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Setting of import tolerances for lufenuron in various commodities of plant and animal origin

EFSA (European Food Safety Authority),
Maria Anastassiadou, Giovanni Bernasconi, Alba Brancato, Luis Carrasco Cabrera,
Lucien Ferreira, Luna Greco, Samira Jarrah, Aija Kazocina, Renata Leuschner,
Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich,
Alejandro Rojas, Angela Sacchi, Miguel Santos, Alois Stanek, Anne Theobald,
Benedicte Vagenende and Alessia Verani

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Syngenta Crop Protection AG submitted a request to the competent national authority in Portugal to set import tolerances for the active substance lufenuron in grapefruits, oranges, limes, pome fruits, peppers, coffee, sugar canes, muscle, fat, liver and kidney on the basis of the authorised uses of lufenuron in Brazil, Chile and Morocco. The data submitted in support of the request were found to be sufficient to derive maximum residue level (MRL) proposals for all commodities under assessment. For oranges, limes, pome fruits, peppers and coffee beans and commodities of animal origin, the submitted data indicated no need to modify the existing EU MRLs. For grapefruits and sugar cane, the residue data indicated that higher MRLs would be needed. Adequate analytical methods for enforcement are available to control the residues of lufenuron in plant and animal matrices. Based on the risk assessment results, EFSA concluded that the existing EU uses and the authorised uses of lufenuron in Brazil, Chile and Morocco will not result in chronic consumer exposure exceeding the toxicological reference value. Considering, however, that the estimated exposure is close to the acceptable daily intake (ADI) and in the light of the expiry of the approval of the active substance, EFSA recommends the review of the existing MRLs taking into account that the MRLs based on the EU uses will become obsolete.

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Correspondence: pesticides.mrl@efsa.europa.eu

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta Crop Protection AG submitted an application to the competent national authority in Portugal (evaluating Member State, EMS) to set import tolerances for the active substance lufenuron in various crops and products of animal origin on the basis of authorised uses of lufenuron in Brazil, Chile and Morocco. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 24 May 2019. The EMS proposed to raise MRLs for lufenuron in grapefruits, oranges, limes, coffee beans and sugar canes imported from Brazil, pome fruits imported from Chile, sweet peppers/bell peppers, imported from Morocco. The EMS also assessed the livestock exposure to lufenuron residues from imported commodities or their by-products and proposed raising of the MRLs in commodities of animal origin.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps and points which needed further clarification and were requested from the EMS. On 8 and 19 May 2020, the EMS submitted the requested information in a revised evaluation report, which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments, including the MRL review according to Article 12 of the Regulation (EU) 396/2005 (MRL review) and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of lufenuron in primary crops has been investigated in fruit crops (tomatoes), leafy crops (head cabbage) and pulses and oilseeds (cotton seed). Lufenuron was the major compound in all studies, suggesting that significant degradation does not occur in plants. Studies investigating the effect of processing on the nature of lufenuron (hydrolysis studies) demonstrated that the active substance is hydrolytically stable under the representative conditions.

As the authorised uses of lufenuron are on imported crops, investigations of residues in rotational crops are not required.

Based on the metabolic pattern identified in metabolism studies and the results of hydrolysis studies, the residue definition for plant products was proposed as 'lufenuron (any ratio of constituent isomers)' for enforcement and risk assessment. This residue definition is applicable to primary crops, rotational crops and processed products.

EFSA concluded that for the crops assessed in the present application, the metabolism of lufenuron in primary crops and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definitions are applicable.

Sufficiently validated analytical methods based on high-performance liquid chromatography with tandem mass spectroscopy (HPLC-MS/MS) are available to quantify residues of lufenuron in the crops under assessment according to the residue definition for enforcement at the validated limit of quantification (LOQ) of 0.01 mg/kg.

The available residue trials were sufficient to derive MRL proposals for all crops under assessment on the basis of authorised uses of lufenuron in Brazil, Chile and Morocco. However, for oranges, limes, pome fruits, peppers and coffee beans, the submitted residue data indicated no need to modify the existing EU MRL. For grapefruits and sugar cane, the residue data indicated that higher MRLs would be needed.

Specific studies investigating the magnitude of residues of lufenuron in processed oranges were submitted with the present application. Based on these data, processing factors (PFs) were derived for lufenuron in orange juice, dry pulp and oil, which are proposed for the inclusion in Annex VI of Regulation (EU) No 396/2005:

- Orange, juice: < 0.03
- Orange/dry pulp: 0.15
- Orange/oil: 24

Among the crops under assessment, citrus fruits, apples and sugar canes may be used for feed purposes. Since import of these commodities in Europe is applied for, these crops or their by-products can enter the EU livestock feed chain. Thus, a potential carry-over of lufenuron residues into food of animal origin was assessed. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all relevant animal species, but the calculated exposure was significantly lower than the livestock exposure calculated by the JMPR, based on which the existing EU

MRLs for lufenuron in commodities of animal origin were recently set. Thus, in the framework of the current assessment, the nature and magnitude of lufenuron residues in livestock was not investigated further. Under the current assessment, the applicant submitted a validated analytical method for the analysis of lufenuron residues in liver and kidney. EFSA concluded that a sufficiently validated enforcement method is available for the determination of lufenuron residues in liver and kidney at the LOQ of 0.01 mg/kg.

The toxicological profile of lufenuron was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.015 mg/kg body weight (bw) per day. Setting of an acute reference dose (ARfD) was not deemed necessary.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). Considering the toxicological profile of the active substance, a short-term dietary risk assessment was not necessary.

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level and the acceptable codex maximum residue limits (CXLs). EFSA updated the calculation with the relevant supervised trials median residue (STMR) values for the crops under consideration as derived from the residue trials submitted in support of this MRL application. For remaining commodities, the STMR values were available as derived by the JMPR in 2018. The contributions of commodities for which no GAP was reported in the framework of the MRL review were not included in the calculation.

The estimated long-term exposure to lufenuron residues accounted for up to 84% of the ADI (NL toddler). The contribution of residues in the crops for which the raising of the lufenuron MRLs is proposed under the current assessment – grapefruit and sugar canes – individually accounts for less than 1% of the ADI. For the remaining commodities under consideration, the exposure is related to residues from authorised uses and acceptable CXLs.

The risk assessment is affected by additional, non-standard uncertainties resulting from the lack of the following information:

- Detailed information on the possible preferential degradation of one of the enantiomers present in the active substance (R/S-enantiomer) leading to a shift of the isomer ratio in treated crops compared to the isomer ratio in the parent compound applied to the crops;
- Information on the toxicological profile of the individual enantiomers, compared to the toxicological profile of the isomer mixture.

It was 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. This introduces an additional uncertainty in the exposure assessment for lufenuron as the consumption of fish could not be taken into account in the exposure calculation due to the lack of data from food surveys performed according to the current standard.

Based on the consumer exposure assessment, EFSA concludes that the existing EU uses and the authorised uses of lufenuron in Brazil, Chile and Morocco will not result in chronic consumer exposure exceeding the toxicological reference value (84% of the ADI). Considering, however, that the estimated exposure is close to the ADI and in the light of the expiry of the approval of the active substance, EFSA recommends the review of the existing MRLs taking into account that the MRLs based on the EU uses will become obsolete.

EFSA proposes to amend the existing MRLs as reported in the summary table below.

Full details of all end points and the consumer risk assessment can be found in Appendices B–D.

Code ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Lufenuron (any ratio of constituent isomers) ^(f)				
110010	Grapefruits	0.01*	0.3	The submitted data are sufficient to derive an import tolerance based on the authorised GAP in Brazil. The Brazilian MRL is set at 0.5 mg/kg. Risk for consumers unlikely
110020	Oranges	0.3	No change	The submitted data do not provide evidence that the existing MRL has to be modified

Code ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
110040	Limes	0.4	No change	The submitted data do not provide evidence that the existing MRL has to be modified
130000	Pome fruits	1.0	No change	The submitted data do not provide evidence that the existing MRL has to be modified
231020	Sweet peppers/ bell peppers	0.8	No change	The submitted data do not provide evidence that the existing MRL has to be modified
620000	Coffee beans	0.07	No change	The submitted data do not provide evidence that the existing MRL has to be modified
900020	Sugar canes	0.01*	Further risk management considerations required	The submitted data are sufficient to derive an MRL proposal of 0.04 mg/kg for the authorised GAP in Brazil. The Brazilian MRL is set at 0.02 mg/kg. Further risk management considerations are required to decide whether modification of the MRL is appropriate considering that the MRL in the country of origin is significantly lower than the MRL proposal derived from the residue trials
1011010 1012010 1013010 1014010 1015010	Swine, Bovine, Sheep, Goat, Horse: muscle	0.08	No change	The submitted data do not provide evidence that the existing MRL has to be modified
1011020 1012020 1013020 1014020 1015020	Swine, Bovine, Sheep, Goat, Horse: fat	2	No change	The submitted data do not provide evidence that the existing MRL has to be modified
1011030 1012030 1013030 1014030 1015030	Swine, Bovine, Sheep, Goat, Horse: liver	0.15	No change	The submitted data do not provide evidence that the existing MRL has to be modified
1011040 1012040 1013040 1014040 1015040	Swine, Bovine, Sheep, Goat, Horse: kidney	0.15	No change	The submitted data do not provide evidence that the existing MRL has to be modified
1020000	Milk	0.15	No change	The submitted data do not provide evidence that the existing MRL has to be modified

MRL: maximum residue level; GAP: Good Agricultural Practice.

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

(F): Fat soluble.

It is noted that the available method for the monitoring of residues of lufenuron in liver and kidney is also appropriate for poultry liver and kidney for which footnotes on an analytical method requirement are attached in Regulation (EU) 2020/856. Based on the current evaluation, the data gap identified for poultry liver and kidney in the framework of the MRL review has been addressed and the corresponding footnotes can be deleted.

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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue levels (MRLs) for lufenuron in grapefruits, oranges, limes, pome fruits, bell peppers, sugar cane, coffee beans and in all products of animal origin, except poultry commodities. The detailed description of the authorised uses of lufenuron on grapefruits, oranges, limes, coffee beans and sugar canes in Brazil, on pome fruits in Chile and on sweet peppers/bell peppers in Morocco, which are the basis for the current MRL application, is reported in Appendix A.

Lufenuron is the ISO common name for (RS)-1-[2,5-dichloro-4-(1,1,2,3,3,3-hexafluoropropoxy)phenyl]-3-(2,6-difluorobenzoyl)urea (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Lufenuron was evaluated in the framework of Directive 91/414/EEC¹ with Portugal designated as the rapporteur Member State (RMS) for the representative uses as an insecticide on grapes and tomatoes. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2009). Lufenuron was approved² for restricted indoor use or in outdoor bait stations as an insecticide on 1 January 2010. The approval of the active substance expired on 31 December 2019. As no application for renewal was submitted in the framework of Regulation (EU) 1107/2009³ for lufenuron, the substance is no longer approved in the European Union (EU).

The EU MRLs for lufenuron are established in Annex II of Regulation (EC) No 396/2005.⁴ The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2017) and the proposed modifications have been implemented in the MRL legislation. After completion of the MRL review, for a number of crops and animal commodities, the Codex maximum residue levels (CXLs) have been taken over in the EU MRL legislation.⁵

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta Crop Protection AG submitted an application to the competent national authority in Portugal (evaluating Member State, EMS) to set import tolerances for the active substance lufenuron in various crops and in the products of animal origin in support of the authorised uses of lufenuron in Brazil, Chile and Morocco. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the EFSA on 24 May 2019. The EMS proposed to raise the MRLs for lufenuron in all commodities under consideration.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation and identified data gaps and points which needed further clarification and were requested from the EMS. On 8 and 19 May 2020, the EMS submitted the requested information in a revised evaluation report, which replaced the previously submitted evaluation report (Portugal, 2019).

EFSA based its assessment on the evaluation report submitted by the EMS (Portugal, 2019), the draft assessment report (DAR) (Portugal, 2006) prepared under Council Directive 91/414/EEC, the Commission review report on lufenuron (European Commission, 2011), the EFSA conclusion on the peer review of the pesticide risk assessment of the active substance lufenuron (EFSA, 2009), the EFSA reasoned opinion on the MRL review (EFSA, 2017), the Scientific report (EFSA, 2019b) and the evaluations of the Joint Meeting on Pesticide residues (JMPR) (FAO, 2015, 2018).

For this application, the data requirements established in Regulation (EU) No 544/2011⁶ and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013). The assessment is

¹ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1–32.

² 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 triflurosulfuron as active substances (Text with EEA relevance) OJ L 172, 2.7.2009, p. 23–33. No longer in force.

³ 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.

⁴ Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1–16.

⁵ For an overview of all MRL Regulations on this active substance, please consult: <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN>

⁶ Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.⁷

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously, are presented in Appendix B.

The evaluation report submitted by the EMS (Portugal, 2019) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of lufenuron in primary crops belonging to the group of fruit crops, leafy crops and pulses/oilseeds has been investigated in the framework of the EU pesticides peer review (EFSA, 2009). Lufenuron is a stable and persistent compound and was the major compound in crops in all studies, suggesting that significant degradation does not occur in plants. Metabolite CGA 238277 was the only minor metabolite identified in head cabbage (3.3% total radioactive residue (TRR)–0.023 mg eq/kg) and tomatoes (0.2–2% TRR; ≤ 0.002 mg eq/kg). Despite the fact that foliar metabolism study on tomatoes was underdosed compared to some of the critical good agricultural practices (GAPs) reported for indoor uses, the metabolic picture of lufenuron was clearly elucidated (EFSA, 2009).

For the authorised uses under consideration, the metabolic behaviour of lufenuron in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Investigations of residues in rotational crops are not required for imported crops.

1.1.3. Nature of residues in processed commodities

Standard hydrolysis studies investigating the nature of residues in processed commodities and simulating processing conditions representative of 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) were assessed in the EU pesticides peer review (EFSA, 2009). It was concluded that the parent compound lufenuron is hydrolytically stable under the representative conditions.

1.1.4. Methods of analysis in plants

Sufficiently validated analytical methods for the determination of lufenuron's isomers (any ratio) in high water, high acid content and dry commodities with a limit of quantification (LOQ) of 0.02 mg/kg became available in the framework of the EU pesticides peer review (EFSA, 2009). Furthermore, the European Union reference laboratories (EURLs) validated Quick, Easy, Cheap, Effective, Rugged and Safe (QuEChERS) and QuOil methods for the determination of lufenuron in the four main plant matrices with an LOQ of 0.01 mg/kg, using HPLC-MS/MS (EURLs, 2016; EFSA, 2017). Hence, lufenuron and its isomers can be monitored in high water content, high acid content, high oil content and dry commodities with an LOQ of 0.01 mg/kg.

Details on the analytical method are presented in Appendix B.1.1.1.

EFSA concludes that sufficiently validated analytical enforcement methods are available to determine lufenuron residues according to the enforcement residue definition in the crops under consideration at the lowest validated LOQ of 0.01 mg/kg.

⁷ 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.

1.1.5. Storage stability of residues in plants

The storage stability of lufenuron in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2009). According to the studies available, lufenuron is stable for 24 months when stored at -18°C in high water, high acid and high oil content commodities.

Details on storage stability data are presented in Appendix B.1.1.2.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies and the capabilities of analytical methods, the following residue definitions for plant commodities were proposed in the framework of the MRL review (EFSA, 2017):

- Residue definition for enforcement and for risk assessment: lufenuron (any ratio of constituent isomers).

The residues of lufenuron are considered fat soluble.

The residue definition is applicable to all primary crops, rotational crops and processed commodities.

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition. Taking into account the available information for the uses assessed in this application, EFSA concluded that the existing residue definition is appropriate, and no modification is required.

Lufenuron is a stable and persistent compound and 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 (EFSA, 2009). Therefore, further investigation on this matter would be desirable.

1.2. Magnitude of residues in plants

In support of the MRL application, the applicant submitted results from residue trials on the following commodities: oranges, limes, apples, peppers, coffee beans and sugar canes.

Samples taken in the context of the available trials were analysed for the parent lufenuron in line with the residue definitions for enforcement and risk assessment (any ratio of constituent isomers).

The analytical methods, based on HPLC-MS/MS, were found to be sufficiently validated to support the determination of residues of lufenuron in the crops under assessment (Portugal, 2019). The validity of the results from trials on peppers was already evaluated as fit for purpose in the framework of the EFSA MRL review (EFSA, 2017).

Samples were stored under conditions ensuring stability of lufenuron residues (Portugal, 2019).

1.2.1. Magnitude of residues in primary crops

Grapefruits and oranges

Authorised GAP in Brazil: 1 appl. \times 3.75 g a.s./hL, PHI: 28 days

Grapefruits and oranges are major crops worldwide for which at least eight GAP compliant residue trials need to be submitted (European Commission, 2017). In support of the authorised use on oranges and grapefruits in Brazil, the applicant submitted eight residue trials on oranges, which were performed in Brazil. From experimental replicates, the mean value was selected. The trials were compliant with the authorised GAP. The applicant proposes to extrapolate residue data from oranges to grapefruit. According to EU guidance document, such an extrapolation is acceptable (European Commission, 2017).

Based on the above, the number of submitted trials is sufficient to derive an MRL proposal of 0.3 mg/kg for lufenuron in oranges and grapefruits. The tolerance of lufenuron in Brazil for these commodities is set at 0.5 mg/kg.⁸ It is noted that the existing EU MRL for lufenuron in oranges is set at 0.3 mg/kg, thus indicating that a modification of the existing MRL in oranges is not required.

⁸ Monografías de Agrotóxicos L05 – Lufenuron.

Limes

Authorised GAP in Brazil: 1 appl. × 3.75 g a.s./hL, PHI: 28 days

Limes are minor crops worldwide for which at least four GAP compliant residue trials need to be submitted (European Commission, 2017). In support of the authorised use on limes in Brazil, the applicant submitted four residue trials on limes, which were performed in Brazil. From experimental replicates, the mean value was selected. The trials were compliant with the authorised GAP.

Based on the above, the number of submitted trials is sufficient to derive an MRL proposal of 0.4 mg/kg for lufenuron in limes. However, since the existing EU MRL for lufenuron in limes is set at 0.4 mg/kg, a modification of the existing MRL in limes is not required. The tolerance of lufenuron in Brazil for these commodities is set at 0.5 mg/kg¹⁰.

Pome fruits (apples, pears, quinces, loquats, medlar)

Authorised GAP in Chile: 3 appl. × 225 g a.s./ha, PHI: 18 days

Apples and pears from the pome fruit group are major crops worldwide for which at least eight GAP compliant residue trials need to be submitted; remaining crops are minor for which four trials are sufficient (European Commission, 2017). In support of the authorised use on pome fruits in Chile, the applicant submitted eight residue trials on apples, which were performed in Chile over the growing seasons of 2016 and 2017. Studies were performed with samples taken at preharvest intervals (PHIs) of 14 and 21 days instead of the 18 days as reported in the GAP. As this deviation is within the tolerance interval of ± 25%, it is considered acceptable. From experimental replicates, the mean value was selected.

The applicant proposes to extrapolate residue data from apples to the whole group of pome fruits. Such an extrapolation is possible according to the European Commission Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2017).

Based on the above, the number of submitted trials is sufficient to derive an MRL proposal of 0.9 mg/kg for lufenuron in pome fruits. It is noted that the existing EU MRL for lufenuron in pome fruit is set at 1.0 mg/kg, thus indicating that a modification of the existing MRL in pome fruit is not required. The tolerance of lufenuron in Chile⁹ for pome fruit is set at 0.5 mg/kg.

Peppers

Authorised indoor GAP in Morocco: 3 appl. × 100 g a.s./ha, PHI: 3 days

Peppers are major crops worldwide for which at least eight GAP compliant residue trials need to be submitted (European Commission, 2017). In support of the authorised indoor use on peppers in Morocco, the applicant submitted eight residue trials on peppers, which were performed in Spain over the growing seasons of 1997 and 1998 and have been previously evaluated by EFSA (EFSA, 2017). From experimental replicates, the mean value was selected. The trials were compliant with the authorised GAP.

Based on the above, the number of submitted trials is sufficient to derive an MRL proposal of 0.8 mg/kg for lufenuron in peppers. It is noted that the existing EU MRL for lufenuron in peppers is set at 0.8 mg/kg, thus indicating that a modification of the existing MRL in peppers is not required. No national MRL is set in Morocco for lufenuron in peppers. The Codex MRL is set at 0.8 mg/kg.¹⁰ This is in line with information available in the technical dossier submitted with this application.

Coffee beans

Authorised GAP in Brazil: 2 appl. × 40 g a.s./ha, PHI: 7 days

Coffee beans are major crops worldwide for which at least eight GAP compliant residue trials need to be submitted (European Commission, 2017). In support of the authorised use on coffee beans in Brazil, the applicant submitted eight residue trials on coffee beans, which were performed in Brazil over the growing seasons of 2006 and 2017. The trials were compliant with the authorised GAP.

Based on the above, the number of submitted trials is sufficient to derive an MRL proposal of 0.07 mg/kg for lufenuron in coffee beans. The tolerance of lufenuron in Brazil for these commodities is set at a lower level of 0.05 mg/kg¹⁰. According to the Technical Guidelines on the MRL setting procedure SANTE/2015/10595 Rev.5.4., the MRL proposal for import tolerance requests should not exceed the MRL approved in the exporting country, taking into account possible differences in the

⁹ Modifica resolución n° 33 exenta, DE 2010, publicada en el diario oficial de 05.02.10, que fija tolerancias máximas de residuos de plaguicidas en alimentos.

¹⁰ Codex Pesticides Database.

residue definition (European Commission, 2018). Thus, even though the residue data set leads to a higher value, the MRL for lufenuron should not exceed the 0.05 mg/kg, to align with the tolerance established in Brazil. However, since the existing EU MRL for lufenuron in coffee beans is set at 0.07 mg/kg, a modification of the existing MRL in coffee beans is not required.

Sugar canes

Authorised GAP in Brazil: 2 appl. × 20 g a.s./ha, PHI: 14 days

Sugar canes are minor crops worldwide for which at least four GAP compliant residue trials need to be submitted (European Commission, 2017). In support of the authorised use on sugar canes in Brazil, the applicant submitted four residue trials on sugar canes, which were performed in Brazil over the growing seasons of 2007 and 2008. The trials were compliant with the authorised GAP.

Based on the above, the number of submitted trials is sufficient to derive an MRL proposal of 0.04 mg/kg for lufenuron in sugar canes. The tolerance of lufenuron in Brazil for sugar canes is set at a lower level of 0.02 mg/kg¹⁰. According to the Technical Guidelines on the MRL setting procedure SANTE/2015/10595 Rev.5.4., the MRL proposal for import tolerance requests should not exceed the MRL approved in the exporting country, taking into account possible differences in the residue definition (European Commission, 2018). Therefore, additional risk management considerations are required to decide whether modification of the MRL is appropriate considering that the MRL in the country of origin is significantly lower than the MRL proposal derived from the residue trials.

1.2.2. Magnitude of residues in rotational crops

Investigations on the magnitude of residues in rotational crops are not required for imported crops.

1.2.3. Magnitude of residues in processed commodities

Studies investigating the effect of processing on the magnitude of residues of lufenuron were assessed in the framework of the peer review and the MRL review (EFSA, 2009, 2017).

Additional data from processing studies with citrus fruits were submitted by the applicant in the current application (Portugal, 2019). Oranges were treated at five times higher rate of application than the one in the authorised GAP (18.8 g a.s./hL instead of 3.75 g a.s./hL) and samples were taken at a PHI of 28 days which corresponds to the one of the GAP. The fruits were processed into juice, dried pulp and orange oil. Results indicate that reduction of residues occurs in juice and dried pulp whereas a concentration of residues is observed in orange oil. Based on these data, processing factors were derived for orange juice, dry pulp and oil, which are proposed for the inclusion in Annex VI of Regulation (EC) No 396/2005. An overview of the study results is resumed in Table B.1.2.3 in Appendix B.

1.2.4. Proposed MRLs

The available residue trials are sufficient to derive MRL proposals for all crops under consideration. For oranges, limes, pome fruits, peppers and coffee beans, the submitted residue data indicated no need to modify the existing EU MRL. For grapefruits and sugar cane, the residue data indicated that a higher MRL would be needed.

In Section 3, EFSA assessed whether residues of lufenuron on these crops resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

Among the crops under assessment, citrus fruit, apple and sugar cane by-products can be used for feed purposes. Since import of these commodities in Europe is applied for, these crops or their by-products can enter the EU livestock feed chain. Hence, it was necessary to update the previous dietary burden calculation for livestock (EFSA, 2019b) to estimate whether the residues of lufenuron in imported citrus fruits, apples, sugar canes and their by-products would have an impact on the levels of residues expected in food of animal origin.

The input values for the exposure calculations for livestock are presented in Appendix D.1.

The results of the dietary burden calculation presented in Appendix B.2. showed that the exposure to lufenuron residues exceeds the trigger value of 0.1 mg/kg DM in all species. However, the calculated dietary burdens are significantly lower than the dietary burdens calculated for EU and

Australian beef and dairy cattle by the JMPR (FAO, 2018), based on which the existing EU MRLs are currently set.¹¹

In the framework of the present assessment, the applicant applied for MRLs in commodities of animal origin which are equal to the existing EU MRLs for lufenuron for all products except muscle. This may be explained by the fact that the current application (2018) was submitted before the implementation of the higher Codex MRLs for lufenuron in animal commodities by Commission Regulation (EU) 2020/856 (EFSA, 2019b). The applicant's higher MRL proposal on bovine, swine, sheep, goat and equine muscle coincides with the proposal for mammalian meat by the JMPR (FAO, 2018). On the basis of the JMPR evaluation, for muscle, a lower MRL was implemented in the EU Regulation as, at EU level, MRLs are established only for muscle (without fat) and not meat (muscle with fat) as done according to the JMPR.

EFSA concluded that the existing EU MRLs for lufenuron in animal commodities are sufficient to account for additional lufenuron residues from the intake of treated imported crops. Thus, in the framework of the current assessment, the nature and magnitude of lufenuron residues in animal commodities was not investigated further. EFSA notes that lufenuron is authorised for the uses as a veterinary drug in fin fish, for which an MRL of 1.35 mg/kg is currently established by Regulation (EU) No 967/2014.¹²

In the framework of the current assessment, EFSA requested a method validation package and internal laboratory validation (ILV) data for the monitoring of lufenuron residues in liver and kidney. The EMS submitted the requested information in a revised evaluation report (Portugal, 2019). Analysis of residues of lufenuron is performed by HPLC-MS/MS. The validated LOQ is at the level of 0.01 mg/kg in both commodities. No confirmatory method was needed as the method is highly selective. EFSA concluded that the analytical method can be considered to be fully validated as enforcement method in terms of specificity, linearity, accuracy and precision based on the provisions of the SANCO/825/00 rev 8.1 guidance document (European Commission, 2010b).

It is noted that the available method for the monitoring of residues of lufenuron in liver and kidney is also appropriate for poultry liver and kidney for which footnotes on an analytical method requirement are attached in Regulation (EU) 2020/856. Based on the current evaluation, the data gap identified for poultry liver and kidney in the framework of the MRL review has been addressed and the corresponding footnotes can be deleted.

3. Consumer risk assessment

EFSA performed a dietary risk assessment for the agreed residue definitions for risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018, EFSA, 2019a). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The input values used in the exposure calculations are summarised in Appendix D.2.

Short-term (acute) dietary risk assessment

Acute exposure calculations were not carried out for lufenuron as an acute reference dose (ARfD) was not deemed necessary to be derived for the active substance.

Long-term (chronic) dietary risk assessment

Lufenuron is an equimolar mixture of the *R*- and *S*-isomer with a chiral centre at the 2-position of the hexafluoropropoxy side chain. The toxicological studies submitted in the framework of the EU pesticide peer review (EFSA, 2009) which were performed with the isomer mixture allowed to derive an acceptable daily intake (ADI) of 0.015 mg/kg bw per day.

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level and the acceptable CXLs (EFSA, 2017). EFSA updated the calculation with the relevant STMR values in the crops under consideration as

¹¹ Commission Regulation (EU) 2020/856 of 9 June 2020 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyantraniliprole, cyazofamid, cyprodinil, fenpyroximate, fludioxonil, fluxapyroxad, imazalil, isofetamid, kresoxim-methyl, lufenuron, mandipropamid, propamocarb, pyraclostrobin, pyriofenone, pyriproxyfen and spinetoram in or on certain products. OJ L 195, 19.6.2020, p. 9–51.

¹² 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.

derived from the residue trials submitted in support of this MRL application (Portugal, 2019). In addition, STMR values were integrated in the risk assessment that are related to the Codex MRLs taken over to Regulation (EU) 2020/856. Food commodities for which no GAP was reported in the framework of the MRL review (EFSA, 2017) and for which no Codex MRLs were included in the EU MRL legislation were not included in the exposure calculation.

The estimated long-term exposure to lufenuron residues accounted for up to 84% of the ADI (NL toddler). The contribution of residues expected in (i) milk (cattle) is up to 47% of the ADI, (ii) apples are up to 25% of the ADI, (iii) pears are up to 8.7% of the ADI, (iv) oranges are up to 2.4% of the ADI, (v) bovine muscle is up to 7.2% of the ADI, (vi) swine muscle is up to 3.7% of the ADI, (vii) swine fat is up to 1.9% of the ADI and (viii) for all other assessed crops is less than 1% of the ADI. EFSA estimates that the chronic exposure to lufenuron resulting from pesticide use is likely to be 84% of the ADI. The contribution of residues in the crops for which the raising of the lufenuron MRLs is proposed under the current assessment – grapefruit and sugar canes – individually accounts for less than 1% of the ADI.

The risk assessment is affected by additional, non-standard uncertainties resulting from the lack of the following information:

- Detailed information on the possible preferential degradation of one of the enantiomers present in the active substance (R/S-enantiomer) leading to a shift of the isomer ratio in treated crops compared to the isomer ratio in the parent compound applied to the crops;
- Information on toxicological profile of the individual enantiomers, compared to the toxicological profile of the isomer mixture.

It was 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. This introduces an additional uncertainty in the exposure assessment for lufenuron as the consumption of fin fish could not be taken into account in the exposure calculation due to the lack of data from food surveys performed according to the current standard.

Based on the consumer exposure assessment, EFSA concluded that the exposure related to the existing MRLs and proposed modifications for lufenuron MRLs will not result in long-term exposure exceeding the toxicological reference value (ADI) established for lufenuron. Considering, however, that the estimated exposure is close to the ADI and in the light of the expiry of the approval of the active substance, EFSA recommends the review of the existing MRLs taking into account that the MRLs based on the EU uses will become obsolete.

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

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive MRL proposals for all crops under assessment on the basis of the authorised uses of lufenuron in Brazil, Chile and Morocco. For oranges, limes, pome fruits, peppers and coffee beans, the submitted residue data indicated no need to modify the existing EU MRL. For sugar canes, although residue data indicated a higher MRL would be needed, additional risk management considerations are required to decide whether modification of the MRL is appropriate considering that the MRL in the country of origin is significantly lower than the MRL proposal derived from the residue trials.

The livestock exposure to lufenuron residues from the intake of citrus fruits, apples and sugar canes treated according to authorised uses would not require modification of the existing EU MRLs for lufenuron in commodities of animal origin. It is noted that the available method for the monitoring of residues of lufenuron in liver and kidney is also appropriate for poultry liver and kidney for which footnotes on an analytical method requirement are attached in Regulation (EU) 2020/856. Based on the current evaluation, the data gap identified for poultry liver and kidney in the framework of the MRL review has been addressed and the corresponding footnotes can be deleted.

EFSA updated the most recent consumer risk assessment for lufenuron and concluded that the residues of lufenuron in crops from the authorised uses of lufenuron in Brazil, Chile and Morocco will not result in chronic consumer exposure exceeding the toxicological reference value (84% of the ADI). The contribution of residues in the crops for which the raising of the lufenuron MRLs is proposed under the current assessment – grapefruit and sugar canes – individually accounts for less than 1% of the ADI.

The risk assessment is affected by additional non-standard uncertainties related to the lack of information on the toxicity/occurrence of the individual isomers, to the additional exposure to lufenuron residues from fin fish and the forthcoming revision of the MRLs for the EU uses following the expiry of the approval of the active substance.

Based on the consumer exposure assessment, EFSA concludes that the existing EU uses and the authorised uses of lufenuron in Brazil, Chile and Morocco will not result in chronic consumer exposure exceeding the toxicological reference value (84% of the ADI). Considering, however, that the estimated exposure is close to the ADI and in the light of the expiry of the approval of the active substance EFSA recommends the review of the existing MRLs taking into account that the MRLs based on the EU uses will become obsolete.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

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
CAS	Chemical Abstract Service
CCPR	Codex Committee on Pesticide Residues
CF	conversion factor for enforcement to risk assessment residue definition
CIRCA	(EU) Communication & Information Resource Centre Administrator
CV	coefficient of variation (relative standard deviation)
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DP	dustable powder
DS	powder for dry seed treatment
EC	emulsifiable concentrate
EDI	estimated daily intake
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC	gas chromatography
GC-MS	gas chromatography with mass spectrometry
GC-MS/MS	gas chromatography with tandem mass spectrometry
GS	growth stage
HPLC	high-performance liquid chromatography
HPLC-MS	high-performance liquid chromatography with mass spectrometry
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 Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rappporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe
SL	soluble concentrate
SP	water-soluble powder
STMR	supervised trials median residue
TAR	total applied radioactivity
TRR	total radioactive residue
UV	ultraviolet (detector)
WG	water-dispersible granule
WHO	World Health Organization

Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

Crop and/or situation	NEU, SEU, MS or country	F G or I ^(a)	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days) ^(d)	Remarks	
				Type ^(b)	Conc. a.s.	method kind	range of growth stages & season ^(c)	number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate			Unit
Limes	Brazil	F	Phyllocoptruta oleivora, Ecdytolopha aurantiana	EC	50 g/L	Foliar treatment – broadcast spraying	n.a.	1			10 L/ plant	3.75	g a.i./hL	28	Application at the start of infestation
Oranges	Brazil	F	Phyllocoptruta oleivora, Ecdytolopha aurantiana	EC	50 g/L	Foliar treatment – broadcast spraying	n.a.	1			10 L/ plant	3.75	g a.i./hL	28	Application at the start of infestation
Grapefruits	Brazil	F	Phyllocoptruta oleivora, Ecdytolopha aurantiana	EC	50 g/L	Foliar treatment – broadcast spraying	n.a.	1			10 L/ plant	3.75	g a.i./hL	28	Application at the start of infestation
Sugar canes	Brazil	F	Diatraea saccharalis	EC	50 g/L	Foliar treatment – broadcast spraying	n.a.	2	14		200 L/ha	20	g a.i./ha	14	Application at the start of infestation
Coffee beans	Brazil	F	Leucoptera coffeella., Olygonichus ilicis	EC	50 g/L	Foliar treatment – broadcast spraying	n.a.	2	30		400 L/ha	40	g a.i./ha	7	Application at the start of infestation
Apples	Chile	F	Cydia pomonella	EC	50 g/L	Foliar treatment – broadcast spraying	n.a.	3	10		2000–4500 L/ha	225	g a.i./ha	18	Application at the start of infestation
Pears	Chile	F	Cydia pomonella	EC	50 g/L	Foliar treatment – broadcast spraying	n.a.	3	10		2000–4500 L/ha	225	g a.i./ha	18	Application at the start of infestation
Quinces	Chile	F	Cydia pomonella	EC	50 g/L	Foliar treatment – broadcast spraying	n.a.	3	10		2000–4500 L/ha	225	g a.i./ha	18	Application at the start of infestation

Crop and/or situation	NEU, SEU, MS or country	F G or I ^(a)	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days) ^(d)	Remarks	
				Type ^(b)	Conc. a.s.	method kind	range of growth stages & season ^(c)	number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate			Unit
Medlar	Chile	F	Cydia pomonella	EC	50 g/L	Foliar treatment – broadcast spraying	n.a.	3	10		2000–4500 L/ha	225	g a.i./ha	18	Application at the start of infestation
Loquats/ Japanese medlars	Chile	F	Cydia pomonella	EC	50 g/L	Foliar treatment – broadcast spraying	n.a.	3	10		2000–4500 L/ha	225	g a.i./ha	18	Application at the start of infestation
Other pome fruit	Chile	F	Cydia pomonella	EC	50 g/L	Foliar treatment – broadcast spraying	n.a.	3	10		2000–4500 L/ha	225	g a.i./ha	18	Application at the start of infestation
Sweet peppers/ bell peppers	Morocco	I	Thrips	WG	40% (w/w)	Foliar treatment – broadcast spraying	n.a.	3	7		500–1000 L/ha	100	g a.i./ha	3	Application at the start of infestation

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; a.i.: active ingredient; EC: emulsifiable concentrate; WG: water dispersible granules; n.a.: not applicable.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).

(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI – minimum preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

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

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

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

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)
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	<p>HPLC–MS/MS (EURLs, 2016; EFSA, 2017):</p> <ul style="list-style-type: none"> • 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 <p>LOQ: 0.01 mg/kg</p>

DAT: days after treatment; a.s.: active substance; PBI: plant-back interval; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method); LOQ: limit of quantification.

B.1.1.2. Storage stability of residues in plants

Plant products (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/ Source
				Value	Unit		
	High water content	Cabbage	–18	24	months	Lufenuron (any ratio of constituent isomers)	EFSA (2009)
	High oil content	Cotton seed	–18	24	months	Lufenuron (any ratio of constituent isomers)	EFSA (2009)
	High acid content	Orange	–18	24	months	Lufenuron (any ratio of constituent isomers)	EFSA (2009)

B.1.2. Magnitude of residues in plants

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

Commodity	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
Oranges, grapefruits	Brazil	2 × 0.05; 0.07; 3 × 0.09; 0.11; 0.15	Residue trials on oranges compliant with the GAP. Extrapolation to grapefruits possible. The existing EU MRL in oranges is set at 0.3 mg/ kg	0.3	0.15	0.09	–
Limes	Brazil	2 × 0.09; 0.10; 0.17	Residue trials on limes compliant with the GAP. The existing EU MRL in limes is set at 0.4 mg/kg.	0.4	0.17	0.10	–
Pome fruits	Chile	0.20; 2 × 0.27; 0.29; 2 × 0.30; 0.35; 0.43	Residue trials on apples compliant with the GAP. Extrapolation to the whole group of pome fruits possible. The existing EU MRL in pome fruits is set at a higher level of 1 mg/kg.	0.9	0.43	0.3	–
Peppers (sweet)	Spain/Indoor	0.06; 0.09; 0.10; 0.13; 0.17; 2 × 0.18; 0.54	Residue trials on sweet peppers performed in Spain in support of the uses in Morocco compliant with the GAP.	0.8	0.54	0.15	–
Coffee beans	Brazil	3 × < 0.01; 2 × 0.01; 2 × 0.03; 0.04	Residue trials on coffee beans compliant with the GAP. The existing EU MRL in coffee beans is set at 0.07 mg/kg.	0.07	0.04	0.01	–
Sugar canes	Brazil	< 0.01; 3 × < 0.016	Residue trials on sugar cane compliant with the GAP.	0.04	0.02	0.02	–

MRL: maximum residue level; GAP: Good Agricultural Practice.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.

(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.

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

(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	No significant residues are expected	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)
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	Not available and not required

a.s.: active substance.

B.1.2.3. Processing factors

Processed commodity	Number of valid studies ^(a)	Processing Factor (PF)		CF _p ^(b)	Comment/Source
		Individual values	Median PF		
Orange, juice	2	< 0.02; < 0.04	< 0.03	–	Portugal (2019)
Orange, peel	2	1.4; 2.0	1.7	–	Portugal (2019)
Orange, dry pulp	2	0.11; 0.18	0.15	–	Portugal (2019)
Orange, oil	2	19; 29	24	–	Portugal (2019)

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

(b): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial.

B.2. Residues in livestock

Dietary burden calculation according to OECD, 2013.

Relevant groups (sub groups)	Dietary burden expressed in				Most critical sub group ^(a)	Most critical commodity ^(b)	Trigger exceeded (Y/N)	Previous assessment (FAO, 2018; EFSA, 2019b)
	mg/kg bw per day		mg/kg DM					
	Median	Maximum	Median	Maximum				
Cattle (all)	0.017	0.017	0.72	0.72	Beef cattle	Apple pomace, wet	Y	1.17
Cattle (dairy only)	0.014	0.014	0.37	0.37	Dairy cattle	Apple pomace, wet	Y	0.6
Sheep (all)	0.015	0.015	0.37	0.37	Lamb	Apple pomace, wet	Y	1.17
Sheep (ewe only)	0.012	0.012	0.37	0.37	Ram/Ewe	Apple pomace, wet	Y	0.6
Swine (all)	0.001	0.001	0.04	0.04	Swine (breeding)	Potato process waste	N	1.17
Poultry (all)	0.001	0.001	0.01	0.01	Turkey	Potato culls	N	0.013
Poultry (layer only)	0.000	0.000	0.01	0.01	Poultry layer	Potato culls	N	0.013

bw: body weight; DM: dry matter.

(a): When one group of livestock includes several subgroups (e.g. poultry 'all' including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

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

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

Livestock (available studies)	Animal	Dose (mg/kg bw per d)	Duration (days)	Comment/Source
	Laying hen	0.21–0.33	14	21N rate 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 (Portugal, 2006)
	Lactating ruminants	0.15–0.17	10	Lactating goat 1.3N/compared to beef cattle, 2N/compared to dairy cattle. 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 (Portugal, 2006)

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	
Can a general residue definition be proposed for animals?	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)	
Fat soluble residues	Yes	
Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs)	<p>HPLC–MS/MS (Portugal, 2006):</p> <ul style="list-style-type: none"> • Method validated in muscle, fat, milk and eggs • ILV available • LOQ: 0.02 mg/kg <p>HPLC–MS/MS (Portugal, 2019):</p> <ul style="list-style-type: none"> • QuEChERS-method validated in liver and kidney • ILV available • LOQ: 0.01 mg/kg 	

HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; ILV: independent laboratory validation
 QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method); LOQ: limit of quantification.

B.2.1.2. Stability of residues in livestock

Animal products (available studies)	Animal	Commodity	T (°C)	Stability period		Compounds covered	Comment/ Source
				Value	Unit		
	Beef	Muscle	-18	9	months	Parent	EFSA (2009)
	Beef	Fat	-18	9	months	Parent	EFSA (2009)
	Beef	Liver	-18	9	months	Parent	EFSA (2009)
	Beef	Kidney	-18	9	months	Parent	EFSA (2009)
	Cow	Milk	-18	9	months	Parent	EFSA (2009)

B.2.2. Magnitude of residues in livestock

The magnitude of residues in livestock is covered by the 2018 assessment by JMPR where higher dietary burdens were estimated. Thus, in the framework of the current assessment, the magnitude of lufenuron residues in livestock was not investigated further.

B.3. Consumer risk assessment

Acute risk assessment not relevant. The derivation of an ARfD has not been considered necessary.

ARfD

Not deemed necessary (EFSA, 2009)

Highest IESTI, according to EFSA PRIMo

Not relevant

Assumptions made for the calculations

Not relevant

ADI

0.015 mg/kg bw per day (EFSA, 2009)

Highest IEDI, according to EFSA PRIMo

From pesticide use: 84% of the ADI (NL toddler)

Contribution of the commodities assessed:

Milk (cattle): 47% of the ADI

Apples: 25% of the ADI

Pears: 8.7% of the ADI

Oranges: 2.4% of the ADI

Bovine muscle: 7.2% of the ADI

Swine muscle: 3.7% of the ADI

Swine fat: 1.9% of the ADI

Other terrestrial animal muscle: 1.9% of the ADI

All other commodities assessed: < 1% of the ADI

Assumptions made for the calculations

The calculation is performed using PRIMo version 3.1. The calculation is based on the median residue (STMR) levels derived for the crops under consideration from the submitted residue trials. For the remaining commodities, the input values were as reported in the MRL review and previous EFSA and JMPR assessments (EFSA, 2009, 2016, 2017, 2019b, FAO, 2015, 2018). The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation.

It was 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. The consumption of fin fish could not be taken into account in the exposure calculation due to the lack of data from food surveys performed according to the current standard

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; STMR: supervised trials median residue; MRL: maximum residue level; GAP: Good Agricultural Practice.

B.4. Recommended MRLs

Code ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Lufenuron (any ratio of constituent isomers) ^(F)				
110010	Grapefruits	0.01*	0.3	The submitted data are sufficient to derive an import tolerance based on the authorised GAP in Brazil. The Brazilian MRL is set at 0.5 mg/kg Risk for consumers unlikely
110020	Oranges	0.3	No change	The submitted data do not provide evidence that the existing MRL has to be modified
110040	Limes	0.4	No change	The submitted data do not provide evidence that the existing MRL has to be modified
130000	Pome fruits	1.0	No change	The submitted data do not provide evidence that the existing MRL has to be modified
231020	Sweet peppers/ bell peppers	0.8	No change	The submitted data do not provide evidence that the existing MRL has to be modified
620000	Coffee beans	0.07	No change	The submitted data do not provide evidence that the existing MRL has to be modified
900020	Sugar canes	0.01*	Further risk management considerations required	The submitted data are sufficient to derive an MRL proposal of 0.04 mg/kg for the authorised GAP in Brazil. The Brazilian MRL is set at 0.02 mg/kg Further risk management considerations are required to decide whether modification of the MRL is appropriate considering that the MRL in the country of origin is significantly lower than the MRL proposal derived from the residue trials
1011010 1012010 1013010 1014010 1015010	Swine, Bovine, Sheep, Goat, Horse: muscle	0.08	No change	The submitted data do not provide evidence that the existing MRL has to be modified
1011020 1012020 1013020 1014020 1015020	Swine, Bovine, Sheep, Goat, Horse: fat	2	No change	The submitted data do not provide evidence that the existing MRL has to be modified
1011030 1012030 1013030 1014030 1015030	Swine, Bovine, Sheep, Goat, Horse: liver	0.15	No change	The submitted data do not provide evidence that the existing MRL has to be modified
1011040 1012040 1013040 1014040 1015040	Swine, Bovine, Sheep, Goat, Horse: kidney	0.15	No change	The submitted data do not provide evidence that the existing MRL has to be modified
1020000	Milk	0.15	No change	The submitted data do not provide evidence that the existing MRL has to be modified

MRL: maximum residue level; GAP: Good Agricultural Practice.

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

(F): Fat soluble.

Appendix C – Pesticide Residue Intake Model (PRIMo)



Lufenuron (F)			
LOQs (mg/kg) range from:	0.01	to:	0.30
Toxicological reference values			
ADI (mg/kg bw per day):	0.015	ARID (mg/kg bw):	not necessary
Source of ADI:	Dir 09/77	Source of ARID:	
Year of evaluation:	2009	Year of evaluation:	

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

Comments:											
Refined calculation mode											
Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
No of diets exceeding the ADI :										Exposure resulting from	
TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)		Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
	MS Diet										
	84%	NL toddler	12.57	47%	Milk: Cattle	22%	Apples	9%	Pears	0.5%	84%
	48%	DE child	7.13	25%	Apples	15%	Milk: Cattle	2%	Oranges	0.0%	48%
	39%	NL child	5.88	19%	Milk: Cattle	12%	Apples	2%	Pears	0.0%	39%
	37%	UK infant	5.62	30%	Milk: Cattle	3%	Apples	2%	Bovine: Muscle/meat	0.1%	37%
	36%	FR toddler 2-3 yr	5.41	23%	Milk: Cattle	6%	Apples	2%	Bovine: Muscle/meat	0.0%	36%
	31%	FR child 3-15 yr	4.70	18%	Milk: Cattle	3%	Apples	2%	Bovine: Muscle/meat	0.0%	31%
	25%	UK toddler	3.72	18%	Milk: Cattle	3%	Apples	2%	Bovine: Muscle/meat	0.0%	25%
	23%	DK child	3.48	16%	Milk: Cattle	5%	Apples	4%	Swine: Muscle/meat	0.0%	23%
	22%	SE general	3.23	10%	Milk: Cattle	7%	Bovine: Muscle/meat	2%	Apples	0.0%	22%
	21%	ES child	3.21	10%	Milk: Cattle	2%	Bovine: Muscle/meat	2%	Apples	0.0%	21%
	20%	DE women 14-50 yr	3.02	10%	Milk: Cattle	5%	Apples	1%	Swine: Muscle/meat	0.0%	20%
	20%	DE general	3.01	10%	Milk: Cattle	5%	Apples	2%	Swine: Muscle/meat	0.0%	20%
	19%	FR infant	2.84	13%	Milk: Cattle	3%	Apples	0.6%	Swine: Muscle/meat	0.0%	19%
	18%	GEMS/Food G11	2.63	6%	Milk: Cattle	3%	Apples	2%	Swine: Muscle/meat	0.0%	18%
	17%	RO general	2.60	9%	Milk: Cattle	3%	Apples	2%	Swine: Muscle/meat	0.1%	17%
	17%	GEMS/Food G15	2.52	5%	Milk: Cattle	2%	Swine: Muscle/meat	2%	Apples	0.1%	17%
	15%	GEMS/Food G08	2.32	4%	Milk: Cattle	3%	Swine: Muscle/meat	2%	Apples	0.0%	15%
	15%	GEMS/Food G07	2.24	5%	Milk: Cattle	2%	Apples	2%	Swine: Muscle/meat	0.0%	15%
	14%	NL general	2.16	7%	Milk: Cattle	3%	Apples	2%	Swine: Muscle/meat	0.0%	14%
	13%	GEMS/Food G10	1.98	4%	Milk: Cattle	2%	Apples	1%	Bovine: Muscle/meat	0.1%	13%
	12%	IE adult	1.80	3%	Milk: Cattle	2%	Other farmed animals: Muscle/meat	1%	Apples	0.0%	12%
	12%	DK adult	1.78	4%	Milk: Cattle	2%	Apples	1%	Swine: Muscle/meat	0.0%	12%
	11%	ES adult	1.71	4%	Milk: Cattle	2%	Apples	1%	Bovine: Muscle/meat	0.0%	11%
	11%	LT adult	1.63	4%	Apples	3%	Milk: Cattle	2%	Swine: Muscle/meat	0.0%	11%
	10%	GEMS/Food G06	1.52	2%	Milk: Cattle	2%	Tomatoes	2%	Apples	0.1%	10%
	9%	FR adult	1.41	4%	Milk: Cattle	2%	Apples	1%	Swine: Muscle/meat	0.0%	9%
	6%	PL general	0.83	4%	Apples	0.6%	Pears	0.5%	Tomatoes	0.0%	6%
	6%	UK adult	0.83	2%	Milk: Cattle	1%	Bovine: Muscle/meat	0.8%	Apples	0.0%	6%
	5%	UK vegetarian	0.79	3%	Milk: Cattle	1%	Apples	0.5%	Oranges	0.0%	5%
	5%	IE child	0.76	3%	Milk: Cattle	1.0%	Swine: Fat tissue	0.7%	Apples	0.0%	5%
	5%	PT general	0.69	2%	Apples	0.7%	Pears	0.5%	Tomatoes	0.0%	5%
	4%	IT toddler	0.59	2%	Apples	0.8%	Tomatoes	0.7%	Pears	0.0%	4%
	3%	FI 3 yr	0.52	2%	Apples	0.4%	Pears	0.3%	Potatoes	0.0%	3%
	3%	IT adult	0.50	2%	Apples	0.6%	Tomatoes	0.5%	Pears	0.0%	3%
	3%	FI 6 yr	0.38	1%	Apples	0.4%	Pears	0.3%	Potatoes	0.0%	3%
	2%	FI adult	0.37	1%	Apples	0.4%	Coffee beans	0.3%	Tomatoes	0.0%	2%

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

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

As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

Show results for all crops

Unprocessed commodities	Results for children				Results for adults											
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				---				No. of commodities for which ARfD/ADI is exceeded (IESTI):				---			
	IESTI				IESTI											
	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)								
Expand/collapse list																
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)																

Processed commodities	Results for children				Results for adults											
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				---				No of processed commodities for which ARfD/ADI is exceeded (IESTI):				---			
	IESTI				IESTI											
	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)								
Expand/collapse list																

Conclusion:

Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Lufenuron (any ratio of constituent isomers)				
Citrus, dried pulp	0.02	STMR × PF (= 0.2)	0.02	STMR × PF (= 0.2)
Apples, wet pomace	1.41	STMR × PF (= 4.7) ^(a)	1.41	STMR × PF (= 4.7) ^(a)
Sugar cane, molasses	0.64	STMR × PF (= 32) ^(a)	0.64	STMR × PF (= 32) ^(a)
Potato, culls	0.01	STMR	0.01	HR
Potato, process waste	0.01	STMR ^(b)	0.01	STMR ^(b)
Potato, dried pulp	0.01	STMR ^(b)	0.01	STMR ^(b)

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

(a): For fruit pomace and sugar cane molasses in the absence of processing factors supported by data, default processing factors of 4.7 and 32, respectively, were included in the calculation to consider the potential concentration of residues in these commodities.

(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.

D.2. Consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Grapefruits	0.09	STMR	Not relevant and not performed	
Oranges	0.09	STMR		
Limes	0.10	STMR		
Pome fruits	0.30	STMR		
Sweet peppers/bell peppers	0.15	STMR		
Coffee beans	0.01	STMR		
Sugar canes	0.02	STMR		
Lemons	0.01	STMR (EFSA, 2017)		
Mandarins	0.01	STMR (EFSA, 2017)		
Apricots	0.03	STMR (tentative) (EFSA, 2017)		
Cherries (sweet)	0.01	STMR (EFSA, 2017)		
Peaches	0.03	STMR (tentative) (EFSA, 2017)		
Plums	0.01	STMR (EFSA, 2017)		
Table grapes	0.01	STMR (EFSA, 2017)		
Wine grapes	0.01	STMR (EFSA, 2017)		
Azarole/Mediterranean medlar	0.29	STMR (EFSA, 2017)		
Figs	0.01	STMR (EFSA, 2017)		
Kaki/Japanese persimmons	0.29	STMR (EFSA, 2017)		
Kiwi fruits	0.01	STMR (EFSA, 2017)		
Potatoes	0.01	STMR (EFSA, 2017)		
Tomatoes	0.08	STMR (FAO, 2015; EFSA, 2016)		
Aubergines/eggplants	0.07	STMR (EFSA, 2017)		
Cucumbers	0.03	STMR (EFSA, 2017)		
Gherkins	0.15	EU MRL		
Courgettes	0.03	STMR (EFSA, 2017)		
Melons	0.04	STMR × PF (EFSA, 2017)		
Pumpkins	0.04	STMR × PF (EFSA, 2017)		

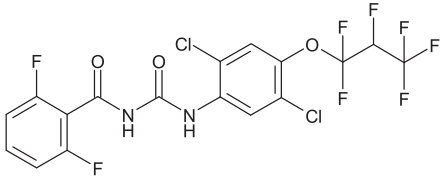
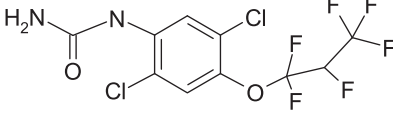
Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Watermelons	0.04	STMR × PF (EFSA, 2017)		
Lamb's lettuces/corn salads	0.01*	EU MRL		
Lettuces	0.01*	EU MRL		
Escaroles/broad-leaved endives	0.01*	EU MRL		
Cresses and other sprouts and shoots	0.01*	EU MRL		
Land cresses	0.01*	EU MRL		
Roman rocket/rucola	0.01*	EU MRL		
Red mustards	0.01*	EU MRL		
Baby leaf crops (including brassica species)	0.01*	EU MRL		
Soya bean	0.01	STMR (FAO, 2015; EFSA, 2016)		
Swine muscle ^(a)	0.25	STMR (FAO, 2018; EFSA, 2019b)		
Swine fat tissue	1.07	STMR (FAO, 2018; EFSA, 2019b)		
Swine liver	0.09	STMR (FAO, 2018; EFSA, 2019b)		
Swine kidney	0.05	STMR (FAO, 2018; EFSA, 2019b)		
Bovine muscle ^(a)	0.25	STMR (FAO, 2018; EFSA, 2019b)		
Bovine fat	1.07	STMR (FAO, 2018; EFSA, 2019b)		
Bovine liver	0.09	STMR (FAO, 2018; EFSA, 2019b)		
Bovine kidney	0.05	STMR (FAO, 2018; EFSA, 2019b)		
Sheep muscle ^(a)	0.25	STMR (FAO, 2018; EFSA, 2019b)		
Sheep fat tissue	1.07	STMR (FAO, 2018; EFSA, 2019b)		
Sheep liver	0.09	STMR (FAO, 2018; EFSA, 2019b)		
Sheep kidney	0.05	STMR (FAO, 2018; EFSA, 2019b)		
Goat muscle ^(a)	0.25	STMR (FAO, 2018; EFSA, 2019b)		
Goat fat tissue	1.07	STMR (FAO, 2018; EFSA, 2019b)		
Goat liver	0.09	STMR (FAO, 2018; EFSA, 2019b)		
Goat kidney	0.05	STMR (FAO, 2018; EFSA, 2019b)		
Equine muscle ^(a)	0.25	STMR (FAO, 2018; EFSA, 2019b)		
Equine fat	1.07	STMR (FAO, 2018; EFSA, 2019b)		
Equine liver	0.09	STMR (FAO, 2018; EFSA, 2019b)		
Equine kidney	0.05	STMR (FAO, 2018; EFSA, 2019b)		
Poultry muscle ^(a)	0.02	STMR (FAO, 2018; EFSA, 2019b)		
Poultry fat tissue	0.03	STMR (FAO, 2018; EFSA, 2019b)		
Poultry liver	0.02	STMR (FAO, 2018; EFSA, 2019b)		
Cattle milk	1.12	STMR (FAO, 2018; EFSA, 2019b)		
Sheep milk	1.12	STMR (FAO, 2018; EFSA, 2019b)		
Goat milk	1.12	STMR (FAO, 2018; EFSA, 2019b)		
Horse milk	1.12	STMR (FAO, 2018; EFSA, 2019b)		
Birds eggs	0.02	STMR (FAO, 2015; EFSA, 2016)		

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

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).

(a): Consumption figures in the EFSA PRIMo are expressed as meat. Since the a.s. is a fat-soluble pesticides, STMR and HR residue values were calculated considering a 80%/90% muscle and 20%/10% fat content for mammal/poultry meat, respectively (FAO, 2016).

Appendix E – Used compound codes

Code/ trivial name	IUPAC name/SMILES notation/InChiKey ^{(a),(b)}	Structural formula ^(b)
lufenuron	(<i>RS</i>)-1-[2,5-dichloro-4-(1,1,2,3,3,3 hexafluoropropoxy) phenyl]-3-(2,6-difluorobenzoyl)urea Clc1 cc(NC(=O)NC(=O)c2c(F)cccc2F)c(Cl)cc1OC(F)(F)C(F)C(F)(F)F PWPJGUXAGUPAHP-LKHHGCMNA-N	
CGA 238277	urea, <i>N</i> -[2,5-dichloro-4-(1,1,2,3,3,3-hexafluoropropoxy) phenyl] Clc1 cc(NC(N) = O)c(Cl)cc1OC(F)(F)C(F)C(F)(F)F GCOYQBALNHRFMV-BUKGPZPNNA-N	

(a): ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 July 2019).

(b): ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 July 2019).