of swine, bovine, sheep, goat, equine and others; see Table 5 and Appendix C), the following two sub-scenarios were calculated:

- **Scenario 1A**:
  - All CXLs and EU MRLs that are sufficiently substantiated or which were recommended for further risk management discussion (labelled as "to be discussed" in Table 5) were considered for the exposure assessment, using the relevant risk assessment value for the current MRL. For the chronic exposure assessment, the calculation is based on the supervised trials median residue levels (STMR) derived for raw agricultural commodities (noting that for bananas, a peeling factor was applied). For the acute exposure assessment, the calculation is based on the highest residue levels (HR) expected in raw agricultural commodities (or the STMR for oilseeds, maize and milk). For bananas, the peeling factor was also included in the acute exposure assessment.
  - For commodities for which the CXLs/MRLs were revoked or are no longer substantiated, the appropriate LOQ was used as input value for the exposure calculation.
  - All other commodities where no GAP was reported in the framework of the MRL review were included in the calculation with the appropriate LOQ.
- **Scenario 1B**:
  - Same input values as in scenario 1A, except for the CXL/MRLs labelled as "to be discussed" in Table 5, for which the appropriate LOQ or MRL proposal was used, assuming that a risk management decision on the lowering of these MRLs would be taken.

The risk assessment scenario as described in ToR 5 (b) (Scenario 2) is not relevant for the assessment of bifenthrin, as all CXLs and ITs set in EU Regulation were implemented and evaluated by EFSA after 2009.

The acute and chronic exposure calculations were compared to current EU TRVs (European Commission, 2018), noting that during the experts' meeting on mammalian toxicology held in September 2022, the experts concluded that these TRVs do not comply with the current scientific standards and therefore recommended to withdraw the existing EU TRVs (see Section 3). Thus, the risk assessment requested in ToR 5 and presented in this review is indicative only.

Screenshots of the report sheet of the indicative PRIMo calculations for scenario 1A and 1B are presented in Appendix B.

In both scenarios (1A and 1B), the highest chronic exposure was calculated for Dutch toddler, representing 40% of the ADI derived at EU level in 2009 (0.015 mg/kg body weight (bw) per day). The contribution of the MRLs set at the LOQ to the exposure represents 2% of the ADI for both scenarios. The highest acute exposure was calculated for sweet peppers, representing 61% of the EU ARfD derived in 2009 (0.03 mg/kg bw).

To give a comprehensive overview, the exposure calculations were also compared to the more conservative TRVs derived by JMPR (FAO, 2009). However, as the experts also noted deficiencies in the toxicological database used by JMPR (see Section 3), the risk assessment with JMPR TRVs is also indicative only.

In both JMPR scenarios (see Appendix B), the highest chronic exposure is calculated for Dutch toddler, representing 60% of the ADI derived by JMPR (0.01 mg/kg bw per day), with a contribution of commodities where the LOQ was used in the exposure calculation, of 3%.

An exceedance of the ARfD derived by JMPR (0.01 mg/kg bw) is identified in both scenarios for table grapes, blueberries and sweet peppers, representing 102%, 146% and 184% of the ARfD, respectively; in scenario 1A, in addition, an exceedance of the ARfD is observed for other edible offals from bovine accounting for 138% of the ARfD. No fall-back GAP was identified for these commodities and the risk assessment could not be further refined.

The toxicological assessment revealed deficiencies regarding the toxicological studies available for bifenthrin (EFSA, 2022) which do not fully comply with the current scientific standards. Considering the high level of uncertainty affecting the TRVs derived in 2009, EFSA did not confirm the previously derived TRVs. Therefore, the risk assessment cannot be finalised.

Conclusions and recommendations

The metabolism of bifenthrin in plants and animals was previously investigated in the framework of the peer review (EFSA, 2011) and the MRL review (EFSA, 2015), as well as by JMPR (FAO, 2011a,b). According to the results of the metabolism studies assessed, the residue definition for enforcement and risk assessment, both for plant and animal products, is bifenthrin (sum of isomers), the residue being fat soluble.

Fully validated analytical methods are available for the enforcement of the proposed residue definition in all four main plant matrices with an LOQ of 0.01 mg/kg. However, no validation data are available to monitor bifenthrin in spices, tea and hops. Bifenthrin can be enforced in 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. According to the EURLs, a QuEChERS (and QuOil) multi-residue analytical method is available with an LOQ of 0.01 mg/kg for the routine analysis of bifenthrin in high water, high acid, high oil and dry commodities. A default LOQ of 0.01 mg/kg is also deemed achievable to monitor bifenthrin in all commodities of animal origin.

The origin of all current MRLs set for bifenthrin (based on formerly approved uses or on CXLs) was investigated, and a list of MRLs was identified as not sufficiently substantiated: CXLs for strawberries, mangoes, papayas, flowering and head brassica, kohlrabies, pulses, tea and hops; EU MRL for herbal infusions and okra. No fall-back MRLs were identified for any of these crops. Moreover, further risk management discussions are required to decide whether the existing EU MRL for baby leaf crops, soya beans, muscle and other edible offals from swine, bovine, sheep, goat and equine, should be maintained or lowered to the LOQ.

A screening of the quality of the TRVs set at EU level and of those established by the JMPR was performed, and the set of toxicological studies used to derive these TRVs was assessed according to the current standards. As critical issues were identified, a Member States experts' consultation took place. Experts concluded that the TRVs cannot be confirmed for bifenthrin since the available data do not provide sufficient evidence to exclude the genotoxicity potential of bifenthrin, the data available were insufficient compared to current standards, and uncertainty factors could not be established. Accordingly, the EU ADI and ARfD derived in 2009 do not comply with the current scientific standards. Therefore, EFSA recommends withdrawing these TRVs. The following data would be required to finalise the toxicological assessment which is a pre-requisite to derive robust TRVs:

- additional studies to conclude on the genotoxic potential of bifenthrin;
- assessment of the validity of analytical methods used in feed, body fluids and tissues, air and any additional matrices used in support of the toxicological studies;
- literature search;
- additional toxicological data to perform the ED assessment;

- comparative in vitro metabolism study on animal species used in pivotal studies and on human material;
- full re-evaluation of the toxicological data package and reporting relevant details on the studies and the results in accordance with the current guidelines.

The same limitations regarding the genotoxicity data package are applicable to JMPR values.

Chronic and acute exposure calculations were performed using revision 3.1 of PRIMo, considering commodities for which CXLs and EU MRLs were found to be sufficiently substantiated, while all CXLs/ MRLs that were revoked or are no longer substantiated were proposed to be lowered to the appropriate LOQ (or MRL proposal), as well as all other commodities for which no GAP was reported under this review. Comparing to the EU TRVs, no exceedances were observed, and the highest chronic exposure represented 40% of the ADI (Dutch toddler). Nevertheless, EFSA emphasises that as the toxicological assessment revealed deficiencies regarding the toxicological studies available for bifenthrin and considering that EU TRVs do not meet the current scientific standards, the indicative risk assessment cannot be finalised, and results presented under the current review are indicative only.

Due to the deficiencies identified regarding the toxicological studies available for bifenthrin, none of the existing EU MRLs/CXLs listed in the table below (Table 8) are recommended for inclusion in Annex II to the Regulation. If a decision on the withdrawing of TRVs is taken, EFSA recommends that risk managers discuss whether all MRLs currently implemented in EU Regulation should be lowered to the respective LOQs.

Table 8: Summary table

Code[(a)]	Commodity	Existing MRL[(b)] (mg/kg)	Outcome of the review	
			MRL proposal (mg/kg)	Comment
Residue definition for enforcement (plants and animal products): Bifenthrin (sum of isomers)[(F)]				
0110000	Citrus fruits	0.05	0.05 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. However, further risk management discussions are needed to decide whether the existing MRL needs to be lowered as the risk assessment could not be finalised, lacking robust TRVs for bifenthrin (EFSA recommends withdrawing the previously derived EU TRVs, as the toxicological database does not fully comply with the current scientific standards).
0120000	Tree nuts	0.05	0.05 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
0151000	Grapes	0.3	0.3 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits. In addition, EFSA noted that the exposure resulting from residues in table grapes exceeded the ARfD derived by JMPR, noting that the toxicological database available to JMPR does not fully comply with the current scientific standards. No fall-back MRL identified.
0152000	Strawberries	1	0.01*	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.
0153000	Cane fruits	1	1 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.

Code[(a)]	Commodity	Existing MRL[(b)] (mg/kg)	Outcome of the review	
			MRL proposal (mg/kg)	Comment
0154010	Blueberries	3	3 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits. In addition, EFSA noted that the exposure resulting from residues in blueberries exceeded the ARfD derived by JMPR, noting that the toxicological database available to JMPR does not fully comply with the current scientific standards. No fall-back MRL identified.
0163020	Bananas	0.1	0.1 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
0163030	Mangoes	0.5	0.01*	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.
0163040	Papayas	0.4	0.01*	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.
0211000	Potatoes	0.05	0.05 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
0212000	Tropical roots and tuber vegetables	0.05		
0213000	Other root and tuber vegetables except sugar	0.05		
0231010	Tomatoes	0.3	0.3 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
0231020	Sweet peppers	0.5	0.5 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits. In addition, EFSA noted that the exposure resulting from residues in sweet peppers exceeded the ARfD derived by JMPR, noting that the toxicological database available to JMPR does not fully comply with the current scientific standards. No fall-back MRL identified.
0231030	Aubergines	0.3	0.3 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
0231040	Okra/lady's fingers	0.2	0.01*	The existing MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.
0241000	Flowering brassica	0.4	0.01*	The existing MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.
0242000	Head brassica	0.4		
0244000	Kohlrabies	0.4		

Code[(a)]	Commodity	Existing MRL[(b)] (mg/kg)	Outcome of the review	
			MRL proposal (mg/kg)	Comment
0251080	Baby leaf crops	4	4 or LOQ Further consideration by risk managers needed	Further risk management discussions are needed to decide whether the existing MRL is substantiated or should be lowered to the LOQ, noting that the current EU MRL is based on the CXL for radish leaves. In addition, it should be discussed whether the existing MRL needs to be lowered as the risk assessment could not be finalised, lacking robust TRVs for bifenthrin (EFSA recommended to withdraw the previously derived EU TRVs, as the toxicological database does not fully comply with the current scientific standards).
0260030	Peas (with pods)	0.9	0.9 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
0260040	Peas (without pods)	0.05	0.05* or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
0300000	Pulses	0.3	0.01*	The existing MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.
0401060	Rapeseeds/canola seeds	0.05	0.05 or LOQ Further risk management considerations required	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
0401070	Soya beans	0.3	0.3 or LOQ Further consideration by risk managers needed	Further risk management discussions are needed to decide whether the existing MRL is substantiated, noting that EU expressed a reservation for the CXL on pulses (covering soya beans), but that sufficient trials on soya beans are available. In addition, it should be discussed whether the existing MRL needs to be lowered as the risk assessment could not be finalised, lacking robust TRVs for bifenthrin (EFSA recommended to withdraw the previously derived EU TRVs, as the toxicological database does not fully comply with the current scientific standards).
0401090	Cotton seeds	0.5	0.5 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
0500090	Wheat	0.5	0.5 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
0610000	Teas	30	0.05*	The existing MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.

Code[(a)]	Commodity	Existing MRL[(b)] (mg/kg)	Outcome of the review	
			MRL proposal (mg/kg)	Comment
0630000	Herbal infusion	0.1	0.02*	The existing MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.
0700000	Hops	20	0.05*	The existing MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.
0820000	Fruit spices	0.03	0.03 or LOQ Further risk management considerations required	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
0840000	Root and rhizome spices	0.05	0.05 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
1011010 1012010 1013010 1014010 1015010 1017010	Muscle from Swine Bovine Sheep Goat Equine Other farmed terrestrial animals	0.2	0.2 or LOQ Further consideration by risk managers needed	Further risk management discussions are needed to decide whether the existing MRL is substantiated, noting that formally no CXL is in place for muscle, and EU uses leading to the maximum dietary burden are no longer authorised. In addition, it should be discussed whether the existing MRL needs to be lowered as the risk assessment could not be finalised, lacking robust TRVs for bifenthrin (EFSA recommended to withdraw the previously derived EU TRVs, as the toxicological database does not fully comply with the current scientific standards).
1011020 1012020 1013020 1014020 1015020 1017020	Fat from Swine Bovine Sheep Goat Equine Other farmed terrestrial animals	3	3 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
1011030 1012030 1013030 1014030 1015030 1017030	Liver from Swine Bovine Sheep Goat Equine Other farmed terrestrial animals	0.2	0.2 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.
1011040 1012040 1013040 1014040 1015040 1017040	Kidney from Swine Bovine Sheep Goat Equine Other farmed terrestrial animals	0.2	0.2 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.

Code[(a)]	Commodity	Existing MRL[(b)] (mg/kg)	Outcome of the review	
			MRL proposal (mg/kg)	Comment
1011050 1012050 1013050 1014050 1015050 1017050	Other edible offals from Swine Bovine Sheep Goat Equine Other farmed terrestrial animals	3	0.2 or LOQ Further consideration by risk managers needed	The EU MRL was derived from the CXL for fat. Further risk management discussions are needed to decide whether a CXL of 0.2 mg/kg (Codex MRL for edible offals) would be more appropriate. In addition, it should be discussed whether the existing MRL needs to be lowered as the risk assessment could not be finalised, lacking robust TRVs for bifenthrin (EFSA recommended to withdraw the previously derived EU TRVs, as the toxicological database does not fully comply with the current scientific standards). EFSA noted that the exposure resulting from residues other edible offals exceeded the ARfD derived by JMPR, noting that the toxicological database available to JMPR does not fully comply with the current scientific standards. No fall-back GAP identified.
1020000	Milk	0.2	0.2 or LOQ Further consideration by risk managers needed	The existing MRL is sufficiently substantiated. Similar recommendations as reported for citrus fruits.

MRL: maximum residue limit; CXL: Codex residue limit; LOQ: limit of quantification; TRV: toxicological reference value; ARfD: acute reference dose; GAP: good agricultural practice.
*: Indicates that the MRL is set at the limit of quantification.
(F): Fat soluble.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): MRL currently set under Regulation (EC) No 2018/687.

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Abbreviations

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CAC	Codex Alimentarius Commission
CCPR	Codex Committee on Pesticide Residues
cGAP	critical good agricultural practice
CXL	Codex maximum residue limit
DAT	days after treatment
DAR	draft assessment report (prepared under Council Directive 91/414/EEC)
DALT	days after last treatment
ECHA	European Chemicals Agency
ED	endocrine disruptor
EURLs	European Reference Laboratories
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GC-ECD	gas chromatography with electron capture detector
GC–MS	gas chromatography with mass spectrometry
GC–MS/MS	gas chromatography with tandem mass spectrometry
HR	highest residue
IT	import tolerance
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC–MS/MS	liquid chromatography – mass spectrometry
LOQ	limit of quantification (determination)
MRL	maximum residue limit
MS	Member States
NOAEL	no observed adverse effect level
n.r.	not relevant
OJ	Official Journal of the European Union
OECD	Organisation for Economic Co-operation and Development
PeF	peeling factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RAC	(ECHA) Risk Assessment Committee
RD	residue definition
SCoPAFF	Standing Committee on Plants, Animals, Food and Feed
STMR	supervised trials median residue
tbd	to be discussed
ToR	Terms of Reference
TRV	toxicological reference value
WHO	World Health Organization
UF	uncertainty factor

Appendix A – Summary of the fall-back GAPs collected from Member States

Not applicable, as Member States reported no import tolerances for bifenthrin.

Appendix B – Pesticide Residue Intake Model (PRIMo)

- PRIMo_EU_(Sc. 1A)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Bifenthrin (F)

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw per day):	0.015	ARfD (mg/kg bw):	0.03
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2018	Year of evaluation:	2018

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments: **The EU TRVs established are not compliant with the current scientific standard. As it is recommended to withdraw them, EFSA emphasises that the risk assessment presented under this review cannot be concluded and is indicative only.**
Scenario 1a: RA considering the EU TRVs. All commodities for which the existing MRL is sufficiently substantiated (and MRLs still to be discussed by risk managers) are included in the calculation; MRLs that are not substantiated are lowered to the appropriate LOQ. All Commodities for which no GAP was reported are lowered to the appropriate LOQ.

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
	40%	NL toddler	6.02	21%	Milk: Cattle	7%	Wheat	2%	Maize/corn	2%	38%
	24%	FR child 3 15 yr	3.63	8%	Milk: Cattle	8%	Wheat	2%	Bovine: Muscle/meat	1.0%	23%
	24%	NL child	3.56	9%	Milk: Cattle	7%	Wheat	1%	Swine: Muscle/meat	2%	22%
	24%	UK infant	3.55	14%	Milk: Cattle	4%	Wheat	1%	Bovine: Muscle/meat	0.6%	23%
	22%	FR toddler 2 3 yr	3.27	10%	Milk: Cattle	5%	Wheat	1%	Bovine: Muscle/meat	0.9%	21%
	21%	DE child	3.20	7%	Wheat	7%	Milk: Cattle	1%	Oranges	2%	20%
	20%	GEMS/Food G06	2.96	12%	Wheat	1%	Tomatoes	0.9%	Milk: Cattle	0.9%	19%
	20%	UK toddler	2.93	7%	Milk: Cattle	7%	Wheat	1%	Bovine: Muscle/meat	0.7%	19%
	19%	GEMS/Food G15	2.87	8%	Wheat	2%	Milk: Cattle	2%	Swine: Muscle/meat	0.8%	18%
	19%	DK child	2.85	7%	Wheat	4%	Milk: Cattle	3%	Swine: Muscle/meat	0.9%	18%
	19%	RO general	2.83	8%	Wheat	4%	Milk: Cattle	1%	Swine: Muscle/meat	0.6%	18%
	19%	ES child	2.81	7%	Wheat	4%	Milk: Cattle	2%	Bovine: Muscle/meat	0.7%	18%
	19%	SE general	2.78	5%	Wheat	5%	Bovine: Muscle/meat	4%	Milk: Cattle	0.5%	18%
	18%	GEMS/Food G11	2.74	6%	Wheat	3%	Milk: Cattle	1%	Swine: Muscle/meat	0.9%	17%
	18%	GEMS/Food G07	2.72	7%	Wheat	2%	Milk: Cattle	1%	Swine: Muscle/meat	0.8%	17%
	18%	GEMS/Food G08	2.70	7%	Wheat	2%	Swine: Muscle/meat	2%	Milk: Cattle	0.9%	17%
	17%	GEMS/Food G10	2.50	7%	Wheat	2%	Milk: Cattle	1%	Soyabeans	0.8%	16%
	14%	IE adult	2.07	4%	Wheat	2%	Milk: Cattle	1%	Sweet potatoes	0.8%	13%
	13%	DE women 14-50 yr	1.97	4%	Milk: Cattle	4%	Wheat	1%	Swine: Muscle/meat	1.0%	12%
	13%	DE general	1.94	4%	Milk: Cattle	3%	Wheat	1%	Swine: Muscle/meat	0.9%	12%
	13%	IT toddler	1.93	11%	Wheat	0.6%	Tomatoes	0.3%	Potatoes	0.4%	13%
	11%	NL general	1.72	3%	Wheat	3%	Milk: Cattle	1%	Swine: Muscle/meat	0.7%	11%
	11%	PT general	1.67	7%	Wheat	2%	Potatoes	1.0%	Wine grapes	0.3%	11%
	10%	ES adult	1.52	4%	Wheat	2%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.5%	10%
	10%	FR infant	1.51	6%	Milk: Cattle	1%	Wheat	0.6%	Potatoes	0.4%	10%
	10%	FR adult	1.49	4%	Wheat	2%	Milk: Cattle	0.9%	Wine grapes	0.6%	9%
	8%	IT adult	1.25	7%	Wheat	0.5%	Tomatoes	0.2%	Potatoes	0.3%	8%
	8%	DK adult	1.25	2%	Wheat	2%	Milk: Cattle	1%	Swine: Muscle/meat	0.3%	8%
	7%	LT adult	1.05	2%	Wheat	1%	Milk: Cattle	1%	Swine: Muscle/meat	0.4%	7%
	7%	UK vegetarian	1.00	3%	Wheat	1%	Milk: Cattle	0.5%	Potatoes	0.3%	6%
	7%	UK adult	0.98	3%	Wheat	1%	Milk: Cattle	0.8%	Bovine: Muscle/meat	0.3%	6%
	6%	FI 3 yr	0.83	2%	Wheat	2%	Potatoes	0.4%	Raspberries (red and yellow)	0.5%	5%
	5%	IE child	0.68	2%	Wheat	1%	Milk: Cattle	0.5%	Swine: Fat tissue	0.1%	4%
	4%	FI 6 yr	0.67	2%	Wheat	1%	Potatoes	0.3%	Raspberries (red and yellow)	0.4%	4%
	4%	FI adult	0.58	2%	Coffee beans	0.5%	Wheat	0.4%	Potatoes	2%	2%
	2%	PL general	0.34	1%	Potatoes	0.4%	Tomatoes	0.1%	Apples	0.3%	2%

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.

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

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
61%	Sweet peppers/bell peppers	0.5/0.31	18
46%	Bovine: Edible offals (other	3/1.9	14
34%	Table grapes	0.3/0.14	10
32%	Blueberries	3/1.6	9.5
29%	Tomatoes	0.3/0.15	8.7
26%	Potatoes	0.05/0.05	7.7
22%	Oranges	0.05/0.05	6.6
22%	Milk: Cattle	0.2/0.05	6.6
19%	Wheat	0.5/0.4	5.8
19%	Swine: Edible offals (other	3/1.9	5.7
19%	Swine: Muscle/meat	0.2/0.46	5.6
18%	Blackberries	1/0.51	5.5
16%	Raspberries (red and yellow)	1/0.51	4.7
14%	Peas (with pods)	0.9/0.5	4.1
13%	Bovine: Fat tissue	3/1.9	4.0

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
49%	Blueberries	3/1.6	15
21%	Bovine: Edible offals (other	3/1.9	6.3
17%	Sweet peppers/bell peppers	0.5/0.31	5.1
17%	Swine: Edible offals (other	3/1.9	5.0
16%	Table grapes	0.3/0.14	4.7
14%	Blackberries	1/0.51	4.2
13%	Swine: Fat tissue	3/1.9	3.9
11%	Wheat	0.5/0.4	3.4
11%	Wine grapes	0.3/0.14	3.3
9%	Raspberries (red and yellow)	1/0.51	2.8
9%	Aubergines/egg plants	0.3/0.1	2.7
9%	Bovine: Muscle	0.2/0.46	2.6
9%	Other farmed animals:	0.2/0.46	2.6
8%	Tomatoes	0.3/0.15	2.4
7%	Swine: Muscle/meat	0.2/0.46	2.2

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
16%	Wheat/milling (flour)	0.5/0.4	4.8
16%	Potatoes/fried	0.05/0.05	4.7
11%	Raspberries/juice	1/0.29	3.4
10%	Potatoes/dried (flakes)	0.05/0.23	3.0
9%	Oranges/juice	0.05/0.05	2.6
9%	Wine grapes/juice	0.3/0.06	2.6
8%	Turnips/boiled	0.05/0.05	2.5
8%	Parsnips/boiled	0.05/0.05	2.5
8%	Sweet potatoes/boiled	0.05/0.05	2.5
7%	Wheat/milling (wholemeal)-ba	0.5/0.4	2.2
7%	Beetroots/boiled	0.05/0.05	2.2
6%	Carrots/juice	0.05/0.05	1.8
4%	Salsifies/boiled	0.05/0.05	1.3
4%	Jerusalem artichokes/boiled	0.05/0.05	1.3
4%	Maize/oil	0.05/1.25	1.2

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
6%	Beetroots/boiled	0.05/0.05	1.9
6%	Wheat/bread/pizza	0.5/0.4	1.8
6%	Peas (with pods)/boiled	0.9/0.5	1.7
5%	Wheat/pasta	0.5/0.4	1.5
5%	Wheat/bread (wholemeal)	0.5/0.4	1.4
4%	Wine grapes/wine	0.3/0.14	1.3
4%	Wine grapes/juice	0.3/0.06	1.2
4%	Parsnips/boiled	0.05/0.05	1.1
3%	Turnips/boiled	0.05/0.05	0.95
3%	Cassava roots/boiled	0.05/0.05	0.95
3%	Celeriacs/boiled	0.05/0.05	0.91
3%	Table grapes/raisins	0.3/0.66	0.81
3%	Sweet potatoes/boiled	0.05/0.05	0.77
3%	Oranges/juice	0.05/0.05	0.76
2%	Maize/oil	0.05/1.25	0.63

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.

- PRIMo_EU_(Sc. 1B)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Bifenthrin (F)

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw per day):	0.01	ARfD (mg/kg bw):	0.01
Source of ADI:	FAO	Source of ARfD:	FAO
Year of evaluation:	2009	Year of evaluation:	2009

Input values | Details - chronic risk assessment | Supplementary results - chronic risk assessment | Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments: +A9:Q53

The EU TRVs established are not compliant with the current scientific standard and EFSA recommends to withdraw them. This indicative RA is performed with the TRVs derived by JMPR (although these TRVs suffer from the same limitations as the EU ones). Therefore, EFSA emphasises that the risk assessment presented under this review cannot be concluded and is indicative only.

Scenario 1a: All commodities for which the existing MRL is sufficiently substantiated (and MRLs still to be discussed by risk managers) are included in the calculation; MRLs that are not substantiated are lowered to the appropriate LOQ. All Commodities for which no GAP was reported are lowered to the appropriate LOQ.

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	60%	NL toddler	6.02	32%	Milk: Cattle	10%	Wheat	4%	Maize/corn	3%	57%
	36%	FR child 3 15 yr	3.62	12%	Milk: Cattle	11%	Wheat	3%	Bovine: Muscle/meat	1%	35%
	36%	NL child	3.55	13%	Milk: Cattle	10%	Wheat	2%	Swine: Muscle/meat	2%	33%
	36%	UK infant	3.55	21%	Milk: Cattle	7%	Wheat	2%	Bovine: Muscle/meat	0.8%	35%
	33%	FR toddler 2 3 yr	3.26	16%	Milk: Cattle	8%	Wheat	2%	Bovine: Muscle/meat	1%	31%
	32%	DE child	3.19	11%	Wheat	10%	Milk: Cattle	2%	Oranges	2%	30%
	30%	GEMS/Food G06	2.96	18%	Wheat	2%	Tomatoes	1%	Milk: Cattle	1%	28%
	29%	UK toddler	2.93	11%	Milk: Cattle	10%	Wheat	2%	Bovine: Muscle/meat	1.0%	28%
	29%	GEMS/Food G15	2.86	11%	Wheat	4%	Milk: Cattle	2%	Swine: Muscle/meat	1%	28%
	28%	DK child	2.85	11%	Wheat	7%	Milk: Cattle	4%	Swine: Muscle/meat	1%	27%
	28%	RO general	2.83	13%	Wheat	6%	Milk: Cattle	2%	Swine: Muscle/meat	0.9%	28%
	28%	ES child	2.79	11%	Wheat	7%	Milk: Cattle	2%	Bovine: Muscle/meat	0.8%	27%
	28%	SE general	2.78	8%	Wheat	8%	Bovine: Muscle/meat	7%	Milk: Cattle	0.7%	27%
	27%	GEMS/Food G11	2.72	9%	Wheat	4%	Milk: Cattle	2%	Swine: Muscle/meat	1%	26%
	27%	GEMS/Food G07	2.71	11%	Wheat	3%	Milk: Cattle	2%	Swine: Muscle/meat	1%	26%
	27%	GEMS/Food G08	2.69	10%	Wheat	3%	Swine: Muscle/meat	3%	Milk: Cattle	1%	26%
	25%	GEMS/Food G10	2.49	10%	Wheat	3%	Milk: Cattle	2%	Soyabeans	1%	24%
	21%	IE adult	2.07	6%	Wheat	2%	Milk: Cattle	2%	Sweet potatoes	1%	20%
	19%	DE women 14-50 yr	1.95	7%	Milk: Cattle	5%	Wheat	2%	Swine: Muscle/meat	1%	18%
	19%	IT toddler	1.93	17%	Wheat	0.9%	Tomatoes	0.4%	Potatoes	0.6%	19%
	19%	DE general	1.91	7%	Milk: Cattle	5%	Wheat	2%	Swine: Muscle/meat	1%	18%
	17%	NL general	1.70	5%	Wheat	4%	Milk: Cattle	2%	Swine: Muscle/meat	1.0%	16%
	17%	PT general	1.67	10%	Wheat	3%	Potatoes	1%	Wine grapes	0.5%	16%
	15%	ES adult	1.52	6%	Wheat	3%	Milk: Cattle	1%	Bovine: Muscle/meat	0.6%	15%
	15%	FR infant	1.51	9%	Milk: Cattle	2%	Wheat	1.0%	Potatoes	0.6%	15%
	15%	FR adult	1.47	6%	Wheat	2%	Milk: Cattle	1%	Wine grapes	0.7%	14%
	13%	IT adult	1.25	10%	Wheat	0.7%	Tomatoes	0.3%	Potatoes	0.5%	12%
	12%	DK adult	1.25	3%	Wheat	3%	Milk: Cattle	2%	Swine: Muscle/meat	0.4%	12%
	10%	LT adult	1.05	3%	Wheat	2%	Milk: Cattle	2%	Swine: Muscle/meat	0.5%	10%
	10%	UK vegetarian	1.00	5%	Wheat	2%	Milk: Cattle	0.7%	Potatoes	0.4%	10%
	10%	UK adult	0.98	4%	Wheat	2%	Milk: Cattle	1%	Bovine: Muscle/meat	0.4%	10%
	8%	FI 3 yr	0.82	3%	Wheat	2%	Potatoes	0.5%	Raspberries (red and yellow)	0.7%	8%
	7%	IE child	0.68	3%	Wheat	2%	Milk: Cattle	0.8%	Swine: Fat tissue	0.2%	7%
	7%	FI 6 yr	0.66	2%	Wheat	2%	Potatoes	0.4%	Raspberries (red and yellow)	0.5%	6%
	4%	FI adult	0.36	0.8%	Wheat	0.6%	Potatoes	0.6%	Coffee beans	0.9%	3%
	3%	PL general	0.34	2%	Potatoes	0.5%	Tomatoes	0.2%	Apples	0.4%	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.

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

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 3

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
184%	Sweet peppers/bell peppers	0.5/0.31	18
138%	Bovine: Edible offals (other	3/1.9	14
102%	Table grapes	0.3/0.14	10
95%	Blueberries	3/1.6	9.5
87%	Tomatoes	0.3/0.15	8.7
77%	Potatoes	0.05/0.05	7.7
66%	Oranges	0.05/0.05	6.6
66%	Milk: Cattle	0.2/0.05	6.6
58%	Wheat	0.5/0.4	5.8
57%	Swine: Edible offals (other	3/1.9	5.7
56%	Swine: Muscle/meat	0.2/0.46	5.6
55%	Blackberries	1/0.51	5.5
47%	Raspberries (red and yellow)	1/0.51	4.7
41%	Peas (with pods)	0.9/0.5	4.1
40%	Bovine: Fat tissue	3/1.9	4.0

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
146%	Blueberries	3/1.6	15
63%	Bovine: Edible offals (other	3/1.9	6.3
51%	Sweet peppers/bell peppers	0.5/0.31	5.1
50%	Swine: Edible offals (other	3/1.9	5.0
47%	Table grapes	0.3/0.14	4.7
42%	Blackberries	1/0.51	4.2
39%	Swine: Fat tissue	3/1.9	3.9
34%	Wheat	0.5/0.4	3.4
33%	Wine grapes	0.3/0.14	3.3
28%	Raspberries (red and yellow)	1/0.51	2.8
27%	Aubergines/egg plants	0.3/0.1	2.7
26%	Bovine: Muscle	0.2/0.46	2.6
26%	Other farmed animals:	0.2/0.46	2.6
24%	Tomatoes	0.3/0.15	2.4
22%	Swine: Muscle/meat	0.2/0.46	2.2

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 4

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
48%	Wheat/milling (flour)	0.5/0.4	4.8
47%	Potatoes/fried	0.05/0.05	4.7
34%	Raspberries/juice	1/0.29	3.4
30%	Potatoes/dried (flakes)	0.05/0.23	3.0
26%	Oranges/juice	0.05/0.05	2.6
26%	Wine grapes/juice	0.3/0.06	2.6
25%	Turnips/boiled	0.05/0.05	2.5
25%	Parsnips/boiled	0.05/0.05	2.5
25%	Sweet potatoes/boiled	0.05/0.05	2.5
22%	Wheat/milling (wholemeal)-ba	0.5/0.4	2.2
22%	Beetroots/boiled	0.05/0.05	2.2
18%	Carrots/juice	0.05/0.05	1.8
13%	Salsifies/boiled	0.05/0.05	1.3
13%	Jerusalem artichokes/boiled	0.05/0.05	1.3
12%	Maize/oil	0.05/1.25	1.2

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
19%	Beetroots/boiled	0.05/0.05	1.9
18%	Wheat/bread/pizza	0.5/0.4	1.8
17%	Peas (with pods)/boiled	0.9/0.5	1.7
15%	Wheat/pasta	0.5/0.4	1.5
14%	Wheat/bread (wholemeal)	0.5/0.4	1.4
13%	Wine grapes/wine	0.3/0.14	1.3
12%	Wine grapes/juice	0.3/0.06	1.2
11%	Parsnips/boiled	0.05/0.05	1.1
10%	Turnips/boiled	0.05/0.05	0.95
9%	Cassava roots/boiled	0.05/0.05	0.95
9%	Celeriacs/boiled	0.05/0.05	0.91
8%	Table grapes/raisins	0.3/0.66	0.81
8%	Sweet potatoes/boiled	0.05/0.05	0.77
8%	Oranges/juice	0.05/0.05	0.76
6%	Maize/oil	0.05/1.25	0.63

Conclusion:
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 4 commodities.

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

- PRIMo_JMPR_(Sc. 1A)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Bifenthrin (F)			
LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.015	ARfD (mg/kg bw):	0.03
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2018	Year of evaluation:	2018

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments: **The EU TRVs established are not compliant with the current scientific standard. As it is recommended to withdraw them, EFSA emphasises that the risk assessment presented under this review cannot be concluded and is indicative only.**
Scenario 1b: RA considering the EU TRVs. All commodities for which the existing MRL is sufficiently substantiated are included in the calculation; MRLs that are not substantiated (and MRLs still to be discussed by risk managers) are lowered to the appropriate LOQ. All Commodities for which no GAP was reported are lowered to the appropriate LOQ.

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
40%	NL toddler	6.01	21%	Milk: Cattle	7%	Wheat	2%	Maize/corn	2%	38%
24%	FR child 3 15 yr	3.57	8%	Milk: Cattle	8%	Wheat	2%	Bovine: Muscle/meat	0.9%	23%
24%	NL child	3.54	9%	Milk: Cattle	7%	Wheat	1%	Swine: Muscle/meat	2%	22%
23%	UK infant	3.47	14%	Milk: Cattle	4%	Wheat	1%	Bovine: Muscle/meat	0.6%	23%
22%	FR toddler 2 3 yr	3.25	10%	Milk: Cattle	5%	Wheat	1%	Bovine: Muscle/meat	0.8%	21%
21%	DE child	3.18	7%	Wheat	7%	Milk: Cattle	1%	Oranges	2%	20%
19%	GEMS/Food G06	2.91	12%	Wheat	1%	Tomatoes	0.9%	Milk: Cattle	1%	19%
19%	UK toddler	2.91	7%	Milk: Cattle	7%	Wheat	1%	Bovine: Muscle/meat	0.7%	19%
19%	DK child	2.85	7%	Wheat	4%	Milk: Cattle	3%	Swine: Muscle/meat	0.9%	18%
19%	RO general	2.83	8%	Wheat	4%	Milk: Cattle	1%	Swine: Muscle/meat	0.6%	18%
19%	GEMS/Food G15	2.79	8%	Wheat	2%	Milk: Cattle	2%	Swine: Muscle/meat	0.8%	18%
19%	SE general	2.78	5%	Wheat	5%	Bovine: Muscle/meat	4%	Milk: Cattle	0.5%	18%
18%	ES child	2.75	7%	Wheat	4%	Milk: Cattle	2%	Bovine: Muscle/meat	0.6%	18%
18%	GEMS/Food G07	2.64	7%	Wheat	2%	Milk: Cattle	1%	Swine: Muscle/meat	0.8%	17%
17%	GEMS/Food G08	2.61	7%	Wheat	2%	Swine: Muscle/meat	2%	Milk: Cattle	0.9%	17%
17%	GEMS/Food G11	2.58	6%	Wheat	3%	Milk: Cattle	1%	Swine: Muscle/meat	1%	16%
16%	GEMS/Food G10	2.36	7%	Wheat	2%	Milk: Cattle	1%	Bovine: Muscle/meat	1.0%	15%
13%	DE women 14-50 yr	1.95	4%	Milk: Cattle	4%	Wheat	1%	Swine: Muscle/meat	0.8%	12%
13%	IT toddler	1.93	11%	Wheat	0.6%	Tomatoes	0.3%	Potatoes	0.4%	13%
13%	DE general	1.91	4%	Milk: Cattle	3%	Wheat	1%	Swine: Muscle/meat	0.8%	12%
13%	IE adult	1.91	4%	Wheat	2%	Milk: Cattle	1%	Sweet potatoes	0.7%	12%
11%	NL general	1.70	3%	Wheat	3%	Milk: Cattle	1%	Swine: Muscle/meat	0.7%	11%
11%	PT general	1.66	7%	Wheat	2%	Potatoes	1.0%	Wine grapes	0.3%	11%
10%	FR infant	1.50	6%	Milk: Cattle	1%	Wheat	0.6%	Potatoes	0.4%	10%
10%	ES adult	1.48	4%	Wheat	2%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.4%	9%
9%	FR adult	1.42	4%	Wheat	2%	Milk: Cattle	0.9%	Wine grapes	0.4%	9%
8%	IT adult	1.25	7%	Wheat	0.5%	Tomatoes	0.2%	Potatoes	0.3%	8%
8%	DK adult	1.25	2%	Wheat	2%	Milk: Cattle	1%	Swine: Muscle/meat	0.3%	8%
7%	LT adult	1.05	2%	Wheat	1%	Milk: Cattle	1%	Swine: Muscle/meat	0.4%	7%
7%	UK vegetarian	1.00	3%	Wheat	1%	Milk: Cattle	0.5%	Potatoes	0.3%	6%
7%	UK adult	0.98	3%	Wheat	1%	Milk: Cattle	0.8%	Bovine: Muscle/meat	0.3%	6%
5%	FI 3 yr	0.82	2%	Wheat	2%	Potatoes	0.4%	Raspberries (red and yellow)	0.4%	5%
5%	IE child	0.68	2%	Wheat	1%	Milk: Cattle	0.5%	Swine: Fat tissue	0.1%	4%
4%	FI 6 yr	0.66	2%	Wheat	1%	Potatoes	0.3%	Raspberries (red and yellow)	0.3%	4%
2%	FI adult	0.36	0.5%	Wheat	0.4%	Potatoes	0.4%	Coffee beans	0.6%	2%
2%	PL general	0.34	1%	Potatoes	0.4%	Tomatoes	0.1%	Apples	0.3%	2%

Conclusion:
The estimated long-term dietary intake (TMDI/NED/IEDI) was below the ADI.
The long-term intake of residues of Bifenthrin (F) is unlikely to present a public health concern.

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

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
61%	Sweet peppers/bell peppers	0.5/0.31	18
34%	Table grapes	0.3/0.14	10
32%	Blueberries	3/1.6	9.5
29%	Tomatoes	0.3/0.15	8.7
26%	Potatoes	0.05/0.05	7.7
22%	Oranges	0.05/0.05	6.6
22%	Milk: Cattle	0.2/0.05	6.6
19%	Wheat	0.5/0.4	5.8
19%	Swine: Muscle/meat	0.01/0.46	5.6
18%	Blackberries	1/0.51	5.5
16%	Raspberries (red and yellow)	1/0.51	4.7
14%	Peas (with pods)	0.9/0.5	4.1
13%	Bovine: Fat tissue	3/1.9	4.0
13%	Grapefruits	0.05/0.05	3.9
11%	Bovine: Muscle/meat	0.01/0.46	3.3

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
49%	Blueberries	3/1.6	15
17%	Sweet peppers/bell peppers	0.5/0.31	5.1
16%	Table grapes	0.3/0.14	4.7
14%	Blackberries	1/0.51	4.2
13%	Swine: Fat tissue	3/1.9	3.9
11%	Wheat	0.5/0.4	3.4
11%	Wine grapes	0.3/0.14	3.3
9%	Raspberries (red and yellow)	1/0.51	2.8
9%	Aubergines/egg plants	0.3/0.1	2.7
9%	Bovine: Muscle	0.01/0.46	2.6
9%	Other farmed animals:	0.01/0.46	2.6
8%	Tomatoes	0.3/0.15	2.4
7%	Swine: Muscle/meat	0.01/0.46	2.2
7%	Equine: Muscle/meat	0.01/0.46	2.2
7%	Sheep: Muscle/meat	0.01/0.46	2.2

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
16%	Wheat/milling (flour)	0.5/0.4	4.8
16%	Potatoes/fried	0.05/0.05	4.7
11%	Raspberries/juice	1/0.29	3.4
10%	Potatoes/dried (flakes)	0.05/0.23	3.0
9%	Oranges/juice	0.05/0.05	2.6
9%	Wine grapes/juice	0.3/0.06	2.6
8%	Turnips/boiled	0.05/0.05	2.5
8%	Parsnips/boiled	0.05/0.05	2.5
8%	Sweet potatoes/boiled	0.05/0.05	2.5
7%	Wheat/milling (wholemeal)-ba	0.5/0.4	2.2
7%	Beetroots/boiled	0.05/0.05	2.2
6%	Carrots/juice	0.05/0.05	1.8
4%	Salsifies/boiled	0.05/0.05	1.3
4%	Jerusalem artichokes/boiled	0.05/0.05	1.3
4%	Maize/oil	0.05/1.25	1.2

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
6%	Beetroots/boiled	0.05/0.05	1.9
6%	Wheat/bread/pizza	0.5/0.4	1.8
6%	Peas (with pods)/boiled	0.9/0.5	1.7
5%	Wheat/pasta	0.5/0.4	1.5
5%	Wheat/bread (wholemeal)	0.5/0.4	1.4
4%	Wine grapes/wine	0.3/0.14	1.3
4%	Wine grapes/juice	0.3/0.06	1.2
4%	Parsnips/boiled	0.05/0.05	1.1
3%	Turnips/boiled	0.05/0.05	0.95
3%	Cassava roots/boiled	0.05/0.05	0.95
3%	Celeriacs/boiled	0.05/0.05	0.91
3%	Table grapes/raisins	0.3/0.66	0.81
3%	Sweet potatoes/boiled	0.05/0.05	0.77
3%	Oranges/juice	0.05/0.05	0.76
2%	Maize/oil	0.05/1.25	0.63

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.

- PRIMo_JMPR_(Sc. 1B)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Bifenthrin (F)

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.01	ARfD (mg/kg bw):	0.01
Source of ADI:	FAO	Source of ARfD:	FAO
Year of evaluation:	2009	Year of evaluation:	2009

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments: The EU TRVs established are not compliant with the current scientific standard and EFSA recommends to withdraw them. This indicative RA is performed with the TRVs derived by JMPR (although these TRVs suffer from the same limitations as the EU ones). **Therefore, EFSA emphasises that the risk assessment presented under this review cannot be concluded and is indicative only.**
Scenario 1b: RA considering the TRVs derived by JMPR. All commodities for which the existing MRL is still justified are included in the calculation; MRLs that are not justified anymore (and MRL still to be discussed by risk managers) are lowered to the appropriate LOQ/MRL proposal. All other commodities are included in

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
60%	NL toddler	6.01	32%	Milk: Cattle	10%	Wheat	4%	Maize/corn	3%	57%
36%	FR child 3 15 yr	3.57	12%	Milk: Cattle	11%	Wheat	3%	Bovine: Muscle/meat	1%	35%
35%	NL child	3.54	13%	Milk: Cattle	10%	Wheat	2%	Swine: Muscle/meat	2%	33%
35%	UK infant	3.47	21%	Milk: Cattle	7%	Wheat	2%	Bovine: Muscle/meat	0.8%	34%
32%	FR toddler 2 3 yr	3.25	16%	Milk: Cattle	8%	Wheat	2%	Bovine: Muscle/meat	1%	31%
32%	DE child	3.18	11%	Wheat	10%	Milk: Cattle	2%	Oranges	2%	30%
29%	GEMS/Food G06	2.91	18%	Wheat	2%	Tomatoes	1%	Milk: Cattle	2%	28%
29%	UK toddler	2.91	11%	Milk: Cattle	10%	Wheat	2%	Bovine: Muscle/meat	1.0%	28%
28%	DK child	2.85	11%	Wheat	7%	Milk: Cattle	4%	Swine: Muscle/meat	1%	27%
28%	RO general	2.83	13%	Wheat	6%	Milk: Cattle	2%	Swine: Muscle/meat	0.9%	28%
28%	GEMS/Food G15	2.79	11%	Wheat	4%	Milk: Cattle	2%	Swine: Muscle/meat	1%	27%
28%	SE general	2.78	8%	Wheat	8%	Bovine: Muscle/meat	7%	Milk: Cattle	0.7%	27%
27%	ES child	2.75	11%	Wheat	7%	Milk: Cattle	2%	Bovine: Muscle/meat	0.8%	27%
26%	GEMS/Food G07	2.64	11%	Wheat	3%	Milk: Cattle	2%	Swine: Muscle/meat	1%	25%
26%	GEMS/Food G08	2.61	10%	Wheat	3%	Swine: Muscle/meat	3%	Milk: Cattle	1%	25%
26%	GEMS/Food G11	2.58	9%	Wheat	4%	Milk: Cattle	2%	Swine: Muscle/meat	2%	25%
24%	GEMS/Food G10	2.36	10%	Wheat	3%	Milk: Cattle	2%	Bovine: Muscle/meat	1%	23%
19%	DE women 14-50 yr	1.95	7%	Milk: Cattle	5%	Wheat	2%	Swine: Muscle/meat	1%	18%
19%	IT toddler	1.93	17%	Wheat	0.9%	Tomatoes	0.4%	Potatoes	0.6%	19%
19%	DE general	1.91	7%	Milk: Cattle	5%	Wheat	2%	Swine: Muscle/meat	1%	18%
19%	IE adult	1.91	6%	Wheat	2%	Milk: Cattle	2%	Sweet potatoes	1%	18%
17%	NL general	1.70	5%	Wheat	4%	Milk: Cattle	2%	Swine: Muscle/meat	1.0%	16%
17%	PT general	1.66	10%	Wheat	3%	Potatoes	1%	Wine grapes	0.5%	16%
15%	FR infant	1.50	9%	Milk: Cattle	2%	Wheat	1.0%	Potatoes	0.7%	14%
15%	ES adult	1.48	6%	Wheat	3%	Milk: Cattle	1%	Bovine: Muscle/meat	0.6%	14%
14%	FR adult	1.42	6%	Wheat	2%	Milk: Cattle	1%	Wine grapes	0.7%	14%
13%	IT adult	1.25	10%	Wheat	0.7%	Tomatoes	0.3%	Potatoes	0.5%	12%
12%	DK adult	1.25	3%	Wheat	3%	Milk: Cattle	2%	Swine: Muscle/meat	0.4%	12%
10%	LT adult	1.05	3%	Wheat	2%	Milk: Cattle	2%	Swine: Muscle/meat	0.5%	10%
10%	UK vegetarian	1.00	5%	Wheat	2%	Milk: Cattle	0.7%	Potatoes	0.4%	10%
10%	UK adult	0.98	4%	Wheat	2%	Milk: Cattle	1%	Bovine: Muscle/meat	0.4%	10%
8%	FI 3 yr	0.82	3%	Wheat	2%	Potatoes	0.5%	Raspberries (red and yellow)	0.7%	8%
7%	IE child	0.68	3%	Wheat	2%	Milk: Cattle	0.8%	Swine: Fat tissue	0.2%	7%
7%	FI 6 yr	0.66	2%	Wheat	2%	Potatoes	0.4%	Raspberries (red and yellow)	0.5%	6%
4%	FI adult	0.36	0.8%	Wheat	0.6%	Potatoes	0.6%	Coffee beans	0.9%	3%
3%	PL general	0.34	2%	Potatoes	0.5%	Tomatoes	0.2%	Apples	0.4%	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.

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

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 2

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
184%	Sweet peppers/bell peppers	0.5/0.31	18
102%	Table grapes	0.3/0.14	10
95%	Blueberries	3/1.6	9.5
87%	Tomatoes	0.3/0.15	8.7
77%	Potatoes	0.05/0.05	7.7
66%	Oranges	0.05/0.05	6.6
66%	Milk: Cattle	0.2/0.05	6.6
58%	Wheat	0.5/0.4	5.8
56%	Swine: Muscle/meat	0.01/0.46	5.6
55%	Blackberries	1/0.51	5.5
47%	Raspberries (red and yellow)	1/0.51	4.7
41%	Peas (with pods)	0.9/0.5	4.1
40%	Bovine: Fat tissue	3/1.9	4.0
39%	Grapefruits	0.05/0.05	3.9
33%	Bovine: Muscle/meat	0.01/0.46	3.3

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
146%	Blueberries	3/1.6	15
51%	Sweet peppers/bell peppers	0.5/0.31	5.1
47%	Table grapes	0.3/0.14	4.7
42%	Blackberries	1/0.51	4.2
39%	Swine: Fat tissue	3/1.9	3.9
34%	Wheat	0.5/0.4	3.4
33%	Wine grapes	0.3/0.14	3.3
28%	Raspberries (red and yellow)	1/0.51	2.8
27%	Aubergines/egg plants	0.3/0.1	2.7
26%	Bovine: Muscle	0.01/0.46	2.6
26%	Other farmed animals:	0.01/0.46	2.6
24%	Tomatoes	0.3/0.15	2.4
22%	Swine: Muscle/meat	0.01/0.46	2.2
22%	Equine: Muscle/meat	0.01/0.46	2.2
22%	Sheep: Muscle/meat	0.01/0.46	2.2

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 3

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
48%	Wheat/milling (flour)	0.5/0.4	4.8
47%	Potatoes/fried	0.05/0.05	4.7
34%	Raspberries/juice	1/0.29	3.4
30%	Potatoes/dried (flakes)	0.05/0.23	3.0
26%	Oranges/juice	0.05/0.05	2.6
26%	Wine grapes/juice	0.3/0.06	2.6
25%	Turnips/boiled	0.05/0.05	2.5
25%	Parsnips/boiled	0.05/0.05	2.5
25%	Sweet potatoes/boiled	0.05/0.05	2.5
22%	Wheat/milling (wholemeal)-ba	0.5/0.4	2.2
22%	Beetroots/boiled	0.05/0.05	2.2
18%	Carrots/juice	0.05/0.05	1.8
13%	Salsifies/boiled	0.05/0.05	1.3
13%	Jerusalem artichokes/boiled	0.05/0.05	1.3
12%	Maize/oil	0.05/1.25	1.2

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
19%	Beetroots/boiled	0.05/0.05	1.9
18%	Wheat/bread/pizza	0.5/0.4	1.8
17%	Peas (with pods)/boiled	0.9/0.5	1.7
15%	Wheat/pasta	0.5/0.4	1.5
14%	Wheat/bread (wholemeal)	0.5/0.4	1.4
13%	Wine grapes/wine	0.3/0.14	1.3
12%	Wine grapes/juice	0.3/0.06	1.2
11%	Parsnips/boiled	0.05/0.05	1.1
10%	Turnips/boiled	0.05/0.05	0.95
9%	Cassava roots/boiled	0.05/0.05	0.95
9%	Celeriacs/boiled	0.05/0.05	0.91
8%	Table grapes/raisins	0.3/0.66	0.81
8%	Sweet potatoes/boiled	0.05/0.05	0.77
8%	Oranges/juice	0.05/0.05	0.76
6%	Maize/oil	0.05/1.25	0.63

Conclusion:
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 3 commodities.

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

Appendix C – Input values for the exposure calculations

Commodity	Existing MRL (mg/kg)	Chronic risk assessment		Acute risk assessment	
		Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Bifenthrin (sum of isomers)(F)					
Citrus fruits	0.05	0.05	STMR (CXL)	0.05	HR (CXL)
Tree nuts	0.05	0.05	STMR (CXL)	0.05	HR (CXL)
Wine and table grapes	0.3	0.06	STMR (CXL)	0.14	HR (CXL)
Strawberries	1	0.01*	LOQ	0.01*	LOQ
Cane fruits (blackberries, dewberries, raspberries)	1	0.29	STMR (CXL)	0.51	HR (CXL)
Blueberries	3	0.67	STMR (CXL)	1.6	HR (CXL)
Bananas	0.1	0.01	STMR (CXL) × PeF (0.2)	0.015	HR (CXL) × PeF (0.2)
Mangoes	0.5	0.01*	LOQ	0.01*	LOQ
Papayas	0.4	0.01*	LOQ	0.01*	LOQ
Potatoes	0.05	0.05	STMR (CXL)	0.05	HR (CXL)
Tropical root and tuber vegetables	0.05	0.05	STMR (CXL)	0.05	HR (CXL)
Other root and tuber vegetable, except sugarbeet	0.05	0.05	STMR (CXL)	0.05	HR (CXL)
Tomatoes	0.3	0.06	STMR (CXL)	0.15	HR (CXL)
Sweet peppers	0.5	0.14	STMR (CXL)	0.31	HR (CXL)
Aubergines (egg plants)	0.3	0.05	STMR (CXL)	0.1	HR (CXL)
Okra/lady's fingers	0.2	0.01*	LOQ	0.01*	LOQ
Flowering brassica	0.4	0.01*	LOQ	0.01*	LOQ
Head brassica	0.4	0.01*	LOQ	0.01*	LOQ
Kohlrabies	0.4	0.01*	LOQ	0.01*	LOQ
Baby leaf crops (incl. brassica species)	4	Scenario 1A: 1.75	STMR (CXL)	Scenario 1A: 2.3	HR (CXL)
		Scenario 1B: 0.01*	LOQ	Scenario 1B: 0.01*	LOQ
Peas (with pods)	0.9	0.23	STMR (CXL)	0.5	HR (CXL)
Peas (without pods)	0.05	0.05	STMR (CXL)	0.05	HR (CXL)
Pulses	0.3	0.01*	LOQ	0.01*	LOQ

Commodity	Existing MRL (mg/kg)	Chronic risk assessment		Acute risk assessment	
		Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Rapeseed/canola seeds	0.05	0.05	STMR (CXL)	0.05	STMR (CXL)
Soya beans	0.3	Scenario 1A: 0.05	STMR (CXL)	Scenario 1A: 0.05	STMR (CXL)
		Scenario 1B: 0.01*	LOQ	Scenario 1B: 0.01*	LOQ
Cotton seeds	0.5	0.05	STMR (CXL)	0.05	STMR (CXL)
Maize/corn	0.05*	0.05*	STMR (CXL)	0.05*	STMR (CXL)
Wheat	0.5(a)	0.25	STMR (CXL)	0.4	HR (CXL)
Tea	30	0.05*	LOQ(b)	0.05*	LOQ(b)
Herbal infusion	0.1	0.02*	LOQ(b)	0.02*	LOQ(b)
Hops	20	0.05*	LOQ(b)	0.05*	LOQ(b)
Spices (fruits)	0.03	0.03	STMR (CXL)	0.03	HR (CXL)
Spices (roots or rhizome)	0.05	0.05	STMR (CXL)	0.05	HR (CXL)
Meat of swine, bovine, sheep, goat, equine, others	0.2	Scenario 1A and 1B: 0.17	0.8 × STMR muscle + 0.2 × STMR fat (JMPR data)	Scenario 1A: 0.46	0.8 × HR muscle + 0.2 × HR fat (JMPR data)
Fat of swine, bovine, sheep, goat, equine, others	3	0.59	STMR (CXL)	1.9	HR (CXL)
Liver and kidney of swine, bovine, sheep, goat, equine, others	0.2	0.07	STMR (CXL)	0.165	HR (CXL)
Other edible offals of swine, bovine, sheep, goat, equine, others	3	Scenario 1A: 0.59	STMR (CXL)	Scenario 1A: 1.9	HR (CXL)
		Scenario 1B: 0.07	STMR (CXL)	Scenario 1B: 0.165	HR (CXL)
Milk of cattle, sheep, goat, horse, other	0.2	0.053	STMR (CXL)	0.053	STMR (CXL)
Other crops/commodities	See Reg. (EU) 2018/687	LOQ(b)			

STMR: median residue value; HR: highest residue; PeF: peeling factor; CXL: Codex maximum residue limit; LOQ: limit of quantification.
*: Indicates that the MRL is set at the limit of quantification.
(F): The active substance is fat soluble.
(a): Post-harvest treatment.
(b): A LOQ of 0.02 mg/kg was applied to herbs, and of 0.05 mg/kg to tea, coffee beans, cocoa beans, carobs, hops and spices. A default LOQ of 0.01 mg/kg for all other commodities was applied.