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

European Food Safety Authority (EFSA),
Himdata Abdourahime, Maria Anastassiadou, Alba Brancato, Daniela Brocca, Luis Carrasco Cabrera, Chloe De Lentdecker, Lucien Ferreira, Luna Greco, Samira Jarrah, Dimitra Kardassi, Renata Leuschner, Alfonso Lostia, Christopher Lythgo, Paula Medina, Ileana Miron, Tunde Molnar, Stefanie Nave, Ragnor Pedersen, Marianna Raczyk, Hermine Reich, Silvia Ruocco, Angela Sacchi, Miguel Santos, Alois Stanek, Juergen Sturma, Jose Tarazona, Anne Theobald, Benedicte Vagenende, Alessia Verani and Laura Villamar-Bouza

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 sedaxane. To assess the occurrence of sedaxane residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Commission Regulation (EU) No 188/2011, the MRLs established by the Codex Alimentarius Commission as well as the European authorisations reported by Member States (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out.

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

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Correspondence: pesticides.mrl@efsa.europa.eu

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Summary

Sedaxane was approved on 1 February 2014 by means of Commission Implementing Regulation (EU) No 826/2013 in the framework of Regulation (EC) No 1107/2009 as amended by Commission Implementing Regulations (EU) No 540/2011 and 541/2011.

As the active substance was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation.

As the basis for the MRL review, on 15 November 2017 EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 15 December 2017 their national Good Agricultural Practices (GAPs) in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State (RMS) France to identify the critical GAPs in the format of a specific GAP overview file. Subsequently, Member States were requested to provide residue data supporting the critical GAPs, within a period of 1 month, by 12 March 2018. On the basis of all the data submitted by Member States and by the EU Reference Laboratories for Pesticides Residues (EURL), EFSA asked the RMS to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report, together with the Pesticide Residues Intake Model (PRIMo) calculations and an updated GAP overview file, were provided by the RMS to EFSA on 16 May 2018. 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 EURL, and taking into account the conclusions derived by EFSA in the framework of Commission Regulation (EU) No 188/2011 and the MRLs established by the Codex Alimentarius Commission, EFSA prepared in September 2018 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 26 October 2018 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of sedaxane in plant was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement and risk assessment in plant commodities can be proposed as sedaxane (sum of isomers). This residue definition is restricted to seed and soil treatments only and it is also applicable to rotational crops and processed commodities. Validated analytical methods are available for the enforcement of the proposed residue definition in the four main matrices at the limit of quantification (LOQ) of 0.01 mg/kg. According to the EURL, the same LOQ of 0.01 mg/kg is achievable in high water, high acid and high oil content commodities, while a LOQ of 0.005 mg/kg is achievable in dry commodities in routine analyses.

The available residue trials data were considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation. MRLs on rotational crops are not necessary, provided that appropriate risk mitigation measures will be taken by Member States when granting national authorisations.

Sedaxane is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to the pertinent OECD guidance. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg dry matter (DM), further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary, when considering the authorised uses in the European Union (EU). Although not required, the metabolism of sedaxane residues in livestock was investigated in lactating goats and laying hens. According to the results of these studies, a general residue definition for monitoring and risk assessment in livestock was suggested as sedaxane (sum of isomers) in the peer review. Analytical methods with a LOQ of 0.01 mg/kg for the sum of isomers in milk, eggs and tissues were considered acceptable in the EFSA conclusion.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA Pesticide Residues Intake model (PRIMo). The highest chronic exposure represented 0.2% the acceptable daily intake (ADI) (UK toddler) and the highest acute exposure amounted to 0.2% of the acute reference dose (ARfD) (sweet corn). These calculations indicate that the uses assessed under this review result in a consumer exposure lower than the toxicological reference values, and thus are unlikely to pose a risk to consumer's health.

Apart from the MRLs evaluated in the framework of this review, internationally recommended codex maximum residue limits (CXLs) have also been established for sedaxane. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out. The highest chronic exposure represented 0.3% of the ADI (UK toddler), and the highest acute exposure amounted to 1% of the ARfD (potatoes).

EFSA also emphasises that the above assessment does not consider the possible impact of plant metabolism on the isomer ratio of sedaxane and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, this issue might be reconsidered when such guidance is available. EFSA notes that in view of the large margin of safety in the exposure calculations, the potential change of isomer ratios in the final residues is not expected to be of concern for the authorised uses reported in the framework of this review. In case future uses of sedaxane would lead to a higher consumer exposure, further information regarding the impact of plant and/or livestock metabolism on the isomer ratio might be required.

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Background

Regulation (EC) No 396/2005[1] (hereinafter referred to as 'the Regulation') establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC[2] a reasoned opinion on the review of the existing MRLs for that active substance.

As sedaxane was approved on 1 February 2014 by means of Commission Implementing Regulation (EU) No 826/2013[3] in the framework of Regulation (EC) No 1107/2009[4] as amended by Commission Implementing Regulations (EU) No 540/2011[5] and 541/2011[6], EFSA initiated the review of all existing MRLs for that active substance.

By way of background information, in the framework of Commission Regulation (EU) No 188/2011[7] sedaxane was evaluated by France, 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, 2013). The approval of sedaxane is restricted to uses for seed treatment only.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC repealed by Regulation (EC) No 1107/2009. It should be noted, however, that, in the framework of Regulation (EC) No 1107/2009, only a few representative uses are evaluated, whereas MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the European Union (EU), and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Regulation (EC) No 1107/2009 is therefore insufficient for the assessment of all existing MRLs for a given active substance.

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

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

As the basis for the MRL review, on 15 November 2017, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 15 December 2017 their Good Agricultural Practices (GAPs) that are authorised nationally, in a standardised way, in the format of specific GAP forms. In the framework of this consultation, 15 Member States provided feedback on their national authorisations of sedaxane. Based on the GAP data submitted, the designated RMS France was asked to identify the critical GAPs to be further considered in the assessment, in the

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

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

[3] Commission Implementing Regulation (EU) No 826/2013 of 29 August 2013 approving the active substance sedaxane, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011. OJ L 232, 30.8.2013, p. 13–17.

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

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

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

[7] Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ L 53, 26.2.2011, p. 51–55.

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 12 March 2018.

On the basis of all the data submitted by Member States and the EU Reference Laboratories for Pesticides Residues (EURL), EFSA asked France to complete the PROFile and to prepare a supporting evaluation report. The PROFile and the supporting evaluation report, together with the Pesticide Residues Intake Model (PRIMo) calculations and an updated GAP overview file, were submitted to EFSA on 16 May 2018. 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 September 2018 a draft reasoned opinion, which was circulated to Member States for commenting via a written procedure. All comments received by 26 October 2018 were considered by EFSA during the finalisation of the reasoned opinion.

The **evaluation report** submitted by the RMS (France, 2018), taking into account also the information provided by Member States during the collection of data, and the **EURL report on analytical methods** (EURL, 2018) 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, 2018a) and the **Member States consultation report** (EFSA, 2018b). 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 **PRIMo** and the **PROFile** as well as the **GAP overview file** listing all authorised uses are key supporting documents and made publicly available as background documents to this reasoned opinion. A screenshot of the report sheet of the PRIMo is presented in Appendix C.

Terms of Reference

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

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

The active substance and its use pattern

Sedaxane is the ISO common name for the mixture of 80–100% two *trans*-isomers 2′-[(1*RS*,2*SR*)-1,1′-bicycloprop-2-yl]-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxanilide and 20–0% two *cis*-isomers 2′-[(1*RS*,2*RS*)-1,1′-bicycloprop-2-yl]-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxanilide (IUPAC).

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

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

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

Procedure	Legal implementation	Remarks
Implementation of CAC 2014	Commission Regulation (EU) No 2016/567[(a)]	Potatoes, sweet corn, pulses, cereals

MRL: maximum residue level.

(a): 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.

For the purpose of this MRL review, all the uses of sedaxane currently authorised within the EU as submitted by the Member States during the GAP collection have been reported by the RMS in the GAP overview file. The critical GAPs identified in the GAP overview file were then summarised in the PROFile and considered in the assessment. The details of the authorised critical GAPs for sedaxane are given in Appendix A. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

Assessment

EFSA has based its assessment on the following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (France, 2018);
- the draft assessment report (DAR) and its addenda prepared under Commission Regulation (EU) No 188/2011 (France, 2011, 2012);
- the conclusion on the peer review of the pesticide risk assessment of the active substance sedaxane (EFSA, 2013);
- the Joint Meeting on Pesticide residues (JMPR) Evaluation report (FAO, 2012, 2014).

The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011[8] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013).

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

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of sedaxane was investigated after seed treatment of cereals (spring wheat), pulses and oilseeds (soybean and canola) and leafy vegetables (Swiss chard) (France, 2012) and assessed in the framework of the peer review (EFSA, 2013). In all the studies, sedaxane was radiolabelled in the phenyl and pyrazole rings of the molecule, with a ratio of *trans*- and *cis*-isomers of 6:1, which is in compliance with the agreed specification of the active substance.

Following seed treatment at an application rate of 40 g a.s./100 kg seed (4N) on wheat, the major component identified in foliage and straw was sedaxane (sum of isomers), representing up to 18% (0.0812 mg eq/kg) and 16% (0.167 mg eq/kg) of the total radioactive residues (TRR) for the phenyl and pyrazole labels, respectively. Another relevant compound identified in wheat foliage and straw was the *trans-p*-phenol (CSCD658906), accounting for up to 16%. At harvest, the TRR in grain were recovered at a trace level (0.004–0.008 mg eq/kg), and therefore, no further metabolite investigation was attempted.

Sedaxane (sum of isomers) was also the major component found in Swiss chard, representing up to 52% of TRR (0.0235 mg eq/kg). Following seed treatment at an application rate of 110 g a.s./100 kg seed on soybean, the most prominent compounds identified in foliage were the glucose conjugate (CSCD667555) and the malonyl conjugate (CSCD667556) of the *N*-desmethyl parent, representing up to 28% and 22% of TRR, respectively. Parent sedaxane (sum of isomers) was also a relevant compound, accounting for 12–23% TRR (0.0166–0.0814 mg eq/kg); however, it was not detected in soybean seeds, where the predominant metabolite was *N*-desmethyl pyrazole acid (CSCD465008) (12% TRR, 0.006 mg eq/kg). Finally, residues of sedaxane are not translocated into canola seed following seed treatment at an application rate of 9.7 g a.s./100 kg seed.

The metabolic pathway of sedaxane was similar in the three crop groups, and therefore, the primary crop metabolism data are sufficient to support the authorised uses on cereals, sugar beet, maize and sweet corn.

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

1.1.2. Nature of residues in rotational crops

Sedaxane is authorised on crops that may be grown in rotation. The field DT_{90} reported in the soil degradation studies evaluated in the framework of the peer review was 1,454 days (EFSA, 2013). The DT_{90} values of metabolite CSCD465008 also exceeded 100 days (> 365 days). Therefore, an investigation of residues in rotational crops following single and multiannual application is required.

Two confined rotational crop studies, one following seed treatment and the other following bare soil application with phenyl-^{14}C- and pyrazole-^{14}C-radiolabelled sedaxane, were available (France, 2012; EFSA, 2013). Sedaxane was applied once to soybean seeds at a rate of 100 g a.s./ha (4N compared to the most critical GAP considered in this review). Wheat (cereals), radish (root and tuber vegetables) and lettuce (leafy vegetables) seeds were planted following re-tilling of soybean plants into the soil at nominal plant-back intervals (PBI) of 30, 120 and 365 days after treatment (DAT) (wheat and radish), and 30, 151 and 365 days (lettuce). Residues found in the representative food commodities were lower than those in feed commodities. In wheat grain, residues were low at all planting intervals (≤ 0.028 mg eq/kg) and further characterisation was not accomplished. The predominant metabolites that were detected in all parts of the crops were CSCD465008 and CSAA798670 (pyrazole acid), accounting for up to 72% (0.088 mg eq/kg) (365 DAT) and 43% TRR (0.023 mg eq/kg) (30 DAT), respectively, in lettuce. Residues from parent sedaxane were below 0.01 mg eq/kg (1–47% TRR), with the exception of radish root (0.015 mg eq/kg; 58% TRR; PBI 30) and wheat straw (0.01 mg eq/kg; 4% TRR; PBI 120).

The pattern of distribution was very similar in the study conducted following bare soil treatment (1 × 100 g a.s./ha on wheat, lettuce and turnip (root and tuber vegetables)) as rotated crops, planted at PBI of 29, 90 and 300 DAT. Residues in crops declined over the period of the study. Sedaxane was found in all the crop parts (6–63% TRR), mainly in wheat: up to 0.029 mg/kg (33% TRR; PBI 90) in forage and 0.155 mg/kg (14% TRR; PBI 29) in straw. In other commodities, residues were below 0.01 mg/kg, except in turnip roots (0.01 mg/kg; 48% TRR; PBI 29).

The overall metabolic pathways in rotated crops result in similar uptake and transformation to those found in primary crops.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of sedaxane was investigated in the framework of the peer review (France, 2012; EFSA, 2013). Studies were conducted with radiolabelled sedaxane on the phenyl and pyrazole rings simulating representative hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6). Sedaxane was found to be hydrolytically stable under standard conditions of pasteurisation, baking/brewing/boiling and sterilisation (France, 2012; EFSA, 2013).

1.1.4. Methods of analysis in plants

In the framework of the peer review (France, 2012; EFSA, 2013), a QuEChERS analytical method based on high-performance liquid chromatography (HPLC) coupled to tandem mass spectrometry (MS/MS) detection was validated in high water, high acid, high oil content commodities and dry commodities, with a limit of quantification (LOQ) of 0.01 mg/kg for sedaxane (sum of isomers). One additional selected reaction monitoring (SRM) transition was monitored for confirmation purposes. An independent laboratory validation (ILV) in wheat whole plant (high water) and in wheat straw was evaluated in the peer review. No ILV is available for the determination of sedaxane in dry commodities and it is considered desirable.

During the completeness check, the EURL provided QuEChERS and QuOil multi-residue methods using liquid chromatography with tandem mass spectrometry (LC–MS/MS) with a LOQ of 0.01 mg/kg for sedaxane (sum of isomers) in high water, high acid and high oil content commodities, and a LOQ of 0.005 mg/kg in dry commodities, for the enforcement of sedaxane in routine analysis (EURL, 2018). During the consultation of Member States, Germany indicated that the data for dry matrices from the EURL could be considered as an ILV of the primary method provided by the applicant (EFSA, 2018b).

1.1.5. Stability of residues in plants

The potential for degradation of sedaxane residues during storage was investigated in the framework of the peer review (France, 2012; EFSA, 2013). The storage stability of the *trans* (SYN508210) and *cis* (SYN508211) isomers was separately examined in high water (spinach and potato), high oil (soybean), high protein (lentil), high starch (wheat grain) and high acid (orange)

content commodities as well as in wheat straw. The results of the studies demonstrated storage stability for the *trans*- and *cis*-isomers of sedaxane for a period of 24 months when stored at −18°C. Additionally, the storage stability of the *cis*- and *trans*-isomers of sedaxane was examined in processed commodities, namely in wheat flour, germ and bran, soybean meal, hulls and oil, and orange pulp, juice and oil. In the case of processed commodities, storage stability was demonstrated for 12 months when stored at −18°C.

1.1.6. Proposed residue definitions

The metabolism of sedaxane was similar in all primary crops assessed. The metabolism in rotational crops is similar to the metabolism observed in primary crops and the processing of sedaxane is not expected to modify the nature of residues.

Based on the results from the available studies, the residue definition for enforcement and risk assessment in plant commodities is proposed as sedaxane (sum of isomers). This residue definition is restricted to seed and soil treatments only and it is also applicable to rotational crops and processed commodities.

A QuEChERS analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in all the four main matrices is available (EFSA, 2013). According to the EURLs, the LOQ of 0.01 mg/kg is achievable in routine analyses. The analytical standards commercially available are for the mixture of isomers (EURL, 2018).

In addition, EFSA emphasises that the above studies do not investigate the possible impact of plant metabolism on the isomer ratio of sedaxane and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of sedaxane residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (France, 2018) as well as the residue trials evaluated in the framework of the peer review (EFSA, 2013). All residue trial samples considered in this framework were stored in compliance with the conditions for which storage stability of residues was demonstrated. Decline of residues during storage of the trial samples is therefore not expected. The number of residue trials and proposed extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2017).

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

- Sweet corn: the available residue trials supporting the southern outdoor GAP were underdosed compared to the most critical GAP. However, a translocation study in maize, evaluated during the peer review and performed with 123.5 g a.s/100 kg seeds (~ 1.65N) resulted in TRR < 0.01 mg eq/kg in sweet corn kernel. Therefore, no residues are expected in sweet corn at the reported GAP and further residue trials are not required.
- Maize: the available residue trials on grain supporting the northern outdoor GAP were underdosed compared to the most critical GAP. Nevertheless, according to the translocation study in maize (see above), the TRR in grain were below 0.01 mg eq/kg. No residues are thus expected in maize grain at the reported GAP and therefore further residue trials are not required.
- It is noted that in the same translocation study, residues in corn stover were found at > 0.07 mg eq/kg, indicating that residues above the LOQ cannot be excluded in this feed item following treatment according to the GAP. However, as this is not expected to have a significant impact on livestock exposure, additional trials are not required.
- Sugar beet: The number of residue trials (four) supporting the northern GAP is not compliant with the data requirements for this crop (eight trials). However, the reduced number of residue trials is considered acceptable in this case because all results were below the LOQ and a no-residue situation is expected. Further residue trials are therefore not required.

1.2.2. Magnitude of residues in rotational crops

Considering the degradation rates of sedaxane (see Section 1.1.2), the maximum application rate of 1 × 25 g a.s/ha per year assessed in this review, a soil bulk density of 1.5 g/cm^3, soil depth of 20 cm and no crop interception, the plateau concentration in soil taking into account accumulation over the years and the following crop not being planted for 100 days after the last application has been calculated as 0.0178 mg a.s./kg soil.

In the available confined rotational crop study performed following seed treatment at 4N compared to the maximum application rate assessed in this review, the predominant metabolites detected in all parts of the crops were CSCD465008 and CSAA798670 (see Section 1.1.2). Since these metabolites are major soil metabolites, it is expected that a potential uptake from the soil might occur (EFSA, 2013).

Therefore, two field rotational crop studies were conducted following bare soil application and seed treatment of spring wheat. In the first study, bare soil was treated at two different rates, 9 and 30 g a.s./ha, representing 0.4N and 1.2N compared to the maximum application rate currently authorised. The test material was incorporated into the soil after the application. Three representative rotational crops, namely spinach (leafy vegetables), radish (root and tuber vegetables) and wheat (cereals) were planted back at three intervals: 60, 120 and 270 PBIs. In the second study, primary wheat crop seeds were treated at a nominal rate of 10 g a.s./100 kg seed (25 g a.s./ha; 1N). The primary crop was destroyed by application of glyphosate approximately 10 days before planting the rotational crops and incorporated back into the soil. Carrot, spinach, barley and oilseed rape were sown as succeeding crops 30, 60, 180 and 365 PBIs.

In both studies, residues of sedaxane (sum of isomers) and metabolites CSCD659089, CSCD668403, CSCD659087 and CSAA798670 were below the LOQ of 0.01 mg/kg in all the parts of the succeeding crops tested. Residues of metabolite CSCD465008 were below the LOQ in all crop parts, except in carrot leaves sampled at 60 PBI (0.02 mg/kg) in the seed treatment study. Therefore, it can be concluded that sowing/planting of succeeding crops after one seasonal application would not lead to a significant uptake of sedaxane.

Nonetheless, given the high persistence of sedaxane (DT_{90} 1,454 days), the potential occurrence of residues following multiannual applications should also be taken into account. Since residue levels measured in the tested soil were not reported in the available studies, the soil concentration after bare soil application at 30 g a.s/ha (highest application rate tested) was calculated assuming a soil mixing (incorporation) depth of 20 cm and soil bulk density of 1.5 g/cm^3. According to this calculation, the soil concentration from the rotational crop study would be 0.01 mg/kg, which is lower than the calculated plateau of 0.0178 mg/kg soil. Hence, the available rotational crops studies do not cover the multiannual applications of sedaxane.

Consequently, following multiannual applications of sedaxane according to the most critical GAP currently authorised, a possible uptake by crops grown in rotation cannot be excluded. Pending on the submission of field rotational crop studies covering the plateau concentration calculated in this review, Member States granting authorisations for sedaxane should take the appropriate risk mitigation measures (e.g. lowering the application rate for cereals to 17 g a.s/ha, also achievable by reducing the seeding grade, expected to be covered by the rotational field study available) in order to avoid the significant presence of sedaxane and its metabolites in rotational crops.

1.2.3. Magnitude of residues in processed commodities

The effect of industrial processing and/or household preparation was assessed on one study conducted on barley for processing into pot barley and barley flour and bran (France, 2012; EFSA, 2013). No residues of the *trans*- and *cis*-isomers above the LOQ of 0.005 mg/kg (for each isomer) were detected in the raw or the processed commodities. Consequently, processing factors could not be calculated. Further processing studies are not required as they are not expected to affect the outcome of the risk assessment.

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. Tentative MRLs were also derived for feed crops (barley, oat, rye and wheat straw, maize/corn stover and sugar beet tops) in view of the future need to set MRLs in feed items. MRLs for rotational crops are not necessary, provided that appropriate risk mitigation measures are taken by Member States when granting national authorisations.

2. Residues in livestock

Sedaxane is authorised for use on cereals and sugar beet tops 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.

It is highlighted that the calculation did not consider residues from rotational crops, as it is assumed that risk mitigation measures will be taken by Member States when granting national authorisations.

Although not required, the metabolism of sedaxane residues in livestock was investigated in lactating goats (0.57 mg/kg body weight (bw) per day) and laying hens (0.82 mg/kg bw per day) at dose rate covering the maximum dietary burdens calculated in this review (300N and 800N for cattle and poultry, respectively) (France, 2012). These studies were assessed in the framework of the peer review (EFSA, 2013). In all the studies, sedaxane was radiolabelled in the phenyl or pyrazole rings of the molecule. In both poultry and goat, the majority of the dosed radioactivity was excreted and residues in tissues, milk and eggs were low. In both species, the highest residues were observed in liver (with TRR of 0.26 mg/kg in hen and 0.61 mg/kg in goat). Residues in muscle and fat were found to be < 0.006 mg/kg and < 0.016, respectively. Regarding egg yolk and white, residues amounted for up to 0.08 and 0.009 mg/kg, respectively, and the plateau was reached after 9 days. Finally, residues represented < 0.19 mg/kg in goat kidney, while in milk they were found to be < 0.045 mg/kg (the plateau was reached after 2 days).

The parent sedaxane was detected mainly in fat (53% TRR, 0.007 mg/kg in hen; 28% TRR, 0.004 mg/kg in goat). In hen, it was also found in egg and muscle, representing up to 12% TRR, but with low concentrations (< 0.002 mg/kg). With respect to goat, parent sedaxane was also present in liver (5.5% TRR, 0.034 mg/kg).

Considering the results of the metabolism studies on ruminants and poultry, and that the biotransformation pathway of sedaxane in ruminants was very similar to that observed in the rat, a general residue definition for monitoring and risk assessment in livestock was suggested as sedaxane (sum of isomers), in the peer review (EFSA, 2013). However, particular attention should be paid to metabolites CSCD658906 and CSCD659087, since they were recovered in high proportion in liver (37% TRR), kidney (44% TRR), egg yolk (32% TRR) and milk (19%), if additional uses involving feed items are proposed in the future. A feeding study with dairy cows was reported in the DAR (France, 2011) and can be considered in future for MRL setting.

A multi-residue QuEChERS method using high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) with a LOQ of 0.01 mg/kg for the sum of isomers in milk, eggs and tissues was considered acceptable in the EFSA conclusion (EFSA, 2013). An analytical method for the determination of the metabolites CSCD658906 and CSCD659087 with LOQ = 0.01 mg/kg was sufficiently validated and reported in the DAR (France, 2011).

3. Consumer risk assessment

In the framework of this review, only the uses of sedaxane reported by the RMS in Appendix A were considered; however, the use of sedaxane was previously also assessed by the JMPR (FAO, 2012, 2014). The CXLs, resulting from these assessments 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 and acute exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA PRIMo (EFSA, 2007). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where a 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.

The exposure values calculated were compared with the toxicological reference values for sedaxane, derived by EFSA (2013). The highest chronic exposure was calculated for UK toddler, representing 0.2% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for sweet corn representing 0.2% of the acute reference dose (ARfD). These calculations indicate that the uses assessed under this review result in a consumer exposure lower than the toxicological reference values. Therefore, these uses are unlikely to pose a risk to consumer's health.

It should be underlined that the calculation does not consider residues in rotational crops, as it is assumed that risk mitigation measures will be taken by Member States when granting national authorisations.

EFSA also emphasises that the above assessment does not consider the possible impact of plant metabolism on the isomer ratio of sedaxane and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, this issue might be reconsidered when such guidance is available. EFSA notes that in view of the large margin of safety in the exposure calculations, the potential change of isomer ratios in the final residues is not expected to be of concern for the authorised uses reported in the framework of this review. In case future uses of sedaxane would lead to a higher consumer exposure, further information regarding the impact of plant and/or livestock metabolism on the isomer ratio might be required.

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.

Chronic and acute exposure calculations were also performed using revision 2 of the EFSA PRIMo and the exposure values calculated were compared with the toxicological reference values derived for sedaxane. The highest chronic exposure was calculated for UK toddler representing 0.3% of the ADI, and the highest acute exposure was calculated for potatoes, representing 1.0% of the ARfD. Based on these calculations, EFSA concludes that the CXLs are not expected to be of concern for European consumers.

Conclusions

The metabolism of sedaxane in plant was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement and risk assessment in plant commodities can be proposed as sedaxane (sum of isomers). This residue definition is restricted to seed and soil treatments only and it is also applicable to rotational crops and processed commodities. Validated analytical methods are available for the enforcement of the proposed residue definition in the four main matrices at the LOQ of 0.01 mg/kg. According to the EURL, the same LOQ of 0.01 mg/kg is achievable in high water, high acid and high oil content commodities, while a LOQ of 0.005 mg/kg is achievable in dry commodities in routine analyses.

The available residue trials data were considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation. MRLs on rotational crops are not necessary, provided that appropriate risk mitigation measures will be taken by Member States when granting national authorisations.

Sedaxane is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to the pertinent OECD guidance. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM, further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary, when considering the authorised uses in the EU. Although not required, the metabolism of sedaxane residues in livestock was investigated in lactating goats and laying hens. According to the results of these studies, a general residue definition for monitoring and risk assessment in livestock was suggested as sedaxane (sum of isomers) in the peer review. Analytical methods with a LOQ of 0.01 mg/kg for the sum of isomers in milk, eggs and tissues were considered acceptable in the EFSA conclusion (EFSA, 2013).

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. The highest chronic

exposure represented 0.2% the ADI (UK toddler) and the highest acute exposure amounted to 0.2% of the ARfD (sweet corn). These calculations indicate that the uses assessed under this review result in a consumer exposure lower than the toxicological reference values, and thus are unlikely to pose a risk to consumer's health.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for sedaxane. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out. The highest chronic exposure represented 0.3% of the ADI (UK toddler), and the highest acute exposure amounted to 1% of the ARfD (potatoes).

EFSA also emphasises that the above assessment does not consider the possible impact of plant metabolism on the isomer ratio of sedaxane and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, this issue might be reconsidered when such guidance is available. EFSA notes that in view of the large margin of safety in the exposure calculations, the potential change of isomer ratios in the final residues is not expected to be of concern for the authorised uses reported in the framework of this review. In case future uses of sedaxane would lead to a higher consumer exposure, further information regarding the impact of plant and/or livestock metabolism on the isomer ratio might be required.

Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 2). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation.

Following the review, EFSA identified the following data gap which is not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- Representative field rotational crops studies covering the most critical GAPs on wheat, barley, maize and rye considered in this review and the plateau concentration calculated in soil.

Pending on the submission of the required field rotational crop studies, Member States granting authorisations for sedaxane should take the appropriate risk mitigation measures (e.g. lowering the application rate to 17 g a.s/ha, also achievable by reducing the seeding grade, expected to be covered by the rotational field study available) in order to avoid the significant presence of sedaxane and its metabolites in rotational crops.

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

- ILV for dry commodities.

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 (existing): sedaxane **Enforcement residue definition (proposed):** sedaxane (sum of isomers)					
211000	Potatoes	0.02	0.02	0.02	Recommended[(a)]
234000	Sweet corn	0.01*	0.01*	0.01*	Recommended[(b)]
300010	Beans (dry)	0.01*	0.01*	0.01*	Recommended[(a)]
300020	Lentils (dry)	0.01*	0.01*	0.01*	Recommended[(a)]
300030	Peas (dry)	0.01*	0.01*	0.01*	Recommended[(a)]
300040	Lupins (dry)	0.01*	0.01*	0.01*	Recommended[(a)]
401060	Rape seed	0.01*	0.01*	0.01*	Recommended[(a)]
401070	Soya bean	0.01*	0.01*	0.01*	Recommended[(a)]
500010	Barley grain	0.01*	0.01*	0.01*	Recommended[(b)]
500020	Buckwheat grain	0.01*	0.01*	0.01*	Recommended[(a)]
500030	Maize grain	0.01*	0.01*	0.01*	Recommended[(b)]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
500040	Millet grain	0.01*	0.01*	0.01*	Recommended[(a)]
500050	Oats grain	0.01*	0.01*	0.01*	Recommended[(b)]
500060	Rice grain	0.01*	0.01*	0.01*	Recommended[(a)]
500070	Rye grain	0.01*	0.01*	0.01*	Recommended[(b)]
500080	Sorghum grain	0.01*	0.01*	0.01*	Recommended[(a)]
500090	Wheat grain	0.01*	0.01*	0.01*	Recommended[(b)]
900010	Sugar beet (root)	0.01*	0.01*	0.01*	Recommended[(b)]
1011010	Swine meat	0.01*	0.01*	0.01*	Recommended[(a)]
1011020	Swine fat	0.01*	0.01*	0.01*	Recommended[(a)]
1011030	Swine liver	0.01*	0.01*	0.01*	Recommended [(a)]
1011040	Swine kidney	0.01*	0.01*	0.01*	Recommended[(a)]
1012010	Bovine meat	0.01*	0.01*	0.01*	Recommended[(a)]
1012020	Bovine fat	0.01*	0.01*	0.01*	Recommended[(a)]
1012030	Bovine liver	0.01*	0.01*	0.01*	Recommended[(a)]
1012040	Bovine kidney	0.01*	0.01*	0.01*	Recommended[(a)]
1013010	Sheep meat	0.01*	0.01*	0.01*	Recommended[(a)]
1013020	Sheep fat	0.01*	0.01*	0.01*	Recommended[(a)]
1013030	Sheep liver	0.01*	0.01*	0.01*	Recommended[(a)]
1013040	Sheep kidney	0.01*	0.01*	0.01*	Recommended[(a)]
1014010	Goat meat	0.01*	0.01*	0.01*	Recommended[(a)]
1014020	Goat fat	0.01*	0.01*	0.01*	Recommended[(a)]
1014030	Goat liver	0.01*	0.01*	0.01*	Recommended[(a)]
1014040	Goat kidney	0.01*	0.01*	0.01*	Recommended[(a)]
1015010	Equine meat	0.01*	0.01*	0.01*	Recommended[(a)]
1015020	Equine fat	0.01*	0.01*	0.01*	Recommended[(a)]
1015030	Equine liver	0.01*	0.01*	0.01*	Recommended[(a)]
1015040	Equine kidney	0.01*	0.01*	0.01*	Recommended[(a)]
1016010	Poultry meat	0.01*	0.01*	0.01*	Recommended[(a)]
1016020	Poultry fat	0.01*	0.01*	0.01*	Recommended[(a)]
1016030	Poultry liver	0.01*	0.01*	0.01*	Recommended[(a)]
1016040	Poultry kidney	0.01*	0.01*	0.01*	Recommended[(a)]
1020010	Cattle milk	0.01*	0.01*	0.01*	Recommended[(a)]
1020020	Sheep milk	0.01*	0.01*	0.01*	Recommended[(a)]
1020030	Goat milk	0.01*	0.01*	0.01*	Recommended[(a)]
1020040	Horse milk	0.01*	0.01*	0.01*	Recommended[(a)]
1030000	Birds' eggs	0.01*	0.01*	0.01*	Recommended[(a)]
–	Other commodities of plant and/or animal origin	See Reg. 2016/567	–	–	Further consideration needed[(c)]

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(a): MRL is derived from 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).
(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination G-III in Appendix E).
(c): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).

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Abbreviations

a.i.	active ingredient
a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DB	dietary burden
DM	dry matter
DT_{90}	period required for 90% dissipation (define method of estimation)
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EURLs	European Union Reference Laboratories for Pesticide Residues (former CRLs)
FAO	Food and Agriculture Organization of the United Nations
FS	flowable concentrate for seed treatment
GAP	Good Agricultural Practice
HPLC	high-performance liquid chromatography
HPLC-MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
InChiKey	International Chemical Identifier Key
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)
LC–MS/MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
Mo	monitoring
MRL	maximum residue level
MRM	multiple reaction monitoring
MS	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEDI	national estimated daily intake
NESTI	national estimated short-term intake
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
R_{ber}	statistical calculation of the MRL by using a non-parametric method
RA	risk assessment
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
SRM	selected reaction monitoring
STMR	supervised trials median residue
TGW	Thousand Grain Weight
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. Authorised outdoor uses in northern EU

Crop and/or situation	MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Barley	AT, CZ, FR	F	*Ustilago hordei*, *Pyreophora graminea*	FS	50 g/L	Seed treatment – general (see also comment field)	0	1 to 1		–	–	10 g a.i./100 kg	n.a.	15 mL product/unit (1 unit = 50 000 seeds) Maximum sowing density: 140'000 seeds/ha representing 21 g a.s./ha
Maize	AT, BE, FR	F	*Sphacelotheca reiliana*, Smut, Black Scurf *Rhizoctonia solani*	FS	500 g/L	Seed treatment – general (see also comment field)	0	1 to 1		–	–	75 g a.i./100 kg	n.a.	15 mL product/unit (1 unit = 50 000 seeds) Maximum sowing density: 140'000 seeds/ha Representing 21 g a.s./ha
Oat	FR	F	*Ustilago avenae*	FS	50 g/L	Seed treatment – general (see also comment field)	0	1 to 1		–	–	10 g a.i./100 kg	n.a.	0.2 L product/100 kg seedsAssuming maximum sowing rate of 170 kg seeds/ha: 17 g a.s./ha
Rye	AT, CZ, FR	F	*Microdochium nivale*, *Urocystis occulta*	FS	50 g/L	Seed treatment – general (see also comment field)	0	1 to 1		–	–	10 g a.i./100 kg	n.a.	0.2 L product/100 kg seeds (20 g a.s./ha) Assuming maximum sowing rate of 200 kg seeds/ha: 20 g 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 & season[c]	Number min–max	Interval between application (min)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Wheat	AT, CZ, FR	F	*Microdochium nivale*, *Fusarium culmorum*, *Rhizoctonia cerealis*, *Tilletia caries*, *Tilletia controversa*, *Ustilago tritici*, *Septoria nodorum*	FS	50 g/L	Seed treatment – general (see also comment field)	0	1 to 1		–	–	10 g a.i./100 kg	n.a.	0.2 L product/100 kg seeds Assuming maximum sowing rate of 250 kg seeds/ha: 25 g a.s./ha For spelt and triticale, this sowing rate is lower (200 kg seeds/ha: 20 g a.s./ha)
Sugar beets	SE, NL	F	Dumping-off diseases (*Pythium ultimum*, *Pleospora betae*/*P. betae*, *Thanatephorus cucumeris*/*Rhizoctonia solani*)	FS	15 g/L	Seed treatment – general (see also comment field)	0	1 to 1		–	–	27 g a.i./100 kg	n.a.	Seed unit: 100.000 seeds Seedling rate: 1 – 1.3 seed unit/ha TGW: 24-33 g/1,000 seeds Slurry volume: 8-20 L/100 kg seeds Max. 43.3 mL product/ha representing 0.7 g a.s./ha

MRL: maximum residue level; MS: Member State; TGW: Thousand Grain Weight; a.i.: active ingredient; a.s.: active substance; n.a.: not applicable; FS: flowable concentrate for seed treatment.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.

A.2. Authorised outdoor uses in southern EU

Crop and/or situation	MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Sweet corn	FR	F	*Sphacelotheca reiliana*, Smut, Black Scurf *Rhizoctonia solani*	FS	500 g/L	Seed treatment – general (see also comment field)	0	1 to 1		–	–	100 g a.i./100 kg	n.a.	100 g a.s./100 kg seeds corresponds to 16.5 g a.s./ha considering the TGW of 150 g and a sowing density of 110.000 seeds/ha
Barley	FR, IT	F	*Ustilago hordei*, *Pyrenophora gramins*	FS	50 g/L	Seed treatment – general (see also comment field)	0	1 to 1		–	–	10 g a.i./100 kg	n.a.	0.2 L product/100 kg seeds Assuming maximum sowing rate of 200 kg seeds/ha: 20 g a.s./ha
Maize	FR	F	*Sphacelotheca reiliana*, Smut, Black Scurf *Rhizoctonia solani*	FS	500 g/L	Seed treatment – general (see also comment field)	0	1 to 1		–	–	75 g a.i./100 kg	n.a.	15 mL product/unit (1 unit = 50,000 seeds) Maximum sowing density: 140'000 seeds/ha
Oat	FR	F	*Ustilago avenae*, *Fusarium* sp., *Microdochium nivale*	FS	50 g/L	Seed treatment – general (see also comment field)	0	1 to 1		–	–	10 g a.i./100 kg	n.a.	0.2 L product/100 kg seeds Assuming maximum sowing rate of 170 kg seeds/ha: 17 g a.s./ha
Rye	IT	F	*Microdochium nivale*, *Urocystis occulta*	FS	50 g/L	Seed treatment – general (see also comment field)	0	1 to 1		–	–	10 g a.i./100 kg	n.a.	10 g a.s./100 kg seeds corresponds to 20 g a.s./ha considering a seeding rate of 200 kg seeds/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 & season[c]	Number min–max	Interval between application (min)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Wheat	FR, IT	F	*Microdochium nivale*, *Fusarium culmorum*, *Rhizoctonia cerealis*, *Tilletia caries*, *Tilletia controversa*, *Ustilago tritici*	FS	50 g/L	Seed treatment – general (see also comment field)	0	1 to 1		–	–	10 g a.i./100 kg	n.a.	0,2 L product/100 kg seeds (25 g a.s./ha) Assuming maximum sowing rate of 250 kg seeds/ha: 25 g a.s./ha For spelt and triticale, this sowing rate is lower (200 kg seeds/ha: 20 g a.s./ha)

MS: Member State; TGW: Thousand Grain Weight; a.i.: active ingredient; a.s.: active substance; n.a.: not applicable; FS: flowable concentrate for seed treatment.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

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

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

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling (BBCH)**	**Comment/ source**
	Leafy crops	Swiss chard	Seed treatment: 1 × 40 g a.s./100 kg seed	14–15 (whole plant)	[phenyl-U-^{14}C]- and [pyrazole-5-^{14}C]-labelled sedaxane (EFSA, 2013)
	Cereals/grass	Wheat	Seed treatment: 1 × 40 g a.s./100 kg seed	22 (forage)	
				41 (hay)	
				89 (grain and straw)	
	Pulses/oilseeds	Soybean	Seed treatment: 1 × 110 g a.s./100 kg seed	16 (forage)	
				61 (hay)	
				Maturity (seeds)	
		Canola	Seed treatment: 1 × 9.7 g a.s./100 kg seed	85–89 (seeds)	

Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/ source**
	Root/tuber crops	Radish	Soybeans as seed treatment: 1 × 100 g a.s./ha	30, 120, 365	[phenyl-U-^{14}C]- and [pyrazole-5-^{14}C]-labelled sedaxane (EFSA, 2013)
		Turnip	Bare soil: 1 × 100 g a.s./ha	29, 90, 300	
	Leafy crops	Lettuce	Soybeans as seed treatment: 1 × 100 g a.s./ha	30, 151, 365	
			Bare soil: 1 × 100 g a.s./ha	29, 90, 300	
	Cereal (small grain)	Wheat	Soybeans as seed treatment: 1 × 100 g a.s./ha	30, 120, 365	
			Bare soil: 1 × 100 g a.s./ha	29, 90, 300	

Processed commodities (hydrolysis study)	**Conditions**	**Stable?**	**Comment/source**
	Pasteurisation (20 min, 90°C, pH 4)	Yes	[phenyl-U-^{14}C]- and [pyrazole-5-^{14}C]-labelled sedaxane (EFSA, 2013)
	Baking, brewing and boiling (60 min, 100°C, pH 5)	Yes	
	Sterilisation (20 min, 120°C, pH 6)	Yes	

Can a general residue definition be proposed for primary crops?	Yes	
Rotational crop and primary crop metabolism similar?	Yes	

Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	
Plant residue definition for monitoring (RD-Mo)	Sedaxane (sum of isomers) (restricted to seed and soil treatments)	
Plant residue definition for risk assessment (RD-RA)	Sedaxane (sum of isomers) (restricted to seed and soil treatments)	
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)	High water, high acid and high oil content commodities and dry commodities (EFSA, 2013): • QuEChERS (HPLC–MS/MS) • LOQ = 0.01 mg/kg for the sum of isomers • Confirmation by monitoring one additional MRM transition • ILV available only for high water content commodities and wheat straw • QuEChERS (high water, high acid and dry commodities) and QuOil (high oil commodities) for enforcement in routine analysis, LOQ = 0.01 mg/kg (high water, high acid and high oil content commodities) and 0.005 mg/kg (dry commodities) (EURL, 2018)	

a.s.: active substance; BBCH: growth stages of mono- and dicotyledonous plants;DAT: days after treatment; PBI: plant-back interval; HPLC–MS/MS:high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method); 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	Spinach and potato	−18	24	Months	Sedaxane: *trans* (SYN508210) and *cis* (SYN508211) isomers	EFSA (2013)
	High oil content	Soybean	−18	24	Months	Sedaxane: *trans* (SYN508210) and *cis* (SYN508211) isomers	EFSA (2013)
	High protein content	Lentil	−18	24	Months	Sedaxane: *trans* (SYN508210) and *cis* (SYN508211) isomers	EFSA (2013)
	High starch content	Wheat grain	−18	24	Months	Sedaxane: *trans* (SYN508210) and *cis* (SYN508211) isomers	EFSA (2013)
	High acid content	Oranges	−18	24	Months	Sedaxane: *trans* (SYN508210) and *cis* (SYN508211) isomers	EFSA (2013)
	Processed products	Wheat (flour, germ, bran)	−18	12	Months	Sedaxane: *trans* (SYN508210) and *cis* (SYN508211) isomers	EFSA (2013)
		Soybean (meal, hulls, oil)	−18	12	Months		
		Orange (pulp, juice, oil)	−18	12	Months		
	Others	Wheat straw	−18	24	Months	Sedaxane: *trans* (SYN508210) and *cis* (SYN508211) isomers	EFSA (2013)

B.1.2. Magnitude of residues in plants

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

Commodity	Region/ indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)
Sweet corn	SEU	9 × < 0.01	Residue data on immature maize (BBCH 63). Trials performed according to a less critical GAP but considered acceptable according to a translocation study in maize (France 2011) and a no-residue situation expected (France, 2018)	0.01*	< 0.01	< 0.01
Maize/corn grains	NEU	10 × < 0.01	Underdosed trials on maize (France, 2018) deemed acceptable according to translocation study on maize (France, 2011)	0.01*	< 0.01	< 0.01
	SEU	9 × < 0.01	Trials on maize performed with dose rates within 25% deviation (France, 2018)	0.01*	< 0.01	< 0.01
Maize/corn stover	NEU	4 × < 0.01	Trials on maize performed with dose rates within 25% deviation (France, 2018)	0.01*[d] (tentative)	< 0.01	< 0.01
	SEU	9 × < 0.01	Trials on maize performed with dose rates within 25% deviation (France, 2018)	0.01*[d] (tentative)	< 0.01	< 0.01
Wheat, barley, oat, rye and triticale grains	NEU	13 × < 0.01	Trials on wheat grain performed with dose rates within 25% deviation (France, 2012; EFSA, 2013). Extrapolation to barley, oat, rye and triticale grain is applicable	0.01*	< 0.01	< 0.01
	SEU	10 × < 0.01	Trials on wheat grain performed with dose rates within 25% deviation (France, 2012; EFSA, 2013). Extrapolation to barley, oat, rye and triticale grain is applicable	0.01*	< 0.01	< 0.01
Wheat, barley, oat, rye and triticale straw	NEU	13 × < 0.01	Trials on wheat straw performed with dose rates within 25% deviation (France, 2012; EFSA, 2013). Extrapolation to barley, oat, rye and triticale straw is applicable	0.01*[d] (tentative)	< 0.01	< 0.01
	SEU	8 × < 0.01; 0.011; 0.012	Trials on wheat straw performed with dose rates within 25% deviation (France, 2012; EFSA, 2013). Extrapolation to barley, oat, rye and triticale straw is applicableR_{ber} = 0.02MRL_{OECD} = 0.01	0.02[d] (tentative)	0.01	0.01

Commodity	Region/ indoor[(a)]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/source	Calculated MRL (mg/kg)	HR[(b)] (mg/kg)	STMR[(c)] (mg/kg)
Sugar beet roots	NEU	4 × < 0.01	Trials on sugar beet roots performed with dose rates within 25% deviation (France, 2018). Reduced number of trials deemed acceptable since residues < LOQ	0.01*	< 0.01	< 0.01
Sugar beet tops	NEU	4 × < 0.01	Trials on sugar beet tops performed with dose rates within 25% deviation (France, 2018). Reduced number of trials deemed acceptable since residues < LOQ	0.01*[(d)] (tentative)	< 0.01	< 0.01

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level; R_{ber}: statistical calculation of the MRL by using a non-parametric method.
*: Indicates that the MRL is proposed at the limit of quantification.
Mo: residue levels expressed according to the monitoring residue definition; RA: residue levels expressed according to risk assessment residue definition.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.
(d): Tentative MRLs are derived for feed commodities in view of the future need to set MRLs in these commodities.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Yes	In the available confined rotational crop study performed following seed treatment at 4N the maximum application rate assessed in this review, the predominant metabolites detected in all parts of the crops were CSCD465008 and CSAA798670 (TRR: 11–72%). Since these metabolites are major soil metabolites, it is expected that a potential uptake from the soil might occur (EFSA, 2013)
Residues in rotational and succeeding crops expected based on field rotational crop study?	Inconclusive	No residues above the LOQ of 0.01 mg/kg were found in rotational crops following application of sedaxane at 1 × 30 g a.s./ha (1.2N, bare soil) or 1 × 25 g a.s./ha (1N, seed treatment). Nevertheless, this study does not cover the multiannual application of sedaxane, and consequently, a possible uptake by crops grown in rotation cannot be excluded

TRR: total radioactive residue; LOQ: limit of quantification; a.s.: active substance.

B.1.2.3. Processing factors

Processing factors could not be calculated as no residues were observed above the LOQ of 0.01 mg/kg in any preprocessing and processed samples. Further studies are not required.

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)	0.0017	0.0017	0.04	0.04	Cattle (dairy)	Beet, sugar, ensiled pulp	No	–
Cattle (dairy only)	0.0017	0.0017	0.04	0.04	Cattle (dairy)	Beet, sugar, ensiled pulp	No	–
Sheep (all)	0.0009	0.0009	0.02	0.02	Sheep (lamb)	Beet, sugar, tops	No	–
Sheep (ewe only)	0.0007	0.0007	0.02	0.02	Sheep (ram/ewe)	Beet, sugar, tops	No	–
Swine (all)	0.0003	0.0003	0.01	0.01	Swine (finishing)	Corn, field, milled by-products	No	–
Poultry (all)	0.0009	0.0009	0.01	0.01	Poultry (layer)	Beet, sugar, tops	No	–
Poultry (layer only)	0.0009	0.0009	0.01	0.01	Poultry (layer)	Beet, sugar, tops	No	–

bw: body weight; DM: dry matter.
(a): When one group of livestock includes several subgroups (e.g. poultry 'all' including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

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

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

Livestock (available studies)	Animal	Dose (mg/kg bw per day)	Duration (days)	Comment/source
	Laying hen	0.82	14	800N compared to the maximum dietary burden calculated for poultry (broiler and all diets). Phenyl-U-^{14}C- or pyrazole-5-^{14}C-sedaxane (EFSA, 2013)
	Lactating ruminants	0.57	7	300N compared to the maximum dietary burden calculated for cattle (dairy and all diets). Phenyl-U-^{14}C- or pyrazole-5-^{14}C-sedaxane (EFSA, 2013)

Time needed to reach a plateau concentration in milk and eggs (days)	Milk	2 days
	Eggs	9 days
Metabolism in rat and ruminant similar	Yes	
Can a general residue definition be proposed for animals?	Yes	
Animal residue definition for monitoring (RD-Mo)	Sedaxane (sum of isomers)	
Animal residue definition for risk assessment (RD-RA)	Sedaxane (sum of isomers)	
Fat soluble residues	No	
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)	Milk, eggs, muscle, fat, liver and kidney (EFSA, 2013): • QuEChERS (HPLC–MS/MS) • LOQ = 0.01 mg/kg for the sum of isomers • Confirmation by monitoring 1 additional MRM transition • ILV available for milk, liver and eggs • No validation data within EURLs (EURL, 2018)	

bw: body weight; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective,Rugged, and Safe (analytical method); LOQ: limit of quantification; 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	All tissues	–	–	–	–	Not available and not required
	Bovine	Milk	–	–	–	–	Not available and not required
	Poultry	Eggs	–	–	–	–	Not available and not required

B.2.2. Magnitude of residues in livestock

MRLs in livestock are not triggered according to the dietary burden calculation.

B.3. Consumer risk assessment

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

ARfD	0.3 mg/kg bw (EFSA, 2013)
Highest IESTI, according to EFSA PRIMo (rev.2)	Sweet corn: 0.2% of ARfD
NESTI (% ARfD)	Not assessed in this review
Assumptions made for the calculations	The calculation is based on the highest residue levels expected in raw agricultural commodities

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

ADI	0.11 mg/kg bw per day (EFSA, 2013)
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.2)	0.2% ADI (UK 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. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation

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

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

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

ADI: acceptable daily intake; bw: body weight.

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

ARfD	0.3 mg/kg bw (EFSA, 2013)
Highest IESTI, according to EFSA PRIMo (rev.2)	Potatoes: 1% of ARfD
NESTI (% ARfD)	Not assessed in this review.
Assumptions made for the calculations	For those commodities having a CXL higher than the EU MRL proposal, the highest residue levels applied in the EU scenario were replaced by the highest residue levels derived by JMPR.

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

ADI	0.11 mg/kg bw per day (EFSA, 2013)
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.2)	0.3% ADI (UK toddler)
NEDI (% ADI)	Not assessed in this review.
Assumptions made for the calculations	For those commodities having a CXL higher than the EU MRL proposal, the median residue levels applied in the EU scenario were replaced by the median residue levels derived by JMPR.

ADI: acceptable daily intake; bw: body weight; NEDI: national estimated daily intake; PRIMo:(EFSA) Pesticide Residues Intake Model; TMDI: theoretical maximum daily intake; NTMDI: national theoretical maximum daily intake.

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 (existing): Sedaxane **Enforcement residue definition (proposed):** Sedaxane (sum of isomers)					
211000	Potatoes	0.02	0.02	0.02	Recommended[a]
234000	Sweet corn	0.01*	0.01*	0.01*	Recommended[b]
300010	Beans (dry)	0.01*	0.01*	0.01*	Recommended[a]
300020	Lentils (dry)	0.01*	0.01*	0.01*	Recommended[a]
300030	Peas (dry)	0.01*	0.01*	0.01*	Recommended[a]
300040	Lupins (dry)	0.01*	0.01*	0.01*	Recommended[a]
401060	Rape seed	0.01*	0.01*	0.01*	Recommended[a]
401070	Soya bean	0.01*	0.01*	0.01*	Recommended[a]
500010	Barley grain	0.01*	0.01*	0.01*	Recommended[b]
500020	Buckwheat grain	0.01*	0.01*	0.01*	Recommended[a]
500030	Maize grain	0.01*	0.01*	0.01*	Recommended[b]
500040	Millet grain	0.01*	0.01*	0.01*	Recommended[a]
500050	Oats grain	0.01*	0.01*	0.01*	Recommended[b]
500060	Rice grain	0.01*	0.01*	0.01*	Recommended[a]
500070	Rye grain	0.01*	0.01*	0.01*	Recommended[b]
500080	Sorghum grain	0.01*	0.01*	0.01*	Recommended[a]
500090	Wheat grain	0.01*	0.01*	0.01*	Recommended[b]
900010	Sugar beet (root)	0.01*	0.01*	0.01*	Recommended[b]
1011010	Swine meat	0.01*	0.01*	0.01*	Recommended[a]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
1011020	Swine fat	0.01*	0.01*	0.01*	Recommended[(a)]
1011030	Swine liver	0.01*	0.01*	0.01*	Recommended[(a)]
1011040	Swine kidney	0.01*	0.01*	0.01*	Recommended[(a)]
1012010	Bovine meat	0.01*	0.01*	0.01*	Recommended[(a)]
1012020	Bovine fat	0.01*	0.01*	0.01*	Recommended[(a)]
1012030	Bovine liver	0.01*	0.01*	0.01*	Recommended[(a)]
1012040	Bovine kidney	0.01*	0.01*	0.01*	Recommended[(a)]
1013010	Sheep meat	0.01*	0.01*	0.01*	Recommended[(a)]
1013020	Sheep fat	0.01*	0.01*	0.01*	Recommended[(a)]
1013030	Sheep liver	0.01*	0.01*	0.01*	Recommended[(a)]
1013040	Sheep kidney	0.01*	0.01*	0.01*	Recommended[(a)]
1014010	Goat meat	0.01*	0.01*	0.01*	Recommended[(a)]
1014020	Goat fat	0.01*	0.01*	0.01*	Recommended[(a)]
1014030	Goat liver	0.01*	0.01*	0.01*	Recommended[(a)]
1014040	Goat kidney	0.01*	0.01*	0.01*	Recommended[(a)]
1015010	Equine meat	0.01*	0.01*	0.01*	Recommended[(a)]
1015020	Equine fat	0.01*	0.01*	0.01*	Recommended[(a)]
1015030	Equine liver	0.01*	0.01*	0.01*	Recommended[(a)]
1015040	Equine kidney	0.01*	0.01*	0.01*	Recommended[(a)]
1016010	Poultry meat	0.01*	0.01*	0.01*	Recommended[(a)]
1016020	Poultry fat	0.01*	0.01*	0.01*	Recommended[(a)]
1016030	Poultry liver	0.01*	0.01*	0.01*	Recommended[(a)]
1016040	Poultry kidney	0.01*	0.01*	0.01*	Recommended[(a)]
1020010	Cattle milk	0.01*	0.01*	0.01*	Recommended[(a)]
1020020	Sheep milk	0.01*	0.01*	0.01*	Recommended[(a)]
1020030	Goat milk	0.01*	0.01*	0.01*	Recommended[(a)]
1020040	Horse milk	0.01*	0.01*	0.01*	Recommended[(a)]
1030000	Birds' eggs	0.01*	0.01*	0.01*	Recommended[(a)]
–	Other commodities of plant and/or animal origin	See Reg. 2016/567	–	–	Further consideration needed[(c)]

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(a): MRL is derived from 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).
(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination G-III in Appendix E).
(c): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).

Appendix C – Pesticide Residue Intake Model (PRIMo)

- PRIMo (CXL)

Sedaxane			
Status of the active substance:	**Approved**	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.11**	ARfD (mg/kg bw):	**0.3**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2013**	Year of evaluation:	**2013**

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI
minimum – maximum

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
0.3	UK Toddler	0.2	Sugar beet (root)	0.0	Wheat	0.0	Potatoes	
0.2	WHO Cluster diet B	0.1	Wheat	0.0	Potatoes	0.0	Maize	
0.2	UK Infant	0.1	Sugar beet (root)	0.0	Potatoes	0.0	Wheat	
0.1	NL child	0.1	Potatoes	0.0	Wheat	0.0	Swine: Meat	
0.1	WHO cluster diet D	0.1	Wheat	0.0	Potatoes	0.0	Bovine: Meat	
0.1	WHO cluster diet E	0.0	Wheat	0.0	Potatoes	0.0	Poultry: Meat	
0.1	DK child	0.1	Wheat	0.0	Rye	0.0	Potatoes	
0.1	WHO Cluster diet F	0.0	Wheat	0.0	Potatoes	0.0	Swine: Meat	
0.1	WHO regional European diet	0.0	Potatoes	0.0	Wheat	0.0	Swine: Meat	
0.1	ES child	0.0	Wheat	0.0	Potatoes	0.0	Bovine: Meat	
0.1	IE adult	0.0	Maize	0.0	Maize	0.0	Potatoes	
0.1	PT General population	0.0	Potatoes	0.0	Wheat	0.0	Rice	
0.1	FR toddler	0.0	Potatoes	0.0	Wheat	0.0	Bovine: Meat	
0.1	DE child	0.0	Wheat	0.0	Potatoes	0.0	Rye	
0.1	IT kids/toddler	0.1	Wheat	0.0	Other cereal	0.0	Potatoes	
0.1	UK vegetarian	0.0	Sugar beet (root)	0.0	Wheat	0.0	Potatoes	
0.1	SE general population 90th percentile	0.0	Potatoes	0.0	Wheat	0.0	Rice	
0.1	UK Adult	0.0	Sugar beet (root)	0.0	Wheat	0.0	Potatoes	
0.1	NL general	0.0	Potatoes	0.0	Wheat	0.0	Swine: Meat	
0.1	LT adult	0.0	Potatoes	0.0	Rye	0.0	Wheat	
0.1	ES adult	0.0	Wheat	0.0	Potatoes	0.0	Bovine: Meat	
0.1	FR infant	0.0	Potatoes	0.0	Wheat	0.0	Bovine: Meat	
0.1	FR all population	0.0	Wheat	0.0	Potatoes	0.0	Poultry: Meat	
0.1	IT adult	0.0	Wheat	0.0	Other cereal	0.0	Potatoes	
0.0	DK adult	0.0	Wheat	0.0	Potatoes	0.0	Rye	
0.0	PL general population	0.0	Potatoes	0.0	Beans	0.0	Peas	
0.0	FI adult	0.0	Potatoes	0.0	Wheat	0.0	Rye	

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

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

The acute risk assessment is based on the ARfD.
For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.
In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.
Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
1.0	Potatoes	0.02/-	0.7	Potatoes	0.02/-	0.2	Potatoes	0.02/-	0.2	Potatoes	0.02/-
0.2	Sweet corn	0.01/-	0.2	Sugar beet (root)	0.01/-	0.1	Sugar beet (root)	0.01/-	0.1	Sugar beet (root)	0.01/-
0.2	Sugar beet (root)	0.01/-	0.2	Sweet corn	0.01/-	0.1	Sweet corn	0.01/-	0.1	Sweet corn	0.01/-
0.1	Beans	0.01/-	0.1	Beans	0.01/-	0.0	Poultry: Meat	0.01/-	0.0	Poultry: Meat	0.01/-
0.0	Wheat	0.01/-	0.0	Wheat	0.01/-	0.0	Wheat	0.01/-	0.0	Wheat	0.01/-
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				**No of commodities for which ARfD/ADI is exceeded:** ---			
		***)				***)	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	
0.1	Potato puree (flakes)	0.02/-		0.0	Bread/pizza	0.01/-	
0.0	Wheat flour	0.01/-		0.0	Potato uree (flakes)	0.02/-	
0.0	Maize flour	0.01/-		0.0	Fried potatoes	0.02/-	
0.0	Fried potatoes	0.02/-		0.0	Maize flour	0.01/-	

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

Conclusion:
For sedaxane, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

- PRIMo (EU)

Sedaxane			
Status of the active substance:	approved	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	0.11	ARfD (mg/kg bw):	0.3
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2013	Year of evaluation:	2013

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI
minimum – maximum

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
0.2	UK Toddler	0.2	Sugar beet (root)	0.0	Wheat	0.0	Sweet corn	
0.1	UK Infant	0.1	Sugar beet (root)	0.0	Wheat	0.0	Maize	
0.1	WHO Cluster diet B	0.1	Wheat	0.0	Maize	0.0	Sugar beet (root)	
0.1	DK child	0.1	Wheat	0.0	Rye	0.0	Oats	
0.1	WHO cluster diet D	0.1	Wheat	0.0	Maize	0.0	Rye	
0.1	IT kids/toddler	0.1	Wheat	0.0	Maize	0.0	Sweet corn	
0.1	IE adult	0.0	Maize	0.0	Maize	0.0	Barley	
0.1	WHO cluster diet E	0.0	Wheat	0.0	Barley	0.0	Maize	
0.1	UK vegetarian	0.0	Sugar beet (root)	0.0	Wheat	0.0	Sweet corn	
0.1	UK Adult	0.0	Sugar beet (root)	0.0	Wheat	0.0	Sweet corn	
0.0	WHO Cluster diet F	0.0	Wheat	0.0	Rye	0.0	Barley	
0.0	DE child	0.0	Wheat	0.0	Rye	0.0	Oats	
0.0	NL child	0.0	Wheat	0.0	Rye	0.0	Maize	
0.0	ES child	0.0	Wheat	0.0	Maize	0.0	Barley	
0.0	PT General population	0.0	Wheat	0.0	Maize	0.0	Rye	
0.0	IT adult	0.0	Wheat	0.0	Maize	0.0	Sweet corn	
0.0	WHO regional European diet	0.0	Wheat	0.0	Barley	0.0	Maize	
0.0	SE general population 90th percentile	0.0	Wheat	0.0	Rye	0.0	Sweet corn	
0.0	FR all population	0.0	Wheat	0.0	Barley		FRUIT (FRESH OR FROZEN)	
0.0	ES adult	0.0	Wheat	0.0	Barley	0.0	Maize	
0.0	DK adult	0.0	Wheat	0.0	Rye	0.0	Oats	
0.0	FR toddler	0.0	Wheat	0.0	Sweet corn		FRUIT (FRESH OR FROZEN)	
0.0	NL general	0.0	Wheat	0.0	Barley	0.0	Rye	
0.0	LT adult	0.0	Rye	0.0	Wheat	0.0	Oats	
0.0	FI adult	0.0	Wheat	0.0	Rye	0.0	Oats	
0.0	FR infant	0.0	Wheat	0.0	Sweet corn		FRUIT (FRESH OR FROZEN)	
0.0	PL general population	0.0	Maize		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	

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

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

The acute risk assessment is based on the ARfD.
For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.
In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.
Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---		
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
0.2	Sweet corn	0.01/-	0.2	Sugar beet (root)	0.01/-	0.1	Sugar beet (root)	0.01/-	0.1	Sugar beet (root)	0.01/-
0.2	Sugar beet (root)	0.01/-	0.2	Sweet corn	0.01/-	0.1	Sweet corn	0.01/-	0.1	Sweet corn	0.01/-
0.0	Wheat	0.01/-	0.0	Wheat	0.01/-	0.0	Wheat	0.01/-	0.0	Wheat	0.01/-
0.0	Maize	0.01/-	0.0	Maize	0.01/-	0.0	Barley	0.01/-	0.0	Barley	0.01/-
0.0	Rye	0.01/-	0.0	Rye	0.01/-	0.0	Rye	0.01/-	0.0	Rye	0.01/-
No of critical MRLs (IESTI 1)		---				**No of critical MRLs (IESTI 2)**		---			

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				No of commodities for which ARfD/ADI is exceeded: ---			
		***)				***)	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	
0.0	Wheat flour	0.01/-		0.0	Bread/pizza	0.01/-	
0.0	Maize flour	0.01/-		0.0	Maize flour	0.01/-	

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

Conclusion:
For sedaxane, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Sedaxane (sum of isomers)				
Barley, grain	0.01*	STMR	0.01*	STMR
Brewer's grain, dried	0.01*	STMR[(a)]	0.01*	STMR[(a)]
Corn, field (Maize), grain	0.01*	STMR	0.01*	STMR
Corn, pop, grain	0.01*	STMR	0.01*	STMR
Corn, field, milled by-pdts	0.01*	STMR[(a)]	0.01*	STMR[(a)]
Corn, field, hominy meal	0.01*	STMR[(a)]	0.01*	STMR[(a)]
Corn, field, distiller's grain (dry)	0.01*	STMR[(a)]	0.01*	STMR[(a)]
Corn, field, gluten feed	0.01*	STMR[(a)]	0.01*	STMR[(a)]
Corn, field, gluten, meal	0.01*	STMR[(a)]	0.01*	STMR[(a)]
Oat, grain	0.01*	STMR	0.01*	STMR
Rye, grain	0.01*	STMR	0.01*	STMR
Triticale, grain	0.01*	STMR	0.01*	STMR
Wheat, grain	0.01*	STMR	0.01*	STMR
Wheat, distiller's grain (dry)	0.01*	STMR[(a)]	0.01*	STMR[(a)]
Wheat gluten, meal	0.01*	STMR[(a)]	0.01*	STMR[(a)]
Wheat, milled by-pdts	0.01*	STMR[(a)]	0.01*	STMR[(a)]
Beet, sugar, dried pulp	0.01*	STMR[(a)]	0.01*	STMR[(a)]
Beet, sugar, ensiled pulp	0.01*	STMR[(a)]	0.01*	STMR[(a)]
Beet, sugar, molasses	0.01*	STMR[(a)]	0.01*	STMR[(a)]
Barley, straw	0.01*	STMR	0.01*	HR
Corn, field, stover (fodder)	0.01*	STMR	0.01*	HR
Corn, pop, stover	0.01*	STMR	0.01*	HR
Oat, straw	0.01*	STMR	0.01*	HR
Rye, straw	0.01*	STMR	0.01*	HR
Triticale, straw	0.01*	STMR	0.01*	HR
Wheat, straw	0.01*	STMR	0.01*	HR
Beet, sugar, tops	0.01*	STMR	0.01*	HR

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
*: Indicates that the input value is proposed at the limit of quantification.
(a): For barley, maize/corn, oat, rye, wheat and sugar beet meals no default processing factor was applied because residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Sedaxane (sum of isomers)				
Sweet corn	0.01*	STMR	0.01*	HR
Maize/corn grains	0.01*	STMR	0.01*	HR
Wheat, barley, oat, rye and triticale grains	0.01*	STMR	0.01*	HR
Sugar beet roots	0.01*	STMR	0.01*	HR

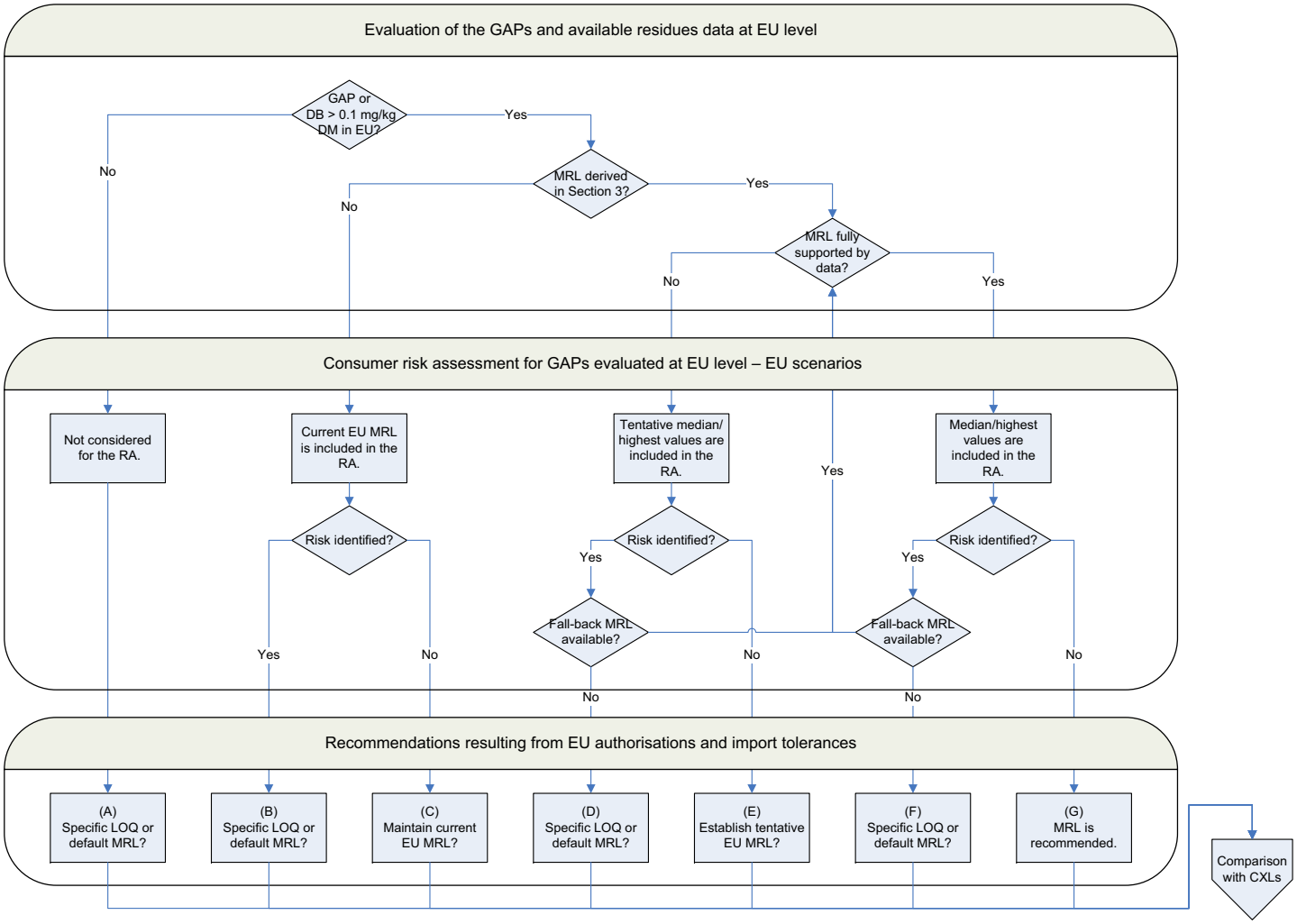
STMR: supervised trials median residue; HR: highest residue.
*: Indicates that the input value is proposed at the limit of quantification.

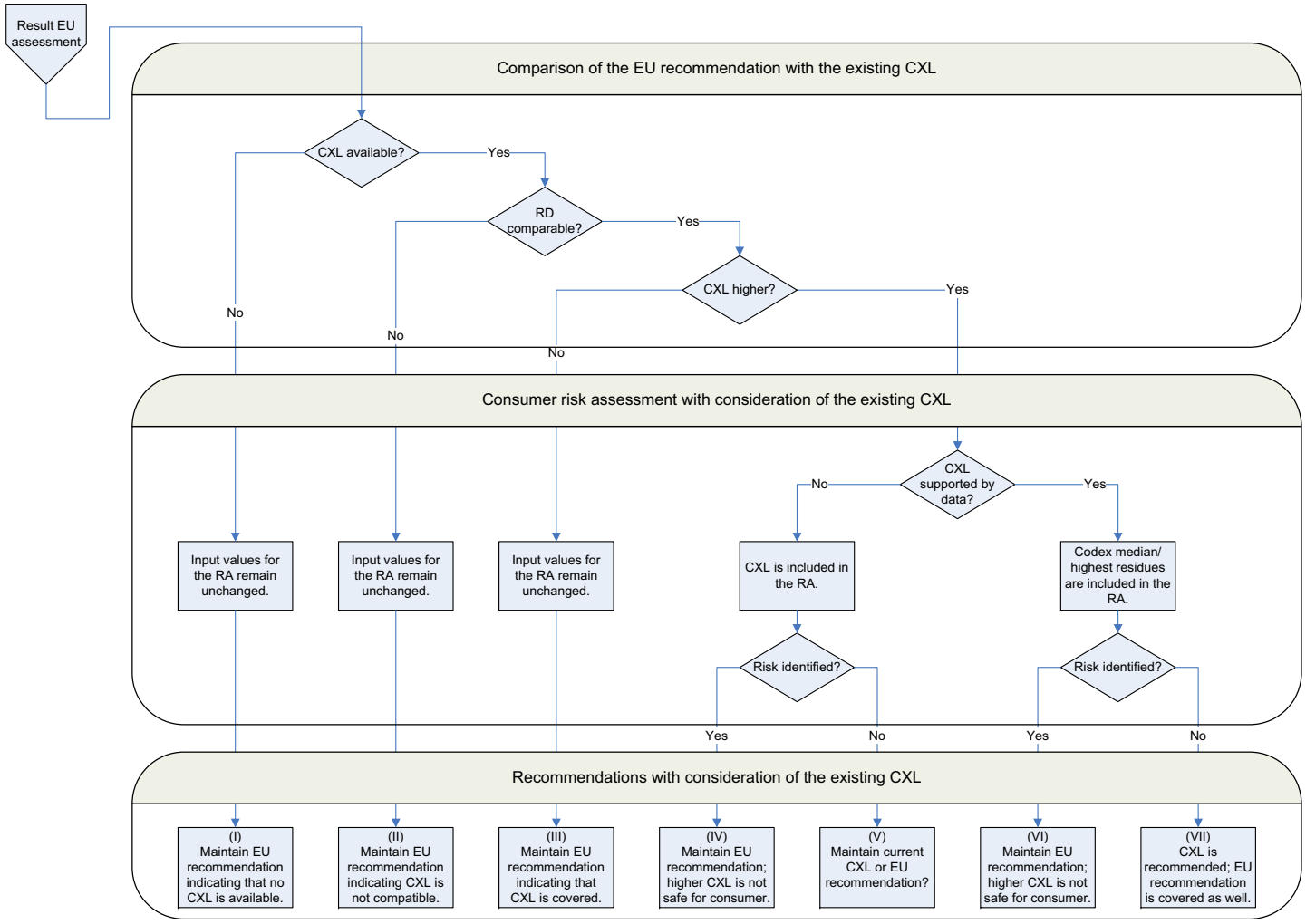
D.3. Consumer risk assessment with consideration of the existing CXLs

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition for plant commodities: Sedaxane (sum of isomers)				
Sweet corn	0.01*	STMR	0.01*	HR
Maize/corn grains	0.01*	STMR	0.01*	HR
Wheat, barley, oat, rye and triticale grains	0.01*	STMR	0.01*	HR
Sugar beet roots	0.01*	STMR	0.01*	HR
Potatoes	0.01	STMR (CXL)	0.02	HR (CXL)
Beans (dry)	0.01*	STMR (CXL)	0.01*	HR (CXL)
Lentils (dry)	0.01*	STMR (CXL)	0.01*	HR (CXL)
Peas (dry)	0.01*	STMR (CXL)	0.01*	HR (CXL)
Lupins (dry)	0.01*	STMR (CXL)	0.01*	HR (CXL)
Rape seed	0.01*	STMR (CXL)	0.01*	HR (CXL)
Soya bean	0.01*	STMR (CXL)	0.01*	HR (CXL)
Buckwheat grain	0.01*	STMR (CXL)	0.01*	HR (CXL)
Millet grain	0.01*	STMR (CXL)	0.01*	HR (CXL)
Rice grain	0.01*	STMR (CXL)	0.01*	HR (CXL)
Sorghum grain	0.01*	STMR (CXL)	0.01*	HR (CXL)
Risk assessment residue definition for animal commodities: Sedaxane (sum of isomers)				
Swine meat	0.01*	CXL	0.01*	CXL
Swine fat	0.01*	CXL	0.01*	CXL
Swine liver	0.01*	CXL	0.01*	CXL
Swine kidney	0.01*	CXL	0.01*	CXL
Bovine and equine meat	0.01*	CXL	0.01*	CXL
Bovine and equine fat	0.01*	CXL	0.01*	CXL
Bovine and equine liver	0.01*	CXL	0.01*	CXL
Bovine and equine kidney	0.01*	CXL	0.01*	CXL
Sheep and goat meat	0.01*	CXL	0.01*	CXL
Sheep and goat fat	0.01*	CXL	0.01*	CXL
Sheep and goat liver	0.01*	CXL	0.01*	CXL
Sheep and goat kidney	0.01*	CXL	0.01*	CXL
Poultry meat	0.01*	CXL	0.01*	CXL
Poultry fat	0.01*	CXL	0.01*	CXL
Poultry liver	0.01*	CXL	0.01*	CXL

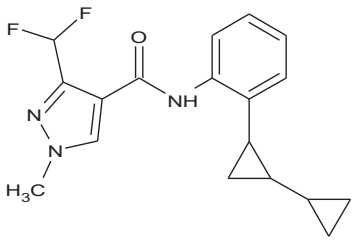
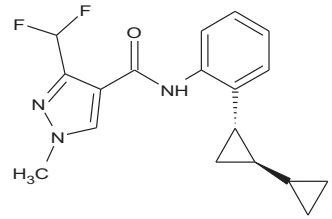
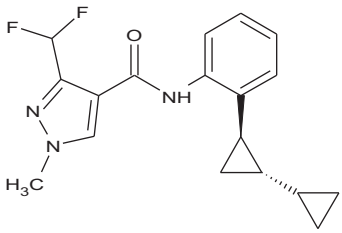
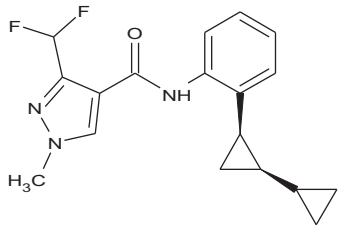
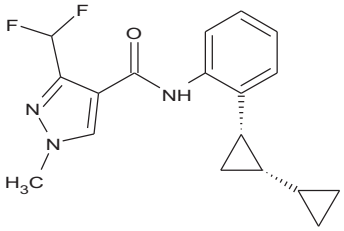
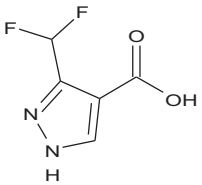
STMR: supervised trials median residue; HR: highest residue; CXL: codex maximum residue limit.
*: Indicates that the input value is proposed at the limit of quantification.

Appendix E – Decision tree for deriving MRL recommendations




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

Appendix F – Used compound codes

Code/trivial name	IUPAC name/SMILES notation/ InChiKey[a]	Structural formula[b]
Sedaxane (SYN524464)	mixture of 80–100% 2 *trans*-isomers 2′-[(1*RS*,2*SR*)-1,1′-bicycloprop-2-yl]-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxanilide and 20–0% 2 *cis*-isomers 2′-[(1*RS*,2*RS*)-1,1′-bicycloprop-2-yl]-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxanilide FC(F)c1nn(C)cc1C(=O)Nc1ccccc1C1CC1C1CC1 XQJQCBDIXRIYRP-UHFFFAOYSA-N	
Trans- (SYN508210)	2′-[(1*R*,2*S*)-1,1′-bicycloprop-2-yl]-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxanilide FC(F)c1nn(C)cc1C(=O)Nc1ccccc1[C@H]1C[C@@H]1C1CC1 XQJQCBDIXRIYRP-CHWSQXEVSA-N 2′-[(1*S*,2*R*)-1,1′-bicycloprop-2-yl]-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxanilide FC(F)c1nn(C)cc1C(=O)Nc1ccccc1[C@@H]1C[C@H]1C1CC1 XQJQCBDIXRIYRP-STQMWFEESA-N	 
Cis- (SYN508211)	2′-[(1*R*,2*R*)-1,1′-bicycloprop-2-yl]-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxanilide FC(F)c1nn(C)cc1C(=O)Nc1ccccc1[C@@H]1C[C@@H]1C1CC1 XQJQCBDIXRIYRP-OLZOCXBDSA-N 2′-[(1*S*,2*S*)-1,1′-bicycloprop-2-yl]-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxanilide FC(F)c1nn(C)cc1C(=O)Nc1ccccc1[C@H]1C[C@H]1C1CC1 XQJQCBDIXRIYRP-QWHCGFSZSA-N	 
CSCD465008	3-(difluoromethyl)-1*H*-pyrazole-4-carboxylic acid OC(=O)c1c[NH]nc1C(F)F IGQNDARULCASRN-UHFFFAOYSA-N	

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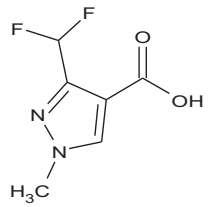
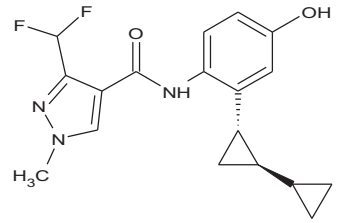
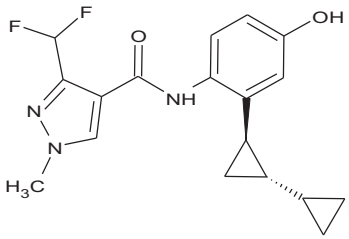
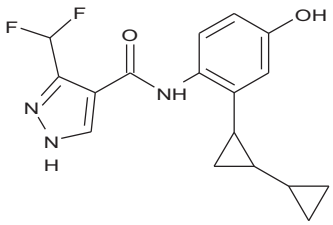
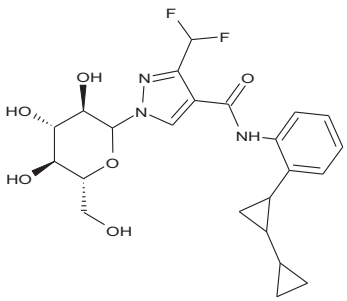
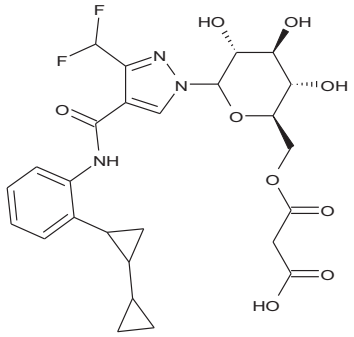
CSAA798670	3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxylic acid FC(F)c1nn(C)cc1C(=O)O RLOHOBNEYHBZID-UHFFFAOYSA-N	
CSCD658906	*N*-{2-[(1*R*,2*S*)-[1,1′-bi(cyclopropyl)]-2-yl]-4-hydroxyphenyl}-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxamide FC(F)c1nn(C)cc1C(=O)Nc1ccc(O)cc1[C@H]1C[C@@H]1C1CC1 OTBMEEKWTGGWFZ-NEPJUHHUSA-N *N*-{2-[(1*S*,2*R*)-[1,1′-bi(cyclopropyl)]-2-yl]-4-hydroxyphenyl}-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxamide FC(F)c1nn(C)cc1C(=O)Nc1ccc(O)cc1[C@@H]1C[C@H]1C1CC1 OTBMEEKWTGGWFZ-NWDGAFQWSA-N	 
CSCD659087	*N*-{2-[[1,1′-bi(cyclopropyl)]-2-yl]-4-hydroxyphenyl}-3-(difluoromethyl)-1*H*-pyrazole-4-carboxamide *(unstated stereochemistry)* O=C(Nc1ccc(O)cc1C1CC1C1CC1)c1c[NH]nc1C(F)F NWXYNAFZOXTHCS-UHFFFAOYSA-N	
CSCD667555	*N*-{2-[[1,1′-bi(cyclopropyl)]-2-yl]phenyl}-3-(difluoromethyl)-1-D-glucopyranosyl-1*H*-pyrazole-4-carboxamide *(unstated stereochemistry)* FC(F)c1nn(cc1C(=O)Nc1ccccc1C1CC1C1CC1)C1O[C@H](CO)[C@H](O)[C@H](O)[C@H]1O LXBAAHMFHQQOIY-UHFFFAOYSA-N	
CSCD667556	*N*-{2-[[1,1′-bi(cyclopropyl)]-2-yl]phenyl}-1-[6-*O*-(carboxyacetyl)-D-glucopyranosyl]-3-(difluoromethyl)-1*H*-pyrazole-4-carboxamide *(unstated stereochemistry)* O=C(O)CC(=O)OC[C@H]1OC(n2nc(C(F)F)c(c2)C(=O)Nc2ccccc2C2CC2C2CC2)[C@H](O)[C@@H](O)[C@@H]1O JBQUOAIYUGEICE-AZPZVGOXSA-N	

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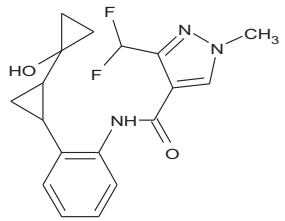
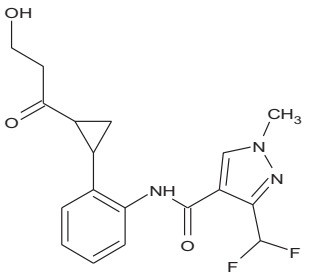
CSCD659089	3-(difluoromethyl)-*N*-{2-[1′-hydroxy[1,1′-bi (cyclopropyl)]-2-yl]phenyl}-1-methyl-1*H*-pyrazole-4-carboxamide (*unstated stereochemistry*) FC(F)c1nn(C)cc1C(=O)Nc1ccccc1C1CC1C1(O)CC1 CMVXXPDCGBBTCH-UHFFFAOYSA-N	
CSCD668403	3-(difluoromethyl)-*N*-{2-[2-(3-hydroxypropanoyl)cyclopropyl]phenyl}-1-methyl-1*H*-pyrazole-4-carboxamide (*unstated stereochemistry*) FC(F)c1nn(C)cc1C(=O)Nc1ccccc1C1CC1C(=O)CCO UCBBJWQTVZYRCC-UHFFFAOYSA-N	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): ACD/Name 2017.2.1 ACD/Labs 2017 Release (File version N40E41, Build 96719, 6 September 2017).
(b): ACD/ChemSketch 2017.2.1 ACD/Labs 2017 Release (File version C40H41, Build 99535, 14 February 2018).