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Modification of the existing maximum residue level for sedaxane in potatoes

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Syngenta France SAS submitted a request to the competent national authority in France to modify the existing maximum residue level (MRL) for the active substance sedaxane in potatoes. The data submitted in support of the request were found to be sufficient to derive an MRL proposal for potatoes. Adequate analytical methods for enforcement are available to control the residues of sedaxane on the commodity under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of sedaxane according to the intended agricultural practice is unlikely to present a risk to consumer health.

Keywords: sedaxane, potatoes, fungicide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta France SAS submitted an application to the competent national authority in France (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance sedaxane in potatoes. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 6 June 2016. To accommodate for the intended use of sedaxane, the EMS proposed to raise the existing MRL in potatoes from 0.02 to 0.15 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points data gaps, which were requested from the EMS. On 7 March 2022, the EMS submitted a revised evaluation report, which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under the previous MRL review assessment, and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of sedaxane was investigated in primary crops belonging to the groups of leafy crops, cereals/grasses and pulses/oilseeds after seed treatment and in rotational crops belonging to the root/tuber crops, leafy crops and cereals. The metabolic pathway was found to be similar in all tested crops. In foliar parts of primary crops, sedaxane was the main residue; in soyabeans, the predominant residue was metabolite CSCD465008. In rotational crops, sedaxane and its soil metabolites CSAA798670 and CSCD465008 were main residues. Studies investigating the effect of processing on the nature of sedaxane (hydrolysis studies) demonstrated that the active substance is stable.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites and the capability of the enforcement method, the residue definition in plant commodities was proposed as 'sedaxane (sum of isomers)' for enforcement and risk assessment. The residue definition is restricted to seed and soil treatments, and it is also applicable to rotational crops and processed products.

Sufficiently validated analytical methods are available to quantify residues in the crop assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in the crop assessed (LOQ).

The available residue trials are sufficient to derive an MRL proposal of 0.15 mg/kg for potatoes. Specific studies investigating the magnitude of sedaxane residues in processed commodities are not required, as the theoretical maximum daily intake (TMDI) is expected to be below the trigger value of 10% of the acceptable daily intake (ADI). Nonetheless, two processing studies are available showing that residues of sedaxane decrease in processed flakes and fried chips. However, only tentative processing factors could be derived.

The occurrence of sedaxane residues in rotational crops was investigated in the framework of the MRL review. From the available studies, the MRL review could not conclude on the magnitude of sedaxane residues in rotational crops if grown in soils containing sedaxane residues at plateau concentrations from its multi-annual uses on primary crops. Pending the submission of new field rotational crop studies, the Member States should consider the need to set specific risk mitigation measures to avoid the presence of sedaxane residues in rotational crops.

As the crop under consideration and its by-products are used as feed items, the potential carry-over of sedaxane residues into food of animal origin was assessed. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all livestock species. The EU pesticides peer review of sedaxane established a residue definition for both enforcement and risk assessment as 'sedaxane (sum of isomers)' in products of animal origin. However, EFSA requested to pay particular attention to the potential human exposure to the major metabolites observed in the metabolism studies in ruminants (namely, CSCD658906, CSCD659087 and CSCD659088) in case of additional uses involving feed items. Based on the toxicological data submitted in this MRL application, these metabolites are anyway unlikely to be genotoxic and their toxicity is covered by the reference values of the parent active substance. Taking into account the dietary burden values calculated, considering the intended use on potatoes and the results of the feeding study in ruminants and the metabolism study in poultry, EFSA concludes that residues of sedaxane and its major metabolites above the LOQ of 0.01 mg/kg are not expected in products of animal origin. A change of the existing MRLs is not necessary.

The toxicological profile of sedaxane was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.11 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.3 mg/kg bw.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The short-term exposure assessment was performed only for potatoes and accounted for a maximum of 5% of the ARfD. In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level and the acceptable Codex maximum residue limits (CXLs). EFSA updated this calculation with the relevant supervised trials median residue value (STMR) derived for potatoes from the residue trials submitted. The estimated long-term dietary intake accounted for a maximum of 0.8% of the ADI (NL toddler diet), with potatoes contributing for a maximum of 0.05% of the ADI.

EFSA concluded that the proposed use of sedaxane on potatoes will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

EFSA emphasises that the above assessment does not consider the possible impact of plant and livestock metabolism on the isomer ratio of sedaxane and further investigation on this matter would in principle be required. In view of the large margin of safety in the exposure calculations, the potential change of isomer ratio in the final residues is not expected to be of concern for the intended use on potatoes and for the authorised uses reported in the MRL review. However, in case future uses of sedaxane would lead to higher consumer exposures, further information regarding the impact of plant and/or livestock metabolism on the isomer ratio might be required.

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

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

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Sedaxane (sum of isomers)				
0211000	Potatoes	0.02	0.15	The MRL proposal reflects the more critical residue situation of the NEU use. The SEU use is sufficiently supported. Risk for consumers unlikely.

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for sedaxane in potatoes. The detailed description of the intended uses of sedaxane in potatoes, which are the basis for the current MRL application, is reported in Appendix A.

Sedaxane is the ISO common name for a mixture of 80–100% of 2 *trans*-isomers 2′-[(1*RS*,2*SR*)-1,1′-bicycloprop-2-yl]-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxanilide and of 20–0% of 2 *cis*-isomers 2′-[(1*RS*,2*RS*)-1,1′-bicycloprop-2-yl]-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxanilide (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Sedaxane was evaluated in the framework of Directive 91/414/EEC[1] in accordance Commission Regulation (EU) No 188/2011[2] with France designated as rapporteur Member State (RMS) for the representative uses as a seed treatment. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2013). Sedaxane was approved[3] for the use as fungicide on 1 February 2014. The approval of sedaxane is restricted to uses for seed treatment only.

The EU MRLs for sedaxane are established in Annex II of Regulation (EC) No 396/2005[4]. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2019a) and the proposed modifications have been implemented in the MRL legislation.

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta France SAS submitted an application to the competent national authority in France (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance sedaxane in potatoes. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 6 June 2016. To accommodate for the intended use of sedaxane, the EMS proposed to raise the existing MRL from 0.02 to 0.15 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps, which were requested from the EMS. On 7 March 2022, the EMS submitted a revised version of the original evaluation report, which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (France, 2016), the draft assessment report (DAR) and its addendum (France, 2011, 2012) prepared under Directive 91/414/EEC, the Commission review report on sedaxane (European Commission, 2013), the conclusion on the peer review of the pesticide risk assessment of the active substance sedaxane as well as the review of existing MRLs according to the Article 12 of Regulation No 396/2005 (EFSA, 2013, 2019a).

For this application, the data requirements established in Regulation (EU) No 544/2011[5] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1996, 1997a–g, 2000, 2010a,b; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[6].

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

The evaluation report submitted by the EMS (France, 2016) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

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

[2] Commission 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.

[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 Text with EEA relevance. OJ L 232, 30.8.2013, p. 13–17.

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

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

[6] 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. Mammalian toxicity

The toxicological profile of sedaxane was assessed in the framework of the EU pesticides peer review and the data were sufficient to derive an acceptable daily intake (ADI) of 0.11 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.3 mg/kg bw (EFSA, 2013; European Commission, 2013).

It is noted that sedaxane does not meet the cut-off criteria regarding its harmonised classification (ECHA, 2019); however, its endocrine-disrupting (ED) potential has not yet been assessed by the EU pesticides peer review (EFSA, 2013).

In the framework of the present MRL application, additional information has been submitted to clarify the toxicity profile of metabolites identified as major metabolites in livestock metabolism and potentially relevant to consumer exposure, in particular, metabolites CSCD658906 (SYN545860), CSCD659088 (SYN551569) and CSCD659087 (SYN546075).

A new toxicokinetic study was conducted on sedaxane in male rats to determine the maximum levels of the metabolites in urine, faeces and plasma. Their systemic exposure was reported as percentage of the area under the blood concentration per time curve (AUC); however, the AUC values were not calculated. Unchanged sedaxane was detected in plasma and faeces, but not urine. In plasma, sedaxane accounted for 7% and 33% of the total AUC, for the low- and high-dose levels of 1 and 80 mg/kg bw, respectively. In faeces, sedaxane accounted for < 6% of an oral dose. Metabolites CSCD659088 (representing ca 4% of the total AUC) and CSCD659087 (whose glucuronide conjugate accounted for 7.9% of the total AUC) were shown to be minor rat metabolites. Metabolite CSCD658906, together with its glucuronide conjugate accounted for < 1.5% of the administered dose in urine, but up to 16.3% of the total AUC (6.5% and 9.8%, respectively) in the low-dose group of 1 mg/kg bw and 7.2% of the total AUC in the high-dose group of 80 mg/kg bw. In addition, these metabolites represented 35% of the radioactivity recovered in bile. Considering the percentage of the metabolite and its glucuronide conjugate in plasma (low dose) and that the toxicity of the glucuronide conjugate is considered similar to that of the unconjugated form, it may be assumed that the metabolite CSCD658906 is a major rat metabolite. Accordingly, the toxicological reference values of sedaxane apply to the metabolite CSCD658906 and its glucuronide conjugate.

In silico genotoxicity profiling of metabolite CSCD658906 (hydroxylated sedaxane on the phenyl ring) presented positive predictions with regard to chromosomal aberration in addition to positive predictions for *in vivo* micronucleus test (as also predicted for the parent compound) and genotoxicity studies were conducted on the metabolite. A reverse mutation test in bacteria was negative, but positive results were obtained in an *in vitro* micronucleus test with and without metabolic activation. The follow-up with *in vivo* micronucleus assay was negative up to the limit dose of 2,000 mg/kg bw, proof of bone marrow exposure being obtained by quantitative plasma analysis. It could be concluded that the metabolite CSCD658906 is unlikely to be genotoxic *in vivo*.

Regarding metabolite CSCD659088, it was concluded unlikely to be genotoxic, based on quantitative structure–activity relationship (QSAR) analysis and read-across from the parent. Metabolite CSCD659087 was also concluded unlikely to be genotoxic based on QSAR analysis and structural similarities with metabolite CSCD658906.

The repeated dose toxicity was assessed by an analogue approach read-across for both CSCD659088 and CSCD659087 metabolites.

Regarding metabolite CSCD659088, the source compound is metabolite 3 (SYN545722) which, although identified only in plasma, representing 10.2–10.8% of the AUC, was considered as a major rat metabolite in the newly submitted toxicokinetic study. Robust read-across and DEREK predictions showed analogy between the two compounds. EFSA notes that the higher polarity of metabolite CSCD659088 with regard to metabolite 3 (100 times more polar given that logP is 2 units lower) represents a potential for poorer absorption and more rapid excretion. A potential for higher reactivity (other than DNA activity) was not fully clarified for CSCD659088; however, overall, lower toxicity would be expected and EFSA supports the conclusion reached by the applicant and the EMS (France, 2016) that the toxicity profile of the metabolite is covered by the ADI and ARfD of the parent sedaxane.

With regard to metabolite CSCD659087, read-across from metabolite CSCD658906 (to account for the new para-aminophenol moiety), supported by metabolite 3 (accounting for the demethylation of the pyrazole ring), both metabolites being identified as major rat metabolites in the newly submitted toxicokinetic study, it was considered appropriate to conclude that the toxicological reference values of sedaxane may apply to CSCD659087.

It is noted that the stereochemistry was not addressed for the three metabolites. This issue was partly investigated for the parent sedaxane for which trans-isomers, cis-isomers and a 1:1 mixture of these two isomers presented similar toxicity profile in a 28-day toxicity study in rats. However, no toxicological information was available on the relative toxicity of the two enantiomers present in the trans- and cis-isomers. The uncertainty related to this issue is unlikely to result in an unacceptable additional risk to consumers considering the high margin of safety identified in the residue section (see Section 4 below).

1.1. Conclusion on the toxicity profile of metabolites

In support of the consumer risk assessment for the intended use on potatoes, it is concluded that metabolites CSCD658906, CSCD659088 (and their respective glucuronide conjugates) and CSCD659087 are unlikely to be genotoxic. Their toxicity profile is therefore covered by the ADI and ARfD established for sedaxane.

2. Residues in plants

2.1. Nature of residues and methods of analysis in plants

2.1.1. Nature of residues in primary crops

The metabolism of sedaxane in primary crops belonging to the group of leafy crops (Swiss chards), cereals/grass (wheat) and pulses/oilseeds (soyabeans, oilseed rape) has been investigated after seed treatment with radiolabelled sedaxane[7] in the framework of the EU pesticides peer review and the MRL review (EFSA, 2013, 2019a).

At harvest, the radioactivity in wheat grain and rapeseeds was too low, at trace levels, and not further investigated. Sedaxane was the main residue in all foliage parts of the tested crops (12–52% of the total radioactive residues, TRR). In soyabeans, sedaxane was not detected and the predominant residue was the metabolite CSCD465008 in its free and conjugated forms (30% TRR). All of the other identified metabolites were present in the crops at much lower proportions and concentrations. It was concluded that following the seed treatment, the metabolic pathway of sedaxane was similar in the three crop groups.

For the intended use, the metabolic behaviour in primary crops is sufficiently addressed.

2.1.2. Nature of residues in rotational crops

Sedaxane is proposed to be used on a crop, potatoes, which can be grown in rotation with other crops. According to the soil degradation studies evaluated in the framework of the peer review, the DT_{90} value of sedaxane was 1,454 days. The DT_{90} value of the relevant soil metabolite CSCD465008 exceeded the trigger value of 100 days, indicating it to exhibit moderate to high persistence in the soil. The other relevant soil metabolite CSAA798670 was less persistent in soil with a maximum DT_{90} value of 59 days (EFSA, 2013). Therefore, further investigation is required (European Commission, 1997c).

Two confined rotational crop metabolism studies with radiolabelled sedaxane were assessed in the framework of the EU pesticide peer review and the MRL review (EFSA, 2013, 2019a). One study was conducted by sowing soyabean seeds treated with the active substance and planting of wheat (cereals), radishes (root/tuber crops) and lettuces (leafy crops) after cut and re-tilling of the soyabean plants. In the second study, sedaxane was applied on a bare soil, later followed by planting/sowing of wheat, lettuces and turnips. Planting/sowing of the rotated crops occurred at three representative plant back intervals (PBIs).

Total radioactive residues declined over the PBI times. Sedaxane was found in all the crop parts (6–63% TRR) in the soil application study, whereas was not quantified (< 0.01 mg eq/kg, 1–47% TRR) in the seed treatment study, except in radish roots at PBI 30 days (58% TRR) and wheat straw at PBI 120 days (4% TRR). Metabolites CSAA798670 and CSCD465008 were the predominant metabolites in all parts of the rotated crops. Both metabolites are major soil metabolites according to the soil degradation studies, and therefore, a potential soil uptake of these metabolites may occur in rotational crops.

[7] The test item used in this as well as the other core studies corresponds to sedaxane, which is a mixture of *trans*-(SYN508210) and *cis*-(SYN508211) isomers, in an approximate 6:1 ratio.

From these studies, it was concluded that the overall metabolic pathway of sedaxane in rotated crops resulted in a similar uptake and transformation to that found in primary crops.

2.1.3. Nature of residues in processed commodities

The effect of processing on the nature of sedaxane was investigated in the framework of the EU pesticides peer review (EFSA, 2013). These studies showed that sedaxane is hydrolytically stable under standard processing conditions. The isomer ratio of the test substance was also shown not to be affected by the conditions employed in the hydrolysis study.

2.1.4. Analytical methods for enforcement purposes in plant commodities

Analytical methods for the determination of sedaxane residues were assessed during the EU pesticides peer review and the MRL review (EFSA, 2013, 2019a). A multiresidue QuEChERS analytical method based on high-performance liquid chromatography (HPLC) coupled to tandem mass spectrometry (MS/MS) detection was validated in all plant matrices, with a limit of quantification (LOQ) of 0.01 mg/kg for sedaxane as sum of its isomers. The QuEChERS and QuOil (LC–MS/MS) multiresidue method is achieving even a lower LOQ of 0.005 mg/kg in dry commodities, but its ILV to confirm reproducibility was not provided (EFSA, 2019a).

EFSA notes that the extraction efficiency for the analytical methods applied for enforcement was not assessed according to the requirements of the extraction efficiency guidance (European Commission, 2017a,b). Futher investigation on this matter has not been requested because the MRL application was submitted before the entry into force of the above-mentioned guidance document.

EFSA concludes that sufficiently validated analytical methods are available to enforce the residues of sedaxane as sum of isomers in the commodity under assessment.

2.1.5. Storage stability of residues in plants

The storage stability of the *trans*- and *cis*-isomers of sedaxane in plants stored under frozen conditions was investigated in all crop matrices as well as in certain processed products in the framework of the EU pesticides peer review (EFSA, 2013). It was demonstrated that in high water content crops (representative for potatoes), residues were stable for at least 24 months when stored at −18°C.

2.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites, the capabilities of the analytical method for routine monitoring, the following residue definitions were proposed by the EU pesticides peer review and confirmed by the EU MRL review (EFSA, 2013, 2019a):

- residue definition for risk assessment: sedaxane (sum of isomers).
- residue definition for enforcement: sedaxane (sum of isomers).

The residue definitions are restricted to seed and soil treatments and are applicable to rotational crops and processed products.

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition.

For the intended seed treatment in potatoes, EFSA concludes that the metabolism of sedaxane is sufficiently addressed and the residue definitions for enforcement and risk assessment applicable.

2.2. Magnitude of residues in plants

2.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted residue trials on potatoes conducted over two seasons. Tubers treated according to the intended good agricultural practice (GAP) were sown in different Northern (eight trials) and Southern (eight trials) European geographical areas. Samples of mature potatoes were collected at two different sampling times, around 90–102 days and up to 147 days following the treatment, thus taking into account both early and late harvest scenarios. For MRL setting and risk assessment, the highest value among the two scenarios was selected.

The number of valid trials per each area is sufficient to derive an MRL proposal for potatoes. The intended use in the NEU showed to be more critical for residues and is driving the MRL proposal of 0.15 mg/kg.

All samples were analysed for the *cis/trans* isomers of sedaxane separately and residues expressed as the sum in compliance with the residue definition for enforcement and risk assessment. According to the assessment of the EMS, the analytical method used was sufficiently validated and fit for purpose. The samples of the residue trials were stored under conditions for which integrity has been demonstrated (France, 2016).

2.2.2. Magnitude of residues in rotational crops

The possible transfer of sedaxane residues to crops that are grown in rotation has been assessed in EU pesticides peer review and the MRL review (EFSA, 2013, 2019a). In the confined rotational crop studies performed at 0.83N, the maximum rate (120 g/ha) expected after sowing of tubers treated according to the intended use, CSCD465008 and CSAA798670 were predominant metabolites (see Section 2.1.2). Accumulation of residues is also expected given the high soil persistence of sedaxane (DT_{90} 1,454 days).

Two field rotational crop studies were conducted following bare soil application at 9 and 30 g/ha, and seed treatment of wheat at 10 g/100 kg seed (25 g/ha). In both studies and all plant parts, residues of sedaxane (sum of isomers), CSCD659089, CSCD668403, CSCD659087, CSAA798670 and CSCD465008, were below the LOQ of 0.01 mg/kg, except in carrot leaves sampled at 60 PBI in the seed treatment study and only for the metabolite CSCD465008 (0.02 mg/kg).

However, these studies do not cover the authorised uses assessed in the MRL review after multiannual applications as well as the intended use on potatoes (the highest rate of 30 g/ha tested in the studies is 0.25N the expected rate after intended use on potatoes). Additional field rotational crop studies were requested by the MRL review (EFSA, 2019a). These studies shall cover the plateau concentration of sedaxane residues in soil as expected according to the most critical primary crop use for rotational crops, also considering the use on potatoes under assessment. Meanwhile, Member States should take the appropriate mitigation measures in order to avoid the presence of sedaxane and its metabolites in rotational crops.

2.2.3. Magnitude of residues in processed commodities

Specific studies to assess the magnitude of sedaxane residues during the processing of potatoes are not necessary as the theoretical maximum daily intake (TMDI) is expected to amount to less than 10% of the ADI (European Commission, 1997d).

Nonetheless, the results of two processing studies with potato tubers treated at an exaggerate rate (5 g/100 kg tubers), peeled and processed to flakes and fried chips were submitted. Residues of sedaxane decreased in processed flakes and fried chips, remaining in the peel of potato. The processing factors reported in Appendix B.2.2.3 shall be considered as tentative because of the shortcoming in the analytical method validation. The EMS concluded that the method used to analyse samples of processed commodities was not fully validated (insufficient number of recoveries per fortification level) (France, 2016).

2.2.4. Proposed MRLs

The available data are considered sufficient to derive an MRL proposal as well as risk assessment values for potatoes (see Appendix B.5). In Section 4, EFSA assessed whether residues on these crops resulting from the intended seed treatment use are likely to pose a consumer health risk.

3. Residues in livestock

Potatoes and their by-products may be used for feed purposes. Hence, it was necessary to update the previous dietary burden for livestock calculated in the MRL review (EFSA, 2019a) with the new use and the more recent calculation methodology (OECD, 2013). Comparing the results of the revised dietary burden calculation with the calculation performed in the framework of the MRL review, it becomes evident that now the exposure exceeds the trigger value in all livestock species. The main contributing commodity is potatoes (process waste and culls).

The input values for the exposure calculations for livestock are presented in Appendix D.1. The results of the dietary burden calculations are presented in Section B.3.

3.1. Nature of residues and methods of analysis in livestock

The metabolism of sedaxane in livestock was investigated in lactating goats and laying hens in the framework of the EU pesticides peer review and the MRL review (EFSA, 2013, 2019a). The metabolic pathway of sedaxane in both species was similar: major part of the radioactivity found in the excreta (mainly faeces) with extensive metabolism into several breakdown products and no accumulation. Total residues in tissues, milk and eggs were low, the highest observed in liver (0.26 mg eq/kg TRR in hens; 0.61 mg eq/kg TRR in goats).

In the goat's metabolism study, sedaxane was identified in fat only (28% TRR) along with CSCD667584 (17% TRR), but their respective concentration was very low (0.004 and 0.003 mg eq/kg, respectively). In liver and kidney, the predominant compounds of the total residues were identified as CSCD658906 (free and conjugated) in liver (37% TRR) and kidney (44% TRR), CSCD659088 in kidney (12.6% TRR) and CSCD659087 in milk (19% TRR). A metabolism study in pigs is not necessary as the metabolism in the rat and goats is similar (EFSA, 2013).

In the metabolism study conducted in laying hens, sedaxane was recovered at significant proportions in egg white, muscle and fat (12–53% TRR) along with the metabolite CSCD658906 (free and conjugated) that occurred in liver and egg yolk at a level >10% of TRR. However, the relative concentrations in all matrices were low (for sedaxane a maximum 0.007 mg eq/kg in fat).

Based on the results of the metabolism studies and considering that the livestock dietary burden as calculated in the MRL review based on the authorised European uses of sedaxane was not triggered, a general residue definition for monitoring and risk assessment was proposed as 'sedaxane (sum of isomers)'. However, EFSA requested to give particular attention to the potential exposure to the major metabolites observed in the metabolism studies in case of additional uses involving feed items.

Methods of analysis for products of animal origin have been assessed during the EU pesticides peer review and the MRL review (EFSA, 2013, 2019a) A multiresidue QuEChERS method using high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) with an LOQ of 0.01 mg/kg is validated for the sum of isomers in milk, eggs and tissues. Additionally, analytical methods determining CSCD658906 and CSCD659087 were considered acceptable (EFSA, 2013).

The storage stability of sedaxane (and its major metabolites) in commodities of animal origin has not been investigated and was concluded as not required (EFSA, 2019a).

3.2. Magnitude of residues in livestock

Feeding studies involving lactating cows were available already at time of the EU pesticides peer review but never assessed previously because not required based on the livestock dietary burden calculations. Since triggered by the intended use on potatoes (see Section 3 Residue in livestock), the feeding study has been assessed in the framework of the present application (France, 2016). The same study was assessed by JMPR (FAO, 2013).

Three lactating cows per treatment group were dosed with 0.1, 0.5 and 2.2 mg/kg in the diet for 28 consecutive days. Samples of milk, liver, kidney, fat and muscle were analysed for sedaxane, CSCD658906 and CSCD659087, measured as a total of free and conjugates. All residue analysis was completed within 30 days of sample collection; hence, storage stability data to support the results of this study are not necessary. The only residue quantified was CSCD658906 in liver (0.027 mg/kg) and kidney (0.018 mg/kg) samples from the highest dose group (2.2 mg/kg DM). In all other tissue and in milk samples at all treatment levels (muscle and fat samples analysed only at the highest treatment level), residues of sedaxane, CSCD658906 and CSCD659087 were below the individual LOQ of 0.01 mg/kg.

The metabolite CSCD659088 was not analysed for in the feeding study. The metabolism study in goats was conducted at an exaggerate dose rate of 20 mg/kg DM feed, corresponding to 24N the highest intake calculated in beef cattle and sheep, 30N/45N the highest intake calculated in dairy cattle and ewe and 34N/59N the highest intake calculated in breeding and finishing pigs, respectively, and therefore, CSCD659088 is not expected to be quantified in all ruminant and pig matrices at the calculated dietary burden (1N).

A feeding study in laying hens is not available. Nevertheless, the metabolism study can be used to estimate the residue levels expected in poultry tissues and eggs. In the metabolism study conducted at the exaggerated dose rate of 12 mg/kg DM feed, corresponding to 83N the highest intake expected in broiler and 96N in laying poultry, sedaxane accounted for a maximum of 0.007 mg/kg.

Taking into account the dietary burden values calculated for the intended use on potatoes and the results of the feeding study in ruminants and the metabolism study in poultry, EFSA concludes that residues of sedaxane and its major metabolites are not expected to occur in products of animal origin. A change of the existing MRLs set at the LOQ of 0.01 mg/kg (CXLs) is not necessary.

4. Consumer risk assessment

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

The toxicological reference values for sedaxane used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the EU pesticides peer review (European Commission, 2013). The list of input values used in the exposure calculation is reported in Appendix D.2.

Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed only for the commodity assessed in this application. The calculation was based on the HR in potatoes as derived from supervised NEU field trials. The highest short-term exposure for potatoes accounted for 5% of the ARfD (See Appendix B.4).

Long-term (chronic) dietary risk assessment

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level and the acceptable CXLs (EFSA, 2019a). EFSA updated the calculation with the relevant STMR value derived from the residue trials submitted in support of this MRL application for potatoes. The crops on which no uses were reported in the MRL review and for which no acceptable CXLs are set were excluded from the chronic exposure calculation. The estimated long-term dietary intake was up to 0.8% of the ADI. The contribution of residues expected in the commodity assessed in this application to the overall long-term exposure is 0.05% of the ADI (See Appendix B.4).

EFSA concluded that the long-term intake of residues of sedaxane resulting from the existing and the intended uses is unlikely to present a risk to consumers' health. EFSA emphasises that the above assessment does not consider the possible impact of plant and livestock metabolism on the isomer ratio of sedaxane and further investigation on this matter would in principle be required. In view of the large margin of safety in the exposure calculations, the potential change of isomer ratio in the final residues is not expected to be of concern for the intended use on potatoes and for the authorised uses reported in the framework of the MRL review. However, in case future uses of sedaxane would lead to higher consumer exposures, further information regarding the impact of plant and/or livestock metabolism on the isomer ratio might be required.

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

5. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for potatoes. EFSA concluded that the proposed use of sedaxane on potatoes will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health. EFSA emphasises that the above assessment does not consider the possible impact of plant and livestock metabolism on the isomer ratio of sedaxane and further investigation on this matter would in principle be required. In view of the large margin of safety in the exposure calculations, the potential change of isomer ratio in the final residues is not expected to be of concern for the intended use on potatoes and for the authorised uses reported in the framework of the MRL review. However, in case future uses of sedaxane would lead to higher consumer exposures, further information regarding the impact of plant and/or livestock metabolism on the isomer ratio might be required.

The MRL recommendations are summarised in Appendix B.5.

References

ECHA (European Chemicals Agency), 2019. Committee for Risk Assessment (RAC) Opinion proposing harmonised classification and labelling at EU level of sedaxane (ISO); N-{2-[[1,1'-bi(cyclopropyl)]-2-yl]phenyl}-3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxamide. CLH-O-0000001412-86-280/F. Adopted 15 March 2019. Available online: www.echa.europa.eu

EFSA (European Food Safety Authority), 2013. Conclusion on the peer review of the pesticide risk assessment of the active substance sedaxane. EFSA Journal 2013;11(1):3057, 76 pp. https://doi.org/10.2903/j.efsa.2013.3057. Available online: www.efsa.europa.eu/efsajournal

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

EFSA (European Food Safety Authority), Abdourahime H, Anastassiadou M, Brancato A, Brocca D, Carrasco Cabrera L, De Lentdecker C, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lostia A, Lythgo C, Medina P, Miron I, Molnar T, Nave S, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2019a. Reasoned Opinion on the review of the existing maximum residue levels for sedaxane according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019;17(1):5544, 42 pp. https://doi.org/10.2903/j.efsa.2019.5544

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

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

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

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

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

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

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

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

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

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

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

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

European Commission, 2013. Review report for the active substance sedaxane. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 16 July 2013 in view of the inclusion of sedaxane in Annex I of Council Directive 91/414/EEC. SANCO/10033/2013-Final, 24 January 2017.

European Commission, 2017a. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev. 10.3, 13 June 2017.

European Commission, 2017b. Technical Guideline on the Evaluation of Extraction Efficiency of Residue Analytical Methods. SANTE 2017/10632, Rev. 3, 22 November 2017.

FAO (Food and Agriculture Organization of the United Nations), 2013. Sedaxane. In: Pesticide residues in food – 2012. Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group Evaluations, Part I, Residues. FAO Plant Production and Protection Paper 216.

FAO (Food and Agriculture Organization of the United Nations), 2016. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 3rd Edition. FAO Plant Production and Protection Paper. 225, 298 pp.

France, 2011. Draft assessment report on the active substance sedaxane prepared by the rapporteur Member State France in the framework of Commission Regulation (EU) No 188/2011, May 2011. Available online: www.efsa.europa.eu

France, 2012. Final addendum to the draft assessment report on the active substance sedaxane, compiled by EFSA, June 2012. Available online: www.efsa.europa.eu
France, 2016. Evaluation report on the modification of MRLs for sedaxane in potatoes. May 2016, revised in February 2022 159 pp. Available online: www.efsa.europa.eu
OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: https://www.oecd.org
OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73ENV/JM/MONO(2013) 8, 4 September 2013.

Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
AUC	area under the blood concentration/time curve
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{90}	period required for 90% dissipation (define method of estimation)
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC	gas chromatography
GC-MS	gas chromatography with mass spectrometry
GC-MS/MS	gas chromatography with tandem mass spectrometry
HPLC	high-performance liquid chromatography
HPLC-MS	high-performance liquid chromatography with mass spectrometry
HPLC-MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC	liquid chromatography
LOD	limit of detection
LOQ	limit of quantification
MN	micronucleus (test)
MRL	maximum residue level
MS	Member States
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PHI	preharvest interval
P_{ow}	partition coefficient between n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
QSAR	quantitative structure–activity relationship
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RAC	raw agricultural commodity

RD	residue definition
RMS	rapporteur Member State
S9	rat liver metabolic activation system
SANCO	Directorate-General for Health and Consumers
SEU	southern Europe
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WHO	World Health Organization

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

Crop and/or situation	NEU, SEU, MS or country	F G or I (a)	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days) (d)	Remarks
				Type (b)	Conc. a.s.	Method kind	Range of growth stages & season (c)	Number min–max	Interval between application (days) min–max	g a.s./hL min–max	Water (L/ha) min–max	Rate min–max	Unit		
Potatoes	NEU	F	*Rhizoctonia solani* [RHIZSO] *Helminthosporium solani* [HELMSO]	FS	40 g/L	Seed treatment	BBCH 00	1	–	–	–	20	g a.i./ton tubers	n/a	120 g a.s./ha Sowing rate: 2.8–6 ton/ha Slurry volume: 500–3,000 mL/ton tubers
Potatoes	SEU	F	*Rhizoctonia solani* [RHIZSO] *Helminthosporium solani* [HELMSO]	FS	40 g/L	Seed treatment	BBCH 00	1	–	–	–	20	g a.i./ton tubers	n/a	120 g a.s./ha Sowing rate: 2.8–6 ton/ha Slurry volume: 500–3,000 mL/ton tubers

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; 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, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI – minimum preharvest interval.

Appendix B – List of end points

B.1. Mammalian toxicology

Other toxicological studies (Annex IIA, point 5.8)

Studies performed on metabolites or impurities	**Metabolite CSCD658906 and its glucuronide conjugate** • Major rat metabolite • ToxTree and OECD QSAR Toolbox prediction of positive *in vivo* MN and chromosomal aberration • Bacterial reverse mutation test (Ames test): negative (± S9) • *In vitro* MN test: positive (± S9) • *In vivo* MN test: negative (exposure of the bone marrow to CSCD658906 demonstrated by quantitative plasma analysis) CSCD658906 is unlikely to be genotoxic. Toxicological reference values of sedaxane apply to the metabolite and its glucuronide conjugate. (France, 2016)
	Metabolite CSCD659088 and its glucuronide conjugate • Minor rat metabolite CSCD659088 is unlikely to be genotoxic, based on QSAR analysis and read-across from the parent. Toxicological reference values of sedaxane apply to the metabolite and its glucuronide conjugate, based on read-across from the parent and metabolite 3 (SYN545722). (France, 2016)
	Metabolite CSCD659087 • Minor rat metabolite CSCD659087 is unlikely to be genotoxic based on QSAR and read-across from metabolite CSCD658906 (and supported by metabolite 3) and its toxicity profile is covered by the ADI and ARfD established for sedaxane. (France, 2016)

Classification with regard to toxicological data (Annex IIA, point 10)

Substance:	Sedaxane
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][8] :	Carc. 2, H351 (suspected of causing cancer) (ATP17[9])
Peer review proposal[10] for harmonised classification according to Regulation (EC) No 1272/2008:	Same as above

B.2. Residues in plants

B.2.1. Nature of residues and analytical methods for enforcement purposes in plant commodities

B.2.1.1. Metabolism studies, analytical methods and residue definitions in plants

Primary crops (available studies)	**Crop groups**	**Crops**	**Application**	**Sampling (DAT)**	**Comment/Source**
	Leafy crops	Swiss chards	Seed treatment: 1 × 40 g a.s./ 100 kg seed	14-15 (whole plant)	[phenyl-U-^{14}C]- and [pyrazole-5-^{14}C]-sedaxane (EFSA, 2013)
	Cereals/grass	Wheat	Seed treatment: 1 × 40 g a.s./ 100 kg seed	22 (forage)	
				41 (hay)	
				89 (grain, straw)	
	Pulses/oilseeds	Soyabeans	Seed treatment: 1 × 110 g a.s./ 100 kg seed	16 (forage)	
				61 (hay)	
				Maturity (seeds)	
		Oilseed rape (canola)	Seed treatment: 1 × 9.7 g a.s./ 100 kg seed	85–89 (seeds)	
Rotational crops (available studies)	**Crop groups**	**Crops**	**Application**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Radish	Soyabean, seed treatment (as primary crop), 1 × 100 g a.s./ha	30, 120, 365	[phenyl-U-^{14}C]- and [pyrazole-5-^{14}C]-sedaxane (EFSA, 2013)
		Turnip	Bare soil, 1 × 100 g a.s./ha	29, 90, 300	

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

[9] Commission Delegated Regulation (EU) 2021/849 of 11 March 2021 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. OJ L 188, 28.05.2021, 27-43.

[10] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.

	Leafy crops	Lettuce	Soyabean, seed treatment (as primary crop), 1 × 100 g a.s./ha	30, 151, 365	
			Bare soil, 1 × 100 g a.s./ha	29, 90, 300	
	Cereal (small grain)	Wheat	Soyabean, seed treatment (as primary crop), 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]-sedaxane (EFSA, 2013)
	Baking, brewing, boiling (60 min, 100°C, pH 5)	Yes	
	Sterilisation (20 min, 120°C, pH 6)	Yes	
	Other processing conditions	–	–

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2013)
Rotational crop and primary crop metabolism similar?	Yes	EFSA (2013)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2013)
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, crop groups, LOQs)	High water, high acid, high oil content commodities, dry commodities (EFSA, 2013): • QuEChERS (HPLC–MS/MS) LOQ = 0.01 mg/kg (sum of isomers) Confirmation by monitoring 1 additional MRM transition ILV available for high water content commodities and wheat straw High water, high acid, high oil content commodities, dry commodities for enforcement in routine analysis (EFSA, 2019a); • QuEChERS or QuOil (LC–MS/MS) LOQ = 0.01 mg/kg (high water, high acid, high oil content) LOQ = 0.005 mg/kg (dry commodities) (no ILV provided)	

DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; a.s.: active substance; MRL: maximum residue level; HPLC–MS/MS: high performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; ILV: independent laboratory validation.

B.2.1.2. Stability of residues in plants

Plant products (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/ Source
				Value	Unit		
	High water content	Spinaches, Potatoes	–18	24	Months	Sedaxane *trans*-isomers	EFSA (2013)
						Sedaxane *cis*-isomers	
	High oil content	Soyabeans	–18	24	Months	Sedaxane *trans*-isomers	EFSA (2013)
						Sedaxane *cis*-isomers	
	High protein content	Lentils	–18	24	Months	Sedaxane *trans*-isomers	EFSA (2013)
						Sedaxane *cis*-isomers	
	High starch content	Wheat grain	–18	24	Months	Sedaxane *trans*-isomers	EFSA (2013)
						Sedaxane *cis*-isomers	
	High acid content	Oranges	–18	24	Months	Sedaxane *trans*-isomers	EFSA (2013)
						Sedaxane *cis*-isomers	
	Processed products	Wheat flour, germ, bran	–18	12	Months	Sedaxane *trans*-isomers	EFSA (2013)
						Sedaxane *cis*-isomers	
		Soyabeans meal, hulls, oil	–18	12	Months	Sedaxane *trans*-isomers	EFSA (2013)
						Sedaxane *cis*-isomers	
		Orange pulp, juice, oil	–18	12	Months	Sedaxane *trans*-isomers	EFSA (2013)
						Sedaxane *cis*-isomers	
	Others	Wheat straw	–18	24	Months	Sedaxane *trans*-isomers	EFSA (2013)
						Sedaxane cis-isomers	

B.2.2. Magnitude of residues in plants

B.2.2.1. Summary of residues data from the supervised residue trials

Commodity	Region/ [a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CF[d]
Potatoes	NEU	4 × < 0.010, 0.011, 0.018, 0.041, 0.102	Residue trials on potatoes compliant with intended GAP. Samples collected between 90 and 147 days after seed treatment and sowing. Higher residue levels observed at a longer PHI are underlined.	**0.15**	0.10	0.01	n/a
	SEU	5 × < 0.010, 0.018, 0.020, 0.037	Residue trials on potatoes compliant with intended GAP. Samples collected between 90 and 123 days after seed treatment and sowing. Higher residue levels observed at a longer PHI are underlined.	0.06	0.04	0.01	n/a

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment.
In bold: the intended use in the NEU showed to be more critical for residues and is driving the MRL proposal of 0.15 mg/kg.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment. n/a, not applicable.

B.2.2.2. 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 at 0.83N, the maximum rate (120 g/ha) expected after sowing of treated tubers according to the intended GAP, CSCD465008 and CSAA798670 were the predominant metabolites in all parts of the rotated crops (11–72% TRR) (EFSA, 2013)
Residues in rotational and succeeding crops expected based on field rotational crop study?	Inconclusive	Two field crop rotational studies conducted following bare soil application at 9 and 30 g/ha, and seed treatment of wheat at 10 g/100 kg seed (25 g/ha). Residues of sedaxane, CSAA798670, CSCD465008 and other metabolites below the LOQ of 0.01 mg/kg, except for CSCD465008 in carrot leaves at 60 PBI in the seed treatment study (0.02 mg/kg). These studies do not cover the authorised uses assessed in the MRL review after multiannual applications as well as the intended use on potatoes. Data gap identified in the MRL review (EFSA, 2019a)

TRR: total radioactive residue; LOQ: limit of quantification.

B.2.2.3. Processing factors

Processed commodity	Number of valid studies[a]	Processing Factor (PF)		CF_P[b]	Comment/Source
		Individual values	Median PF		
Potato, flakes	2	0.44; 0.83	0.64	n/a	Tentative[c] France, 2016
Potato, peeled fried chips	2	0.34; 0.42	0.38	n/a	Tentative[c] France, 2016

PF: processing factor.

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur). Since < LOD, residues of the *cis*-isomers of sedaxane were not summed to the residues of the *trans*-isomers of sedaxane in potato flakes and fried chips.

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

(c): A tentative PF is derived based on a limited data set and the shortcoming on the method of analysis validation.

B.3. Residues in livestock

Dietary burden calculation according to OECD, 2013.

Relevant groups	Dietary burden expressed in				Most critical diet[a]	Most critical commodity[b]		Trigger exceeded (Yes/No)	Previous assessment (EFSA, 2019a)
	mg/kg bw per day		mg/kg DM					0.1	Max burden
	Median	Maximum	Median	Maximum				mg/kg DM	mg/kg DM
Cattle (all diets)	0.020	0.026	0.69	0.83	Dairy cattle	Potato	Process waste	Yes	0.04[c]
Cattle (dairy only)	0.020	0.026	0.53	0.66	Dairy cattle	Potato	Process waste	Yes	0.04[c]
Sheep (all diets)	0.023	0.028	0.69	0.83	Ram/ Ewe	Potato	Process waste	Yes	0.02
Sheep (ewe only)	0.023	0.028	0.69	0.83	Ram/ Ewe	Potato	Process waste	Yes	0.02
Swine (all diets)	0.008	0.014	0.36	0.59	Swine (breeding)	Potato	Process waste	Yes	0.01
Poultry (all diets)	0.007	0.010	0.10	0.14	Poultry broiler	Potato	Culls	Yes	0.01
Poultry (layer only)	0.005	0.009	0.08	0.12	Poultry layer	Potato	Culls	Yes	0.01

bw: body weight; DM: dry matter.
(a): When several diets are relevant (e.g. cattle, sheep and poultry 'all diets'), the most critical diet 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'.
(c): Higher dietary burdens for beef (0.92 mg/kg DM) and lactating cattle (0.081 mg/kg DM) derived by JMPR (FAO, 2013) have been considered during the MRL review for the assessment of the CXLs in products of animal origin (EFSA, 2019a).

B.3.1. Nature of residues and methods of analysis in livestock

B.3.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

Livestock (available studies)	Animal	Dose (mg/kg DM/day)	Duration (days)	Comment/Source
	Laying hens	12	14	[phenyl-U-^{14}C]- and [pyrazole-5-^{14}C]-sedaxane (EFSA, 2013)
	Lactating ruminants	20	7	Goat, [phenyl-U-^{14}C]- and [pyrazole-5-^{14}C]-sedaxane (EFSA, 2013)
	Pig	–	–	Not required
	Fish	n/a	n/a	

Time needed to reach a plateau concentration in milk and eggs (days)	Milk: ca. 2 days	EFSA (2013)
	Eggs: ca. 9 days	EFSA (2013)
Metabolism in rat and ruminant similar	Yes	EFSA (2013)
Can a general residue definition be proposed for animals?	Yes	EFSA (2013)
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	EFSA (2019a)
Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs)	Milk, eggs, muscle, fat, liver, kidney: • QuEChERS HPLC–MS/MS, LOQ = 0.01 mg/kg Confirmation by monitoring 1 additional MRM transition ILV available for milk, liver and eggs (EFSA, 2013) No validation data within EURLs (EFSA, 2019a)	

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

B.3.1.2. Stability of residues in livestock

Not available and not required (EFSA, 2019a).

B.3.2. Magnitude of residues in livestock

B.3.2.1. Summary of the residue data from livestock feeding studies

Calculations performed with Animal model 2017[11]

Animal commodity	Residues at the closet feeding level (mg/kg)		Estimated value at 1N level		MRL proposal (mg/kg)	CF	STMR (mg/kg)	HR (mg/kg)
	Mean	Highest	$STMR_{Mo}$ (mg/kg)	HR_{Mo} (mg/kg)				
Cattle (all diets)								
Closest feeding level[(a)]:	0.5	mg/kg DM	0.6	N Beef cattle (highest diet)				
Muscle	0.01	0.01	0.01	0.01	**0.01***			
Fat	0.01	0.01	0.01	0.01	**0.01***			
Liver	0.01	0.01	0.01	0.01	**0.01***			
Kidney	0.01	0.01	0.01	0.01	**0.01***			

[11] https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en

Animal commodity	Residues at the closet feeding level (mg/kg)		Estimated value at 1N level		MRL proposal (mg/kg)	CF	STMR (mg/kg)	HR (mg/kg)
	Mean	Highest	$STMR_{Mo}$ (mg/kg)	HR_{Mo} (mg/kg)				
Cattle (dairy only)								
Closest feeding level[(a)]:	0.5	mg/kg DM	0.8	N Dairy cattle				
Milk[(b)]	0.01	0.01	0.01	0.01	**0.01***			
Sheep (all diets)								
Closest feeding level[(a)]:	0.5	mg/kg DM	0.6	N Ram/Ewe (highest diet)				
Muscle	0.01	0.01	0.01	0.01	**0.01***			
Fat	0.01	0.01	0.01	0.01	**0.01***			
Liver	0.01	0.01	0.01	0.01	**0.01***			
Kidney	0.01	0.01	0.01	0.01	**0.01***			
Sheep (dairy only)								
Closest feeding level[(a)]:	0.5	mg/kg DM	0.6	N Ewe				
Milk[(b)]	0.01	0.01	0.01	0.01	**0.01***			
Swine								
Closest feeding level[(a)]:	0.5	mg/kg DM	0.8	N Breeding (highest diet)				
Muscle	0.01	0.01	0.01	0.01	**0.01***			
Fat	0.01	0.01	0.01	0.01	**0.01***			
Liver	0.01	0.01	0.01	0.01	**0.01***			
Kidney	0.01	0.01	0.01	0.01	**0.01***			

MRL: maximum residue level; CF: conversion factor for enforcement to risk assessment residue definition; STMR: supervised trials median residue; HR: highest residue.
*: Indicates that the MRL proposal is at the limit of quantification (LOQ).
(a): Closest feeding level and N dose rate related to the maximum dietary burden.
(b): The mean residue level for milk was recalculated at the 1N rate for the median dietary burden.

B.4. Consumer risk assessment

ARfD	0.3 mg/kg bw (European Commission, 2013)
Highest IESTI, according to EFSA PRIMo	Potatoes: 5% of ARfD (UK infant diet)
Assumptions made for the calculations	The calculation is based on the highest residue level expected in raw agricultural commodity under assessment (potatoes). Calculations performed with PRIMo revision 3.1

ADI	0.11 mg/kg bw per day (European Commission, 2013)
Highest IEDI, according to EFSA PRIMo	0.8% ADI (NL toddler diet) Contribution of crop assessed: Potatoes: 0.05% of ADI (PT general diet)
Assumptions made for the calculations	The calculation is based on the median residue level derived for raw agricultural commodities in the framework of the MRL review (EFSA, 2019a) and in the present MRL application on potatoes. The contributions of commodities where no GAP and no safe CXL was reported in the framework of the MRL review were not included in the calculation. Calculations performed with PRIMo revision 3.1

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

B.5. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Sedaxane (sum of isomers)				
0211000	Potatoes	0.02	0.15	The MRL proposal reflects the more critical residue situation of the NEU use. The SEU use is sufficiently supported. Risk for consumers unlikely.

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

Appendix C – Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Sedaxane (sum of isomers)

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw/day):	0.11	ARfD (mg/kg bw):	0.3
Source of ADI:	European	Source of ARfD:	European Commision
Year of evaluation:	2013	Year of evaluation:	2013

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

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

Comments: MRLs according to Reg. (EU) 2020/785 excpet the intended use on potatoes

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	0.78%	NL toddler	0.86	0.54%	Milk: Cattle	0.06%	Maize/corn	0.05%	Sugar beet roots		0.8%
	0.47%	UK infant	0.52	0.35%	Milk: Cattle	0.03%	Potatoes	0.02%	Wheat		0.5%
	0.41%	NL child	0.45	0.22%	Milk: Cattle	0.08%	Sugar beet roots	0.04%	Wheat		0.4%
	0.38%	FR toddler 2 3 yr	0.42	0.27%	Milk: Cattle	0.03%	Wheat	0.03%	Sugar beet roots		0.4%
	0.36%	FR child 3 15 yr	0.40	0.21%	Milk: Cattle	0.04%	Wheat	0.03%	Sugar beet roots		0.4%
	0.32%	UK toddler	0.36	0.19%	Milk: Cattle	0.04%	Wheat	0.03%	Potatoes		0.3%
	0.28%	DE child	0.31	0.18%	Milk: Cattle	0.04%	Wheat	0.02%	Potatoes		0.3%
	0.28%	DK child	0.31	0.11%	Milk: Cattle	0.05%	Rye	0.04%	Wheat		0.3%
	0.24%	RO general	0.26	0.11%	Milk: Cattle	0.05%	Wheat	0.03%	Potatoes		0.2%
	0.23%	SE general	0.26	0.11%	Milk: Cattle	0.04%	Bovine: Muscle/meat	0.04%	Potatoes		0.2%
	0.23%	ES child	0.25	0.11%	Milk: Cattle	0.04%	Wheat	0.02%	Potatoes		0.2%
	0.22%	GEMS/Food G11	0.24	0.07%	Milk: Cattle	0.04%	Potatoes	0.03%	Soyabeans		0.2%
	0.21%	DE general	0.23	0.11%	Milk: Cattle	0.04%	Sugar beet roots	0.02%	Wheat		0.2%
	0.21%	DE women 14-50 yr	0.23	0.11%	Milk: Cattle	0.04%	Sugar beet roots	0.02%	Wheat		0.2%
	0.21%	GEMS/Food G15	0.23	0.06%	Milk: Cattle	0.04%	Wheat	0.03%	Potatoes		0.2%
	0.21%	GEMS/Food G10	0.23	0.05%	Milk: Cattle	0.04%	Wheat	0.03%	Soyabeans		0.2%
	0.20%	GEMS/Food G07	0.22	0.06%	Milk: Cattle	0.04%	Wheat	0.03%	Potatoes		0.2%
	0.20%	FR infant	0.22	0.15%	Milk: Cattle	0.02%	Potatoes	0.01%	Sugar beet roots		0.2%
	0.20%	GEMS/Food G08	0.22	0.05%	Milk: Cattle	0.04%	Wheat	0.04%	Potatoes		0.2%
	0.18%	NL general	0.19	0.08%	Milk: Cattle	0.03%	Sugar beet roots	0.02%	Potatoes		0.2%
	0.18%	GEMS/Food G06	0.19	0.07%	Wheat	0.02%	Milk: Cattle	0.02%	Potatoes		0.2%
	0.12%	IE adult	0.13	0.04%	Milk: Cattle	0.02%	Wheat	0.02%	Potatoes		0.1%
	0.11%	ES adult	0.12	0.04%	Milk: Cattle	0.02%	Wheat	0.01%	Potatoes		0.1%
	0.11%	LT adult	0.12	0.04%	Milk: Cattle	0.03%	Potatoes	0.01%	Rye		0.1%
	0.10%	PT general	0.11	0.05%	Potatoes	0.04%	Wheat	0.01%	Rice		0.1%
	0.10%	FR adult	0.11	0.04%	Milk: Cattle	0.02%	Wheat	0.01%	Sugar beet roots		0.1%
	0.10%	DK adult	0.11	0.05%	Milk: Cattle	0.01%	Potatoes	0.01%	Wheat		0.1%
	0.09%	IT toddler	0.09	0.06%	Wheat	0.01%	Other cereals	0.01%	Potatoes		0.1%
	0.08%	UK adult	0.09	0.03%	Milk: Cattle	0.02%	Wheat	0.01%	Potatoes		0.1%
	0.08%	UK vegetarian	0.09	0.03%	Milk: Cattle	0.02%	Wheat	0.01%	Potatoes		0.1%
	0.07%	FI 3 yr	0.08	0.04%	Potatoes	0.01%	Wheat	0.01%	Rye		0.1%
	0.06%	FI 6 yr	0.07	0.04%	Potatoes	0.01%	Wheat	0.01%	Rye		0.1%
	0.06%	IE child	0.06	0.03%	Milk: Cattle	0.01%	Wheat	0.01%	Potatoes		0.1%
	0.05%	IT adult	0.06	0.04%	Wheat	0.01%	Other cereals	0.01%	Potatoes		0.1%
	0.03%	PL general	0.03	0.03%	Potatoes	0.00%	Beans	0.00%	Peas		0.0%
	0.02%	FI adult	0.03	0.01%	Potatoes	0.01%	Rye	0.00%	Wheat		0.0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Sedaxane (sum of isomers) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
5%	Potatoes	0.15 / 0.1	15
0.4%	Milk: Cattle	0.01 / 0.01	1.2
0.1%	Sweet corn	0.01 / 0.01	0.43
0.08%	Milk: Goat	0.01 / 0.01	0.24
0.06%	Beans	0.01 / 0.01	0.18
0.06%	Poultry: Muscle/meat	0.01 / 0.01	0.17
0.05%	Wheat	0.01 / 0.01	0.14
0.04%	Rice	0.01 / 0.01	0.13
0.04%	Eggs: Chicken	0.01 / 0.01	0.12
0.04%	Swine: Muscle/meat	0.01 / 0.01	0.12
0.03%	Bovine: Liver	0.01 / 0.01	0.08
0.02%	Bovine: Edible offals (other than liver and kidney)	0.01 / 0.01	0.07
0.02%	Bovine: Muscle/meat	0.01 / 0.01	0.07
0.02%	Other farmed animals: Muscle/meat	0.01 / 0.01	0.07
0.02%	Maize/corn	0.01 / 0.01	0.07

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1.0%	Potatoes	0.15 / 0.1	3.0
0.1%	Milk: Cattle	0.01 / 0.01	0.39
0.06%	Milk: Goat	0.01 / 0.01	0.18
0.05%	Sweet corn	0.01 / 0.01	0.16
0.05%	Milk: Sheep	0.01 / 0.01	0.15
0.04%	Poultry: Muscle	0.01 / 0.01	0.12
0.03%	Rice	0.01 / 0.01	0.09
0.03%	Wheat	0.01 / 0.01	0.08
0.02%	Beans	0.01 / 0.01	0.07
0.02%	Lentils	0.01 / 0.01	0.06
0.02%	Bovine: Muscle	0.01 / 0.01	0.06
0.02%	Other farmed animals: Muscle/meat	0.01 / 0.01	0.06
0.02%	Soyabeans	0.01 / 0.01	0.06
0.02%	Rye	0.01 / 0.01	0.05
0.02%	Swine: Muscle/meat	0.01 / 0.01	0.05

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
3%	Potatoes / fried	0.15 / 0.1	9.3
0.37%	Sugar beets (root) / sugar	0.01 / 0.12	1.1
0.20%	Potatoes / dried (flakes)	0.15 / 0.05	0.59
0.08%	Maize / oil	0.01 / 0.25	0.23
0.04%	Wheat / milling (flour)	0.01 / 0.01	0.12
0.03%	Lentils / boiled	0.01 / 0.01	0.08
0.02%	Peas / canned	0.01 / 0	0.07
0.02%	Rice / milling (polishing)	0.01 / 0	0.06
0.02%	Wheat / milling (wholemeal)-baking	0.01 / 0.01	0.06
0.02%	Millet / boiled	0.01 / 0	0.05
0.02%	Buckwheat / bulgur and grits	0.01 / 0.01	0.05
0.01%	Soyabeans / soya drink	0.01 / 0.01	0.04
0.01%	Rye / boiled	0.01 / 0.01	0.04
0.01%	Oat / boiled	0.01 / 0.01	0.04
0.01%	Buckwheat / boiled	0.01 / 0.01	0.04

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.146%	Sugar beets (root) / sugar	0.01 / 0.12	0.44
0.042%	Maize / oil	0.01 / 0.25	0.13
0.028%	Potatoes / chips	0.15 / 0.01	0.08
0.024%	Barley / beer	0.01 / 0	0.07
0.024%	Beans / canned	0.01 / 0.01	0.07
0.019%	Potatoes / dried (flakes)	0.15 / 0.05	0.06
0.015%	Wheat / bread/pizza	0.01 / 0.01	0.04
0.013%	Rice / milling (polishing)	0.01 / 0	0.04
0.013%	Wheat / pasta	0.01 / 0.01	0.04
0.012%	Wheat / bread (wholemeal)	0.01 / 0.01	0.03
0.009%	Peas / canned	0.01 / 0	0.03
0.008%	Millet / boiled	0.01 / 0	0.02
0.005%	Oat / boiled	0.01 / 0.01	0.02

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Sedaxane (sum of isomers) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/source	Input value (mg/kg)	Comment/source
Risk assessment residue definition: Sedaxane (sum of isomers)				
Barley straw	0.01	STMR (EFSA, 2019a)	0.01	HR (EFSA, 2019a)
Beet, sugar tops	0.01	STMR (EFSA, 2019a)	0.01	HR (EFSA, 2019a)
Corn, field stover (fodder)	0.01	STMR (EFSA, 2019a)	0.01	HR (EFSA, 2019a)
Corn, pop stover (fodder)	0.01	STMR (EFSA, 2019a)	0.01	HR (EFSA, 2019a)
Oat straw	0.01	STMR (EFSA, 2019a)	0.01	HR (EFSA, 2019a)
Rye straw	0.01	STMR (EFSA, 2019a)	0.01	HR (EFSA, 2019a)
Triticale straw	0.01	STMR (EFSA, 2019a)	0.01	HR (EFSA, 2019a)
Wheat straw	0.01	STMR (EFSA, 2019a)	0.01	HR (EFSA, 2019a)
Potato culls	0.01	STMR	0.10	HR
Barley grain	0.01	STMR (EFSA, 2019a)	0.01	STMR (EFSA, 2019a)
Corn, field (Maize) grain	0.01	STMR (EFSA, 2019a)	0.01	STMR (EFSA, 2019a)
Corn, pop grain	0.01	STMR (EFSA, 2019a)	0.01	STMR (EFSA, 2019a)
Oat grain	0.01	STMR (EFSA, 2019a)	0.01	STMR (EFSA, 2019a)
Rye grain	0.01	STMR (EFSA, 2019a)	0.01	STMR (EFSA, 2019a)
Triticale grain	0.01	STMR (EFSA, 2019a)	0.01	STMR (EFSA, 2019a)
Wheat grain	0.01	STMR (EFSA, 2019a)	0.01	STMR (EFSA, 2019a)
Beet, sugar dried pulp	0.01	STMR[(a)] (EFSA, 2019a)	0.01	STMR[(a)] (EFSA, 2019a)
Beet, sugar ensiled pulp	0.01	STMR[(a)] (EFSA, 2019a)	0.01	STMR[(a)] (EFSA, 2019a)
Beet, sugar molasses	0.01	STMR[(a)] (EFSA, 2019a)	0.01	STMR[(a)] (EFSA, 2019a)
Brewer's grain dried	0.01	STMR[(a)] (EFSA, 2019a)	0.01	STMR[(a)] (EFSA, 2019a)
Corn, field milled by-products	0.01	STMR[(a)] (EFSA, 2019a)	0.01	STMR[(a)] (EFSA, 2019a)
Corn, field hominy meal	0.01	STMR[(a)] (EFSA, 2019a)	0.01	STMR[(a)] (EFSA, 2019a)
Corn, field gluten feed	0.01	STMR[(a)] (EFSA, 2019a)	0.01	STMR[(a)] (EFSA, 2019a)
Corn, field gluten, meal	0.01	STMR[(a)] (EFSA, 2019a)	0.01	STMR[(a)] (EFSA, 2019a)
Distiller's grain dried	0.01	STMR[(a)] (EFSA, 2019a)	0.01	STMR[(a)] (EFSA, 2019a)
Potato process waste	0.20	STMR × default PF (20)[(b)]	0.20	STMR × default PF (20)[(b)]
Potato dried pulp	0.38	STMR × default PF (38)[(b)]	0.38	STMR × default PF (38)[(b)]
Wheat gluten meal	0.01	STMR[(a)] (EFSA, 2019a)	0.01	STMR[(a)] (EFSA, 2019a)
Wheat milled by-products	0.01	STMR[(a)] (EFSA, 2019a)	0.01	STMR[(a)] (EFSA, 2019a)

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

(a): For maize/corn, wheat and sugar beet by-products, the default processing factor was not applied because sedaxane residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected (EFSA, 2019a).

(b): In the absence of processing factors supported by data, default processing factors (in bracket) were respectively included in the calculation to consider the potential concentration of residues in these commodities.

D.2. Consumer risk assessment

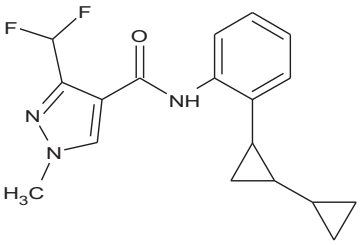
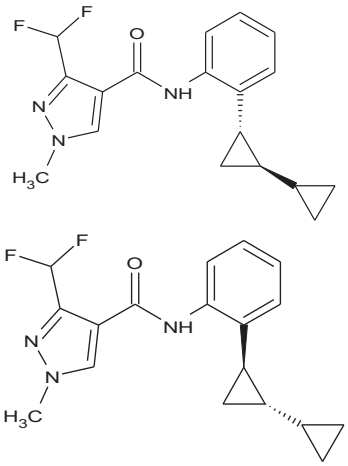
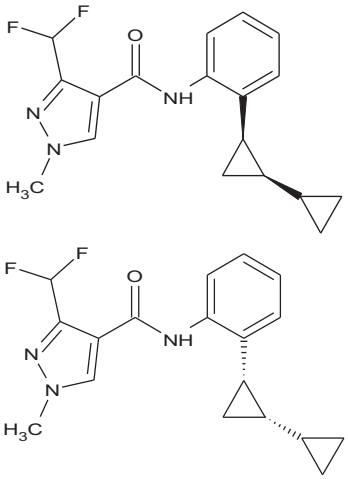
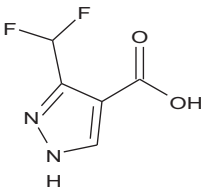
Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment[(a)]
Risk assessment residue definition: Sedaxane (sum of isomers)						
Potatoes	**0.15**	**Intended**	**0.01**	**STMR-RAC**	**0.10**	**HR-RAC**
Sweet corn	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Beans	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	STMR-RAC
Lentils	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	STMR-RAC
Peas	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	STMR-RAC
Lupins/lupini beans	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	STMR-RAC
Other pulses	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Rapeseeds/ canola seeds	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	STMR-RAC
Soyabeans	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	STMR-RAC
Barley	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	STMR-RAC
Buckwheat and other pseudo-cereals	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	STMR-RAC
Maize/corn	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	STMR-RAC
Common millet/p. millet	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	STMR-RAC
Oat	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	STMR-RAC
Rice	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	STMR-RAC
Rye	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	STMR-RAC
Sorghum	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	STMR-RAC
Wheat	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	STMR-RAC
Other cereals	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Sugar beet roots	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Swine: Muscle/meat	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Swine: Fat tissue	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Swine: Liver	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Swine: Kidney	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Swine: Edible offal (other than liver and kidney)	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Swine: Other products	0.01	FAO (2013)	0.01	STMR-RAC	0.01	HR-RAC
Bovine: Muscle/meat	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Bovine: Fat tissue	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Bovine: Liver	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Bovine: Kidney	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Bovine: Edible offal (other than liver and kidney)	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Bovine: Other products	0.01	FAO (2013)	0.01	STMR-RAC	0.01	HR-RAC
Sheep: Muscle/meat	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Sheep: Fat tissue	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Sheep: Liver	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Sheep: Kidney	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC

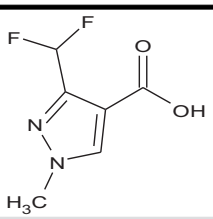
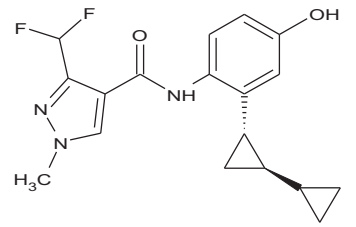
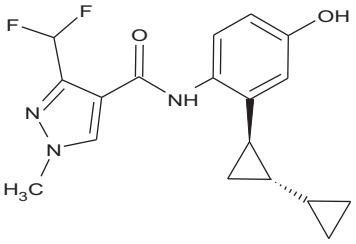
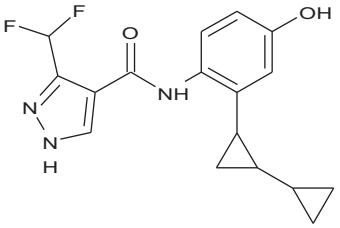
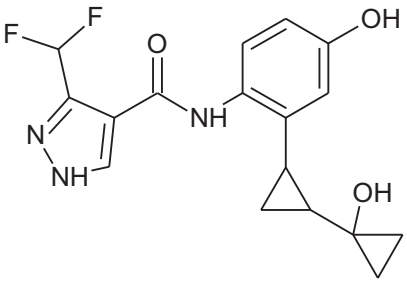
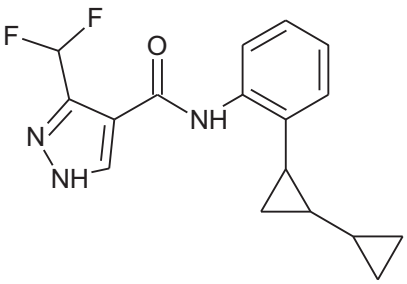
Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment[(a)]
Sheep: Edible offal (other than liver and kidney)	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Sheep: other products	0.01	FAO (2013)	0.01	STMR-RAC	0.01	HR-RAC
Goat: Muscle/meat	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Goat: Fat tissue	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Goat: Liver	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Goat: Kidney	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Goat: Edible offal (other than liver and kidney)	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Goat: other products	0.01	FAO (2013)	0.01	STMR-RAC	0.01	HR-RAC
Equine: Muscle/meat	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Equine: Fat tissue	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Equine: Liver	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Equine: Kidney	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Equine: Edible offal (other than liver and kidney)	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Equine: Other products	0.01	FAO (2013)	0.01	STMR-RAC	0.01	HR-RAC
Poultry: Muscle/meat	0.01	FAO (2013)	0.01	STMR-RAC	0.01	HR-RAC
Poultry: Fat tissue	0.01	FAO (2013)	0.01	STMR-RAC	0.01	HR-RAC
Poultry: Liver	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Poultry: Kidney	0.01	FAO (2013)	0.01	STMR-RAC	0.01	HR-RAC
Poultry: Edible offal (other than liver and kidney)	0.01	FAO (2013)	0.01	STMR-RAC	0.01	HR-RAC
Poultry: Other products	0.01	FAO (2013)	0.01	STMR-RAC	0.01	HR-RAC
Other farmed animals: Muscle/meat	0.01	FAO (2013)	0.01	STMR-RAC	0.01	HR-RAC
Other farmed animals: Fat tissue	0.01	FAO (2013)	0.01	STMR-RAC	0.01	HR-RAC
Other farmed animals: Liver	0.01	FAO (2013)	0.01	STMR-RAC	0.01	HR-RAC
Other farmed animals: Kidney	0.01	FAO (2013)	0.01	STMR-RAC	0.01	HR-RAC
Other farmed animals: Edible offal (other than liver and kidney)	0.01	FAO (2013)	0.01	STMR-RAC	0.01	HR-RAC
Other farmed animals: Other products	0.01	FAO (2013)	0.01	STMR-RAC	0.01	HR-RAC
Milk: Cattle	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	STMR-RAC
Milk: Sheep	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	STMR-RAC
Milk: Goat	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	STMR-RAC
Milk: Horse	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	STMR-RAC
Milk: Others	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	STMR-RAC
Eggs: Chicken	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Eggs: Duck	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Eggs: Goose	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC

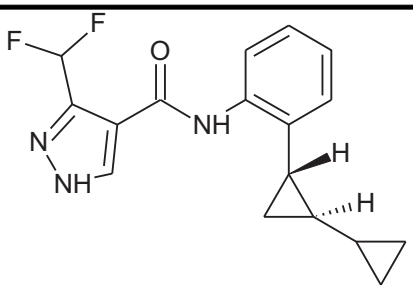
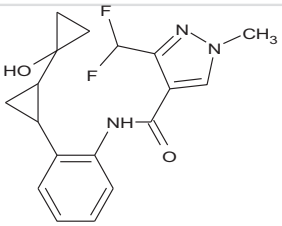
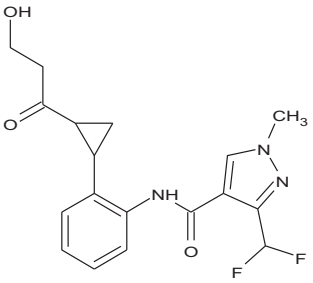
Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment[(a)]
Eggs: Quail	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC
Eggs: Others	0.01	EFSA (2019a)	0.01	STMR-RAC	0.01	HR-RAC

STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; PeF: Peeling factor.
(a): Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.

Appendix E – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
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	

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
CSAA798670	3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxylic acid FC(F)c1nn(C)cc1C(=O)O RLOHOBNEYHBZID-UHFFFAOYSA-N	
CSCD658906 (SYN545860)	*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 (SYN546075)	*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	
CSCD659088 (SYN551569)	3-(difluoromethyl)-N-{4-hydroxy-2-[1′-hydroxy[1,1′-bi(cyclopropan)]-2-yl]phenyl}-1H-pyrazole-4-carboxamide *(unstated stereochemistry)* O = C(Nc1ccc(O)cc1C1CC1C1(O)CC1)c1c[NH]nc1C(F)F BNTOQUZBYNMNCT-UHFFFAOYSA-N	
Metabolite 3 (SYN545722)	N-{2-[[1,1′-bi(cyclopropan)]-2-yl]phenyl}-3-(difluoromethyl)-1H-pyrazole-4-carboxamide *(Unstated stereochemistry)* O = C(Nc1ccccc1C1CC1C1CC1)c1c[NH]nc1C(F)F GUSVIGSBDHVWDF-UHFFFAOYSA-N	

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
CSCD667584	N-{2-[(1R,2S)-[1,1′-bi(cyclopropan)]-2-yl]phenyl}-3-(difluoromethyl)-1H-pyrazole-4-carboxamide O = C(Nc1ccccc1[C@H]1C[C@@H]1C1CC1)c1c[NH]nc1C(F)F GUSVIGSBDHVWDF-VXGBXAGGSA-N	
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): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116563, 15 June 2020).
(c): ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C25H41, Build 121153, 22 March 2021).