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Evaluation of confirmatory data following the Article 12 MRL review for napropamide

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Abstract

The applicant UPL Europe Ltd submitted a request to the competent national authority in Slovenia to evaluate the confirmatory data that were identified for napropamide in the framework of the maximum residue levels (MRLs) review under Article 12 of Regulation (EC) No 396/2005 as not available. To address the data gaps, a new storage stability study on grapes (high acid content commodity) was submitted while a metabolism study in fruit crops following foliar treatment, residue trials on fresh herbs and edible flowers and an analytical method for matrices difficult to analyse were not submitted. Therefore, only the data gap for storage stability was satisfactorily addressed. The new information provided required a revision of the tentative MRLs for commodities where confirmatory data were indicated. An update of the consumer risk assessment for napropamide was performed considering the new data submitted and it did not indicate any consumer intake concerns in relation to the chronic exposure.

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Summary

In 2018, when the European Food Safety Authority (EFSA) reviewed the existing maximum residue levels (MRLs) for napropamide according to Article 12 of Regulation (EC) No 396/2005, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified. The following data gaps were noted:

- 1) A representative study investigating primary crop metabolism in fruit crops following foliar treatment (data gap relevant for blueberries, cranberries, currants, gooseberries, rose hips and elderberries).
- 2) Residue trials on table/wine grapes, figs, granate apples/pomegranate, sweet peppers/bell peppers, watermelons, Chinese cabbages, kales, kohlrabies, fresh herbs, herbal infusions from flowers, herbal infusion from leaves and herbs, herbal infusion from roots and fresh spices.
- 3) A storage stability study on high acid content commodities (data gap relevant for citrus fruit and for berries and small fruits).
- 4) An analytical method for matrices difficult to analyse (data gap relevant for herbal infusions from flowers, leaves and herbs, roots and fruit spices).

Tentative MRL proposals have been implemented in the MRL legislation by Commission Regulation (EU) 2020/770, including footnotes related to data gaps numbers 1, 3 and 4. Data gap number 2 was only translated into a footnote for the crop group herbs and edible flowers, for the remaining crops no footnotes were implemented in the MRL regulation, because no residue trials were provided during the MRL review to support the authorised GAPs. The Commission Regulation (EU) 2020/770 indicates the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRL by 12 June 2022.

In accordance with the agreed procedure set out in the working document SANTE/10235/2016, UPL Europe Ltd submitted an application to the competent national authority in Slovenia (rapporteur Member State, RMS) to evaluate the confirmatory data identified during the MRL review.

The application, alongside the dossier containing the supporting data in IUCLID format, was submitted through the EFSA Central Submission System on 3 August 2022. The appointed RMS Slovenia assessed the dossier and declared its admissibility on 30 August 2022. 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 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 run from 27 March 2023 to 17 April 2023. No additional data nor comments were submitted in the framework of the consultation.

At the end of the commenting period, the RMS proceeded drafting the evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA. When assessing the evaluation report, EFSA identified points which needed further clarifications. On 24 April 2023, the applicant provided the requested information in an updated IUCLID dossier. The additional information was duly considered by the RMS who submitted a revised evaluation report to EFSA on 24 April 2023 (Slovenia, 2023), which replaced the previously submitted evaluation report.

The summary table below provides an overview of the assessment of confirmatory data and the recommended MRL modifications to Regulation (EU) No 396/2005.

Code ^(a)	Commodity	Existing MRL ^(b)	Data gap(s) Art.12 Review	Proposed MRL	Conclusion/ recommendation
Enforcement residue definition: Napropamide (sum of isomers)					
0110000	Citrus fruit	0.01* (ft 1)	Footnote related to data gap No 3. [storage stability unavailable]	0.01*	The data gap identified by EFSA concerning storage stability has been addressed. EFSA proposes to confirm the existing MRL. The updated consumer risk assessment for napropamide did not indicate any consumer intake concerns.
0110010	Grapefruits				
0110020	Oranges				
0110030	Lemons				
0110040	Limes				
0110990	Others				

Code ^(a)	Commodity	Existing MRL ^(b)	Data gap(s) Art.12 Review	Proposed MRL	Conclusion/ recommendation
0152000	Strawberries	0.01* (ft 1)	Footnote related to data gap No 3. [storage stability unavailable]	0.01*	The data gap identified by EFSA concerning storage stability has been addressed. EFSA proposes to confirm the existing MRL. The updated consumer risk assessment for napropamide did not indicate any consumer intake concerns.
0153000	Cane fruits	0.01* (ft 1)	Footnote related to data gap No 3. [storage stability unavailable]	0.01*	The data gap identified by EFSA concerning storage stability has been addressed. EFSA proposes to confirm the existing MRL. The updated consumer risk assessment for napropamide did not indicate any consumer intake concerns.
0153010	Blackberries				
0153020	Dewberries				
0153030	Raspberries (red and yellow)				
0153990	Others				
0154010	Blueberries	0.02* (ft 1)	Footnote related to data gaps No 1 and 3. [crop metabolism and storage stability unavailable]	0.01*	The data gap identified by EFSA concerning storage stability has been addressed. However, the data gap concerning crop metabolism in fruit crops following foliar treatment has not been addressed. The applicant indicated that no metabolism study was submitted since the use on berries is no longer supported. Therefore, EFSA proposes to lower the existing MRL to the LOQ of 0.01 mg/kg.
0154020	Cranberries				
0154030	Currants (black, red and white)				
0154040	Gooseberries (green, red and yellow)				
0154050	Rose hips				
0154080	Elderberries				
0256000	Herbs and edible flowers	0.05 (ft 1)	Footnote related to data gap No 2. [additional residue trials]	0.01*	The data gap identified by EFSA concerning additional residue trials has not been addressed. The applicant indicated that no additional residue trials are provided as the use on these crops is no longer supported. Therefore, EFSA proposes to lower the existing MRL to the LOQ of 0.01 mg/kg.
0256010	Chervil				
0256020	Chives				
0256030	Celery leaves				
0256040	Parsley				
0256050	Sage				
0256060	Rosemary				
0256070	Thyme				
0256080	Basil and edible flowers				
0256090	Laurel/bay leaves				
0256100	Tarragon				
0256990	Others				
0630000	Herbal infusions	0.05* (ft 1)	Footnote related to data gap No 4. [analytical methods unavailable]	0.05*	The data gap identified by EFSA concerning analytical enforcement method for matrices difficult to analyse has not been addressed. The applicant indicated that no analytical method is provided as the use on these crops is no longer supported. Therefore, in the absence of a more sensitive analytical method, EFSA proposes to maintain the
0631000	Herbal infusions from flowers	0.05* (ft 1)	Footnote related to data gap No 4. [analytical methods unavailable]	0.05*	
0631010	Chamomile				
0631020	Hibiscus/roselle				
0631030	Rose				
0631040	Jasmine				

Code ^(a)	Commodity	Existing MRL ^(b)	Data gap(s) Art.12 Review	Proposed MRL	Conclusion/ recommendation
0631050	Lime/linden				existing MRL at the LOQ of 0.05 mg/kg.
0631990	Others				
0632000	Herbal infusions from leaves and herbs	0.05* (ft 1)	Footnote related to data gap No 4. [analytical methods unavailable]	0.05*	
0632010	Strawberry				
0632020	Rooibos				
0632030	Mate/maté				
0632990	Others				
0633000	Herbal infusions from roots	0.05* (ft 1)	Footnote related to data gap No 4. [analytical methods unavailable]	0.05*	
0633010	Valerian				
0633020	Ginseng				
0633990	Others				
0639000	Herbal infusions from any other parts of the plant	0.05* (ft 1)	Footnote related to data gap No 4. [analytical methods unavailable]	0.05*	
0820000	Fruit spices	0.05* (ft 1)	Footnote related to data gap No 4. [analytical methods unavailable]	0.05*	The data gap identified by EFSA concerning analytical enforcement method for matrices difficult to analyse has not been addressed. The applicant indicated that no analytical method is provided as the use on these crops is no longer supported. Therefore, EFSA proposes to maintain the existing MRL at the LOQ of 0.05 mg/kg.
0820010	Allspice/pimento				
0820020	Sichuan pepper				
0820030	Caraway				
0820040	Cardamom				
0820050	Juniper berry				
0820060	Peppercorn (black, green and white)				
0820070	Vanilla				
0820080	Tamarind				
0820990	Others				

MRL: maximum residue level; LOQ: limit of quantification.

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

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

(b): Existing EU MRL and corresponding footnote on confirmatory data.

ft 1: The European Food Safety Authority identified some information on storage stability as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

ft 2: The European Food Safety Authority identified some information on storage stability and crop metabolism as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

ft 3: The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

ft 4: The European Food Safety Authority identified some information on analytical methods as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

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Assessment

The review of existing maximum residue levels (MRLs) for the active substance napropamide according to Article 12 of Regulation (EC) No 396/2005¹ (MRL review) has been performed in 2018 (EFSA, 2018b). The European Food Safety Authority (EFSA) identified some information as unavailable (data gaps) and derived tentative MRLs for those uses not fully supported by data but for which no risk to consumers was identified.

Following the review of existing MRLs, the legal limits have been modified by Commission Regulation (EU) 2020/770², including footnotes for tentative MRLs that specified the type of information that was identified as missing. Any party having an interest in maintaining the proposed tentative MRLs was requested to address the confirmatory data by 12 June 2022.

In accordance with the specific provisions set out in the working document of the European Commission SANTE/10235/2016 (European Commission, 2020) and the 'Transparency Regulation' (EU) 2019/1381³, the applicant UPL Europe Ltd submitted on 8 August 2022 an application to the competent national authority in Slovenia to evaluate the confirmatory data identified during the MRL review, alongside the dossier containing the supporting data using the IUCLID format. To address the data gaps identified by EFSA, the applicant provided a new study on storage stability of napropamide in grapes. Although not indicated as confirmatory data following the MRL review, the applicant provided new residue trials on grapes. EFSA assessed in the present application only the studies linked to the confirmatory data reported in the Commission Regulation (EU) 2020/770. Therefore, the provided residues trials on grapes have not been assessed since they were not linked to confirmatory data.

The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA. EFSA assessed the application as requested by the European Commission in accordance with Article 10 of Regulation (EC) No 396/2005. When assessing the evaluation report, EFSA identified points which needed further clarifications. On 24 April, the applicant provided the requested information in an updated IUCLID dossier. The additional information was duly considered by the RMS who submitted a revised evaluation report to EFSA on 24 April (Slovenia, 2023), which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the RMS (Slovenia, 2023) and the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2018b).

For this application, the data requirements established in Regulation (EU) No 544/2011⁴ and the relevant guidance documents at the date of implementation of the confirmatory data requirements by Commission Regulation (EU) 2020/770 are applicable. 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 546/2011⁵.

An updated list of end points, including the end points of relevant studies assessed previously and the confirmatory data evaluated in this application, is presented in Appendix B.

The evaluation report submitted by the RMS (Slovenia, 2023) is considered a supporting document to this reasoned opinion and, thus, is made publicly available as a background document to this reasoned opinion.⁶

¹ 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, 16.3.2005, p. 1–16.

² Commission Regulation (EU) 2020/770 of 8 June 2020 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for myclobutanil, napropamide and sintofen in or on certain products. OJ L 184, 12.6.2020, p. 1–24.

³ 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, p. 1–28.

⁴ Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

⁵ 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.

⁶ 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-2022-00540>

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 napropamide following soil treatments has been investigated in four different crop groups (fruits, leafy crops, root crops and pulses/oilseeds) and assessed in the framework of the peer review of the active substance under Directive 91/414/EEC (EFSA, 2010). The conclusion of the peer review was that napropamide is metabolised by the same metabolic pathway when applied as a soil treatment in fruits, leafy crops, root crops and pulses/oilseeds. However, no study investigating the nature of residues in fruit crops after foliar applications was available. Therefore, EFSA review of the existing MRLs for napropamide according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2018b) identified a data gap for a representative study investigating primary crop metabolism in fruit crops following foliar treatment (data gap relevant for blueberries, cranberries, currants, gooseberries, rose hips and elderberries).

EFSA concludes that the data gap number 1⁷ has not been addressed. The applicant indicated that no metabolism study was submitted with the present application since the use of napropamide on berries is no longer supported.

1.1.2. Nature of residues in rotational crops

Not relevant for the current assessment.

1.1.3. Nature of residues in processed commodities

Not relevant for the current assessment.

1.1.4. Analytical methods for enforcement purposes in plant commodities

An analytical method based on a gas chromatography with mass selective detector (GC-MSD) for the determination of napropamide in high water and high oil content matrices with a limit of quantification of 0.01 mg/kg (LOQ) was assessed during the peer review (EFSA, 2010). Moreover, the EURL reported an analytical method based on gas chromatography with tandem mass spectrometry (GC-MS/MS) for high water, high acid, high oil and dry matrices with an LOQ of 0.01 mg/kg (CEN, 2018). However, since analytical methods are missing for difficult to analyse matrices, the MRL review identified a data gap for an analytical method for such matrices (data gap relevant for herbal infusions from flowers, leaves and herbs, roots and fruit spices) (EFSA, 2018b).

EFSA concludes that the data gap number 4⁸ has not been addressed. The applicant indicated that analytical method is not provided with the present application since the use of napropamide on crops belonging to a matrix group 'difficult to analyse' (herbal infusions from flowers, leaves and herbs, roots and fruit spices) is no longer supported.

1.1.5. Stability of residues in plants

In the framework of the peer review, storage stability of napropamide was demonstrated for high water and high oil content matrices at approximately -18°C for up to 11 and 12 months, respectively (EFSA, 2010). However, there was no data available regarding the storage stability of napropamide in high-acid content commodities. Therefore, during the MRL review, a data gap was identified for a storage stability study on high-acid content matrices (data gap relevant for citrus fruits and for berries and small fruits) (EFSA, 2018b).

To address this data gap, the applicant provided with the present application a new storage stability study conducted on grapes (high acid content commodity) with napropamide-M (Slovenia, 2023).

EFSA assessed the provided GLP study conducted according to the OECD Guidance (OECD, 2007). EFSA confirmed that the study was performed according to the Guidance Document criteria, notably fortifications were done at 10 × LOQ, samples were analysed in triplicates at day 0 and after 3, 6, 12

⁷ Data gap Number 1 refers to the submission of a representative study investigating primary crop metabolism in fruit crops following foliar treatment.

⁸ Data gap Number 4 refers to the submission analytical method for matrices difficult to analyse.

and 16 months along with control samples and with a validated analytical method. The storage stability was demonstrated in grapes for the whole study duration with recovery of test material above 70% after 16 months.

EFSA notes that the study was conducted with napropamide-M as test material, so with one of the two enantiomers of the napropamide active substance (racemic mixture). Therefore, the submitted study clarifies the storage stability only of this specific napropamide isomer in a high acid content commodity and not of the racemic mixture of isomers. However, considering that storage stability of the napropamide active substance (racemate) is already demonstrated in high water and high oil matrices under the same conditions as of the submitted study (storage stability measured at -18°C), the results of the submitted study on the napropamide-M enantiomer are considered sufficient to confirm the storage stability of the napropamide active substance (racemate) in high acid content matrices.

EFSA concluded that the data gap number 3⁹ identified in the framework of the MRL review is addressed.

1.1.6. Proposed residue definitions

Since the metabolism of napropamide following soil treatments is similar in fruits, leafy crops, root crops and pulses/oilseeds, the same residue definition for enforcement and risk assessment common to all commodities was proposed by the peer review and MRL review (EFSA, 2010, 2018b) as 'napropamide (sum of isomers)' with this residue definition restricted to soil treatments.

Regarding foliar treatments, a study investigating the nature of the residue in fruit crops after foliar applications was identified as data gap by the MRL review (EFSA, 2018b). Considering that this data gap has not been addressed, the previously derived residue definitions restricted to soil treatments are still applicable.

1.2. Magnitude of residues in plants

During the MRL review, EFSA identified a data gap related to residue trials on table/wine grapes, figs, granate apples/pomegranates, sweet peppers/bell peppers, watermelons, Chinese cabbages, kales, kohlrabies, fresh herbs, herbal infusions from flowers, herbal infusions from leaves and herbs, herbal infusions from roots and fresh spices (EFSA, 2018b). This data gap on residue trials was translated into a footnote in the MRL legislation by Commission Regulation (EU) 2020/770 only for the crop group herbs and edible flowers, because for the remaining crops no residue trials were provided during the MRL review to support the authorised GAPs.

EFSA concludes that the data gap number 2¹⁰ concerning additional residue trials on herbs and edible flowers has not been addressed. The applicant indicated that no additional residue trials are provided as the use on this crop group is no longer supported. Therefore, EFSA proposes to lower the existing MRL of 0.05 mg/kg to the LOQ of 0.01 mg/kg for napropamide in herbs and edible flowers.

Moreover, EFSA notes that the applicant provided with the present application new residue trials on grapes in support of the authorised NEU and SEU GAPs which confirmed that residues of napropamide are not expected to occur above the LOQ of 0.01 mg/kg in grapes. However, the provided residue trials on grapes have not been assessed in detail since they were not linked to confirmatory data of Commission Regulation (EU) 2020/770.

2. Residues in livestock

The confirmatory data assessed in this evaluation do not have an impact on pesticide residues expected in commodities of animal origin. Thus, the previous assessment of residues in livestock (EFSA, 2018b) is still valid.

3. Consumer risk assessment

EFSA updated the previous risk assessment performed using PRIMo rev.2 in the framework of the MRL review (latest consumer risk assessment of napropamide (EFSA, 2018b)), taking into account the confirmatory data submitted under this application.

⁹ Data gap number 3 refers to the submission of a storage stability study on high-acid content commodities.

¹⁰ Data gap number 2 refers to the submission of residue trials on herbs and edible flowers.

Since some confirmatory data have not been submitted, as the applicant indicated that uses on these related crops are no longer supported, EFSA proposes to lower the respective MRLs to the LOQs for blueberries, cranberries, currants, gooseberries, rose hips, elderberries, herbs and edible flowers, herbal infusions and fruit spices (see Appendix B.4). Thus, these commodities will be excluded from the consumer exposure calculations. While for all other crops with authorised uses in EU and provided confirmatory data, the input values used for the risk assessment remain the same as the ones applied by the MRL review. It is therefore expected that the confirmatory data submitted in the context of the present application should not trigger a significant modification of the previous consumer dietary exposure calculations.

However, the dietary exposure calculations derived in the MRL review were updated to consider the revision 3.1 of the EFSA PRIMo (EFSA, 2018a, 2019). The revision 3.1 of the EFSA PRIMo 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 profile of napropamide was assessed in the framework of the EU pesticides peer review and the data were sufficient to derive an acceptable daily intake (ADI) of 0.3 mg/kg bw per day, while an acute reference dose (ARfD) was not deemed necessary (European Commission, 2017).

The input values used to perform the revised exposure assessment are reported in Appendix D.1. The outcome of the calculations is reported in Appendix B.3. The highest calculated chronic intake accounted for 0.1% of the ADI (NL toddler diet).

Considering the very low exposure derived from the authorised uses, representing only 0.1% of the ADI, EFSA concludes that a potential change of isomer ratios in the final residue will not be of concern. In case future uses of napropamide would lead to a higher consumer exposure, further information regarding the impact of plant and livestock metabolism on the isomer ratio might be required.

It is concluded that the revised consumer exposure assessment to napropamide will not exceed the toxicological reference value and therefore is unlikely to pose a risk to consumers' health.

4. Conclusion and Recommendations

To address the data gaps identified in the framework of the MRL review (EFSA, 2018b), the applicant provided a new study on storage stability of napropamide in grapes. Additionally, unrelated to Article 12 confirmatory data request, the applicant submitted new residue trials on grapes in support of the authorised Northern and Southern GAPs. EFSA assessed in the present application only the studies linked to the confirmatory data reported in the Commission Regulation (EU) 2020/770. The provided residue trials on grapes have not been assessed in detail since they were not linked to confirmatory data.

The data gaps related to storage stability of napropamide in high-acid content commodities (data gap number 3) has been sufficiently addressed. Whereas all other confirmatory data, i.e. a representative study investigating primary crop metabolism in fruit crops following foliar treatment (data gap 1), residue trials on fresh herbs and edible flowers (data gap 2) and an analytical method for matrices difficult to analyse (data gap 4) were not addressed.

EFSA updated the consumer risk assessment conducted in the framework of the MRL review (EFSA, 2018b), using the revision 3.1 of the EFSA PRIMo and considering the new data submitted under this application. The crops for which the tentative MRLs could not be confirmed and were proposed to be lowered to the analytically achievable LOQ, were excluded from the consumer exposure calculation.

It is concluded that the revised consumer exposure assessment to napropamide will not exceed the toxicological reference value (ADI) and therefore is unlikely to pose a risk to consumers' health.

The overview of the assessment of confirmatory data and the recommended MRL modifications are summarised in Appendix B.4.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
cGAP	critical GAP
DAT	days after treatment
EDI	estimated daily intake
EMS	evaluating Member State
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organization of the United Nations
GC–MSD	gas chromatography with mass selective detector
GC–MS/MS	gas chromatography with tandem mass spectrometry
IEDI	international estimated daily intake
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment

RAC	raw agricultural commodity
Rber	statistical calculation of the MRL by using a non-parametric method
RD	residue definition
RMS	rapporteur Member State
SEU	southern Europe
STMR	supervised trials median residue

Appendix A – Summary of GAPS assessed in the evaluation of confirmatory data

Not applicable.

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

Primary crops (available studies)	Crop groups	Crop(s)	Application(s)	Sampling (DAT)	Comment/ Source	
	Fruit crops	Apples		Soil, first application with 4.61 kg a.s./ha and second application of 4.53 kg a.s./ha (151 days after first treatment)	186 days after first treatment and 35 days after the second treatment.	Denmark (2005), EFSA (2010)
		Tomatoes		Soil, 1 × 2.5 kg a.s./ha	Tomatoes planted at 4–6 leaf stage; harvested at fruit production.	
	Root crops	Potatoes		Soil, 1 × 2.0 kg a.s./ha	61	Denmark (2005), EFSA (2010)
	Leafy crops	Cabbages		Soil, 1 × 2.5 kg a.s./ha	55–60	
	Pulses/oilseeds	Oilseed rape		Soil, 1 × 2.0 kg a.s./ha	Forage: 124 and 195 DAT; Pods: 256 and 292 DAT	
Rotational crops (available studies)	Crop groups	Crop(s)	Application(s)	PBI (DAT)	Comment/ Source	
	Root/tuber crops	Carrot		Bare soil, 4.8 kg a.s./ha	60, 180 and 364	Denmark (2005)
	Leafy crops	Lettuce		Bare soil, 4.8 kg a.s./ha	60, 180 and 364	Denmark (2005)
	Cereal (small grain)	Spring wheat		Bare soil, 4.8 kg a.s./ha	60, 180 and 364	Denmark (2005)
Processed commodities (hydrolysis study)	Conditions		Stable?	Comment/Source		
	Pasteurisation (20 min, 90°C, pH 4)		Not triggered	Residues were below 0.1 mg/kg and the overall chronic exposure < 1% ADI (EFSA, 2018b).		
	Baking, brewing and boiling (60 min, 100°C, pH 5)					
	Sterilisation (20 min, 120°C, pH 6)					
	Other processing conditions		—	—		

Can a general residue definition be proposed for primary crops?	No	'napropamide (sum of isomers)' residue definition restricted to soil treatments
Rotational crop and primary crop metabolism similar?	Yes	For soil treatments
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not applicable	–
Plant residue definition for monitoring (RD-Mo)	Napropamide (sum of isomers) [for soil treatments only]	
Plant residue definition for risk assessment (RD-RA)	Napropamide (sum of isomers) [for soil treatments only]	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	<p>GC-MS/MS (CEN, 2018; EFSA, 2018a):</p> <ul style="list-style-type: none"> Fully validated in high water, high acid, high oil and dry commodities LOQ 0.01 mg/kg 	

DAT: days after treatment; a.s.: active substance; PBI: plant-back interval; ADI: acceptable daily intake; GC-MS/MS: gas chromatography with tandem mass spectrometry; LOQ: limit of quantification.

B.1.1.2. Stability of residues in plants

Plant products (available)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/ Source
				Value	Unit		
	High-water content	Cabbages	–18	11	Month	Napropamide	EFSA (2010)
	High-oil content	Oilseed rape	–18	12	Month	Napropamide	EFSA (2010)
	High-acid content	Grapes	–18	16	Month	Napropamide-M (isomer of the parent (racemate))	Slovenia (2023)

B.1.2. Magnitude of residues in plants

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

Not applicable.

B.1.2.2. Residues in rotational crops

Not relevant.

B.1.2.3. Processing factors

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

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

Acute Risk Assessment: not relevant since an acute reference dose (ARfD) was not deemed necessary (EFSA, 2010).

Chronic Risk Assessment:

ADI	0.3 mg/kg bw per day (European Commission, 2017)
Highest IEDI, according to EFSA PRIMo	0.1% ADI (NL toddler diet)
Assumptions made for the calculations	<p>EFSA updated the previous risk assessment performed in the framework of the MRL review (latest consumer risk assessment of napropamide (EFSA, 2018b)), taking into account the confirmatory data submitted under this application.</p> <p>For blueberries, cranberries, currants, gooseberries, rose hips, elderberries, herbs and edible flowers, herbal infusions and fruit spices the confirmatory data have not been submitted, as the applicant indicated that uses on these crops are no longer supported. Therefore, these commodities were not included in the calculation while for other crops on which authorised uses were reported in the MRL review the input values remain the same as the ones of the MRL review.</p> <p>Calculation performed with PRIMo rev 3.1.</p>

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; MRL: maximum residue level.

B.4. Recommended MRLs

Code ^(a)	Commodity	Existing MRL ^(b)	Data gap(s) Art.12 Review	Proposed MRL	Conclusion/ recommendation
Enforcement residue definition: Napropamide (sum of isomers)					
0110000	Citrus fruit	0.01* (ft 1)	Footnote related to data gap No 3. [storage stability unavailable]	0.01*	The data gap identified by EFSA concerning storage stability has been addressed. EFSA proposes to confirm the existing MRL. The updated consumer risk assessment for napropamide did not indicate any consumer intake concerns.
0110010	Grapefruits				
0110020	Oranges				
0110030	Lemons				
0110040	Limes				
0110990	Others				
0152000	Strawberries	0.01* (ft 1)	Footnote related to data gap No 3. [storage stability unavailable]	0.01*	The data gap identified by EFSA concerning storage stability has been addressed. EFSA proposes to confirm the existing MRL. The updated consumer risk assessment for napropamide did not indicate any consumer intake concerns.
0153000	Cane fruits	0.01* (ft 1)	Footnote related to data gap No 3. [storage stability unavailable]	0.01*	The data gap identified by EFSA concerning storage stability has been addressed. EFSA proposes to confirm the existing MRL. The updated consumer risk assessment for napropamide did not indicate any consumer intake concerns.
0153010	Blackberries				
0153020	Dewberries				
0153030	Raspberries (red and yellow)				
0153990	Others				
0154010	Blueberries	0.02* (ft 1)	Footnote related to data gaps No 1 and 3. [crop metabolism and storage stability unavailable]	0.01*	The data gap identified by EFSA concerning storage stability has been addressed. However, the data gap concerning crop metabolism in fruit crops
0154020	Cranberries				
0154030	Currants (black, red and white)				
0154040					

Code ^(a)	Commodity	Existing MRL ^(b)	Data gap(s) Art.12 Review	Proposed MRL	Conclusion/ recommendation
	Gooseberries (green, red and yellow)				following foliar treatment has not been addressed. The applicant indicated that no metabolism study was submitted since the use on berries is no longer supported. Therefore, EFSA proposes to lower the existing MRL to the LOQ of 0.01 mg/kg.
0154050	Rose hips				
0154080	Elderberries				
0256000	Herbs and edible flowers	0.05 (ft 1)	Footnote related to data gap No 2. [additional residue trials]	0.01*	The data gap identified by EFSA concerning additional residue trials has not been addressed. The applicant indicated that no additional residue trials are provided as the use on these crops is no longer supported. Therefore, EFSA proposes to lower the existing MRL to the LOQ of 0.01 mg/kg.
0256010	Chervil				
0256020	Chives				
0256030	Celery leaves				
0256040	Parsley				
0256050	Sage				
0256060	Rosemary				
0256070	Thyme				
0256080	Basil and edible flowers				
0256090	Laurel/bay leaves				
0256100	Tarragon				
0256990	Others				
0630000	Herbal infusions	0.05* (ft 1)	Footnote related to data gap No 4. [analytical methods unavailable]	0.05*	The data gap identified by EFSA concerning analytical enforcement method for matrices difficult to analyse has not been addressed. The applicant indicated that no analytical method is provided as the use on these crops is no longer supported. Therefore, in the absence of a more sensitive analytical method, EFSA proposes to maintain the existing MRL at the LOQ of 0.05 mg/kg.
0631000	Herbal infusions from flowers	0.05* (ft 1)	Footnote related to data gap No 4. [analytical methods unavailable]	0.05*	
0631010	Chamomile				
0631020	Hibiscus/roselle				
0631030	Rose				
0631040	Jasmine				
0631050	Lime/linden				
0631990	Others				
0632000	Herbal infusions from leaves and herbs	0.05* (ft 1)	Footnote related to data gap No 4. [analytical methods unavailable]	0.05*	
0632010	Strawberry				
0632020	Rooibos				
0632030	Mate/maté				
0632990	Others				
0633000	Herbal infusions from roots	0.05* (ft 1)	Footnote related to data gap No 4. [analytical methods unavailable]	0.05*	
0633010	Valerian				
0633020	Ginseng				
0633990	Others				
0639000	Herbal infusions from any other parts of the plant	0.05* (ft 1)	Footnote related to data gap No 4. [analytical methods unavailable]	0.05*	

Code ^(a)	Commodity	Existing MRL ^(b)	Data gap(s) Art.12 Review	Proposed MRL	Conclusion/ recommendation
0820000	Fruit spices	0.05* (ft 1)	Footnote related to data gap No 4. [analytical methods unavailable]	0.05*	The data gap identified by EFSA concerning analytical enforcement method for matrices difficult to analyse has not been addressed. The applicant indicated that no analytical method is provided as the use on these crops is no longer supported. Therefore, EFSA proposes to maintain the existing MRL at the LOQ of 0.05 mg/kg.
0820010	Allspice/pimento				
0820020	Sichuan pepper				
0820030	Caraway				
0820040	Cardamom				
0820050	Juniper berry				
0820060	Peppercorn (black, green and white)				
0820070	Vanilla				
0820080	Tamarind				
0820990	Others				

MRL: maximum residue level; LOQ: limit of quantification.

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

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

(b): Existing EU MRL and corresponding footnote on confirmatory data.

ft 5: The European Food Safety Authority identified some information on storage stability as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

ft 6: The European Food Safety Authority identified some information on storage stability and crop metabolism as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

ft 7: The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

ft 8: The European Food Safety Authority identified some information on analytical methods as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

Appendix C – Pesticide Residue Intake Model (PRIMo)



Napropamide		
LOQs (mg/kg) range from:	0.01	to: 0.05
Toxicological reference values		
ADI (mg/kg bw per day):	0.3	ARID (mg/kg bw): insert valid entry
Source of ADI:		Source of ARID:
Year of evaluation:		Year of evaluation:

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
											MRLs set at the LOQ (in % of ADI)
											commodities not under assessment (in % of ADI)
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			
TMDI/IEDI calculation (based on average food consumption)	0.1%	NL toddler	0.28	0.0%	Apples	0.0%	Pears	0.0%	Potatoes		0.1%
	0.1%	DE child	0.24	0.0%	Apples	0.0%	Oranges	0.0%	Potatoes		0.1%
	0.1%	NL child	0.16	0.0%	Apples	0.0%	Potatoes	0.0%	Oranges		0.1%
	0.0%	GEMS/Food G11	0.14	0.0%	Potatoes	0.0%	Soyabeans	0.0%	Apples		0.0%
	0.0%	GEMS/Food G10	0.13	0.0%	Soyabeans	0.0%	Potatoes	0.0%	Tomatoes		0.0%
	0.0%	GEMS/Food G08	0.13	0.0%	Potatoes	0.0%	Soyabeans	0.0%	Apples		0.0%
	0.0%	GEMS/Food G07	0.12	0.0%	Potatoes	0.0%	Soyabeans	0.0%	Oranges		0.0%
	0.0%	GEMS/Food G06	0.12	0.0%	Tomatoes	0.0%	Potatoes	0.0%	Soyabeans		0.0%
	0.0%	GEMS/Food G15	0.12	0.0%	Potatoes	0.0%	Soyabeans	0.0%	Tomatoes		0.0%
	0.0%	RO general	0.11	0.0%	Potatoes	0.0%	Tomatoes	0.0%	Head cabbages		0.0%
	0.0%	FR toddler 2 3 yr	0.10	0.0%	Apples	0.0%	Potatoes	0.0%	Oranges		0.0%
	0.0%	FR child 3 15 yr	0.10	0.0%	Oranges	0.0%	Apples	0.0%	Potatoes		0.0%
	0.0%	IE adult	0.10	0.0%	Potatoes	0.0%	Oranges	0.0%	Apples		0.0%
	0.0%	PT general	0.10	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		0.0%
	0.0%	SE general	0.09	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		0.0%
	0.0%	UK toddler	0.09	0.0%	Potatoes	0.0%	Oranges	0.0%	Apples		0.0%
	0.0%	DE women 14-50 yr	0.08	0.0%	Apples	0.0%	Oranges	0.0%	Potatoes		0.0%
	0.0%	FI 3 yr	0.08	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		0.0%
	0.0%	UK infant	0.08	0.0%	Potatoes	0.0%	Apples	0.0%	Oranges		0.0%
	0.0%	DE general	0.08	0.0%	Apples	0.0%	Oranges	0.0%	Potatoes		0.0%
	0.0%	ES child	0.08	0.0%	Oranges	0.0%	Potatoes	0.0%	Apples		0.0%
	0.0%	PL general	0.08	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		0.0%
	0.0%	NL general	0.08	0.0%	Potatoes	0.0%	Apples	0.0%	Oranges		0.0%
	0.0%	DK child	0.07	0.0%	Potatoes	0.0%	Apples	0.0%	Pears		0.0%
	0.0%	LT adult	0.07	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		0.0%
	0.0%	FI 6 yr	0.06	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		0.0%
	0.0%	FR infant	0.06	0.0%	Potatoes	0.0%	Apples	0.0%	Bears (with pods)		0.0%
	0.0%	IT toddler	0.05	0.0%	Tomatoes	0.0%	Potatoes	0.0%	Apples		0.0%
	0.0%	ES adult	0.05	0.0%	Oranges	0.0%	Potatoes	0.0%	Tomatoes		0.0%
	0.0%	IT adult	0.04	0.0%	Tomatoes	0.0%	Apples	0.0%	Potatoes		0.0%
	0.0%	UK vegetarian	0.04	0.0%	Potatoes	0.0%	Oranges	0.0%	Tomatoes		0.0%
	0.0%	FR adult	0.04	0.0%	Apples	0.0%	Potatoes	0.0%	Oranges		0.0%
0.0%	DK adult	0.04	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		0.0%	
0.0%	UK adult	0.03	0.0%	Potatoes	0.0%	Oranges	0.0%	Tomatoes		0.0%	
0.0%	FI adult	0.03	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		0.0%	
0.0%	IE child	0.01	0.0%	Potatoes	0.0%	Apples	0.0%	Oranges		0.0%	

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

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

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.
 The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

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

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

Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value ^(a) (mg/kg)	Comment ^(b)	Input value ^(a) (mg/kg)	Comment ^(b)
Grapefruits	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Oranges	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Lemons	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Limes	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Mandarins	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Almonds	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Chestnuts	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Hazelnuts/cobnuts	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Pecans	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Pine nut kernels	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Pistachios	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Walnuts	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Apples	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Pears	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Quinces	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Medlar	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Loquats/Japanese medlars	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Apricots	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Cherries (sweet)	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Peaches	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Plums	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Strawberries	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Blackberries	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Dewberries	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Raspberries (red and yellow)	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Potatoes	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Celeriacs/turnip rooted celeries	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Horseradishes	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Radishes	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Swedes/rutabagas	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Turnips	0.01	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Tomatoes	0.01	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Aubergines/egg plants	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Broccoli	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Cauliflowers	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Brussels sprouts	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Head cabbages	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Lamb's lettuce/ corn salads	0.05	EFSA (2018b)	0.05	STMR-RAC	n/a	n/a

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value ^(a) (mg/kg)	Comment ^(b)	Input value ^(a) (mg/kg)	Comment ^(b)
Roman rocket/ rucola	0.05	EFSA (2018b)	0.05	STMR-RAC	n/a	n/a
Red mustards	0.05	EFSA (2018b)	0.05	STMR-RAC	n/a	n/a
Baby leaf crops (including brassica species)	0.05	EFSA (2018b)	0.05	STMR-RAC	n/a	n/a
Beans (with pods)	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Linseeds	0.02	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Peanuts/ groundnuts	0.01*	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Poppy seeds	0.02	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Sesame seeds	0.02	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Sunflower seeds	0.02	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Rapeseeds/canola seeds	0.02	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Soyabean	0.02	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Mustard seeds	0.02	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Cotton seeds	0.02	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Pumpkin seeds	0.02	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Safflower seeds	0.02	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Borage seeds	0.02	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Gold of pleasure seeds	0.02	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Hemp seeds	0.02	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a
Castor beans	0.02	EFSA (2018b)	0.01	STMR-RAC	n/a	n/a

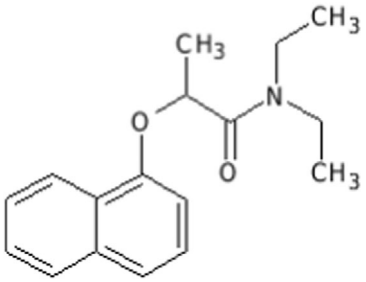
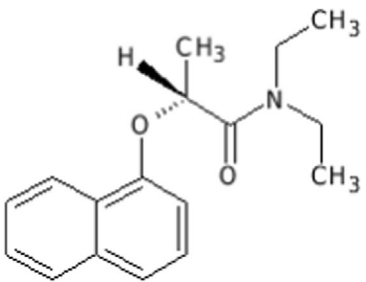
STMR-RAC: supervised trials median residue in raw agricultural commodity; n/a: not applicable.

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

(a): Figures in the table are rounded to 2 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): Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.

Appendix E – Used compound codes

Code/trivial name ^(a)	IUPAC name/SMILES notation/InChiKey ^(b)	Structural formula ^(c)
Napropamide	(<i>RS</i>)- <i>N,N</i> -diethyl-2-(1-naphthyloxy)propionamide CCN(CC)C(=O)C(C)Oc1cccc2ccccc21 WXZVAROIGSFCEJ-UHFFFAOYSA-N	
Napropamide-M	(<i>R</i>)- <i>N,N</i> -diethyl-2-(1-naphthyloxy)propionamide CCN(CC)C(=O)[C@H](C)Oc1cccc2ccccc21 WXZVAROIGSFCEJ-CYBMUJFWSA-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 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 7 July 2021).

(c): ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 28 August 2021).