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Targeted review of maximum residue levels (MRLs) for fenpropathrin

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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 fenpropathrin 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.

Keywords: consumer risk assessment, toxicological evaluation, residue definitions, MRL setting, fenpropathrin, 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 fenpropathrin.

In accordance with the terms of reference, EFSA investigated the origin of the current EU MRLs for fenpropathrin, 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 fenpropathrin has been established as an import tolerance. EFSA also screened the appropriateness of the toxicological reference values (TRVs) derived by the Joint Meeting on Pesticide residues (JMPR) according to the current data requirements and standards.

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.

The metabolism of fenpropathrin in plant and animal was previously investigated by JMPR. According to the results of the metabolism studies assessed, the residue definition for enforcement and risk assessment, both for plant and animal products, is fenpropathrin. The residue is fat soluble.

Analytical methods are available for the enforcement of the proposed residue definition in high water content, high oil content and high acid content commodities, as well as in coffee with an LOQ of 0.01 mg/kg and in tea with an LOQ of 0.05 mg/kg. Fenpropathrin can be enforced in food of animal origin with an LOQ of 0.01 mg/kg in muscle, fat, milk and eggs. According to the EURLs, a QuEChERS multi-residue analytical method is available with an LOQ of 0.01 mg/kg for the routine analysis of fenpropathrin in high water content, high acid content, high oil content and dry commodities, as well as in commodities of animal origin (egg, muscle and liver). Based on the experience gained with these matrices, an LOQ of 0.01 mg/kg is deemed achievable also for animal fat and kidney.

The origin of all current MRLs set for fenpropathrin (based on formerly approved uses or on CXLs) was investigated, and it was concluded that none of the existing MRLs were sufficiently substantiated. No fall-back MRLs were identified for any of the crops under assessment (citrus fruits, strawberries, melon, tea).

A screening of the appropriateness of the TRVs set by the JMPR was performed, and the set of toxicological studies used to derive these TRVs was assessed according to the current data requirements and standards. It was concluded that the TRVs cannot be confirmed for fenpropathrin since 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 2012 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:

- submission of the available studies with a full evaluation of the toxicological data package and reporting relevant details on the studies and the results in accordance with the current guidelines, including an assessment of the reliability and relevance of each individual study and assessment of the validity of the analytical methods used in feed, body fluids and tissues, air and any additional matrices used in support of the toxicological studies;
- an interspecies comparative *in vitro* metabolism study on animal species used in pivotal studies and on human material;
- additional toxicological data to perform an ED assessment;
- an up-to-date search for published literature;

- an assessment of the toxicological relevance of impurities potentially present in the technical specification.

Chronic and acute exposure calculations were performed using revision 3.1 of PRIMo, considering all CXLs/MRLs no longer substantiated at the appropriate LOQ, as well as all other commodities for which no GAP was reported under this review. Comparing to the current TRVs, no exceedances were observed, and the highest chronic exposure represented 4% of the ADI (Dutch toddler) and the highest acute exposure amounted to 5% of the ARfD (potatoes). Nevertheless, EFSA emphasises that as the toxicological assessment revealed deficiencies regarding the toxicological studies available for fenpropathrin and considering that the 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.

It is concluded that none of the existing EU MRLs/CXLs listed in the table below are recommended for inclusion in Annex II to the Regulation.

Summary table

Code[(a)]	Commodity	Existing MRL[(b)] (mg/kg)	Outcome of the review	
			MRL proposal (mg/kg)	Comment
Residue definition for enforcement: fenpropathrin[(F)]				
0110000	Citrus fruits	2	0.01*	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.
0152000	Strawberries	2	0.01*	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.
0233010	Melons	1	0.01*	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.
0610000	Tea	2	0.05*	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.

MRL: maximum residue limit; LOQ: limit of quantification.
*: Indicates that the MRL is set at the limit of quantification.
(F): Fat soluble.
(a): Commodity code number according to Annex I of Regulation.
(b): MRL currently set under Regulation (EC) No 839/2008.

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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 ten 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 fenpropathrin.

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 fenpropathrin.

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 fenpropathrin. 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, 16.3.2005, 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 fenpropathrin, 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 1907/2006OJ L 353, 31.12.2008, p. 1.

Assessment

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

- In Section 1 (Regulatory background information on fenpropathrin), 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). Since no studies are available at EU level, EFSA summarises the available data from JMPR reports.
- 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 available from JMPR reports.
- In Section 2.3 (Existing MRLs), information on the origin of the current MRLs 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 by the 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 and 2 is performed as requested in ToR 5 (a) and (b). 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 by the JMPR, however, noting that EFSA proposes to withdraw the 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).

No draft assessment report (DAR) and no EFSA conclusion are available. Therefore, EFSA has based its assessment on the following documents:

- Scientific support for preparing an EU position in the 45th and 47th Sessions of the Codex Committee on Pesticide Residues (CCPR) (EFSA, 2013, 2015);
- the reports and evaluations of the JMPR (FAO, 1993, 2006, 2012, 2014);
- the reports of the Codex Committee on Pesticide residues (CCPR, 2007, 2015).

As requested by the terms of reference (ToR 2), Member States were invited to submit by 18 October 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, seven Member States (CZ, DE, ES, FR, IT, NL and SE) provided feedback regarding fenpropathrin 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 main supporting document to this reasoned opinion and, thus, made publicly available.

On the basis of the data submitted by the MSs, the EURLs, the data available in the Joint Meeting on Pesticide residues (JMPR) Evaluation reports and taking into account the screening of the available toxicological data with regards 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 April 2023. Comments received by 2 May 2023 were considered during the finalisation of this reasoned opinion (ToR 13).

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 fenpropathrin

The key events concerning the regulatory history of fenpropathrin, 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	Commission Regulation (EC) No 2076/2002 of 20 November 2002 extending the time period referred to in Article 8(2) of Council Directive 91/414/EEC and concerning the non-inclusion of certain active substances in Annex I to that Directive and the withdrawal of authorisations for plant protection products containing these substances.[(a)]
EFSA conclusion available	No	–
MRL review performed	No	–
EU MRL applications or other EU assessments	Yes, see comments	Implementation of EU MRLs: Existing MRLs above the LOQ were legally implemented in Regulation (EC) 839/2008[(b)] and have never been modified since. Implementation of certain CXL adopted by CAC, 2007: Following discussion in CCPR 39 (CCPR, 2007) (i.e. CXL for tea). This CXL value was included in Regulation (EC) 839/2008. MRL application (Art. 43): EFSA Scientific support for preparing an EU position in the 47th Session of the Codex Committee on Pesticide Residues (CCPR) (EFSA, 2015).[(c)]
Classification under CLP Regulation	See comments	Acute Tox 3*, H301 'toxic if swallowed'; Acute Tox 4*, H312 'harmful in contact with skin'; Acute Tox 2*, H330 'fatal if inhaled' (harmonised classification according to CLP00[(d)]) Accordingly, fenpropathrin does not fall under cut off criteria[(e)]
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[(f)]) has not been performed.

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.

*: Indicates a minimum classification that must be classified in a more severe hazard category in the event that further information is available which shows that the hazard(s) meet the criteria for classification in the more severe category (see Annex VI, section 1,2,1 of CLP Regulation).

(a): Commission Regulation (EC) No 2076/2002 of 20 November 2002 extending the time period referred to in Article 8(2) of Council Directive 91/414/EEC and concerning the non-inclusion of certain active substances in Annex I to that Directive and the withdrawal of authorisations for plant protection products containing these substances. OJ L 319, 23.11.2002, p. 3–11.

(b): Commission Regulation (EC) No 839/2008 of 31 July 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards Annexes II, III and IV on maximum residue levels of pesticides in or on certain products. OJ L 234, 30.8.2008, p. 1–216.

(c): EFSA (European Food Safety Authority), 2015. Scientific support for preparing an EU position in the 47th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2015;13(7):4208, 178 pp. https://doi.org/10.2903/j.efsa.2015

(d): Annex VI of 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, pp. 1–1355.

(e): Annex II of Regulation (EC) No 1107/2009 of the European Parliament and of the Council.

(f): 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.

2. Residue definitions and existing EU MRLs

2.1. Nature of residues and residue definitions

As requested in point 8 of the Terms of Reference, EFSA summarised in this section the information used to derive the residue definitions for plant and animal products. Table 2 covers the studies that were submitted to the JMPR in the framework of the setting of CXLs.

Table 2: Available metabolism studies

Primary crops	Crop groups	Crop(s)	Application(s)	Sampling (DAT)	Comment/Source
	Fruit crops	Apple	Foliar appl., 3 × 450 g a.s./ha	14	[cyclopropyl-1-^{14}C]- and [benzyl-^{14}C]-Fenpropathrin (FAO, 2014)
		Tomato	Indoor, foliar appl., 4 × 224 g a.s./ha	19	[cyclopropyl-1-^{14}C]- and [benzyl-^{14}C]-Fenpropathrin (FAO, 2014)
			Indoor, foliar appl., 4 × 224 g a.s./ha	3	[cyclopropyl-1-^{14}C]- and [phenoxyphenyl-^{14}C]-Fenpropathrin (FAO, 2014)
	Root crops	–	–	–	–
	Leafy crops	Cabbage	Indoor, direct appl. on leaves, equivalent to 90 g a.s./ha	0, 3, 7, 14, 21, 28, 35 and 42	[cyano-^{14}C]-, cyclopropyl-1-^{14}C]- and [phenoxyphenyl-^{14}C]-Fenpropathrin (FAO, 2014)
	Cereals/grass	–	–	–	–
	Pulses/ oilseeds	Bean	Indoor, foliar appl., 3 × 224 g a.s./ha	15	[cyclopropyl-1-^{14}C]- and [benzyl-^{14}C]-Fenpropathrin (FAO, 2014)
		Cotton	Indoor, direct appl. with a syringe, 4 appl. For a total rate of 4.7–4.8 mg ^{14}C-fenpropathrin	66, 111	cyclopropyl-1-^{14}C]- and [phenoxyphenyl-^{14}C]-Fenpropathrin (FAO, 2014)
			Outdoor, soil appl, 500 g a.s./ha	Not reported	cyclopropyl-1-^{14}C]- and [phenoxyphenyl-^{14}C]-Fenpropathrin (FAO, 2014)
			Outdoor, foliar appl., 4 × 336 g a.s./ha	21	cyclopropyl-1-^{14}C]- and [phenoxyphenyl-^{14}C]-Fenpropathrin (FAO, 2014)

Livestock	Animal	Dose	Duration (day)	Comment/Source
	Laying hen	0.5 or 5 mg/kg bw/ day	10	[cyclopropyl-1-^{14}C]- or [benzyl-^{14}C]-Fenpropathrin (FAO, 2014)
	Ruminant, lactating goat	50 ppm in the diet	5	cyclopropyl-1-^{14}C]- or [phenoxyphenyl-^{14}C]-Fenpropathrin (FAO, 2014)
	Ruminant, lactating cow	110 ppm in the diet	21	[benzyl-^{14}C]-Fenpropathrin (FAO, 1993)
	Pigs	–	–	Study not required[(a)]

a.s.: active substance; DAT: days after treatment; bw: body weight; ppm: party per million.

(a): The metabolism and residue levels in pig commodities were not discussed in the JMPR reports, but MRLs were recommended for all mammals other than marine mammals (FAO, 2014), thus it is assumed that the metabolism in rats and ruminants is similar.

Metabolism studies on apple, tomato, cabbage, bean and cotton were assessed by the JMPR (FAO, 2014). In all investigated crops, fenpropathrin is the main compound after treatment and produces a wide range of metabolites following cleavage of the molecule. Poor translocation through the plant and from the soil was observed. The identified metabolites, including common metabolites of other pyrethroid insecticides, were not considered of toxicological significance. The meeting concluded that the parent fenpropathrin was a suitable marker for plant commodities for both enforcement and

dietary risk assessment and the residue definition for monitoring and risk assessment in plant commodities was proposed as fenpropathrin. The residue definitions are applicable to all crop groups.

The nature of fenpropathrin residues in livestock was investigated and assessed by the JMPR (FAO, 1993, 2014). The metabolism studies on lactating goats and laying hens, indicate that fenpropathrin is the main residue in milk, fat, meat and eggs with low concentrations in liver and kidney where a wide range of metabolites were observed. Several of those are common metabolites to other pyrethroid insecticides. The meeting concluded that the parent fenpropathrin was a suitable marker for animal commodities for both enforcement and dietary risk assessment and the residue definition for monitoring and risk assessment in animal commodities was proposed as fenpropathrin.

Table 3 below summarises the residue definitions for enforcement and risk assessment derived by the JMPR (FAO, 2014). The EU residue definitions for enforcement are set in Regulation (EC) No 396/2005.

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	Fenpropathrin (default residue definition established in Annex IIIA of Regulation (EC) No 396/2005)	Fenpropathrin (FAO, 2014)
	Animal products	Fenpropathrin (default residue definition established in Annex IIIA of Regulation (EC) No 396/2005)	Fenpropathrin. The residue is fat soluble (FAO, 2014)
RD for risk assessment	Plant products	Not assessed at EU level	Fenpropathrin (FAO, 2014)
	Animal products	Not assessed at EU level	Fenpropathrin (FAO, 2014)

Comments: The default enforcement residue definitions set at EU level for plant and animal commodities are identical to the ones derived by JMPR.
In the framework of CCPR 2015, the EU delegation expressed some reservations due to the lack of data on the technical specifications of the active substance used by the JMPR to derive the residue definition.

2.2. Analytical methods for MRLs enforcement

Analytical methods for the determination of fenpropathrin residues were assessed in the framework of the JMPR evaluation (FAO, 2014).

Analytical methods are available to enforce residues of fenpropathrin in high acid content, high water content and high oil content commodities with an LOQ of 0.01 mg/kg. A method was reported to monitor fenpropathrin in tea with an LOQ of 0.05 mg/kg and in coffee with an LOQ of 0.01 mg/kg. Fenpropathrin can be enforced in food of animal origin with an LOQ of 0.01 mg/kg in milk, meat, fat and eggs (FAO, 2014).

During the data collection, the EURLs provided information on a QuEChERS multi-residue analytical method using GC–MS/MS technique, with an LOQ of 0.01 mg/kg for the routine analysis of fenpropathrin in high water, high acid, high oil and dry commodities. No data were provided regarding the possible enforcement of fenpropathrin in specific matrices, like tea (EURLs, 2022). According to the EURLs, in commodities of animal origin (egg, muscle and liver), fenpropathrin can be monitored with a default LOQ of 0.01 mg/kg. Based on the experience gained with these matrices, an LOQ of 0.01 mg/kg is deemed achievable also for animal fat and kidney. The EURLs also informed that the analytical standard for fenpropathrin (sum of isomers) is commercially available.

It is concluded that analytical methods are available for all commodities under assessment.

Table 4 provides an overview of the available analytical methods and their respective LOQs.

Table 4: Analytical methods available

Commodity group		Analytical method available	LOQ (mg/kg)	Source
Plant commodities	High water	Yes (QuEChERS method with GC–MS/MS)	0.01	EURLs (2022)
		Yes (DFG S19 method with GC–MS; GC-ECD)	0.01	FAO (2014)
	High oil	Yes (QuEChERS and QuOil methods with GC–MS/MS)	0.01	EURLs (2022)
		Yes (GC-ECD and LC–MS/MS)	0.01	FAO (2014)
	High acid	Yes (QuEChERS method with GC–MS/MS)	0.01	EURLs (2022)
		Yes (DFG S19 method with GC–MS, GC-ECD, GC-NPD)	0.01	FAO (2014)
	Dry	Yes (QuEChERS method with GC–MS/MS or LC–MS/MS)	0.01	EURLs (2022)
	Tea	Yes (GC-ECD)	0.05	FAO (2014)
	Coffee	Yes (LC–MS/MS)	0.01	FAO (2014)
Animal commodities	Muscle	Yes (QuEChERS method with GC–MS/MS)	0.01	EURLs (2022)
		Yes (DFG S19 method with GC–MS; GC-ECD)	0.01	FAO (2014)
	Kidney	Yes (QuEChERS method with GC–MS/MS)	0.01	EURLs (2022)
		Yes (GC-ECD)	0.01	FAO (2014)
	Liver	Yes (QuEChERS method with GC–MS/MS)	0.01	EURLs (2022)
		Yes (GC-ECD)	0.01	FAO (2014)
	Fat	Yes (QuEChERS method with GC–MS/MS)	0.01	EURLs (2022)
		Yes (DFG S19 method with GC–MS; GC-ECD)	0.01	FAO (2014)
	Milk	Yes (DFG S19 method with GC–MS; GC-ECD)	0.01	FAO (2014)
	Eggs	Yes (QuEChERS method with GC–MS/MS)	0.01	EURLs (2022)
		Yes (DFG S19 method with GC–MS; GC-ECD)	0.01	FAO (2014)

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; GC-NPD: gas chromatography with nitrogen-phosphorus detector; 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 fenpropathrin are established in Annex IIIA of Regulation (EC) No 396/2005. For a number of food products, the origin of these MRLs is unclear. One Codex Maximum Residue Limits (CXLs) may have been taken over in the EU legislation. It should be noted that in the framework of the current review, Member States and UK 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 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 not substantiated 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 ToR 3, 5 and 6, in cases where the current CXLs are not sufficiently substantiated, information on possible fall-back GAPs and the associated fall-back MRLs should be included in Table 5. In the last column of this table, additional considerations relevant for taking a risk management decision are also reported.

Table 5: Background information on current MRLs for fenpropathrin established at a level above the LOQ, and verification whether these values are sufficiently substantiated

Commodity	Existing MRL (mg/kg)	Source of existing MRL	cGAP for existing MRL	Existing MRL substantiated? (Y/N)	Fall-back GAP	Fall-back MRL (mg/kg)	Comment
Citrus fruits	2	See comments	See comments	N	No fall-back GAP identified	–	The existing EU MRL was legally implemented in Regulation (EC) 839/2008 and has never been modified. In 2014, JMPR derived a CXL of 2 mg/kg (FAO, 2014). This Codex MRL was adopted although the EU expressed a reservation in the CCPR47/CAC (CAC, 2015). Consequently, the CXL proposal has not been legally implemented. Existing MRL is not substantiated as no EU uses and no IT in place. Furthermore, the EU reservation expressed for the CXL proposal is still valid (CCPR, 2015).
Strawberries	2	See comments	See comments	N	No fall-back GAP identified	–	The existing EU MRL was legally implemented in Regulation (EC) 839/2008 and has never been modified. In 2014, JMPR derived a CXL of 2 mg/kg (FAO, 2014). This Codex MRL was adopted although the EU expressed a reservation in the CCPR47/CAC (CAC, 2015). Consequently, the CXL proposal has not been legally implemented. Existing MRL is not substantiated as no EU uses and no IT in place. Furthermore, the EU reservation expressed for the CXL proposal is still valid (CCPR, 2015).
Melons	1	See comments	No approved use or label	N	No fall-back GAP identified	–	The existing EU MRL was legally implemented in Regulation (EC) 839/2008 and has never been modified. The origin of this MRL is unclear. Existing MRL is not substantiated as no EU uses, no IT and no CXL in place.

Commodity	Existing MRL (mg/kg)	Source of existing MRL	cGAP for existing MRL	Existing MRL substantiated? (Y/N)	Fall-back GAP	Fall-back MRL (mg/kg)	Comment
Teas	2	See comments	See comments	N	No fall-back GAP identified	–	The existing EU MRL was legally implemented in Regulation (EC) 839/2008 and has never been modified. A Codex MRL proposal of 2 mg/kg was derived based on an Indian GAP (FAO, 2006) and adopted by CCPR39 /CAC in 2007. In 2015, a new Codex MRL proposal of 3 mg/kg was derived based on the same GAP (FAO, 2014). This Codex MRL was adopted although the EU expressed a reservation in CCPR47/CAC in 2015. Consequently, the CXL proposal has not been legally implemented. Existing MRL is not substantiated as no EU uses and no IT in place. Furthermore, the EU reservation expressed for the CXL proposal is still valid (CCPR, 2015).

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.

3. Toxicological reference values

EFSA was mandated to examine the available information to screen the quality of the toxicological reference values (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). EFSA assessed the appropriateness of these TRVs in the light of the currently available information and of the completeness of the underlying toxicological dataset according to the current standards.

The TRVs for fenpropathrin reported in Table 6 were derived by the JMPR in 2012, the active substance was never peer reviewed at the EU level. The JMPR values were used for a tentative assessment for the Codex MRL proposals (EFSA, 2013, 2015). EFSA noted then that no firm conclusion could be made on the appropriateness of the TRVs, in particular with regards to the unknown stereo-composition of the tested material assessed by the JMPR.

Table 6: Toxicological reference values (TRVs) set by the JMPR

TRV	Value	Reference	Comments
ADI	0.03 mg/kg bw per day	FAO (1993, 2012)	Based on the occurrence of tremors in the 90-day and 1-year toxicity studies in dogs and applying an UF of 100. This ADI is supported by a multigeneration reproductive toxicity study in rats (for body tremors, muscle twitches and mortality) and is further supported by the developmental toxicity studies in rats (for decreases in body weight gain and feed consumption).
ARfD	0.03 mg/kg bw	FAO (2012)	Based on a threshold dose established from a published study measuring motor activity at the time of peak effects following a single oral dose in rats and applying an UF of 100. This ARfD is supported by the developmental toxicity studies in rats (for decrease in maternal body weight gain and feed consumption during the first 2 days of treatment).

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

EFSA screened the completeness and the appropriateness of the toxicological data reported in the JMPR monograph (FAO, 2012) used to derive the TRVs, focusing on the question whether the information is sufficient to assess whether they meet current quality (i.e. reliability and reporting) standards and the EU data requirements.[9] The original studies are not available to EFSA.

The JMPR reports that most of the studies do not comply with good laboratory practice (GLP) as they were conducted before the implementation of GLP.

With regards to the toxicological data package needed to derive an ADI and ARfD, the following data gaps were identified according to the current data requirements:

- an assessment of the validity of the analytical methods used in feed, body fluids and tissues, air and any additional matrices used in support of the toxicological studies;
- toxicological relevance of impurities potentially present in the technical specification;
- an interspecies comparative *in vitro* metabolism study performed on animal species used in pivotal studies and on human material, to determine the relevance of the toxicological animal data to humans and whether additional testing of potential unique human metabolites would be required;
- an up-to-date search for published literature;
- the endocrine disruptive potential of fenpropathrin 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.

With regards to the JMPR report, it is noted that the JMPR evaluation in 2012 was not a complete re-evaluation, but an amendment of a previous one from 1993. In 2012, only a small number of new studies were reviewed and an ARfD established; the ADI, as derived in 1993 was then confirmed. The 1993 evaluation report is not considered a reliable source of information due to the lack of reporting of

[9] 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.

details on the methods and results of the toxicological studies, such as the presentation of the tabulated results, that does not allow an independent review; the same applies to the 2012 report. An assessment of the relevance and reliability of each study when compared to the current OECD test guidelines would also be needed. For instance, in the JMPR assessment a developmental neurotoxicity (DNT) study is reported. It is noted that the DNT study is critical for the risk assessment of fenpropathrin due to the neurotoxic mode of action of the active substance and substantiated by the effects triggering the ADI. DNT studies are complex to interpret and with the information reported in the JMPR it cannot be concluded a no observed adverse effect level/lowest observable adverse effect level (NOAEL/LOAEL) for the study with an acceptable uncertainty, also considering that lower mean absolute brain weight and length were noted in pups but dismissed and no clear incidence, severity and starting dose-related effect can be retrieved.

Considering the data gaps and uncertainties identified, it is concluded that the data available are insufficient to assess the strength of the toxicological reference values compared to current standards, and uncertainty factors could not be established. Accordingly, considering that the ADI and ARfD derived by the JMPR in 2012 do not comply with the current scientific standards, EFSA would recommend their withdrawal.

4. Consumer risk assessment

In order to address ToR 5, ToR 6 and ToR 11, EFSA calculated the chronic and acute dietary exposure, based on the residue definition for risk assessment derived by JMPR, i.e. fenpropathrin. 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.

The following scenario was calculated (Scenario 1):

- For commodities for which the CXLs/MRLs 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.

The risk assessment scenario as described in ToR 5 (b) (Scenario 2) is relevant for the assessment of fenpropathrin as all CXLs set in EU Regulation were implemented before and including 2009. However, as the CXLs are not substantiated, the scenario 2 would be identical to scenario 1.

The acute and chronic exposure calculations were compared to current EU TRVs (FAO, 2012), noting that EFSA concluded that these TRVs do not comply with the current scientific standards and 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 PRIMo calculations for scenario 1 are presented in Appendix B.

The highest chronic exposure was calculated for Dutch toddler, representing 4% of the ADI. The contribution of the MRLs set at the LOQ to the exposure represents 4% of the ADI. The highest acute exposure was calculated for potatoes, representing 5% of the ARfD.

The toxicological assessment revealed deficiencies regarding the toxicological studies available for fenpropathrin. Considering the high level of uncertainty affecting the TRVs derived by JMPR in 2012, EFSA did not confirm these TRVs, and the risk assessment cannot be finalised.

Conclusions and recommendations

The metabolism of fenpropathrin in plant and animal was previously investigated by the JMPR. According to the results of the metabolism studies assessed, the residue definition for enforcement and risk assessment, both for plant and animal products, is fenpropathrin. The residue is fat soluble.

Analytical methods are available for the enforcement of the proposed residue definition in high water content, high oil content and high acid content, as well as in coffee with an LOQ of 0.01 mg/kg and in tea with an LOQ of 0.05 mg/kg. Fenpropathrin can be enforced in food of animal origin with an LOQ of 0.01 mg/kg in muscle, fat, milk and eggs. According to the EURLs, a QuEChERS multi-residue analytical method is available with an LOQ of 0.01 mg/kg for the routine analysis of fenpropathrin in high water content, high acid content, high oil content and dry commodities, as well as in commodities of animal origin (egg, muscle and liver). Based on the experience gained with these matrices, an LOQ of 0.01 mg/kg is deemed achievable also for animal fat and kidney.

The origin of all current MRLs set for fenpropathrin (based on formerly approved uses or on CXLs) was investigated, and it was concluded that none of the existing MRLs were sufficiently substantiated. No fall-back MRLs were identified for any of the crops under assessment (citrus fruits, strawberries, melon, tea).

A screening of the appropriateness of the TRVs set by the JMPR was performed, and the set of toxicological studies used to derive these TRVs was assessed according to the current data requirements and standards. It was concluded that the TRVs cannot be confirmed for fenpropathrin since the data available were insufficient compared to current standards, and uncertainty factors could not be established. Accordingly, the ADI and ARfD derived in 2012 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:

- submission of the available studies with a full evaluation of the toxicological data package and reporting relevant details on the studies and the results in accordance with the current guidelines, including an assessment of the reliability and relevance of each individual study and assessment of the validity of the analytical methods used in feed, body fluids and tissues, air and any additional matrices used in support of the toxicological studies;
- an interspecies comparative *in vitro* metabolism study on animal species used in pivotal studies and on human material;
- additional toxicological data to perform an ED assessment;
- an up-to-date search for published literature;
- an assessment of the toxicological relevance of impurities potentially present in the technical specification.

Chronic and acute exposure calculations were performed using revision 3.1 of PRIMo, considering all CXLs/MRLs no longer substantiated at the appropriate LOQ, as well as all other commodities for which no GAP was reported under this review. Comparing to the current TRVs, no exceedances were observed, and the highest chronic exposure represented 4% of the ADI (Dutch toddler) and the highest acute exposure amounted to 5% of the ARfD (potatoes). Nevertheless, EFSA emphasises that as the toxicological assessment revealed deficiencies regarding the toxicological studies available for fenpropathrin and considering that the 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.

It is concluded that none of the existing EU MRLs/CXLs listed in the Table 7 are recommended for inclusion in Annex II to the Regulation.

Table 7: Summary table

Code[(a)]	Commodity	Existing MRL[(b)] (mg/kg)	Outcome of the review	
			MRL proposal (mg/kg)	Comment
Residue definition for enforcement: fenpropathrin[(F)]				
0110000	Citrus fruits	2	0.01*	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.
0152000	Strawberries	2	0.01*	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.
0233010	Melons	1	0.01*	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.
0610000	Tea	2	0.05*	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.

MRL: maximum residue limit; LOQ: limit of quantification.
*: 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 839/2008.

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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
CLP	classification, labelling and packaging
CXL	Codex maximum residue limit
DAT	days after treatment
DAR	draft assessment report (prepared under Council Directive 91/414/EEC)
DNT	developmental neurotoxicity
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
GC-NPD	gas chromatography with nitrogen-phosphorus detector
IT	import tolerance
LOAEL	lowest observable adverse effect level
LOQ	limit of quantification (determination)
MRL	maximum residue limit
MS	Member States
NOAEL	no observed adverse effect level
QuEChERS	Quick, Easy, Cheap, Effective, Rugged and Safe (analytical method)
RA	risk assessment
RD	residue definition
SCoPAFF	Standing Committee on Plants, Animals, Food and Feed
ToR	Terms of Reference
TRV	toxicological reference value
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 fenpropathrin.

Appendix B – Pesticide Residue Intake Model (PRIMo)

- PRIMo_EU_(Sc. 1 and Sc.2)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Fenpropathrin

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.03	ARfD (mg/kg bw):	0.03
Source of ADI:	JMPR	Source of ARfD:	JMPR
Year of evaluation:	2012	Year of evaluation:	2012

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	4%	NL toddler	1.24	2%	Milk: Cattle	0.4%	Apples	0.2%	Maize/corn	4%	
	2%	NL child	0.66	0.8%	Milk: Cattle	0.3%	Sugar beet roots	0.2%	Apples	2%	
	2%	DE child	0.63	0.7%	Milk: Cattle	0.4%	Apples	0.1%	Wheat	2%	
	2%	UK infant	0.61	1%	Milk: Cattle	0.1%	Potatoes	0.1%	Wheat	2%	
	2%	FR toddler 2 3 yr	0.56	1.0%	Milk: Cattle	0.1%	Apples	0.1%	Wheat	2%	
	2%	FR child 3 15 yr	0.55	0.8%	Milk: Cattle	0.2%	Wheat	0.1%	Sugar beet roots	2%	
	1%	UK toddler	0.45	0.7%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	1%	
	1%	DK child	0.41	0.4%	Milk: Cattle	0.2%	Rye	0.1%	Wheat	1%	
	1%	GEMS/Food G11	0.40	0.3%	Milk: Cattle	0.1%	Potatoes	0.1%	Soyabeans	1%	
	1%	GEMS/Food G06	0.38	0.2%	Wheat	0.1%	Tomatoes	0.1%	Milk: Cattle	1%	
	1%	RO general	0.38	0.4%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes	1%	
	1%	GEMS/Food G07	0.38	0.2%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	1%	
	1%	ES child	0.37	0.4%	Milk: Cattle	0.1%	Wheat	0.1%	Cocoa beans	1%	
	1%	SE general	0.37	0.4%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Potatoes	1%	
	1%	GEMS/Food G15	0.37	0.2%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes	1%	
	1%	GEMS/Food G08	0.37	0.2%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	1%	
	1%	GEMS/Food G10	0.36	0.2%	Milk: Cattle	0.1%	Wheat	0.1%	Soyabeans	1%	
	1%	DE women 14-50 yr	0.35	0.4%	Milk: Cattle	0.2%	Sugar beet roots	0.1%	Apples	1%	
	1%	DE general	0.34	0.4%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Apples	1%	
	1%	IE adult	0.33	0.1%	Milk: Cattle	0.1%	Sweet potatoes	0.1%	Wheat	1%	
	1.0%	FR infant	0.29	0.6%	Milk: Cattle	0.1%	Potatoes	0.1%	Apples	1.0%	
	1.0%	NL general	0.29	0.3%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Potatoes	1.0%	
	0.7%	PT general	0.21	0.2%	Potatoes	0.1%	Wheat	0.1%	Wine grapes	0.7%	
	0.7%	ES adult	0.21	0.2%	Milk: Cattle	0.1%	Wheat	0.0%	Oranges	0.7%	
	0.7%	FR adult	0.20	0.1%	Milk: Cattle	0.1%	Wine grapes	0.1%	Wheat	0.7%	
	0.6%	FI 3 yr	0.18	0.2%	Potatoes	0.0%	Bananas	0.0%	Wheat	0.6%	
	0.5%	IT toddler	0.16	0.2%	Wheat	0.1%	Other cereals	0.0%	Tomatoes	0.5%	
	0.5%	DK adult	0.16	0.2%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat	0.5%	
	0.5%	LT adult	0.16	0.1%	Milk: Cattle	0.1%	Potatoes	0.1%	Apples	0.5%	
	0.5%	UK vegetarian	0.15	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Potatoes	0.5%	
	0.5%	FI 6 yr	0.14	0.1%	Potatoes	0.0%	Cocoa beans	0.0%	Wheat	0.5%	
	0.5%	UK adult	0.14	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Potatoes	0.5%	
	0.4%	FI adult	0.13	0.2%	Coffee beans	0.0%	Potatoes	0.0%	Rye	0.4%	
	0.4%	IT adult	0.12	0.1%	Wheat	0.0%	Tomatoes	0.0%	Apples	0.4%	
	0.3%	PL general	0.10	0.1%	Potatoes	0.1%	Apples	0.0%	Tomatoes	0.3%	
	0.3%	IE child	0.08	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.3%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Fenpropathrin 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)
5%	Potatoes	0.01/0.01	1.5
5%	Melons	0.01/0.01	1.5
5%	Pears	0.01/0.01	1.4
4%	Oranges	0.01/0.01	1.3
4%	Milk: Cattle	0.01/0.01	1.2
4%	Watermelons	0.01/0.01	1.2
4%	Apples	0.01/0.01	1.1
3%	Pineapples	0.01/0.01	1.0
3%	Bananas	0.01/0.01	0.97
3%	Peaches	0.01/0.01	0.95
3%	Mangoes	0.01/0.01	0.79
3%	Grapefruits	0.01/0.01	0.79
2%	Table grapes	0.01/0.01	0.73
2%	Cucumbers	0.01/0.01	0.66
2%	Carrots	0.01/0.01	0.63

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)
1%	Head cabbages	0.01/0.01	0.42
1%	Watermelons	0.01/0.01	0.41
1%	Melons	0.01/0.01	0.39
1%	Milk: Cattle	0.01/0.01	0.39
1%	Swedes/rutabagas	0.01/0.01	0.34
1%	Table grapes	0.01/0.01	0.34
1%	Oranges	0.01/0.01	0.31
1%	Pears	0.01/0.01	0.31
1.0%	Potatoes	0.01/0.01	0.30
1.0%	Pineapples	0.01/0.01	0.30
0.9%	Yams	0.01/0.01	0.28
0.9%	Apples	0.01/0.01	0.28
0.9%	Cucumbers	0.01/0.01	0.28
0.9%	Aubergines/egg plants	0.01/0.01	0.27
0.9%	Mangoes	0.01/0.01	0.26

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)
4%	Sugar beets (root)/sugar	0.01/0.12	1.1
3%	Potatoes/fried	0.01/0.01	0.93
3%	Pumpkins/boiled	0.01/0.01	0.89
3%	Witloofs/boiled	0.01/0.01	0.89
3%	Broccoli/boiled	0.01/0.01	0.79
2%	Cauliflowers/boiled	0.01/0.01	0.70
2%	Escaroles/broad-leaved endiv	0.01/0.01	0.66
2%	Potatoes/dried (flakes)	0.01/0.05	0.59
2%	Leeks/boiled	0.01/0.01	0.57
2%	Apples/juice	0.01/0.01	0.54
2%	Oranges/juice	0.01/0.01	0.53
2%	Turnips/boiled	0.01/0.01	0.51
2%	Parsnips/boiled	0.01/0.01	0.51
2%	Sweet potatoes/boiled	0.01/0.01	0.50
2%	Florence fennels/boiled	0.01/0.01	0.45

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)
2%	Pumpkins/boiled	0.01/0.01	0.55
1%	Sugar beets (root)/sugar	0.01/0.12	0.44
1%	Cauliflowers/boiled	0.01/0.01	0.42
1%	Beetroots/boiled	0.01/0.01	0.39
1%	Celeries/boiled	0.01/0.01	0.34
1%	Apples/juice	0.01/0.01	0.33
0.8%	Broccoli/boiled	0.01/0.01	0.24
0.8%	Courgettes/boiled	0.01/0.01	0.23
0.7%	Parsnips/boiled	0.01/0.01	0.21
0.7%	Kohlrabies/boiled	0.01/0.01	0.21
0.7%	Wine grapes/juice	0.01/0.01	0.21
0.7%	Escaroles/broad-leaved	0.01/0.01	0.20
0.6%	Florence fennels/boiled	0.01/0.01	0.19
0.6%	Turnips/boiled	0.01/0.01	0.19
0.6%	Cassava roots/boiled	0.01/0.01	0.19

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Fenpropathrin is unlikely to present a public health risk.
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: Fenpropathrin(F)					
Citrus fruits	2	0.01*	LOQ	0.01*	LOQ
Strawberries	2	0.01*	LOQ	0.01*	LOQ
Melons	1	0.01*	LOQ	0.01*	LOQ
Teas	2	0.05*	LOQ	0.05*	LOQ
Other crops/ commodities	See Reg. (EC) 839/2008	LOQ(a)			

LOQ: limit of quantification.
*: Indicates that the MRL is set at the limit of quantification.
(F): the active substance is fat soluble.
(a): An LOQ of 0.02 mg/kg was applied to herbal infusions and of 0.05 mg/kg to cocoa beans, carobs, hops and spices. A default LOQ of 0.01 mg/kg for all other commodities was applied.