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REASONED OPINION

Modification of the existing maximum residue level for mandipropamid in radish leaves

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Syngenta Crop Protection AG submitted a request to the competent national authority in the Netherlands to modify the existing maximum residue level (MRL) for the active substance mandipropamid in radish leaves (classified under the subgroup of kales), based on an intended indoor use on radishes. The residue data in radish leaves submitted in support of the request were found to be sufficient to derive an MRL proposal for this commodity. Adequate analytical methods for enforcement are available to control the residues of mandipropamid 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 long-term intake of residues resulting from the use of mandipropamid according to the reported agricultural practice is unlikely to present a risk to consumer health. The reliable end points, appropriate for use in regulatory risk assessment are presented.

KEYWORDS

consumer risk assessment, mandipropamid, MRL, pesticide, radish leaves

CONTENTS

SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta Crop Protection AG submitted an application to the competent national authority in the Netherlands (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance mandipropamid in radish leaves.

The application, alongside the dossier containing the supporting data in IUCLID format, was submitted through the European Food Safety Authority (EFSA) Central Submission System on 3 February 2023. The appointed EMS the Netherlands assessed the dossier and declared its admissibility on 21 April 2023. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA and a public consultation was launched on the dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The consultation ran from 7 June 2023 to 28 June 2023. No additional data or comments were submitted in the framework of the consultation.

At the end of the commenting period, the EMS proceeded to draft the 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 31 July 2023. To accommodate for the intended use of mandipropamid in radish leaves (classified under the subgroup of kales), the EMS proposed to raise the existing MRL from 25 to 50 mg/kg.

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 Directive 91/414/EEC in accordance with Commission Regulation (EU) No 188/2011, the data evaluated under previous EFSA assessments, the scientific reports in support of the preparation of an EU position for the preparation of the Codex Committee on Pesticide Residues (CCPR) meetings and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of mandipropamid following foliar applications was investigated in primary crops belonging to the groups of fruit crops, leafy crops and root crops. Studies investigating the effect of processing on the nature of mandipropamid (hydrolysis studies) demonstrated that the active substance is stable. The metabolism in rotational crops was considered similar to the pathways observed in primary crops.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological relevance of metabolites and the capability of the enforcement methods, the residue definition for plant products was proposed as 'mandipropamid (any ratio of constituent isomers)' for enforcement. For risk assessment, the residue definition was proposed as 'mandipropamid (any ratio of constituent isomers)' for fruit and leafy crops and as 'sum of mandipropamid and SYN 500003', for root crops. The residue definition for root crops is tentative, pending on the submission of toxicological information for hazard characterisation of the metabolite SYN 500003. These residue definitions are applicable to primary crops, rotational crops and processed products.

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

Sufficiently validated analytical methods using liquid chromatography with tandem mass spectrometry (LC–MS/MS) are available to quantify residues of mandipropamid in radish leaves. The applicant provided the validation data for the QuEChERS (Quick, Easy, Cheap, Effective, Rugged and Safe) multi-residue method by LC–MS/MS in high-water content matrix, to which the crop under assessment belongs. These methods enable quantification of residues at or above 0.01 mg/kg (limit of quantification, LOQ). None of the analytical methods available is stereo-selective. The extraction efficiency of the QuEChERS method for high-water content matrices was proven.

Specific studies investigating the magnitude of mandipropamid residues in processed commodities are not required, as the individual contribution of radish leaves to the total theoretical maximum daily intake (TMDI) is expected to be below the trigger value of 10% of the acceptable daily intake (ADI).

The crops under assessment can be grown in rotation. The occurrence of mandipropamid residues in rotational crops was investigated in the framework of the EU pesticides peer review. Based on the available information on the nature and magnitude of residues, EFSA concluded that significant residue levels are unlikely to occur in rotational crops, provided that the active substance is used according to the proposed Good Agricultural Practice (GAP). Additionally, the applicant submitted under the current application, the results of four crop field rotational crops studies performed at 1.5N the intended seasonal application rate of mandipropamid in radishes applied as a single application to bare soil. No residues on mandipropamid were measured above the LOQ of 0.01 mg/kg in succeeding crops (representative for the root, leafy and cereal groups) in any of the plant back intervals.

Residues of mandipropamid in commodities of animal origin were not assessed since radish leaves are not considered as a relevant fed item to livestock according to the current guidance.

The toxicological profile of mandipropamid was assessed in the framework of the EU pesticides peer review and the data were sufficient to derive an ADI of 0.15 mg/kg body weight (bw) per day. An acute reference dose (ARfD) was deemed unnecessary. For the plant metabolite SYN 500003, included in the tentative residue definition for risk assessment for root crops, EFSA identified toxicological information as unavailable which was requested as confirmatory data following the MRL review. However, the lack of a complete toxicological characterisation on the metabolite SYN 500003 is not considered as a relevant data gap for the crop under assessment in the present MRL application (leafy crop).

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). Considering the toxicological profile of the active substance, a short-term dietary risk assessment was not required. EFSA updated the chronic risk assessment conducted in the framework of the MRL review with the median residue [supervised trials median residue (STMR)] value for kales as derived from residue trials on radishes and residues occurring in radish leaves as well as the STMRs derived by EFSA after the MRL review and the STMR for the Codex MRLs assessed by EFSA and implemented in the EU MRL legislation. The estimated long-term dietary intake accounted for a maximum of 6% of ADI (NL toddler diet). The contribution of residues expected in radish leaves to the overall long-term exposure accounted for 0.96% of the ADI.

EFSA concluded that the proposed use of mandipropamid on radish leaves will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers' health. However, the consumer risk assessment shall be regarded as indicative as affected by non-standard uncertainty related to the lack of hazard characterisation of the metabolite SYN 500003, tentatively included in the residue definition for risk assessment of root crops.

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 to D.

Code[a]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Mandipropamid (any ratio of constituent isomers)				
0243020-008	Radish leaves [Included in part B of Annex I of the Commission Regulation (EU) 2018/62[b] under kales]	25	50 (Further risk management consideration)	The submitted residue data on radish leaves are sufficient to derive an MRL proposal for this commodity based on the intended use 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 Part A of Annex I It is noted that the current MRL in kales (25 mg/kg) is lower than the proposed MRL in radish leaves. Therefore, a risk Managers' consideration is needed on how to implement the proposed MRL on radish leaves Because, contrary to radish leaves, kale leaves are used as feed items. Therefore, should a new use on kales be applied for, the Member State granting authorisations would need to investigate the magnitude of residues in food commodities of animal origin

Abbreviations: GAP, Good Agricultural Practice; MRL, maximum residue level.

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

[b]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. OJ L 18, 23.1.2018, pp. 1–73.

ASSESSMENT

The European Food Safety Authority (EFSA) received an application to modify the existing MRL for mandipropamid in radish leaves. The detailed description of the intended use of mandipropamid, which is the basis for the current MRL application, is reported in Appendix A.

Mandipropamid is the ISO common name for (*2RS*)-2-(4-chlorophenyl)-*N*-{2-[3-methoxy-4-(prop-2-ynyloxy)phenyl] ethyl}-2-(prop-2-ynyloxy)acetamide (IUPAC). The chemical structures of the active substance and its main metabolite are reported in Appendix E.

Mandipropamid was evaluated in the framework of Directive 91/414/EEC[1] in accordance with Commission Regulation (EU) No 188/2011[2] with Austria designated as rapporteur Member State (RMS) for the representative use as a foliar treatment on greenhouse crops of melons, tomatoes, lettuce and cucumbers and field crops of potatoes, tomatoes, melons, cucumbers, lettuce and grapes. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2012). Mandipropamid was approved[3] for the use as a fungicide on 1 August 2013.

The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2018b) and the proposed modifications have been implemented in the MRL legislation. After the completion of the MRL review, EFSA has issued several reasoned opinions on the modification of the MRLs for mandipropamid (EFSA, 2018c, 2019c, 2020). The proposals from these reasoned opinions have been considered in recent MRL regulations[4] An additional opinion on the modification of the MRL for papayas based on uses in Brazil (EFSA, 2023a) which draft regulation (PLAN/2023/750) is not published in the EU MRL legislation yet. Codex maximum residue limits (CXLs) for mandipropamid have been also implemented in the EU MRL legislation (EFSA, 2019d, 2022). In the framework of the preparation of the EU position for the 54th Session of the CCPR, EFSA recently issued a scientific report on Codex MRL proposals for mandipropamid in various plant and animal commodities (EFSA, 2023b, FAO, 2023). However, in the subsequent 54th Session of the CCPR, a reservation of the EU on the advancement of some of the Codex MRL proposals for mandipropamid was noted (CAC, 2023); Hence, EFSA did not consider those CXLs in the present assessment.

In accordance with Article 6 of Regulation (EC) No 396/2005 and following the provisions set by the 'Transparency Regulation' (EU) 2019/1381[5], the applicant Syngenta Crop Protection AG submitted on 3 February 2023 an application to the competent national authority in the Netherlands, alongside the dossier containing the supporting data using the IUCLID format.

The appointed EMS the Netherlands assessed the dossier and declared its admissibility on 21 April 2023. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA and a public consultation was launched on the dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The consultation ran from 7 June 2023 to 28 June 2023. No additional data or comments were submitted in the framework of the consultation.

At the end of the commenting period, the EMS proceeded to draft the 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 31 July 2023. To accommodate for the intended use of mandipropamid in radish leaves, the EMS proposed to raise the existing MRL from 25 to 50 mg/kg.

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

EFSA based its assessment on the evaluation report submitted by the EMS (Netherlands, 2023), the DAR and its addenda (Austria, 2006, 2012) prepared under Directive 91/414/EEC, the Commission review report on mandipropamid (European Commission, 2018), the conclusion on the peer review of the pesticide risk assessment of the active substance mandipropamid (EFSA, 2012), as well as the conclusions from previous EFSA opinions on mandipropamid (EFSA, 2018b, 2018c, 2019c, 2020, 2023a), including the reasoned opinion on the MRL review according to Article 12 of Regulation No 396/2005 (EFSA, 2018b) and the Scientific reports in support to the preparation of an EU position for the preparation of the CCPR meetings (EFSA, 2019d, 2022, 2023b).

For this application, the data requirements established in Regulation (EU) No 544/2011[6] and the guidance documents applicable at the date of submission of the IUCLID application are applicable (European Commission, 1997a, 1997b, 1997c,

[1]Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, pp. 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 No L 53, 26.2.2011, pp. 51–55.

[3]Commission Implementing Regulation (EU) No 188/2013 of 5 March 2013 approving the active substance mandipropamid, 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. OJ L 62, 6.3.2013, pp. 13–16.

[4]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.

[5]Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, PE/41/2019/REV/1. OJ L 231, 6.9.2019, pp. 1–28.

[6]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, pp. 1–66.

1997d, 1997e, 1997f, 1997g, 2010, 2017, 2021, 2022; 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.[7]

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 (Netherlands, 2023) and the exposure calculations using the PRIMo are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.[8]

1 | RESIDUES IN PLANTS

1.1 | Nature of residues and methods of analysis in plants

1.1.1 | Nature of residues in primary crops

The metabolism of mandipropamid after foliar applications was investigated in fruit crops, leafy crops and root crops in the framework of the EU pesticides peer review and the MRL review (EFSA, 2012, 2018b). In fruits and leafy crops, metabolism was similar with mandipropamid representing the major part of the total radioactive residues [53%–94% total radioactive residue (TRR)]. In root crops, mandipropamid extensively degraded to several fractions, none in significant amounts, except for the metabolite SYN 500003 (11% TRR in potato peel; 13% TRR in potato pulp). Translocation of residues from the root to the areal part of the crops (leaves) was limited. In the metabolism studies, the possible changes in the stereochemistry of the active substance were not investigated. EFSA would recommend considering this point according to the guidance document on the risk assessment of compounds that may have stereoisomers (EFSA, 2019b) in the framework of the peer review for the renewal of approval of mandipropamid.

Since the crops under consideration belong to the leafy crop group, EFSA concluded that the metabolic behaviour in primary crops is sufficiently addressed, and further studies are not required for the intended use.

1.1.2 | Nature of residues in rotational crops

Radishes may be grown in rotation. According to the soil degradation studies evaluated in the framework of the EU pesticides peer review, the DT_{90} value of mandipropamid ranged from 42 to 240 days. The metabolite SYN 500003 was not identified as a relevant soil metabolite under aerobic conditions (EFSA, 2012). Since the trigger value of 100 days was exceeded for mandipropamid, studies investigating the nature of residues in rotational crops are required (European Commission, 1997c). Confined rotational crop studies were assessed in the EU pesticides peer review. Based on the results of the confined rotational crop study, it was concluded that metabolism in rotational crops is similar to the pathways observed in primary crops (EFSA, 2012).

1.1.3 | Nature of residues in processed commodities

Information regarding the nature of residues in processed commodities was previously assessed in the framework of the EU pesticides peer review in studies performed under standard hydrolysis conditions representative of pasteurisation, boiling/cooking and sterilisation. From these studies, it was concluded that processing by pasteurisation, baking/brewing/boiling and sterilisation is not expected to have a significant impact on the composition of residues in matrices of plant origin (EFSA, 2012).

EFSA concluded that the nature of residues of the active substance under standard hydrolysis conditions is sufficiently addressed, and further studies are not required for the intended use.

1.1.4 | Analytical methods for enforcement purposes in plant commodities

Analytical methods for the determination of mandipropamid residues in plant commodities were investigated in the EU pesticides peer review as well as in the MRL review and in a previous MRL assessment (EFSA, 2012, 2018b, 2018c).

[7]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, pp. 127–175.

[8]Background documents to this reasoned opinion are published on OpenEFSA portal and are available at the following link: https://open.efsa.europa.eu/study-inventory/EFSA-Q-2023-00292.

During the peer review, a multi-residue analytical method (DFG-S19) using LC–MS/MS was validated for the determination of mandipropamid in high-water, high-acid, high-oil and dry content commodities with a LOQ of 0.01 mg/kg (EFSA, 2012). In the context of the MRL review, further methods using LC–MS/MS for the four main plant matrices with a LOQ of 0.01 mg/kg were reported (EFSA, 2018b). In addition, a QuEChERS multi-residue method by high performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) (EN 15662:2009- method 2) was also previously evaluated by EFSA (EFSA, 2018b, 2018c) and independently validated for high water (broccoli), dry matrix (wheat straw) and difficult matrices (cocoa beans) at an LOQ of 0.01 mg/kg. The QuEChERS validation data were re-proposed (Netherlands, 2023). EFSA concluded that sufficiently validated analytical methods are available to enforce residues of mandipropamid in the crop under assessment (high-water content commodity).

The applicant addressed the extraction efficiency of the QuEChERS method proposed to enforce residues of mandipropamid by cross-validation against the method used in the metabolism studies in lettuce and tomato (high-water matrices).[9] Total extracted radioactivity with the extraction solvent used in the crop metabolism studies (acetonitrile/water, 4/1, v/v) was very high (> 97% TRR in lettuces; 87.7% TRR in tomatoes). On the other hand, the solvent system, used in the QuEChERS procedure was acetonitrile with the addition of a suitable volume of water if necessary (i.e. taking into account the natural water content of the samples). The comparison of the extraction efficiency was conducted by extracting aged field tomato and lettuce samples containing incurred residues of mandipropamid and analysing them with each high performance liquid chromatography (HPLC) procedure. The amount of residues extracted from the samples analysed with the QuEChERS solvent system differed by less than 30% compared to the extraction solvent system of the metabolism studies. Therefore, the suitability of the extraction solvent of the QuEChERS method was sufficiently validated according to the extraction efficiency Technical Guideline (European Commission, 2022).

EFSA concluded that for the crops under consideration in the present MRL applications (concerning high-water content matrices), sufficiently validated analytical methods are available. However, it is noted that none of the methods available is stereo-selective.

1.1.5 | Storage stability of residues in plants

The storage stability of mandipropamid in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review and the MRL review (EFSA, 2012, 2018b). In the high-water content matrices, to which group the crop under assessment belongs, mandipropamid residues were stable for at least 24 months when stored at –20°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 the analytical enforcement method, the following residue definitions were proposed during the MRL review:

- residue definition for enforcement: Mandipropamid (any ratio of constituent isomers)
- residue definition for risk assessment:
  - Mandipropamid (any ratio of constituent isomers) for fruit crops and leafy crops.
  - Sum of mandipropamid and SYN 500003, for root crops as tentative residue definition, pending on the submission of toxicological information for hazard characterisation of the metabolite SYN 500003.

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical to the above-mentioned residue definition. The same residue definitions for primary crops are also applicable to rotational crops and processed products.

EFSA concluded that these residue definitions are appropriate for the crop under assessment and no further information is required. The lack of a complete toxicological characterisation on the metabolite SYN 500003 is not a relevant data gap for radish leaves (leafy crop).

1.2 | Magnitude of residues in plants

1.2.1 | Magnitude of residues in primary crops

Radishes (EU greenhouse, foliar treatment): 2 × 150 g a.s./ha; interval between applications: 10 days; pre-harvest interval (PHI): 14 days.

[9]EFSA did not consider the cross-validation data for grapes (high-acid content matrix) included in the study submitted since out of scope in the present MRL request.

In support of the MRL application, the applicant submitted four independent GAP-compliant residue trials performed on radishes grown in indoor conditions. The trials were conducted in The Netherlands and Germany during the growing season of 2020 and 2021. Samples were obtained from treated radish roots and leaves.

Before analyses, the samples were stored under conditions for which the integrity had been demonstrated. The samples of radish leaves were analysed for the parent compound in accordance with the residue definition for enforcement and risk assessment for leafy crops. According to the EMS, the method used to analyse samples for mandipropamid residues (QuEChERS method) was sufficiently validated and fit for purpose. In addition, the extraction efficiency was demonstrated as the QuEChERS method was also proposed for enforcement (see Section 1.1.4).

Samples of radish tubers were also analysed for residues of mandipropamid and the metabolite SYN 500003. The latter was never quantified (LOQ of 0.005 mg/kg, HPLC analytical method coded GRM001.01A).

The number of trials is sufficient to derive an MRL proposal of 50 mg/kg for the intended use of mandipropamid on radish leaves. Residue data from radish roots indicate that, according to the intended use pattern, residues in radish roots will not occur above the existing MRL of 0.3 mg/kg in radishes.

1.2.2 | Magnitude of residues in rotational crops

The occurrence of mandipropamid residues in rotational crops was investigated in the framework of the EU pesticides peer review and the MRL review (EFSA, 2012, 2018b). The maximum application rate proposed for crops that can be grown in rotation was 900 g a.s./ha. Based on the available information from the confined rotational crop study, it was concluded that significant residue levels are unlikely to occur in rotational crops and field studies on the magnitude of residues in rotational crops were not triggered. The current application of mandipropamid in radish leaves has an annual application rate of 600 a.s. g/ha (two cycles of 2 × 150 g/ha). Since the maximum application rate is lower than the one assessed in the peer review and the MRL review, it is concluded that no residues are expected, provided the active substance is applied according to the proposed GAP.

Additionally, even if crop field trials were concluded as not triggered in the EU pesticides peer review (EFSA, 2012) and in this MRL application, the applicant submitted four rotational field trials performed in SEU and NEU. Mandipropamid was applied to bare soil as a single application at an application rate of 900 g a.s./ha. The succeeding crops (spinach, short cycle carrots and spring wheat, representative for leafy, root and cereal groups, respectively) were planted at plant back intervals (PBIs) of 30–32, 119–124 and 271–364 days. Crops were harvested at growth stages of mono- and dicotyledonous plants (BBCH) 43 (immature spinach) and BBCH 49 (mature spinach and carrot), at BBCH 41/BBCH 69 (spring wheat whole plant) and BBCH 89 (spring wheat grain and straw). No residues of mandipropamid were measured above the LOQ of 0.01 mg/kg in succeeding crops (root, leafy and cereals) at any PBI. Thus, confirming the previous conclusion that residues in rotational crops are not expected to occur when mandipropamid is used according to the intended GAP.

1.2.3 | Magnitude of residues in processed commodities

Specific processing studies for the crop under assessment are not available and are not necessary because the total TMDI for the crop under assessment is expected to be less than 10% of the ADI.

1.2.4 | Proposed MRLs

The available data are considered sufficient to derive an MRL proposal as well as risk assessment values for radish leaves (see Appendix B.4). 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 of the above cited Regulation.

In Appendix B.3 EFSA assessed whether residues resulting from the intended use are likely to pose a consumer health risk.

2 | RESIDUES IN LIVESTOCK

Not assessed, as radishes are not considered as a relevant fed item to livestock according to the current guidance (OECD, 2013).

EFSA notes that according to the Commission Regulation (EU) 2018/62 radish leaves are classified under the subgroup of kales. Contrary to radish leaves, kale leaves are a typical livestock feed item. Should any use be intended on kales, further investigations of the carry-over from of residues from kale leaves into 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, 2018a, 2019a). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the assessment of acute and chronic exposure according to the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference value for mandipropamid used in the risk assessment (i.e. ADI of 0.15 mg/kg body weight per day), was derived in the framework of the EU pesticides peer review. Considering the toxicological profile of the active substance, the setting of an ARfD was deemed unnecessary (European Commission, 2018).

Short-term (acute) dietary risk assessment. Considering the toxicological profile of the active substance, a short-term dietary risk assessment was not required.

Long-term (chronic) dietary risk assessment. The long-term exposure assessment was performed, considering the STMR values derived for radish leaves assessed in this application. The PRIMo model contains only the consumption data for commodities listed in Part A of Annex I of Regulation (EC) 2018/62. Therefore, consumption figures for radish leaves are not available. Thus, the exposure calculations have been performed with the consumption of kales instead. For the remaining commodities covered by the MRL regulation, the STMR derived in the framework of the MRL review and the STMR values derived in EFSA opinions issued after the MRL review were selected as input values (EFSA, 2018b, 2018c, 2019c, 2020). The STMR for the Codex MRLs (CXLs) implemented in the EU MRL regulation were also included in the calculation (EFSA, 2019d, 2022; FAO, 2008, 2018, 2021). The proposed MRL in papayas, which is under implementation in the EU MRL regulation, was also included in the calculation (EFSA, 2023a). The risk assessment assumes that the metabolite SYN 500003 is of similar toxicity as the parent compound. The complete list of input values used in the exposure calculations is available in Appendix C.

Exceedances of the ADI are not indicated for any of the consumer groups. The highest estimated long-term dietary exposure is reported for the NL toddler diet, representing up to 6% of the ADI of mandipropamid. The contribution of residues expected in kales (as a surrogate for radish leaves dietary exposure) to the overall long-term exposure is less than (see Appendix B.3).

It is noted that the above risk assessment disregards the possible impact of the isomer ratio due to plant or livestock metabolism. Considering, however, that the active substance consists of enantiomers which are applied as a racemic mixture and that the toxicological studies were carried out according to these specifications (EFSA, 2012), a change of isomer ratio in the residue might, in the worst-case situation, lead to a duplication of the toxicological burden of the residue. Since the exposure calculations represent less than 50% of the ADI, EFSA concludes that the potential change of isomer ratios of mandipropamid in the final residue will not be of concern for the proposed use assessed in the framework of this application. In case future uses of mandipropamid would lead to higher consumer exposure, further information regarding the impact of plant and livestock metabolism on the isomer ratio might be required.

The consumer risk assessment is indicative and affected by the non-standard uncertainty related to the lack of hazard characterisation of the metabolite SYN 500003 relevant for root crops. If the metabolite SYN 500003 possesses higher toxicity than the parent, the overall consumer risk might be underestimated due to the contribution of residues from the authorised uses in root crops (potatoes, beetroots, radishes, onions, spring onions).

EFSA concluded that the indicative long-term intake of residues of mandipropamid 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 available in Appendix C.

4 | CONCLUSION AND RECOMMENDATIONS

The data submitted in this application were found to be sufficient to derive an MRL proposal for radish leaves. Risk Manager's 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 Part A of Annex I of the above cited Regulation.

The intended indoor use proposed in this application refers to the crop radishes that cover both radish roots (food product code 0213080) and radish leaves (subgroup food product code 0243020-008). However, the current application is proposing an MRL modification for radish leaves only. A change of the existing MRL for radish roots was not requested as not necessary. Residues in radish roots measured in the residue trials submitted indicate that the intended use pattern will not result in residues in the roots above the current MRL of 0.3 mg/kg in radishes.

EFSA concluded that the proposed use of mandipropamid on radishes will not result in a consumer exposure exceeding the toxicological reference value and is unlikely to pose a risk to the consumers' health. However, the consumer risk assessment shall be regarded as indicative as affected by non-standard uncertainty related to the lack of hazard characterisation of the metabolite SYN 500003, tentatively included in the residue definition for risk assessment of root crops.

The MRL recommendations are summarised in Appendix B.4.

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
cGAP	critical GAP
CXL	Codex maximum residue limit
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DT_{90}	period required for 90% dissipation (define method of estimation)
dw	dry weight
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
HPLC	high performance liquid chromatography
HPLC–MS/MS	high performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
K_{oc}	organic carbon adsorption coefficient
LC	liquid chromatography
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
SEU	southern Europe
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WHO	World Health Organization

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CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

European Commission

QUESTION NUMBER

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APPENDIX A

Summary of intended GAP triggering the amendment of existing EU MRLs

				Preparation		Application				Application rate per treatment					
Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or Group of pests controlled	Type[b]	Conc. a.s. (g/L)	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	PHI (days)	Remarks
Radishes	EU	G	Downy mildew *(Hyaloperonospora Parasitica)* PEROPA	SC	250	Foliar treatment - broadcast spraying	11–49	2 per crop cycle (max 4 per year)	10	15–75	200–1000	150	g a.s./ha	14	Restrictions: Total application rate 300 g a.s./ha per crop cycle, 600 g a.s./ha per year

Abbreviations: a.s., active substance; GAP, Good Agricultural Practice; MRL, maximum residue level; MS, Member State; NEU, northern European Union; PHI, minimum pre-harvest interval; SC, suspension concentrate; SEU, southern European Union.

[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.

APPENDIX B

List of end points

B.1 | RESIDUES IN PLANTS

B.1.1 | Nature of residues and analytical methods for enforcement purposes in plant commodities

B.1.1.1 | Metabolism studies, analytical methods and residue definitions in plants

	Crop groups	Crops	Applications	Sampling (DALA)	Comment/source
Primary crops (available studies)	Fruit crops	Grapes	Foliar, 6 × 143–151 g a.s./ha	0, 14, 28	Radiolabelled a.s.: methoxyphenyl-(U)-^{14}C or chlorophenyl-(U)-^{14}C mandipropamid (EFSA, 2012)
			Foliar, 6 × 411–464 g a.s./ha	28	
		Tomatoes	Foliar, 266 + 295 + 147 + 149 g a.s./ha	0, 3, 7, 14, 28	Radiolabelled a.s.: [1-^{14}C]-mandipropamid (EFSA, 2012)
	Root crops	Potatoes	Foliar, 6 × 146–158 g a.s./ha	7, 21	Radiolabelled a.s.: methoxyphenyl-(U)-^{14}C or chlorophenyl-(U)-^{14}C mandipropamid (EFSA, 2012)
			Foliar, 6 × 418–458 g a.s./ha	21	
	Leafy crops	Lettuces	Foliar, 2 × 140–160 g a.s./ha	3, 14	

	Crop groups	Crops	Application	PBI (DAT)	Comment/source
Rotational crops (available studies)	Root/tuber crops	Radishes	Bare soil, 1 × 900 g a.s./ha	29, 58, 120	Radiolabelled a.s.: methoxyphenyl-(U)-^{14}C or chlorophenyl-(U)-^{14}C mandipropamid (EFSA, 2012)
	Leafy crops	Lettuces	Bare soil, 1 × 900 g a.s./ha	29, 58, 120, 365	
	Cereal (small grain)	Spring wheat	Bare soil, 1 × 900 g a.s./ha	29, 58, 120, 365	

	Conditions	Stable?	Comment/source
Processed commodities (hydrolysis study)	Pasteurisation (20 min, 90°C, pH 4)	Yes	Radiolabelled a.s.: methoxyphenyl-(U)-^{14}C or chlorophenyl-(U)-^{14}C mandipropamid (EFSA, 2012)
	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?	No	EFSA (2018b)
Rotational crop and primary crop metabolism similar?	Yes	EFSA (2012)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2012)

Plant residue definition for monitoring (RD-Mo)	Mandipropamid (any ratio of constituent isomers)
Plant residue definition for risk assessment (RD-RA)	Fruit crops, leafy crops: mandipropamid (any ratio of constituent isomers) (EFSA, 2012, 2018b) Root crops: sum of mandipropamid and SYN 500003 (tentative, pending the submission of toxicological information on SYN 500003) (EFSA, 2012, 2018b)
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high water content, high oil content, high acid content and dry matrices: • DFG-S19 (LC–MS/MS), LOQ 0.01 mg/kg • ILV available (EFSA, 2012) Matrices with high water content: • QuEChERS (HPLC–MS/MS); LOQ 0.01 mg/kg • ILV available (EFSA, 2018b,c) Extraction efficiency demonstrated in high water content commodities (Netherlands, 2023)

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; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; ILV: independent laboratory validation.

B.1.1.2. | Stability of residues in plants

	Category	Commodity	*T* (°C)	Stability period		Compounds covered	Comment/source
				Value	Unit		
Plant products (available studies)	High-water content	Tomatoes, lettuces, cucumber, potatoes	–20	24	Months	Parent	EFSA (2018b)
	High-water content	Potatoes	–20	32	Months	SYN 500003	EFSA (2018b)
	High-oil content	Soyabeans	–20	24	Months	Parent	EFSA (2018b)
	Dry/High starch	Wheat	–20	24	Months	Parent	EFSA (2018b)
	High-acid content	Grapes	-20	24	Months	Parent	EFSA (2018b)

B.1.2 | Magnitude of residues in plants

B.1.2.1 | 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]
• Radishes	EU	Leaves: 1.3; 1.5; 14; 17	Residue trials on radishes compliant with GAP SYN 500003 was only measured for radish roots (relevant for residue definition of root crops) and it was always below 0.005 mg/kg (LOQ).	50	17	7.75	1
		Roots: Mo: 0.03; 0.04; 0.08; 0.09 RA[e]: 0.04; 0.05; 0.09; 0.10		0.2[f]	Mo: 0.09 RA: 0.10	Mo: 0.06 RA: 0.07	1[g]

Abbreviations: GAP, Good Agricultural Practice; Mo, monitoring; MRL, maximum residue level; N/A, not applicable; RA, risk assessment.

[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.

[e]Residue values for risk assessment calculated without molecular weight conversion according to the tentative residue definition for risk assessment in root crops.

[f]MRL value derived for radish roots is lower than the existing MRL (CXL). A change of the MRL on radish is not needed to cover the intended use on radish leaves.

[g]Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment is proposed as 1 because residue levels of the metabolite SYN 500003 were below the LOQ of 0.005 in all trials submitted (EFSA, 2019c).

B.1.2.2 | Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	No	Residues are not expected in rotational crops EFSA (2012)
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	EFSA (2012, 2018b) Four rotational field trials in in NEU and SEU performed at a rate of 900 g/ha (1.5N the intended use on radish leaves) applied to bare soil. Residues of parent mandipropamid were not measured above the LOQ of 0.01 mg/kg at any PBI of 30 – 32, 119 – 124 and 271 – 364 days in succeeding crops (root, leafy and cereals) (Netherlands, 2023).

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.

B.3 | CONSUMER RISK ASSESSMENT

Not relevant since no ARfD has been considered necessary.

ADI	0.15 mg/kg bw per day (European Commission, 2018)
Highest IEDI, according to EFSA PRIMo	6% ADI (NL toddler diet) Contribution of crops assessed: Radish leaves (based on kale consumption data): 0.96% of ADI (PT, general diet)
Assumptions made for the calculations	The calculation is based on the median residue level (STMR) entered for kales as derived from the submitted residue trials on radishes. EFSA notes that a minor uncertainty exists on the chronic exposure from radish leaves. As the consumption data on radish leaves is lacking, calculations were performed based on the consumption of kales. For the remaining commodities, the STMR values and the STMR-pulp (edible portion, for citrus and papayas) as derived in the MRL review and in opinions published after the MRL review (EFSA, 2018b,c, 2019c, 2020, 2023a) were included in the calculation. The contributions of commodities where no GAP or safe CXL was reported in the framework of the MRL review or in the recently issued EFSA scientific reports (EFSA, 2019d, 2022) were not included in the calculation. For the root crops potatoes, onions and spring onions, the STMR derived for raw agricultural commodities was multiplied by the conversion factor for risk assessment of 2, which was derived from the metabolism study on potatoes to take into consideration the contribution of the metabolite SYN 500003 provisionally included in the residue definition for risk assessment of root crops. For the root crops beetroots and radishes, the median residue levels were multiplied by a CF of 1, since residue levels of the metabolite SYN 500003 were below the LOQ in all the trials submitted (EFSA, 2019c). The risk assessment assumes that the metabolite SYN 500003 is of similar toxicity as the parent compound and, therefore, shall be regarded as indicative. 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.4 | RECOMMENDED MRLS

Code[a]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Mandipropamid (any ratio of constituent isomers)				
0243020-008	Radish leaves (Included in part B of Annex I of the Commission Regulation (EU) 2018/62[b] under kales)	25	50 (Further risk management consideration)	The submitted residue data on radish leaves are sufficient to derive an MRL proposal for this commodity based on the intended use 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 Part A of Annex I It is noted that the current MRL in kales (25 mg/kg) is lower than the proposed MRL in radish leaves. Therefore, a risk Managers' consideration is needed on how to implement the proposed MRL on radish leaves Because, contrary to radish leaves, kale leaves are used as feed items. Therefore, should a new use on kales be applied for, the Member State granting authorisations would need to investigate the magnitude of residues in food commodities of animal origin

Abbreviations: GAP, Good Agricultural Practice; MRL, maximum residue level.

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

[b]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. OJ L 18, 23.1.2018, pp. 1–73.

APPENDIX C

Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Mandipropamid

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

Toxicological reference values

ADI (mg/kg bw per day):	0.15	ARfD (mg/kg bw):	not necessary
Source of ADI:	European	Source of ARfD:	European
Year of evaluation:	2018	Year of evaluation:	2018

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 PLAN/2023/750 (not yet published), exept for the crop under assessment (radish leaves/kales)

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)	6%	NL toddler	8.59	3%	Spinaches	0.9%	Escaroles/broad-leaved endives	0.5%	Table grapes	0.4%	6%
	4%	SE general	5.96	2%	Lettuces	0.8%	Chinese cabbages/pe-tsai	0.5%	Head cabbages	0.1%	4%
	4%	GEMS/Food G10	5.70	1%	Lettuces	0.6%	Chinese cabbages/pe-tsai	0.3%	Head cabbages	0.0%	4%
	4%	IT adult	5.45	1%	Lettuces	0.6%	Other lettuce and other salad plants	0.4%	Spinaches		4%
	3%	ES adult	4.73	2%	Lettuces	0.3%	Chards/beet leaves	0.3%	Spinaches	0.0%	3%
	3%	GEMS/Food G06	4.67	0.8%	Tomatoes	0.4%	Lettuces	0.4%	Table grapes	0.0%	3%
	3%	IE adult	4.60	0.7%	Other leafy brassica	0.5%	Spinaches	0.4%	Wine grapes	0.0%	3%
	3%	DE child	4.60	0.8%	Spinaches	0.5%	Table grapes	0.3%	Lettuces	0.1%	3%
	3%	GEMS/Food G08	4.44	0.7%	Lettuces	0.4%	Head cabbages	0.4%	Wine grapes	0.1%	3%
	3%	NL child	4.37	0.9%	Spinaches	0.4%	Escaroles/broad-leaved endives	0.4%	Table grapes	0.2%	3%
	3%	IT toddler	4.31	1%	Lettuces	0.4%	Other lettuce and other salad plants	0.3%	Tomatoes		3%
	3%	GEMS/Food G07	4.19	0.9%	Lettuces	0.5%	Wine grapes	0.2%	Tomatoes	0.1%	3%
	3%	ES child	4.08	2%	Lettuces	0.3%	Spinaches	0.3%	Chards/beet leaves	0.1%	3%
	3%	GEMS/Food G11	4.06	0.5%	Celeries	0.3%	Spinaches	0.3%	Wine grapes	0.1%	3%
	3%	PT general	3.95	1.0%	Kales	0.8%	Wine grapes	0.4%	Lettuces		3%
	3%	RO general	3.77	1%	Head cabbages	0.6%	Wine grapes	0.4%	Tomatoes	0.1%	3%
	2%	GEMS/Food G15	3.72	0.7%	Head cabbages	0.4%	Lettuces	0.3%	Wine grapes	0.1%	2%
	2%	NL general	3.65	0.6%	Spinaches	0.4%	Escaroles/broad-leaved endives	0.4%	Lettuces	0.1%	2%
	2%	FR adult	3.15	0.8%	Wine grapes	0.6%	Other lettuce and other salad plants	0.2%	Spinaches	0.0%	2%
	2%	FR child 3 15 yr	2.85	0.4%	Other lettuce and other salad plants	0.4%	Spinaches	0.2%	Tomatoes	0.2%	2%
	2%	DE women 14-50 yr	2.61	0.4%	Lettuces	0.3%	Wine grapes	0.2%	Spinaches	0.1%	2%
	2%	DE general	2.60	0.4%	Lettuces	0.3%	Wine grapes	0.2%	Spinaches	0.1%	2%
	2%	FR toddler 2 3 yr	2.39	0.6%	Spinaches	0.2%	Milk: Cattle	0.1%	Beans (with pods)	0.2%	2%
	2%	FR infant	2.36	1%	Spinaches	0.1%	Chards/beet leaves	0.1%	Milk: Cattle	0.1%	2%
	1%	UK vegetarian	2.23	0.5%	Lettuces	0.3%	Wine grapes	0.1%	Tomatoes	0.0%	1%
	1%	UK adult	1.97	0.4%	Lettuces	0.4%	Wine grapes	0.1%	HOPS (dried)	0.0%	1%
	1%	DK adult	1.66	0.3%	Lettuces	0.3%	Wine grapes	0.1%	Tomatoes	0.0%	1%
	1%	DK child	1.58	0.5%	Lettuces	0.1%	Tomatoes	0.1%	Milk: Cattle	0.1%	1%
	1%	FI adult	1.56	0.5%	Lettuces	0.1%	Tomatoes	0.1%	Wine grapes		1%
	1.0%	FI 6 yr	1.46	0.3%	Lettuces	0.2%	Spinaches	0.1%	Chinese cabbages/pe-tsai		1.0%
	0.9%	PL general	1.33	0.3%	Head cabbages	0.2%	Tomatoes	0.1%	Table grapes		0.9%
	0.9%	FI 3 yr	1.29	0.2%	Spinaches	0.1%	Lettuces	0.1%	Tomatoes		0.9%
	0.8%	UK toddler	1.22	0.1%	Milk: Cattle	0.1%	Tomatoes	0.1%	Spinaches	0.1%	0.8%
	0.8%	LT adult	1.20	0.3%	Head cabbages	0.2%	Lettuces	0.1%	Tomatoes	0.0%	0.8%
	0.6%	UK infant	0.93	0.3%	Milk: Cattle	0.1%	Head cabbages	0.1%	Tomatoes	0.3%	0.6%
	0.2%	IE child	0.26	0.0%	Lettuces	0.0%	Milk: Cattle	0.0%	Head cabbages	0.0%	0.2%

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

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

Show results for all crops

Unprocessed commodities

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

Processed commodities

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

Conclusion:

APPENDIX D

Input values for the exposure calculations

D.1 | Consumer risk assessment

Commodity	Existing/ proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment
Risk assessment residue definition: Mandipropamid (any ratio of constituent isomers)						
Grapefruits	0.2	FAO (2021)	0.01	STMR (CXL)-Pulp	Considering the toxicological profile of the active substance, an acute risk assessment was not needed as the setting of an ARfD for the active substance was considered not necessary	
Oranges	0.4	FAO (2021)	0.01	STMR (CXL)-Pulp		
Lemons	0.5	FAO (2021)	0.01	STMR (CXL)-Pulp		
Limes	0.5	FAO (2021)	0.01	STMR (CXL)-Pulp		
Mandarins	0.5	FAO (2021)	0.01	STMR (CXL)-Pulp		
Table grapes	2	FAO (2008), EFSA (2018b)	0.51	STMR (CXL)-RAC		
Wine grapes	2	FAO (2008), EFSA (2018b)	0.51	STMR (CXL)-RAC		
Kumquats	0.5	FAO (2021)	0.1	STMR (CXL)-RAC		
Papayas	0.8[b]	EFSA (2023a)	0.01	STMR-Pulp		
Tomatoes	3	EFSA (2018b)	0.34	STMR-RAC		
Sweet peppers/bell peppers	1	FAO (2008), EFSA (2018b)	0.12	STMR (CXL)-RAC		
Aubergines/egg plants	3	EFSA (2018b)	0.34	STMR-RAC		
Cucumbers	0.2	FAO (2008), EFSA (2018b)	0.02	STMR (CXL)-RAC		
Courgettes	0.2	FAO (2008), EFSA (2018b)	0.04	STMR (CXL)-RAC		
Melons	0.5	FAO (2008), EFSA (2018b)	0.12	STMR (CXL)-RAC		
Pumpkins	0.3	EFSA (2018b)	0.07	STMR-RAC		
Watermelons	0.3	Extrapolated from pumpkins	0.07	STMR-RAC		
Other cucurbits - inedible peel	0.3	Extrapolated from pumpkins	0.07	STMR-RAC		
Broccoli	2	FAO (2008), EFSA (2018b)	0.44	STMR-RAC		
Cauliflowers	0.3	EFSA (2019c)	0.01	STMR (CXL)-RAC		
Brussels sprouts	0.2	EFSA (2019c)	0.04	STMR-RAC		
Head cabbages	3	FAO (2008), EFSA (2018b)	1.21	STMR (CXL)-RAC		
Chinese cabbages/ pe-tsai	25	FAO (2008), EFSA (2018b)	5.65	STMR (CXL)-RAC		
Kales/radish leaves	**50**	**Intended use**	7.75	STMR-RAC		
Other leafy brassica	25	FAO (2008), EFSA (2018b)	5.65	STMR (CXL)-RAC		
Kohlrabies	0.1	EFSA (2020)	0.01	STMR-RAC		
Lamb's lettuce/corn salads	25	FAO (2008), EFSA (2018b)	5.65	STMR (CXL)-RAC		
Lettuces	25	FAO (2008), EFSA (2018b)	5.65	STMR (CXL)-RAC		
Escaroles/broad-leaved endives	25	FAO (2008), EFSA (2018b)	5.65	STMR (CXL)-RAC		
Cress and other sprouts and shoots	25	FAO (2008), EFSA (2018b)	5.65	STMR (CXL)-RAC		
Land cress	25	FAO (2008), EFSA (2018b)	5.65	STMR (CXL)-RAC		
Roman rocket/rucola	25	FAO (2008), EFSA (2018b)	5.65	STMR (CXL)-RAC		

			Chronic risk assessment		Acute risk assessment	
Commodity	Existing/ proposed MRL (mg/kg)	Source	Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment
Red mustards	25	FAO (2008), EFSA (2018b)	5.65	STMR (CXL)-RAC		
Baby leaf crops (including brassica species)	25	FAO (2008), EFSA (2018b)	5.65	STMR (CXL)-RAC		
Other lettuce and other salad plants	25	FAO (2008), EFSA (2018b)	5.65	STMR (CXL)-RAC		
Spinaches	25	FAO (2008), EFSA (2018b)	5.65	STMR (CXL)-RAC		
Purslanes	25	FAO (2008), EFSA (2018b)	5.65	STMR (CXL)-RAC		
Chards/beet leaves	25	FAO (2008), EFSA (2018b)	5.65	STMR (CXL)-RAC		
Other spinach and similar	25	FAO (2008), EFSA (2018b)	5.65	STMR (CXL)-RAC		
Grape leaves and similar species	25	FAO (2008), EFSA (2018b)	5.65	STMR (CXL)-RAC		
Watercress	25	FAO (2008), EFSA (2018b)	5.65	STMR (CXL)-RAC		
Witloofs/Belgian endives	0.15	EFSA (2019c)	0.02	STMR-RAC		
Chervil	30	EFSA (2020)	7.10	STMR-RAC		
Chives	30	EFSA (2020)	7.10	STMR-RAC		
Celery leaves	30	EFSA (2020)	7.10	STMR-RAC		
Parsley	30	EFSA (2020)	7.10	STMR-RAC		
Sage	30	EFSA (2020)	7.10	STMR-RAC		
Rosemary	30	EFSA (2020)	7.10	STMR-RAC		
Thyme	30	EFSA (2020)	7.10	STMR-RAC		
Basil and edible flowers	30	EFSA (2020)	7.10	STMR-RAC		
Laurel/bay leaves	30	EFSA (2020)	7.10	STMR-RAC		
Tarragon	30	EFSA (2020)	7.10	STMR-RAC		
Other herbs	30	EFSA (2020)	7.10	STMR-RAC		
Bens with pods	1	FAO (2018)	0.22	STMR (CXL)-RAC		
Peas (without pods)	0.3	EFSA (2019c)	0.03	STMR-RAC		
Celeries	20	FAO (2008), EFSA (2018b)	2.70	STMR (CXL)-RAC		
Globe artichokes	0.3	EFSA (2019c)	0.06	STMR-RAC		
Cocoa beans	0.06	FAO (2018), EFSA (2018c)	0.01	STMR-RAC		
HOPS (dried)	90	EFSA (2018b)	28.50	STMR-RAC		
Swine: Muscle/meat	0.01	FAO (2021)	0.01	LOQ		
Swine: Fat tissue	0.02	FAO (2021)	0.01	STMR-RAC		
Swine: Liver	0.01	FAO (2021)				
Swine: Kidney	0.01	FAO (2021)	0.01	LOQ		
Swine: Edible offals (other than liver and kidney)	0.01	FAO (2021)	0.01	LOQ		
Swine: Other products	0.01	FAO (2021)	0.01	LOQ		
Bovine: Muscle/meat	0.01	FAO (2021)	0.01	LOQ		
Bovine: Fat tissue	0.02	FAO (2021)	0.01	STMR-RAC		
Bovine: Liver	0.01	FAO (2021)	0.01	LOQ		
Bovine: Kidney	0.01	FAO (2021)	0.01	LOQ		
Bovine: Edible offal (other than liver and kidney)	0.01	FAO (2021)	0.01	LOQ		
Bovine: Other products	0.01	FAO (2021)	0.01	LOQ		

Commodity	Existing/ proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment
Sheep: Muscle/meat	0.01	FAO (2021)	0.01	LOQ		
Sheep: Fat tissue	0.02	FAO (2021)	0.01	STMR-RAC		
Sheep: Liver	0.01	FAO (2021)	0.01	LOQ		
Sheep: Kidney	0.01	FAO (2021)	0.01	LOQ		
Sheep: Edible offal (other than liver and kidney)	0.01	FAO (2021)	0.01	LOQ		
Sheep: other products	0.01	FAO (2021)	0.01	LOQ		
Goat: Muscle/meat	0.01	FAO (2021)	0.01	LOQ		
Goat: Fat tissue	0.02	FAO (2021)	0.01	STMR-RAC		
Goat: Liver	0.01	FAO (2021)	0.01	LOQ		
Goat: Kidney	0.01	FAO (2021)	0.01	LOQ		
Goat: Edible offal (other than liver and kidney)	0.01	FAO (2021)	0.01	LOQ		
Goat: other products	0.01	FAO (2021)	0.01	LOQ		
Equine: Muscle/meat	0.01	FAO (2021)	0.01	LOQ		
Equine: Fat tissue	0.02	FAO (2021)	0.01	STMR-RAC		
Equine: Liver	0.01	FAO (2021)	0.01	LOQ		
Equine: Kidney	0.01	FAO (2021)	0.01	LOQ		
Equine: Edible offal (other than liver and kidney)	0.01	FAO (2021)	0.01	LOQ		
Equine: Other products	0.01	FAO (2021)	0.01	LOQ		
Other farmed animals: Muscle/ meat	0.01	FAO (2021)	0.02	LOQ		
Other farmed animals: Fat tissue	0.02	FAO (2021)	0.02	MRL		
Other farmed animals: Liver	0.01	FAO (2021)	0.01	LOQ		
Other farmed animals: Kidney	0.01	FAO (2021)	0.01	LOQ		
Milk: Cattle	0.01	FAO (2021)	0.01	LOQ		
Milk: Sheep	0.01	FAO (2021)	0.01	LOQ		
Milk: Goat	0.01	FAO (2021)	0.01	LOQ		
Milk: Horse	0.01	FAO (2021)	0.01	LOQ		
Milk: Others	0.01	FAO (2021)	0.01	LOQ		
Risk assessment residue definition: sum of mandipropamid and SYN 500003 [tentative, pending on information on the toxicological of metabolite SYN 500003]						
Potatoes	0.1[c]	EFSA (2018b)	0.02	STMR-RAC × CF (2)	A short-term dietary risk assessment may be required, pending on the submission of toxicological information for the metabolite SYN 500003	
Beetroots	0.1[c]	EFSA (2019c)	0.04	STMR-RAC × CF (1)		
Radishes	0.3[c]	EFSA (2019c)	0.07	STMR-RAC × CF (1)		
Onions	0.1[c]	FAO (2008), EFSA (2018b)	0.02	STMR (CXL)-RAC × CF (2)		
Spring, green and Welsh onions	7[c]	FAO (2008), EFSA (2018b)	0.96	STMR (CXL)-RAC × CF (2)		

Abbreviations: ARfD, acute reference dose; CF, conversion factor for enforcement to risk assessment residue definition; CXL, codex maximum residue limit; HR-RAC, highest residue in raw agricultural commodity; PeF, Peeling factor; STMR-RAC, supervised trials median residue in raw agricultural commodity.

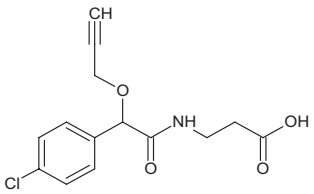
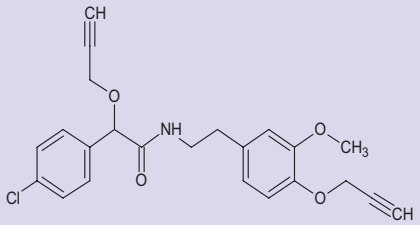
[a]Figures in the table are rounded to two digits, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce dietary burden calculations, the unrounded values need to be used.

[b]MRL proposal recently assessed by EFSA (EFSA, 2023a). Draft regulation PLAN/2023/750 is not yet published in the EU Official Journal.

[c]Tentative MRL which is not fully supported by data but for which no risk to consumers was identified (assuming the metabolite SYN 500003 toxicity is covered by the toxicological profile of parent compound) (EFSA, 2018b, 2019c).

APPENDIX E

Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Mandipropamid	(*2RS*)-2-(4-chlorophenyl)-*N*-{2-[3-methoxy-4-(prop-2-ynyloxy)phenyl] ethyl}-2-(prop-2-ynyloxy)acetamide Clc1ccc(cc1)C(OCC#C)C(=O)NCCc2ccc(OCC#C)c(OC)c2 KWLVWJPJKJMCSH-UHFFFAOYSA-N	
SYN 500003 R740990 EZA15629 CA 4013 U1 U29b	*N*-{(2*RS*)-2-(4-chlorophenyl)-2-[(prop-2-yn-1-yl)oxy]acetyl}-β-alanine Clc1ccc(cc1)C(OCC#C)C(=O)NCCC(=O)O ZNNAJYNLYSBVRG-UHFFFAOYSA-N	

Abbreviations: InChiKey, International Chemical Identifier Key; IUPAC, International Union of Pure and Applied Chemistry; SMILES, simplified molecular-input line-entry system.

[a]The metabolite name in bold is the name used in the conclusion.

[b]ACD/Name 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 07 Jul 2021).

[c]ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 28 Aug 2021).