REASONED OPINION

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

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Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance fenoxycarb. To assess the occurrence of fenoxycarb residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC as well as the European authorisations reported by Member States (including the supporting residues data). 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: fenoxycarb, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, carbamate, insecticide

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Summary

Fenoxycarb was included in Annex I to Directive 91/414/EEC on 1 June 2011 by Commission Directive 2011/20/EU, 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 the Netherlands, the designated 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 11 April 2017 and finalised on 9 June 2017. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 9 August 2017.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional information provided by the RMS and Member States, EFSA prepared in November 2017 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 5 December 2017 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of fenoxycarb has been assessed in fruit crops (oranges and apples) following soil, local and foliar spray applications. Based on the metabolism in primary crops, the residue definition for monitoring and risk assessment can be proposed as fenoxycarb only. This residue definition is limited to fruit crops only. The same residue definition applies to processed commodities. A specific residue definition for rotational crops is not deemed necessary considering the very limited persistence of fenoxycarb in the soil. Fully validated analytical methods are available to enforce the proposed residue definition in high acid, high water and high fat content commodities at the limit of quantification (LOQ) of 0.02 mg/kg. Moreover, according to the information provided by the EURLs, a lower LOQ of 0.01 mg/kg is achievable by routine analyses in high acid, high water, high fat content and dry commodities.

Regarding the magnitude of residues in primary crops, the available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for oranges, lemons, mandarins and apricots where the available data were insufficient to derive MRLs. Tentative MRLs were derived for table olives.

Fenoxycarb is authorised for use on apples and apples pomace might be fed to livestock. Livestock dietary burdens were therefore calculated and the dietary burdens calculated for cattle and sheep were found to exceed the trigger value of 0.1 mg/kg DM. The nature of fenoxycarb residues in commodities of animal origin was investigated in lactating goats and in laying hens. Based on the results of the available studies, metabolite CGA 294850 and its conjugates should in principle be included in the residue definition. Nevertheless, according to the metabolism studies, after exposure to the maximum dietary burden calculated for ruminants, residue levels are expected to remain below the enforcement LOQ of 0.01 mg/kg in milk, muscle, fat, liver and kidney. Hence, in the framework of this review, the residue definition for ruminants can be proposed as parent compound only, by default, and MRLs and risk assessment values for the relevant commodities in ruminants can be established at the LOQ level. A fully validated analytical method is available for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg. MRLs for swine and poultry products are not required because these species are not expected to be exposed to fenoxycarb residues. Since log P_{ow} of fenoxycarb is higher than 3 and considering that in general residues in fat were higher than in the others tissue, EFSA concludes that the residue in commodities of animal origin is fat soluble. It is noted that in case additional uses on crops fed to livestock will be granted in the future, the proposed default residue definition may need to be reconsidered.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure was calculated for German children diet, representing 22% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for oranges, representing 13% of the acute reference dose (ARfD).

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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 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 that active substance. As fenoxycarb was included in Annex I to Council Directive 91/414/EEC on 1 June 2017 by means of Commission Directive 2011/20/EU[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.

The Netherlands, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for fenoxycarb and to prepare a supporting evaluation report (Netherlands, 2012). The evaluation report was submitted to EFSA on 26 January 2012 while the PROFile was made available on 25 January 2017. Both documents 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 11 April 2017 and finalised on 9 June 2017. Additional evaluation reports were submitted by the Netherlands, the Czech Republic, Greece, France, Hungary, Italy, Portugal and the European Union Reference Laboratories for Pesticide Residues (Czech Republic, 2017; Greece, 2017a,b; EURL, 2013; France, 2017; Hungary, 2017; Italy, 2017; Portugal, 2017; Netherlands, 2017) and, after having considered all the information provided by RMS and Member States, EFSA prepared a completeness check report which was made available to all Member States on 9 August 2017. Further clarifications were sought from Member States via a written procedure in August 2017.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, and the additional information provided by the Member States, EFSA prepared in November 2017 a draft reasoned opinion, which was submitted to 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 2011/20/EU of 2 March 2011 amending Council Directive 91/414/EEC to include fenoxycarb as active substance and amending Decision 2008/934/EC. OJ No L 58, 3.3.2011, p. 45–48.

[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 5 December 2017 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation reports submitted by the RMS (Netherlands, 2012, 2017) and the evaluation reports submitted by the Czech Republic, Greece, France, Hungary, Italy, Portugal and the European Union Reference Laboratories for Pesticide Residues (Czech Republic, 2017; Greece, 2017a,b; EURL, 2013; France, 2017; Hungary, 2017; Italy, 2017; Portugal, 2017) 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, 2017a) and the Member States consultation report (EFSA, 2017b). 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 and acute exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) (excel file) and the PROFile are key supporting documents and made publicly available as background documents to this reasoned opinion. Furthermore, a screenshot of the Report sheet of the PRIMo(EU) is presented in Appendix C.

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

Fenoxycarb is the ISO common name for ethyl 2-(4-phenoxyphenoxy)ethylcarbamate (IUPAC).

Fenoxycarb belongs to the group of carbamate compounds which are used as insecticides. Fenoxycarb is an insecticide (insect growth regulator (IGR)) which disrupt insect-specific transformations.

The chemical structure of the active substance and its main metabolites are reported in Appendix F.

Fenoxycarb was evaluated in the framework of Directive 91/414/EEC with the Netherlands designated as RMS. The representative uses supported for the peer review process were outdoor foliar spraying to control insects, as Lepidoptera, Tortricidae on apples and pears. Following the peer review, which was carried out by EFSA (2010), a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2011/20/EU, which entered into force on 1 June 2011. According to Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011, fenoxycarb is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to uses as insecticide only. According to the Annex to the approval Directive, pending further studies in the area of ecotoxicology, Member States are recommended to implement mitigation measures to protect bees (no application during flowering) when granting national authorisations.

The EU MRLs for fenoxycarb are established in Annexes IIIA of Regulation (EC) No 396/2005 and CXL(s) for active substance are not available. An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below (Table 1).

Table 1: Overview of the MRL changes since the entry into force of Regulation (EC) No 396/2005

Procedure	Legal implementation	Remarks
MRL application, Art. 10	Reg. (EU) 2016/486[(a)]	Reasoned opinion on the modification of the maximum residue levels for fenoxycarb in peaches and olives (EFSA, 2015)

MRL: maximum residue level.

(a): Commission Regulation (EU) 2016/486 of 29 March 2016 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 cyazofamid, cycloxydim, difluoroacetic acid, fenoxycarb, flumetralin, fluopicolide, flupyradifurone, fluxapyroxad, kresoxim-methyl, mandestrobin, mepanipyrim, metalaxyl-M, pendimethalin and tefluthrin in or on certain products. OJ L 90, 6.4.2016, p. 1–66.

For the purpose of this MRL review, the critical uses of fenoxycarb currently authorised within the EU have been collected by the RMS and reported in the PROFile. The additional good agricultural practices (GAPs) reported by Member States during the completeness check were also considered. The details of the authorised GAPs for fenoxycarb are given in Appendix A. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

Assessment

EFSA has based its assessment on the PROFile submitted by the RMS, the evaluation report accompanying the PROFile (Netherlands, 2012), the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (Netherlands, 2007, 2009, 2010), the conclusion on the peer review of the pesticide risk assessment of the active substance fenoxycarb (EFSA, 2010), the previous reasoned opinion on fenoxycarb (EFSA, 2015; France, 2015) as well as the evaluation reports submitted during the completeness check (Czech Republic, 2017; France, 2017; Greece, 2017a,b; Hungary, 2017; Italy, 2017; Portugal, 2017; Netherlands, 2017). 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[7] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b, 2017; 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 fenoxycarb in fruit crops (oranges and apples) was investigated during the peer review under Directive 91/414/EEC. In the same framework, an additional study on Bermuda grass was considered as supporting information (Netherlands, 2009).

In oranges, following local treatment of fruits and leaves by coating, fenoxycarb was the major component of the residue accounting for up to 80% of the total radioactive residue (TRR), corresponding to 8.4 mg eq/kg. Several other metabolites were identified, none of them accounting for more than 10% of the TRR. Total residues in oranges following the soil application at two different dose rates were below < 0.006 mg eq/kg at both dose levels. No further characterisation/identification of the residues was performed.

In apples following spray application, the degradation of the parent was more extensive, with the parent compound accounting for a maximum of 44% of the TRR in the whole fruit. Several other metabolites were identified, none of them accounting for more than 10% of the TRR.

The additional study in grass, confirms the metabolic pattern observed in apples and oranges: parent compound amounted for a maximum of 55% of the TRR and no other compounds were present at significant levels.

In summary, fenoxycarb is slowly degraded in oranges, but more quickly metabolised/degraded in apple. Total residue levels and metabolite patterns for A- and B-label treatments were comparable and the metabolism pathways in oranges and apple were similar. The major pathways in the degradation of fenoxycarb are ring hydroxylation followed by conjugation, cleavage of the ether linkages and/or hydroxylation followed by conjugation and reaction or removal of the side chain and/or hydroxylation followed by conjugation.

The metabolism study on apples is considered to be representative of the most critical GAPs (cGAPs) assessed in this review in terms of application method. It is noted that in this study residues were analysed 82 and 112 days after last treatment, not reflecting the preharvest intervals (PHIs) of the cGAPs (14–60 days). Nevertheless, since in the metabolism study parent compound was the main component of the residue, a more extensive metabolism is not expected to occur at shorter PHIs.

[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.

Therefore, following applications according to the authorised uses, fenoxycarb is expected to be still the major component of the residue in fruits.

1.1.2. Nature of residues in rotational crops

The crops evaluated in the framework of this MRL review are not expected to be grown in rotation; moreover the $DT_{90field}$ values for fenoxycarb in soil ranged from 14 to 30 days, not exceeding the trigger value of 100 days. Further investigation of residues in rotational crops is therefore not required.

Although not required, a confined rotational crop study was assessed in the framework of the peer review (Netherlands, 2009). In this study, radishes, mustard seeds and wheat were planted 30, 60, 95 and 121 days after bare soil application of radiolabelled fenoxycarb at 208 g/ha (0.5N the maximum total dose rate considered in this review).

Total residues were below or at the limit of quantification (LOQ) in all rotated crops, except in leaves from radish sowed 30 days after treatment (DAT), where TRR accounted for 0.025 mg eq/kg. Following extraction and identification of the residue, the extracts were shown to contain one large polar fraction (around 50% of the extracted radioactivity) and a small amount of fenoxycarb (< 0.004 mg eq/kg).

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of fenoxycarb was investigated in the framework of the peer review (Netherlands, 2009). Studies were conducted 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) and fenoxycarb showed to be stable. Therefore, 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 (EFSA, 2010).

1.1.4. Methods of analysis in plants

In the framework of the peer review under Directive 91/414/EEC, a DFG S19 multiresidue method using gas chromatography with mass spectrometric (GC–MS) quantification and its independent laboratory validation (ILV) were considered sufficiently validated for the enforcement of fenoxycarb in high water content (apples), high acid content (oranges) and high oil content commodities (walnuts) at the LOQ of 0.02 mg/kg (Netherlands, 2009, 2010).

A confirmatory high-performance liquid chromatography with tandem mass spectrometric (HPLC–MS/MS) method with an LOQ of 0.01 mg/kg in high water content (apples, plums), high acid content (oranges) and high fat content commodities (olives) was also evaluated in the framework of the peer review and considered in a previous MRL assessment (Netherlands, 2009, 2010, France, 2015). Additional validation data on pistachios (liquid chromatography with tandem mass spectrometric (LC–MS/MS) method validated at the LOQ of 0.01 mg/kg) were submitted in the framework of this review (Greece, 2017b; Italy, 2017).

Additional information on the availability of analytical method for the enforcement of fenoxycarb during routine laboratory analyses was also provided by the EURLs in the framework of this review. According to the information received, by using a Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) method an LOQ of 0.01 mg/kg is achievable for routine analyses of fenoxycarb in high water, high acid, high fat and dry commodities (EURL, 2013).

1.1.5. Stability of residues in plants

In the framework of the peer review, storage stability of fenoxycarb was demonstrated for a period of 24 months at −20°C in commodities with high water content (apples) and high acid content (oranges) (Netherlands, 2009). An additional storage stability study evaluated in the framework of a previous MRL application showed parent fenoxycarb to be stable for 24 months in high oil content (walnuts and olives) and high water content commodities (potatoes) stored at −18°C (France, 2015).

1.1.6. Proposed residue definitions

Based on the metabolism in primary crops, the residue definition for monitoring and risk assessment can be proposed as fenoxycarb only. This residue definition is limited to fruit crops only. The same residue definition applies to processed commodities. A specific residue definition for

rotational crops is not deemed necessary considering the very limited persistence of fenoxycarb in the soil. Fully validated analytical methods are available to enforce the proposed residue definition in high acid, high water and high fat content commodities at the LOQ of 0.02 mg/kg. Moreover, according to the information provided by the EURLs, a lower LOQ of 0.01 mg/kg is achievable by routine analyses in high acid, high water, high fat content and dry commodities.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of fenoxycarb residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Netherlands, 2012), including residue trials evaluated in the framework of the peer review (Netherlands, 2009) or in the framework of a previous MRL application (France, 2015) and additional data submitted during the completeness check (France, 2017; Greece, 2017a; Hungary, 2017; Italy, 2017; Portugal, 2017). All residue trial samples considered in this framework were stored in compliance with the demonstrated storage conditions. Decline of residues during storage of the trial samples is therefore 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, 2017).

Residue trials are not available to support the authorisations on oranges, lemons, mandarins and apricots. Therefore, MRL or risk assessment values for these crops could not be derived by EFSA and the following data gaps were identified:

- Oranges, lemons, mandarins: eight trials on oranges and/or grapefruits and eight trials on lemons and/or mandarins all compliant with the southern outdoor GAP for oranges, lemons and mandarins.
- Apricots: four trials compliant with the northern outdoor GAP.

For all other crops, available residue trials are sufficient to derive MRL and risk assessment values, taking note of the following considerations:

- Peaches: trials supporting the northern outdoor GAP are not available. Although MRL and risk assessment values can be derived from the southern data set, four trials compliant with the northern outdoor GAP are still required.
- Plums: the number of trials supporting the northern outdoor GAP is not compliant with the data requirement for this crop. Nevertheless, considering that the southern GAP fully supported by data is expected to be more critical, no additional trials supporting the northern outdoor GAP are required.
- Table grapes: available trials supporting the northern outdoor GAP were performed according to a more critical GAP (PHI of 21 days instead of 45). Nevertheless, considering that the southern GAP fully supported by data is more critical, no additional trials supporting the northern outdoor GAP are required.
- Table olives: residue trials supporting the outdoor southern GAP were all overdosed. Although tentative MRL and risk assessment values can be derived from this data set, four trials compliant with the southern outdoor GAP are still required.

1.2.2. Magnitude of residues in rotational crops

Since fenoxycarb is not persistent in the soil and is only authorised for use on perennial crops, there is no need to investigate the magnitude on the residue in rotational crops (see also Section 1.1.2).

1.2.3. Magnitude of residues in processed commodities

Studies investigating the magnitude of residues in processed commodities of apples, plums, peaches, wine grapes and olives for oil production were reported during the peer review (Netherlands, 2009), in a previous reasoned opinion (France, 2015) and in the present review (France, 2017).

Robust processing factors for enforcement and risk assessment were derived for canned peaches; canned and dry plums; plums jam; wine grape juice and must; wine grape dry and wet pomace; virgin olive oil after cold press and refined olive oil after warm press.

For all other processed commodities, no robust processing factors for enforcement and risk assessment could be derived as they were not sufficiently supported by studies (a minimum of 3 processing studies is normally required) and the derived processing factors should therefore be considered as indicative only.

Further processing studies are not required in this case as they are not expected to affect the outcome of the risk assessment. 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 MRL proposals as well as risk assessment values for all commodities under evaluation, except for oranges, lemons, mandarins and apricots where the available data were insufficient to derive MRLs. Tentative MRLs were derived for table olives.

2. Residues in livestock

Fenoxycarb is authorised for use on apples. As apples pomace might be used to fed livestock, dietary burdens were calculated for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D. Dietary burdens calculated for cattle and sheep were found to exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues was therefore assessed in ruminants.

It is highlighted that for others feed item, no residue data were available (citrus fruits). The animal intake of fenoxycarb residues via these commodities has therefore not been assessed and may have been underestimated.

The nature of fenoxycarb residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (Netherlands, 2009). Reported metabolism studies include two studies in lactating goats and one study in laying hens using phenoxyphenoxy and phenyl-B labelled fenoxycarb.

Lactating goats were dosed with 0.8–3 mg/kg body weight (bw) per day of fenoxycarb, corresponding to approximately 80–300 times the maximum exposure of beef cattle. In the study performed at the lower dose, the highest residue levels were found in liver and kidney (2.5 and 2.6 mg eq/kg, respectively), while in muscle and fat residues accounted for a maximum of 0.10 and 0.15 mg eq/kg, respectively. The identity of residues in tissues was not established. Residues in milk did not reach a plateau level during dosing.

In the study performed at the higher dose (300N), the total radioactive residues accounted for a maximum of 0.75, 0.09, 0.74, 1.4 and 3.1 mg eq/kg in milk, muscle, fat, kidney and liver, respectively. A plateau in milk was reached on day 2. Fenoxycarb represented the main component of the residue only in muscle (7.6% of the TRR). In other tissues and in milk, parent compound (not present in kidney and ranging from 2.4% of the TRR in milk to 21% of TRR in fat) was found at lower levels compared to other metabolites. In particular, the metabolite CGA 294850 and its glucuronide and sulfate conjugates were by far the main components of the residues in milk (accounting for up to 36% of the TRR) and in tissues other than muscle (accounting for up to 66% of the TRR in fat).

Although not required (none of the crops under assessment is fed to poultry), the metabolism study in hens is reported for completeness. In this study, laying hens were dosed with 7.9 mg/kg bw per day of fenoxycarb. The study demonstrates that transfer of residues to eggs and tissues is relatively low. Most of the total administered dose was recovered in excreta (90% of applied radioactivity (AR)) and limited translocation was observed in eggs (max 0.09% in egg yolk). Mean residues in muscle, liver, and fat were 0.23, 2.1, and 0.91 mg eq/kg, respectively. A plateau was reached in egg white (mean plateau level 0.026 mg eq/kg) on day 5 whereas in yolk it reached on day 8 (1.39 mg eq/kg). Fenoxycarb was the major compound in fat (41% TRR). In other tissues the parent compound was extensively metabolised to several major metabolites, in liver, in particular to sulfate conjugates of CGA 294848 and CGA 294850 (13–16% TRR), whereas in muscle and yolk only the latter was a major metabolite (12–25% TRR).

The storage stability of fenoxycarb and its metabolites CGA 294850 and CGA 294851 in animal products was evaluated under the peer review of Directive 91/414/EEC (Netherlands, 2009). Studies demonstrated that parent is stable in muscle, liver, kidney, milk and eggs for up to 22 months when stored deep frozen. For the metabolites, the same storage stability period has been demonstrated in

liver, kidney, milk and eggs. Nevertheless, a significant degradation of metabolites CGA 294850 and CGA 294851 has been observed in muscle after 2 months storage. For this tissue, an exact storage stability period could not be determined because storage periods shorter than 2 months were not investigated. Storage stability in fat has not been investigated.

An analytical method and its ILV were evaluated during the peer review and found to be sufficiently validated for the enforcement of fenoxycarb in liver, fat, muscle and milk with an LOQ 0.01 mg/kg (Netherlands, 2009). In addition, an extended DFG S19 method using LC–MS/MS and its ILV for enforcement of fenoxycarb in muscle, fat and milk at the LOQ 0.01 mg/kg was submitted in the framework of this review (France, 2017). Moreover, according to the information received by the EURLs, screening validation data indicate that fenoxycarb can be enforced in all commodities of animal commodities at an LOQ of 0.01 mg/kg (EURL, 2013).

In the metabolism studies on both ruminant and poultry, the presence of several metabolites (in particular metabolite CGA 294850 and its conjugates) indicate extensive metabolism involving oxidation of the (A)-phenyl ring followed by conjugation. Therefore, based on the results of the available studies, metabolite CGA 294850 and its conjugates should in principle be included in the residue definition. Nevertheless, according to the above-mentioned metabolism studies, after exposure to the maximum dietary burden (about 80–300 times lower than the dose level of the metabolism studies), residue levels are expected to remain below the enforcement LOQ of 0.01 mg/kg in milk, muscle, fat, liver and kidney. This is also confirmed by a livestock feeding study on dairy cows dosed with fenoxycarb at 0.043, 0.13 and 0.43 mg/kg bw per day for 28–30 consecutive days. In this study, residues of parent and metabolites CGA 294850 and CGA 294851 at the feeding level closest to the maximum calculated dietary burden (0.043 mg/kg bw per day corresponding to 4.3N) were below the LOQ of 0.01 mg/kg in all tissues analysed and in milk.

Hence, in the framework of this review, the residue definition for ruminants can be proposed as parent compound only, by default, and MRLs and risk assessment values for the relevant commodities in ruminants can be established at the LOQ level. A fully validated analytical method is available for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg. Considering that, based on the metabolism studies, it was possible to conclude that no residues are expected in ruminants commodities, the data gap identified on the storage stability for the metabolites in fat and muscle is not expected to have an impact on the derived MRLs. MRLs for swine and poultry products are not required because these species are not expected to be exposed to fenoxycarb residues. Since log P_{ow} of fenoxycarb is higher than 3 and considering that in general residues in fat were higher than in the others tissue, EFSA concludes that the residue in commodities of animal origin is fat soluble.

It is noted that in case additional uses on crops fed to livestock will be granted in the future, the proposed default residue definition may need to be reconsidered.

3. Consumer risk assessment

Chronic and acute 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 E. Hence, for those commodities where a (tentative) 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 those commodities where data were insufficient to derive an MRL in Section 1, EFSA considered the existing EU MRL for an indicative calculation. All input values included in the exposure calculations are summarised in Appendix D.

The exposures calculated were compared with the toxicological reference values for fenoxycarb, derived by EFSA (2010) under Directive 91/414/EEC. The highest chronic exposure was calculated for German children diet, representing 22% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for oranges, representing 13% of the acute reference dose (ARfD). Although uncertainties remain due to the data gaps identified in the magnitude of residues in primary crops, this indicative exposure calculation did not indicate a risk to consumers.

Conclusions

The metabolism of fenoxycarb has been assessed in fruit crops (oranges and apples) following soil, local and foliar spray applications. Based on the metabolism in primary crops, the residue definition for monitoring and risk assessment can be proposed as fenoxycarb only. This residue definition is limited

to fruit crops only. The same residue definition applies to processed commodities. A specific residue definition for rotational crops is not deemed necessary considering the very limited persistence of fenoxycarb in the soil. Fully validated analytical methods are available to enforce the proposed residue definition in high acid, high water and high fat content commodities at the LOQ of 0.02 mg/kg. Moreover, according to the information provided by the EURLs, a lower LOQ of 0.01 mg/kg is achievable by routine analyses in high acid, high water, high fat content and dry commodities.

Regarding the magnitude of residues in primary crops, the available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for oranges, lemons, mandarins and apricots where the available data were insufficient to derive MRLs. Tentative MRLs were derived for table olives.

Fenoxycarb is authorised for use on apples and apples pomace might be fed to livestock. Livestock dietary burdens were therefore calculated and the dietary burdens calculated for cattle and sheep were found to exceed the trigger value of 0.1 mg/kg DM. The nature of fenoxycarb residues in commodities of animal origin was investigated in lactating goats and in laying hens. Based on the results of the available studies, metabolite CGA 294850 and its conjugates should in principle be included in the residue definition. Nevertheless, according to the metabolism studies, after exposure to the maximum dietary burden calculated for ruminants, residue levels are expected to remain below the enforcement LOQ of 0.01 mg/kg in milk, muscle, fat, liver and kidney. Hence, in the framework of this review, the residue definition for ruminants can be proposed as parent compound only, by default, and MRLs and risk assessment values for the relevant commodities in ruminants can be established at the LOQ level. A fully validated analytical method is available for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg. MRLs for swine and poultry products are not required because these species are not expected to be exposed to fenoxycarb residues. Since log P_{ow} of fenoxycarb is higher than 3 and considering that in general residues in fat were higher than in the others tissue, EFSA concludes that the residue in commodities of animal origin is fat soluble. It is noted that in case additional uses on crops fed to livestock will be granted in the future, the proposed default residue definition may need to be reconsidered.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure was calculated for German children diet, representing 22% of the ADI, and the highest acute exposure was calculated for oranges, representing 13% of the ARfD.

Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 2). 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 Table 2 footnotes for details). In particular, some tentative MRLs and some existing EU MRLs need to be confirmed by the following data:

- additional residue trials on table olives, oranges, lemons, mandarins and apricots.

It is highlighted, however, that some of the MRLs derived result from a GAP in one climatic zone only, whereas other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gap which is not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- additional residue trials supporting the northern outdoor GAP on peaches.

It is also noted that more critical northern outdoor GAPs not supported by data are authorised in FR for pome fruits (see comment field of the GAP table in Appendix A for details).

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

Furthermore, in line with the outcome of the peer review, Member States are recommended to implement mitigation measures to protect bees (e.g. no application during flowering) when granting national authorisations.

Table 2: Summary table

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Enforcement residue definition: fenoxycarb (F)				
110020	Oranges	2	2	Further consideration needed[(a)]
110030	Lemons	2	2	Further consideration needed[(a)]
110050	Mandarins	2	2	Further consideration needed[(a)]
120080	Pecans	0.05*	0.05	Recommended[(b)]
120110	Walnuts	0.05*	0.05	Recommended[(b)]
130010	Apples	1	0.7	Recommended[(b)]
130020	Pears	1	0.7	Recommended[(b)]
130030	Quinces	1	0.7	Recommended[(b)]
130040	Medlar	1	0.7	Recommended[(b)]
130050	Loquat	1	0.7	Recommended[(b)]
140010	Apricots	1	1	Further consideration needed[(a)]
140030	Peaches	1.5	1.5	Recommended[(b)]
140040	Plums	1	0.6	Recommended[(b)]
0151010	Table grapes	1	0.5	Recommended[(b)]
151020	Wine grapes	1	0.5	Recommended[(b)]
161030	Table olives	3	3	Further consideration needed[(c)]
402010	Olives for oil production	3	3	Recommended[(b)]
1012010	Bovine meat	0.05*	0.01*	Recommended[(b)]
1012020	Bovine fat	0.05*	0.01*	Recommended[(b)]
1012030	Bovine liver	0.05*	0.01*	Recommended[(b)]
1012040	Bovine kidney	0.05*	0.01*	Recommended[(b)]
1013010	Sheep meat	0.05*	0.01*	Recommended[(b)]
1013020	Sheep fat	0.05*	0.01*	Recommended[(b)]
1013030	Sheep liver	0.05*	0.01*	Recommended[(b)]
1013040	Sheep kidney	0.05*	0.01*	Recommended[(b)]
1014010	Goat meat	0.05*	0.01*	Recommended[(b)]
1014020	Goat fat	0.05*	0.01*	Recommended[(b)]
1014030	Goat liver	0.05*	0.01*	Recommended[(b)]
1014040	Goat kidney	0.05*	0.01*	Recommended[(b)]
1015010	Horse meat	0.05*	0.01*	Recommended[(b)]
1015020	Horse fat	0.05*	0.01*	Recommended[(b)]
1015030	Horse liver	0.05*	0.01*	Recommended[(b)]
1015040	Horse kidney	0.05*	0.01*	Recommended[(b)]
1020010	Cattle milk	0.05*	0.01*	Recommended[(b)]
1020020	Sheep milk	0.05*	0.01*	Recommended[(b)]
1020030	Goat milk	0.05*	0.01*	Recommended[(b)]
1020040	Horse milk	0.05*	0.01*	Recommended[(b)]
–	Other commodities of plant and animal origin	See Reg. (EC) No 149/2008	–	Further consideration needed[(d)]

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(F): MRL is expressed as mg/kg of fat contained in the whole product.
(a): GAP evaluated at 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 E).
(b): MRL is derived from a GAP evaluated at 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 E).
(c): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination E-I in Appendix E).
(d): There are no relevant authorisations or import tolerances reported at 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 E).

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Abbreviations

a.i.	active ingredient
a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
cGAP	critical GAP
CXL	codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DB	dietary burden
DM	dry matter
DT_{90}	period required for 90% dissipation (define method of estimation) estimated daily intake
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EURLs	European Union Reference Laboratories for Pesticide Residues (former CRLs)
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC–MS	gas chromatography with mass spectrometry
HPLC–MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HPLC-UVD	high-performance liquid chromatography with ultraviolet detector
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
IGR	insect growth regulator
ILV	independent laboratory validation
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LC–MS/MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
Mo	monitoring
MRL	maximum residue level
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PF	processing factor
PHI	preharvest interval

P_{ow}	partition coefficient between *n*-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
QqQ	triple-quadrupole (mass spectrometry)
Q-ToF	quadrupole-time of flight (mass spectrometry)
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SEU	southern European Union
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
TAR	total applied radioactivity
TRR	total radioactive residue
WG	water-dispersible granule
WHO	World Health Organization

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

Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application											PHI or waiting period (days)	Comments
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		
Critical outdoor GAPs for Northern Europe																					
Apples	*Malus domestica*	NEU	Outdoor	NL	Insects	WG	250.0	g/L	Foliar treatment – spraying	75	81	–	2	10	10	0.08	0.15	kg a.i./ha	21	A more critical GAP (2 × 0.225; PHI: 14 days) authorised in FR is not supported by data
Pears	*Pyrus communis*	NEU	Outdoor	NL	Insects	WG	250.0	g/L	Foliar treatment – spraying	75	81	–	2	10	10	0.08	0.15	kg a.i./ha	21	A more critical GAP (2 × 0.225; PHI: 14 days) authorised in FR is not supported by data
Quinces	*Cydonia oblonga*	NEU	Outdoor	HU	Insects	WG	250.0	g/L	Foliar treatment – spraying	75	81	–	2	14	21	0.08	0.15	kg a.i./ha	21	A more critical GAP (2 × 0.225; PHI: 14 days) authorised in FR is not supported by data
Medlars	*Mespilus germanica*	NEU	Outdoor	HU	Insects	WG	250.0	g/L	Foliar treatment – spraying	75	81	–	2	14	21	0.08	0.15	kg a.i./ha	21	A more critical GAP (2 × 0.225; PHI: 14 days) authorised in FR is not supported by data
Loquats	*Eriobotrya japonica*	NEU	Outdoor	HU	Insects	WG	250.0	g/L	Foliar treatment – spraying	75	81	–	2	14	21	0.08	0.15	kg a.i./ha	21	A more critical GAP (2 × 0.225; PHI: 14 days) authorised in FR is not supported by data
Apricots	*Armeniaca vulgaris*, syn: *Prunus armeniaca*	NEU	Outdoor	HU		WG	25.0	% (w/w)	Foliar treatment – spraying	n.a.	n.a.	1	2	10	14	0.08	0.10	kg a.i./ha	21	800–1,000 L/ha
Peaches	*Persica vulgaris*, syn: *Prunus persica*	NEU	Outdoor	HU	Insects	WG	250.0	g/L	Foliar treatment – spraying	75	81	–	1	–	–	0.08	0.10	kg a.i./ha	21	–
Plums	*Prunus domestica*	NEU	Outdoor	NL	Insects	WG	250.0	g/L	Foliar treatment – spraying	75	81	1	2	14	–	–	0.15	kg a.i./ha	21	Covers also CZ and HU GAPs
Table grapes	*Vitis vinifera*	NEU	Outdoor	CZ	*Eupoecilia ambiguella*, *Lobesia botrana*	WG	250.0	g/kg	Foliar treatment – spraying	n.a.	n.a.	1	2	14	–	0.13	0.15	kg a.i./ha	45	Covers also HU GAP

Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments
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		
Wine grapes	*Vitis vinifera*	NEU	Outdoor	FR	*Clysia ambiguella*, *Polychrosis botrana*	WG	250.0	g/kg	Foliar treatment – spraying	71	85	–	2	12	12	–	0.15	kg a.i./ha	21	200–1,500 L/ha
Critical outdoor GAPs for Southern Europe																				
Oranges	*Citrus sinensis*	SEU	Outdoor	EL		WG	25.0	% (w/w)	Foliar treatment – spraying	n.a.	n.a.	–	1	–	–	–	0.15	kg a.i./ha	45	Corresponding to 0.01 kg/hL (1,500 L/ha)
Lemons	*Citrus limon*	SEU	Outdoor	EL		WG	25.0	% (w/w)	Foliar treatment – spraying	n.a.	n.a.	–	1	–	–	–	0.15	kg a.i./ha	45	Corresponding to 0.01 kg/hL (1,500 L/ha)
Mandarins	*Citrus reticulata*, syn: *Citrus deliciosa*	SEU	Outdoor	EL		WG	25.0	% (w/w)	Foliar treatment – spraying	n.a.	n.a.	–	1	–	–	–	0.15	kg a.i./ha	45	Corresponding to 0.01 kg/hL (1,500 L/ha)
Pecans	*Carya illinoinensis*	SEU	Outdoor	PT		WG	25.0	% (w/w)	Foliar treatment – spraying	n.a.	n.a.	–	2	–	–	–	0.08	kg a.i./ha	21	0.0075 kg a.s./hL
Walnuts	*Juglans nigra*; *Juglans regia*	SEU	Outdoor	FR	*Cydia pomonella*	WG	25.0	% (w/w)	Foliar treatment – spraying	71	85	–	2	12	–	–	0.09	kg a.i./ha	21	1,000–1,200 L/ha. Spray at infestation, 0,0075 kg as/hL. Covers also PT GAP
Apples	*Malus domestica*	SEU	Outdoor	FR	Leaf rollers	WG	25.0	% (w/w)	Foliar treatment – spraying	71	85	–	2	12	15	–	0.23	kg a.i./ha	14	Corresponding to 0.015 kg/hL (200–1,500 L/ha). Covers also PT and IT GAPs. A more critical GAP authorised in EL (2 × 1.15 kg/ha; PHI: 20 days) is not supported by data
Pears	*Pyrus communis*	SEU	Outdoor	FR	Leaf rollers	WG	25.0	% (w/w)	Foliar treatment – spraying	71	85	–	2	12	15	–	0.23	kg a.i./ha	14	Corresponding to 0.015 kg/hL (200–1,500 L/ha). Covers also PT GAP. A more critical GAP authorised in EL (2 × 1.15 kg/ha; PHI: 30 days) is not supported by data
Quinces	*Cydonia oblonga*	SEU	Outdoor	FR	Leaf rollers	WG	25.0	% (w/w)	Foliar treatment – spraying	71	85	–	2	12	15	–	0.23	kg a.i./ha	14	Corresponding to 0.015 kg/hL (200–1,500 L/ha). Covers also PT GAP

Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments
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		
Medlars	*Mespilus germanica*	SEU	Outdoor	FR	Leaf rollers	WG	25.0	% (w/w)	Foliar treatment – spraying	71	85	–	2	12	15	–	0.23	kg a.i./ha	14	Corresponding to 0.015 kg/hL (200–1,500 L/ha)
Loquats	*Eriobotrya japonica*	SEU	Outdoor	FR	Leaf rollers	WG	25.0	% (w/w)	Foliar treatment – spraying	71	85	–	2	12	15	–	0.23	kg a.i./ha	14	Corresponding to 0.015 kg/hL (200–1,500 L/ha). Covers also PT GAP
Peaches	*Persica vulgaris*, syn: *Prunus persica*	SEU	Outdoor	FR	*Grapholita molesta*	WG	250.0	g/kg	Foliar treatment – spraying	71	85	–	2	12	12	–	0.23	kg a.i./ha	14	GAP evaluated by EFSA in 2015. Corresponding to 0.015 kg/hL (200–1,500 L/ha). At infestation. Covers also PT, IT and EL GAPs
Plums	*Prunus domestica*	SEU	Outdoor	FR	Leaf rollers	WG	250.0	g/kg	Foliar treatment – spraying	71	85	–	2	10	10	–	0.23	kg a.i./ha	21	Covers also PT and EL GAPs
Table grapes	*Vitis vinifera*	SEU	Outdoor	FR, EL	*Polychrosis botrana*, *Clysia ambiguella*	WG	250.0	g/kg	Foliar treatment – spraying	71	85	–	2	12	–	–	0.15	kg a.i./ha	21	200–1,500 L/ha
Wine grapes	*Vitis vinifera*	SEU	Outdoor	FR, EL	*Polychrosis botrana*, *Clysia ambiguella*	WG	250.0	g/kg	Foliar treatment – spraying	71	85	–	2	12	–	–	0.15	kg a.i./ha	21	200–1,500 L/ha
Table olives	*Olea europaea*	SEU	Outdoor	FR, PT	*Saissetia oleae*	WG	250.0	g/kg	Foliar treatment – spraying	71	85	–	2	10	10	–	0.15	kg a.i./ha	60	A more critical GAP with application rate of 0.23 kg/ha evaluated by EFSA in 2015
Olives for oil production	*Olea europaea* var. europaea	SEU	Outdoor	CY, ES	*Saissetia oleae*	WP	250.0	g/kg	Foliar treatment – spraying	71	85	–	2	10	15	–	0.23	kg a.i./ha	60	GAP evaluated by EFSA in 2015. It covers also PT, EL and FR GAPs. A different GAP authorised in IT (1 × 375 g/ha; PHI: 60 days), is not supported by data

GAP: Good Agricultural Practice; BBCH: growth stages of mono- and dicotyledonous plants; PHI: pre-harvest interval; SEU: southern European Union; a.i.: active ingredient; WG: water-dispersible granule.

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	Oranges	Soil [(a)], 31 or 313 g/ha	61, 166, 252
			Local application[(a)] on oranges, leaves and branches, 3.4 g/L	0 (5 h), 29, 55, 104
			Local application[(b)] on oranges at 2.9 mg a.s./orange	90
		Apples	Spray application[(a)] to run-off 2 × 10 g/hL, 3 × 10 g/hL and 1 × 300 g/hL	82, 112
	Cereals/grass crops	Bermuda grass	Spray application[(b)], 1 × 230 g/ha or 1 × 507 g/ha	0, 1, 3, 7, 14, 21
	Source: Netherlands (2009)			
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**
	Root/tuber crops	Radish	Bare soil[(a)], 208 g a.s./ha	30, 60, 95, 121
	Leafy crops	Mustard seed	Bare soil[(a)], 208 g a.s./ha	30, 60, 95, 121
	Cereal (small grain)	Wheat	Bare soil[(a)], 208 g a.s./ha	30, 60, 95, 121
	Source: Netherlands (2009)			
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: Netherlands (2009)			

(a): Study performed with fenoxycarb labelled at both phenyl A and phenyl B rings.
(b): Study performed with fenoxycarb labelled at phenyl B ring only.

Can a general residue definition be proposed for primary crops?	No
Rotational crop and primary crop metabolism similar?	Not applicable (DT_{90} < 100 days and authorised for use on permanent crops only)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes
Plant residue definition for monitoring (RD-Mo)	**Fruit crops**: fenoxycarb
Plant residue definition for risk assessment (RD-RA)	**Fruit crops**: fenoxycarb
Conversion factor (monitoring to risk assessment)	Not applicable
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	High acid, high water, high oil content: • Primary: GC–MS, 0.02 mg/kg (incl. ILV) (Netherlands, 2009, 2010) • Confirmatory: HPLC–MS/MS, 0.01 mg/kg (Netherlands, 2009, 2010; France, 2015; Italy, 2017; Spain, 2017b) • QuEChERS: LC–MS/MS, 0.01 mg/kg (EURLs, 2017) Dry content: • QuEChERS: LC-QqQ-MS/MS, 0.01 mg/kg (EURLs, 2017)

a.i.: active ingredient; DAT: days after treatment; PBI: plant-back interval; HPLC-MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LC-MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability (months/years)**
	High water content	Apples[(a)]	−20	24 months
		Potatoes[(b)]	−18	24 months
	High oil content	Walnuts[(b)]	−18	24 months
		Olives[(b)]	−18	
	High acid content	Oranges[(a)]	−20	24 months

(a): Study evaluated during the peer review (Netherlands, 2009).
(b): Study evaluated during a previous MRL application (France, 2015).

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 Mandarins	SEU	–	No residue trials available	–	–	–
Pecans Walnuts	SEU	3 × < 0.01; 2 × < 0.05	Trials on walnuts with dose rate within 25% deviation (Netherlands, 2012; France, 2017; Portugal, 2017). Extrapolation to pecans possible MRL_{OECD} = 0.05	0.05	0.05	0.01
Pome fruits	NEU	0.02; 3 × 0.03; 0.10; 0.12; 0.17; 0.19; 0.27	Trials on apples compliant with GAP (Netherlands, 2009). Extrapolation to pome fruits possible MRL_{OECD} = 0.46	0.5	0.27	0.10
	SEU	0.08; 0.10; 2 × 0.16; 2 × 0.17; 0.22; 0.23; 0.24; 0.42; 0.43	Trials on apples compliant with GAP (Netherlands, 2009; France, 2017; Greece, 2017a; Italy, 2017; Portugal, 2017). Extrapolation to pome fruits possible MRL_{OECD} = 0.67	0.7	0.43	0.17
Peaches	NEU	–	No residue trials available	–	–	–
	SEU	0.26; 0.29; 0.38; 0.4; 0.44; 0.46; 0.77; 0.81	Trials on peaches compliant with GAP (Netherlands, 2012; France, 2015) MRL_{OECD} = 1.43	1.5	0.81	0.42
Apricots	NEU	–	No residue trials available	–	–	–
Plums	NEU	3 × 0.04; 2 x < 0.05; 0.05	Trials on plums compliant with GAP (Netherlands, 2012; Hungary, 2017). Since the SEU GAP is expected to be more critical, no additional trials are required MRL_{OECD} = 0.1	0.15	0.05	0.05
	SEU	< 0.01; 0.03; 0.04; 2 × 0.06; 0.07; 0.17; 0.33	Trials on plums compliant with GAP (France, 2017; Greece, 2017a; Portugal, 2017) MRL_{OECD} = 0.52	0.6	0.33	0.06

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]
Table grapes	NEU	0.07; 3 × 0.09; 0.1; 0.11; 2 × 0.19; 0.34	Residue trials on grapes performed according to a more critical GAP (PHI 21 days instead 45 days) (Netherlands, 2009). No additional trials required since the SEU GAP is expected to be more critical MRL_{OECD} = 0.49	0.5	0.34	0.10
	SEU	2 × < 0.02; 0.04; 0.05; 0.08; 0.17; 0.18; 0.24	Trials on grapes compliant with GAP (France, 2017; Greece, 2017a; Portugal, 2017) MRL_{OECD} = 0.44	0.5	0.24	0.07
Wine grapes	NEU	0.07; 3 × 0.09; 0.09; 0.09; 0.1; 0.11; 2 × 0.19; 0.19; 0.34	Trials on grapes compliant with GAP (Netherlands, 2009) MRL_{OECD} = 0.49	0.5	0.34	0.10
	SEU	2 × < 0.02; 0.04; 0.05; < 0.02; 0.08; 0.17; 0.18; < 0.02; 0.04; 0.17; 0.24	Trials on grapes compliant with GAP (France, 2017; Greece, 2017a; Portugal, 2017) MRL_{OECD} = 0.44	0.5	0.24	0.07
Olives for oil production	SEU	0.03; 0.04; 0.11; 2 × 0.22; 0.25; 0.97; 1; 1.5	Residue trials on olives compliant with GAP (Netherlands, 2012; France, 2015) MRL_{OECD} = 2.61	3	1.50	0.22
Table olives	SEU	0.03; 0.04; 0.11; 2 × 0.22; 0.25; 0.97; 1; 1.5	Residue trials on olives overdosed compared to the GAP for table olives (Netherlands, 2012; France, 2015) MRL_{OECD} = 2.61	3[d] (tentative)	1.50	0.22

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level.
*: 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): Tentative MRL is derived from overdosed trials.

B.1.2.2. Residues in succeeding crops

Confined rotational crop study (quantitative aspect)	Not triggered (fenoxycarb is not persistent in soil and is only authorised for use on perennial crops)
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 (source)	Median PF
Robust processing factors (sufficiently supported by data)			
Peaches, canned[b]	4	< 0.02; 3× 0.04	0.04
Plums, canned[c]	4	0.15, 0.21, 0.73, 0.92	0.47
Plums, dried (prunes)[c]	4	2.32, 3.18, 3.50, 4.85	3.34
Plums, jam[c]	4	0.06, 0.07, 0.20, 0.31	0.14
Wine grapes, juice[c]	6	0.02, 0.05, 0.10, 0.12, 0.27, 0.5	0.11
Wine grapes, dry pomace[c]	4	3.81, 4.48, 11.82, 12.92	8.15
Wine grapes, wet pomace[c]	4	1.33, 1.64, 5, 6.67	3.32
Wine grapes, must[c]	4	0.03, 0.26, 0.50, 0.75	0.38
Olives for oil production, virgin oil after cold press[b]	4	3.83; 3.87; 3.96; 4.67	3.91
Olives for oil production, refined oil after warm press[b]	4	3.33; 3.62; 4.19; 4.67	3.91
Indicative processing factors (limited data set)			
Apples, juice[d]	1	0.1	0.10
Apples, wet pomace[d]	1	3.55	3.55
Apples, dry pomace[d]	1	13.80	13.80
Apples, sauce[d]	1	0.73	0.73
Wine grapes, red wine (unheated)[c]	2	< 0.05, 0.12	0.09
Wine grapes, white wine[c]	2	0.05, 0.10	0.08

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Studies evaluated in the framework of a previous MRL assessment (EFSA, 2015; France, 2015).
(c): Studies evaluated in the framework of this review (France, 2017).
(d): Study evaluated in the framework of the peer review (Netherlands, 2009).

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)	0.01	0.01	0.43	0.43	Cattle (beef)	Apple, pomace, wet	Yes
Cattle (dairy only)	0.008	0.008	0.21	0.21	Cattle (dairy)	Apple, pomace, wet	Yes
Sheep (all diets)	0.009	0.009	0.21	0.21	Sheep (lamb)	Apple, pomace, wet	Yes
Sheep (ewe only)	0.007	0.007	0.21	0.21	Sheep (ram/ewe)	Apple, pomace, wet	Yes
Swine (all diets)	0.0000	0.0000	0.00	0.00	Swine (breeding)	–	No
Poultry (all diets)	0.0000	0.0000	0.00	0.00	Poultry (broiler)	–	No
Poultry (layer only)	0.0000	0.0000	0.00	0.00	Poultry (layer)	–	No

bw: body weight; DM: dry matter.
(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	7.9[(a)]	8	None of the crops under assessment is fed to poultry
	Lactating goat	0.8[(b)]	5	80N/compared to maximum dietary burden beef cattle
		3[(a)]	4	300N/compared to maximum dietary burden beef cattle
	Sources: Netherlands (2010); France (2017)			

bw: body weight.
(a): Study performed with phenyl-B-labelled fenoxycarb.
(b): Study performed with phenoxyphenoxy fenoxycarb.

Time needed to reach a plateau concentration in milk and eggs (days)	Milk: 2 Eggs: 8 days (egg yolk) and 5 days (eggs white)
Metabolism in rat and ruminant similar (Yes/No)	Yes
Animal residue definition for monitoring (RD-Mo)	**Ruminants:** fenoxycarb, by default
Animal residue definition for risk assessment (RD-RA)	**Ruminants:** fenoxycarb, by default
Conversion factor (monitoring to risk assessment)	Not applicable
Fat soluble residues (Yes/No)	Yes
Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs)	HPLC-UVD, ILV and confirmatory method available, LOQ of 0.01 mg/kg for muscle, liver, fat, milk (Netherlands, 2009) LC–MS/MS, ILV available, LOQ of 0.01 mg/kg for muscle, fat and milk (France, 2017) According to the EURLs, an LOQ of 0.01 mg/kg can be also achieved by screening methods using LC-MS-Q-ToF (EURLs, 2017)

B.2.1.2. Stability of residues in livestock

Animal products (available studies)	Animal	Commodity	T (°C)	Stability (months/years)
	Bovine	Muscle	−20	22 months
	Bovine	Liver	−20	22 months
	Bovine	Kidney	−20	22 months
	Cow/goat	Milk	−20	22 months
	Poultry	Egg	−20	22 months
	Reported storage stability refers to fenoxycarb. Metabolites CGA 294850 and CGA 294851 stable for up to 22 months in milk, eggs and liver but not stable in beef muscle (< 2 months) (Netherlands, 2009). Storage stability has not been demonstrated in fat. No additional studies required since, based on the metabolism study, it is possible to conclude that no residues are expected in animal tissues.			

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) Based on the metabolism study, at the calculated dietary burden, no residues above the LOQ are expected in tissues					
Muscle	–	–	0.01	0.01	0.01*
Fat	–	–	0.01	0.01	0.01*
Liver	–	–	0.01	0.01	0.01*
Kidney	–	–	0.01	0.01	0.01*
Cattle (dairy only) Based on the metabolism study, at the calculated dietary burden, no residues above the LOQ are expected in milk					
Milk	–	–	0.01	0.01	0.01*
Sheep (all diets) Based on the metabolism study, at the calculated dietary burden, no residues above the LOQ are expected in tissues					
Muscle	–	–	0.01	0.01	0.01*
Fat	–	–	0.01	0.01	0.01*
Liver	–	–	0.01	0.01	0.01*
Kidney	–	–	0.01	0.01	0.01*
Sheep (dairy only) Based on the metabolism study, at the calculated dietary burden, no residues above the LOQ are expected in milk					
Milk	–	–	0.01	0.01	0.01*
Swine None of the crops under assessment is fed to swine. Therefore, there is no need to set MRLs in swine tissues					
Poultry (all diets) None of the crops under assessment is fed to poultry. Therefore, there is no need to set MRLs in poultry tissues					
Poultry (layer only) None of the crops under assessment is fed to poultry. Therefore, there is no need to set MRLs in eggs					

STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level; LOQ: limit of quantification.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): The mean residue levels for milk, eggs and tissues measured in the metabolism studies were recalculated at the 1N rate for the median dietary burden.
(b): The mean residue level in milk and the highest residue levels in eggs and tissues measured in the metabolism studies were recalculated at the 1N rate for the maximum dietary burden.

B.3. Consumer risk assessment

ADI	0.053 mg/kg bw per day (EFSA, 2010)
Highest IEDI, according to EFSA PRIMo	22% ADI (DE, child)
Assumptions made for the calculations	The calculation is based on the median residue levels in the raw agricultural commodities 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	2.0 mg/kg bw (EFSA, 2010)
Highest IESTI, according to EFSA PRIMo	13% ARfD (oranges)
Assumptions made for the calculations	The calculation is based on the highest residue levels in the raw agricultural commodities For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; ARfD: acute reference dose; IESTI: international estimated short-term intake.

B.4. Proposed MRLs

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Enforcement residue definition: fenoxycarb (F)				
110020	Oranges	2	2	Further consideration needed [a]
110030	Lemons	2	2	Further consideration needed [a]
110050	Mandarins	2	2	Further consideration needed[a]
120080	Pecans	0.05*	0.05	Recommended[b]
120110	Walnuts	0.05*	0.05	Recommended[b]
130010	Apples	1	0.7	Recommended[b]
130020	Pears	1	0.7	Recommended[b]
130030	Quinces	1	0.7	Recommended[b]
130040	Medlar	1	0.7	Recommended[b]
130050	Loquat	1	0.7	Recommended[b]
140010	Apricots	1	1	Further consideration needed[a]
140030	Peaches	1.5	1.5	Recommended[b]
140040	Plums	1	0.6	Recommended[b]
0151010	Table grapes	1	0.5	Recommended[b]
151020	Wine grapes	1	0.5	Recommended[b]
161030	Table olives	3	3	Further consideration needed[c]
402010	Olives for oil production	3	3	Recommended[b]
1012010	Bovine meat	0.05*	0.01*	Recommended[b]
1012020	Bovine fat	0.05*	0.01*	Recommended[b]
1012030	Bovine liver	0.05*	0.01*	Recommended[b]
1012040	Bovine kidney	0.05*	0.01*	Recommended[b]
1013010	Sheep meat	0.05*	0.01*	Recommended[b]
1013020	Sheep fat	0.05*	0.01*	Recommended[b]
1013030	Sheep liver	0.05*	0.01*	Recommended[b]
1013040	Sheep kidney	0.05*	0.01*	Recommended[b]
1014010	Goat meat	0.05*	0.01*	Recommended[b]

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
1014020	Goat fat	0.05*	0.01*	Recommended[(b)]
1014030	Goat liver	0.05*	0.01*	Recommended[(b)]
1014040	Goat kidney	0.05*	0.01*	Recommended[(b)]
1015010	Horse meat	0.05*	0.01*	Recommended[(b)]
1015020	Horse fat	0.05*	0.01*	Recommended[(b)]
1015030	Horse liver	0.05*	0.01*	Recommended[(b)]
1015040	Horse kidney	0.05*	0.01*	Recommended[(b)]
1020010	Cattle milk	0.05*	0.01*	Recommended[(b)]
1020020	Sheep milk	0.05*	0.01*	Recommended[(b)]
1020030	Goat milk	0.05*	0.01*	Recommended[(b)]
1020040	Horse milk	0.05*	0.01*	Recommended[(b)]
–	Other commodities of plant and animal origin	See Reg. (EC) No 149/2008	–	Further consideration needed[(d)]

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(F): MRL is expressed as mg/kg of fat contained in the whole product.
(a): GAP evaluated at 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 E).
(b): MRL is derived from a GAP evaluated at 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 E).
(c): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination E-I in Appendix E).
(d): There are no relevant authorisations or import tolerances reported at 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 E).

Appendix C – Pesticide Residue Intake Model (PRIMo)

Fenoxycarb			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.053**	ARfD (mg/kg bw):	**2**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2010**	Year of evaluation:	**2010**

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum: 1 – 22

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	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	pTMRLs at LOQ (in % of ADI)
22.1	DE child	14.4	Oranges	3.9	Apples	1.5	Mandarins	
18.3	NL child	11.8	Oranges	2.8	Mandarins	2.0	Apples	
10.4	FR toddler	7.5	Oranges	1.0	Mandarins	0.8	Apples	
10.2	ES child	8.2	Oranges	0.6	Mandarins	0.4	Apples	
9.7	UK Toddler	7.5	Oranges	1.1	Mandarins	0.5	Apples	
8.9	IE adult	3.9	Oranges	2.2	Mandarins	1.2	Lemons	
7.6	WHO Cluster diet B	3.2	Oranges	1.2	Mandarins	0.9	Lemons	
7.5	NL general	5.6	Oranges	0.8	Mandarins	0.4	Apples	
6.6	UK Infant	4.9	Oranges	0.7	Milk and cream	0.5	Apples	
6.4	ES adult	4.9	Oranges	0.5	Mandarins	0.2	Apples	
5.7	SE general population 90th percentile	2.8	Oranges	1.7	Mandarins	0.3	Apples	
5.4	FR infant	3.4	Oranges	0.8	Apples	0.5	Mandarins	
4.6	WHO Cluster diet F	3.3	Oranges	0.7	Mandarins	0.2	Apples	
4.4	FI adult	3.7	Oranges	0.4	Mandarins	0.1	Apples	
4.2	PT General population	2.3	Oranges	0.5	Wine grapes	0.3	Apples	
4.0	UK vegetarian	3.3	Oranges	0.2	Apples	0.2	Mandarins	
3.6	IT kids/toddler	1.8	Oranges	0.8	Mandarins	0.3	Apples	
3.4	FR all population	1.1	Oranges	0.8	Wine grapes	0.7	Mandarins	
3.3	WHO cluster diet E	1.7	Oranges	0.6	Mandarins	0.3	Wine grapes	
3.2	WHO regional European diet	1.9	Oranges	0.4	Mandarins	0.2	Apples	
3.0	IT adult	1.4	Oranges	0.6	Mandarins	0.3	Peaches	
2.8	UK Adult	2.1	Oranges	0.2	Mandarins	0.2	Wine grapes	
2.4	DK child	0.7	Apples	0.6	Oranges	0.3	Mandarins	
2.0	WHO cluster diet D	0.9	Oranges	0.3	Mandarins	0.2	Apples	
1.7	DK adult	0.5	Oranges	0.3	Mandarins	0.3	Wine grapes	
1.3	PL general population	0.7	Apples	0.2	Lemons	0.1	Mandarins	
1.1	LT adult	0.6	Apples	0.3	Oranges	0.1	Milk and cream	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Fenoxycarb is unlikely to present a public health concern.

Acute risk assessment/children – refined calculations				Acute risk assessment/adults/general population – refined calculations			

The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---		
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
13.3	Oranges	2/-	9.6	Oranges	2/-	2.6	Oranges	2/-	2.1	Oranges	2/-
5.6	Mandarins	2/-	4.2	Mandarins	2/-	1.3	Mandarins	2/-	1.0	Mandarins	2/-
3.4	Lemons	2/-	2.6	Lemons	2/-	0.7	Peaches	0.81/-	0.5	Peaches	0.81/-
2.4	Peaches	0.81/-	1.8	Peaches	0.81/-	0.7	Lemons	2/-	0.5	Table grapes	0.34/-
2.1	Apples	0.43/-	1.6	Apples	0.43/-	0.5	Table grapes	0.34/-	0.5	Lemons	2/-
No of critical MRLs (IESTI 1)		---				**No of critical MRLs (IESTI 2)**		---			

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---						No of commodities for which ARfD/ADI is exceeded: ---					
		***)						***)			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
5.0	Orange juice	2/-				1.0	Orange juice	2/-			
1.1	Apple juice	0.43/-				0.1	Apple juice	0.43/-			
0.7	Peach juice	0.81/-				0.1	Peach preserved with	0.81/-			
0.6	Grape juice	0.34/-				0.1	Wine	0.34/-			
0.4	Pear juice	0.43/-				0.0	Quince jelly	0.43/-			

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL.

***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:

For Fenoxycarb, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: fenoxycarb				
Apples, wet pomace	0.85	STMR × 5[(a)]	0.85	STMR × 5[(a)]

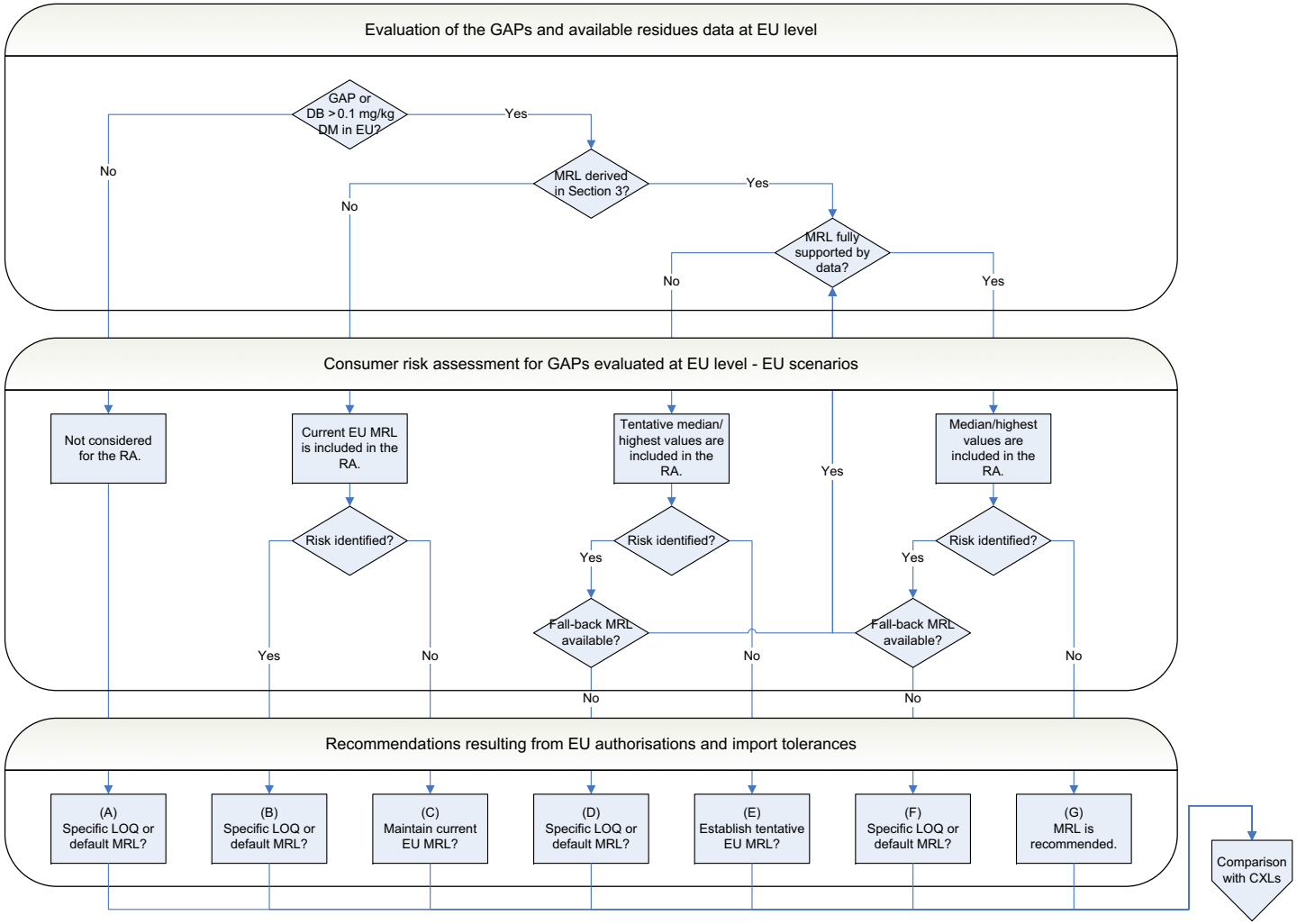
STMR: supervised trials median residue.
(a): For apples wet pomace, in the absence of a robust processing factor, the default processing factor of 5 was included in the calculation to consider the potential concentration of residues in this commodity.

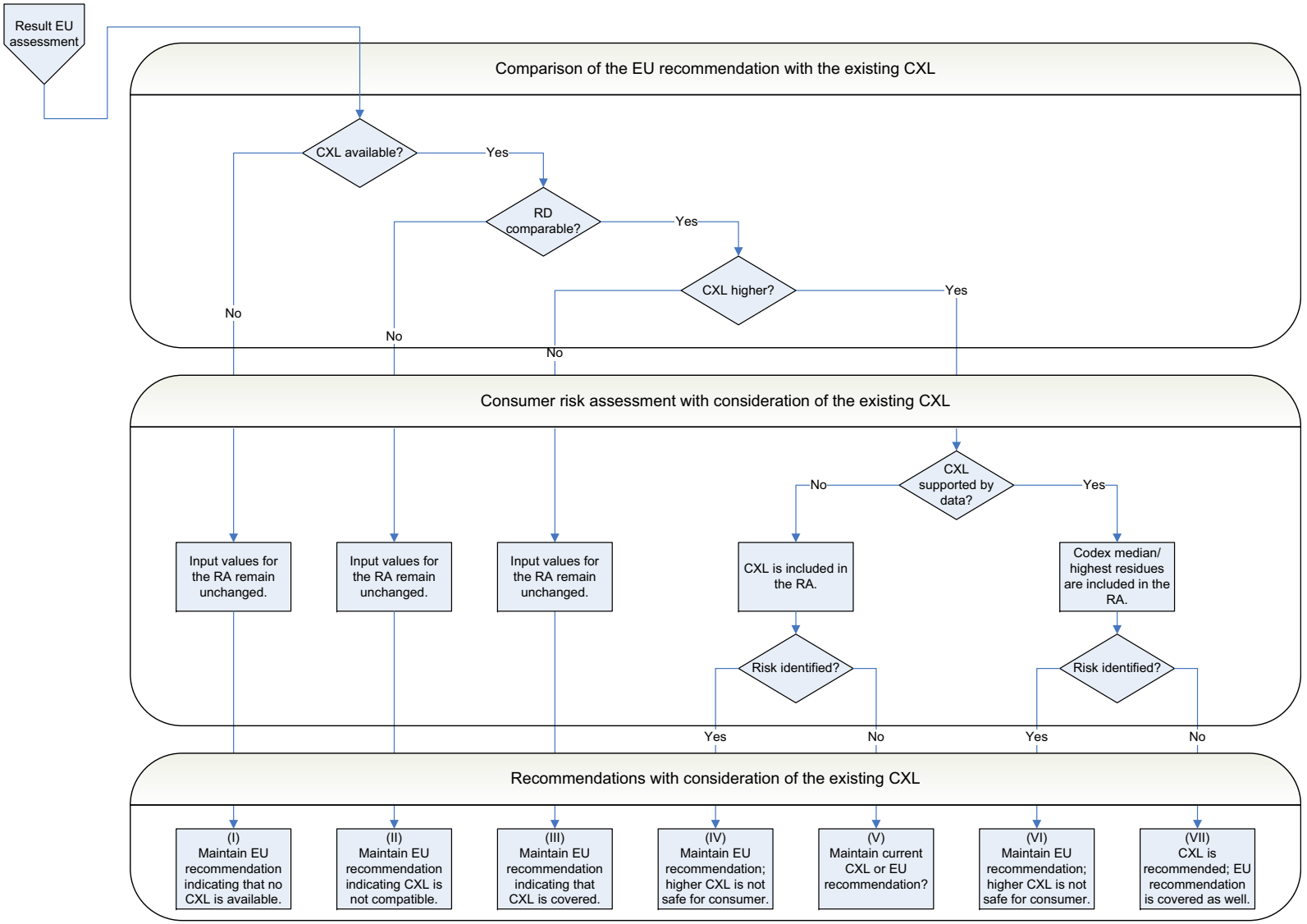
D.2. Consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: fenoxycarb				
Oranges	2	EU MRL	2	EU MRL
Lemons	2	EU MRL	2	EU MRL
Mandarins	2	EU MRL	2	EU MRL
Pecans	0.01	STMR	0.05	HR
Walnuts	0.01	STMR	0.05	HR
Apples	0.17	STMR	0.43	HR
Pears	0.17	STMR	0.43	HR
Quinces	0.17	STMR	0.43	HR
Medlars	0.17	STMR	0.43	HR
Loquats/Japanese medlars	0.17	STMR	0.43	HR
Apricots	1	EU MRL	1	EU MRL
Peaches	0.42	STMR	0.81	HR
Plums	0.06	STMR	0.33	HR
Table grapes	0.1	STMR	0.34	HR
Wine grapes	0.1	STMR	0.34	HR
Table olives	0.22	STMR (tentative)	1.5	HR (tentative)
Olives for oil production	0.22	STMR	1.5	HR
Ruminant meat Equine meat	0.01*	0.8 × STMR muscle + 0.2 × STMR fat	0.01*	0.8 × HR muscle + 0.2 × HR fat
Ruminant fat Equine fat	0.01*	STMR	0.01*	HR
Ruminant liver Equine liver	0.01*	STMR	0.01*	HR
Ruminant kidney Equine kidney	0.01*	STMR	0.01*	HR
Ruminant milk Equine milk	0.01*	STMR	0.01*	HR

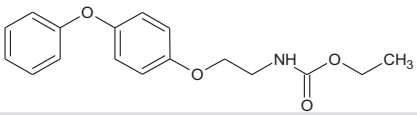
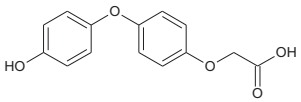
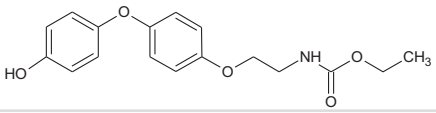
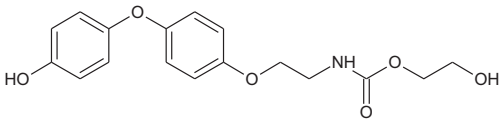
STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level.
*: Indicates that the input value is proposed at the limit of quantification.

Appendix E – 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 F – Used compound codes

Code/trivial name	Chemical name/SMILES notation	Structural formula
Fenoxycarb	ethyl 2-(4-phenoxyphenoxy)ethylcarbamate O=C(OCC)NCCOc1ccc(cc1)Oc2ccccc2	
CGA 294848	[4-(4-eydroxyphenoxy)phenoxy]acetic acid Oc1ccc(cc1)Oc2ccc(OCC(=O)O)cc2	
CGA 294850	ethyl {2-[4-(4-hydroxyphenoxy)phenoxy] ethyl}carbamate Oc1ccc(cc1)Oc2ccc(OCCNC(=O)OCC)cc2	
CGA 294851	2-hydroxyethyl {2-[4-(4-hydroxyphenoxy) phenoxy]ethyl}carbamate Oc1ccc(cc1)Oc2ccc(OCCNC(=O)OCCO)cc2	

SMILES: simplified molecular-input line-entry system.