REASONED OPINION

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Review of the existing maximum residue levels for oxyfluorfen 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 oxyfluorfen. To assess the occurrence of oxyfluorfen residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Commission Regulation (EC) No 33/2008, 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 one existing European MRL still requires further consideration by risk managers.

Keywords: oxyfluorfen, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, herbicide

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Summary

Oxyfluorfen was approved on 1 January 2012 by means of Commission Implementing Regulation (EU) No 798/2011 in the framework of Regulation (EC) No 1107/2009 as amended by Commission Implementing Regulations (EU) No 540/2011 and 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.

As the basis for the MRL review, on 14 August 2019, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 13 September 2019 their national Good Agricultural Practices (GAPs) in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State (RMS), Spain, to identify the critical GAPs in the format of a specific GAP overview file. Subsequently, Member States were requested to provide residue data supporting the critical GAPs, within a period of 1 month, by 23 December 2019. On the basis of all the data submitted by Member States and by the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked the RMS to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report, together with Pesticide Residues Intake Model (PRIMo) calculations were provided by the RMS to EFSA on 27 March 2020. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report. Along with the clarifications, the RMS provided an updated GAP overview file.

Based on the information provided by the RMS, Member States and the EURLs, and taking into account the conclusions derived by EFSA in the framework of Commission Regulation (EC) No 33/2008, EFSA prepared in July 2020 a draft reasoned opinion, which was circulated to Member States and EURLs for consultation via a written procedure. Comments received by 4 August 2020 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of oxyfluorfen in plant was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement and risk assessment can be proposed as oxyfluorfen. A specific residue definition for rotational crops is not deemed necessary considering the very limited uptake of oxyfluorfen from the soil. Processing is not expected to impact the metabolism of oxyfluorfen; nevertheless, processing factors were derived for olive for oil production.

Fully validated analytical methods are available for the enforcement of the proposed residue definition in all plant matrices at the limit of quantification (LOQ) of 0.01 mg/kg. According to the EURLs, the LOQ of 0.01 mg/kg is achievable by using the QuEChERS method in routine analyses.

Available residue trials data were considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for globe artichoke where no data were available to derive an MRL.

Even though oxyfluorfen is persistent in the soil, it was concluded that oxyfluorfen residues did not accumulate in rotational crops provided that oxyfluorfen is applied in compliance with the uses currently authorised.

Oxyfluorfen is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM, further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary. Nevertheless, metabolism studies performed in lactating goats and laying hens were available; however, they were not considered appropriate to propose a residue definition.

An analytical method for the determination of oxyfluorfen at the LOQ of 0.01 mg/kg in all animal matrices is available. According to the EURLs, the LOQ of 0.01 mg/kg is achievable in milk, egg, muscle and liver, by using the QuEChERS method in routine analyses.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMo. For globe artichoke where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure represented 7% of the acceptable daily intake (ADI) for the diets DE child and NL toddler; the highest acute exposure amounted to 0.5% of the acute reference dose (ARfD) for pears. Although uncertainties remain due to the data gap identified, the indicative exposure calculation did not indicate a risk to consumer's health.

Table of contents

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 oxyfluorfen was approved on 1 January 2012 by means of Commission Implementing Regulation (EU) No 798/2011[3] in the framework of Regulation (EC) No 1107/2009[4] as amended by Commission Implementing Regulations (EU) No 540/2011[5] and 541/2011[6], EFSA initiated the review of all existing MRLs for that active substance.

By way of background information, in the framework of Commission Regulation (EC) No 33/2008[7], oxyfluorfen was evaluated by Spain, designated as rapporteur Member State (RMS). Subsequently, a peer review on the initial evaluation of the RMS was conducted by EFSA, leading to the conclusions as set out in the EFSA scientific output (EFSA, 2010). Furthermore, according to the provisions of the approval regulation, confirmatory information was requested, among others, as regards to confirmatory data relevant for environmental fate and behaviour and ecotoxicology sections by 31 December 2013. The confirmatory data submitted were assessed (EFSA, 2014) and the European Commission requested EFSA to deliver its conclusion in view of new data (EFSA, 2015). Subsequently, specific provisions were implemented under Regulation (EU) No 2017/359[8] to further restrict the application rate of this 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 repealed by Regulation (EC) No 1107/2009. It should be noted, however, that, in the framework of Regulation (EC) No 1107/2009, 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 Regulation (EC) No 1107/2009 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.

[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 Implementing Regulation (EU) No 798/2011 of 9 August 2011 approving the active substance oxyfluorfen, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and Commission Decision 2008/934/EC. OJ L 205, 10.8.2011, p. 9–14.

[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.

[7] Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I. OJ L 15, 18.1.2008, p. 5–12.

[8] Commission Implementing Regulation (EU) 2017/359 of 28 February 2017 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance oxyfluorfen. OJ L 54, 1.3.2017, p. 8–10.

As the basis for the MRL review, on 14 August 2019, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 13 September 2019 their Good Agricultural Practices (GAPs) that are authorised nationally, in a standardised way, in the format of specific GAP forms. In the framework of this consultation, 16 Member States provided feedback on their national authorisations of oxyfluorfen. Based on the GAP data submitted, the designated RMS, Spain, was asked to identify the critical GAPs to be further considered in the assessment, in the format of a specific GAP overview file. Subsequently, in a second step, Member States were requested to provide residue data supporting the critical GAPs by 23 December 2019.

On the basis of all the data submitted by Member States and the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked Spain to complete the PROFile and to prepare a supporting evaluation report. The PROFile and the supporting evaluation report, together with the Pesticide Residues Intake Model (PRIMo) calculations, were submitted to EFSA on 27 March 2020. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report. Along with the clarifications, the RMS provided an updated GAP overview file.

Considering all the available information, EFSA prepared in July 2020 a draft reasoned opinion, which was circulated to Member States and EURLs for commenting via a written procedure. All comments received by 4 August 2020 were considered by EFSA during the finalisation of the reasoned opinion.

The **evaluation report** submitted by the RMS (Spain, 2019), taking into account also the information provided by Member States during the collection of data, and the **EURLs report on analytical methods** (EURLs, 2019) are considered as main supporting documents to this reasoned opinion and, thus, made publicly available.

In addition, further supporting documents to this reasoned opinion are the **completeness check report** (EFSA, 2020a) and the **Member States consultation report** (EFSA, 2020b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Furthermore, the exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (**PRIMo**) and the **PROFile** as well as the **GAP overview file** listing all authorised uses are key supporting documents and made publicly available as background documents to this reasoned opinion. A screenshot of the report sheet of the PRIMo 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

Oxyfluorfen is the ISO common name for 2-chloro-4-(trifluoromethyl)phenyl 3-ethoxy-4-nitrophenyl ether (IUPAC). The chemical structure of the active substance and its main metabolite is reported in Appendix F.

The approval of oxyfluorfen is restricted to uses as herbicide for banded applications close to ground from autumn to early spring, at a rate not exceeding 150 g a.s./ha per year (Regulation (EU) No 2017/359).

The EU MRLs for oxyfluorfen are established in Annexes IIIA of Regulation (EC) No 396/2005. Codex maximum residue limits (CXLs) for oxyfluorfen are not available. There are no MRL changes occurred since the entry into force of the Regulation mentioned above.

For the purpose of this MRL review, all the uses of oxyfluorfen currently authorised within the EU as submitted by the Member States during the GAP collection, have been reported by the RMS in the GAP overview file. The critical GAPs identified in the GAP overview file were then summarised in the PROFile and considered in the assessment. The details of the authorised critical GAPs for oxyfluorfen 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 following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (Spain, 2019);
- the draft assessment report (DAR) prepared under Council Directive 91/414/EEC (Spain, 2006);
- the final addendum of the additional report (AR) prepared under Commission Regulation (EC) No 33/2008 (Spain, 2010);
- the conclusion on the peer review of the pesticide risk assessment of the active substance oxyfluorfen (EFSA, 2010);
- the updated review report on oxyfluorfen, following the submission and evaluation of confirmatory data submitted post-approval of the substance (European Commission, 2017a).

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[9] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b, 2017b; OECD, 2008, 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 oxyfluorfen was investigated after soil treatment in fruits (dormant apple and peach trees, and pre-plantation of tomato) and after foliar treatment in leafy crops (alfalfa) and in root/tuber vegetables (onions) and assessed in the framework of the peer review (Spain, 2006, 2010, EFSA, 2010). In the studies on apple, oxyfluorfen was radiolabelled in the nitrophenyl (^{14}C-NPR) ring of the molecule or in the trifluoromethyl (CF_3) group. In all other studies, oxyfluorfen was radiolabelled in the chlorophenyl (^{14}C-CPR) or nitrophenyl (^{14}C-NPR) ring of the molecule.

After one soil application of 11.2 kg a.s./ha under dormant peach trees, no residues were detected in mature peaches 126 days after treatment (DAT). Thus, no metabolic pathway could be identified. In other inedible plant samples, like leaves, twigs and immature fruits, residues were mostly below 0.01 mg eq/kg (except in leaves 63 DAT; 0.06 mg eq/kg).

On semi-dwarf apple trees, oxyfluorfen radiolabelled in the CF_3 group was applied once to the soil at 2.2 kg a.s./ha, while with the NPR label, one soil treatment was performed in three different plots at 2.2, 4.5 and 9 kg a.s./ha. No residues were detected in any of the edible or non-edible samples.

After one soil treatment of 2.8 kg a.s./ha 32 days before transplanting tomatoes, no residues were detected with the NPR label, while residues were measured up to 0.016 mg eq/kg in CPR samples (ripe tomatoes 103 DAT) and 83% of total radioactive residues (TRRs) (0.013 mg eq/kg) was found to be volatile compound.

As TRRs in fruit crops were very low even at highly overdosed treatments, the characterisation of the residues was mainly attempted in the study conducted in alfalfa with the CPR label where TRRs were up to 0.199 mg eq/kg. However, the low radioactivity in the different extracts and fractions did not permit a definite characterisation of the residues (EFSA, 2010).

After one application of 2.24 kg a.s./ha on alfalfa (as application was done at early stage, most of the active ingredient reached the soil), the only compound identified as a major metabolite was trifluoroacetic acid (TFAA) increasing with time from 17% TRR (0.02 mg eq/kg) to 53% TRR (0.11 mg eq/kg). Oxyfluorfen was extensively degraded and almost not detected (2% TRR; 0.001 mg eq/kg). Cleavage of the ether linkage between the chlorophenyl and the nitrophenyl rings was observed.

After two foliar applications of 1.4 kg a.s./ha on onions, TRRs were up to 0.017 mg eq/kg at maturity with CPR label and up to 0.065 mg eq/kg with NPR label. In the CPR label, 74% TRR

[9] 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, 11.06.2011, p. 127–175.

remained unidentified, only volatile radioactivity (likely TFAA considering the previous studies on alfalfa) was found representing 12.9% TRR (0.002 mg eq/kg). In NPR label, residue levels were four times higher, but no compounds were identified. Cleavage of the ether linkage between the chlorophenyl and nitrophenyl rings and production of volatile radioactivity from CPR label was observed.

Oxyfluorfen was shown to be extensively degraded in plants. The metabolic pathway of oxyfluorfen was similar in tomato, onion and alfalfa, proceeding first by cleavage of the parent structure at the ether bond between the two phenyl rings, followed by further degradations of the chlorophenyl ring to volatile radioactivity identified as TFAA (EFSA, 2010).

1.1.2. Nature of residues in rotational crops

Oxyfluorfen is authorised on crops that may be grown in rotation. The field DT_{90} reported in the soil degradation studies evaluated in the framework of the peer review was up to 571 days in clay loam (EFSA, 2010). It is therefore required to investigate the nature of oxyfluorfen in rotational crops.

One confined rotational crop study with oxyfluorfen radiolabelled on the NPR or CPR ring was available for this review (Spain, 2006, 2010, EFSA, 2010). Oxyfluorfen was applied at a rate of 1.1 kg a.s./ha onto bare soil. Crops were planted at plant back intervals (PBI) of 0, 31, 61, 91 and 123 DAT. Crops planted at each interval consisted of fruiting vegetables (tomato, pepper, squash), leafy vegetables (Swiss chard, collard), roots (beet, turnip) and cereals (wheat).

No residues above 0.01 mg eq/kg were found in fruiting vegetables, leafy crops or roots at any PBI. In wheat grains, residues were not detected, while in wheat chaff and straw residues were observed up to 0.06 mg eq/kg. The rotational crop study confirmed the limited uptake of residues from the soil (EFSA, 2010).

Even at an overdosed application rate, residue levels were too low to identify any metabolites and it cannot be concluded whether the metabolic pathway of oxyfluorfen is the same in primary and rotational crops. However, a study to further characterise the residues was not deemed necessary.

1.1.3. Nature of residues in processed commodities

There were no studies investigating the nature of residues of oxyfluorfen in processed commodities available for this review. In all commodities that could be processed, residues were below 0.1 mg/kg (except in olives for oil production) and the total theoretical maximum daily intake is below 10% of the acceptable daily intake (ADI). Therefore, the investigation of the nature of residues in processed commodities is not required.

For what regards olives for oil production, residue levels were above 0.1 mg/kg since olives were present on the ground while soil was treated or dropped to the soil not long after the treatment. However, considering the kind of processing these olives are subject to, there would be no need to simulate representative hydrolytic conditions for pasteurisation, boiling/brewing/baking or sterilisation.

In addition, it is not expected that processing impacts the metabolism of oxyfluorfen. The nature of the active substance and its behaviour in the environment showed that oxyfluorfen is stable to hydrolysis and the main degradation pathway would be photolytic (Spain, 2010).

1.1.4. Methods of analysis in plants

During the peer review, a hyphenated analytical method based on gas chromatography coupled to electron capture detection (GC-ECD) was validated in all four main plant matrices, with a limit of quantification (LOQ) of 0.01 mg/kg (EFSA, 2010). Mass spectrometry detection (GC-MS) was used for confirmation purposes. This primary method is supported by an independent laboratory validation (ILV).

During the completeness check, the EURLs provided a QuEChERS multi-residue analytical method (QuOil method in high oil content commodities) using liquid chromatography with tandem mass spectrometry (LC-MS/MS) or GC-MS/MS analytical technique, with an LOQ of 0.01 mg/kg for the routine analysis of oxyfluorfen in high water content, high acid content, high fat content and dry commodities (EURLs, 2019). In high water content, high acid content and dry commodities even lower levels were successfully validated down to 0.005 mg/kg.

1.1.5. Stability of residues in plants

The storage stability of oxyfluorfen was investigated in the framework of the peer review (Spain, 2006; EFSA, 2010).

In high water content, high acid content, high oil content and dry/high starch content commodities, the available studies demonstrated storage stability for oxyfluorfen for a period of 36 months when stored at −10°C.

1.1.6. Proposed residue definitions

In plants, oxyfluorfen was extensively metabolised and its metabolic pathway was similar in tomato, onion and alfalfa. Considering the very limited uptake of oxyfluorfen from the soil, a specific residue definition for rotational crops is not deemed necessary. The processing of oxyfluorfen is not expected to modify the nature of oxyfluorfen residues.

Based on the metabolism studies, neither the parent nor any other components were observed in significant proportions to constitute an appropriate marker and the residue definition for monitoring was thus limited by default to oxyfluorfen only. Considering that TFAA was detected only in alfalfa and that this compound is not specific to oxyfluorfen, it was decided not to include this compound in the residue definition for risk assessment and the same definition as for monitoring was proposed (EFSA, 2010). These residue definitions are found to be still applicable under the current review.

An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in all plant matrices is available (EFSA, 2010). According to the EURLs, the LOQ of 0.01 mg/kg is achievable by using the QuEChERS (or QuOil) method in routine analyses (EURLs, 2019).

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of oxyfluorfen residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Spain, 2019) as well as the residue trials evaluated in the framework of the peer review (Spain, 2006, 2010; EFSA, 2010). All residue trial samples considered in this framework were stored in compliance with the conditions for which storage stability of residues was demonstrated. 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, 2017b).

According to the RMS, a no residue situation can be anticipated for all orchards, considering the nature of oxyfluorfen (non-systemic herbicide) and the fact that it is applied directly to the soil in banded application. A no residue situation is also confirmed by the available metabolism studies showing that there is no uptake of residues from the soil, and by the available residue trials performed on orchards, grapes and table olives (where olives are picked only from the tree).

Residue trials are not available to support the authorisations on globe artichokes. As the time of application of oxyfluorfen can be up to BBCH 39 according to the reported GAP, a no residue situation cannot be anticipated for this crop. Therefore, MRL and risk assessment values could not be derived, and the following data gap was identified:

- Globe artichokes: four trials on globe artichoke compliant with the southern outdoor GAP are required.

For all other crops, data were sufficient to derive MRL and risk assessment values, taking note of the following considerations:

- Granate apples: no residue trials are available. However, based on the metabolism studies and on the results of the overdosed residue trials performed on orchards (apples, pears, apricots), a no residue situation can be anticipated. Therefore, MRL and risk assessment values can be derived at the LOQ (0.01 mg/kg) and no additional trials are required.
- Brussel sprouts and head cabbages: no residue trials are available. However, based on the available metabolism studies and considering banded applications of oxyfluorfen to the ground at BBCH 00, a no residue situation can be anticipated. Therefore, MRL and risk assessment values can be derived at the LOQ (0.01 mg/kg) and no additional trials are required.

1.2.2. Magnitude of residues in rotational crops

There were no studies investigating the magnitude of residues in rotational crops available for this review. Nevertheless, the available confined rotational crop study showed that oxyfluorfen residues did not accumulate in fruiting vegetables, root and leafy crops, or in cereal grains at any plant back interval, even 0 DAT (see Section 1.1.2).

Considering the degradation rates of oxyfluorfen (DT_{90} > 365 days) and taking into account the maximum application rate of 150 g a.s./ha per year assessed under this review, the RMS calculated as a worst assumption a total soil concentration of oxyfluorfen in soil (PEC soil total), resulting from the multiannual use of this active substance at the critical GAP (PEC plateau background) plus the maximal seasonal application rate to cover possible crop failure, of 0.26 mg/kg (EFSA, 2020a).

In the available confined rotational crop study, the soil concentrations of residues were measured, ranging from 0.73 to 1.08 mg/kg at application and from 0.163 to 0.920 mg/kg at planting. This overdosed study demonstrates that no residues occur in rotational crops even considering a soil concentration of 0.92 mg/kg, which is a substantial margin of safety.

Based on this confined rotational crop study covering the plateau concentration levels estimated in soil, it can be concluded that oxyfluorfen residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that oxyfluorfen is applied in compliance with the GAPs reported in Appendix A.

1.2.3. Magnitude of residues in processed commodities

Since residue levels in olives for oil production were above 0.1 mg/kg, the effect of industrial processing and/or household preparation was assessed in studies conducted on olives (Spain, 2019). An overview of all available processing studies is available in Appendix B.1.2.3.

Robust processing factors (PFs) fully supported by data could be derived for olive oil, while a tentative PF was calculated for olive press cake. Results showed that residues tend to concentrate in oil.

For olive oil, a separate calculation has been performed to reflect two possible practices: (1) olives present on the ground while soil is treated (according to the most critical GAP); (2) olives dropped to the soil not long after the treatment. As a worst assumption, the highest PF obtained from the first situation was considered.

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

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for globe artichoke where no data were available and for which residue trials are still required (see Section 1.2.1).

2. Residues in livestock

Oxyfluorfen is authorised for use on crops (head cabbage, sunflower, apple, citrus) that might be fed to livestock. Livestock dietary burden calculations were therefore performed 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.

Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg dry matter (DM), further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary.

Although not required, the metabolism of oxyfluorfen residues in livestock was investigated in lactating goats and laying hens at dose rates covering the maximum dietary burdens calculated in this review (Spain, 2019). Feeding studies were also available. These studies were assessed in the framework of the peer review (Spain, 2006; EFSA, 2010).

The metabolism studies conducted with ^{14}C-CPR or ^{14}C-NPR radiolabelled oxyfluorfen showed that residues in animal matrices were mainly composed of the parent and metabolites structurally related to the parent. However, these studies were not considered appropriate since they were conducted with oxyfluorfen, whereas the plant metabolism data have shown that parent oxyfluorfen is not present in

plant commodities following application of this active substance (EFSA, 2010). Nevertheless, additional data are not required as no residue definitions and no MRLs are needed for animal matrices.

An analytical method using GC-ECD was fully validated for the determination of oxyfluorfen at the LOQ of 0.01 mg/kg in all animal matrices (EFSA, 2010).

According to the EURLs, the LOQ of 0.01 mg/kg is achievable in infant formula (milk), muscle, egg and liver by using the QuEChERS method in routine analyses. Even lower levels were successfully validated down to 0.001 mg/kg in egg and muscle, down to 0.002 mg/kg in liver and down to 0.0025 mg/kg in infant formula (milk) (EURLs, 2019).

Storage stability of oxyfluorfen was investigated and demonstrated oxyfluorfen to be stable at –10°C for a period of 14 months in muscle and liver, and of 12 months in milk and eggs (Spain, 2006; EFSA, 2010).

3. Consumer risk assessment

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where an MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). For globe artichoke 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 exposure values calculated were compared with the toxicological reference values for oxyfluorfen, derived by EFSA (2010). The highest chronic exposure was calculated for DE child and NL toddler, representing 7% of the ADI, and the highest acute exposure was calculated for pears, representing 0.5% of the acute reference dose (ARfD). Although uncertainties remain due to the data gap identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumer's health.

Conclusions

The metabolism of oxyfluorfen in plant was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement and risk assessment can be proposed as oxyfluorfen. A specific residue definition for rotational crops is not deemed necessary considering the very limited uptake of oxyfluorfen from the soil. Processing is not expected to impact the metabolism of oxyfluorfen, nevertheless processing factors were derived for olive for oil production.

Fully validated analytical methods are available for the enforcement of the proposed residue definition in all plant matrices at the LOQ of 0.01 mg/kg. According to the EURLs, the LOQ of 0.01 mg/kg is achievable by using the QuEChERS method in routine analyses.

Available residue trials data were considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for globe artichoke where no data were available to derive an MRL.

Even though oxyfluorfen is persistent in the soil, it was concluded that oxyfluorfen residues did not accumulate in rotational crops provided that oxyfluorfen is applied in compliance with the uses currently authorised.

Oxyfluorfen is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM, further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary. Nevertheless, metabolism studies performed in lactating goats and laying hens were available; however, they were not considered appropriate to propose a residue definition.

An analytical method for the determination of oxyfluorfen at the LOQ of 0.01 mg/kg in all animal matrices is available. According to the EURLs, the LOQ of 0.01 mg/kg is achievable in milk, egg, muscle and liver, by using the QuEChERS method in routine analyses.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMo. For globe artichoke

where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure represented 7% of the ADI for the diets DE child and NL toddler; the highest acute exposure amounted to 0.5% of the ARfD for pears. Although uncertainties remain due to the data gap identified, the indicative exposure calculation did not indicate a risk to consumer's health.

Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 1). 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 1 footnotes for details). In particular, one existing EU MRL needs to be confirmed by the following data:

- four residue trials supporting the southern outdoor GAP on globe artichokes.

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

Table 1: Summary table

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition: oxyfluorfen					
110010	Grapefruit	0.05	–	0.01*	Recommended[(a)]
110020	Oranges	0.05	–	0.01*	Recommended[(a)]
110030	Lemons	0.05	–	0.01*	Recommended[(a)]
110040	Limes	0.05	–	0.01*	Recommended[(a)]
110050	Mandarins	0.05	–	0.01*	Recommended[(a)]
120010	Almonds	0.05	–	0.01*	Recommended[(a)]
120040	Chestnuts	0.05	–	0.01*	Recommended[(a)]
120060	Hazelnuts/cobnuts	0.05	–	0.01*	Recommended[(a)]
120100	Pistachios	0.05	–	0.01*	Recommended[(a)]
120110	Walnuts	0.05	–	0.01*	Recommended[(a)]
130010	Apples	0.1	–	0.01*	Recommended[(a)]
130020	Pears	0.1	–	0.01*	Recommended[(a)]
130030	Quinces	0.1	–	0.01*	Recommended[(a)]
130040	Medlar	0.1	–	0.01*	Recommended[(a)]
130050	Loquat/Japanese medlar	0.1	–	0.01*	Recommended[(a)]
140010	Apricots	0.1	–	0.01*	Recommended[(a)]
140020	Cherries	0.1	–	0.01*	Recommended[(a)]
140030	Peaches	0.1	–	0.01*	Recommended[(a)]
140040	Plums	0.05	–	0.01*	Recommended[(a)]
151010	Table grapes	0.1	–	0.01*	Recommended[(a)]
151020	Wine grapes	0.1	–	0.01*	Recommended[(a)]
161030	Table olives	1	–	0.01*	Recommended[(a)]
161060	Kaki/persimmon	0.05	–	0.01*	Recommended[(a)]
163050	Granate apple/ pomegranate	0.05	–	0.01*	Recommended[(a)]
220020	Onions	0.05	–	0.01*	Recommended[(a)]
242010	Brussels sprouts	0.05	–	0.01*	Recommended[(a)]
242020	Head cabbage	0.05	–	0.01*	Recommended[(a)]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
270050	Globe artichokes	0.05	–	0.05	Further consideration needed[(b)]
401050	Sunflower seed	0.05	–	0.01*	Recommended[(a)]
402010	Olives for oil production	1	–	1	Recommended[(a)]
–	Other commodities of plant and/or animal origin	See Reg. 149/2008	–	–	Further consideration needed[(c)]

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(a): 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 H-I in Appendix E).
(b): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination D-I in Appendix E).
(c): 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.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
CAS	Chemical Abstract Service
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CV	coefficient of variation (relative standard deviation)
CXL	codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DB	dietary burden
DM	dry matter
DP	dustable powder
DS	powder for dry seed treatment
DT_{90}	period required for 90% dissipation (define method of estimation)
EC	emulsifiable concentrate
ECD	electron capture detector
EDI	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	gas chromatography
GC-ECD	gas chromatography with electron capture detector
GC-MS	gas chromatography with mass spectrometry
GC-MS/MS	gas chromatography with tandem mass spectrometry
GS	growth stage
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LC	liquid chromatography
LC-MS/MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
Mo	Monitoring
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEDI	national estimated daily intake
NESTI	national estimated short-term intake
NTMDI	national theoretical maximum daily intake
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PHI	pre-harvest interval
P_{ow}	partition coefficient between *n*-octanol and water
ppm	parts per million (10^{-6})
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RD	residue definition
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern European Union
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
TAR	total applied radioactivity
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UV	ultraviolet (detector)
WHO	World Health Organization

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

A.1. Authorised outdoor uses in northern EU

Crop and/or situation	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	Min interval between application (days)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Onions	PL	F	Dicotyledonous	SC	480 g/L	Foliar treatment – spraying	13–18	2	7	–	–	24 g a.s./ha	n.a.	–

MS: Member State; a.s.: active substance.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(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.

A.2. Authorised outdoor uses in southern EU

Crop and/or situation	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	Min interval between application (days)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Grapefruits	ES	F	Weeds, annual grasses, broadleaves	–	–	Soil treatment – spraying		1	–	–	–	150 g a.s./ha	15	Timing: preemergence of the weeds (autumn–spring). Banded application with tractor (low pressure: 1–2 atm. (100–200 L/ha), max. treated area: 1/3, max. rate: 150 g a.s./ha/year). Do not treat < 4 years plantations. PHI: 15–21 days

Crop and/or situation	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	Min interval between application (days)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Oranges	ES	F	Weeds, annual grasses, broadleaves	–	–	Soil treatment – spraying	–	1	–	–	–	150 g a.s./ha	15	At preemergence of the weeds (autumn–spring). Banded application with tractor (low pressure: 1–2 atm. (100–200 L/ha), max. treated area: 1/3, max. rate: 150 g a.s./ha/year). Do not treat < 4 years plantations. PHI: 15–21 days
Lemons	ES	F	Weeds, annual grasses, broadleaves	–	–	Soil treatment – spraying	–	1	–	–	–	150 g a.s./ha	15	At preemergence of the weeds (autumn–spring). Banded application with tractor (low pressure: 1–2 atm. (100–200 L/ha), max. treated area: 1/3, max. rate: 150 g a.s./ha/year). Do not treat < 4 years plantations. PHI: 15–21 days
Limes	ES	F	Weeds, annual grasses, broadleaves	–	–	Soil treatment – spraying	–	1	–	–	–	150 g a.s./ha	15	At preemergence of the weeds (autumn–spring). Banded application with tractor (low pressure: 1–2 atm. (100–200 L/ha), max. treated area: 1/3, max. rate: 150 g a.s./ha/year). Do not treat < 4 years plantations. PHI: 15–21 days

Crop and/or situation	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	Min interval between application (days)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Mandarins	ES	F	Annual grasses	SC	150 g/L	Soil treatment – spraying	–	1	–	–	75–200	150 g a.s./ha	15	At preemergence or early postemergence of the weeds. Banded application with tractor (low pressure: 1–2 atm., maximum treated area: 1/3 or 1/5 in the irrigation line, maximum rate: 150 g a.s./ha/year)
Almonds	PT	F	Weeds	SC	30 g/L	Soil treatment – spraying	0 to 0	1	–	–	–	150 g a.s./ha	180	–
Chestnuts	ES	F	Annual, perennial grasses (Monocotyle donous and dicotyledonous)	SC	30 g/L	Soil treatment – spraying	59	1	–	–	–	120 g a.s./ha	n.a.	–
Hazelnuts	IT	F	Grass and broadleaves weeds	SC	500 g/L	Soil treatment – spraying	0 to 0	1	–	–	–	135 g a.s./ha	n.a.	Spraying close to the ground, in banded applications where only a 30% of the total surface is treated. During dormancy, from autumn until beginning of spring
Pistachios	ES	F	Annual, perennial grasses (Monocotyle donous and dicotyledonous)	SC	30 g/L	Soil treatment – spraying	59	1	–	–	–	120 g a.s./ha	n.a.	–

Crop and/or situation	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	Min interval between application (days)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Walnuts	ES	F	Annual, perennial grasses (Monocotyledonous and dicotyledonous)	SC	30 g/L	Soil treatment – spraying	59	1	–	–	–	120 g a.s./ha	n.a.	–
Apples	PT, ES	F	Weeds, annual grasses	–	–	Soil treatment – spraying	0 to 0	1	–	–	–	150 g a.s./ha	180	–
Pears	PT, ES	F	Weeds, annual grasses	–	–	Soil treatment – spraying	0 to 0	1	–	–	–	150 g a.s./ha	180	–
Quinces	PT, ES	F	Weeds, annual grasses	–	–	Soil treatment – spraying	0 to 0	1	–	–	–	150 g a.s./ha	180	–
Medlars	ES	F	Weeds, annual grasses	–	–	Soil treatment – spraying	0 to 0	1	–	–	–	150 g a.s./ha	180	–
Loquats	ES	F	Weeds, annual grasses	–	–	Soil treatment – spraying	0 to 0	1	–	–	–	150 g a.s./ha	180	–
Apricots	IT	F	Annual grasses		240 g/L	Soil treatment – spraying	0 to 0	1	–	–	400	144 g a.s./ha	120	Spraying close to the ground, in banded applications where only a 30% of the total surface is treated. During dormancy, from autumn until beginning of spring
Cherries	PT	F	Weeds	–	–	Soil treatment – spraying	0 to 0	1	–	–	–	150 g a.s./ha	180	–

Crop and/or situation	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	Min interval between application (days)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Peaches	PT	F	Weeds	–	–	Soil treatment – spraying	0 to 0	1	–	–	–	150 g a.s./ha	180	–
Plums	PT	F	Weeds	–	–	Soil treatment – spraying	0 to 0	1	–	–	–	150 g a.s./ha	180	–
Table grapes	PT, ES	F	Weeds	–	–	Soil treatment – spraying	0 to 0	1	–	–	–	150 g a.s./ha	180	Application method: boom spraying directed to ground, banded application Application time: dormant
Wine grapes	PT, ES	F	Weeds	–	–	Soil treatment – spraying	0 to 0	1	–	–	–	150 g a.s./ha	180	Application method: boom spraying directed to ground, banded application Application time: dormant
Table olives	ES	F	Annual grasses	SC	150 g/L	Soil treatment – spraying		1	–	–	200	150 g a.s./ha	7	At preemergence or early postemergence of the weeds. Banded application with tractor (low pressure: 1–2 atm., max. treated area: 1/3 or 1/5 in the irrigation line). Not applied with dropped olives to the soil (olives picked from the tree)
Kaki	ES	F	Annual, perennial grasses (Monocotyle donous and dicotyledonous)	SC	30 g/L	Soil treatment – spraying	59	1	–	–	–	120 g a.s./ha	n.a.	–
Granate apples	PT	F	Weeds	SC	480 g/L	Soil treatment – spraying	0 to 0	1	–	–	–	144 g a.s./ha	n.a.	–

Crop and/or situation	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	Min interval between application (days)	a.s./ hL min–max	Water L/ha min–max	Rate and unit		
Onions	IT	F	Weeds			Foliar treatment – spraying	12 to 13	2	–	–	–	96 g a.s./ ha	n.a.	Max. total rate per season: 144 g a.s./ha
Brussels sprouts	PT	F	Weeds	SC	480 g/L	Soil treatment – spraying	0 to 0	1	–	–	–	144 g a.s./ ha	n.a.	–
Head cabbages	PT	F	Weeds	SC	480 g/L	Soil treatment – spraying	0 to 0	1	–	–	–	144 g a.s./ ha	n.a.	–
Globe artichokes	IT	F	Grass and broadleaves weeds	EC	240 g/L	Soil treatment – spraying	0 to 39	1	–	–	–	135 g a.s./ ha	n.a.	Spraying on the crop row in banded applications where only a 30% of the total surface is treated. During post–emergency of the crop (winter)
Sunflower seeds	IT	F	Dicot weeds (annual & perennial)	SC	480 g/L	Soil treatment – spraying	0 to 9	1	–	–	–	150 g a.s./ ha	n.a.	Pre–emergence of crop
Olives for oil production	PT, ES, IT	F	Weeds	SC	480 g/L	Soil treatment – spraying	81 to 89	1	–	–	–	144 g a.s./ ha	7	At preemergence or early postemergence of the weeds. Banded application close to the ground with tractor (maximum treated area: 1/3) Not specified, treatment with or without olives to the ground

MS: Member State; a.s.: active substance.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(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	Tomato	Soil, 32 days priors to transplanting tomatoes, 1 × 2.8 kg a.s./ha	Ripe tomato: 103, 113, 126, 147 DAT Leaves, stems: 32, 61, 147 DAT	Radiolabelled oxyfluorfen, in the chlorophenyl ring (^{14}C-CPR) or nitrophenyl ring (^{14}C-NPR) (Spain, 2006, 2010, EFSA, 2010)
		Peach	Soil, 1 × 11.2 kg a.s./ha	Twigs: 0, 8, 16, 30 DAT Leaves: 63 DAT Immature fruit: 63, 91 DAT Mature fruit: 126 DAT	Radiolabelled oxyfluorfen, ^{14}C-CPR or ^{14}C-NPR (Spain, 2006, 2010, EFSA, 2010)
		Apple	Soil, 1 × 2.2 kg a.s./ha	Immature fruits: 32, 63 DAT Mature fruits: 95, 103 DAT Twigs and leaf/stem: 0, 7, 14, 32, 63, 95 and 126 DAT	Radiolabelled oxyfluorfen in the trifluoromethyl (CF_3) group (Spain, 2006, 2010, EFSA, 2010)
			Soil, in three plots: 1 × 2.2, 1 × 4.5 and 1 × 9 kg a.s./ha, respectively	Immature fruits: 32, 63 DAT Mature fruits: 95, 103 DAT Twigs and leaf/stem: 0, 7, 14, 32, 63, 95 and 126 DAT	Radiolabelled oxyfluorfen ^{14}C-NPR (Spain, 2006, 2010, EFSA, 2010)
	Root crops	Onion	Foliar post-emergence, 2 × 1.4 kg a.s./ha, 24 days interval (first application at four-leaf stage)	15, 24, 43, 53 DAT	Radiolabelled oxyfluorfen, ^{14}C-CPR or ^{14}C-NPR Onions were let dry for 10 days before processing (Spain, 2006, 2010, EFSA, 2010)
	Leafy crops	Alfalfa	Foliar (early stage, so much of a.s. reached the soil), 1 × 2.24 kg a.s./ha	45, 76, 109, 158 DAT	Radiolabelled oxyfluorfen, ^{14}C-CPR or ^{14}C-NPR (Spain, 2006, 2010, EFSA, 2010)

Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	Fruits/ fruiting vegetables	Tomato	Bare soil, 1.1 kg a.s./ha	0, 31, 61, 91, 123	Radiolabelled oxyfluorfen, ^{14}C-CPR or ^{14}C-NPR (Spain, 2006, 2010, EFSA, 2010)
		Squash	Bare soil, 1.1 kg a.s./ha	0, 31, 61, 91, 123	Radiolabelled oxyfluorfen, ^{14}C-CPR or ^{14}C-NPR (Spain, 2006, 2010, EFSA, 2010)
		Pepper	Bare soil, 1.1 kg a.s./ha	0, 31, 61, 91, 123	Radiolabelled oxyfluorfen, ^{14}C-CPR or ^{14}C-NPR (Spain, 2006, 2010, EFSA, 2010)
	Root/tuber crops	Turnip	Bare soil, 1.1 kg a.s./ha	61, 91, 123	Radiolabelled oxyfluorfen, ^{14}C-CPR or ^{14}C-NPR (Spain, 2006, 2010, EFSA, 2010)
		Beet	Bare soil, 1.1 kg a.s./ha	0, 31, 61, 91, 123	Radiolabelled oxyfluorfen, ^{14}C-CPR or ^{14}C-NPR (Spain, 2006, 2010, EFSA, 2010)
	Leafy crops	Swiss chard	Bare soil, 1.1 kg a.s./ha	0, 31, 61, 91, 123	Radiolabelled oxyfluorfen, ^{14}C-CPR or ^{14}C-NPR (Spain, 2006, 2010, EFSA, 2010)
		Collard	Bare soil, 1.1 kg a.s./ha	61, 91, 123	Radiolabelled oxyfluorfen, ^{14}C-CPR or ^{14}C-NPR (Spain, 2006, 2010, EFSA, 2010)
	Cereal (small grain)	Wheat	Bare soil, 1.1 kg a.s./ha	Spring wheat: 0, 31, 61 Winter wheat: 91, 123	Results at 91 and 123 DAT were not reported. Radiolabelled oxyfluorfen, ^{14}C-CPR or ^{14}C-NPR (Spain, 2006, 2010, EFSA, 2010)

Processed commodities (hydrolysis study)	**Conditions**	**Stable?**	**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)	Not triggered	–
	Baking, brewing and boiling (60 min, 100°C, pH 5)	Not triggered	–
	Sterilisation (20 min, 120°C, pH 6)	Not triggered	–

Can a general residue definition be proposed for primary crops?	Yes	Metabolism of oxyfluorfen investigated in three different groups (fruit crops, roots/tubers, leafy crops).
Rotational crop and primary crop metabolism similar?	Not applicable	No conclusion possible since residues in rotational crops too low to allow identification of metabolites (most values < 0.01 mg/kg). However, no further study and no specific residue definition are required for rotational crops considering the limited uptake from the soil.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not applicable	No hydrolysis studies available and not needed as the total theoretical maximum daily intake is below 10% of the ADI and residue levels in raw commodities are below 0.1 mg/kg (except in olives for oil production, but for which processing studies are available). Considering the nature of the active substance, it is not expected that processing impacts the metabolism of oxyfluorfen.
Plant residue definition for monitoring (RD-Mo)	Oxyfluorfen	
Plant residue definition for risk assessment (RD-RA)	Oxyfluorfen	
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)	Matrices with high water content, high oil content, high acid content and dry matrices: • Multiresidue method DFG-S19 with GC-ECD, LOQ 0.01 mg/kg Confirmation by GC–MS ILV available (Spain, 2006; EFSA, 2010) QuEChERS multi-residue analytical method (QuOil in high oil content commodities), LOQ 0.01 mg/kg. In high water content, high acid content and dry commodities even lower levels were successfully validated: 0.005 mg/kg (EURLs, 2019).	

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; GC-ECD: gas chromatography with electron capture detector; GC–MS: gas chromatography with mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method).

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**	**Comment/Source**
				Value	**Unit**		
	High water content	Alfalfa, banana, apple, cabbage, onion, peach	–10	36	Months	Oxyfluorfen	Spain (2006), EFSA (2010)
	High oil content	Cotton seeds, almond	–10	36	Months	Oxyfluorfen	Spain (2006), EFSA (2010)
	Dry/High starch content	Wheat grain	–10	36	Months	Oxyfluorfen	Spain (2006), EFSA (2010)
	High acid content	Orange, strawberry	–10	36	Months	Oxyfluorfen	Spain (2006), EFSA (2010)

B.1.2. Magnitude of residues in plants

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

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 Lemons Limes Mandarins	SEU	7 × < 0.01	Combined data set of overdosed trials on oranges (3) and mandarins (4) performed with 6N rate (Spain, 2019) deemed acceptable since residues < LOQ. Extrapolation to other citrus fruits is applicable	0.01*	0.01	0.01	1.00
Almonds Hazelnuts/cobnuts	SEU	8 × < 0.01	Combined data set of overdosed residue trials on apples (4) and on apricots (4), deemed acceptable as residue levels < LOQ (Spain, 2006, 2019). Extrapolation to almond and hazelnut is applicable	0.01*	0.01	0.01	1.00
Chestnuts Pistachios Walnuts	SEU	8 × < 0.01	Combined data set of overdosed residue trials on apples/pears (4) and citrus (4) performed with 8–10N rate; acceptable as residue levels < LOQ in all orchards (Spain, 2010, 2019). Extrapolation to chestnut, walnut and pistachio is applicable	0.01*	0.01	0.01	1.00
Apples Pears Quinces Medlars Loquats/Japanese medlars	SEU	8 × < 0.01	Combined data set of overdosed residue trials on apples (4) and pears (4), performed with up to 10N rate; deemed acceptable as residue levels < LOQ (Spain, 2010, 2019). Extrapolation to the whole group of pome fruits is applicable	0.01*	0.01	0.01	1.00
Apricots	SEU	4 × < 0.01	Overdosed trials on apricots performed with 6N rate; deemed acceptable as residue levels < LOQ (Spain, 2019)	0.01*	0.01	0.01	1.00
Cherries (sweet) Peaches Plums	SEU	8 × < 0.01	Combined data set of overdosed trials on apricots (4) and apples (4) performed with 6N rate, deemed acceptable as residue levels < LOQ (Spain, 2019). Extrapolation to other stone fruits is applicable	0.01*	0.01	0.01	1.00

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]
Table grapes	SEU	5 × < 0.01	Overdosed trials on grapes performed with 10N rate (EFSA 2010; Spain, 2019), deemed acceptable as residue levels < LOQ	0.01*	0.01	0.01	1.00
Wine grapes	SEU	5 × < 0.01	Overdosed trials on grapes performed with 10N rate (EFSA 2010; Spain, 2019), deemed acceptable as residue levels < LOQ	0.01*	0.01	0.01	1.00
Table olives	SEU	23 × < 0.01	Overdosed trials on olives (sampled from the tree) performed with 6N rate (Spain, 2019); deemed acceptable since residues < LOQ	0.01*	0.01	0.01	1.00
Kaki/Japanese persimmons	SEU	4 × < 0.01	Combined dataset of overdosed residue trials on apples (1) and pears (3), performed with 6N rate; deemed acceptable as residue levels < LOQ (Spain, 2010, 2019). Extrapolation to kaki is applicable	0.01*	0.01	0.01	1.00
Granate apples/pomegranates	SEU	–	A no residue situation can be anticipated based on the overdosed metabolism studies and residue trials on orchards. In addition, oxyfluorfen is a non-systemic a.s. applied as a soil treatment at BBCH 00 (Spain, 2019)	0.01*	< 0.01	< 0.01	1.00
Onions	NEU	4 × < 0.01	Overdosed trials on onions performed with 1 treatment at 10N rate (Spain, 2019), deemed acceptable since residues < LOQ	0.01*	0.01	0.01	1.00
	SEU	4 × <0.01	Overdosed trials on onions performed with 1 treatment at 2.5N rate (Spain, 2019), deemed acceptable since residues <LOQ	0.01*	0.01	0.01	1.00
Brussel sprouts	SEU	–	A no residue situation can be anticipated based on the overdosed metabolism studies on leafy crops and rotational crops. In addition, oxyfluorfen is a non-systemic a.s. applied as a soil treatment at BBCH 00 (Spain, 2019)	0.01*	< 0.01	< 0.01	1.00

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]
Head cabbage	SEU	–	A no residue situation can be anticipated based on the overdosed metabolism studies on leafy crops and rotational crops. In addition, oxyfluorfen is a non-systemic a.s. applied as a soil treatment at BBCH 00 (Spain, 2019)	0.01*	<0.01	<0.01	1.00
Globe artichokes	SEU	–	No data available A no residue situation cannot be anticipated based on metabolism studies. Trials compliant with GAP are required	–	–	–	–
Sunflower seeds	SEU	7 × < 0.01	Trials on sunflower compliant with the GAP (Spain, 2019)	0.01*	0.01	0.01	1.00
Olives for oil production	SEU	2 × < 0.01; 0.01; 0.03; 0.05; 0.06; 0.07; 0.09; 0.13; 0.16; 0.17; 2 × 0.20; 0.23; 0.27; 0.30; 0.33; 0.55; 0.78	Overdosed trials on olives (sampled from the ground in accordance with possible practices). Trial results scaled down with the GAP (Spain, 2019) MRL_{OECD} = 0.98	1.00	0.78	0.16	1.00

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

Overall summary

Residues in rotational and succeeding crops expected based on confined rotational crop study?	No	TRRs < 0.01 mg/kg in all rotational commodities, except in inedible parts of cereals like straw and chaff at plant back intervals of 0, 31 and 61 days (0.02 to 0.06 mg/kg)
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	Highly overdosed confined study showed that no residues occur in rotational crops even with soil concentration of 0.92 mg/kg. In addition, this study is covering the maximum PEC soil total estimated for oxyfluorfen residues

TRR: total radioactive residue.

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		
Olive, oil	8	5.6; 4.7; 3.5; 4.62; 4.35; 4.0; 5.1; 2.5; 4.19; 3.12; 4.55; 2.81; 11.00; 5.07	4.45	1	Presence of olives on the soil at application sampled from the ground[c] (Spain, 2019)
	6	8.7; 4.6; 2.2; 2.3; 4.1; 3.6; 7.3; 3.7; 2.74; 2.00; 11.00; 5.07; 1.09; 4.19; 3.60; 3.36	3.65	1	Olives dropped to the soil not long after the application sampled from the ground[c] (Spain, 2019)
Olive, press cake	2	0.50; 0.96	0.73	1	Tentative[d] (Spain, 2019)

PF: Processing factor (=Residue level in processed commodity expressed according to RD-Mo/Residue level in raw commodity expressed according to RD-Mo);
CF_p: Conversion factor for risk assessment in processed commodity (=Residue level in processed commodity expressed according to RD-RA/Residue level in processed commodity expressed according to RD-Mo).
(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Median of the individual conversion factors for each processing residues trial.
(c): A separate calculation was performed to anticipate two possible situations. The PF obtained from the worst-case situation was selected to perform the risk assessment.
(d): A tentative PF is derived based on a limited data set (mean value of 2 PFs).

B.2. Residues in livestock

Relevant groups (subgroups)	Dietary burden expressed in				Most critical subgroup[a]	Most critical commodity[b]	Trigger exceeded (Yes/No)	Comments
	mg/kg bw per day		mg/kg DM					
	Median	Maximum	Median	Maximum				
Cattle (all)	0.001	0.001	0.02	0.02	Dairy cattle	Cabbage, heads leaves	No	–
Cattle (dairy only)	0.001	0.001	0.02	0.02	Dairy cattle	Cabbage, heads leaves	No	–
Sheep (all)	0.000	0.000	0.01	0.01	Lamb	Cabbage, heads leaves	No	–
Sheep (ewe only)	0.000	0.000	0.01	0.01	Ram/Ewe	Cabbage, heads leaves	No	–
Swine (all)	0.000	0.000	0.01	0.01	Swine (breeding)	Cabbage, heads leaves	No	–
Poultry (all)	0.000	0.000	0.00	0.00	Poultry layer	Cabbage, heads leaves	No	–
Poultry (layer only)	0.000	0.000	0.00	0.00	Poultry layer	Cabbage, heads leaves	No	–

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 day)	Duration (days)	Comment/Source
	Laying hens	1.03 (^{14}C-CPR label) Or 1.08 (^{14}C-NPR label)	7	^{14}C-CPR or ^{14}C-NPR radiolabelled oxyfluorfen (Spain, 2006). However, study considered not valid to conclude on a residue definition, since conducted with oxyfluorfen, whereas the plant metabolism data have shown the parent is not present in plant commodities (EFSA, 2010) Dose rate recalculated assuming body weight of 1.9 kg and feed intake of 0.13 kg per day
	Lactating ruminants	0.58	7	Lactating goats, ^{14}C-CPR or ^{14}C-NPR radiolabelled oxyfluorfen (Spain, 2006). However, study considered not valid to conclude on a residue definition, since conducted with oxyfluorfen, whereas the plant metabolism data have shown the parent is not present in plant commodities (EFSA, 2010) Dose rate recalculated assuming mean body weight of 51.7 kg and feed intake of 2 kg per day

Time needed to reach a plateau concentration in milk and eggs (days)	Milk: –	No plateau identified, but there was no evidence of accumulation of residues in milk (Spain, 2006)
	Eggs: –	No plateau was reached during the seven-day dosing period. In the available feeding study, a plateau was reached in 10 days (Spain, 2006)
Metabolism in rat and ruminant similar	Yes	When considering oxyfluorfen only (EFSA, 2010)
Can a general residue definition be proposed for animals?	Not applicable	Metabolism studies were available but performed with oxyfluorfen, whereas the plant metabolism data have shown the parent is not present in feedstuff. Thus, these studies are not appropriate to conclude on a residue definition (EFSA, 2010). Nevertheless, considering the limited intake by livestock, a residue definition and MRLs are not required under the current review
Animal residue definition for monitoring (RD-Mo)	Not required	
Animal residue definition for risk assessment (RD-RA)	Not required	
Fat soluble residues	Yes	Yes, when considering oxyfluorfen only. Log Pow = 4.86 (>3) at 18 °C (EFSA, 2010) Fat contained the highest concentration of parent compound showing a potential for accumulation in fat (Spain, 2006).
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)	Although not required, analytical methods are available: • Multiresidue method DFG-S19 with GC-ECD, for the determination of oxyfluorfen with an LOQ 0.01 mg/kg in milk, eggs, muscle, fat and liver Confirmation by GC–MS ILV available validated in milk and fat (Spain, 2006, 2010; EFSA, 2010) • Oxyfluorfen can be monitored by GC-MS/MS in infant formula (milk), muscle, egg and liver with an LOQ of 0.01 mg/kg. In egg and muscle lower levels were successfully validated down to 0.001 mg/kg, in liver down to 0.002 mg/kg and in infant formula (milk) down to 0.0025 mg/kg. Screening data generated for commodities of animal origin showed that oxyfluorfen can be monitored in eggs with an SDL of 0.001 mg/kg. (EURLs, 2019)	

bw: body weight; GC-ECD: gas chromatography with electron capture detector; GC MS: gas chromatography with mass spectrometry; GC–MS/MS: gas chromatography with tandem mass spectrometry; Pow: partition coefficient between *n*-octanol and water; LOQ: limit of quantification; ILV: independent laboratory validation; SDL: screening detection limit.

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		
	Bovine	Muscle	–10	14	Months	oxyfluorfen	Spain (2006)
	Bovine	Liver	–10	14	Months	oxyfluorfen	Spain (2006)
	Bovine	Milk	–10	12	Months	oxyfluorfen	Spain (2006)
	Poultry	Eggs	–10	12	Months	oxyfluorfen	Spain (2006)

B.2.2. Magnitude of residues in livestock

Feeding studies are not required.

B.3. Consumer risk assessment

ARfD	0.3 mg/kg bw (European Commission, 2017a)
Highest IESTI, according to EFSA PRIMo (rev.3.1)	Pears: 0.5% of the ARfD
NESTI (% ARfD)	Not assessed in this review
Assumptions made for the calculations	The calculation is based on the highest residue levels expected in raw agricultural commodities, except for sunflower seeds and olives for oil production where the median residue levels derived is used. For globe artichoke where data were insufficient to derive an MRL, EFSA considered the existing EU MRL

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; NESTI: national estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; MRL: maximum residue level.

ADI	0.003 mg/kg bw per day (European Commission, 2017a)
TMDI according to EFSA PRIMo	Not assessed in this review
NTMDI, according to (to be specified)	Not assessed in this review
Highest IEDI, according to EFSA PRIMo (rev.3.1)	7% ADI (DE child/NL toddler)
NEDI (% ADI)	Not assessed in this review
Assumptions made for the calculations	The calculation is based on the median residue levels derived for raw agricultural commodities. For globe artichoke where data were insufficient to derive an MRL, EFSA considered the existing EU MRL The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation

ADI: acceptable daily intake; bw: body weight; TMDI: theoretical maximum daily intake; NTMDI: national theoretical maximum daily intake; IEDI: international estimated daily intake; NEDI: national estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; MRL: maximum residue level; GAP: Good Agricultural Practice.

Consumer exposure assessment through drinking water resulting from groundwater metabolite(s) according to SANCO/221/2000 rev.10 Final (25/02/2003)

Metabolite(s)	Not assessed in this review
ADI (mg/kg bw per day)	Not assessed in this review
Intake of groundwater metabolites (% ADI)	Not assessed in this review

B.4. Proposed MRLs

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition: oxyfluorfen					
110010	Grapefruit	0.05	–	0.01*	Recommended[(a)]
110020	Oranges	0.05	–	0.01*	Recommended[(a)]
110030	Lemons	0.05	–	0.01*	Recommended[(a)]
110040	Limes	0.05	–	0.01*	Recommended[(a)]
110050	Mandarins	0.05	–	0.01*	Recommended[(a)]
120010	Almonds	0.05	–	0.01*	Recommended[(a)]
120040	Chestnuts	0.05	–	0.01*	Recommended[(a)]
120060	Hazelnuts/cobnuts	0.05	–	0.01*	Recommended[(a)]
120100	Pistachios	0.05	–	0.01*	Recommended[(a)]
120110	Walnuts	0.05	–	0.01*	Recommended[(a)]
130010	Apples	0.1	–	0.01*	Recommended[(a)]
130020	Pears	0.1	–	0.01*	Recommended[(a)]
130030	Quinces	0.1	–	0.01*	Recommended[(a)]
130040	Medlar	0.1	–	0.01*	Recommended[(a)]
130050	Loquat/Japanese medlar	0.1	–	0.01*	Recommended[(a)]
140010	Apricots	0.1	–	0.01*	Recommended[(a)]
140020	Cherries	0.1	–	0.01*	Recommended[(a)]
140030	Peaches	0.1	–	0.01*	Recommended[(a)]
140040	Plums	0.05	–	0.01*	Recommended[(a)]
151010	Table grapes	0.1	–	0.01*	Recommended[(a)]
151020	Wine grapes	0.1	–	0.01*	Recommended[(a)]
161030	Table olives	1	–	0.01*	Recommended[(a)]
161060	Kaki/persimmon	0.05	–	0.01*	Recommended[(a)]
163050	Granate apple/pomegranate	0.05	–	0.01*	Recommended[(a)]
220020	Onions	0.05	–	0.01*	Recommended[(a)]
242010	Brussels sprouts	0.05	–	0.01*	Recommended[(a)]
242020	Head cabbage	0.05	–	0.01*	Recommended[(a)]
270050	Globe artichokes	0.05	–	0.05	Further consideration needed[(b)]
401050	Sunflower seed	0.05	–	0.01*	Recommended[(a)]
402010	Olives for oil production	1	–	1	Recommended[(a)]
–	Other commodities of plant and/or animal origin	See Reg. 149/2008	–	–	Further consideration needed[(c)]

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(a): 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 H-I in Appendix E).
(b): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination D-I in Appendix E).
(c): 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)

- PRIMo(EU)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

OXYFLUORFEN

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

Toxicological reference values

ADI (mg/kg bw per day):	0.003	ARfD (mg/kg bw):	0.3
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2017a	Year of evaluation:	2017a

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
	7%	DE child	0.22	4%	Apples	1%	Oranges	0.5%	Table grapes		7%
	7%	NL toddler	0.22	4%	Apples	1%	Pears	0.7%	Oranges		7%
	6%	GEMS/Food G08	0.19	4%	Olives for oil production	0.4%	Apples	0.3%	Wine grapes		6%
	6%	ES child	0.17	4%	Olives for oil production	0.7%	Oranges	0.4%	Apples		6%
	4%	NL child	0.12	2%	Apples	0.5%	Oranges	0.4%	Pears		4%
	4%	GEMS/Food G06	0.12	2%	Olives for oil production	0.4%	Table grapes	0.3%	Oranges		4%
	4%	GEMS/Food G07	0.11	2%	Olives for oil production	0.5%	Wine grapes	0.5%	Oranges		4%
	4%	GEMS/Food G10	0.11	2%	Olives for oil production	0.4%	Oranges	0.3%	Apples		4%
	4%	ES adult	0.11	2%	Olives for oil production	0.4%	Oranges	0.3%	Apples		4%
	3%	PT general	0.10	1%	Olives for oil production	0.8%	Wine grapes	0.4%	Apples		3%
	3%	GEMS/Food G11	0.09	1%	Olives for oil production	0.5%	Apples	0.3%	Wine grapes		3%
	3%	FR child 3 15 yr	0.09	1%	Oranges	0.6%	Olives for oil production	0.6%	Apples		3%
	3%	GEMS/Food G15	0.09	1.0%	Olives for oil production	0.4%	Apples	0.3%	Wine grapes		3%
	3%	DE women 14-50 yr	0.08	0.9%	Apples	0.6%	Oranges	0.5%	Olives for oil production		3%
	3%	DE general	0.08	0.8%	Apples	0.5%	Oranges	0.5%	Olives for oil production		3%
	2%	RO general	0.07	0.6%	Wine grapes	0.5%	Head cabbages	0.5%	Apples		2%
	2%	FR toddler 2 3 yr	0.07	1%	Apples	0.5%	Oranges	0.3%	Mandarins		2%
	2%	IE adult	0.07	0.4%	Wine grapes	0.3%	Oranges	0.2%	Apples		2%
	2%	FR adult	0.06	0.8%	Wine grapes	0.4%	Olives for oil production	0.3%	Apples		2%
	2%	UK toddler	0.05	0.7%	Oranges	0.6%	Apples	0.1%	Mandarins		2%
	2%	NL general	0.05	0.5%	Apples	0.3%	Oranges	0.2%	Wine grapes		2%
	1%	SE general	0.04	0.4%	Apples	0.2%	Oranges	0.2%	Head cabbages		1%
	1%	DK child	0.04	0.8%	Apples	0.2%	Pears	0.1%	Onions		1%
	1%	UK infant	0.04	0.5%	Apples	0.4%	Oranges	0.1%	Pears		1%
	1%	PL general	0.04	0.7%	Apples	0.1%	Head cabbages	0.1%	Onions		1%
	1%	UK vegetarian	0.03	0.3%	Oranges	0.3%	Wine grapes	0.2%	Apples		1%
	1%	DK adult	0.03	0.3%	Apples	0.3%	Wine grapes	0.1%	Pears		1%
	1.0%	IT toddler	0.03	0.3%	Apples	0.2%	Oranges	0.1%	Peaches		1.0%
	0.9%	FI 3 yr	0.03	0.3%	Apples	0.1%	Onions	0.1%	Mandarins		0.9%
	0.9%	IT adult	0.03	0.3%	Apples	0.1%	Peaches	0.1%	Oranges		0.9%
	0.9%	FR infant	0.03	0.6%	Apples	0.1%	Oranges	0.1%	Pears		0.9%
	0.9%	UK adult	0.03	0.4%	Wine grapes	0.2%	Oranges	0.1%	Apples		0.9%
	0.9%	LT adult	0.03	0.6%	Apples	0.1%	Head cabbages	0.1%	Pears		0.9%
	0.7%	FI 6 yr	0.02	0.2%	Apples	0.1%	Mandarins	0.1%	Onions		0.7%
	0.6%	FI adult	0.02	0.2%	Apples	0.1%	Oranges	0.1%	Wine grapes		0.6%
	0.2%	IE child	0.01	0.1%	Apples	0.0%	Oranges	0.0%	Table grapes		0.2%

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

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.5%	Pears	0.01/0.01	1.4
0.4%	Oranges	0.01/0.01	1.3
0.4%	Apples	0.01/0.01	1.1
0.3%	Peaches	0.01/0.01	0.95
0.3%	Globe artichokes	0.05/0.05	0.88
0.3%	Grapefruits	0.01/0.01	0.79
0.2%	Table grapes	0.01/0.01	0.73
0.2%	Mandarins	0.01/0.01	0.59
0.2%	Granate	0.01/0.01	0.55
0.2%	Kaki/Japanese persimmons	0.01/0.01	0.47
0.1%	Head cabbages	0.01/0.01	0.44
0.1%	Plums	0.01/0.01	0.42
0.1%	Apricots	0.01/0.01	0.35
0.1%	Lemons	0.01/0.01	0.34
0.08%	Quinces	0.01/0.01	0.25

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.2%	Globe artichokes	0.05/0.05	0.65
0.1%	Head cabbages	0.01/0.01	0.42
0.1%	Table grapes	0.01/0.01	0.34
0.1%	Oranges	0.01/0.01	0.31
0.1%	Pears	0.01/0.01	0.31
0.09%	Apples	0.01/0.01	0.28
0.08%	Wine grapes	0.01/0.01	0.24
0.07%	Kaki/Japanese persimmons	0.01/0.01	0.22
0.06%	Peaches	0.01/0.01	0.19
0.06%	Mandarins	0.01/0.01	0.18
0.06%	Grapefruits	0.01/0.01	0.18
0.06%	Plums	0.01/0.01	0.18
0.06%	Granate	0.01/0.01	0.18
0.05%	Quinces	0.01/0.01	0.15
0.05%	Onions	0.01/0.01	0.15

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.2%	Olives for oil production/oils	1/0.71	0.66
0.2%	Apples/juice	0.01/0.01	0.54
0.2%	Oranges/juice	0.01/0.01	0.53
0.1%	Wine grapes/juice	0.01/0.01	0.44
0.1%	Pears/juice	0.01/0.01	0.33
0.1%	Peaches/canned	0.01/0.01	0.26
0.1%	Peaches/juice	0.01/0.01	0.17
0.0%	Brussels sprouts/boiled	0.01/0.01	0.10
0.0%	Plums/juice	0.01/0.01	0.09
0.0%	Head cabbages/canned	0.01/0.01	0.06
0.0%	Lemons/jam	0.01/0.01	0.03
0.0%	Lemons/jam	0.01/0.01	0.03
0.0%	Pomegranates/juice	0.01/0.01	0.03
0.0%	Sunflower seeds/oils	0.01/0.02	0.02
0.0%	Table olives/canned	0.01/0.01	0.01

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Apples/juice	0.01/0.01	0.33
0.07%	Wine grapes/juice	0.01/0.01	0.21
0.05%	Oranges/juice	0.01/0.01	0.15
0.04%	Grapefruits/juice	0.01/0.01	0.11
0.03%	Wine grapes/wine	0.01/0.01	0.09
0.03%	Onions/boiled	0.01/0.01	0.09
0.03%	Head cabbages/canned	0.01/0.01	0.09
0.03%	Peaches/canned	0.01/0.01	0.08
0.02%	Table grapes/raisins	0.01/0.05	0.06
0.01%	Lemons/juice	0.01/0.01	0.02
0.00%	Table olives/canned	0.01/0.01	0.01
0.00%	Quinces/jam	0.01/0.01	0.01
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of OXYFLUORFEN is unlikely to present a public health risk.
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 1: oxyfluorfen				
Cabbage, heads leaves	0.01*	STMR	0.01*	HR
Apple pomace, wet	0.01*	STMR[(a)]	0.01*	STMR[(a)]
Citrus dried pulp	0.01*	STMR[(a)]	0.01*	STMR[(a)]
Sunflower meal	0.01*	STMR[(a)]	0.01*	STMR[(a)]

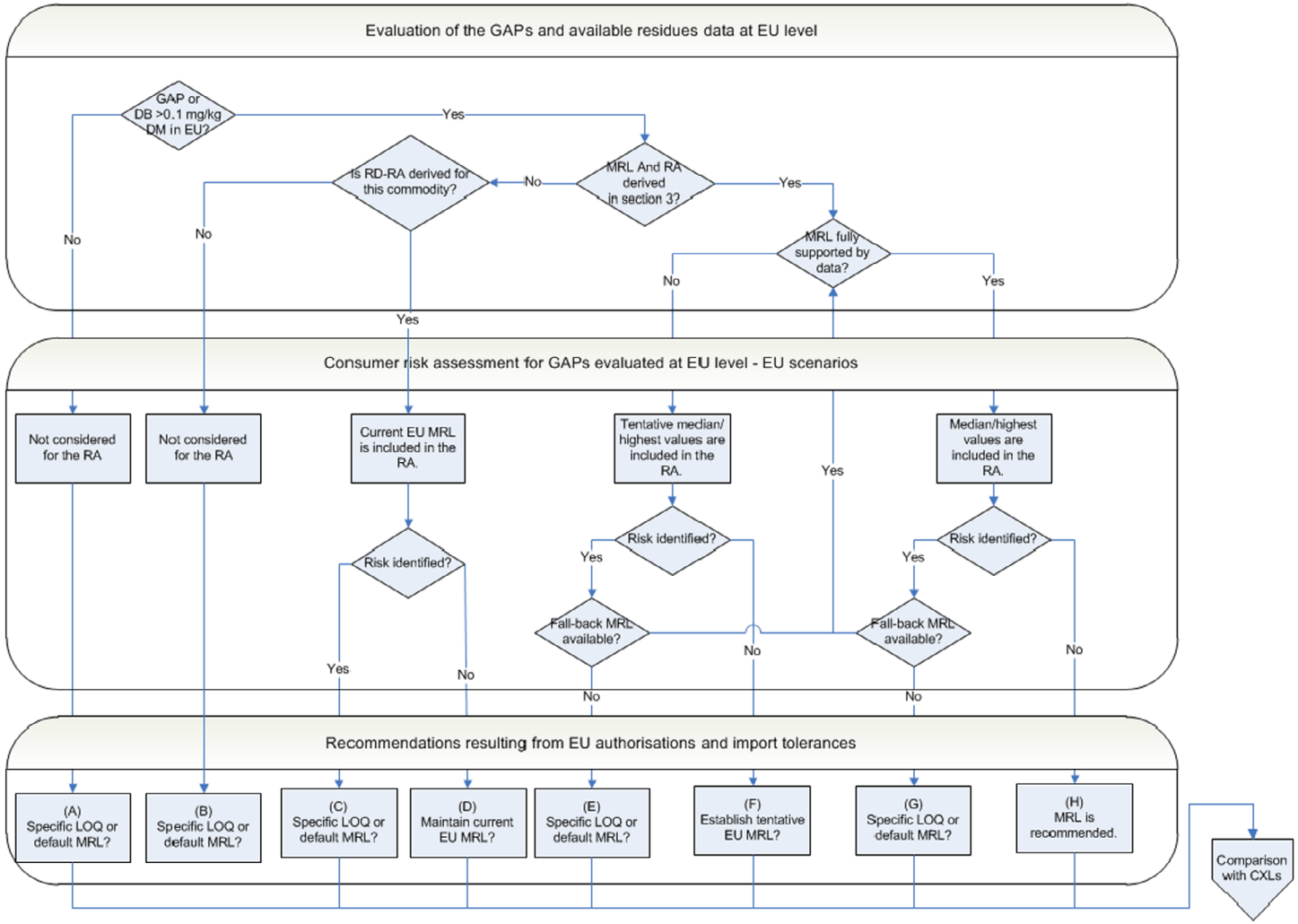
STMR: supervised trials median residue; HR: highest residue.
*: Indicates that the input value is proposed at the limit of quantification.
(a): For apple pomace, citrus dried pulp and sunflower meal, no default processing factor was applied because oxyfluorfen is applied to the ground early in the growing season and residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.

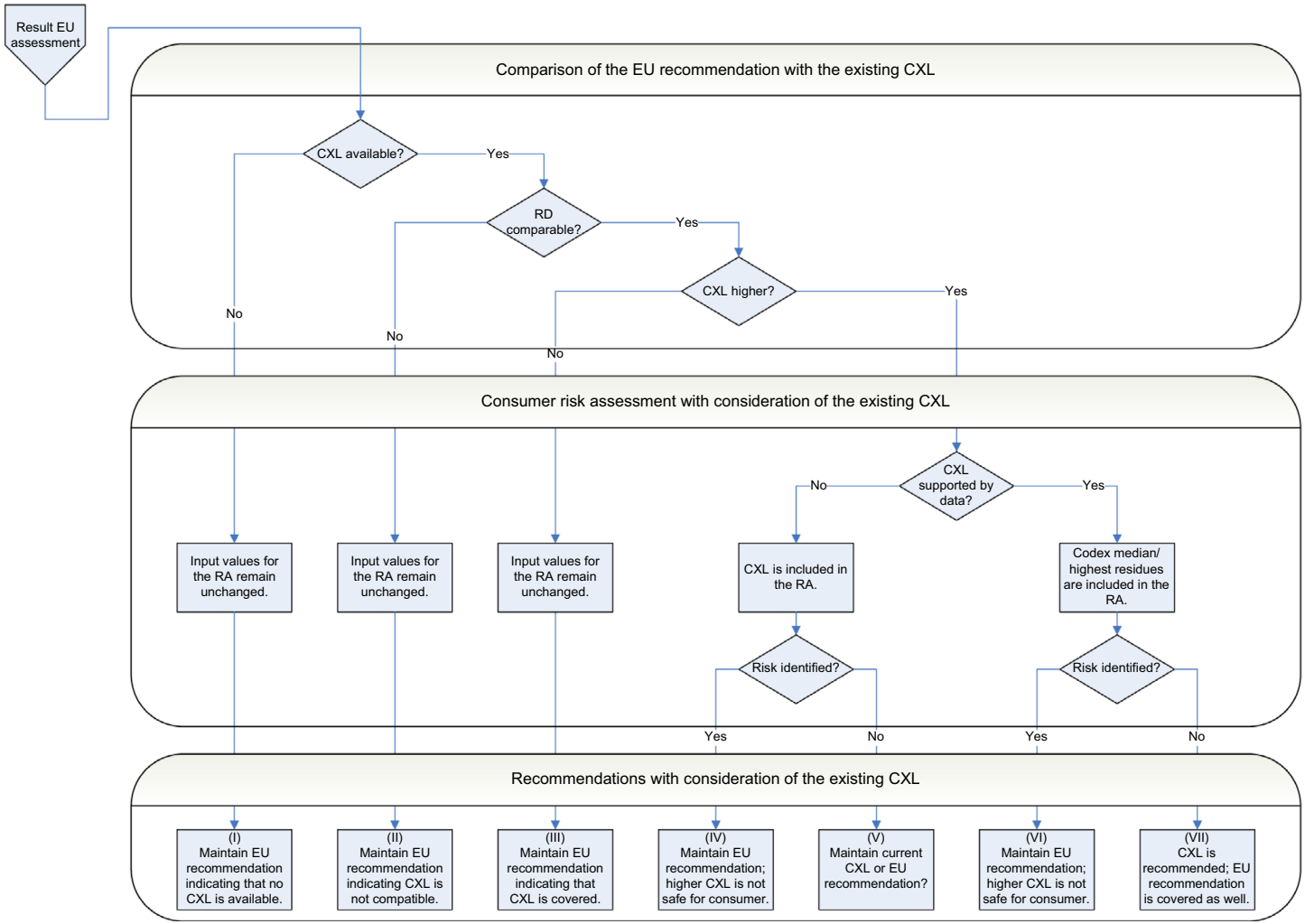
D.2. Consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: oxyfluorfen				
Grapefruits	0.01*	STMR	0.01*	HR
Oranges	0.01*	STMR	0.01*	HR
Lemons	0.01*	STMR	0.01*	HR
Limes	0.01*	STMR	0.01*	HR
Mandarins	0.01*	STMR	0.01*	HR
Almonds	0.01*	STMR	0.01*	HR
Chestnuts	0.01*	STMR	0.01*	HR
Hazelnuts/cobnuts	0.01*	STMR	0.01*	HR
Pistachios	0.01*	STMR	0.01*	HR
Walnuts	0.01*	STMR	0.01*	HR
Apples	0.01*	STMR	0.01*	HR
Pears	0.01*	STMR	0.01*	HR
Quinces	0.01*	STMR	0.01*	HR
Medlar	0.01*	STMR	0.01*	HR
Loquats/Japanese medlars	0.01*	STMR	0.01*	HR
Apricots	0.01*	STMR	0.01*	HR
Cherries (sweet)	0.01*	STMR	0.01*	HR
Peaches	0.01*	STMR	0.01*	HR
Plums	0.01*	STMR	0.01*	HR
Table grapes	0.01*	STMR	0.01*	HR
Wine grapes	0.01*	STMR	0.01*	HR
Table olives	0.01*	STMR	0.01*	HR
Kaki/Japanese persimmons	0.01*	STMR	0.01*	HR
Granate apples/pomegranates	0.01*	STMR	0.01*	HR
Onions	0.01*	STMR	0.01*	HR
Brussels sprouts	0.01*	STMR	0.01*	HR
Head cabbages	0.01*	STMR	0.01*	HR
Globe artichokes	0.05	EU MRL	0.05	EU MRL
Sunflower seeds	0.01*	STMR	0.01*	STMR
Olives for oil production	0.16	STMR	0.16	STMR

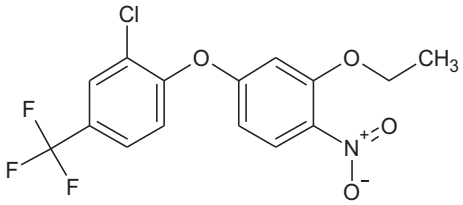
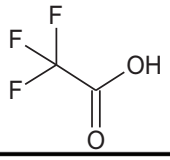
STMR: supervised trials median residue; HR: highest residue; EU MRL: existing European maximum residue level.
*: Indicates that the input value is proposed at the limit of quantification.

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[a]	IUPAC name/SMILES notation/ InChiKey[b]	Structural formula[c]
Oxyfluorfen	2-chloro-4-(trifluoromethyl)phenyl 3-ethoxy-4-nitrophenyl ether Clc1cc(ccc1Oc1ccc([N+]([O-])=O)c(OCC)c1)C(F)(F)F OQMBBFQZGJFLBU-UHFFFAOYNA-N	
Trifluoroacetic acid (TFAA)	2,2,2-Trifluoroacetic acid FC(F)(F)C(C)=O DTQVDTLACAAQTR-UHFFFAOYSA-N	

(a): The m'etabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 July 2019).
(c): ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 July 2019).