REASONED OPINION

EFSA Journal

APPROVED: 18 November 2016

doi: 10.2903/j.efsa.2017.4652

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

European Food Safety Authority (EFSA)

Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at the European level for the pesticide active substance lufenuron. To assess the occurrence of lufenuron residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission as well as the authorisations reported by the Member States (including the supporting residues data) and import tolerances. Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was missing. Hence, the consumer risk assessment is considered indicative only and some MRL proposals derived by EFSA still require further consideration by risk managers.

Keywords: lufenuron, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, benzoylurea, insecticide

Requestor: European Commission

Question number: EFSA-Q-2010-00191

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Acknowledgement: An editorial amendment was carried out to correct the footnotes to Table 1. This does not materially affect the contents or outcome of this scientific output. To avoid confusion, the older version has been removed from the EFSA Journal, but is available on request, as is a version showing all the changes made. EFSA wishes to thank the rapporteur Member State, Portugal, for the preparatory work on this reasoned opinion.

Suggested citation: EFSA (European Food Safety Authority), 2017. Reasoned opinion on the review of the existing maximum residue levels for lufenuron according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2017;15(1):4652, 41 pp. doi:10.2903/j.efsa.2017.4652

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

Summary

Lufenuron was included in Annex I to Directive 91/414/EEC on 1 January 2010 by Commission Directive 2009/77/EC, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. As the active substance was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation. To collect the relevant pesticide residues data, EFSA asked Portugal, designated as the rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report provided by the RMS were made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period, which was initiated by EFSA on 29 March 2016 and finalised on 29 May 2016. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 21 June 2016.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission and the additional information provided by the RMS and the Member States, EFSA prepared a draft reasoned opinion in August 2016, which was circulated to the Member States for consultation via a written procedure. Comments received by 16 September 2016 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The primary crop metabolism of lufenuron was investigated in three different crop categories. Lufenuron was the major compound in all studies and is therefore the only significant residue expected in plant commodities. The metabolic profile observed in the confined rotational crops studies was similar and hydrolysis studies demonstrated that processing by pasteurisation, baking/brewing/boiling and sterilisation is not expected to have a significant impact on the composition of residues. Therefore, the following general residue definition for monitoring and risk assessment is proposed: lufenuron (any ratio of constituent isomers). A validated analytical method for enforcement of the proposed residue definition in the four main analytical matrices is available.

The available residue trials were sufficient to derive (tentative) MRL proposals as well as risk assessment values for all commodities under evaluation, except for strawberries, gherkins, lettuces and other salad plants including *Brassicaceae* where the available data were insufficient.

In the confined rotational crop studies, the low residues which were observed in lettuce and carrots were deemed to be due to soil contamination. Due to the very high log K_{ow}, it was concluded that lufenuron can easily be adsorbed into the soil and not taken up by plants. It was therefore concluded that significant residues are not expected in the succeeding crops and rotational crop field trials were therefore not required.

Studies investigating the magnitude of residues in several processed commodities of grapes, tomatoes, apples and melons (peeled) are available. Robust processing factors were derived for apples (juice, dry pomace and sauce), wine grapes (juice and must), raisins and tomatoes (peeled and canned, sauce and juice) as well as for peeled melon. The other processing factors derived in this review are only indicative because the available data sets are limited.

Only the dietary burden calculated for cattle (all) was found to exceed the trigger value of 0.1 mg/kg dry matter (DM).

The metabolism of lufenuron was investigated in goats and laying hens and lufenuron was the only significant residue. Therefore, as for primary crops, lufenuron (any ratio of constituent isomers) is an appropriate residue definition for monitoring and risk assessment in commodities of animal origin. This residue definition is fat soluble. A validated analytical method for the determination of lufenuron and its isomers in muscle, fat, milk and eggs is available but a validation of this method on liver and kidney is still missing.

The feeding study performed on dairy cow was fully reliable to derive MRL and risk assessment values bovine products. According to the OECD guidance, these values also apply to equine products. In the absence of validated analytical method for liver and kidney, MRLs and risk assessment values derived for these tissues remain tentative. MRLs for sheep, swine and poultry products as well as for milk were not derived because the related groups of livestock are not expected to be exposed to significant levels of lufenuron residues.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). For cucurbits with inedible peel, the peeling factor derived on melons was taken into account. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing European Union (EU) MRL for an indicative calculation. The highest chronic exposure represented 9.0% of the acceptable daily intake (ADI) (DE child). Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance.

Apart from the MRLs evaluated in the framework of this review, internationally recommended codex maximum residue limits (CXLs) have also been established for lufenuron. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out and the highest chronic exposure represented 24.5% of the ADI (FR toddler).

The above risk assessments were performed disregarding the possible impact of the isomer ratios due to plant or livestock metabolism. Considering, however, that the isomer ratio of the lufenuron is an equimolar mixture of *R*- and *S*-enantiomer and that toxicological studies have been carried out according to these specifications, a change in isomer ratios in the residue might, in the worst-case situation, lead to a duplication of the toxicological burden of the residue. Since the exposure calculations represent less than 50% of the ADI, EFSA concludes that the potential change in isomer ratios in the final residue will not be of concern for the authorised uses reported in the framework of this review. In case future uses of lufenuron would lead to a higher consumer exposure, further information regarding the impact of plant and livestock metabolism on the isomer ratio might be required.

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Background

Regulation (EC) No 396/2005[1] (hereinafter referred to as 'the Regulation') establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at the European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC[2] a reasoned opinion on the review of the existing MRLs for lufenuron. As lufenuron was included in Annex I to Council Directive 91/414/EEC on 1 January 2010 by means of Commission Directive 2009/07/EC,[3] and has been deemed to be approved under Regulation (EC) No 1107/2009[4], in accordance with Commission Implementing Regulation (EU) No 540/2011[5], as amended by Commission Implementing Regulation (EU) No 541/2011[6], EFSA initiated the review of all existing MRLs for that active substance.

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

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

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

Portugal, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for lufenuron and to prepare a supporting evaluation report (Portugal, 2010). The PROFile and the supporting evaluation report were submitted to EFSA on 15 December 2010 and made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period which was initiated by EFSA on 29 March 2016 and finalised on 29 May 2016. Additional evaluation reports were submitted by the EU Reference Laboratories (EURLs), Portugal and Greece (EURLs, 2016; Greece, 2016; Portugal, 2016) and, after having considered all the information provided by the RMS and the Member States, EFSA prepared a completeness check report which was made available to all the Member States on 21 June 2016. Further clarifications were sought from the Member States via a written procedure in June–July 2016.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission (codex maximum residue limit; CXLs) and the additional information provided by the Member States, EFSA prepared a draft reasoned opinion in August 2016, which was submitted to the Member States for commenting via a written procedure. All

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

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

[3] Commission Directive 2009/77/EC of 1 July 2009 amending Council Directive 91/414/EEC to include chlorsulfuron, cyromazine, dimethachlor, etofenprox, lufenuron, penconazole, tri-allate and triflusulfuron as active substances. OJ L 172, 2.7.2009, p. 23–33.

[4] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

[5] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.

[6] Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187–188.

comments received by 16 September 2016 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation reports submitted by the RMS (Portugal 2010, 2016) and the evaluation reports submitted by the EURLs and Greece (EURLs, 2016; Greece, 2016) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

In addition, key supporting documents to this reasoned opinion are the completeness check report (EFSA, 2016a) and the Member States consultation report (EFSA, 2016b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Also, the chronic exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) and the PROFile are key supporting documents and made publicly available.

Considering the importance of the completeness check and consultation report, all documents are considered as background documents to this reasoned opinion and, thus, are made publicly available.

Terms of Reference

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

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

The active substance and its use pattern

Lufenuron is the ISO common name for (*RS*)-1-[2,5-dichloro-4-(1,1,2,3,3,3-hexafluoro-propoxy)-phenyl]-3-(2,6-difluorobenzoyl)-urea (IUPAC).

Lufenuron belongs to the group of benzoylurea compounds which are used as insecticides, to the class of chitin synthesis inhibitors. It acts mostly by ingestion; larvae are unable to moult, and also cease feeding. Lufenuron is used as a foliar application and bait stations for the control of fruit fly in a range of crops.

The chemical structure of the active substance and its main metabolite are reported in Appendix E.

Lufenuron was evaluated in the framework of Directive 91/414/EEC with Portugal designated as the rapporteur Member State (RMS). The representative uses supported for the peer review process were as an insecticide on grapes and tomatoes. Following the peer review, which was carried out by EFSA (EFSA, 2009), a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2009/77/EC, which entered into force on 1 January 2010. According to Regulation (EU) No 540/2011, lufenuron is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to indoor uses or use in outdoor bait stations as an insecticide only. After the Annex I inclusion, confirmatory data in the area of ecotoxicology addressing the gaps identified during the peer review were submitted in the framework of Directive 91/414/EEC. On 21 November 2011, the Standing Committee on the Food Chain and Animal Health agreed that the conclusions of the original risk assessment were not substantially modified by the submitted confirmatory data (European Commission, 2011). No further review by EFSA was considered necessary.

The EU MRLs for lufenuron are established in Annex IIIA of Regulation (EC) No 396/2005 and CXLs for active substance are also established by the Codex Alimentarius Commission (CAC). It is also noted that an MRL on fin fish resulting from the use of lufenuron as a veterinary medicine is laid down in Regulation (EU) No 967/2014[7]. For the purpose of this MRL review, the critical uses of lufenuron currently authorised within the EU, as well as uses authorised in third countries that might have a significant impact on international trade, have been collected by the RMS and reported in the PROFile. The additional good agricultural practices (GAPs) reported by the Member States during the completeness check were also considered. The details of the authorised GAPs for lufenuron are given in Appendix A.

[7] Commission implementing Regulation (EU) No 967/2014 of 12 September 2014 amending Regulation (EU) No 37/2010, as regards the substance 'lufenuron. OJ L 272, 13.9.2014, p. 3–5.

Assessment

EFSA has based its assessment on the PROFile submitted by the RMS, the evaluation report accompanying the PROFile (Portugal, 2010), the draft assessment report (DAR) prepared under Council Directive 91/414/EEC (Portugal, 2006), the conclusion on the peer review of the pesticide risk assessment of the active substance lufenuron (EFSA, 2009), the Joint Meeting on Pesticide residues (JMPR) Evaluation report (FAO, 2015), as well as the evaluation reports submitted during the completeness check (EURLs, 2016; Greece, 2016; Portugal, 2016). The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011[8] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b, 2011 and OECD, 2011, 2013).

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

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of lufenuron was investigated in representatives of three different crop categories: fruit crops, leafy crops, and pulses and oilseeds (Portugal, 2006). Lufenuron was the major compound in all studies, which indicate that significant degradation does not occur in plant. Only one minor metabolite CGA 238277[9] was identified in head cabbage (0.6% total radioactive residue (TRR) – 0.012 mg eq/kg), cabbage wrapper leaves (3.3% TRR – 0.023 mg eq/kg) and tomatoes (0.2–2% TRR; ≤ 0.002 mg/kg). It was noted that the foliar metabolism study performed on tomatoes was underdosed compared to some of the critical GAPs (cGAPs) reported for indoor conditions (only 30% of the critical authorised application rate). However, in spite of this low dosing, the metabolic picture was clearly elucidated. Lufenuron is a stable and persistent compound and it is the only significant residue found in plant commodities.

1.1.2. Nature of residues in rotational crops

According to the soil degradation studies evaluated in the framework of the peer review, period required for 90% dissipation (DT_{90}) values of lufenuron range between 503 and 1,444 days, which is higher than the trigger value of 100 days (EFSA, 2009). Therefore, further investigation of residues in rotational crops was required.

Two confined rotational crops studies were reported during the peer review of lufenuron (Portugal, 2006). In the first study performed with the application rate of 150 g a.s./ha, the only significant residue identified was lufenuron. This is consistent with the fact that lufenuron is known as an environmentally persistent compound. In the second study performed with the application rate of 130 g a.s./ha, TRR was too low for identification (< 0.005 mg eq/kg) in all investigated crops, at any investigated plant back intervals (PBI) (76, 126, 306 and 331 days after treatment (DAT)).

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of residues was investigated in the framework of the peer review (Portugal, 2006). Studies were conducted with lufenuron, simulating representative hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6). From these studies, it was concluded that processing by pasteurisation, baking/brewing/boiling and sterilisation is not expected to have a significant impact on the composition of residues in matrices of plant origin.

[8] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

[9] CGA 238277: [2,5-dichloro-4-(1,1,2,3,3,3-hexafluoro-propoxy)-phenyl]-urea; see Appendix E.

1.1.4. Methods of analysis in plants

During the peer review, a multiresidue analytical method using high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) and its independent laboratory validation (ILV) were validated for the determination of lufenuron and its isomers in high water, high acid content and dry commodities, with an limit of quantification (LOQ) of 0.02 mg/kg (EFSA, 2009). Furthermore, the EURLs also reported validation data for Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) and QuOil methods using HPLC–MS/MS. These methods are applicable for the determination of lufenuron in the four main plant matrices, with an LOQ of 0.01 mg/kg (EURLs, 2016).

Hence, it is concluded that lufenuron and its isomers can be enforced with an LOQ of 0.01 mg/kg in high water content, high acid content, high oil content and dry commodities.

1.1.5. Stability of residues in plants

In the framework of the peer review, storage stability of lufenuron was demonstrated for a period of 24 months at −18°C in commodities with high water, high acid and high oil content (EFSA, 2009).

1.1.6. Proposed residue definitions

Lufenuron is a stable and persistent compound and it is the only significant residue that was observed in the metabolism studies. Therefore, a general residue definition for monitoring and risk assessment including any constituent isomers of lufenuron only was agreed during the peer review (EFSA, 2009). In line with the other actives substances which contain isomers, EFSA proposes to slightly modify the wording of the residue definition for lufenuron (any ratio of constituent isomers).

Lufenuron is not degraded through the plant metabolism. However, during the peer review, it was already emphasised that the above studies do not investigate the possible impact of plant metabolism on the isomer ratio of lufenuron. In addition, it was highlighted that light energy can cause photolytic conversion of one isomer to another. Therefore, further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of lufenuron residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Portugal, 2010), including residue trials evaluated in the framework of the peer review (EFSA, 2009). During the completeness check, the RMS confirmed that almost all residue trial samples considered in this framework were stored in compliance with the demonstrated storage conditions (EFSA, 2016a). Storage conditions for the residue performed on peaches were not reported but, considering that storage stability in high water content and high acid content commodities was demonstrated for 24 months, decline of residues during storage of the trial samples is not expected.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2016).

In line with the European restrictions for lufenuron, outdoor uses of lufenuron are exclusively limited to targeted application as bait stations. The outdoor GAPs reported in this review are compliant with this restriction. Significant residues in plants resulting from this kind of use are not expected. Therefore, for all crops where only the use in bait stations is authorised, MRL and risk assessment values can be set at the enforcement LOQ (0.01* mg/kg) and further residue trials are not required. For the other crops, the following considerations were made by EFSA.

For strawberries, gherkins as well as for lettuces and other salad plants, MRL or risk assessment values could not be derived and the following data gaps were identified:

- Strawberries: only two trials compliant with the indoor GAP are available. Since strawberry is a major crop in Europe, six additional trials compliant with the indoor GAP are required.
- Gherkins: trials compliant with GAP are not available. The extrapolation from the trials performed on cucumbers is not possible because GAPs are different. Trials on cucumbers were performed with two applications while the cGAP on gherkins is authorised for three

applications. Considering that lufenuron is very persistent and that preharvest interval (PHI) for these GAPs is very short and equivalent to the minimum interval between applications (7 days), it is not considered acceptable to use trials performed with two applications to support a GAP with three applications. Therefore, four trials on cucumbers, gherkins or courgettes, and compliant with the indoor GAP for gherkins are required.
- Lettuces: trials compliant with GAP are not available. Therefore, eight trials on lettuces (open leaf varieties), and compliant with the indoor GAP for lettuces, are required.
- Other salads plants including *Brassicaceae* (lamb's lettuce, escaroles, cresses, land cresses, roman rocket, red mustards and baby leaf crops): trials compliant with GAP are not available. Therefore, eight trials on lettuces (open leaf varieties), and compliant with the indoor GAP for other salad plants including *Brassicaceae*, are required.

For peaches, apricots, potatoes, tomatoes and cucumbers, available residue trials are sufficient to derive (tentative) MRL and risk assessment values, taking note of the following data gap and considerations:

- Peaches and apricots: Nine trials performed on peaches and compliant with GAP are available but data on apricots are not available. According to the current guidance document for extrapolations, a minimum of four trials performed on apricots are required to derive a common MRL on peaches and apricots. In the absence of these data, MRLs and risk assessment values for peaches and apricots are tentative.
- Potatoes: only three trials compliant with GAP are available. However, these trials show residue levels below the LOQ of 0.02 mg/kg. In addition, four overdosed trials (performed with two applications instead of one) also show results below LOQ (0.01 mg/kg). Therefore, a no residues situation is expected in potatoes and further residue trials are not required.
- Tomatoes: the number of residue trials supporting the import tolerance on tomatoes is not compliant with the data requirements (four trials instead of eight). However, the available data clearly confirm that this GAP (3 × 30 g a.s./ha; PHI 7 days) is less critical than the indoor GAP reported in Europe (3 × 100 g a.s./ha; PHI 7 days). Therefore, the available limited data set is considered acceptable in this case. Further residue trials are therefore not required.
- Cucumbers: although appropriate MRL and risk assessment values can be derived from the indoor GAP reported by Hungary and Portugal (2 × 113 g a.s./ha; PHI 7 days), a more cGAP reported by Greece (with three applications) is not supported by data. Therefore, eight trials compliant with the indoor GAP reported by Greece are still required. It is noted that these trials would also allow to derive MRL and risk assessment values for gherkins, for which the same GAP is authorised.

1.2.2. Magnitude of residues in rotational crops

In the confined rotational crop studies evaluated during the peer review (see also Section 1.1.2), the total radioactivity was generally < 0.01 mg eq/kg with the exception of lettuce (0.047 mg eq/kg) and carrots (0.023 mg eq/kg) in the study performed with 150 g a.s./ha. However, lufenuron was quantified in very low amounts in lettuce (0.025 mg/kg) and was not found in carrots.

It is highlighted that lufenuron is a very persistent compound that can accumulate in soil for up to 6 years and that the confined metabolism studies were performed with lower application rate (1 × 130 or 1 × 150 g a.s./ha) compared to the most cGAPs reported for indoor uses (3 × 100 g a.s./ha). This was already discussed during the peer review and the meeting of expert also considered that, due to the very high log K_{ow}, lufenuron is most probably adsorbed into the soil rather than taken up by plants. It was therefore concluded that the positive residues observed in lettuce and carrots may be due to soil contamination and that significant residues are not expected in the succeeding crops (EFSA, 2009). Rotational crop field trials are therefore not required.

1.2.3. Magnitude of residues in processed commodities

Studies investigating the magnitude of residues in raisins, wine and several processed commodities of tomatoes were reported in the framework of the peer review (Portugal, 2006). In addition, further processing studies performed on wine grape (juice and must), apples, as well as peeling factors for melons were reported in the framework of this MRL review (Portugal, 2010). An overview of all available processing studies is available in Appendix B.1.2.3. Robust processing factors were derived for apples (juice, dry pomace and sauce), wine grapes (juice and must), raisins and tomatoes

(peeled and canned, sauce and juice) as well as for peeled melon. The other processing factors derived in this review are only indicative because the available datasets are limited.

Further processing studies are not required as they are not expected to affect the outcome of the risk assessment. However, if more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

1.2.4. Proposed MRLs

Consequently, the available data are considered sufficient to derive (tentative) MRL proposals as well as risk assessment values for all commodities under evaluation, except for strawberries, gherkins, lettuces and other salad plants including *Brassicaceae* where the available data were insufficient.

2. Residues in livestock

Lufenuron is authorised for use on citrus fruits, apples and potatoes that might be fed to livestock. Livestock dietary burdens were therefore calculated for different groups of livestock according to the OECD guidance (OECD, 2013), which has now also been agreed upon at the European level. The input values for all relevant commodities are summarised in Appendix C. Only the dietary burden calculated for cattle (all) was found to exceed the trigger value of 0.1 mg/kg dry matter (DM). Behaviour of residues was therefore assessed in this group of livestock.

2.1. Nature of residues and methods of analysis in livestock

The metabolism of lufenuron was investigated in goats and laying hens (Portugal, 2006). As expected for such a stable compound, lufenuron was the only significant residue that was observed in the metabolism studies. Therefore, lufenuron is the appropriate residue definition for monitoring and risk assessment in commodities of animal origin. This is in line with the conclusion of the peer review where a residue definition for monitoring and risk assessment including any constituent isomers of lufenuron only was already proposed (EFSA, 2009). As for plant commodities, EFSA proposes to slightly modify the wording of the residue definition for lufenuron (any ratio of constituent isomers). This residue definition is fat soluble.

During the peer review, it was already emphasised that the above studies do not investigate the possible impact of the livestock metabolism on the isomer ratio of lufenuron. Further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

A multiresidue analytical method using HPLC–MS/MS was validated for the determination of lufenuron and its isomers with an LOQ of 0.02 mg/kg in muscle, fat, milk and eggs. This method is supported by an ILV and a confirmatory method was evaluated and found acceptable (EFSA, 2009). However, a validation of this method on liver and kidney was not performed and is missing.

Storage stability of lufenuron and its isomers was demonstrated for a period of 9 months at −18°C in muscle, fat, liver, kidney and milk (EFSA, 2009).

2.2. Magnitude of residues in livestock

Two feeding studies performed on ruminants (dairy cow and beef cattle) were evaluated by the RMS in the DAR (Portugal, 2006). In the study performed on dairy cow, three dose levels were tested (0.039, 0.23 and 0.42 mg lufenuron/kg body weight (bw) per day). The tested levels all cover the calculated dietary burdens for cattle. On the opposite, the feeding levels used in the beef cattle study are too low (0.0006 and 0.031 mg/kg bw per day). Therefore, the results of the dairy cow study were considered more reliable to derive MRL and risk assessment values. During the completeness check, the RMS confirmed that most of the samples were stored in compliance with the demonstrated storage conditions of 9 months (EFSA, 2016a). A few samples were stored for a maximum of 12 months but it is deemed acceptable in this case considering the small deviation and the fact that lufenuron is a very stable compound. A decline of residues during storage of the samples is therefore not expected. MRLs and risk assessment values for bovine products were derived according to the OECD guidance on this matter which was agreed upon at the European level (OECD, 2013). The overview of the study results used to derive the risk assessment values and the MRL proposals are summarised in Appendix B.2.2. According to the OECD guidance, MRLs and risk assessment values derived for bovine also apply to

equine products. It is noted that in the absence of validated analytical method for liver and kidney, MRLs and risk assessment values derived for these tissues should only remain tentative.

MRLs for sheep, swine and poultry products as well as for milk are not required because the related groups of livestock are not expected to be exposed to significant levels of lufenuron residues.

3. Consumer risk assessment

In the framework of this review, only the uses of lufenuron reported in Appendix A were considered; however, the use of lufenuron was previously also assessed by the JMPR (FAO, 2015). The CXLs, resulting from this assessment by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. To facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs.

3.1. Consumer risk assessment without consideration of the existing CXLs

Chronic exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA PRIMo (EFSA, 2007). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix D. Hence, for those commodities where an MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). For all commodities of plant origin, input values refer to the raw agricultural commodities, except for cucurbits with inedible peel, where the peeling factor is taken into account. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. All input values included in the exposure calculations are summarised in Appendix C. Acute exposure calculations were not carried out because an acute reference dose (ArfD) was not deemed necessary for this active substance.

The exposures calculated were compared with the toxicological reference value for lufenuron, derived by EFSA (2009) under Directive 91/414/EEC. The highest chronic exposure was calculated for German children, representing 9.0% of the acceptable daily intake (ADI). Although uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumers.

3.2. Consumer risk assessment with consideration of the existing CXLs

To include the CXLs in the calculations of the consumer exposure, CXLs were compared with the EU MRL proposals in compliance with Appendix D and all data relevant to the consumer exposure assessment have been collected from JMPR evaluations. It is noted that the data gap identified for a validated analytical method for enforcement in liver and kidney also applies to the existing CXLs on these tissues. In addition, since the LOQ for enforcement in livestock commodities is 0.02 mg/kg, the CXL of 0.01 mg/kg on poultry tissues needs to be reconsidered up to the current LOQ of 0.02* mg/kg. This value was also used for risk assessment for those commodities where CXLs was set at the LOQ (poultry meat, liver and eggs). An overview of the input values used for this exposure calculation is also provided in Appendix C.

Chronic exposure calculations were also performed using revision 2 of the EFSA PRIMo and the exposures calculated were compared with the toxicological reference value derived for lufenuron. The highest chronic exposure was calculated for French toddlers, representing 24.5% of the ADI. Based on these calculations, EFSA concludes that the CXLs are not expected to be of concern for European consumers.

3.3. Additional considerations on the consumer risk assessment

It is noted that the above risk assessments are only relevant for lufenuron residues related to the pesticide use. However, lufenuron may also be used as a veterinary medicine on fin fish. To accommodate this use, an MRL of 1.35 mg/kg for fin fish was implemented for lufenuron (*RS*-isomers) in Regulation (EU) 967/2014. Rational for this MRL setting was reported in the European public MRL assessment report of EMA (2015). In this report, the chronic exposure calculation was performed considering a daily portion of 5 g fish/kg bw per day (300 g fish/person per day). However, the highest daily consumption considered in the EFSA PRIMo is 1.2 g/kg bw per day (WHO Cluster diet B).

This value is also consistent with the consumption data considered in a recent opinion prepared by EFSA as regards recommendations on the fish consumption with view to exposure to mercury (EFSA Scientific Committee, 2015). Based on this consumption data, and considering the veterinary MRL of 1.35 mg/kg (conservative approach with regard to chronic intake calculations), the contribution of the veterinary use of lufenuron to the chronic exposure would be of 10% of the ADI. Therefore, EFSA estimates that the chronic exposure to lufenuron resulting from both pesticide (24.5% ADI) and veterinary uses (10% ADI) is likely to be lower than 35% of the ADI.

It is highlighted that the possible impact of the isomer ratios due to plant or livestock metabolism was not assessed by EFSA. Similarly, EMA assessed lufenuron (RS-isomers) and did also assume that the isomers ratio remained unchanged in fish. Considering, however, that the isomer ratio of the lufenuron is an equimolar mixture of *R*- and S-enantiomer and that toxicological studies have been carried out according to these specifications (EFSA, 2009), a change in isomer ratios in the residue might, in the worst-case situation, lead to a duplication of the toxicological burden of the residue. Since the above exposure calculations represent in any case less than 50% of the ADI, EFSA concludes that the potential change in isomer ratios in the final residue will not be of concern for the authorised uses reported in the framework of this review. In case future uses of lufenuron would lead to a higher consumer exposure, further information regarding the impact of plant and livestock metabolism on the isomer ratio might be required.

Conclusions

The primary crop metabolism of lufenuron was investigated in three different crop categories. Lufenuron was the major compound in all studies and is therefore the only significant residue expected in plant commodities. The metabolic profile observed in the confined rotational crops studies was similar and hydrolysis studies demonstrated that processing by pasteurisation, baking/brewing/boiling and sterilisation is not expected to have a significant impact on the composition of residues. Therefore, the following general residue definition for monitoring and risk assessment is proposed: lufenuron (any ratio of constituent isomers). A validated analytical method for enforcement of the proposed residue definition in the four main analytical matrices is available.

The available residue trials were sufficient to derive (tentative) MRL proposals as well as risk assessment values for all commodities under evaluation, except for strawberries, gherkins, lettuces and other salad plants including *Brassicaceae* where the available data were insufficient.

In the confined rotational crop studies, the low residues which were observed in lettuce and carrots were deemed to be due to soil contamination. Due to the very high log K_{ow}, it was concluded that lufenuron can easily be adsorbed into the soil and not taken up by plants. It was therefore concluded that significant residues are not expected in the succeeding crops and rotational crop field trials were therefore not required.

Studies investigating the magnitude of residues in several processed commodities of grapes, tomatoes, apples and melons (peeled) are available. Robust processing factors were derived for apples (juice, dry pomace and sauce), wine grapes (juice and must), raisins and tomatoes (peeled and canned, sauce and juice) as well as for peeled melon. The other processing factors derived in this review are only indicative because the available datasets are limited.

Only the dietary burden calculated for cattle (all) was found to exceed the trigger value of 0.1 mg/kg DM.

The metabolism of lufenuron was investigated in goats and laying hens and lufenuron was the only significant residue. Therefore, as for primary crops, lufenuron (any ratio of constituent isomers) is an appropriate residue definition for monitoring and risk assessment in commodities of animal origin. This residue definition is fat soluble. A validated analytical method for the determination of lufenuron and its isomers in muscle, fat, milk and eggs is available but a validation of this method on liver and kidney is still missing.

The feeding study performed on dairy cow was fully reliable to derive MRL and risk assessment values bovine products. According to the OECD guidance, these values also apply to equine products. In the absence of validated analytical method for liver and kidney, MRLs and risk assessment values derived for these tissues remain tentative. MRLs for sheep, swine and poultry products as well as for milk were not derived because the related groups of livestock are not expected to be exposed to significant levels of lufenuron residues.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For cucurbits with inedible peel, the peeling

factor derived on melons was taken into account. For those commoditieswhere data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure represented 9.0% of the ADI (DE child). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for lufenuron. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out and the highest chronic exposure represented 24.5% of the ADI (FR toddler). The chronic exposure also taking into account the veterinary use of lufenuron was also estimated. It was concluded that the chronic exposure to lufenuron resulting from both pesticide (24.5% ADI) and veterinary uses (10% ADI) was lower than 35 % of the ADI.

The above risk assessments were performed disregarding the possible impact of the isomer ratios due to plant or livestock metabolism. Considering, however, that the isomer ratio of the lufenuron is an equimolar mixture of *R*- and *S*-enantiomer and that toxicological studies have been carried out according to these specifications, a change in isomer ratios in the residue might, in the worst-case situation, lead to a duplication of the toxicological burden of the residue. Since the exposure calculations represent less than 50% of the ADI, EFSA concludes that the potential change in isomer ratios in the final residue will not be of concern for the authorised uses reported in the framework of this review. In case future uses of lufenuron would lead to a higher consumer exposure, further information regarding the impact of plant and livestock metabolism on the isomer ratio might be required.

Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix D of the reasoned opinion (see summary table). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see summary table footnotes for details). In particular, some tentative MRLs and existing EU MRLs need to be confirmed by the following data:

- a validated analytical method for enforcement of lufenuron in liver and kidney tissues;
- additional residue trials supporting the indoor GAPs on apricots, peaches, strawberries, gherkins, lettuces, other salads plants including *Brassicaceae* (lamb's lettuce, escaroles, cresses, land cresses, roman rocket, red mustards, baby leaf crops).

It is highlighted that the MRL derived for cucumbers results from an indoor GAP supported by data, whereas more critical indoor GAP reported by Greece was not supported by data. EFSA therefore identified the following data gap which is not expected to impact on the validity of the MRL derived but which might have an impact on national authorisations:

- eight residue trials supporting the indoor GAP on cucumbers reported by Greece (3 × 100 g a.s./ha; PHI 7 days);

If the above reported data gaps are not addressed in the future, the Member States are recommended to withdraw or modify the relevant authorisations at national level (Table 1).

Table 1: Summary table

Code number[(1)]	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition (existing): lufenuron[(F)] **Enforcement residue definition (proposed):** lufenuron (any ratio of constituent isomers)[(F)]					
110020	Oranges	1	–	0.01*	Recommended[(a)]
110030	Lemons	1	–	0.01*	Recommended[(a)]
110040	Limes	1	–	0.01*	Recommended[(a)]
110050	Mandarins	1	–	0.01*	Recommended[(a)]
130010	Apples	0.5	–	0.15	Recommended[(a)]
130020	Pears	0.5	–	0.15	Recommended[(a)]
130030	Quinces	0.2	–	0.15	Recommended[(a)]

Code number(1)	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
130040	Medlar	0.2	–	0.15	Recommended(a)
130050	Loquats/Japanese medlars	0.2	–	0.15	Recommended(a)
140010	Apricots	1	–	0.2	Further consideration needed(b)
140020	Cherries (sweet)	1	–	0.01*	Recommended(a)
140030	Peaches	1	–	0.2	Further consideration needed(b)
140040	Plums	1	–	0.01*	Recommended(a)
151010	Table grapes	1	–	0.01*	Recommended(a)
151020	Wine grapes	1	–	0.01*	Recommended(a)
152000	Strawberries	1	–	1	Further consideration needed(c)
161020	Figs	0.02*	–	0.01*	Recommended(a)
161060	Kaki/Japanese persimmons	0.02*	–	0.01*	Recommended(a)
162010	Kiwi fruits	0.02*	–	0.01*	Recommended(a)
211000	Potatoes	0.05	0.01*	0.01*	Recommended(e)
231010	Tomatoes	0.5	0.4	0.4	Recommended(h)
231020	Sweet peppers/bell peppers	1	0.8	0.8	Recommended(h)
231030	Aubergines/eggplants	0.2	–	0.3	Recommended(a)
232010	Cucumbers	0.2	0.09	0.15	Recommended(e)
232020	Gherkins	0.2	–	0.2	Further consideration needed(c)
232030	Courgettes	0.2	–	0.15	Recommended(a)
233010	Melons	0.3	0.4	0.4	Recommended(e)
233020	Pumpkins	0.2	–	0.4	Recommended(a)
233030	Watermelons	0.3	–	0.4	Recommended(a)
251010	Lamb's lettuces/corn salads	0.02*	–	0.02	Further consideration needed(c)
251020	Lettuces	0.5	–	0.5	Further consideration needed(c)
251030	Escaroles/broad-leaved endives	0.02*	–	0.02	Further consideration needed(c)
251040	Cresses and other sprouts and shoots	0.02*	–	0.02	Further consideration needed(c)
251050	Land cresses	0.02*	–	0.02	Further consideration needed(c)
251060	Roman rocket/rucola	0.02*	–	0.02	Further consideration needed(c)
251070	Red mustards	0.02*	–	0.02	Further consideration needed(c)
251080	Baby leaf crops (including *Brassica* species)	0.02*	–	0.02	Further consideration needed(c)
401070	Soya bean	0.02*	0.01*	0.01*	Recommended(i)
1011010	Swine muscle	0.02*	0.03	0.03	Recommended(i)
1011020	Swine fat tissue	0.02*	0.7	0.7	Recommended(i)
1011030	Swine liver	0.02*	0.04	0.04	Further consideration needed(g)
1011040	Swine kidney	0.02*	0.04	0.04	Further consideration needed(g)
1012010	Bovine muscle	0.02*	0.03	0.03	Recommended(h)
1012020	Bovine fat tissue	0.02*	0.7	0.7	Recommended(h)
1012030	Bovine liver	0.02*	0.04	0.04	Further consideration needed(f)
1012040	Bovine kidney	0.02*	0.04	0.04	Further consideration needed(f)
1013010	Sheep muscle	0.02*	0.03	0.03	Recommended(i)
1013020	Sheep fat tissue	0.02*	0.7	0.7	Recommended(i)
1013030	Sheep liver	0.02*	0.04	0.04	Further consideration needed(g)
1013040	Sheep kidney	0.02*	0.04	0.04	Further consideration needed(g)
1014010	Goat muscle	0.02*	0.03	0.03	Recommended(i)

Code number(1)	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
1014020	Goat fat tissue	0.02*	0.7	0.7	Recommended(i)
1014030	Goat liver	0.02*	0.04	0.04	Further consideration needed(g)
1014040	Goat kidney	0.02*	0.04	0.04	Further consideration needed(g)
1015010	Equine muscle	0.02*	0.03	0.03	Recommended(h)
1015020	Equine fat tissue	0.02*	0.7	0.7	Recommended(h)
1015030	Equine liver	0.02*	0.04	0.04	Further consideration needed(f)
1015040	Equine kidney	0.02*	0.04	0.04	Further consideration needed(f)
1016010	Poultry muscle	0.02*	0.01*	0.02*	Recommended(i)
1016020	Poultry fat tissue	0.02*	0.04	0.04	Recommended(i)
1016030	Poultry liver	0.02*	0.02	0.02*	Further consideration needed(g)
1020010	Cattle milk	0.02*	0.1	0.1	Recommended(i)
1020020	Sheep milk	0.02*	0.1	0.1	Recommended(i)
1020030	Goat milk	0.02*	0.1	0.1	Recommended(i)
1020040	Horse milk	0.02*	0.1	0.1	Recommended(i)
1030000	Birds eggs	0.02*	0.02	0.02*	Recommended(i)
–	Other commodities of plant and/or animal origin	See Reg. (EC) No 839/2008	–	–	Further consideration needed(d)

MRL: maximum residue level; CXL: codex maximum residue limit.
*Indicates that the MRL is set/proposed at the limit of quantification.
(1): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005.
(F): Residue is fat soluble.
(a): MRL is derived from a GAP evaluated at the EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).
(b): Tentative MRL is derived from a GAP evaluated at the EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available (combination E-I in Appendix D).
(c): GAP evaluated at the EU level is not supported by data but no risk to consumers was identified for the existing EU MRL; no CXL is available (combination C-I in Appendix D).
(d): There are no relevant authorisations or import tolerances reported at the EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).
(e): MRL is derived from a GAP evaluated at the EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination G-III in Appendix D).
(f): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination E-V in Appendix D).
(g): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at the EU level (combination A-V in Appendix D).
(h): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at the EU level, which is also fully supported by data, leads to a lower MRL (combination G-VII in Appendix D).
(i): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix D).

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Abbreviations

a.i.	active ingredient
a.s.	active substance
ADI	acceptable daily intake
ArfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight

CAC	Codex Alimentarius Commission
CEN	European Committee for Standardization (Comité Européen de Normalisation)
cGAP	critical GAP
CXL	codex maximum residue limit
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{90}	period required for 90% dissipation (define method of estimation)
EC	emulsifiable concentrate
EMS	evaluating Member State
EURLs	EU Reference Laboratories (former CRLs)
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
HPLC–MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
*K*ow	coefficient between *n*-octanol and water
LOQ	limit of quantification
MRL	maximum residue level
MS/MS	tandem mass spectrometry detector
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RAC	raw agricultural commodity
RB	bait (ready for use)
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SCPAFF	Standing Committee on Plants, Animals, Food and Feed (formerly: Standing Committee on the Food Chain and Animal Health (SCFCAH))
SEU	southern European Union
STMR	supervised trials median residue
TRR	total radioactive residue
WHO	World Health Organization

Appendix A – Summary of authorised uses considered for the review of MRLs

Critical outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Oranges	*Citrus sinensis*	SEU	Outdoor	ES, IT	*Ceratitis capitata*	RB	3.0	% (w/w)	Local treatment – general (see also comment field)	n.a.	n.a.		1	n.a.	n.a.	14.4	28.8	g a.i./ha	n.a.	Authorised in bait stations only. 12 or 24 baits/ha (1.2 g a.i./bait)
Lemons	*Citrus limon*	SEU	Outdoor	ES, IT	*Ceratitis capitata*	RB	3.0	% (w/w)	Local treatment – general (see also comment field)	n.a.	n.a.		1	n.a.	n.a.	14.4	28.8	g a.i./ha	n.a.	See oranges
Limes	*Citrus aurantiifolia*	SEU	Outdoor	ES	*Ceratitis capitata*	RB	3.0	% (w/w)	Local treatment – general (see also comment field)	n.a.	n.a.		1	n.a.	n.a.	14.4	28.8	g a.i./ha	n.a.	See oranges
Mandarins	*Citrus reticulata*, syn: *Citrus deliciosa*	SEU	Outdoor	ES, IT	*Ceratitis capitata*	RB	3.0	% (w/w)	Local treatment – general (see also comment field)	n.a.	n.a.		1	n.a.	n.a.	14.4	28.8	g a.i./ha	n.a.	See oranges
Apples	*Malus domestica*	SEU	Outdoor	ES, IT	*Ceratitis capitata*	RB	3.0	% (w/w)	Local treatment – general (see also comment field)	n.a.	n.a.		1	n.a.	n.a.	14.4	28.8	g a.i./ha	n.a.	See oranges
Pears	*Pyrus communis*	SEU	Outdoor	ES, IT	*Ceratitis capitata*	RB	3.0	% (w/w)	Local treatment – general (see also comment field)	n.a.	n.a.		1	n.a.	n.a.	14.4	28.8	g a.i./ha	n.a.	See oranges
Apricots	*Armeniaca vulgaris*, syn: *Prunus armeniaca*	SEU	Outdoor	ES, IT	*Ceratitis capitata*	RB	3.0	% (w/w)	Local treatment – general (see also comment field)	n.a.	n.a.		1	n.a.	n.a.	14.4	28.8	g a.i./ha	n.a.	See oranges

Critical outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Cherries	*Cerasus avium*, syn: *Prunus avium*	SEU	Outdoor	ES	*Ceratitis capitata*	RB	3.0	% (w/w)	Local treatment – general (see also comment field)	n.a.	n.a.		1	n.a.	n.a.	14.4	28.8	g a.i./ha	n.a.	See oranges
Peaches	*Persica vulgaris*, syn: *Prunus persica*	SEU	Outdoor	ES, IT	*Ceratitis capitata*	RB	3.0	% (w/w)	Local treatment – general (see also comment field)	n.a.	n.a.		1	n.a.	n.a.	14.4	28.8	g a.i./ha	n.a.	See oranges
Plums	*Prunus domestica*	SEU	Outdoor	ES, IT	*Ceratitis capitata*	RB	3.0	% (w/w)	Local treatment – general (see also comment field)	n.a.	n.a.		1	n.a.	n.a.	14.4	28.8	g a.i./ha	n.a.	See oranges
Table grapes	*Vitis vinifera*	SEU	Outdoor	ES, IT	*Ceratitis capitata*	RB	3.0	% (w/w)	Local treatment – general (see also comment field)	n.a.	n.a.		1	n.a.	n.a.	14.4	28.8	g a.i./ha	n.a.	See oranges
Wine grapes	*Vitis vinifera*	SEU	Outdoor	ES, IT	*Ceratitis capitata*	RB	3.0	% (w/w)	Local treatment – general (see also comment field)	n.a.	n.a.		1	n.a.	n.a.	14.4	28.8	g a.i./ha	n.a.	See oranges
Figs	*Ficus carica*	SEU	Outdoor	ES, IT	*Ceratitis capitata*	RB	3.0	% (w/w)	Local treatment – general (see also comment field)	n.a.	n.a.		1	n.a.	n.a.	14.4	28.8	g a.i./ha	n.a.	See oranges
Kaki	*Diospyros kaki*	SEU	Outdoor	ES, IT	*Ceratitis capitata*	RB	3.0	% (w/w)	Local treatment – general (see also comment field)	n.a.	n.a.		1	n.a.	n.a.	14.4	28.8	g a.i./ha	n.a.	See oranges
Kiwi fruits	*Actinidia deliciosa; Actinidia chinensis*	SEU	Outdoor	ES	*Ceratitis capitata*	RB	3.0	% (w/w)	Local treatment – general (see also comment field)	n.a.	n.a.		1	n.a.	n.a.	14.4	28.8	g a.i./ha	n.a.	See oranges

Critical indoor GAPs for Northern and Southern Europe (including post-harvest treatments)

Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Strawberries	*Fragaria x ananassa*	NEU/SEU	Indoor	IT, PT	*Frankliniella* sp.	EC	50.0	g/L	Foliar treatment – spraying			1	2	7	14	0.05	100	g a.i./ha	7	
Tomatoes	*Lycopersicon esculentum*	NEU/SEU	Indoor	ES, HU, EL, PT	*Frankliniella* sp.	EC	50.0	g/L	Foliar treatment – spraying			1	3	7			100	g a.i./ha	7	
Sweet peppers	*Capsicum annuum*	NEU/SEU	Indoor	ES, HU, EL, PT	*Frankliniella* sp.	EC	50.0	g/L	Foliar treatment – spraying			1	3	7			100	g a.i./ha	7	
Aubergines	*Solanum melongena*	NEU/SEU	Indoor	EL	*Helicoverpa armigera*; *Spodoptera* sp.; *Frankliniella occidentalis*; *Thrips tabaci*	EC	50.0	g/L	Foliar treatment – spraying			1	3	7		50	100	g a.i./ha	7	
Cucumbers	*Cucumis sativus*	NEU/SEU	Indoor	HU, PT	*Frankliniella* sp.	EC	50.0	g/L	Foliar treatment – spraying			1	2	7			113	g a.i./ha	7	Also authorised in EL: 3 × 100 g a.i./ha; PHI 7 days (no data)
Gherkins	*Cucumis sativus*	NEU/SEU	Indoor	EL	*Helicoverpa armigera*; *Spodoptera* sp.; *Frankliniella occidentalis*; *Thrips tabaci*	EC	50.0	g/L	Foliar treatment – spraying			1	3	7			100	g a.i./ha	7	
Courgettes	*Cucurbita pepo* Zucchini group	NEU/SEU	Indoor	PT		EC	50.0	g/L	Foliar treatment – spraying			1	2	7			100	g a.i./ha	7	

Critical indoor GAPs for Northern and Southern Europe (including post-harvest treatments)

Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Melons	*Cucumis melo*	NEU/SEU	Indoor	EL	*Helicoverpa armigera*; *Spodoptera* sp.; *Frankliniella occidentalis*; *Thrips tabaci*	EC	50.0	g/L	Foliar treatment – spraying			1	3	7		50	100	g a.i./ ha	3	
Pumpkins	*Cucurbita maxima*	NEU/SEU	Indoor	EL	*Helicoverpa armigera*; *Spodoptera* sp.; *Frankliniella occidentalis*; *Thrips tabaci*	EC	50.0	g/L	Foliar treatment – spraying			1	3	7		50	100	g a.i./ ha	3	
Watermelons	*Citrullus vulgaris*, syn: *Citrullus lanatus*	NEU/SEU	Indoor	EL	*Helicoverpa armigera*; *Spodoptera* sp.; *Frankliniella occidentalis*; *Thrips tabaci*	EC	50.0	g/L	Foliar treatment – spraying			1	3	7		50	100	g a.i./ ha	3	
Lamb's lettuces	*Valerianella locusta*	NEU/SEU	Indoor	ES	*Frankliniella occidentalis*; *Heliothis armigera*; *Laphygma exigua*	EC	50.0	g/L	Foliar treatment – spraying			1	3	7	10		30	g a.i./ ha	7	

Critical indoor GAPs for Northern and Southern Europe (including post-harvest treatments)

Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Lettuces	*Lactuca sativa*	NEU/SEU	Indoor	ES	*Frankliniella occidentalis; Heliothis armigera*	EC	50.0	g/L	Foliar treatment – spraying			1	3	7	10		100	g a.i./ ha	7	
Escaroles	*Cichorium endivia* var. *latifolia*	NEU/SEU	Indoor	ES	*Frankliniella occidentalis; Heliothis armigera; Laphygma exigua*	EC	50.0	g/L	Foliar treatment – spraying			1	3	7	10		30	g a.i./ ha	7	
Cresses	*Lepidium sativum* subsp. *sativum*	NEU/SEU	Indoor	ES	*Frankliniella occidentalis; Heliothis armigera; Laphygma exigua*	EC	50.0	g/L	Foliar treatment – spraying			1	3	7	10		30	g a.i./ ha	7	
Land cresses	*Barbarea verna*	NEU/SEU	Indoor	ES	*Frankliniella occidentalis; Heliothis armigera; Laphygma exigua*	EC	50.0	g/L	Foliar treatment – spraying			1	3	7	10		30	g a.i./ ha	7	
Roman rocket	*Eruca sativa*	NEU/SEU	Indoor	ES	*Frankliniella occidentalis; Heliothis armigera; Laphygma exigua*	EC	50.0	g/L	Foliar treatment – spraying			1	3	7	10		30	g a.i./ ha	7	

Critical indoor GAPs for Northern and Southern Europe (including post-harvest treatments)

Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Red mustards	*Brassica juncea* var. *rugosa*	NEU/SEU	Indoor	ES	*Frankliniella occidentalis; Heliothis armigera; Laphygma exigua*	EC	50.0	g/L	Foliar treatment – spraying			1	3	7	10		30	g a.i./ ha	7	
Baby leaf crops	*Not specified*	NEU/SEU	Indoor	ES	*Frankliniella occidentalis; Heliothis armigera; Laphygma exigua*	EC	50.0	g/L	Foliar treatment – spraying			1	3	7	10		30	g a.i./ ha	7	

Critical GAPs for import tolerances (non-European indoor, outdoor or post-harvest treatments)

Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Apples	*Malus domestica*	Non-EU	Outdoor	DZ, MA, TN	Insects	EC	50.0	g/L	Foliar treatment – spraying			1	2	14			50	g a.i./ ha	28	GAP authorised in Algeria, Morocco and Tunisia (certificates of homologation were provided by the RMS)
Pears	*Pyrus communis*	Non-EU	Outdoor	DZ, MA, TN	Insects	EC	50.0	g/L	Foliar treatment – spraying			1	2	14			50	g a.i./ ha	28	See apples

Critical GAPs for import tolerances (non-European indoor, outdoor or post-harvest treatments)																				
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Quinces	*Cydonia oblonga*	Non-EU	Outdoor	DZ, MA, TN	Insects	EC	50.0	g/L	Foliar treatment – spraying			1	2	14			50	g a.i./ ha	28	See apples
Medlars	*Mespilus germanica*	Non-EU	Outdoor	DZ, MA, TN	Insects	EC	50.0	g/L	Foliar treatment – spraying			1	2	14			50	g a.i./ ha	28	See apples
Loquats	*Eriobotrya japonica*	Non-EU	Outdoor	DZ, MA, TN	Insects	EC	50.0	g/L	Foliar treatment – spraying			1	2	14			50	g a.i./ ha	28	See apples
Apricots	*Armeniaca vulgaris*, syn: *Prunus armeniaca*	Non-EU	Outdoor	DZ	Insects	EC	50.0	g/L	Foliar treatment – spraying			1	2	14			50	g a.i./ ha	28	GAP authorised in Algeria (certificate of homologation was provided by the RMS)
Peaches	*Persica vulgaris*, syn: *Prunus persica*	Non-EU	Outdoor	DZ	Insects	EC	50.0	g/L	Foliar treatment – spraying			1	2	14			50	g a.i./ ha	28	See apricots
Potatoes	*Solanum tuberosum* subsp. *tuberosum*	Non-EU	Outdoor	DZ	Insects	EC	50.0	g/L	Foliar treatment – spraying				1				20	g a.i./ ha	21	GAP authorised in Algeria (certificate of homologation was provided by the RMS)
Tomatoes	*Lycopersicon esculentum*	Non-EU	Outdoor	MA	Insects	EC	50.0	g/L	Foliar treatment – spraying			1	3	7			30	g a.i./ ha	7	GAP authorised in Morocco (certificate of homologation was provided by the RMS)

Appendix B – List of end points

B.1. Residues in plants

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

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

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling** (DAT)
	Fruit crops	Tomatoes	Foliar: 3 x 30 g a.s./ha	0, 12, 28
	Leafy crops	Head cabbage	Foliar: 3 x 20 g a.s./ha	0, 28
	Pulses/oilseeds	Cotton seed	Foliar: 3 x 30 g a.s./ha	0, 14, 28, 52, 84
	Source: Portugal, 2006			
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI** (DAT)
	Root/tuber crops	Carrots	Bare soil, 150 g a.s./ha	63
		Sugar beet	Bare soil, 130 g a.s./ha	306
	Leafy crops	Lettuce	Bare soil, 150 g a.s./ha	63
			Bare soil, 130 g a.s./ha	76
	Cereal (small grain)	Wheat and maize	Bare soil, 150 g a.s./ha	63
			Bare soil, 130 g a.s./ha	126, 331
	Source: Portugal, 2006			
Processed commodities (hydrolysis study)	**Conditions**			**Investigated?**
	Pasteurisation (20 min, 90°C, pH 4)			Yes
	Baking, brewing and boiling (60 min, 100°C, pH 5)			Yes
	Sterilisation (20 min, 120°C, pH 6)			Yes
	Source: Portugal, 2006			

Can a general residue definition be proposed for primary crops?	Yes
Rotational crop and primary crop metabolism similar?	Yes
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes
Plant residue definition for monitoring (RD-Mo)	Lufenuron (any ratio of constituent isomers)
Plant residue definition for risk assessment (RD-RA)	Lufenuron (any ratio of constituent isomers)
Conversion factor (monitoring to risk assessment)	Not relevant
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	HPLC–MS/MS (EURLs, 2016): • QuEChERS method (EURL-FV – 2014-M15) validated in high water and high acid content commodities • QuOil method (BVL L 13.04-5:2013-08) validated on high oil content commodities • QuEChERS method (EN 15662:2008) validated in dry commodities • LOQ: 0.01 mg/kg

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T** (°C)	**Stability** (Months/years)
	High water content	Cabbage	−18	24 months
	High oil content	Cotton seed	−18	24 months
	High acid content	Orange	−18	24 months
	Source: EFSA, 2009			

B.1.2. Magnitude of residues in plants

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

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg)[b]	STMR (mg/kg)[c]
Oranges Lemons Limes Mandarins	SEU	–	Use in bait stations only. No residues are expected	0.01*	0.01	0.01
Pome fruits	SEU	–	Use in bait stations only. Use in bait stations only. No residues are expected. No authorised use on quinces, medlars and loquats in SEU	0.01	0.01	0.01
	Import (DZ, MA, TN)	NEU: 0.02; 0.03; 0.03; 0.04; 0.05; 0.05; 0.07; 0.08 SEU: 0.03; 0.03; 0.04; 0.04; 0.05; 0.05; 0.07; 0.08	Combined data set of eight SEU trials and eight NEU trials, all performed on apples and compliant with GAP (Portugal, 2010). Extrapolation to other pome fruits is applicable MRL_{OECD} = 0.14	0.15	0.08	0.05
Peaches Apricots	SEU	–	Use in bait stations only. No residues are expected	0.01*	0.01	0.01
	Import (DZ)	Peaches: 0.02; 0.14; 0.03; 0.03; 0.02; 0.01; 0.04; 0.03; 0.07; 0.05 Apricots: no data available	Trials performed in SEU compliant with GAP for peaches and apricots (25% deviation on application rate) (Portugal, 2010). Since data on apricots are missing, the MRL proposal should remain tentative MRL_{OECD} = 0.2	0.2 (tentative)	0.14	0.03
Cherries (sweet)	SEU	–	Use in bait stations only. No residues are expected	0.01*	0.01	0.01
Plums	SEU	–	Use in bait stations only. No residues are expected	0.01*	0.01	0.01
Table and wine grapes	SEU	–	Use in bait stations only. No residues are expected	0.01*	0.01	0.01
Strawberries	Indoor	0.18; 0.42	Trials compliant with GAP (Portugal, 2010) but not sufficient to derive an MRL	–	–	–
Figs	SEU	–	Use in bait stations only. No residues are expected	0.01*	0.01	0.01
Kaki/Japanese persimmons	SEU	–	Use in bait stations only. No residues are expected	0.01*	0.01	0.01
Kiwi fruits	SEU	–	Use in bait stations only. No residues are expected	0.01*	0.01	0.01
Potatoes	Import (DZ)	Two applications (overdosed): 4 × < 0.01 One application (GAP-compliant): 3 × < 0.02	Trials performed in SEU: Four trials performed with two applications instead of one (acceptable since residues < 0.01 mg/kg) and three trials compliant with GAP (Portugal, 2010)	0.01*	0.01	0.01

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg)[b]	STMR (mg/kg)[c]
Tomatoes Aubergines	Indoor	0.02; 0.04; 0.04; 0.05; 0.06[d]; 0.08[d]; 0.08; 0.08; 0.09[d]; 0.09; 0.10; 0.11; 0.25	Trials performed on tomatoes and compliant with GAP (EFSA, 2009; Portugal, 2010). Extrapolation to aubergines is applicable MRL_{OECD} = 0.31	0.3	0.25	0.07
	Import (MA)	< 0.02; < 0.02; 0.05; 0.06	Trials performed on tomatoes in SEU and compliant with GAP (Portugal, 2010). The available limited data set is acceptable since the import tolerance GAP is less critical than the EU indoor GAP. No authorised import tolerance for aubergines MRL_{OECD} = 0.12	0.15	0.06	0.04
Sweet peppers/ bell peppers	Indoor	0.06; 0.07; 0.08; 0.13; 0.13; 0.17; 0.19; 0.47	Trials on sweet peppers compliant with GAP (Portugal, 2010) MRL_{OECD} = 0.69	0.7	0.47	0.13
Cucumbers Courgettes	Indoor	0.01; 0.02; 0.02; 0.02; 0.02; 0.03; 0.03; 0.03; 0.06; 0.06; 0.06	Trials on cucumbers compliant with GAP (25% deviation on the application rate) (Portugal, 2010). Extrapolation to courgettes is applicable. For cucumbers, the most critical GAP reported by Greece is not supported by data MRL_{OECD} = 0.11	0.15	0.06	0.03
Gherkins	Indoor	–	Trials compliant with GAP are not available. Extrapolation from cucumbers not possible because the trials were performed with only two applications instead of three	–	–	–
Melons Pumpkins Watermelons	Indoor	0.03; 0.03; 0.06; 0.07; 0.09; 0.14; 0.19; 0.19	Trials on melons compliant with GAP for all cucurbits with inedible peel (Portugal, 2010) MRL_{OECD} = 0.36	0.4	0.19	0.08
Lettuces	Indoor	–	No data available	–	–	–
Other salad plants including *Brassicaceae*	Indoor	–	No data available	–	–	–

OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level; GAP: Good Agricultural Practice.
*Indicates that the MRL is proposed at the limit of quantification.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue.
(c): Supervised trials median residue.
(d): These values correspond to higher residue levels observed at a longer PHI.

B.1.2.2. Residues in succeeding crops

Confined rotational crop study (quantitative aspect)	Residues were generally < 0.01 mg/kg after treatment with 130 and 150 g a.s./ha. The low radioactivity observed in carrot and lettuce (0.023–0.047 mg eq/kg) was considered to be due to soil contamination; significant residues are not expected in the succeeding crops (EFSA, 2009)
Field rotational crop study	Not available and not required

B.1.2.3. Processing factors

Processed commodity	Number of studies[a]	Processing factor (PF)	
		Individual values	Median PF
Robust processing factors (sufficiently supported by data)			
Apples, juice (extrapolated to pears)	4	0.2; 0.2; 0.2; 0.2	0.2[b]
Apples, dry pomace (extrapolated to pears)	4	16; 18; 18; 19	18
Apples, sauce	4	0.2; 0.2; 0.2; 0.2	0.2[b]
Table grapes, raisins	4	5.7; 5.7; 5.9; 7.3	5.8
Wine grapes, juice	4	0.08; 0.13; 0.14; 0.22	0.14[b]
Wine grapes, must	5	0.44; 0.61; 0.86; 2.4; 2.9	0.86
Tomatoes, peeled and canned	4	0.17; 0.17; 0.17; 0.17	0.17[b]
Tomatoes, sauce	4	0.79; 0.83; 0.86; 0.90	0.85
Tomatoes, juice	4	0.17; 0.17; 0.17; 0.17	0.17[b]
Melons, peeled (extrapolated to other cucurbits with inedible peel)	4	0.14; 0.33; 0.67; 0.67	0.5[b]
Indicative processing factors (limited data set)			
Apples, wet pomace (extrapolated to pears)	2	3.6; 5.8	4.7
Wine grapes, wet pomace	1	4.4	4.4
Wine grapes, red wine (unheated)	2	0.08; 0.13	0.11[b]
Wine grapes, white wine	2	0.14; 0.22	0.18[b]

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Residues were < LOQ in this processed item; therefore, the calculated processing factor (considering the LOQ of 0.02 mg/kg in processed item) is overestimated.

B.2. Residues in livestock

Relevant groups	Dietary burden expressed in				Most critical diet[a]	Most critical commodity[a]	Trigger exceeded (Y/N)
	mg/kg bw per day		mg/kg DM				
	Med.	Max.	Med.	Max.			
Cattle (all diets)	0.0029	0.0029	0.12	0.12	Cattle (beef)	Apple, wet pomace	Y
Cattle (dairy only)	0.0026	0.0026	0.07	0.07	Cattle (dairy)	Apple, wet pomace	N
Sheep (all diets)	0.0027	0.0027	0.07	0.07	Sheep (lamb)	Potato, process waste	N
Sheep (ewe only)	0.0023	0.0023	0.07	0.07	Sheep (ram/ewe)	Apple, wet pomace	N
Swine (all diets)	0.0010	0.0010	0.04	0.04	Swine (breading)	Potato, process waste	N
Poultry (all diets)	0.0007	0.0007	0.01	0.01	Poultry (turkey)	Potato, culls	N
Poultry (layer only)	0.0005	0.0005	0.01	0.01	Poultry (layer)	Potato, culls	N

(a): Calculated for the maximum dietary burden.

B.2.1. Nature of residues and methods of analysis in livestock

B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

Livestock (available studies)	**Animal**	**Dose** (mg/kg bw per day)	**Duration** (days)	**N rate/comment**
	Laying hen	0.21–0.33[(a)]	14	21N rate
	Lactating goat	0.15–0.17[(b)]	10	1.3N/compared to beef cattle 2N/compared to dairy cattle
	Source: Portugal, 2006 (a): Nominal doses of 3.4–5.2 mg/kg DM; theoretical administrated dose converted in mg/kg bw per day assuming a feed intake of 0.12 kg DM/day and a standard body weight of 1.9 kg (b): Nominal doses of 5.4–6 mg/kg DM; theoretical administrated dose converted in mg/kg bw per day assuming a feed intake of 2 kg DM/day and a standard body weight of 70 kg			

Time needed to reach a plateau concentration in milk and eggs (days)	Milk: 8–10 days Eggs: 10–11 days
Metabolism in rat and ruminant similar (Yes/No)	Yes
Animal residue definition for monitoring (RD-Mo)	Lufenuron (any ratio of constituent isomers)
Animal residue definition for risk assessment (RD-RA)	Lufenuron (any ratio of constituent isomers)
Conversion factor (monitoring to risk assessment)	Not relevant
Fat soluble residues (Yes/No)	Yes
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	HPLC–MS/MS (Portugal, 2006): • Method validated in muscle, fat, milk and eggs • ILV available • Missing validation for liver/kidney • LOQ: 0.02 mg/kg

B.2.1.2. Stability of residues in livestock

Animal products (available studies)	**Animal**	**Commodity**	**T** (°C)	**Stability** (Months)
	Beef	Muscle	–18	9
	Beef	Fat	–18	9
	Beef	Liver	–18	9
	Beef	Kidney	–18	9
	Cow	Milk	–18	9
	Source: EFSA, 2009			

B.2.2. Magnitude of residues in livestock

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

Animal commodity	Residues at the closest feeding level (mg/kg)		Estimated value at 1N		MRL proposal (mg/kg)
	Mean	Highest	STMR[a] (mg/kg)	HR[b] (mg/kg)	
Cattle (all diets) – Closest feeding level (0.039 mg/kg bw; 13.5N rate)[c]					
Muscle	0.03	0.05	< 0.02	< 0.02	0.02*
Fat	0.75	1.2	0.06	0.09	0.09
Liver	0.06	0.07	< 0.02	< 0.02	0.02*,[d] (tentative)
Kidney	0.04	0.04	< 0.02	< 0.02	0.02*,[d] (tentative)
Cattle (dairy only) – MRLs are not required since the trigger value is not exceeded					
Sheep (all diets) – MRLs are not required since the trigger value is not exceeded					
Sheep (dairy only) – MRLs are not required since the trigger value is not exceeded					
Swine – MRLs are not required since the trigger value is not exceeded					
Poultry (all diets) – MRLs are not required since the trigger value is not exceeded					
Poultry (layer only) – MRLs are not required since the trigger value is not exceeded					

*Indicates that the MRL is proposed at the limit of quantification.
n.a.: not applicable; MRL: maximum residue level; STMR: supervised trials median residue; HR: highest residue.
(a): Mean residue level, recalculated at the 1N rate for the median dietary burden.
(b): Highest residue level for tissues and eggs and mean residue level for milk recalculated at the 1 N rate for the maximum dietary burden.
(c): Closest feeding level and N dose rate related to the maximum dietary burden.
(d): MRL proposal is tentative because a validated analytical method for enforcement in liver and kidney is missing.

B.3. Consumer risk assessment

B.3.1. Consumer risk assessment without consideration of the existing CXLs

ADI	0.015 mg/kg bw per day (EFSA, 2009)
Highest IEDI, according to EFSA PRIMo	9.0% ADI (DE, child)
Assumptions made for the calculations	The calculation is based on the median residue levels in the raw agricultural commodities, except for cucurbits with inedible peel, where the relevant peeling factor was applied For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation

ARfD	Not deemed necessary (EFSA, 2009)
Highest IESTI, according to EFSA PRIMo	Not relevant
Assumptions made for the calculations	Not relevant

B.3.2. Consumer risk assessment with consideration of the existing CXLs

ADI	0.015 mg/kg bw per day (EFSA, 2009)
Highest IEDI, according to EFSA PRIMo	24.5% ADI (FR, toddler)
Assumptions made for the calculations	The residue definition for these CXLs is deemed comparable with the EU proposals considering that the wording 'lufenuron' includes also all the constituent isomers For those commodities having a CXL higher that the EU MRL proposal, median residue levels applied in the EU scenario were replaced by the median residue levels derived by JMPR

ARfD	Not deemed necessary (EFSA, 2009)
Highest IESTI, according to EFSA PRIMo	Not relevant
Assumptions made for the calculations	Not relevant

B.4. Proposed MRLs

Code number[(1)]	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition (existing): lufenuron[(F)] **Enforcement residue definition (proposed):** lufenuron (any ratio of constituent isomers)[(F)]					
110020	Oranges	1	–	0.01*	Recommended[(a)]
110030	Lemons	1	–	0.01*	Recommended[(a)]
110040	Limes	1	–	0.01*	Recommended[(a)]
110050	Mandarins	1	–	0.01*	Recommended[(a)]
130010	Apples	0.5	–	0.15	Recommended[(a)]
130020	Pears	0.5	–	0.15	Recommended[(a)]
130030	Quinces	0.2	–	0.15	Recommended[(a)]
130040	Medlar	0.2	–	0.15	Recommended[(a)]
130050	Loquats/Japanese medlars	0.2	–	0.15	Recommended[(a)]
140010	Apricots	1	–	0.2	Further consideration needed[(b)]
140020	Cherries (sweet)	1	–	0.01*	Recommended[(a)]
140030	Peaches	1	–	0.2	Further consideration needed[(b)]
140040	Plums	1	–	0.01*	Recommended[(a)]
151010	Table grapes	1	–	0.01*	Recommended[(a)]
151020	Wine grapes	1	–	0.01*	Recommended[(a)]
152000	Strawberries	1	–	1	Further consideration needed[(c)]
161020	Figs	0.02*	–	0.01*	Recommended[(a)]
161060	Kaki/Japanese persimmons	0.02*	–	0.01*	Recommended[(a)]
162010	Kiwi fruits	0.02*	–	0.01*	Recommended[(a)]
211000	Potatoes	0.05	0.01*	0.01*	Recommended[(e)]
231010	Tomatoes	0.5	0.4	0.4	Recommended[(h)]
231020	Sweet peppers/bell peppers	1	0.8	0.8	Recommended[(h)]
231030	Aubergines/eggplants	0.2	–	0.3	Recommended[(a)]
232010	Cucumbers	0.2	0.09	0.15	Recommended[(e)]
232020	Gherkins	0.2	–	0.2	Further consideration needed[(c)]

Code number[1]	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
232030	Courgettes	0.2	–	0.15	Recommended[a]
233010	Melons	0.3	0.4	0.4	Recommended[e]
233020	Pumpkins	0.2	–	0.4	Recommended[a]
233030	Watermelons	0.3	–	0.4	Recommended[a]
251010	Lamb's lettuces/corn salads	0.02*	–	0.02	Further consideration needed[c]
251020	Lettuces	0.5	–	0.5	Further consideration needed[c]
251030	Escaroles/broad-leaved endives	0.02*	–	0.02	Further consideration needed[c]
251040	Cresses and other sprouts and shoots	0.02*	–	0.02	Further consideration needed[c]
251050	Land cresses	0.02*	–	0.02	Further consideration needed[c]
251060	Roman rocket/rucola	0.02*	–	0.02	Further consideration needed[c]
251070	Red mustards	0.02*	–	0.02	Further consideration needed[c]
251080	Baby leaf crops (including *Brassica* species)	0.02*	–	0.02	Further consideration needed[c]
401070	Soya bean	0.02*	0.01*	0.01*	Recommended[i]
1011010	Swine muscle	0.02*	0.03	0.03	Recommended[i]
1011020	Swine fat tissue	0.02*	0.7	0.7	Recommended[i]
1011030	Swine liver	0.02*	0.04	0.04	Further consideration needed[g]
1011040	Swine kidney	0.02*	0.04	0.04	Further consideration needed[g]
1012010	Bovine muscle	0.02*	0.03	0.03	Recommended[h]
1012020	Bovine fat tissue	0.02*	0.7	0.7	Recommended[h]
1012030	Bovine liver	0.02*	0.04	0.04	Further consideration needed[f]
1012040	Bovine kidney	0.02*	0.04	0.04	Further consideration needed[f]
1013010	Sheep muscle	0.02*	0.03	0.03	Recommended[i]
1013020	Sheep fat tissue	0.02*	0.7	0.7	Recommended[i]
1013030	Sheep liver	0.02*	0.04	0.04	Further consideration needed[g]
1013040	Sheep kidney	0.02*	0.04	0.04	Further consideration needed[g]
1014010	Goat muscle	0.02*	0.03	0.03	Recommended[i]
1014020	Goat fat tissue	0.02*	0.7	0.7	Recommended[i]
1014030	Goat liver	0.02*	0.04	0.04	Further consideration needed[g]
1014040	Goat kidney	0.02*	0.04	0.04	Further consideration needed[g]
1015010	Equine muscle	0.02*	0.03	0.03	Recommended[h]
1015020	Equine fat tissue	0.02*	0.7	0.7	Recommended[h]
1015030	Equine liver	0.02*	0.04	0.04	Further consideration needed[f]
1015040	Equine kidney	0.02*	0.04	0.04	Further consideration needed[f]
1016010	Poultry muscle	0.02*	0.01*	0.02*	Recommended[i]
1016020	Poultry fat tissue	0.02*	0.04	0.04	Recommended[i]
1016030	Poultry liver	0.02*	0.02	0.02*	Further consideration needed[g]
1020010	Cattle milk	0.02*	0.1	0.1	Recommended[i]
1020020	Sheep milk	0.02*	0.1	0.1	Recommended[i]
1020030	Goat milk	0.02*	0.1	0.1	Recommended[i]
1020040	Horse milk	0.02*	0.1	0.1	Recommended[i]

Code number(1)	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
1030000	Birds eggs	0.02*	0.02	0.02*	Recommended(i)
–	Other commodities of plant and/or animal origin	See Reg. (EC) No 839/2008	–	–	Further consideration needed(d)

MRL: maximum residue level; CXL: codex maximum residue limit.
*Indicates that the MRL is set/proposed at the limit of quantification.
(1): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005.
(F): Residue is fat soluble.
(a): MRL is derived from a GAP evaluated at the EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).
(b): Tentative MRL is derived from a GAP evaluated at the EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available (combination E-I in Appendix D).
(c): GAP evaluated at the EU level is not supported by data but no risk to consumers was identified for the existing EU MRL; no CXL is available (combination C-I in Appendix D).
(d): There are no relevant authorisations or import tolerances reported at the EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).
(e): MRL is derived from a GAP evaluated at the EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination G-III in Appendix D).
(f): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; GAP evaluated at the EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination E-V in Appendix D).
(g): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at the EU level (combination A-V in Appendix D).
(h): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at the EU level, which is also fully supported by data, leads to a lower MRL (combination G-VII in Appendix D).
(i): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at the EU level (combination A-VII in Appendix D).

Appendix C – Input values for the exposure calculations

C.1. Livestock dietary burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Citrus, dried pulp	0.01*	STMR[(a)]	0.01*	STMR[(a)]
Apples, wet pomace	0.21	STMR × PF	0.21	STMR × PF
Potatoes, culls	0.01*	STMR	0.01*	HR
Potatoes, dried pulp	0.01*	STMR[(b)]	0.01*	STMR[(b)]
Potatoes, process waste	0.01*	STMR[(b)]	0.01*	STMR[(b)]

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
*Indicates that the input value is proposed at the limit of quantification.
(a): For citrus dried pulp, no default processing factor was applied because, lufenuron being used in bait stations only, residues are expected to be below the LOQ and concentration of residues in these commodities is therefore not expected.
(b): For potatoes dried pulp and process waste, no default processing factor was applied because residues are expected to be below the LOQ and concentration of residues in these commodities is therefore not expected.

C.2. Consumer risk assessment without consideration of the existing CXLs

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Oranges	0.01*	STMR
Lemons	0.01*	STMR
Limes	0.01*	STMR
Mandarins	0.01*	STMR
Pome fruits	0.05	STMR
Apricots	0.03	STMR (tentative)
Cherries (sweet)	0.01*	STMR
Peaches	0.03	STMR (tentative)
Plums	0.01*	STMR
Table grapes	0.01*	STMR
Wine grapes	0.01*	STMR
Strawberries	1	EU MRL
Figs	0.01*	STMR
Kaki/Japanese persimmons	0.01*	STMR
Kiwi fruits	0.01*	STMR
Potatoes	0.01*	STMR
Tomatoes	0.07	STMR
Sweet peppers/bell peppers	0.13	STMR
Aubergines/eggplants	0.07	STMR
Cucumbers	0.03	STMR
Gherkins	0.2	EU MRL
Courgettes	0.03	STMR
Melons	0.04	STMR × PF
Pumpkins	0.04	STMR × PF
Watermelons	0.04	STMR × PF
Lamb's lettuces/corn salads	0.02	EU MRL
Lettuces	0.5	EU MRL

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Escaroles/broad-leaved endives	0.02	EU MRL
Cresses and other sprouts and shoots	0.02	EU MRL
Land cresses	0.02	EU MRL
Roman rocket/rucola	0.02	EU MRL
Red mustards	0.02	EU MRL
Baby leaf crops (including *Brassica* species)	0.02	EU MRL
Bovine meat	0.03	0.8 × STMR muscle + 0.2 × STMR fat
Bovine fat	0.06	STMR
Bovine liver	0.02*	STMR (tentative)
Bovine kidney	0.02*	STMR (tentative)
Equine meat	0.03	0.8 × STMR muscle + 0.2 × STMR fat
Equine fat	0.06	STMR
Equine liver	0.02*	STMR (tentative)
Equine kidney	0.02*	STMR (tentative)

STMR: supervised trials median residue; MRL: maximum residue level; PF: processing factor.
*Indicates that the input value is proposed at the limit of quantification.

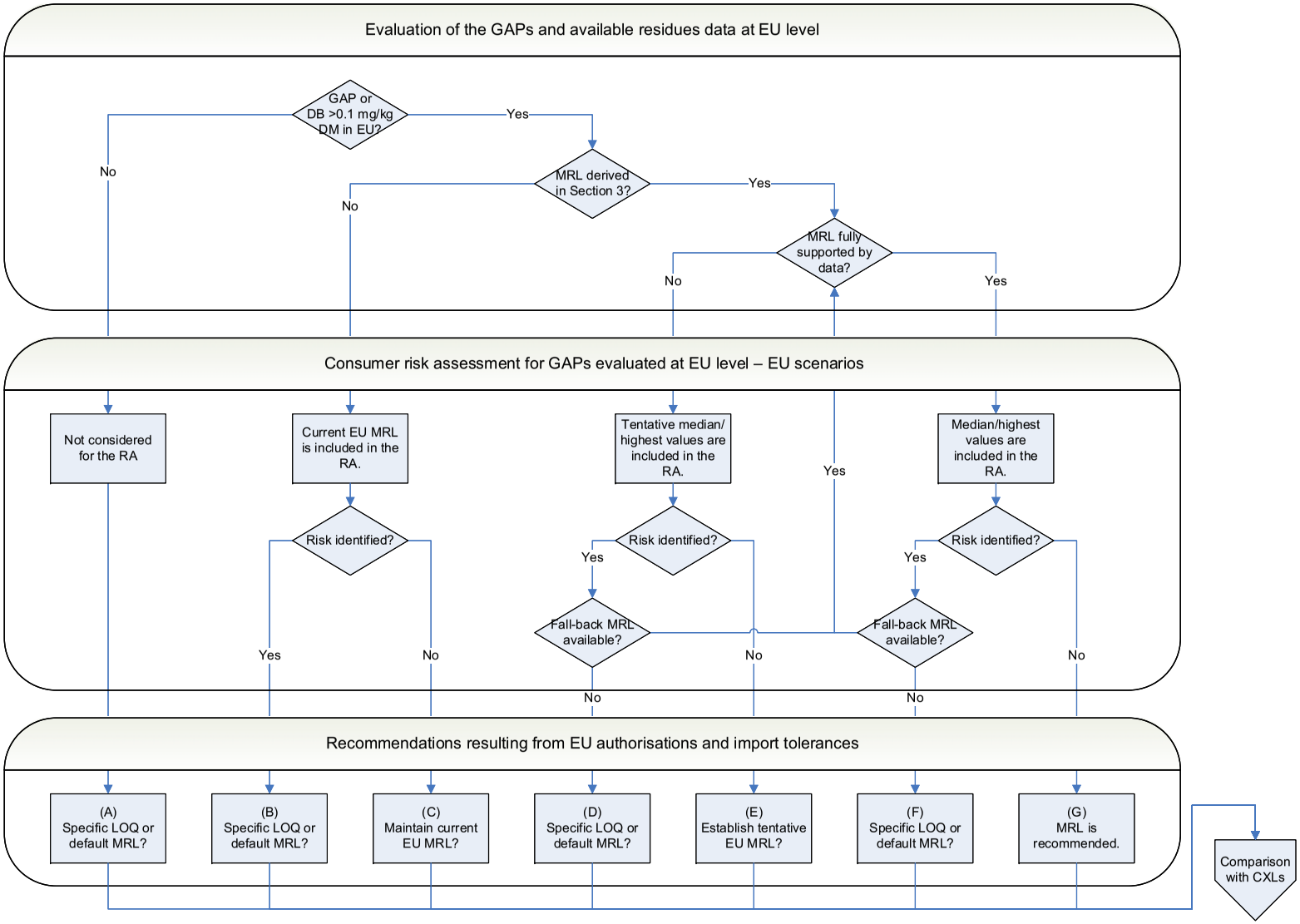
C.3. Consumer risk assessment with consideration of the existing CXLs

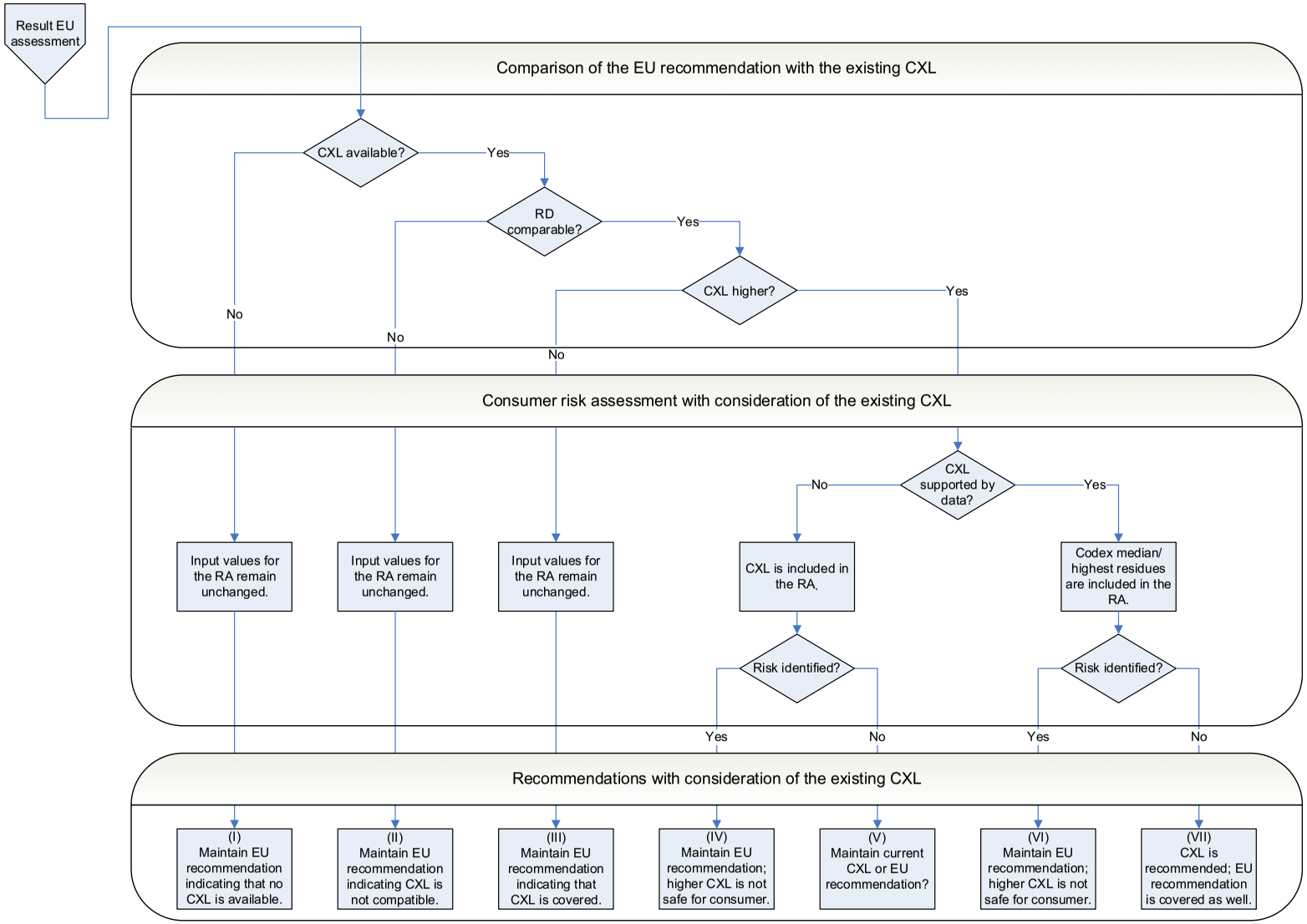
Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Oranges	0.01*	STMR
Lemons	0.01*	STMR
Limes	0.01*	STMR
Mandarins	0.01*	STMR
Pome fruits	0.05	STMR
Apricots	0.03	STMR (tentative)
Cherries (sweet)	0.01*	STMR
Peaches	0.03	STMR (tentative)
Plums	0.01*	STMR
Table grapes	0.01*	STMR
Wine grapes	0.01*	STMR
Strawberries	1	EU MRL
Figs	0.01*	STMR
Kaki/Japanese persimmons	0.01*	STMR
Kiwi fruits	0.01*	STMR
Potatoes	0.01*	STMR
Tomatoes	0.08	STMR (CXL)
Sweet peppers/bell peppers	0.15	STMR (CXL)
Aubergines/eggplants	0.07	STMR
Cucumbers	0.03	STMR
Gherkins	0.2	EU MRL
Courgettes	0.03	STMR
Melons	0.04	STMR × PF
Pumpkins	0.04	STMR × PF
Watermelons	0.04	STMR × PF
Lamb's lettuces/corn salads	0.02	EU MRL

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Lettuces	0.5	EU MRL
Escaroles/broad-leaved endives	0.02	EU MRL
Cresses and other sprouts and shoots	0.02	EU MRL
Land cresses	0.02	EU MRL
Roman rocket/rucola	0.02	EU MRL
Red mustards	0.02	EU MRL
Baby leaf crops (including *Brassica* species)	0.02	EU MRL
Soya bean	0.01*	STMR (CXL)
Swine meat	0.07	STMR (CXL)
Swine fat tissue	0.30	STMR (CXL)
Swine liver	0.03	STMR (CXL, tentative)
Swine kidney	0.03	STMR (CXL, tentative)
Bovine meat	0.07	STMR (CXL)
Bovine fat	0.30	STMR (CXL)
Bovine liver	0.03	STMR (CXL, tentative)
Bovine kidney	0.03	STMR (CXL, tentative)
Sheep meat	0.07	STMR (CXL)
Sheep fat tissue	0.30	STMR (CXL)
Sheep liver	0.03	STMR (CXL, tentative)
Sheep kidney	0.03	STMR (CXL, tentative)
Goat meat	0.07	STMR (CXL)
Goat fat tissue	0.30	STMR (CXL)
Goat liver	0.03	STMR (CXL, tentative)
Goat kidney	0.03	STMR (CXL, tentative)
Equine meat	0.07	STMR (CXL)
Equine fat	0.30	STMR (CXL)
Equine liver	0.03	STMR (CXL, tentative)
Equine kidney	0.03	STMR (CXL, tentative)
Poultry meat	0.02*	STMR (CXL)
Poultry fat tissue	0.03	STMR (CXL)
Poultry liver	0.02*	STMR (CXL, tentative)
Cattle milk	0.07	STMR (CXL)
Sheep milk	0.07	STMR (CXL)
Goat milk	0.07	STMR (CXL)
Horse milk	0.07	STMR (CXL)
Birds eggs	0.02*	STMR (CXL)

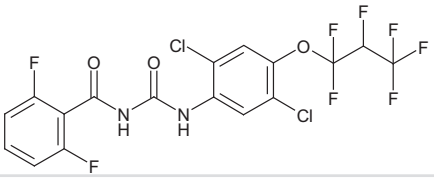
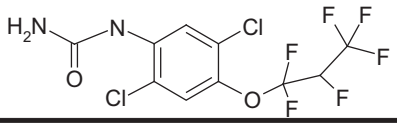
CXL: codex maximum residue limit; STMR: supervised trials median residue; MRL: maximum residue level; PF: processing factor.
*Indicates that the input value is proposed at the limit of quantification.

Appendix D – Decision tree for deriving MRL recommendations




Result EU assessment
Comparison of the EU recommendation with the existing CXL
CXL available?
Yes
No
RD comparable?
Yes
No
CXL higher?
Yes
No
Consumer risk assessment with consideration of the existing CXL
CXL supported by data?
No
Yes
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
CXL is included in the RA.
Codex median/ highest residues are included in the RA.
Risk identified?
Risk identified?
Yes
No
Yes
No
Recommendations with consideration of the existing CXL
(I) Maintain EU recommendation indicating that no CXL is available.
(II) Maintain EU recommendation indicating CXL is not compatible.
(III) Maintain EU recommendation indicating that CXL is covered.
(IV) Maintain EU recommendation; higher CXL is not safe for consumer.
(V) Maintain current CXL or EU recommendation?
(VI) Maintain EU recommendation; higher CXL is not safe for consumer.
(VII) CXL is recommended; EU recommendation is covered as well.

Appendix E – Used compound codes

Code/trivial name	Chemical name/SMILES notation	Structural formula
Lufenuron	(*RS*)-1-[2,5-Dichloro-4-(1,1,2,3,3,3-hexafluoro-propoxy)-phenyl]-3-(2,6-difluorobenzoyl)-urea c1cc(c(c(c1)F)C(=O)NC(=O)Nc2cc(c(cc2Cl)OC(C(C(F)(F)F)(F)F)(F)F)Cl)F	
CGA 238277	[2,5-Dichloro-4-(1,1,2,3,3,3-hexafluoro-propoxy)-phenyl]-urea NC(=O)Nc1cc(Cl)c(OC(F)(F)C(F)C(F)(F)F)cc1Cl	

SMILES: simplified molecular-input line-entry system.