REASONED OPINION

EFSA Journal

APPROVED: 6 October 2021

doi: 10.2903/j.efsa.2021.6908

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

European Food Safety Authority (EFSA),
Giulia Bellisai, Giovanni Bernasconi, Alba Brancato, Luis Carrasco Cabrera, Lucien Ferreira, German Giner, Luna Greco, Samira Jarrah, Aija Kazocina, Renata Leuschner, Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Silvia Ruocco, Miguel Santos, Alessia Pia Scarlato, Anne Theobald, Benedicte Vagenende and Alessia Verani

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 spirodiclofen. Although this active substance is no longer authorised within the European Union, MRLs were established by the Codex Alimentarius Commission (codex maximum residue limits; CXLs) and import tolerances were reported by Member States (including the supporting residues data). Based on the assessment of the available data, EFSA assessed the CXLs and import tolerances requested, and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, as spirodiclofen is classified as carcinogenic 1B with threshold, all MRL proposals derived by EFSA still require further consideration by risk managers.

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

Requestor: European Commission

Question number: EFSA-Q-2010-01079

Correspondence: pesticides.mrl@efsa.europa.eu

Declarations of interest: The declarations of interest of all scientific experts active in EFSA's work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch.

Acknowledgement: EFSA wishes to thank the rapporteur Member State, Austria, for the preparatory work and Stathis Anagnos, Laszlo Bura, Andrea Mioč, Marta Szot, Aikaterini Vlachou for the support provided to this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Bellisai G, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Giner G, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Ruocco S, Santos M, Scarlato AP, Theobald A, Vagenende B and Verani A, 2021. Reasoned Opinion on the review of the existing maximum residue levels for spirodiclofen according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2021;19(11):6908, 46 pp. https://doi.org/10.2903/j.efsa.2021.6908

ISSN: 1831-4732

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

Summary

Spirodiclofen was initially included in Annex I to Directive 91/414/EEC on 1 August 2010 by Commission Directive 2010/25, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as implemented by Commission Implementing Regulation (EU) No 541/2011. Considering that no application was submitted to support the renewal of spirodiclofen, its approval expired on 31 July 2020. The substance is no longer approved in the European Union (EU).

As the active substance was approved after the entry into force of Regulation (EC) No 396/2005 on 1 August 2010, 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 18 August 2020, EFSA initiated the collection of data for this active substance. In a first step, Member States and the UK were invited to submit by 18 September 2020 their good agricultural practices (GAPs) in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State (RMS), Austria, to identify the critical GAPs in the format of a specific GAP overview file. Subsequently, Member States and the UK were requested to provide residue data supporting the critical GAPs, within a period of 1 month, by 13 January 2021. On the basis of all the data submitted by Member States and 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, and an updated GAP overview file was provided by the RMS to EFSA on 8 February 2021. 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.

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 Directive 91/414/EEC and the MRLs established by the Codex Alimentarius Commission, EFSA prepared in August 2021 a draft reasoned opinion, which was circulated to Member States and the EURLs for consultation via a written procedure. Comments received by 3 September 2021 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of spirodiclofen in plant was investigated in the fruit crop group only. According to the results of the metabolism studies, the residue definition for enforcement and risk assessment can be proposed as spirodiclofen (limited to the fruit crop group). This residue definition is also applicable to processed commodities of fruits. A specific residue definition for rotational crops is not deemed necessary considering that only import tolerances on perennial and/or semi-permanent crops were submitted to EFSA under this MRL review. Sufficiently validated analytical methods are available for the enforcement of the proposed residue definition in the four main plant matrix groups at the limit of quantification (LOQ) of 0.02 mg/kg. According to the EURLs, the LOQ of 0.01 mg/kg in plant matrices is achievable by using QuEChERS-based methods 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.

Spirodiclofen is authorised in third countries on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013). 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 spirodiclofen residues in livestock was investigated in lactating goats at dose rate covering the maximum dietary burdens calculated in this review. According to the results of these studies, the residue definition for enforcement and risk assessment in ruminants was proposed as spirodiclofen-enol (M01), expressed as spirodiclofen. This residue definition is also applicable to swine. An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.005 mg/kg in milk, 0.01 mg/kg in fat and muscle and 0.05 mg/kg in kidney and liver is available. According to the EURLs, the LOQ of 0.01 mg/kg is achievable in routine analysis in milk and liver. The same LOQ is expected to be achievable in the other animal matrices.

Data from livestock feeding study on lactating cows confirmed that residues of spirodiclofen-enol (M01) would remain well below 0.01 mg/kg in edible tissues and milk of ruminants, and thus, MRLs for animal matrices are not set for the import tolerances currently in place.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMo. The highest chronic exposure represented 7% of the ADI (Dutch toddler). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for spirodiclofen. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out. The highest chronic exposure represented 32% of the ADI (Dutch toddler).

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.

Spirodiclofen was initially included in Annex I to Directive 91/414/EEC on 1 August 2010 by Commission Directive 2010/25[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 implemented by Commission Implementing Regulation (EU) No 541/2011[6]. Therefore, EFSA initiated the review of all existing MRLs for that active substance.

By way of background information, in the framework of Directive 91/414/EEC, spirodiclofen was evaluated by the Netherlands, 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, 2009). The approval of the active substance expired on 31 July 2020. As no application for renewal was submitted in the framework of Regulation (EU) 1107/2009 for spirodiclofen, the substance is no longer approved in the European Union (EU). Spirodiclofen is classified as carcinogenic category 1B with threshold according to Commission Regulation (EC) No 1272/2008[7] as amended by Commission Regulation (EU) 2018/1480[8] based on RAC opinion of ECHA (ECHA, 2016), where it was concluded that a threshold dose exists, below which no carcinogenic effects occur. Following the expiration of the approval and the decision on the classification and labelling, the toxicological reference values were not rediscussed.

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 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 Directive 2010/25/EU of 18 March 2010 amending Council Directive 91/414/EEC to include penoxsulam, proquinazid and spirodiclofen as active substances. OJ L 69, 19.3.2010, p. 11–15.

[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] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355.

[8] Commission Regulation (EU) 2018/1480 of 4 October 2018 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting Commission Regulation (EU) 2017/776. OJ L 251, 5.10.2018, p. 1–12.

As the basis for the MRL review, on 18 August 2020, EFSA initiated the collection of data for this active substance. In a first step, Member States and UK[9] were invited to submit by 18 September 2020 their good agricultural practices (GAPs) in a standardised way, in the format of specific GAP forms. Since spirodiclofen is no longer approved in the EU, the GAP collection was limited to GAPs in non-EU countries for which import tolerances (IT) are authorised. In the framework of this consultation, seven Member States provided feedback on their national authorisations of spirodiclofen. Based on the GAP data submitted, the designated RMS, Austria, 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 13 January 2021.

On the basis of all the data submitted by Member States and the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked Austria to complete the PROFile and to prepare a supporting evaluation report. The PROFile and the supporting evaluation report, and an updated GAP overview file, were submitted to EFSA on 8 February 2021. 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.

Considering all the available information, and taking into account the MRLs established by the Codex Alimentarius Commission (CAC) (i.e. codex maximum residue limit; CXLs), EFSA prepared in August 2021 a draft reasoned opinion, which was circulated to Member States and the EURLs for commenting via a written procedure. All comments received by 3 September 2021 considered by EFSA during the finalisation of the reasoned opinion.

The **evaluation report** submitted by the RMS (Austria, 2021), taking into account also the information provided by Member States during the collection of data, and the **EURLs report on analytical methods** (EURLs, 2021) 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, 2021a) and the **Member States consultation report** (EFSA, 2021b). 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 import tolerances 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

Spirodiclofen is the ISO common name for 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutyrate (IUPAC).

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

The EU MRLs for spirodiclofen are established in Annex IIIA of Regulation (EC) No 396/2005. Codex maximum residue limits (CXLs) for spirodiclofen were also established by the Codex Alimentarius Commission (CAC). An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below (Table 1).

[9] The United Kingdom withdrew from EU on 1 February 2020. In accordance with the Agreement on the Withdrawal of the United Kingdom from the EU, and with the established transition period, the EU requirements on data reporting also apply to the United Kingdom data collected until 31 December 2020.

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

Procedure	Legal implementation	Remarks
MRL application	Commission Regulation (EU) 2016/1902[(a)]	Berries (EFSA, 2016).
	Commission Regulation (EU) No 34/2013[(b)]	Strawberries, bananas, avocado, mango and papaya (EFSA, 2012).
Implementation of CAC	Commission Regulation (EU) 2016/567[(c)]	Blueberries, CCPR 47th (EFSA, 2015).
	Commission Regulation (EU) No 520/2011[(d)]	Limes, mandarins, tree nuts (except almonds), pome fruits, stone fruits, currants (red, black and white), papaya, tomatoes, hops, swine (liver and kidney), sheep (liver and kidney), goat (liver and kidney), horse (liver and kidney), CCPR 42nd (EFSA, 2010).

(a): Commission Regulation (EU) 2016/1902 of 27 October 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 acetamiprid, ametoctradin, azoxystrobin, cyfluthrin, difluoroacetic acid, dimethomorph, fenpyrazamine, flonicamid, fluazinam, fludioxonil, flupyradifurone, flutriafol, fluxapyroxad, metconazole, proquinazid, prothioconazole, pyriproxyfen, spirodiclofen and trifloxystrobin in or on certain products. OJ L 298, 4.11.2016, p. 1–60.

(b): Commission Regulation (EU) No 34/2013 of 16 January 2013 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2-phenylphenol, ametoctradin, Aureobasidium pullulans strains DSM 14940 and DSM 14941, cyproconazole, difenoconazole, dithiocarbamates, folpet, propamocarb, spinosad, spirodiclofen, tebufenpyrad and tetraconazole in or on certain products. OJ L 25, 26.1.2013, p. 1–48.

(c): Commission Regulation (EU) 2016/567 of 6 April 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 chlorantraniliprole, cyflumetofen, cyprodinil, dimethomorph, dithiocarbamates, fenamidone, fluopyram, flutolanil, imazamox, metrafenone, myclobutanil, propiconazole, sedaxane and spirodiclofen in or on certain products. OJ L 100, 15.4.2016, p. 1–60.

(d): Commission Regulation (EU) No 520/2011 of 25 May 2011 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 benalaxyl, boscalid, buprofezin, carbofuran, carbosulfan, cypermethrin, fluopicolide, hexythiazox, indoxacarb, metaflumizone, methoxyfenozide, paraquat, prochloraz, spirodiclofen, prothioconazole and zoxamide in or on certain products. OJ L 140, 27.5.2011, p. 2–47.

For the purpose of this MRL review, all the uses of spirodiclofen currently authorised in third countries 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 spirodiclofen are given in Appendix A.

Assessment

EFSA has based its assessment on the following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (Austria, 2021);
- the draft assessment report (DAR) and its addendum prepared under Council Directive 91/414/EEC (Netherlands, 2004, 2009);
- the conclusion on the peer review of the pesticide risk assessment of the active substance spirodiclofen (EFSA, 2009);
- the Joint Meeting on Pesticide residues (JMPR) Evaluation report (FAO, 2009);
- the previous reasoned opinion(s) on spirodiclofen (EFSA, 2012, 2016).

The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011[10] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 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.

[10] 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.

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 spirodiclofen was investigated after foliar treatment in fruits (oranges, lemons, apples, grapes) (Netherlands, 2004). A translocation study from leaves into grapefruits was also available (Netherlands, 2004). All studies were assessed in the framework of the peer review (EFSA, 2009). In all studies, spirodiclofen was radiolabelled in the dihydrofuranone ring of the molecule.

In citrus fruits (oranges and lemons), the single spray application was done early in the growing season (oranges, PHI 160 days) or close to harvest (lemons, PHI 21 days) at dose levels covering the notified critical GAPs (cGAPs) (1.2–1.6N). In both studies, spirodiclofen was the predominant component of the residue in the peel, representing 34% of the total radioactive residues (TRR) (0.02 mg eq/kg) in orange and 75% TRR (0.2 mg eq./kg) in lemons. Up to 27 metabolites could be detected, none of them individually exceeding 10% TRR or 0.01 mg eq./kg. Total residues in the pulp accounted for less than 0.01 mg eq./kg and further characterisation was not carried out.

Apples and grapes were treated with one single spray application at 1,007 g a.s./ha (apples) and 224 g a.s./ha (grapes), early (apples PHI 84, grapes PHI 64) or late in the growing season (apples PHI 23, grapes PHI 21). In both crops, applications early in the growing season led to higher amount of degradation products than applications close to harvest, but spirodiclofen was still the main component of the residue (58–89% TRR after early application and 96–99% TRR after late application) after both applications. In apples, several metabolites were identified after the early application, but none of them individually exceeding 10% TRR or 0.01 mg eq./kg. In apples having received a late application, only trace amounts (< 0.001 mg eq./kg) of the metabolites were detected in the fruits. In grapes, 11 metabolites were detected after the late application, together amounting to only 3.5% TRR (0.07 mg eq./kg). However, after early application, metabolite M08 (2,4-dichloro-mandelic acid glucoside) was detected at significant levels, i.e. 12% TRR (0.14 mg eq./kg) in grapes. Metabolites M04 (2,4-dichloro-mandelic acid cyclohexyl ester glucosylpentoside) and M05 (2,4-dichloro-mandelic acid hydroxy-cyclohexyl ester) were also detected at levels exceeding 0.01 mg eq./kg (< 10% TRR).

In a separate translocation experiment with grapefruit, it was shown that less than 0.1% of the radioactivity applied to leaves immediately surrounding the fruits was transported into the fruits.

The peer review concluded that the metabolic pathway was similar in all the fruit investigated and this conclusion is still valid to this MRL review.

1.1.2. Nature of residues in rotational crops

Only import tolerances on perennial and/or semi-permanent crops were submitted to EFSA in the framework of this MRL review for spirodiclofen. For completeness, it is noted that the lab DT_{90} reported in the soil degradation studies evaluated in the framework of the peer review was 43 days (EFSA, 2009), and no different metabolites than in treated crops were generated in soil. Therefore, studies investigating the nature of spirodiclofen on rotational crops were not reported and are not required.

1.1.3. Nature of residues in processed commodities

Standard hydrolysis studies simulating the effect on the nature of spirodiclofen residues under processing conditions representative of pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6) were assessed in the conclusion of the peer review (Netherlands, 2004; EFSA, 2009). Studies were conducted with radiolabelled spirodiclofen on the dihydrofuranone ring of the molecule.

Spirodiclofen was stable to hydrolysis under standard conditions of pasteurisation, representative for fruit processing like preparation of juice, wine, sauce and preserves (Netherlands, 2004; EFSA, 2009). However, it was significantly hydrolysed to spirodiclofen-enol (M01) under conditions representative for baking/brewing/boiling and sterilisation, where the said metabolite represented 55% and 51% of the total applied radioactivity (TAR), respectively. Under these two hydrolysis conditions, the nature of the residue in the processed commodities was different from that found in raw agricultural commodities.

1.1.4. Methods of analysis in plants

In the framework of the peer review (Netherlands, 2004; EFSA, 2009), the multiresidue method DFG S19 using GC-ECD detection as primary detection and GC-MS as confirmation was validated for the determination of parent spirodiclofen residues in high water (apples) content, high acid (oranges) content, high oil content (rapeseed) and dry matrices (wheat) at the limit of quantification (LOQ) of 0.02 mg/kg. Independent laboratory validation (ILV) was also available.

During the completeness check, the EURLs provided validation results on Quick, Easy, Cheap, Effective, Rugged and Safe (QuEChERS) multiresidue method using LC-MS/MS with an LOQ of 0.01 mg/kg in the main four plant matrix groups and 0.05 mg/kg in matrices difficult to be analysed (tea and black pepper) for the enforcement of spirodiclofen in routine analysis (EURLs, 2021).

1.1.5. Stability of residues in plants

The storage stability of parent spirodiclofen was investigated in the framework of the peer review (EFSA, 2009) and in studies submitted under a previous MRL application (EFSA, 2012).

The available studies demonstrated storage stability for spirodiclofen for a period of 13 and 14 months when stored at –15°C in high water content and high oil content matrices, respectively. Longer storage period, i.e. 24 months at –18°C, was demonstrated for high acid content commodities.

Moreover, the storage stability of spirodiclofen was studied in processed commodities. In processed commodities from grape (raisins, juice) and apple (dried, juice), spirodiclofen was found to be stable for 8 months when stored at –15°C, while in prunes, the demonstrated stability was up to 10 months when stored at –15°C.

1.1.6. Proposed residue definitions

The metabolism of spirodiclofen was investigated in the fruit crop group only and found to be similar in the representatives of this group. Only import tolerances on perennial and/or semi-permanent crops were submitted to EFSA in the framework of this MRL review, and thus, a specific residue definition for rotated crops is not required.

Parent spirodiclofen was the predominant component of the residue in fruits and found to be a sufficient marker. Hence, EFSA considers the residue definition for enforcement set as spirodiclofen by the peer review as still applicable.

For risk assessment, a number of metabolites were quantified at non-significant levels, except in grapes harvested 64 days after treatment, where metabolites M08, M04 and M05 were detected at levels exceeding 0.01 mg eq./kg, in an underdosed metabolism study (0.4N compared to the targeted rate of the GAP under evaluation). The toxicological profile of these three metabolites was discussed by the peer review and it was concluded that the toxicity was covered by that of the parent (EFSA, 2009). Furthermore, considering that according to the import tolerances currently in place, the application is done close to the harvest (PHIs 2–14 days), and that the metabolic pattern observed in the four tested fruits showed that at PHI of 21–23 days, only residues of parent spirodiclofen can be expected, EFSA proposes limiting the residue definition for risk assessment to parent spirodiclofen, as agreed by the peer review.

Under hydrolysis, parent spirodiclofen was stable under conditions of pasteurisation; however, it was degraded to spirodiclofen-enol (M01) under test conditions representing baking/brewing/boiling and sterilisation. Since spirodiclofen is intended for use only on fruits, and fruit processing such as preparation of juice, wine, sauce and preserves are covered by typical pasteurisation conditions (pH 4, 90°C), the peer review did not include spirodiclofen-enol in the risk assessment residue definition for processed commodities (EFSA, 2009). In the frame of a previous MRL application, it was postulated that processing conditions involving higher temperatures might occur in the production of fruit jam and in that case, the formation of spirodiclofen-enol could not be completely disregarded (EFSA, 2012). Considering that spirodiclofen-enol was found to have similar toxicological properties to spirodiclofen (EFSA, 2009), the dietary exposure assessment performed for unprocessed fruits would not underestimate the consumer exposure for processed commodities, even if part of the spirodiclofen residues are converted to the degradation product. Hence, EFSA concludes that the same residue definition for enforcement and risk assessment for raw commodities, i.e. spirodiclofen, can be applied to processed commodities. It is noted, however, that the inclusion of spirodiclofen-enol (M01) in the residue definition for risk assessment for processed commodities might be reconsidered in the future if import tolerances other than on fruit are granted.

An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.02 mg/kg in the four main plant matrix groups is available (EFSA, 2009). According to the EURLs, the LOQ of 0.01 is achievable in plant matrices by using multiresidue QuEChERS methods in routine analyses, and 0.05 mg/kg in matrices difficult to be analysed (tea, black pepper) (EURLs, 2021). The analytical standard for spirodiclofen is commercially available.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of spirodiclofen residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Austria, 2021), which also includes residue trials assessed in a previous MRL application (EFSA, 2012). 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. It is noted that storage stability conditions for dry commodities (chestnuts) were not demonstrated, however, since residue trials on chestnuts were extrapolated from almonds and pecans, the missing information on storage conditions for dry commodities is not expected to have any influence on the assessment.

The number of residue trials and extrapolations was evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs applicable to the present MRL review (European Commission, 2017).

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

- Citrus fruits: according to guideline SANCO 7525/VI/95-rev.10.3 (European Commission, 2017), a minimum of 50% of trials on citrus should be performed on lemons or mandarins to extrapolate to the whole citrus fruits group; however, since residue levels observed in trials performed on oranges, grapefruits and lemons were shown not to be significantly different, all values were pooled together to derive an MRL proposal for the whole group of citrus fruits and no additional trials are required.
- Mango and papaya: extrapolation from avocado to mango and papaya is not explicitly mentioned in the guideline SANCO 7525/VI/95-rev.10.3 (European Commission, 2017). In the frame of a previous MRL application (EFSA, 2012), such extrapolation was accepted on the basis that spirodiclofen is not systemic and the proposed MRL will not pose a risk to consumers. It was noted, however, that data on the following aspects should have been provided: (a) form and morphology of the different trees (avocado, mango, papaya) when used in commercial production, (b) ratio of mass to fruit surface of the three fruits as harvested, (c) indication of fruit diameter and mass increase rates over the 14 day harvest interval and (d) consideration if the different matrix types (avocado – high oil content, mango and papaya – high water content) has an influence on the residue behaviour. Since MRLs for mango and papaya were finally legally implemented (Commission Regulation (EU) No 34/2013[11]) by risk managers, the additional data are considered only desirable.

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 and they are not required (see Section 1.1.2).

1.2.3. Magnitude of residues in processed commodities

The effect of industrial processing and/or household preparation was assessed on studies conducted on oranges and grapes (EFSA, 2009; Austria, 2021). An overview of all available processing studies is available in Appendix B.1.2.3. Robust processing factors (fully supported by data) could be derived for citrus (extrapolated from oranges) peeled, juice, dry pomace and wet pomace and grape

[11] Commission Regulation (EU) No 34/2013 of 16 January 2013 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2-phenylphenol, ametoctradin, Aureobasidium pullulans strains DSM 14940 and DSM 14941, cyproconazole, difenoconazole, dithiocarbamates, folpet, propamocarb, spinosad, spirodiclofen, tebufenpyrad and tetraconazole in or on certain products. OJ L 25, 26.1.2013, p. 1–48.

raisins. It is noted that only two studies were available for orange wet pomace and according to the old data requirements at least three studies are required. However, the information available is considered sufficient to derive a robust PF since the calculated processing factors (based on the two studies) do not deviate by more than 50%. On the other hand, a tentative processing factor (not fully supported by data) was derived for orange marmalade.

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.

2. Residues in livestock

Spirodiclofen is authorised in third countries for use on citrus fruits 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 spirodiclofen residues in livestock was investigated in lactating goats at dose rate covering the maximum dietary burdens calculated in this review. This study, which was performed with spirodiclofen radiolabelled in the dihydrofuranone ring of the molecule, was assessed in the framework of the peer review (Netherlands 2004; EFSA 2009) and included by the RMS in the ER (Austria, 2021).

After oral administration of [dihydrofuranone-3-^{14}C] spirodiclofen, total radioactive residues (TRR) were higher in the excretory organs, i.e. kidney (2.92 mg eq./kg) and liver (0.78 mg eq./kg) than in fat (0.14 mg eq./kg) and muscle (0.068 mg eq./kg). TRR in milk amounted for 0.1 mg eq./kg. The major metabolic product in goat tissues and milk was spirodiclofen-enol (M01) (81–95% TRR; 0.057–2.78 mg eq./kg). Parent spirodiclofen was not found in the analysed goat matrices. As spirodiclofen-enol was the main component of the residue in the goat study and its toxicity was covered by that of the parent, the peer review defined the residue for enforcement and risk assessment as spirodiclofen-enol (M01), expressed as spirodiclofen (EFSA, 2009). This residue definition is applicable to ruminants and swine. It is noted, however, that the residue definition for enforcement set in Regulation (EC) No 396/2005 is spirodiclofen.

An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.005 mg/kg in milk, 0.01 mg/kg in fat and muscle and 0.05 mg/kg in kidney and liver is available (EFSA, 2009; Netherlands, 2009). During Member States consultation, EURLs informed EFSA that spirodiclofen-enol can be monitored in milk and liver with an LOQ of 0.01 mg/kg in routine analysis (even lower levels, down to 0.005 mg/kg were successfully validated). Based on the experience gained on these two matrices, an LOQ of 0.01 mg/kg is supposed to be also achievable for the other animal matrices, namely muscle, fat, kidney and eggs (EURLs, 2021). The analytical standard for spirodiclofen-enol (M01) is commercially available.

No storage stability study was available; nonetheless, samples from the metabolism study conducted with goats showed that no changes in metabolite pattern occurred within 5 months of storage at –20°C, indicating that metabolites detected initially did not degrade during that storage period (Netherlands, 2009). A separate storage stability study for livestock is not required for the currently authorised import tolerances.

Livestock feeding studies are considered unnecessary; however, a feeding study with dairy cattle was evaluated under the peer review (EFSA, 2009; Netherlands, 2009). Samples were analysed within 1 month after sampling. Data from this study confirm that residues of spirodiclofen-enol will remain well below 0.01 mg/kg in edible tissues and milk of ruminants. EFSA concludes that it is not necessary to propose MRLs for animal matrices for the import tolerances currently in place.

3. Consumer risk assessment

In the framework of this review, only the import tolerances of spirodiclofen reported by the RMS in Appendix A were considered; however, the use of spirodiclofen was previously also assessed by the JMPR (FAO, 2009). The CXLs, resulting from this assessment by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. To facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs.

3.1. Consumer risk assessment without consideration of the existing CXLs

Chronic exposure calculations for all crops reported in the framework of this review were performed using revision 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). All input values included in the exposure calculations are summarised in Appendix D. Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance.

The exposure values calculated were compared with the toxicological reference value for spirodiclofen, derived by EFSA in the framework of the peer review for the first approval (EFSA, 2009). The highest chronic exposure was calculated for Dutch (NL) toddler, representing 7% of the acceptable daily intake (ADI). This calculation indicate that the import tolerances assessed under this review result in a consumer exposure lower than the toxicological reference value. Therefore, these uses are unlikely to pose a risk to consumer's health.

3.2. Consumer risk assessment with consideration of the existing CXLs

To include the CXLs in the calculations of the consumer exposure, CXLs were compared with the EU MRL proposals in compliance with Appendix E and all data relevant to the consumer exposure assessment have been collected from JMPR evaluations. An overview of the input values used for this exposure calculation is also provided in Appendix D. For plant commodities, EU and JMPR residue definitions for enforcement and risk assessment are the same, i.e. spirodiclofen. For livestock, the residue definition (monitoring and risk assessment) set by JMPR was spirodiclofen (fat soluble), while the one proposed in this review is spirodiclofen-enol (M01) (partly fat soluble), expressed as spirodiclofen. Nevertheless, since according to the uses assessed by the JMPR (FAO, 2009), no residues of spirodiclofen or spirodiclofen-enol (M01) are expected in tissues and milk at the mean and maximum calculated dietary burdens, the CXLs for livestock could be considered further in the risk assessment.

Chronic exposure calculations were also performed using revision 3.1 of the EFSA PRIMo and the exposure values calculated were compared with the toxicological reference value derived for spirodiclofen. The highest chronic exposure was calculated for Dutch (NL) toddler, representing 32% of the ADI. Based on these calculations, EFSA concludes that the CXLs are not expected to be of concern for European consumers.

Conclusions

Considering that no application was received to support the renewal of the approval of spirodiclofen and the expiry date for its approval was 31 July 2020, the assessment was limited to uses authorised in third countries and CXLs.

The metabolism of spirodiclofen in plant was investigated in the fruit crop group only. According to the results of the metabolism studies, the residue definition for enforcement and risk assessment can be proposed as spirodiclofen (limited to the fruit crop group). This residue definition is also applicable to processed commodities of fruits. A specific residue definition for rotational crops is not deemed necessary considering that only import tolerances on perennial and/or semi-permanent crops were submitted to EFSA under this MRL review. Sufficiently validated analytical methods are available for the enforcement of the proposed residue definition in the four main plant matrix groups at the LOQ of

0.02 mg/kg. According to the EURLs, the LOQ of 0.01 mg/kg in plant matrices is achievable by using QuEChERS-based methods 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.

Spirodiclofen is authorised in third countries on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013). 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 spirodiclofen residues in livestock was investigated in lactating goats at dose rate covering the maximum dietary burdens calculated in this review. According to the results of these studies, the residue definition for enforcement and risk assessment in ruminants was proposed as spirodiclofen-enol (M01), expressed as spirodiclofen. This residue definition is also applicable to swine. An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.005 mg/kg in milk, 0.01 mg/kg in fat and muscle and 0.05 mg/kg in kidney and liver is available. According to the EURLs, the LOQ of 0.01 mg/kg is achievable in routine analysis in milk and liver. The same LOQ is expected to be achievable in the other animal matrices.

Data from livestock feeding study on lactating cows confirmed that residues of spirodiclofen-enol (M01) would remain well below 0.01 mg/kg in edible tissues and milk of ruminants, and thus, MRLs for animal matrices are not set for the import tolerances currently in place.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMo. The highest chronic exposure represented 7% of the ADI (Dutch toddler). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for spirodiclofen. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out. The highest chronic exposure represented 32% of the ADI (Dutch toddler).

Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 2). It is highlighted that although no data gaps were identified in this assessment, none of the MRL values listed in the table are recommended for inclusion in Annex II to the Regulation as they require further consideration by risk mangers given that spirodiclofen is classified as carcinogenic category 1B with a threshold, in accordance with Regulation (EC) No 1272/2008.

It is noted that following the expiry of the approval and the decision on the classification and labelling, the toxicological reference values were not rediscussed. It is proposed to discuss with risk managers to establish a mechanism for periodic review of toxicological reference values for substances not any longer approved in the EU and for which no recent toxicological assessment was performed.

It is also noted that, in line with the existing CXL for mammalian milk and considering the enforcement methods currently available, the proposed MRL for milk is lower than the default LOQ of 0.01 mg/kg. In case risk managers wish to set the MRLs for milks at the default LOQ of 0.01 mg/kg, this will not result in an exceedance of the ADI.

Minor deficiencies were also identified in the assessment, but these deficiencies are not expected to impact on the validity of the MRLs derived. The following data are therefore considered desirable but not essential:

- Form and morphology of avocado, mango and papaya trees when used in commercial production;
- Ratio of mass to fruit surface of avocado, mango and papaya as harvested;
- Indication of fruit (avocado, mango, papaya) diameter and mass increase rates over the 14-day harvest interval;
- Consideration if the different matrix types (avocado – high oil content; mango and – high water content) has an influence on the residue behaviour.

Table 2: 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 1: spirodiclofen[F]					
110010	Grapefruit	0.5	0.4	0.4	Further consideration needed[a]
110020	Oranges	0.5	0.4	0.4	Further consideration needed[a]
110030	Lemons	0.5	0.4	0.4	Further consideration needed[a]
110040	Limes	0.4	0.4	0.4	Further consideration needed[a]
110050	Mandarins	0.4	0.4	0.4	Further consideration needed[a]
120010	Almonds	0.1	0.05	0.06	Further consideration needed[a]
120020	Brazil nuts	0.05	0.05	0.06	Further consideration needed[a]
120030	Cashew nuts	0.05	0.05	0.06	Further consideration needed[a]
120040	Chestnuts	0.05	0.05	0.06	Further consideration needed[a]
120050	Coconuts	0.05	0.05	0.05	Further consideration needed[b]
120060	Hazelnuts	0.05	0.05	0.05	Further consideration needed[b]
120070	Macadamia	0.05	0.05	0.06	Further consideration needed[a]
120080	Pecans	0.05	0.05	0.06	Further consideration needed[a]
120090	Pine nuts	0.05	0.05	0.05	Further consideration needed[b]
120100	Pistachios	0.05	0.05	0.06	Further consideration needed[a]
120110	Walnuts	0.05	0.05	0.06	Further consideration needed[a]
130010	Apples	0.8	0.8	0.8	Further consideration needed[b]
130020	Pears	0.8	0.8	0.8	Further consideration needed[b]
130030	Quinces	0.8	0.8	0.8	Further consideration needed[b]
130040	Medlar	0.8	0.8	0.8	Further consideration needed[b]
130050	Loquat	0.8	0.8	0.8	Further consideration needed[b]
140010	Apricots	2	2	2	Further consideration needed[b]
140020	Cherries	2	2	2	Further consideration needed[b]
140030	Peaches	2	2	2	Further consideration needed[b]
140040	Plums	2	2	2	Further consideration needed[b]
151010	Table grapes	2	0.2	3	Further consideration needed[a]
151020	Wine grapes	0.2	0.2	0.2	Further consideration needed[b]
152000	Strawberries	2	2	2	Further consideration needed[b]
154010	Blueberries	4	4	4	Further consideration needed[b]
154030	Currants (red, black and white)	1	1	1	Further consideration needed[b]
163010	Avocados	1	0.9	0.9	Further consideration needed[a]
163030	Mangoes	1	-	0.9	Further consideration needed[c]
163040	Papaya	1	0.03*	0.9	Further consideration needed[a]
231010	Tomatoes	0.5	0.5	0.5	Further consideration needed[b]
231020	Peppers	0.2	0.2	0.2	Further consideration needed[b]
232010	Cucumbers	0.1	0.07	0.07	Further consideration needed[b]
232020	Gherkins	0.1	0.07	0.07	Further consideration needed[b]
620000	Coffee beans	0.05*	0.05*[e]	0.05*	Further consideration needed[b]
700000	'Hops (dried), including hop pellets and unconcentrated powder'	40	40	40	Further consideration needed[b]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition 2 (existing): spirodiclofen[(F)] **Enforcement residue definition 2 (proposed)**: spirodiclofen-enol (M01), expressed as spirodiclofen					
1011010	Swine meat	0.01*	0.01*	0.01*	Further consideration needed[(b)]
1011020	Swine fat (free of lean meat)	0.05*	0.01*	0.01*	Further consideration needed[(b)]
1011030	Swine liver	0.05*	0.05*	0.05*	Further consideration needed[(b)]
1011040	Swine kidney	0.05*	0.05*	0.05*	Further consideration needed[(b)]
1012010	Bovine meat	0.01*	0.01*	0.01*	Further consideration needed[(b)]
1012020	Bovine fat	0.05*	0.01*	0.01*	Further consideration needed[(b)]
1012030	Bovine liver	0.05*	0.05*	0.05*	Further consideration needed[(b)]
1012040	Bovine kidney	0.05*	0.05*	0.05*	Further consideration needed[(b)]
1013010	Sheep meat	0.01*	0.01*	0.01*	Further consideration needed[(b)]
1013020	Sheep fat	0.05*	0.01*	0.01*	Further consideration needed[(b)]
1013030	Sheep liver	0.05*	0.05*	0.05*	Further consideration needed[(b)]
1013040	Sheep kidney	0.05*	0.05*	0.05*	Further consideration needed[(b)]
1014010	Goat meat	0.01*	0.01*	0.01*	Further consideration needed[(b)]
1014020	Goat fat	0.05*	0.01*	0.01*	Further consideration needed[(b)]
1014030	Goat liver	0.05*	0.05*	0.05*	Further consideration needed[(b)]
1014040	Goat kidney	0.05*	0.05*	0.05*	Further consideration needed[(b)]
1015010	Horse meat	0.01*	0.01*	0.01*	Further consideration needed[(b)]
1015020	Horse fat	0.05*	0.01*	0.01*	Further consideration needed[(b)]
1015030	Horse liver	0.05*	0.05*	0.05*	Further consideration needed[(b)]
1015040	Horse kidney	0.05*	0.05*	0.05*	Further consideration needed[(b)]
1020010	Cattle milk	0.004*	0.005*[(f)]	0.005*	Further consideration needed[(b)]
1020020	Sheep milk	0.004*	0.005*[(f)]	0.005*	Further consideration needed[(b)]
1020030	Goat milk	0.004*	0.005*[(f)]	0.005*	Further consideration needed[(b)]
1020040	Horse milk	0.004*	0.005*[(f)]	0.005*	Further consideration needed[(b)]
–	Other commodities of plant and/or animal origin	Reg. (EU) 2016/1902	–	–	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): The residue definition is fat soluble.
(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; existing CXL is covered by the recommended MRL (combination H-III in Appendix E). It is noted that spirodiclofen is classified as carcinogenic category 1B with a threshold, in accordance with Regulation (EC) No 1272/2008.
(b): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix E). It is noted that spirodiclofen is classified as carcinogenic category 1B with a threshold, in accordance with Regulation (EC) No 1272/2008.
(c): 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). It is noted that spirodiclofen is classified as carcinogenic category 1B with a threshold, in accordance with Regulation (EC) No 1272/2008.
(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).
(e): CXL of 0.03* mg/kg was rounded up to the LOQ of 0.05* mg/kg, which was proposed by EURLs at EU level for enforcement of this matrix.
(f): CXL of 0.004* mg/kg was rounded up to the LOQ of 0.005* mg/kg, which was the LOQ of the method evaluated at EU level for enforcement of this matrix.

References

Austria, 2021. Evaluation report prepared under Article 12.1 of Regulation (EC) No 396/2005. Review of the existing MRLs for spirodiclofen, 8 February 2021. Available online: www.efsa.europa.eu

ECHA (European Chemicals Agency), 2016. Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of spirodiclofen (ISO), December 2016. Available online: https://echa.europa.eu/documents/10162/c7ef3111-dc3d-fe8e-e753-5e93234ee847

EFSA (European Food Safety Authority), 2009. Conclusion on the peer review of the pesticide risk assessment of the active substance spirodiclofen. EFSA Journal 2009;7(8):339, 86 pp. 102903/j.efsa.2009.339r

EFSA (European Food Safety Authority), 2010. Scientific and technical support for preparing a EU position in the 42nd Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2010;8(11):1560, 51 pp. https://doi.org/10.2903/j.efsa.2010.1560

EFSA (European Food Safety Authority), 2012. Reasoned opinion on the modification of the existing maximum residue levels for spirodiclofen in strawberries, bananas, avocado, mango and papaya. EFSA Journal 2012;10(7):2821, 30 pp. 102903/j.efsa.2012.2821

EFSA (European Food Safety Authority), 2015. Scientific support for preparing an EU position in the 46th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2015;13(7):4208, 178 pp. https://doi.org/10.2903/j.efsa.2015

EFSA (European Food Safety Authority), 2016. Reasoned opinion on the modification of the maximum residue levels for spirodiclofen in berries. EFSA Journal 2016;14(4):4457, 17 pp. https://doi.org/10.2903/j.efsa.2016.4457

EFSA (European Food Safety Authority), 2021a. Completeness check report on the review of the existing MRLs of spirodiclofen prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 29 July 2021. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2021b. Member States consultation report on the review of the existing MRLs of spirodiclofen prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 20 September 2021. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), Brancato A, Brocca D, Ferreira L, Greco L, Jarrah S, Leuschner R, Medina P, Miron I, Nougadere A, Pedersen R, Reich H, Santos M, Stanek A, Tarazona J, Theobald A and Villamar-Bouza L, 2018. Guidance on use of EFSA Pesticide Residue Intake Model (EFSA PRIMo revision 3). EFSA Journal 2018;16(1):5147, 43 pp. https://doi.org/10.2903/j.efsa.2018.5147

EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Tarazona J, Theobald A and Verani A, 2019. Pesticide Residue Intake Model- EFSA PRIMo revision 3.1 (update of EFSA PRIMo revision 3). EFSA supporting publication 2019;EN-1605, 15 pp. https://doi.org/10.2903/sp.efsa.2019.en-1605

EURLs (European Union Reference Laboratories for Pesticide Residues), 2021. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Analytical methods validated by the EURLs and overall capability of official laboratories to be considered for the review of the existing MRLs for spirodiclofen. January 2021. Available online: www.efsa.europa.eu

European Commission, 1996. Appendix G. Livestock feeding studies. 7031/VI/95-rev. 4, 22 July 1996.

European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/VI/95-rev. 3, 22 July 1997.

European Commission, 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev. 6, 22 July 1997.

European Commission, 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev. 2, 22 July 1997.

European Commission, 1997d. Appendix E. Processing studies. 7035/VI/95-rev. 5, 22 July 1997.

European Commission, 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3, 22 July 1997.

European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev. 5, 22 July 1997.

European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals.7039/VI/95 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2000. Residue analytical methods. For pre-registration data requirements for Annex II (part A, section 4) and Annex III (part A, section 5) of Directive 91/414. SANCO/3029/99-rev. 4. 11 July 2000.

European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.

European Commission, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.10.3, June 2017.

FAO (Food and Agriculture Organization of the United Nations), 2009. Spirodiclofen. In: Pesticide residues in food – 2009. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 196.

Netherlands, 2004. Draft Assessment Report (DAR) on the active substance spirodiclofen prepared by the rapporteur Member State the Netherlands in the framework of Directive 91/414/EEC, April 2004. Available online: www.efsa.europa.eu

Netherlands, 2009. Final addendum to the draft assessment report on the active substance spirodiclofen prepared by the rapporteur Member State the Netherlands in the framework of Council Directive 91/414/EEC, compiled by EFSA, June 2009. Available online: www.efsa.europa.eu

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org

OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 4 September 2013.

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
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CCPR	Codex Committee on Pesticide Residues
cGAP	critical GAP
CXL	codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{90}	period required for 90% dissipation (define method of estimation)
ECD	electron capture detector
EDI	estimated daily intake
EMA	European Medicines Agency (former EMEA)
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
ESI	electrospray ionisation
EURLs	European Union Reference Laboratories for Pesticide Residues (former CRLs)
FAO	Food and Agriculture Organization of the United Nations
FID	flame ionisation detector
FLD	fluorescence detector
FPD	flame photometric detector
GAP	Good Agricultural Practice
GC	gas chromatography
GC-ECD	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-FPD	gas chromatography with flame photometric detector
GC-MS	gas chromatography with mass spectrometry
GC-MS/MS	gas chromatography with tandem mass spectrometry
GR	granule
HPLC-MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
ILV	independent laboratory validation
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{ow}	n-octanol/water partitioning coefficient
LC–MS/MS	liquid chromatography with tandem mass spectrometry

LOQ	limit of quantification
Mo	monitoring
MRL	maximum residue level
NEDI	national estimated daily intake
NTMDI	national theoretical maximum daily intake
OECD	Organisation for Economic Co-operation and Development
PAFF	Standing Committee on Plants, Animals, Food and Feed
PBI	plant back interval
PF	processing factor
PHI	preharvest 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
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
WHO	World Health Organization

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

A.1. Import tolerance

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 and season[c]	Number min–max	Interval between application (min)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Grapefruits	US	F	Broad mite, Citrus flat mite (false spider mite), Citrus red mite, Citrus rust mite (silver mite), Pink citrus rust mite, Sixspotted mite, Texas citrus mite, Twospotted spider mite, Yuma spider mite	SC	240 g/L	Foliar treatment – general (see also comment field)	n.a.	1–1		–	–	370 g a.s./ha	7	Rate without horticultural oil – 0.21–0.37 Kg a.s./ha. Rate with horticultural oil 0.31–0.37 Kg a.s./ha.
Oranges	US	F	Broad mite, Citrus flat mite (false spider mite), Citrus red mite, Citrus rust mite (silver mite), Pink citrus rust mite, Sixspotted mite, Texas citrus mite, Twospotted spider mite, Yuma spider mite	SC	240 g/L	Foliar treatment – general (see also comment field)	n.a.	1–1		–	–	370 g a.s./ha	7	Rate without horticultural oil – 0.21–0.37 Kg a.s./ha. Rate with horticultural oil 0.31–0.37 Kg a.s./ha.

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 and season[c]	Number min–max	Interval between application (min)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Lemons	US	F	Broad mite, Citrus flat mite (false spider mite), Citrus red mite, Citrus rust mite (silver mite), Pink citrus rust mite, Sixspotted mite, Texas citrus mite, Twospotted spider mite, Yuma spider mite	SC	240 g/L	Foliar treatment – general (see also comment field)	n.a.	1–1		–	–	370 g a.s./ha	7	Rate without horticultural oil – 0.21–0.37 Kg a.s./ha. Rate with horticultural oil 0.31–0.37 Kg a.s./ha.
Limes	US	F	Broad mite, Citrus flat mite (false spider mite), Citrus red mite, Citrus rust mite (silver mite), Pink citrus rust mite, Sixspotted mite, Texas citrus mite, Twospotted spider mite, Yuma spider mite	SC	240 g/L	Foliar treatment – general (see also comment field)	n.a.	1–1		–	–	370 g a.s./ha	7	Rate without horticultural oil – 0.21–0.37 Kg a.s./ha. Rate with horticultural oil 0.31–0.37 Kg a.s./ha.
Mandarins	US	F	Broad mite, Citrus flat mite (false spider mite), Citrus red mite, Citrus rust mite (silver mite), Pink citrus rust mite, Sixspotted mite, Texas citrus mite, Twospotted spider mite, Yuma spider mite	SC	240 g/L	Foliar treatment – general (see also comment field)	n.a.	1–1		–	–	370 g a.s./ha	7	Rate without horticultural oil – 0.21–0.37 Kg a.s./ha. Rate with horticultural oil 0.31–0.37 Kg a.s./ha.

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 and season[c]	Number min–max	Interval between application (min)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Almonds	US	F	Pecan leaf scorch mite, Brown mite, European red mite, Pacific spider mite, Twospotted spider mite	SC	240 g/L	Foliar treatment – general (see also comment field)	n.a.	1–1		–	–	590 g a.s./ha	7	
Brazil nuts	US	F	Pecan leaf scorch mite, Brown mite, European red mite, Pacific spider mite, Twospotted spider mite	SC	240 g/L	Foliar treatment – general (see also comment field)	n.a.	1–1		–	–	590 g a.s./ha	7	
Cashew nuts	US	F	Pecan leaf scorch mite, Brown mite, European red mite, Pacific spider mite, Twospotted spider mite	SC	240 g/L	Foliar treatment – general (see also comment field)	n.a.	1–1		–	–	590 g a.s./ha	7	
Chestnuts	US	F	Pecan leaf scorch mite, Brown mite, European red mite, Pacific spider mite, Twospotted spider mite	SC	240 g/L	Foliar treatment – general (see also comment field)	n.a.	1–1		–	–	590 g a.s./ha	7	
Macadamias	US	F	Pecan leaf scorch mite, Brown mite, European red mite, Pacific spider mite, Twospotted spider mite	SC	240 g/L	Foliar treatment – general (see also comment field)	n.a.	1–1		–	–	590 g a.s./ha	7	

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 and season[c]	Number min–max	Interval between application (min)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Pecans	US	F	Pecan leaf scorch mite, Brown mite, European red mite, Pacific spider mite, Twospotted spider mite	SC	240 g/L	Foliar treatment – general (see also comment field)	n.a.	1–1		–	–	590 g a.s./ha	7	
Pistachios	US	F	Pecan leaf scorch mite, Brown mite, European red mite, Pacific spider mite, Twospotted spider mite	SC	240 g/L	Foliar treatment – general (see also comment field)	n.a.	1–1		–	–	590 g a.s./ha	7	
Walnuts	US	F	Pecan leaf scorch mite, Brown mite, European red mite, Pacific spider mite, Twospotted spider mite	SC	240 g/L	Foliar treatment – general (see also comment field)	n.a.	1–1		–	–	590 g a.s./ha	7	
Table grapes	US	F	European red mite, Grape erineum mite (blister mite), Pacific spider mite, Twospotted spider mite, Willamette spider mite	SC	240 g/L	Foliar treatment – general (see also comment field)	n.a.	1–1		–	–	590 g a.s./ha	14	

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 and season[c]	Number min–max	Interval between application (min)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Avocados	US	F	Avocado brown mite, Avocado red mite, Broad mite, Carmine spider mite, Citrus red mite, Flat mite (black and red), Mango spider mite, Papaya leaf edgeroller mite, Persea mite, Sixspotted mite, Texas citrus mite, Twospotted spider mite	SC	240 g/L	Foliar treatment – general (see also comment field)	n.a.	1–1		–	–	350 g a.s./ha	2	
Mangoes	US	F	Avocado brown mite, Avocado red mite, Broad mite, Carmine spider mite, Citrus red mite, Flat mite (black and red), Mango spider mite, Papaya leaf edgeroller mite, Persea mite, Sixspotted mite, Texas citrus mite, Twospotted spider mite	SC	240 g/L	Foliar treatment – general (see also comment field)	n.a.	1–1		–	–	350 g a.s./ha	2	

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 and season[c]	Number min–max	Interval between application (min)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Papayas	US	F	Avocado brown mite, Avocado red mite, Broad mite, Carmine spider mite, Citrus red mite, Flat mite (black and red), Mango spider mite, Papaya leaf edgeroller mite, Persea mite, Sixspotted mite, Texas citrus mite, Twospotted spider mite	SC	240 g/L	Foliar treatment – general (see also comment field)	n.a.	1–1		–	–	350 g a.s./ha	2	

MS: Member State; a.s.: active substance; SC: suspension concentrate.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system. 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.
(c): 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	Oranges	Foliar: 1 × 600 g a.s./ha	160	Radiolabelled active substance: [dihydrofuranone-3-^{14}C] spirodiclofen (EFSA, 2009)
		Lemons	Foliar: 1 × 450 g a.s./ha	21	
		Grapefruits	Foliar painting application: 1 × 450 g a.s./ha	85	
		Apples	Foliar: 1 × 1,006 g a.s./ha Foliar: 1 × 1,007 g a.s./ha	23 84	
		Grapes	Foliar: 1 × 224 g a.s./ha Foliar: 1 × 224 g a.s./ha	21 64	
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	–	–	–	Not available and not required as only import tolerances are considered in the present review.
	Leafy crops	–	–	–	
	Cereal (small grain)	–	–	–	

Processed commodities (hydrolysis study)	**Conditions**	**Stable?**	**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)	Yes	Parent spirodiclofen (99% TAR), spirodiclofen-enol (8% TAR) (EFSA, 2009)
	Baking, brewing and boiling (60 min, 100°C, pH 5)	No	Parent spirodiclofen (35% TAR), spirodiclofen-enol (55% TAR) (EFSA, 2009)
	Sterilisation (20 min, 120°C, pH 6)	No	Parent spirodiclofen (37% TAR), spirodiclofen-enol (51% TAR) (EFSA, 2009)

Can a general residue definition be proposed for primary crops?	No	Metabolism investigated in fruit crop group only
Rotational crop and primary crop metabolism similar?	Not applicable	No study available and not required
Residue pattern in processed commodities similar to residue pattern in raw commodities?	No	Parent spirodiclofen stable only to pasteurisation (typical for fruit processing). It degrades to spirodiclofen-enol (M01) under hydrolytic conditions of baking/brewing/boiling and sterilisation. Dietary exposure assessment performed for unprocessed fruits would not underestimate the consumer exposure for processed commodities, even if part of the spirodiclofen residues are converted to the degradation product.
Plant residue definition for monitoring (RD-Mo)	Fruit crop group (raw and processed): spirodiclofen	
Plant residue definition for risk assessment (RD-RA)	Fruit crop group (raw and processed): spirodiclofen	
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)	High water content, high oil content, high acid content and dry commodities (EFSA, 2009): • Multiresidue method DFG S19 (GC-ECD) • LOQ = 0.02 mg/kg for parent spirodiclofen in four main matrices • Confirmation method (GC–MS) available • ILV available in high water and high oil content commodities, applicable to the other two matrix groups • QuEChERS (LC–MS/MS) for enforcement of parent spirodiclofen with LOQ = 0.01 mg/kg in four main plant matrices, and 0.05 mg/kg in difficult matrices (tea, black pepper) in routine analysis (EURLs, 2021).	

DAT: days after treatment; PBI: plant-back interval; GC-ECD: has chromatography with electron capture detector; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; Quick, Easy, Cheap, Effective, Rugged, and Safe; ILV: independent laboratory validation.

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	Peach	–15	13	Months	Spirodiclofen	EFSA (2012)
	High oil content	Almond (nutmeat, hulls)	–15	14	Months	Spirodiclofen	EFSA (2012)
	High acid content	Orange (fruit, peel) grape	–18	24	Months	Spirodiclofen	EFSA (2009, 2012)
	Processed products	Grape (raisins, juice)	–15	8	Months	Spirodiclofen	EFSA (2012)
		Apple (dried, juice)	–15	8	Months	Spirodiclofen	EFSA (2012)
		Plum (prunes)	–15	10	Months	Spirodiclofen	EFSA (2012)

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[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)
Grapefruits Oranges Lemons Limes Mandarins	Import (US)	Oranges: 0.062; 0.067; 0.093; 0.105; 0.110; 0.121; 0.128; 0.129; 0.132; 0.135; 0.177[d]; 0.202 Grapefruit: 0.082[d]; 0.084; 0.088; 0.120; 0.172; 0.284 Lemon: 0.034[d]; 0.042; 0.149; 0.189; 0.287	Combined dataset of trials on orange (12), grapefruit (6) and lemon (4) performed with application rates within 25% deviation or (in 6 trials) PHI 7 ± 2, deemed acceptable. No significant differences among three datasets according to Kruskal–Wallis, and thus extrapolation to the whole citrus fruit is acceptable (Austria, 2021). MRL_{OECD} = 0.39	0.4	0.29	0.12

Commodity	Region[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)
Almonds Brazil nuts Cashew nuts Chestnuts Macadamias Pecans Pistachios Walnuts	Import (US)	Almonds: 2 × < 0.01; 0.023; 2 × 0.024 Pecans: 2 × 0.011; 0.013; 0.015; 0.042[d]	Combined dataset of trials on almonds (5) and pecans (5) performed with application rates within 25% deviation. One almond residue (0.024 mg/kg) corresponds to PHI 5, deemed acceptable. Extrapolation to the whole group of tree nuts is applicable (Austria, 2021). MRL_{OECD} = 0.06	0.06	0.04	0.01
Table grapes	Import (US)	0.334; 0.356; 0.447; 0.545; 0.587; 0.609; 0.628; 0.632; 0.744; 0.791; 0.879; 0.982; 0.992; 1.66; 1.92[d]; 1.95	Trials on grapes performed with application rates or PHI within 25% deviation (Austria, 2021). MRL_{OECD} = 2.95	3	1.95	0.69
Avocados Mangoes Papayas	Import (US)	0.04; 0.065; 0.07; 0.15[d]; 0.47	Trials on avocado compliant with GAP. Extrapolation to mango and papaya is acceptable as spirodiclofen is not systemic and the proposed MRL will not pose a risk to consumers (EFSA, 2012; Austria, 2021). MRL_{OECD} = 0.87	0.9	0.47	0.07

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: 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): Selected value corresponds to higher residue levels observed at longer PHI.

B.1.2.2. Residues in rotational crops

(a) Overall summary

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Not triggered	No study available and not required as only import tolerances are considered in the present review.
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	No study available and not required as only import tolerances are considered in the present review.

B.1.2.3. Processing factors

Processed commodity	Number of valid studies[a]	Processing Factor (PF)		Comment/Source
		Individual values	Median PF	
Citrus, peeled	3	Oranges: 0.04; 0.06; 0.22;	0.06	Austria (2021)
Citrus, juice	3	Oranges: < 0.01; < 0.02; 0.05	< 0.02	Austria (2021)
Citrus, dry pomace	3	Oranges: 0.65; 1.33; 1.38	1.33	Austria (2021)
Citrus, wet pomace	2	Oranges: 0.27; 0.42	0.35	Austria (2021)[b]
Orange, marmalade	1	< 0.56	< 0.56	Tentative[c] (EFSA, 2009)
Grapes, raisins	4	1.52; 2.08; 2.30;4.03	2.19	EFSA (2009), Austria (2021)

PF: Processing factor (=Residue level in processed commodity expressed according to RD-Mo/Residue level in raw 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): Robust PF derived since the calculated processing factors (based on two studies) do not deviate by more than 50%.
(c): A tentative PF is derived based on a limited dataset.

B.2. Residues in livestock

Relevant groups (subgroups)	Dietary burden expressed in				Most critical subgroup[a]	Most critical commodity[b]	Trigger exceeded (Y/N)	Comments
	mg/kg bw per day		mg/kg DM					
	Median	Maximum	Median	Maximum				
Cattle (all)	0.001	0.001	0.04	0.04	Dairy cattle	Citrus, dried pulp	No	–
Cattle (dairy only)	0.001	0.001	0.04	0.04	Dairy cattle	Citrus, dried pulp	No	–
Sheep (all)	–	–	–	–	–	–	–	–
Sheep (ewe only)	–	–	–	–	–	–	–	–
Swine (all)	0.001	0.001	0.03	0.03	Swine (breeding)	Citrus, dried pulp	No	–
Poultry (all)	–	–	–	–	–	–	–	–
Poultry (layer only)	–	–	–	–	–	–	–	–
Fish	–	–	–	–	–	–	–	–

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 hen	–	–	Not available and not required (dietary burden not triggered)
	Lactating goat	10.7	3	10700N compared to the maximum dietary burden calculated for cattle (all diets and dairy). [dihydrofuranone-3-^{14}C] spirodiclofen (EFSA, 2009)
	Pig	–	–	Not available and not required (dietary burden not triggered)

Time needed to reach a plateau concentration in milk and eggs (days)	Milk: -	No plateau reached in metabolism studies. No residues in milk in feeding studies (any feeding level) after dosing for 29 consecutive days.
	Eggs: -	Not available and not required.
Metabolism in rat and ruminant similar	Yes	EFSA (2009)
Can a general residue definition be proposed for animals?	No	Only the metabolism studies for ruminants are available. No need to propose a RD for poultry for the import tolerances currently in place.
Animal residue definition for monitoring (RD-Mo)	Ruminants and swine: spirodiclofen-enol (M01), expressed as spirodiclofen	
Animal residue definition for risk assessment (RD-RA)	Ruminants and swine: spirodiclofen-enol (M01), expressed as spirodiclofen	
Fat soluble residues	Partially fat soluble	Log K_{ow} (spirodiclofen) = 5.83 (fat soluble) Log K_{ow} (spirodiclofen-enol) <3 (pH 7) Residue levels in fat (0.14 mg/kg) higher than in muscle (0.068 mg/kg) (partially fat soluble)
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)	Milk, muscle, fat, liver, kidney (EFSA, 2009): • HPLC-MS/MS • LOQ (milk) = 0.005 mg/kg for spirodiclofen-enol (M01), expressed as parent • LOQ (fat and muscle) = 0.01 mg/kg for spirodiclofen-enol (M01), expressed as parent • LOQ (kidney and liver) = 0.05 mg/kg for spirodiclofen-enol (M01), expressed as parent • Confirmation by monitoring 1 additional MRM transition • ILV on meat and milk available, applicable to other commodities • Validation details of QuEChERS (LC–MS/MS) for enforcement of spirodiclofen-enol (M01) with LOQ = 0.01 mg/kg in milk and liver. Same LOQ is supposed to be achievable for the other animal matrices (muscle, fat, kidney, eggs) (EURLs, 2021).	

Bw: body weight; HPLC–MS/MS: high performance liquid chromatography with tandem mass spectrometry; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; ILV: independent laboratory validation.

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	–20	5	Months	Spirodiclofen-enol	Data from metabolism studies (EFSA, 2009)
	Bovine	Fat	–20	5	Months	Spirodiclofen-enol	
	Bovine	Liver	–20	5	Months	Spirodiclofen-enol	
	Bovine	Kidney	–20	5	Months	Spirodiclofen-enol	
	Bovine	Milk	–20	5	Months	Spirodiclofen-enol	

B.2.2. Magnitude of residues in livestock

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

Not relevant under this review as no MRLs are needed in animal commodities for the import tolerances currently in place (livestock dietary burdens are not triggered).

B.3. Consumer risk assessment

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

Acute risk assessment not relevant since no ARfD has been considered necessary.

ADI	0.015 mg/kg bw per day (European Commission, 2010)
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% (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, except for citrus fruits where the derived peeling factor was also applied. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation.

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

Consumer exposure assessment through drinking water resulting from groundwater metabolite(s) according to SANCO/221/2000 rev.10 Final (25/2/2003).

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

Acute risk assessment not relevant since no ARfD has been considered necessary.

ADI	0.015 mg/kg bw per day (European Commission, 2010)
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)	32% (NL toddler)
NEDI (% ADI)	Not assessed in this review.
Assumptions made for the calculations	For the import tolerances evaluated at EU level, EU risk assessment values were found to cover CXLs. For the additional uses evaluated under JMPR, CXLs and median residue levels derived by JMPR were considered in the calculation.

ARfD: acute reference dose; ADI: acceptable daily intake; bw: body weight; TMDI: theoretical maximum daily intake; NTMDI: national theoretical maximum daily intake; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; NEDI: national estimated daily intake; CXL: codex maximum residue limit; JMPR: Joint FAO/WHO Meeting on Pesticide Residues.

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 1: spirodiclofen[F]					
110010	Grapefruit	0.5	0.4	0.4	Further consideration needed[a]
110020	Oranges	0.5	0.4	0.4	Further consideration needed[a]
110030	Lemons	0.5	0.4	0.4	Further consideration needed[a]
110040	Limes	0.4	0.4	0.4	Further consideration needed[a]
110050	Mandarins	0.4	0.4	0.4	Further consideration needed[a]
120010	Almonds	0.1	0.05	0.06	Further consideration needed[a]
120020	Brazil nuts	0.05	0.05	0.06	Further consideration needed[a]
120030	Cashew nuts	0.05	0.05	0.06	Further consideration needed[a]
120040	Chestnuts	0.05	0.05	0.06	Further consideration needed[a]
120050	Coconuts	0.05	0.05	0.05	Further consideration needed[b]
120060	Hazelnuts	0.05	0.05	0.05	Further consideration needed[b]
120070	Macadamia	0.05	0.05	0.06	Further consideration needed[a]
120080	Pecans	0.05	0.05	0.06	Further consideration needed[a]
120090	Pine nuts	0.05	0.05	0.05	Further consideration needed[b]
120100	Pistachios	0.05	0.05	0.06	Further consideration needed[a]
120110	Walnuts	0.05	0.05	0.06	Further consideration needed[a]
130010	Apples	0.8	0.8	0.8	Further consideration needed[b]
130020	Pears	0.8	0.8	0.8	Further consideration needed[b]
130030	Quinces	0.8	0.8	0.8	Further consideration needed[b]
130040	Medlar	0.8	0.8	0.8	Further consideration needed[b]
130050	Loquat	0.8	0.8	0.8	Further consideration needed[b]
140010	Apricots	2	2	2	Further consideration needed[b]
140020	Cherries	2	2	2	Further consideration needed[b]
140030	Peaches	2	2	2	Further consideration needed[b]
140040	Plums	2	2	2	Further consideration needed[b]
151010	Table grapes	2	0.2	3	Further consideration needed[a]
151020	Wine grapes	0.2	0.2	0.2	Further consideration needed[b]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
152000	Strawberries	2	2	2	Further consideration needed[(b)]
154010	Blueberries	4	4	4	Further consideration needed[(b)]
154030	Currants (red, black and white)	1	1	1	Further consideration needed[(b)]
163010	Avocados	1	0.9	0.9	Further consideration needed[(a)]
163030	Mangoes	1	–	0.9	Further consideration needed[(c)]
163040	Papaya	1	0.03*	0.9	Further consideration needed[(a)]
231010	Tomatoes	0.5	0.5	0.5	Further consideration needed[(b)]
231020	Peppers	0.2	0.2	0.2	Further consideration needed[(b)]
232010	Cucumbers	0.1	0.07	0.07	Further consideration needed[(b)]
232020	Gherkins	0.1	0.07	0.07	Further consideration needed[(b)]
620000	Coffee beans	0.05*	0.05*[,(e)]	0.05*	Further consideration needed[(b)]
700000	'Hops (dried), including hop pellets and unconcentrated powder'	40	40	40	Further consideration needed[(b)]
Enforcement residue definition 2 (existing): spirodiclofen[(F)] **Enforcement residue definition 2 (proposed)**: spirodiclofen-enol (M01), expressed as spirodiclofen					
1011010	Swine meat	0.01*	0.01*	0.01*	Further consideration needed[(b)]
1011020	Swine fat (free of lean meat)	0.05*	0.01*	0.01*	Further consideration needed[(b)]
1011030	Swine liver	0.05*	0.05*	0.05*	Further consideration needed[(b)]
1011040	Swine kidney	0.05*	0.05*	0.05*	Further consideration needed[(b)]
1012010	Bovine meat	0.01*	0.01*	0.01*	Further consideration needed[(b)]
1012020	Bovine fat	0.05*	0.01*	0.01*	Further consideration needed[(b)]
1012030	Bovine liver	0.05*	0.05*	0.05*	Further consideration needed[(b)]
1012040	Bovine kidney	0.05*	0.05*	0.05*	Further consideration needed[(b)]
1013010	Sheep meat	0.01*	0.01*	0.01*	Further consideration needed[(b)]
1013020	Sheep fat	0.05*	0.01*	0.01*	Further consideration needed[(b)]
1013030	Sheep liver	0.05*	0.05*	0.05*	Further consideration needed[(b)]
1013040	Sheep kidney	0.05*	0.05*	0.05*	Further consideration needed[(b)]
1014010	Goat meat	0.01*	0.01*	0.01*	Further consideration needed[(b)]
1014020	Goat fat	0.05*	0.01*	0.01*	Further consideration needed[(b)]
1014030	Goat liver	0.05*	0.05*	0.05*	Further consideration needed[(b)]
1014040	Goat kidney	0.05*	0.05*	0.05*	Further consideration needed[(b)]
1015010	Horse meat	0.01*	0.01*	0.01*	Further consideration needed[(b)]
1015020	Horse fat	0.05*	0.01*	0.01*	Further consideration needed[(b)]
1015030	Horse liver	0.05*	0.05*	0.05*	Further consideration needed[(b)]
1015040	Horse kidney	0.05*	0.05*	0.05*	Further consideration needed[(b)]
1020010	Cattle milk	0.004*	0.005*[,(f)]	0.005*	Further consideration needed[(b)]
1020020	Sheep milk	0.004*	0.005*[,(f)]	0.005*	Further consideration needed[(b)]
1020030	Goat milk	0.004*	0.005*[,(f)]	0.005*	Further consideration needed[(b)]
1020040	Horse milk	0.004*	0.005*[,(f)]	0.005*	Further consideration needed[(b)]
–	Other commodities of plant and/or animal origin	Reg. (EU) 2016/1902	–	–	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): The residue definition is fat soluble.
(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; existing CXL is covered by the recommended MRL (combination H-III in Appendix E). It is noted that spirodiclofen is classified as carcinogenic category 1B with a threshold, in accordance with Regulation (EC) No 1272/2008.
(b): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix E). It is noted that spirodiclofen is classified as carcinogenic category 1B with a threshold, in accordance with Regulation (EC) No 1272/2008.
(c): 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). It is noted that spirodiclofen is classified as carcinogenic category 1B with a threshold, in accordance with Regulation (EC) No 1272/2008.
(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).
(e): CXL of 0.03* mg/kg was rounded up to the LOQ of 0.05* mg/kg, which was proposed by EURLs at EU level for enforcement of this matrix.
(f): CXL of 0.004* mg/kg was rounded up to the LOQ of 0.005* mg/kg, which was the LOQ of the method evaluated at EU level for enforcement of this matrix.

Appendix C – Pesticide Residue Intake Model (PRIMo)

- PRIMo(EU)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Spirodiclofen

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw per day):	0.015	ARfD (mg/kg bw):	not necessary
Source of ADI:	EC	Source of ARfD:	
Year of evaluation:	2010	Year of evaluation:	

Input values

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

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

Comments:

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	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
	7%	NL toddler	1.10	7%	Table grapes	0.1%	Oranges	0.1%	Mangoes		7%
	7%	DE child	0.98	6%	Table grapes	0.2%	Oranges	0.0%	Mandarins		7%
	5%	GEMS/Food G06	0.75	5%	Table grapes	0.0%	Mangoes	0.0%	Oranges		5%
	5%	NL child	0.73	5%	Table grapes	0.1%	Oranges	0.0%	Mangoes		5%
	2%	GEMS/Food G11	0.31	2%	Table grapes	0.0%	Oranges	0.0%	Mangoes		2%
	2%	FR child 3 15 yr	0.27	2%	Table grapes	0.2%	Oranges	0.0%	Avocados		2%
	2%	GEMS/Food G07	0.25	2%	Table grapes	0.1%	Oranges	0.0%	Avocados		2%
	2%	GEMS/Food G15	0.24	2%	Table grapes	0.0%	Oranges	0.0%	Mandarins		2%
	2%	GEMS/Food G08	0.24	2%	Table grapes	0.0%	Oranges	0.0%	Lemons		2%
	2%	IE adult	0.23	1%	Table grapes	0.1%	Mangoes	0.1%	Avocados		2%
	2%	DE women 14-50 yr	0.23	1%	Table grapes	0.1%	Oranges	0.0%	Mangoes		2%
	1%	PL general	0.22	1%	Table grapes	0.0%	Lemons	0.0%	Walnuts		1%
	1%	GEMS/Food G10	0.22	1%	Table grapes	0.1%	Oranges	0.0%	Avocados		1%
	1%	PT general	0.20	1%	Table grapes	0.0%	Oranges	0.0%	Mandarins		1%
	1%	DE general	0.19	1%	Table grapes	0.1%	Oranges	0.0%	Mangoes		1%
	1%	UK toddler	0.19	1%	Table grapes	0.1%	Oranges	0.0%	Mandarins		1%
	1%	NL general	0.18	1%	Table grapes	0.0%	Oranges	0.0%	Mandarins		1%
	1%	FI 3 yr	0.16	1%	Table grapes	0.0%	Mandarins	0.0%	Oranges		1%
	0.9%	RO general	0.13	0.8%	Table grapes	0.0%	Oranges	0.0%	Walnuts		0.9%
	0.9%	DK child	0.13	0.8%	Table grapes	0.0%	Oranges	0.0%	Mangoes		0.9%
	0.8%	FI 6 yr	0.12	0.8%	Table grapes	0.0%	Mandarins	0.0%	Oranges		0.8%
	0.8%	DK adult	0.12	0.8%	Table grapes	0.0%	Avocados	0.0%	Oranges		0.8%
	0.6%	IT adult	0.09	0.6%	Table grapes	0.0%	Oranges	0.0%	Mandarins		0.6%
	0.6%	FR adult	0.09	0.5%	Table grapes	0.0%	Oranges	0.0%	Avocados		0.6%
	0.5%	IT toddler	0.08	0.5%	Table grapes	0.0%	Oranges	0.0%	Mandarins		0.5%
	0.4%	UK vegetarian	0.06	0.4%	Table grapes	0.0%	Oranges	0.0%	Avocados		0.4%
	0.4%	FI adult	0.06	0.4%	Table grapes	0.0%	Oranges	0.0%	Mandarins		0.4%
	0.3%	ES adult	0.04	0.2%	Table grapes	0.1%	Oranges	0.0%	Mandarins		0.3%
	0.3%	ES child	0.04	0.2%	Table grapes	0.1%	Oranges	0.0%	Mandarins		0.3%
	0.3%	UK adult	0.04	0.2%	Table grapes	0.0%	Oranges	0.0%	Avocados		0.3%
	0.3%	IE child	0.04	0.3%	Table grapes	0.0%	Oranges	0.0%	Mangoes		0.3%
	0.2%	FR toddler 2 3 yr	0.03	0.1%	Oranges	0.0%	Mandarins	0.0%	Table grapes		0.2%
	0.2%	UK infant	0.03	0.1%	Table grapes	0.1%	Oranges	0.0%	Grapefruits		0.2%
	0.1%	SE general	0.01	0.0%	Oranges	0.0%	Mandarins	0.0%	Avocados		0.1%
	0.1%	LT adult	0.01	0.1%	Table grapes	0.0%	Oranges	0.0%	Mandarins		0.1%
	0.0%	FR infant	0.00	0.0%	Oranges	0.0%	Mandarins	0.0%	Mangoes		0.0%

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

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

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

Show results for all crops

Unprocessed commodities

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

Processed commodities

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

Conclusion:

- PRIMo(CXL)

European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Spirodiclofen

LOQs (mg/kg) range from: 0.004 to: 0.05

Toxicological reference values

ADI (mg/kg bw per day):	0.015	ARfD (mg/kg bw):	not necessary
Source of ADI:	EC	Source of ARfD:	
Year of evaluation:	2010	Year of evaluation:	

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

Comments:

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	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
	32%	NL toddler	4.81	14%	Apples	7%	Table grapes	6%	Pears		32%
	28%	DE child	4.26	17%	Apples	6%	Table grapes	0.9%	Pears		28%
	17%	NL child	2.56	8%	Apples	5%	Table grapes	2%	Pears		17%
	10%	GEMS/Food G06	1.54	5%	Table grapes	2%	Tomatoes	1%	Apples		10%
	8%	DE women 14-50 yr	1.18	3%	Apples	1%	Table grapes	0.4%	Milk: Cattle		8%
	8%	DE general	1.14	3%	Apples	1%	Table grapes	0.5%	HOPS (dried)		8%
	7%	FR child 3 15 yr	1.03	2%	Apples	2%	Table grapes	0.8%	Milk: Cattle		7%
	7%	DK child	1.01	3%	Apples	0.9%	Pears	0.8%	Table grapes		7%
	7%	GEMS/Food G15	1.00	2%	Table grapes	1%	Apples	0.6%	Tomatoes		7%
	7%	FR toddler 2 3 yr	0.99	4%	Apples	1.0%	Milk: Cattle	0.4%	Pears		7%
	6%	RO general	0.97	2%	Apples	1%	Tomatoes	0.8%	Table grapes		6%
	6%	GEMS/Food G11	0.96	2%	Apples	2%	Table grapes	0.5%	Tomatoes		6%
	6%	GEMS/Food G08	0.91	2%	Apples	2%	Table grapes	0.6%	Tomatoes		6%
	6%	PL general	0.87	3%	Apples	1%	Table grapes	0.5%	Tomatoes		6%
	6%	GEMS/Food G07	0.87	2%	Table grapes	1%	Apples	0.6%	Wine grapes		6%
	6%	IE adult	0.86	1%	Table grapes	1.0%	Apples	0.7%	Peaches		6%
	6%	PT general	0.85	1%	Apples	1%	Table grapes	1.0%	Wine grapes		6%
	5%	UK toddler	0.80	2%	Apples	1%	Table grapes	0.7%	Milk: Cattle		5%
	5%	GEMS/Food G10	0.78	1%	Table grapes	1%	Apples	0.7%	Tomatoes		5%
	5%	NL general	0.73	2%	Apples	1%	Table grapes	0.3%	Milk: Cattle		5%
	5%	UK infant	0.73	2%	Apples	1%	Milk: Cattle	0.3%	Pears		5%
	4%	ES child	0.67	2%	Apples	0.6%	Pears	0.5%	Tomatoes		4%
	4%	IT toddler	0.65	1%	Apples	0.8%	Tomatoes	0.7%	Peaches		4%
	4%	IT adult	0.60	1%	Apples	0.8%	Peaches	0.6%	Tomatoes		4%
	4%	SE general	0.59	1%	Apples	0.5%	Pears	0.4%	Milk: Cattle		4%
	4%	FR adult	0.58	1%	Apples	0.9%	Wine grapes	0.5%	Table grapes		4%
	4%	DK adult	0.58	1%	Apples	0.8%	Table grapes	0.4%	Pears		4%
	4%	FI 3 yr	0.57	1%	Apples	1%	Table grapes	0.3%	Tomatoes		4%
	4%	FI adult	0.57	2%	Coffee beans	0.8%	Apples	0.4%	Table grapes		4%
	4%	LT adult	0.53	2%	Apples	0.3%	Tomatoes	0.2%	Pears		4%
	3%	ES adult	0.52	1%	Apples	0.5%	Peaches	0.4%	Pears		3%
	3%	FR infant	0.51	2%	Apples	0.6%	Milk: Cattle	0.2%	Pears		3%
	3%	FI 6 yr	0.41	0.8%	Table grapes	0.8%	Apples	0.2%	Pears		3%
	3%	UK vegetarian	0.39	0.8%	Apples	0.4%	Table grapes	0.3%	Tomatoes		3%
	2%	UK adult	0.36	0.5%	Apples	0.5%	HOPS (dried)	0.4%	Wine grapes		2%
	1.0%	IE child	0.15	0.4%	Apples	0.3%	Table grapes	0.1%	Milk: Cattle		1.0%

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

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

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

Show results for all crops

Unprocessed commodities

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

Processed commodities

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

Conclusion:

Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: spirodiclofen				
Citrus dried pulp	0.16	STMR × PF (1.3)	0.16	STMR × PF (1.3)

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

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

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: spirodiclofen		
Citrus fruits	0.007	STMR × PF (0.06)
Almonds	0.014	STMR
Brazil nuts	0.014	STMR
Cashew nuts	0.014	STMR
Chestnuts	0.014	STMR
Macadamias	0.014	STMR
Pecans	0.014	STMR
Pistachios	0.014	STMR
Walnuts	0.014	STMR
Table grapes	0.688	STMR
Avocados	0.070	STMR
Mangoes	0.070	STMR
Papayas	0.070	STMR

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

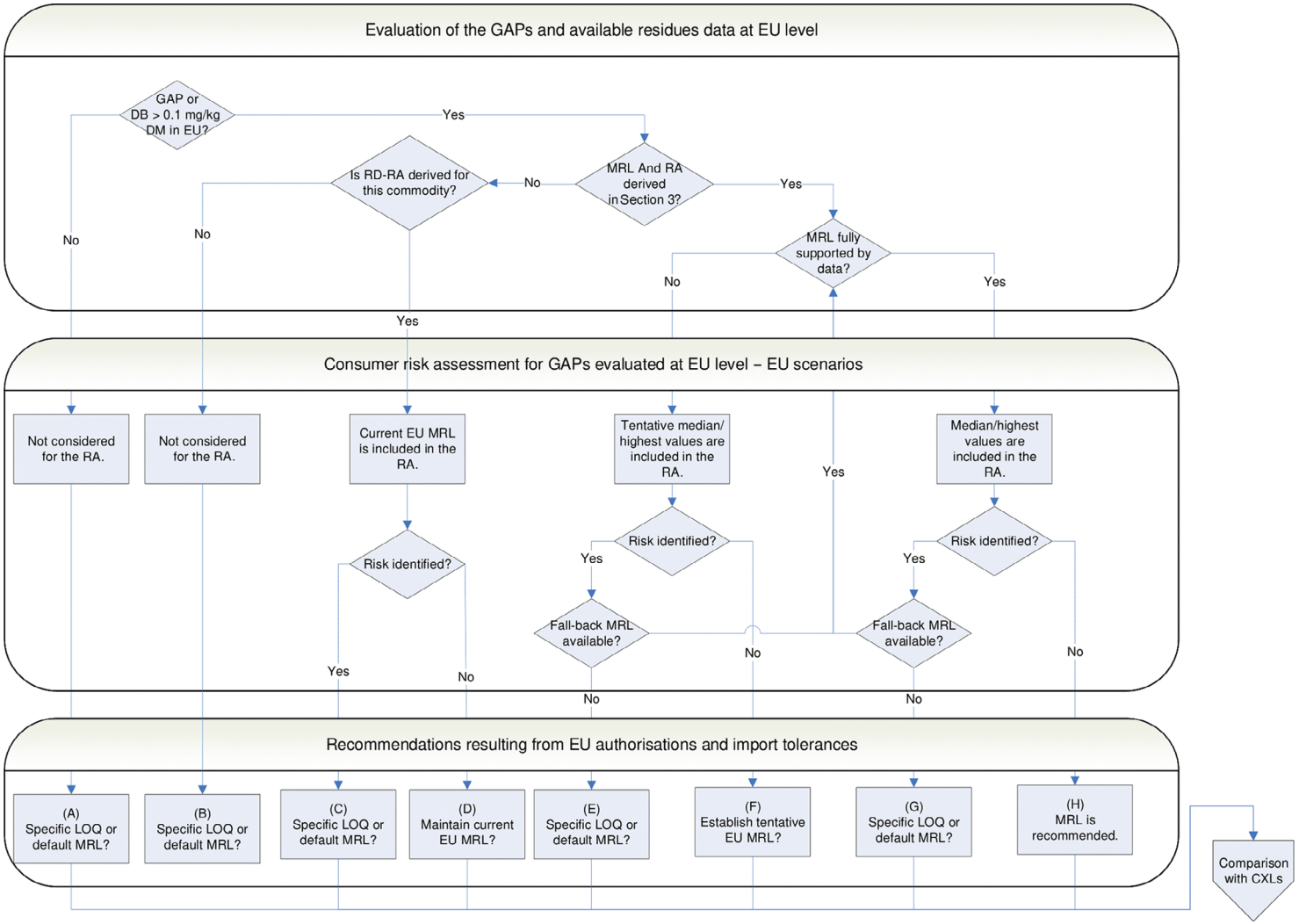
D.3. Consumer risk assessment with consideration of the existing CXLs

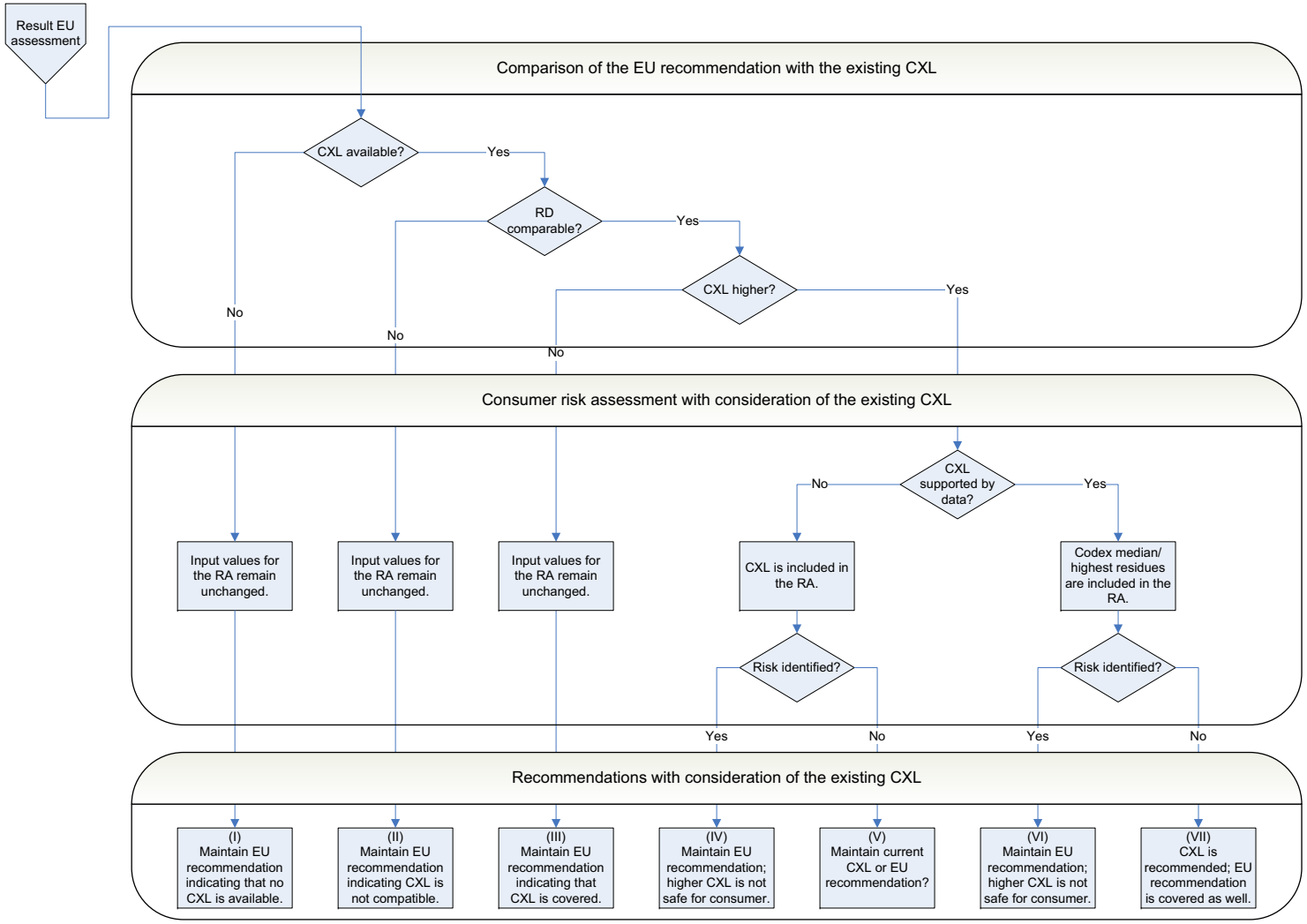
Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition 1: spirodiclofen		
Citrus fruits	0.007	STMR × PF (0.06)
Almonds	0.014	STMR
Brazil nuts	0.014	STMR
Cashew nuts	0.014	STMR
Chestnuts	0.014	STMR
Coconuts	0.016	STMR (CXL)
Hazelnuts	0.016	STMR (CXL)
Macadamias	0.014	STMR
Pecans	0.014	STMR
Pine nuts	0.016	STMR (CXL)
Pistachios	0.014	STMR
Walnuts	0.014	STMR

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Pome fruits	0.2	STMR (CXL)
Stone fruits	0.32	STMR (CXL)
Table grapes	0.688	STMR
Wine grapes	0.059	STMR (CXL)
Strawberries	0.062	STMR (CXL)
Blueberries	0.920	STMR (CXL)
Currants (red, black and white)	0.040	STMR (CXL)
Avocados	0.070	STMR
Mangoes	0.070	STMR
Papayas	0.070	STMR
Tomatoes	0.080	STMR (CXL)
Peppers	0.080	STMR (CXL)
Cucumbers	0.030	STMR (CXL)
Gherkins	0.030	STMR (CXL)
Coffee beans	0.05*[(a)]	CXL
'Hops (dried), including hop pellets and unconcentrated powder'	11.0	STMR (CXL)
Risk assessment residue definition 2: spirodiclofen-enol (M01), expressed as spirodiclofen		
Swine meat	0.01*	CXL muscle
Swine fat	0.01*	CXL
Swine liver	0.05*	CXL
Swine kidney	0.05*	CXL
Bovine and equine meat	0.01*	CXL muscle
Bovine and equine fat	0.01*	CXL
Bovine and equine liver	0.05*	CXL
Bovine and equine kidney	0.05*	CXL
Sheep and goat meat	0.01*	CXL muscle
Sheep and goat fat	0.01*	CXL
Sheep and goat liver	0.05*	CXL
Sheep and goat kidney	0.05*	CXL
Cattle and horse milk	0.005*[(b)]	CXL
Sheep and goat milk	0.005*[(b)]	CXL

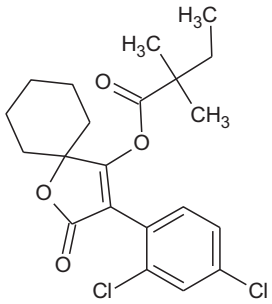
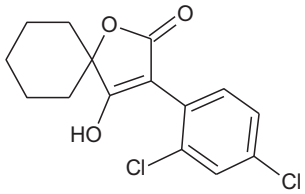
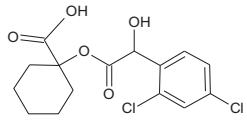
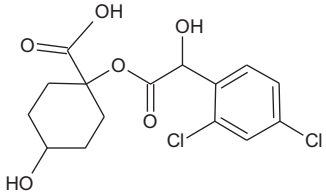
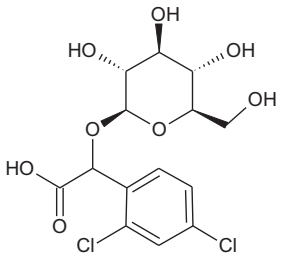
STMR: supervised trials median residue; PF: processing factor; CXL: codex maximum residue limit.
*: Indicates that the input value is proposed at the limit of quantification.
(a): CXL of 0.03* mg/kg was rounded up to the LOQ of 0.05* mg/kg, which was proposed by EURLs at EU level for enforcement of this matrix.
(b): CXL of 0.004* mg/kg was rounded up to the LOQ of 0.005* mg/kg which was derived at EU level for enforcement of this matrix.

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
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
CXL supported by data?
No
Yes
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]
Spirodiclofen	3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutyrate CC(C)(CC)C(=O)OC1=C(C(=O)OC21CCCCC2)c1ccc(Cl)cc1Cl DTDSAWVUFPGDMX-UHFFFAOYSA-N	
Spirodiclofen-enol (M01)	3-(2,4-dichlorophenyl)-4-hydroxy-1-oxaspiro[4.5]dec-3-en-2-one Clc1ccc(C=2C(=O)OC3(CCCCC3)C=2O)c(Cl)c1 KIKARNYYJSEROI-UHFFFAOYSA-N	
M04	Glucosyl pentoside derivative of 1-{[(2,4-dichlorophenyl)(hydroxy)acetyl]oxy}cyclohexane-1-carboxylic acid Note: it was not determined if the conjugate corresponds to a dimer or glucose and a pentoside moiety are attached in two different positions of the molecule.	Glucosyl pentoside derivative of 
M05	1-{[(2,4-dichlorophenyl)(hydroxy)acetyl]oxy}-4-hydroxycyclohexane-1-carboxylic acid (one of the possible isomers, position of the hydroxyl moiety in the cyclohexane has not been definitively determined)	
M08	(2,4-dichlorophenyl)(β-D-glucopyranosyloxy)acetic acid Clc1ccc(C(O[C@@H]2O[C@H](CO)[C@@H](O)[C@H](O)[C@H]2O)C(=O)O)c(Cl)c1 GCSIFAGRQUUVJD-HWHXPSIMSA-N	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116563, 15 June 2020).
(c): ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C25H41, Build 121153, 22 March 2021).