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## Modification of the existing maximum residue level for oxathiapiprolin in kales/radish leaves

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### Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant DLR-Rheinpfalz submitted a request to the competent national authority in Germany to modify the existing maximum residue level (MRL) for the active substance oxathiapiprolin in kales, with the specific intention to derive an MRL in radish leaves (classified under the subgroup of kales), based on an intended NEU use on radishes. The residue data in radish leaves submitted in support of the request were found to be sufficient to derive MRL proposal for this commodity which could be applicable also for kales. Adequate analytical methods for enforcement are available to control the residues of oxathiapiprolin in radishes at the validated LOQ of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the long-term intake of residues resulting from the use of oxathiapiprolin on radishes according to the reported agricultural practice is unlikely to present a risk to consumer health.

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## Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, DLR-Rheinpfalz submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance oxathiapiprolin in kales with the specific intention to derive an MRL in radish leaves (classified under the subgroup of kales). In fact, the amendment of the existing MRL in kales is triggered by an intended use on radishes and residues occurring in radish leaves. According to Part B of the Annex I of the Commission Regulation (EU) 2018/62 radish leaves are classified under the subgroup of kales and consequently the MRL derived for kales applies to radish leaves. 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 1 October 2021. To accommodate for the intended use of oxathiapiprolin on radishes and the residues occurring in radish leaves, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) to 1.5 mg/kg in kales.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

Based on the conclusions derived by EFSA in the framework of Regulation (EC) No 1107/2009, the data evaluated under previous MRLs assessments, and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of oxathiapiprolin following foliar treatment in crops belonging to fruit, leafy and root crop groups has been investigated in the European Union (EU) pesticides peer review and following soil treatment in the framework of a previous EFSA MRL assessment. The main residue in most primary crops following foliar treatment was parent oxathiapiprolin, with exception of mature grapes, where metabolites containing the pyrazole moiety (IN-E8S72 and IN-WR791) were major residues. Following soil treatment, the main components of the total radioactive residue (TRR) in primary crops were metabolites IN-E8S72, IN-WR791, IN-RZB20 and IN-RZB21/IN-RZD74. The actual amounts, however, were low, except for metabolite IN-WR791 in courgettes.

The metabolism of oxathiapiprolin in rotational crops was investigated in the EU pesticides peer review and was found to be different; residues were exclusively composed of metabolites containing pyrazole moiety (IN-E8S72 and its conjugate IN-SXS67). In the framework of a previous assessment, new metabolism studies were evaluated and the conclusions of the peer review were confirmed. The main metabolites present in rotational crops were IN-E8S72 (and IN-SXS67), IN-WR791, IN-RZB20 and IN-RZB21/IN-RZD74.

Studies investigating the effect of processing on the nature of oxathiapiprolin (hydrolysis studies) demonstrated that the active substance is stable.

Based on the metabolic pattern identified in the metabolism studies, hydrolysis studies and the toxicological significance of metabolites, the residue definitions for plant products (raw and processed) were proposed by the peer review as 'oxathiapiprolin' for enforcement and risk assessment. The same residue definition is implemented in the Regulation (EC) No 396/2005.

EFSA concluded that for the crops assessed in this application, metabolism of oxathiapiprolin in primary and in rotational crops, and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definitions are applicable.

Sufficiently validated analytical methods are available to quantify residues in the commodities under consideration, according to the enforcement residue definition, at or above the validated limit of quantification (LOQ) of 0.01 mg/kg.

The available residue trials on radish leaves are sufficient to derive MRL proposal of 1.5 mg/kg for this commodity which could be applicable also for kales. The data on residues in radish roots were also provided but were below the LOQ, confirming the existing EU MRL.

Radishes can be grown in a crop rotation. Considering the highest residue levels observed in crops from various field studies, it can be concluded that residues of oxathiapiprolin will be below 0.01 mg/kg in food commodities and below 0.05 mg/kg in feed commodities grown in a 30-day crop rotation. However, for metabolites IN-E8S72, IN-SXS67 and IN-WR791 it cannot be excluded that significant residues might occur in food or feed items. In order to avoid residues in crops that have relatively short vegetation period and are rotated within short plant-back intervals, as in a case of radishes, Member States granting authorisations of oxathiapiprolin might consider applying risk mitigation measures.

Specific studies investigating the magnitude of oxathiapiprolin residues in processed commodities are not required, as exposure from the consumption of radish leaves (raw or processed) is insignificant.

Residues of oxathiapiprolin in commodities of animal origin were not assessed since radishes are normally not fed to livestock. However, as the MRL is proposed for kales, which is a livestock feeding item, the Member States granting authorisations of oxathiapiprolin on kales resulting in residues above the LOQ, shall assess the potential carry-over of residues in kales into food commodities of animal origin.

The toxicological profile of oxathiapiprolin was assessed in the framework of the EU pesticides peer review under Regulation (EC) No 1107/2009 and the data were sufficient to derive an acceptable daily intake (ADI) of 0.14 mg/kg body weight (bw) per day. An acute reference dose (ARFD) was deemed unnecessary.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The long-term exposure assessment was performed, taking into account the STMR value for kales as derived from residue trials on radishes and residues occurring in radish leaves, assessed in this application and STMR values as derived in previous EFSA assessments. For remaining crops, the existing EU MRLs were used as input values. The consumption data for such a minor crop as radish leaves are not available and therefore calculations were performed based on the consumption of kales, thus representing a more conservative scenario. The estimated long-term dietary intake accounted for a maximum of 3% of the ADI (NL toddler diet). The contribution of residues expected in radish leaves/kales to the overall long-term exposure is negligible.

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

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 <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
<b>Enforcement residue definition: Oxathiapiprolin</b>				
0243020	Kales (MRL applicable for radish leaves 0243020-008)	0.01*	Kales/Radish leaves 1.5 (further risk management consideration)	<p>The submitted residue data on radish leaves are sufficient to derive an MRL proposal for this commodity, which could be applicable also for kales, on the basis of the intended NEU use on radishes. The residue data on radish roots indicate no residues above the LOQ of 0.01 mg/kg.</p> <p>Risk Managers' considerations are needed on how to implement the MRL since radish leaves are included in part B of Annex I of the Commission Regulation (EU) 2018/62 and classified under the subgroup of kales, referred to in the Part A of Annex I.</p> <p>It is further noted that for kales there are currently no reported uses in the EU, which would require the modification of the existing EU MRL. Should a new use on kales be applied for, the MSs granting authorisations would need to investigate the magnitude of residues in food commodities of animal origin.</p> <p>Risk for consumers unlikely.</p>

MRL: maximum residue level; NEU: northern Europe.

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

\*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).

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## Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for oxathiapiprolin in kales.

The amendment of existing MRL in kales is triggered by an intended NEU use on radishes and residues occurring in radish leaves. It is noted that there are currently no registered EU uses or import tolerances on kales, and the existing EU MRL is set at the limit of quantification of 0.01 mg/kg. According to Part B of the Annex I of Commission Regulation (EU) 2018/62<sup>1</sup> radish leaves are classified under the subgroup of kales and consequently the MRL derived for kales applies to radish leaves. The detailed description of the intended use of oxathiapiprolin on radishes, is reported in Appendix A.

Oxathiapiprolin is the ISO common name for 1-(4-{4-[(5*RS*)-5-(2,6-difluorophenyl)-4,5-dihydro-1,2-oxazol-3-yl]-1,3-thiazol-2-yl}-1-piperidyl)-2-[5-methyl-3-(trifluoromethyl)-1*H*-pyrazol-1-yl]ethanone (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Oxathiapiprolin was evaluated in the framework of Regulation (EC) No 1107/2009<sup>2</sup> with Ireland designated as rapporteur Member State (RMS) for the representative uses as a foliar treatment on grapes, potatoes, tomatoes and aubergines. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (2016). Oxathiapiprolin was approved<sup>3</sup> for the use as fungicide on 3 March 2017.

The EU MRLs for oxathiapiprolin are established in Annex II of Regulation (EC) No 396/2005<sup>4</sup>. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) is not foreseen as proposals for setting MRLs covering the representative uses according to good agricultural practices (GAP) in the EU were assessed during the approval of oxathiapiprolin under Regulation (EC) No 1107/2009 and implemented in Regulation in accordance with Article 11(2) of the Regulation (EC) 1107/2009. So far EFSA has issued two reasoned opinions on the modification of MRLs for oxathiapiprolin (EFSA, 2019b, 2020) and provided a scientific support for preparing an EU position in the 51st Session of the Codex Committee on Pesticide Residues (CCPR) (EFSA, 2019c). The proposals from these reasoned opinions have been considered in recent MRL regulations.<sup>5</sup>

In accordance with Article 6 of Regulation (EC) No 396/2005, DLR-Rheinpfalz submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to modify the existing MRL for the active substance oxathiapiprolin in kales with the particular intention to derive an MRL in radish leaves. 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 EFSA on 1 October 2021. To accommodate for the intended use of oxathiapiprolin on radishes, the EMS proposed to raise the existing MRL for kales from the limit of quantification (LOQ) to 1.5 mg/kg in order to derive a new MRL in radish leaves (classified under the subgroup of kales).

EFSA based its assessment on the evaluation report submitted by the EMS (Germany, 2021), the DAR and its addendum (Ireland, 2015, 2016) prepared under Regulation (EC) 1107/2009, the Commission review report on oxathiapiprolin (European Commission, 2016), the conclusion on the peer review of the pesticide risk assessment of the active substance oxathiapiprolin (EFSA, 2016), as well as the conclusions from previous EFSA opinions on oxathiapiprolin (EFSA, 2019b,c, 2020).

For this application, the data requirements established in Regulation (EU) No 283/2013<sup>6</sup> and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 2010, 2013, 2017, 2020, 2021; OECD, 2007a–h, 2008a,b, 2009a,b, 2011,

<sup>1</sup> Commission Regulation (EU) 2018/62 of 17 January 2018 replacing Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council. C/2018/0138. OJ L 18, 23.1.2018, p. 1–73.

<sup>2</sup> 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.

<sup>3</sup> Commission Implementing Regulation (EU) 2017/239 of 10 February 2017 approving the active substance oxathiapiprolin in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 C/2017/0694 OJ L 36, 11.2.2017, p. 39–42.

<sup>4</sup> 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.

<sup>5</sup> For an overview of all MRL Regulations on this active substance, please consult: <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as>

<sup>6</sup> Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, 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. OJ L 93, 3.4.2013, p. 1–84.

2013, 2016, 2018). 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<sup>7</sup>.

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 (Germany, 2021) 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. Residues in plants

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

#### 1.1.1. Nature of residues in primary crops

In the framework of the EU pesticides peer review, the metabolism of oxathiapiprolin in primary crops belonging to fruit (grapes), leaf (lettuces) and root (potatoes) crops has been investigated following foliar application (3 applications of 70 g a.s./ha; radiolabelling in pyrazole and thiazole moiety) (EFSA, 2016). Due to the low total radioactive residue (TRR) at harvest, identification of the residues was not attempted in potato tubers. In grapes, lettuce and potato leaves, oxathiapiprolin was observed as the major component of the TRR, accounting for 25–85%. In contrast, in mature grapes, 2 months after the last application, the main components were identified as metabolites IN-E8S72 and IN-WR791, representing 14.4% and 18.6% TRR (0.06 mg/kg), respectively. The peer review concluded that in primary crops the metabolism proceeds by hydroxylation of the molecule at the phenyl ring, the cleavage of the bond between the piperidine and pyrazole rings to form the thiazole-containing metabolites (IN-Q9L80 and IN-QPS10) or the pyrazole metabolites (IN-E8S72, IN-KJ552, IN-R7B20 and IN-WR791). Further conjugation leads to additional glucoside-conjugated metabolites (IN-SXS67) (EFSA, 2016). It is noted that oxathiapiprolin is a 1:1 racemic mixture of two enantiomers and that according to chiral analysis performed during the metabolism studies of grapes and lettuce, overall net retention of stereochemistry was maintained throughout the study.

Additional studies were evaluated by EFSA assessment in 2019, where the nature of oxathiapiprolin was investigated after soil application (600 g a.s./ha; radiolabelling in pyrazole and isoxazoline moiety) in root (potatoes), leafy (lettuces) and fruit (courgettes) crops (EFSA, 2019b). The main components of the TRR in immature and mature edible plant parts (potatoes, lettuce and courgettes) exceeding the trigger value of 10% were metabolites IN-E8S72, IN-WR791, IN-RZB20 and IN-RZB21/IN-RZD74. The actual amounts, however, were low, being above 0.01 mg/kg only for metabolite IN-WR791 in courgettes (0.016 mg/kg). All metabolites identified have also been observed in rotational crops and, to a lesser extent, in primary crops following foliar application (EFSA, 2016, 2019b).

For the intended foliar use on radishes, the metabolic behaviour in roots and leaves, is sufficiently elucidated.

#### 1.1.2. Nature of residues in rotational crops

The intended use for this application is on radishes, which can be grown in rotation with other crops.

According to the soil degradation studies, the maximum  $DT_{90}$  value of oxathiapiprolin from field studies is 682 days. The maximum  $DT_{90}$  values for relevant soil metabolites of oxathiapiprolin are as follows:  $DT_{90lab}$  of 1,585 days for metabolite IN-E8S72, 2,266 days for metabolite IN-QPS10 and 565 days for metabolite IN-RAB06 in the absence of field data, and  $DT_{90field}$  of 632 days for metabolite IN-RDT31 (EFSA, 2016). Hence, the nature and magnitude of oxathiapiprolin residues in rotational crops has to be further investigated.

The nature of oxathiapiprolin in rotational crops has been investigated in the EU pesticides peer review in studies where bare soil was treated at an application rate of 210 g a.s./ha, sowing wheat,

<sup>7</sup> 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.

lettuces and turnips as rotational crops 30, 120 and 365 days after the soil treatment (Ireland, 2015; EFSA, 2016). The peer review concluded that in rotational crops the metabolism differs from that in primary crops and it is exclusively composed of metabolites containing the pyrazole moiety (especially metabolite IN-E8S72 and its glucose-conjugated IN-SXS67) accounting for more than 50% of the TRR. Oxathiapiprolin metabolites denoting the structure of the parent compound and metabolites containing the thiazole moiety were almost never detected. The metabolic profile in rotational crops is mostly the result of a preferential uptake from soil of the metabolites containing the pyrazole moiety. Based on these studies and considering that the pyrazole metabolite IN-E8S72 is of lower toxicity than oxathiapiprolin, metabolite IN-E8S72 and its conjugate IN-SXS67 were not included in the plant residue definitions that were proposed as oxathiapiprolin for monitoring and risk assessment (EFSA, 2016).

In the framework of a previous EFSA assessment (EFSA, 2019b), new metabolism studies were submitted where the nature of [ $^{14}\text{C}$ ]-oxathiapiprolin was investigated in turnips, lettuces and wheat grown as rotational crops 30, 120 and 365 days following the soil treatment with oxathiapiprolin at a rate of 600 g a.s./ha. These new studies confirmed the conclusions of the peer review. The main metabolites present in rotational crops were IN-E8S72 (and IN-SXS67), IN-WR791, IN-RZB20 and IN-RZB21/IN-RZD74.

In addition, the comparison of both studies indicated that there is no significant difference in the magnitude of residues in crops from the low and the high dose rate studies. The persistent soil metabolites, which have been identified in the soil degradation studies (i.e. IN-RAB06, IN-QPS10 and IN-RDT31) were not identified in the rotational crop metabolism studies (EFSA, 2019b).

### 1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of oxathiapiprolin was investigated in the framework of the EU pesticides peer review (EFSA, 2016). These studies showed that oxathiapiprolin is hydrolytically stable under standard processing conditions.

### 1.1.4. Methods of analysis in plants

Analytical methods for the determination of oxathiapiprolin residues in high oil, high starch, high water and high acid content commodities of plant origin were assessed during the EU pesticides peer review (EFSA, 2016).

Sufficiently validated analytical methods are available for the determination of oxathiapiprolin at the validated LOQ of 0.01 mg/kg in radish and kale leaves (high water matrix).

### 1.1.5. Storage stability of residues in plants

The storage stability of oxathiapiprolin in plant parts stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2016). For plant parts belonging to high water matrices, such as radish roots and leaves, the freezer storage stability of oxathiapiprolin has been proven for 18 months when stored at  $-20^{\circ}\text{C}$ .

### 1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and the capabilities of enforcement analytical methods, the following residue definitions were proposed (EFSA, 2016, 2019b):

- residue definition for risk assessment: oxathiapiprolin
- residue definition for enforcement: oxathiapiprolin

The same residue definitions 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.

Taking in account the proposed use assessed in this application, EFSA concluded that these residue definitions are appropriate and no modification or further information is required.



## 1.2. Magnitude of residues in plants

### 1.2.1. Magnitude of residues in primary crops

**Radishes** (NEU, outdoor use, foliar spray):  $2 \times 15$  g a.s./ha; interval between applications: 7–10 days; preharvest interval (PHI): 7 days.

In support of the MRL application, the applicant submitted four GAP-compliant residue trials performed on small radishes. Trials were conducted in Germany during growth season of 2019 and all trials were considered as independent and representative of the NEU zone.

Samples were obtained from radish roots and leaves. The samples prior to analyses were stored under conditions for which integrity of the samples has been demonstrated. According to the assessment of the EMS, the methods used to analyse samples for oxathiapiprolin residues were sufficiently validated and fit for purpose (Germany, 2021).

The submitted residue data indicate that oxathiapiprolin residues in radish leaves occur at levels that would require an MRL of 1.5 mg/kg. Residue data from radish roots indicate that, according to the intended use pattern, residues in radish roots will not occur above the LOQ of 0.01 mg/kg.

EFSA notes that a use on kales was not reported in the framework of the present application and the existing MRL is set at the LOQ of 0.01 mg/kg. Member States should pay attention when granting authorisations of plant protection products containing oxathiapiprolin on kales.

### 1.2.2. Magnitude of residues in rotational crops

Radishes can be grown in rotation with other crops. The maximum seasonal application in the intended GAP is 30 g a.s./ha, but no information is provided concerning how many rotations of radishes per year on the same plot is typical agricultural practice in Germany.

Rotational crop studies (European field trials) performed with 115–210 g a.s./ha (soil treatment or application on cereals) were assessed in the framework of the EU pesticides peer review (EFSA, 2016).

In the framework of a previous EFSA assessment (EFSA, 2019b), a wide range of rotational crop field trials performed in the USA and Canada were considered. Bare soil was treated with 272–560 g a.s./ha and rotational crops were planted at three plant-back intervals (PBIs). It is noted that North American studies were also taken into account in the EFSA conclusion on the potential residue levels in rotational crops (EFSA, 2016). Since the trials were performed with application rates exceeding the EU representative uses, the peer review decided to scale down the residues observed in rotational crops to the maximum European seasonal application rate of the representative use (90 g a.s./ha). Overall, it was concluded that residues of oxathiapiprolin, IN-WR791, IN-E8S72 and IN-SXS67 are not expected in significant levels in rotational crops (EFSA, 2016).

Considering the highest residue levels observed in crops from all available rotational crop field studies (EU and non-EU), which were performed under varying conditions at application rates ranging from 115 to 560 g/ha, it can be concluded that for the PBI of 30 days, residues of oxathiapiprolin will be below 0.01 mg/kg in food commodities and below 0.05 mg/kg in feed commodities grown in a crop rotation (EFSA, 2019b).

Residues of metabolites IN-E8S72 and IN-SXS67 (expressed as IN-E8S72) might be present in cereal grain and pulses (0.011 mg/kg), immature leafy vegetables (0.19 mg/kg), legumes with/without pods (0.03–0.05 mg/kg), oilseed (0.09 mg/kg) and fruits (0.022 mg/kg). Residues of these metabolites in feed commodities could occur in forage, fodder and hay of cereals (0.20–0.75 mg/kg), forage of legumes/pulses (0.077 mg/kg), fodder of pulses (0.29 mg/kg) and foliage of root crops (0.03 mg/kg). Metabolite IN-WR791 was present up to 0.012 mg/kg only in leafy vegetables. Based on the available data, only metabolites IN-E8S72 and IN-SXS67 may be expected to occur at levels above 0.05 mg/kg in feed commodities (EFSA, 2019b).

In order to avoid residues of oxathiapiprolin metabolites in crops that have relatively short vegetation period and are rotated within short PBIs as in the case of radishes, Member States granting authorisations of oxathiapiprolin should consider applying risk mitigation measures.

### 1.2.3. Magnitude of residues in processed commodities

Specific processing studies with radishes are not required, as exposure from the consumption of radish leaves (raw or processed) is not expected to be significant to consumers (see Appendix B.3).

#### 1.2.4. Proposed MRLs

The available residues data are considered sufficient to derive an MRL proposal for radish leaves which could be applicable also for kales as well as risk assessment values for kales according to the intended use of oxathiapiprolin on radishes (see Appendix B.1.2.1). Risk Managers considerations are needed on how to implement the MRL since radish leaves are included in part B of Annex I of the Commission Regulation (EU) 2018/62 and classified under the subgroup of kales, referred to in the Part A of Annex I.

In Section 3, EFSA assessed whether residues in radishes resulting from the intended use are likely to pose a consumer health risk.

## 2. Residues in livestock

Not relevant, as radishes are normally not used for feed purposes.

EFSA notes that the proposed MRL for kales is not triggered by a use on kales, which is a typical livestock feed item. Should any use be intended on kales in the EU resulting in residues above the LOQ of 0.01 mg/kg, further investigations of residue carry-over from kales into the products of animal origin are required.

## 3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019a). This exposure assessment model contains food consumption data for different sub-groups 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 value for oxathiapiprolin used in the risk assessment (i.e. acceptable daily intake (ADI) value of 0.14 mg/kg body weight (bw) per day) was derived in the framework of the EU pesticides peer review (EFSA, 2016; European Commission, 2016). Considering the toxicological profile of the active substance, a short-term dietary risk assessment was not required.

The long-term exposure assessment was performed, taking into account the STMR values derived for radishes (and referring to kales) assessed in this application. The PRIMo model contains the consumption data for commodities listed in Part A of Annex I of Regulation (EC) 2018/62 and therefore consumption figures for radish leaves are not available. Thus, the calculations were performed based on consumption of kales as reported by Member States. For the remaining commodities, the existing MRLs were used as input values unless STMR values were available from previous EFSA assessments (EFSA, 2016, 2019b, 2020). The complete list of input values is presented in Appendix D.1.

The estimated long-term dietary intake accounted for a maximum of 3% of the ADI (NL toddler diet). The contribution of residues expected in kale leaves to the overall long-term exposure is negligible (see Appendix B.3). EFSA concluded that the long-term intake of residues of oxathiapiprolin resulting from the intended and authorised uses is unlikely to present a risk to consumer health.

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

## 4. Conclusion and Recommendations

The data submitted in support of this MRL application on radishes were found to be sufficient to derive an MRL proposal for radish leaves, which could be applicable also for kales. Risk Managers considerations are needed on how to implement the MRL since radish leaves are included in part B of Annex I of the Commission Regulation (EU) 2018/62 and classified under the subgroup of kales, referred to in the Part A of Annex I.

Residues in radish roots were not detected and an MRL modification for radish roots is not required and was not applied for by the applicant.

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

It is noted that, in order to avoid the occurrence of residues of metabolites IN-E8S72, IN-SXS67 and IN-WR791 in crops that have relatively short vegetation period and are rotated within short plant-back intervals, as in a case of radishes, Member States granting authorisations of oxathiapiprolin might consider applying risk mitigation measures.

Finally, EFSA notes that the proposed MRL for kales is not triggered by a direct use on kales, which is a typical livestock feed item. Should any use be intended on kales in the EU resulting in residues above the LOQ of 0.01 mg/kg, further investigations of residue carry-over from kales into the products of animal origin are required.

The MRL recommendations are summarised in Appendix B.4.

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## Abbreviations

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
CCPR	Codex Committee on Pesticide Residues
CF	conversion factor for enforcement to risk assessment residue definition
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DT <sub>90</sub>	period required for 90% dissipation (define method of estimation)
EMS	evaluating Member State
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
HPLC–MS/MS	high-performance liquid chromatography with tandem mass spectrometry

HR	highest residue
IEDI	international estimated daily intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
MRL	maximum residue level
NEU	northern Europe
O	oil dispersion
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PHI	preharvest interval
$P_{ow}$	partition coefficient between n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rappporteur Member State
SANCO	Directorate-General for Health and Consumers
SEU	southern Europe
STMR	supervised trials median residue
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 <sup>(a)</sup>	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days) <sup>(d)</sup>	Remarks
				Type <sup>(b)</sup>	Conc. a.s. (g/L)	Method kind	Range of growth stages and season <sup>(c)</sup>	Number min–max	Interval between application (days) min–max	g a.s./hL min–max	Water (L/ha) min–max	Rate max	Unit		
Radishes	NEU	F	Downey mildew	OD	100	Foliar spray	From BBCH 13	2	7–10	–	200–400	15	g a.s./ha	7	–

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; OD: oil dispersion.

(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. Residues in plants

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

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

Primary crops (available studies)	Crop groups	Crop(s)	Application(s)	Sampling (DAT)	Comment/Source
	Fruit crops	Grapes	Foliar: 3 × 70 g/ha (BBCH 63-65; BBCH 73 and 77; 14-day interval)	Foliage: 0 DAT <sub>1,2,3</sub> , 14 DAT <sub>2,3</sub> , 76 DALA Berries: 14 DAT <sub>2,3</sub> , 0 DAT <sub>3</sub> , 76 DALA	Radiolabelled active substance: pyrazole- <sup>14</sup> C- and thiazole- <sup>14</sup> C-oxathiapiprolin (EFSA, 2016)
		Courgettes	Soil: 1 × 600 g/ha (pre-planting)	44 DAT, 79 DAT (maturity)	Radiolabelled active substance: pyrazole- <sup>14</sup> C- and isoxazoline- <sup>14</sup> C-oxathiapiprolin (EFSA, 2019b)
	Root crops	Potatoes	Soil: 1 × 600 g/ha (pre-planting)	Foliage, tubers: 37 DAT, 72 DAT (maturity)	Radiolabelled active substance: pyrazole- <sup>14</sup> C- and isoxazoline- <sup>14</sup> C-oxathiapiprolin (EFSA, 2019b)
			Foliar: 3 × 70 g/ha (BBCH 53; BBCH 59 and 69; 14-day interval)	Foliage, tubers: 0 DAT <sub>2</sub> (foliage only), 14 DAT <sub>1,2,3</sub> , 28 DAT <sub>3</sub>	Radiolabelled active substance: pyrazole- <sup>14</sup> C- and thiazole- <sup>14</sup> C-oxathiapiprolin (EFSA, 2016)
	Leafy crops	Lettuces	Foliar: 3 × 70 g/ha (BBCH 15; BBCH 17 and 19; 10-day interval)	0 DAT <sub>1,2,3</sub> , 10 DAT <sub>1,2</sub> , 0 DAT <sub>3</sub> , 3, 7, 14 DALA	Radiolabelled active substance: pyrazole- <sup>14</sup> C- and thiazole- <sup>14</sup> C-oxathiapiprolin (EFSA, 2016)
			Soil: 1 × 600 g/ha (pre-planting)	30, 44, 57 DAT	Radiolabelled active substance: pyrazole- <sup>14</sup> C- and isoxazoline- <sup>14</sup> C-oxathiapiprolin (EFSA, 2019b)
Rotational crops (available studies)	Crop groups	Crop(s)	Application(s)	PBI (DAT)	Comment/Source
	Root/tuber crops	Turnips	Soil: 1 × 210 g/ha	30, 120 and 365 DAT	Radiolabelled active substance: pyrazole- <sup>14</sup> C-, thiazole- <sup>14</sup> C- and isoxazoline- <sup>14</sup> C oxathiapiprolin (EFSA, 2016)
			Soil: 1 × 600 g/ha		Radiolabelled active substance: pyrazole- <sup>14</sup> C and isoxazoline- <sup>14</sup> C oxathiapiprolin (EFSA, 2019b)
	Leafy crops	Lettuces	Soil: 1 × 210 g/ha	30, 120 and 365 DAT	Radiolabelled active substance: pyrazole- <sup>14</sup> C-, thiazole- <sup>14</sup> C- and isoxazoline- <sup>14</sup> C oxathiapiprolin. (EFSA, 2016)

			Soil: 1 × 600 g/ha		Radiolabelled active substance: pyrazole- <sup>14</sup> C and isoxazoline- <sup>14</sup> C oxathiapiprolin (EFSA, 2019b)
	Cereal (small grain)	Wheat	Soil: 1 × 210 g/ha	30, 120 and 365 DAT	Radiolabelled active substance: pyrazole- <sup>14</sup> C-, thiazole- <sup>14</sup> C- and isoxazoline- <sup>14</sup> C oxathiapiprolin (EFSA, 2016)
			Soil: 1 × 600 g/ha		Radiolabelled active substance: pyrazole- <sup>14</sup> C and isoxazoline- <sup>14</sup> C oxathiapiprolin (EFSA 2019b)
<b>Processed commodities</b> (hydrolysis study)	<b>Conditions</b>		<b>Stable?</b>		<b>Comment/Source</b>
	Pasteurisation (20 min, 90°C, pH 4)		Yes		
	Baking, brewing and boiling (60 min, 100°C, pH 5)		Yes		
	Sterilisation (20 min, 120°C, pH 6)		Yes		



Can a general residue definition be proposed for primary crops?	Yes	
Rotational crop and primary crop metabolism similar?	No	<p>Metabolism in primary and rotational crops is different; a limited degradation of oxathiapiprolin in plants was found in primary metabolism, while in the rotational crop metabolism a preferential uptake of pyrazole metabolites from soil was observed. Metabolite IN-E8S72 and its conjugate IN-SXS67 were main residues in rotational crops; IN-E8S72 and its conjugate IN-SXS67 concluded to be of lower toxicity and thus both compounds were not included in the plant residue definitions (EFSA, 2016).</p> <p>A new metabolism study confirmed the conclusions of the peer review. The main metabolites present in rotational crops were IN-E8S72 (and IN-SXS67), IN-WR791, IN-RZB20 and IN-RZB21/IN-RZD74 (EFSA, 2019b).</p>
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2016)
Plant residue definition for monitoring (RD-Mo)	Oxathiapiprolin (Regulation (EC) No 396/2005)	
Plant residue definition for risk assessment (RD-RA)	Oxathiapiprolin (EFSA, 2016, 2019b)	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	<p>Multi residue method: DFG-S19, LC-MS/MS, LOQ: 0.01 mg/kg in dry, high water and acid matrices (EFSA, 2016) and in difficult to analyse matrices (coffee beans, hops (dried cones), black tea (leaves) dried tobacco) (EFSA, 2019b).</p> <p>Single residue method: HPLC-MS/MS, LOQ: 0.01 mg/kg in high oil, dry, high water and acid matrices (EFSA, 2016).</p>	

DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; a.s.: active substance; MRL: maximum residue level; LC-MS/MS: liquid chromatography with tandem mass spectrometry; HPLC-MS/MS: high performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification.

### B.1.1.2. Stability of residues in plants

Plant product (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/ Source
				Value	Unit		
	High water content	Tomatoes	-20	18	Months	Oxathiapiprolin, IN-Q7H09, IN-RDG40, IN-E8S72, IN-RZB20, IN-RZD74, IN-SXS67, and IN-WR791	EFSA (2016)
	High oil content	Soybean, seeds					
	High protein content	Beans, dried seeds					
	Dry/High starch	Potatoes Wheat					
	High acid content	Grapes					
	Others	Wheat, forage					
		Rape, dry pomace					
		Wheat, straw					

## B.1.2. Magnitude of residues in plants

### B.1.2.1. Summary of residues data from the supervised residue trials

Commodity	Region <sup>(a)</sup>	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR <sup>(b)</sup> (mg/kg)	STMR <sup>(c)</sup> (mg/kg)
<b>Enforcement residue definition/Risk assessment residue definition: Oxathiapiprolin</b>						
Radishes	NEU	Roots: 4 × < 0.01	Residue trials on radishes compliant with GAP. MRL <sub>OECD</sub> = 1.245 mg/kg	0.01* (=Existing EU MRL)	< 0.01	< 0.01
		Leaves: 0.26; 0.34; 0.49; 0.57		1.5	0.57	0.42

MRL: maximum residue level; GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development.

\*: Indicates that the MRL is proposed at the limit of quantification.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, 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.

### B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Yes	EFSA (2016, 2019b)
Residues in rotational and succeeding crops expected based on field rotational crop study?	Yes	<p>Rotational crop field studies in Europe at 115 g/ha bare soil or on cereals at 210 g/ha (14- to 39-, 120- and 270- to 317-day PBI) (EFSA, 2016).</p> <p>Rotational crop field studies performed in USA/Canada at 272–560 g/ha bare soil (5 to 21-, 63 to 140- and 319 to 359-day PBI) in all crop groups (EFSA, 2019b).</p> <p>The samples were analysed for oxathiapiprolin and its metabolites IN-WR791, IN-RDG40, IN-E8S72, IN-Q7H09, IN-SXS67, IN-RZB20 and IN-RZD74.</p> <p>Residues of oxathiapiprolin are expected to be below 0.01 mg/kg in food commodities and below 0.05 mg/kg in feed commodities grown in a crop rotation.</p> <p>Metabolites IN-E8S72 and IN-SXS67 (expressed as IN-E8S72) and IN-WR791 were present in food and feed commodities at levels above 0.01 or 0.05 mg/kg, respectively (EFSA, 2019b).</p>

PBI: plant-back interval.

### B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application.

## B.2. Residues in livestock

Not relevant, since radishes are normally not fed to livestock.

EFSA notes that the proposed MRL for kales is not triggered by a use on kales, which is a typical livestock feed item. Should any use be intended on kales in the EU resulting in residues above the LOQ of 0.01 mg/kg, further investigations of residue carry-over from kales into the products of animal origin are required.

## B.3. Consumer risk assessment

Acute risk assessment not relevant since no ARfD has been considered necessary (European Commission, 2016).

ADI	0.14 mg/kg bw per day (European Commission, 2016)
Highest IEDI, according to EFSA PRIMo	3% ADI (NL toddler diet) Contribution of crops assessed: Radish leaves (based on kale consumption data): 0.06% of ADI (PT, general diet)
Assumptions made for the calculations	The calculation is based on the median residue level in kales as derived from the submitted residue trials on radishes. EFSA notes that that a minor uncertainty exists on the chronic exposure from radish leaves. As the consumption data on radish leaves are lacking, calculations were performed based on consumption of kales. For the remaining commodities, the STMR values were available as derived in previous EFSA assessments.  Calculations performed with PRIMo revision 3.1.

ADI: acceptable daily intake; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; MRL: maximum residue level; STMR: supervised trials median residue.

#### B.4. Recommended MRLs

Code <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
<b>Enforcement residue definition: Oxathiapiprolin</b>				
0243020	Kales (MRL applicable for radish leaves 0243020-008)	0.01*	Kales/ Radish leaves  1.5 (further risk management consideration)	The submitted residue data on radish leaves are sufficient to derive an MRL proposal for this commodity, which could be applicable also for kales, on the basis of the intended NEU use on radishes. The residue data on radish roots indicate no residues above the LOQ of 0.01 mg/kg.  Risk Managers' considerations are needed on how to implement the MRL since radish leaves are included in part B of Annex I of the Commission Regulation (EU) 2018/62 and classified under the subgroup of kales, referred to in the Part A of Annex I.  It is further noted that for kales there are currently no reported uses in the EU, which would require the modification of the existing EU MRL. Should a new use on kales be applied for, the MSs granting authorisations would need to investigate the magnitude of residues in food commodities of animal origin.  Risk for consumers unlikely.

MRL: maximum residue level; NEU: northern Europe.

\*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

## Appendix C – Pesticide Residue Intake Model (PRIMo)



Oxathiapiprolin			
LOOs (mg/kg) range from:		0.01	to: 1.5
Toxicological reference values			
ADI (mg/kg bw per day):		0.14	ARLD (mg/kg bw): not necessary
Source of ADI:		EC	Source of ARLD:
Year of evaluation:		2016	Year of evaluation:
		EC	2016

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

Chronic risk assessment: JMPR methodology (IEDI/TMDI)										
No of diets exceeding the ADI :										Exposure resulting from
Calculated exposure (% of ADI)		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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	3%	MS Diet	4.44	2%	Spinaches	0.4%	Milk: Cattle	0.2%	Escaroles/broad-leaved endives	0.8%
	1%	NL toddler	2.01	0.6%	Spinaches	0.2%	Milk: Cattle	0.1%	Escaroles/broad-leaved endives	0.4%
	1%	SE general	2.00	0.4%	Chinese cabbages/pe-tsai	0.4%	Lettuces	0.2%	Spinaches	0.2%
	1%	DE child	1.99	0.5%	Spinaches	0.1%	Milk: Cattle	0.1%	Table grapes	0.4%
	1%	GEMS/Food G10	1.78	0.3%	Chinese cabbages/pe-tsai	0.3%	Lettuces	0.1%	Spinaches	0.2%
	1%	IT adult	1.67	0.4%	Lettuces	0.2%	Spinaches	0.2%	Other spinach and similar	0.1%
	1%	ES adult	1.58	0.5%	Lettuces	0.2%	Chards/beet leaves	0.2%	Spinaches	0.1%
	1%	ES child	1.58	0.4%	Lettuces	0.2%	Spinaches	0.2%	Chards/beet leaves	0.2%
	1%	FR infant	1.50	0.6%	Spinaches	0.1%	Milk: Cattle	0.1%	Leeks	0.2%
	1%	IE adult	1.42	0.3%	Spinaches	0.1%	Wine grapes	0.1%	Lettuces	0.2%
	1%	GEMS/Food G11	1.42	0.2%	Spinaches	0.1%	Leeks	0.1%	Wine grapes	0.2%
	1%	FR toddler 2 3 yr	1.40	0.4%	Spinaches	0.2%	Milk: Cattle	0.1%	Leeks	0.4%
	1.0%	NL general	1.37	0.4%	Spinaches	0.1%	Escaroles/broad-leaved endives	0.1%	Lettuces	0.2%
	1.0%	IT toddler	1.36	0.3%	Lettuces	0.1%	Chards/beet leaves	0.1%	Spinaches	0.1%
	1.0%	FR child 3 15 yr	1.34	0.3%	Spinaches	0.2%	Milk: Cattle	0.1%	Other lettuce and other salad plants	0.3%
	0.9%	GEMS/Food G06	1.31	0.1%	Spinaches	0.1%	Tomatoes	0.1%	Lettuces	0.2%
	0.9%	GEMS/Food G07	1.27	0.2%	Lettuces	0.1%	Wine grapes	0.1%	Spinaches	0.2%
	0.9%	GEMS/Food G08	1.20	0.2%	Lettuces	0.1%	Wine grapes	0.1%	Spinaches	0.2%
	0.7%	FR adult	1.04	0.2%	Wine grapes	0.1%	Other lettuce and other salad plants	0.1%	Spinaches	0.1%
	0.7%	DE women 14-50 yr	1.00	0.1%	Spinaches	0.1%	Lettuces	0.1%	Milk: Cattle	0.2%
	0.7%	GEMS/Food G15	0.97	0.1%	Lettuces	0.1%	Wine grapes	0.1%	Head cabbages	0.2%
	0.7%	DE general	0.96	0.1%	Spinaches	0.1%	Lettuces	0.1%	Milk: Cattle	0.2%
	0.6%	RO general	0.88	0.1%	Wine grapes	0.1%	Head cabbages	0.1%	Milk: Cattle	0.2%
	0.5%	PT general	0.76	0.2%	Wine grapes	0.1%	Lettuces	0.1%	Kales	0.1%
	0.5%	DK child	0.75	0.1%	Lettuces	0.1%	Milk: Cattle	0.0%	Rye	0.2%
	0.5%	FI adult	0.73	0.2%	Coffee beans	0.1%	Lettuces	0.0%	Chinese cabbages/pe-tsai	0.2%
	0.5%	UK infant	0.71	0.3%	Milk: Cattle	0.0%	Spinaches	0.0%	Potatoes	0.4%
	0.5%	UK toddler	0.66	0.1%	Milk: Cattle	0.1%	Spinaches	0.0%	Wheat	0.3%
	0.5%	UK vegetarian	0.66	0.1%	Lettuces	0.1%	Spinaches	0.1%	Wine grapes	0.1%
	0.4%	FI 3 yr	0.63	0.2%	Spinaches	0.0%	Chinese cabbages/pe-tsai	0.0%	Potatoes	0.1%
0.4%	FI 6 yr	0.62	0.1%	Spinaches	0.1%	Lettuces	0.1%	Chinese cabbages/pe-tsai	0.1%	
0.4%	UK adult	0.55	0.1%	Lettuces	0.1%	Wine grapes	0.0%	Spinaches	0.1%	
0.4%	DK adult	0.52	0.1%	Lettuces	0.1%	Wine grapes	0.0%	Milk: Cattle	0.1%	
0.3%	PL general	0.35	0.0%	Chinese cabbages/pe-tsai	0.0%	Head cabbages	0.0%	Table grapes	0.0%	
0.2%	LT adult	0.33	0.1%	Lettuces	0.0%	Head cabbages	0.0%	Milk: Cattle	0.1%	
0.1%	IE child	0.13	0.0%	Milk: Cattle	0.0%	Spinaches	0.0%	Wheat	0.0%	

**Conclusion:**  
 The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.  
 The long-term intake of residues of Oxathiapiprolin 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.

<b>Acute risk assessment/children</b>	<b>Acute risk assessment/adults/general population</b>
<a href="#">Details - acute risk assessment/children</a>	<a href="#">Details - acute risk assessment/adults</a>

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

**Show results for all crops**

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

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

**Conclusion:**

## Appendix D – Input values for the exposure calculations

### D.1. Consumer risk assessment

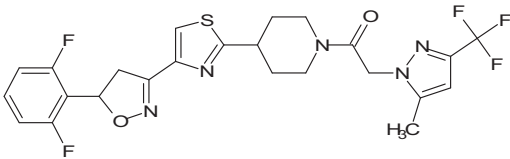
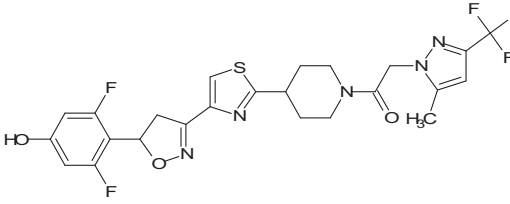
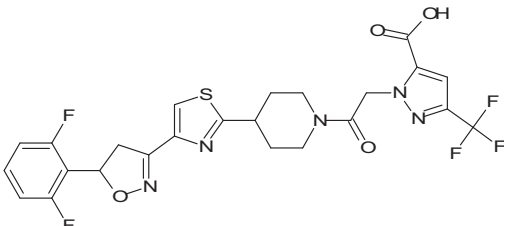
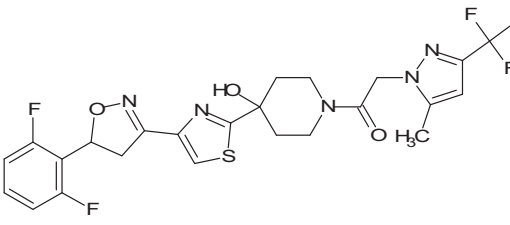
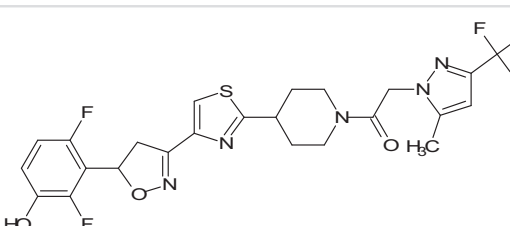
Commodity	Existing/ proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<b>Risk assessment residue definition: Oxathiapiprolin</b>						
<b>Kales (residues in radish leaves)</b>	<b>1.5</b>	<b>Intended use</b>	<b>0.42</b>	<b>STMR-RAC</b>	Not performed since no ARfD was established and it was not considered necessary (European Commission, 2016).	
Grapefruits	0.05	EFSA (2020)	0.01	STMR-RAC <sub>pulp</sub>		
Oranges	0.05	EFSA (2020)	0.01	STMR-RAC <sub>pulp</sub>		
Lemons	0.05	EFSA (2020)	0.01	STMR-RAC <sub>pulp</sub>		
Limes	0.05	EFSA (2020)	0.01	STMR-RAC <sub>pulp</sub>		
Mandarins	0.05	EFSA (2020)	0.01	STMR-RAC <sub>pulp</sub>		
Other citrus fruit	0.05	EFSA (2020)	0.01	STMR-RAC <sub>pulp</sub>		
Table grapes	0.7	EFSA (2019b)	0.12	STMR-RAC		
Wine grapes	0.7	EFSA (2019b)	0.12	STMR-RAC		
Blackberries	0.5	EFSA (2020)	0.01	STMR-RAC		
Raspberries (red and yellow)	0.5	EFSA (2020)	0.01	STMR-RAC		
Potatoes	0.01	EFSA (2016)	0.01	STMR-RAC		
Garlic	0.04	EFSA (2019b)	0.01	STMR-RAC		
Onions	0.04	EFSA (2019b)	0.01	STMR-RAC		
Shallots	0.04	EFSA (2019b)	0.01	STMR-RAC		
Spring onions/green onions and Welsh onions	2	EFSA (2019b)	0.57	STMR-RAC		
Other bulb vegetables	2	EFSA (2019b)	0.57	STMR-RAC		
Tomatoes	0.4	EFSA (2019b)	0.04	STMR-RAC		
Sweet peppers/bell peppers	0.2	EFSA (2019b)	0.04	STMR-RAC		
Aubergines/egg plants	0.4	EFSA (2019b)	0.04	STMR-RAC		
Okra/lady's fingers	0.2	EFSA (2019b)	0.04	STMR-RAC		
Other solanaceae	0.2	EFSA (2019b)	0.04	STMR-RAC		
Cucumbers	0.2	EFSA (2019b)	0.03	STMR-RAC		
Gherkins	0.2	EFSA (2019b)	0.03	STMR-RAC		
Courgettes	0.2	EFSA (2019b)	0.03	STMR-RAC		
Other cucurbits - edible peel	0.2	EFSA (2019b)	0.03	STMR-RAC		
Melons	0.2	EFSA (2019b)	0.05	STMR-RAC		
Pumpkins	0.2	EFSA (2019b)	0.05	STMR-RAC		
Watermelons	0.2	EFSA (2019b)	0.05	STMR-RAC		
Other cucurbits - inedible peel	0.2	EFSA (2019b)	0.05	STMR-RAC		
Broccoli	1.5	EFSA (2019b)	0.12	STMR-RAC		
Cauliflowers	1.5	EFSA (2019b)	0.12	STMR-RAC		
Head cabbages	0.7	EFSA (2019b)	0.14	STMR-RAC		

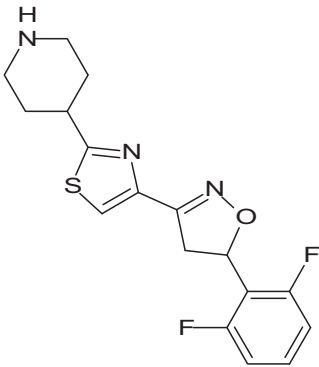
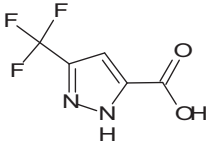
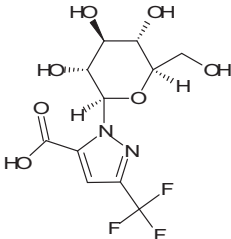
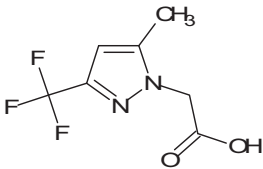
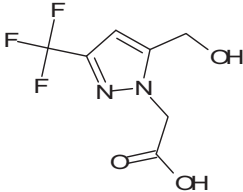
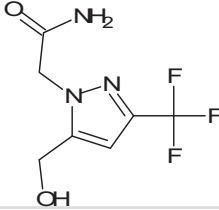
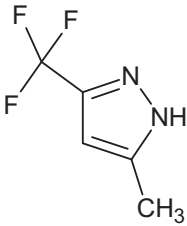


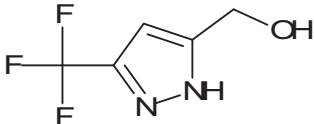
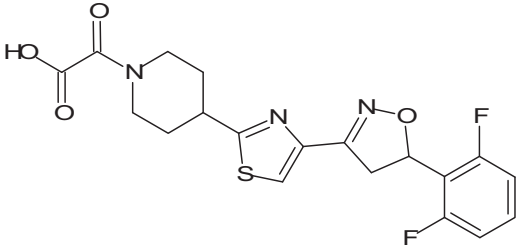
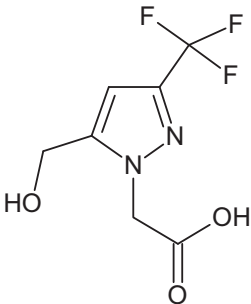
Commodity	Existing/ proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Chinese cabbages/ pe-tsai	9	EFSA (2020)	2.9	STMR-RAC		
Lamb's lettuce/corn salads	5	EFSA (2019b)	1.3	STMR-RAC		
Lettuces	5	EFSA (2019b)	1.3	STMR-RAC		
Escaroles/broad- leaved endives	5	EFSA (2019b)	1.3	STMR-RAC		
Cress and other sprouts and shoots	5	EFSA (2019b)	1.3	STMR-RAC		
Land cress	5	EFSA (2019b)	1.3	STMR-RAC		
Roman rocket/ rucola	5	EFSA (2019b)	1.3	STMR-RAC		
Red mustards	5	EFSA (2019b)	1.3	STMR-RAC		
Baby leaf crops (including brassica species)	5	EFSA (2019b)	1.3	STMR-RAC		
Other lettuce and other salad plants	5	EFSA (2019b)	1.3	STMR-RAC		
Spinaches	15	EFSA (2019b)	3.35	STMR-RAC		
Purslanes	15	EFSA (2019b)	3.35	STMR-RAC		
Chards/beet leaves	15	EFSA (2019b)	3.35	STMR-RAC		
Other spinach and similar	15	EFSA (2019b)	3.35	STMR-RAC		
Grape leaves and similar species	40	EFSA (2016)	8.8	STMR-RAC		
Basil and edible flowers	10	EFSA (2020)	3.05	STMR-RAC		
Peas (with pods)	1	EFSA (2019b)	0.29	STMR-RAC		
Asparagus	2	EFSA (2020)	0.55	STMR-RAC		
Leeks	2	EFSA (2019b)	0.57	STMR-RAC		
Sunflower seeds	0.01	EFSA (2019b)	0.01	STMR-RAC		
Ginseng root	0.15	EFSA (2019b)	0.05	STMR-RAC		
HOPS (dried)	8	EFSA (2019b)	1.6	STMR-RAC		
Other commodities	MRL	Reg. (EU) 2021/1807				

STMR-RAC: supervised trials median residue in raw agricultural commodity.

## Appendix E – Used compound codes

Code/trivial name	Chemical name/SMILES notation <sup>(a)</sup>	Structural formula <sup>(b)</sup>
Oxathiapiprolin	1-(4-{4-[(5 <i>RS</i> )-5-(2,6-difluorophenyl)-4,5-dihydroisoxazol-3-yl]thiazol-2-yl}-1-piperidyl)-2-[5-methyl-3-(trifluoromethyl)-1 <i>H</i> -pyrazol-1-yl]ethanone  <chem>FC(F)(F)c1cc(C)n(n1)CC(=O)N1CCC(CC1)c1nc(cs1)C=1CC(ON=1)c1c(F)cccc1F</chem> IAQLCKZJGNTRDO-UHFFFAOYSA-N	
IN-Q7H09	1-(4-{4-[(5 <i>RS</i> )-5-(2,6-difluoro-4-hydroxyphenyl)-4,5-dihydro-1,2-oxazol-3-yl]-1,3-thiazol-2-yl}piperidin-1-yl)-2-[5-methyl-3-(trifluoromethyl)-1 <i>H</i> -pyrazol-1-yl]ethanone  <chem>FC(F)(F)c1cc(C)n(n1)CC(=O)N2CCC(CC2)c3nc(cs3)C=4CC(ON=4)c5c(F)cc(O)cc5F</chem> XYJWPIOIQYWLNP-UHFFFAOYSA-N	
IN-RAB06	1-[2-(4-{4-[(5 <i>RS</i> )-5-(2,6-difluorophenyl)-4,5-dihydro-1,2-oxazol-3-yl]-1,3-thiazol-2-yl}piperidin-1-yl)-2-oxoethyl]-3-(trifluoromethyl)-1 <i>H</i> -pyrazole-5-carboxylic acid  <chem>O=C(O)c5cc(nn5CC(=O)N1CCC(CC1)c2nc(cs2)C=3CC(ON=3)c4c(F)cccc4F)C(F)(F)F</chem> QALOLIVQRGAZRP-UHFFFAOYSA-N	
IN-RDT31	1-(4-{4-[(5 <i>RS</i> )-5-(2,6-difluorophenyl)-4,5-dihydro-1,2-oxazol-3-yl]-1,3-thiazol-2-yl}-4-hydroxypiperidin-1-yl)-2-[5-methyl-3-(trifluoromethyl)-1 <i>H</i> -pyrazol-1-yl]ethanone  <chem>FC(F)(F)c1cc(C)n(n1)CC(=O)N2CCC(O)(CC2)c3nc(cs3)C=4CC(ON=4)c5c(F)cccc5F</chem> WNMKBALSHJAXGE-UHFFFAOYSA-N	
IN-RDG40	1-(4-{4-[(5 <i>RS</i> )-5-(2,6-difluoro-3-hydroxyphenyl)-4,5-dihydro-1,2-oxazol-3-yl]-1,3-thiazol-2-yl}piperidin-1-yl)-2-[5-methyl-3-(trifluoromethyl)-1 <i>H</i> -pyrazol-1-yl]ethanone  <chem>FC(F)(F)c1cc(C)n(n1)CC(=O)N2CCC(CC2)c3nc(cs3)C=4CC(ON=4)c5c(F)ccc(O)c5F</chem> MCUWVCQCPFWXQQ-UHFFFAOYSA-N	

Code/trivial name	Chemical name/SMILES notation <sup>(a)</sup>	Structural formula <sup>(b)</sup>
IN-QPS10	4-{4-[(5 <i>RS</i> )-5-(2,6-difluorophenyl)-4,5-dihydro-1,2-oxazol-3-yl]-1,3-thiazol-2-yl}piperidine <chem>Fc1cccc(F)c1C2CC(=NO2)c3csc(n3)C4CCNCC4</chem> HZZFIEJFXTXVHO-UHFFFAOYSA-N	
IN-E8S72	3-(trifluoromethyl)-1 <i>H</i> -pyrazole-5-carboxylic acid <chem>FC(F)(F)c1cc(nn1)C(=O)O</chem> CIVNBJPTGRMGRS-UHFFFAOYSA-N	
IN-SXS67	1-β-D-glucopyranosyl-3-(trifluoromethyl)-1 <i>H</i> -pyrazole-5-carboxylic acid <chem>O = C(O)c2cc(nn2[C@@H]1O[C@@H](CO)[C@@H](O)[C@@H](O)[C@@H]1O)C(F)(F)F</chem> IYVPJWXJEGAHCP-DDIGBBAMSA-N	
IN-WR791	[5-methyl-3-(trifluoromethyl)-1 <i>H</i> -pyrazol-1-yl]acetic acid <chem>OC(=O)Cn1nc(cc1C)C(F)(F)F</chem> RBHQAI FXLJIFFM-UHFFFAOYSA-N	
IN-RZB20	[5-(hydroxymethyl)-3-(trifluoromethyl)-1 <i>H</i> -pyrazol-1-yl]acetic acid <chem>OC(=O)Cn1nc(cc1CO)C(F)(F)F</chem> LGHWWTCDTBCQI-UHFFFAOYSA-N	
IN-RZB21	5-(Hydroxymethyl)-3-(trifluoromethyl)-1 <i>H</i> pyrazole-1-acetamide <chem>O = C(N)Cn1nc(cc1CO)C(F)(F)F</chem> LDXIZNIPWOQNPY-UHFFFAOYSA-N	
IN-KJ552	5-methyl-3-(trifluoromethyl)-1 <i>H</i> -pyrazole <chem>FC(F)(F)c1cc(C)[NH]n1</chem> DLCHCAYDSKIFIN-UHFFFAOYSA-N	

Code/trivial name	Chemical name/SMILES notation <sup>(a)</sup>	Structural formula <sup>(b)</sup>
IN-RZD74	<b>[3-(trifluoromethyl)-1H-pyrazol-5-yl] methanol</b> <chem>FC(F)(F)c1cc(CO)nn1</chem> KUVPCLYQVMRTPU-UHFFFAOYSA-N	
IN-Q9L80	<b>(4-{4-[(5<i>S</i>)-5-(2,6-difluorophenyl)-4,5-dihydro-1,2-oxazol-3-yl]-1,3-thiazol-2-yl}piperidin-1-yl)(oxo)acetic acid</b> <chem>O=C(O)C(=O)N1CCCC(CC1)c2nc(cs2)C=3CC(ON=3)c4c(F)cccc4F</chem> SPPNZGUAGRQIX-UHFFFAOYSA-N	
IN-R7B20	<b>[5-(hydroxymethyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]acetic acid</b> <chem>OC(=O)Cn1nc(cc1CO)C(F)(F)F</chem> LGHWWTCDTBCQI-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).