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

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Abstract
According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance napropamide. To assess the occurrence of napropamide residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC as well as the European authorisations reported by Member States (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was missing. Hence, the consumer risk assessment is considered indicative only and some MRL proposals derived by EFSA still require further consideration by risk managers.

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Keywords: napropamide, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, amide, herbicide

Requestor: European Commission
Question number: EFSA-Q-2009-00029
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Acknowledgement: EFSA wishes to thank the rapporteur Member State Denmark for the preparatory work on this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Brancato A, Brocca D, Carrasco Cabrera L, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lostia A, Lythgo C, Medina P, Miron I, Molnar T, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B and Villamar-Bouza L, 2018. Reasoned Opinion on the review of the existing maximum residue levels for napropamide according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(8):5394, 62 pp. https://doi.org/10.2903/j.efsa.2018.5394

ISSN: 1831-4732

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Summary

Napropamide was included in Annex I to Directive 91/414/EEC on 1 January 2011 by Commission Directive 2010/83/EC, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. As the active substance was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation.

As the basis for the MRL review, on 16 June 2017 EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit their national Good Agricultural Practices (GAPs) by 16 July 2017, in a standardised way, in the format of specific GAP forms allowing the rapporteur Member State (RMS), Denmark, to identify the critical GAPs, in the format of specific GAP overview file. The RMS did not report any uses authorised in third countries that might have a significant impact on international trade. Member States were invited to provide the requested information supporting the critical GAPs in the form of a detailed evaluation report, as specified in the GAP overview file. The collection of supporting data initiated on 10 October 2017 and finalised on 10 November 2017.

On the basis of all the data submitted by Member States, EFSA, according to the process, should ask Denmark as the designated RMS, to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and the supporting evaluation report were provided by the RMS to EFSA on 12 January 2018. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional information provided by the RMS and Member States, EFSA prepared in April 2018 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 9 May 2018 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of napropamide following soil treatment in fruits, leafy vegetables, root crops and pulses/oilseeds is similar. A residue definition for risk assessment common to all commodities is proposed as napropamide (sum of isomers); this residue definition is restricted to soil treatments. As no metabolism studies following foliar treatments were available, the same residue definition was applied on a tentative basis to this type of treatment. A residue definition for enforcement for all crops under review is proposed as napropamide (sum of isomers). A validated analytical method for the main four plant matrices with a limit of quantification (LOQ) of 0.01 mg/kg is available.

The data on metabolism and distribution of napropamide in rotational crops indicated that the metabolism in rotational crops is similar to the pathway observed in primary crops. According to the confined rotational crop study, significant residues are not expected in rotational crops planted with plant-back interval (PBI) of 180 days.

Storage stability data is available for high water and high oil content matrices, but no data is available for high acid and dry content matrices.

Studies investigating the stability of napropamide to hydrolysis under standard conditions of pasteurisation, baking/brewing/boiling and sterilisation were not available for this review. Nevertheless, these studies are not necessary since residue levels are expected to remain below 0.1 mg/kg in raw commodities and overall chronic exposure is very low. Studies investigating the magnitude of residues in processed commodities are not required.

The available data are considered sufficient to derive appropriate MRL proposals as well as risk assessment values for all crops under review, except for table/wine grapes, figs, granate apples/pomegranate, sweet peppers/bell peppers, watermelons, turnip tops, fresh herbs, herbal infusions and fresh spices where the available data were insufficient to derive tentative MRLs.

Studies investigating the metabolism in livestock were conducted on lactating goats and laying hens. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg dry matter (DM), further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure was calculated for France, all population, representing 0.2% of the acceptable
daily intake (ADI). Although some uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumers. Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance. Considering the very low exposure derived from the authorised uses, it was concluded 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.
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Review of the existing MRLs for napropamide

Background

Regulation (EC) No 396/2005\(^1\) (hereinafter referred to as ‘the Regulation’) establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC\(^2\) a reasoned opinion on the review of the existing MRLs for that active substance. As napropamide was included in Annex I to Council Directive 91/414/EEC on 1 January 2011 by means of Commission Directive 2010/83/EU\(^3\), and has been deemed to be approved under Regulation (EC) No 1107/2009\(^4\), in accordance with Commission Implementing Regulation (EU) No 540/2011\(^5\), as amended by Commission Implementing Regulation (EU) No 541/2011\(^6\), EFSA initiated the review of all existing MRLs for that active substance.

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

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

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

As the basis for the MRL review, on 16 June 2017 EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit their national Good Agricultural Practices (GAPs) that are authorised in different Member States by 16 July 2017, in a standardised way in the format of specific GAP forms allowing the rapporteur Member State Denmark to identify the critical GAPs, in the format of specific GAP overview file. The RMS did not report any uses authorised in third countries that might have a significant impact on international trade. Member States were invited to provide the requested information supporting the critical GAPs in the form of a detailed evaluation report, as specified in the GAP overview file. The collection of supporting data initiated on 10 October 2017 and finalised on 10 November 2017.

In this frame, evaluation reports were submitted by Austria, Belgium, Czech Republic, Finland, France, Germany, Greece, Italy, Lithuania, the Netherlands, the United Kingdom and the European Union Reference Laboratories for Pesticide Residues (Austria, 2017; Belgium, 2017; Czech Republic, 2017; Finland, 2017; France, 2017; Germany, 2017; Greece, 2017; Italy, 2017; Lithuania, 2017; Netherlands, 2017; United Kingdom, 2017, EURL, 2018).

On the basis of all the data submitted by Member States, EFSA, according to the process, should ask Denmark as the designated RMS, to complete the Pesticide Residues Overview File (PROFile) and

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1 Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
2 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32. Repealed by Regulation (EC) No 1107/2009.
3 Commission Directive 2010/83/EU of 30 November 2010 amending Council Directive 91/414/EEC to include napropamide as active substance. OJ No L 315, 1.12.2010, p. 29–31.
4 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
5 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.
6 Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187–188.
to prepare a supporting evaluation report. The PROFile and the supporting evaluation were provided by the RMS to EFSA on 12 January 2018. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional information provided by the Member States, EFSA prepared in April 2018 a draft reasoned opinion, which was submitted to Member States for commenting via a written procedure. All comments received by 9 May 2018 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Denmark, 2018) and the evaluation reports submitted by Member States Austria, Belgium, the Czech Republic, Finland, France, Germany, Greece, Italy, Lithuania, the Netherlands, the United Kingdom and the EURL (Austria, 2017; Belgium, 2017; Czech Republic, 2017; Finland, 2017; France, 2017; Germany, 2017; Greece, 2017; Italy, 2017; Lithuania, 2017; Netherlands, 2017; United Kingdom, 2017, EURL, 2018) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

In addition, key supporting documents to this reasoned opinion are the completeness check report (EFSA, 2018a) and the Member States consultation report (EFSA, 2018b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Also, the chronic exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) and the PROFile as well as the GAP overview file listing all authorised uses are key supporting documents and made publicly available as background documents to this reasoned opinion. Furthermore, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

**Terms of Reference**

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

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

**The active substance and its use pattern**

Napropamide is the ISO common name for (RS)-N,N-diethyl-2-(1-naphthyloxy)propionamide (IUPAC). Napropamide is a racemic mixture.

Napropamide belongs to the group of amide compounds which are used as herbicides. It is a selective systemic herbicide, absorbed by the roots, with translocation acropetally. It inhibits root development and growth.

The chemical structure of the active substance is reported in Appendix F.

Napropamide was evaluated in the framework of Directive 91/414/EEC with Denmark designated as RMS. The representative uses supported for the peer review process were as a preplanting herbicide to head cabbages, Brussels sprouts, cauliflowers, broccoli, calabrese, tomatoes and oilseed rape. Following the peer review, which was carried out by EFSA, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2010/83/EU, which entered into force on 1 January 2011. According to Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011, napropamide is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to uses as herbicide only.

The EU MRLs for napropamide are established in Annexes IIIA of Regulation (EC) No 396/2005 and codex maximum residue limits (CXLs) for active substance are not available. There are no MRL changes occurred since the entry into force of the Regulation mentioned above.

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

EFSA has based its assessment on the PROFile submitted by the RMS, the evaluation report accompanying the PROFile (Denmark, 2018), the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (Denmark, 2005), the conclusion on the peer review of the pesticide risk assessment of the active substance napropamide (EFSA, 2010) as well as the evaluation reports submitted during the completeness check (Austria, 2017; Belgium, 2017; Czech Republic, 2017; Finland, 2017; France, 2017; Germany, 2017; Greece, 2017; Italy, 2017; Lithuania, 2017; Netherlands, 2017; United Kingdom, 2017; EURL, 2018). The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011 and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013).

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

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of napropamide was investigated in fruit crops (apples, tomatoes), leafy crops (cabbages), root crops (potatoes) and pulses/oilseeds (oilseed rape) following soil treatment (Denmark, 2005), and assessed in the framework of the peer review (EFSA, 2010). At harvest, due to the limited amount of radioactive material present, metabolites were only identified in cabbages, tomatoes and potatoes.

Two soil applications of 4.61 kg a.s./ha and 4.53 kg a.s./ha (151 days after the first treatment) were made around the base of the apple tree. The first harvest of apples was at maturity 186 days after the first treatment and 35 days after the second treatment. The mean total radioactive residue (TRR) in mature apples was 0.0032 mg eq/kg. The mean residue in the second harvest 1 year later was 0.0105 mg eq/kg. Metabolites were all detected at very low levels (< 0.01 mg/kg). After the incorporation of napropamide in the soil with a dose corresponding to 2.5 kg a.s./ha, tomato plants at the 4–6 leaf stage were planted and harvested at fruit production. Napropamide accounted for 0.4% TRR (0.0002 mg eq/kg) in tomatoes. Metabolites were all detected at very low levels (< 0.01 mg/kg).

It can be concluded from the studies on apples and tomatoes that the uptake of napropamide in fruits from soil applications is very limited.

After the incorporation of napropamide in the soil with a dose corresponding to 2.5 kg a.s./ha, cabbages were planted at the 6–8 leaf stage and harvested at maturity 55–60 days after treatment (DAT). Napropamide was detected at trace levels amounting to 0.8% of TRR (0.001 mg eq/kg) and 0.9% of TRR (0.004 mg eq/kg) in cabbage heart and whole cabbage, respectively. Metabolites were all detected at very low levels (< 0.01 mg/kg). It can be concluded that the uptake of napropamide in leafy crops from soil applications is very limited.

After the incorporation of napropamide in the soil with a dose corresponding to 2.0 kg a.s./ha, potatoes were planted. Potato plants were harvested 61 DAT and were separated into potato foliage, peel and pulp for analysis. The residues in foliage comprised traces of napropamide (1.11% of TRR; < 0.01 mg/kg) and all metabolites were present in concentrations below 0.01 mg/kg. A similar pattern was seen in potato peel. Napropamide was not detected in potato pulp and only traces of the metabolites were identified, all present in concentrations below 0.01 mg/kg.

After the incorporation of napropamide in the soil with a dose corresponding to 2.0 kg a.s./ha, oilseed rape seeds were sown. Forage samples were taken 124 DAT and 195 DAT. Samples of pods were taken 256 DAT and 292 DAT (harvest). It could be concluded from the results of this study that napropamide is extensively metabolised in oilseed rape plants and is present in levels below 0.01 mg/kg.

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, p. 127–175.
Conclusively, napropamide is metabolised by the same metabolic pathway when applied as a soil treatment in fruits, leafy crops, root crops and pulses/oilseeds. No study investigating the nature of residues in fruit crops after foliar applications is available and therefore a data gap is identified.

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

1.1.2. Nature of residues in rotational crops

Napropamide is authorised on crops that may be grown in rotation. For napropamide, the longest single order field DT_{50} is 127 days, associated with a DT_{90} of 422 days (EFSA, 2010).

One confined rotational crop study was assessed in the framework of the peer review (EFSA, 2010). Napropamide was incorporated in the soil corresponding to an application rate of 4.8 kg a.s./ha. Spring wheat, carrot and lettuce were planted 60, 180 and 364 DAT. Napropamide was detected at very low levels (0.001 mg/kg; 1.3% of TRR) in lettuce 60 DAT. Napropamide was not detected in wheat straw. In carrot root, napropamide amounted to 0.05 mg/kg (36% of TRR) 60 DAT, 0.02 mg/kg (33.3% of TRR) 180 DAT and 0.009 mg/kg (15.0% of TRR) 364 DAT, respectively. Unchanged napropamide was found in mature commodities at levels generally below 0.01 mg eq/kg, except in carrot roots, where the levels were 0.05 and 0.02 mg eq/kg for the 60 and 180 days intervals, respectively. At 365 DAT, residues levels were below 0.01 mg/kg in all plant tissues. The metabolites identified in rotational crops suggested that the metabolism is similar to that in primary crops (EFSA, 2010).

1.1.3. Nature of residues in processed commodities

There were no studies investigating the nature of residues of napropamide in processed commodities available for this review. For all commodities, residues were below 0.1 mg/kg. Furthermore, the overall chronic exposure is very low (< 1% acceptable daily intake (ADI)). Therefore, the investigation of the nature of residues in processed commodities is not required.

1.1.4. Methods of analysis in plants

During the peer review, a multiresidue analytical method using gas chromatography with mass selective detector (GC-MSD) was validated for the determination of napropamide in high water and high oil content matrices with a limit of quantification (LOQ) of 0.01 mg/kg (EFSA, 2010). Furthermore, the EURL reported a multiresidue analytical method using gas chromatography with tandem mass spectrometry (GC-MS/MS) for high water, high acid, high oil content and dry matrices with a LOQ of 0.01 mg/kg (EURL, 2018). Hence, it is concluded that napropamide can be enforced with a LOQ of 0.01 mg/kg in high water content, high acid content, high oil content and dry commodities. Since analytical methods are missing for matrices which are difficult to analyse such as herbal infusions from flowers, leaves and herbs, roots as well as fruit spices, a data gap is set for these crops.

1.1.5. Stability of residues in plants

In the framework of the peer review, storage stability of napropamide was demonstrated for high water content and high oil content matrices at approximately –18°C for up to 11 and 12 months, respectively (EFSA, 2010). There is no data available for high acid content and therefore a data gap is identified for high acid content crops. There is no data available for dry content commodities, however since the GAP on chestnuts (only crop belonging to the dry commodity in this review) is supported by trials performed on high water content crops, the storage stability study on dry commodities is considered a minor deficiency.

1.1.6. Proposed residue definitions

The metabolism of napropamide when applied as soil treatment is similar in fruits, leafy crops, root crops and pulses/oilseeds. Therefore, a residue definition for risk assessment common to all commodities can be proposed as napropamide (sum of isomers); this residue definition is restricted to soil treatments. Regarding foliar treatments, a study investigating the nature of residue in fruit crops...
after foliar applications is missing and required. In the meanwhile, the same residue definition as for soil treatment was considered on a tentative basis to assess GAPs with this type of treatment.

For enforcement, the residue definition is proposed as napropamide (sum of isomers). An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in the four main plant matrices is available (European Union Reference Laboratories for Pesticide Residues, 2018).

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of napropamide residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Denmark, 2018) including residue trials evaluated in the framework of the peer review (EFSA, 2010). Residue trial samples from crops with high water and high oil content matrices considered in this framework were stored in compliance with the demonstrated storage conditions.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2017).

Residue trials are not available to support the authorisations on figs, granate apples (pomegranates), table/wine grapes, sweet peppers/bell peppers, turnip tops, watermelons, fresh herbs (chervil, chives, celery leaves, parsley, sage, rosemary, basil, laurel and tarragon), herbal infusions from flowers, herbal infusions from leaves and herbs, herbal infusions from roots and fresh spices. Therefore, MRL or risk assessment values for these crops could not be derived by EFSA and the following data gaps were identified:

- Table/wine grapes: Eight trials on table/wine grapes compliant with the southern outdoor GAP and eight trials on table/wine grapes compliant with the northern outdoor GAPs are required.
- Figs: Four trials on figs compliant with the southern outdoor GAP are required.
- Granate apples/pomegranates: Four trials on granate apples/pomegranates compliant with the southern outdoor GAP are required.
- Turnip tops: Eight trials compliant with the northern outdoor GAP on turnip tops are needed.
- Sweet peppers/bell peppers: Eight trials on sweet peppers/bell peppers compliant with the northern outdoor GAP and eight trials on sweet peppers/bell peppers compliant with the southern outdoor GAP are required.
- Watermelons: Eight trials on watermelons compliant with the southern outdoor GAP are required.
- Chinese cabbages/pe-tsai, kales: Four trials compliant with the northern outdoor GAP and four trials compliant with the southern outdoor GAP are required.
- Kohlrabies: Four trials compliant with the northern outdoor GAP and four trials compliant with the southern outdoor GAP are required.
- Fresh herbs: Four trials compliant with the northern outdoor GAP on sage, thyme, basil and tarragon are required and four trials compliant with the southern outdoor GAP on chervil, chives, celery leaves, parsley, sage, rosemary, thyme, basil, laurel and tarragon are required.
- Herbal infusions: Four trials on herbal infusions from flowers, four trials on herbal infusions from leaves and herbs and four trials on herbal infusions from roots compliant with the northern/southern outdoor GAPs are required.
- Fresh spices: Four trials on fresh spices compliant with the northern/southern outdoor GAPs are required.

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

- Grapefruits, oranges, lemons, mandarins, apples, pears, apricots, peaches, plums: The number of residue trials supporting the southern outdoor GAPs is not compliant with the data requirements for these crops. However, the reduced number of residue trials is considered acceptable in these cases because all results were below the LOQ and a no-residue situation is expected. Further residue trials are therefore not required.
- Strawberries: The number of residue trials supporting the northern and southern GAPs for strawberries is not compliant with the data requirements for this crop. However, the reduced number of residue trials is considered acceptable in this case because all results were below...
the LOQ and a no-residue situation is expected when the application is done at an early crop stage (BBCH < 09). Further residue trials are therefore not required.

- **Potatoes**: The number of residue trials supporting the southern outdoor GAPs is not compliant with the data requirements for this crop. However, the reduced number of residue trials is considered acceptable in these cases because all results were below the LOQ and a no-residue situation is expected. Further residue trials are therefore not required.

- **Tomatoes**: Based on the southern European Union (SEU) data set, a no-residue situation is expected after soil treatment early in the growing season. Although no northern residue trials are available, a similar conclusion is expected for the northern GAP (equivalent to southern GAP). Further residue trials are therefore not required.

- **Swedes/rutabagas; turnips**: The northern GAP is not supported by GAP-compliant trials. However, a no-residue situation is foreseen for root crops, since a clearly more critical GAP on potatoes, which is supported by trials done with three times the application rate reported for the GAP on swedes/rutabagas, showed a no-residue situation. In addition, the metabolism study performed on potatoes with twice the application rate reported for the GAP on swedes/rutabagas indicated that no residues are expected. Therefore, further residue trials on swedes/rutabagas are not required.

- **Roman rocket/rucola**: Although appropriate MRL and risk assessment values can be derived from the indoor data, four trials compliant with the southern GAP are still required.

- **Beans (with pods)**: The number of residue trials supporting the northern GAP for beans (with pods) is not compliant. However, the reduced number of residue trials is considered acceptable in this case because all results were below the LOQ and a no-residue situation is expected. Further residue trials are therefore not required and MRL and risk assessment can be proposed at the enforcement LOQ (0.01 mg/kg).

- **Sesame seeds, rapeseeds/canola seeds, borage seeds, gold of pleasure seeds and hemp seeds**: Although appropriate MRL and risk assessment values can be derived from the northern data, five additional trials on rapeseeds/canola seeds compliant with the southern GAP are required.

### 1.2.2. Magnitude of residues in rotational crops

A field study was reported by the RMS (Denmark, 2005) and assessed in the framework of the peer-review (EFSA, 2010). Unlabelled napropamide was incorporated in the soil to a 5-cm depth before drilling winter oilseed rape. Each treated plot received a different formulation of napropamide, corresponding to about 0.95 kg a.s./ha. When wheat was grown as a rotational crop to oilseed rape, residues of napropamide in wheat straw and grains were below the LOQ of 0.01 mg/kg (EFSA, 2010).

The metabolism study on rotational crops showed a potential transfer of soil residues of napropamide above 0.01 mg/kg in root crops for plant-back intervals (PBIs) up to 180 days (EFSA, 2010). The plateau accumulated predicted environmental concentration (PEC) soil with a mixing depth of 20 cm (soil bulk density 1.5 g/cm³) assuming no crop interception (which is appropriate for all annual crops at BBCH 09) resulting from a single annual application of 4.5 kg a.s./ha, using the DT₅₀ of 127 days is 0.24 mg/kg just before an application and 1.74 mg/kg immediately after an application. For a plant-back period of 180 days the PEC soil would be 0.61 mg/kg. The soil concentration in the confined rotational crops study immediately after application is 4.29 mg/kg (Denmark, 2010), ca. 2.5 times that of the estimated concentration immediately after the application. Therefore, it can be concluded that the rotational crop metabolism study covers the soil plateau concentration. Detectable amounts of napropamide are expected to be below 0.01 mg/kg at periods longer that 180 DAT, and therefore, it can be concluded that sowing/planting of succeeding crop 180 days after last application would not lead to a significant uptake of napropamide. This information should be considered by risk managers for the adoption of possible mitigation measures.

### 1.2.3. Magnitude of residues in processed commodities

Residues were below 0.1 mg/kg for all commodities and the total theoretical maximum daily intake was below 10% of the ADI. Therefore, the investigation of the nature of residues in processed commodities was not required. However, a processing study in tomatoes was assessed by the RMS (Denmark, 2005). Residues of napropamide were below the LOQ of 0.05 mg/kg in all samples and therefore no processing factors could be calculated.
Further processing studies are not required as they are not expected to affect the outcome of the risk assessment. However, if processing factors are to be requested by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

### 1.2.4. Proposed MRLs

Overall, the available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for table/wine grapes, figs, granate apples/pomegranate, sweet peppers/bell peppers, watermelons, Chinese cabbages/pe-tsai, kales, kohlrabies, fresh herbs, herbal infusions and fresh spices where the available data were insufficient to derive tentative MRLs.

### 2. Residues in livestock

Napropamide is authorised for use on crops (e.g. potatoes, kales) that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg dry matter (DM), further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary. It is noted that residue trials on turnip tops are missing, however this is unlikely to impact the dietary assessment determined.

Although not required, studies investigating the metabolism of napropamide in livestock were conducted on lactating goats and laying hens (Denmark, 2005). Lactating goats were dosed twice a day with an oral administration of [14C-1-naphthyl]-napropamide in gelatine capsules over a period of four consecutive days. The dose rate corresponds to 9.9 mg/kg feed (equivalent to 0.28 mg/kg body weight (bw) per day). The TRR in liver and kidney was 0.153 mg/kg eq. and 0.0365 mg/kg eq., respectively. In other tissues and milk TRR were very low (< 0.01 mg/kg). No metabolite fractions were detected at relevant levels in any tissues.

Laying hens were dosed with napropamide once daily with an oral dose of 1.145 mg [14C-1-naphthyl]-napropamide in gelatine capsules over a period of 10 consecutive days, corresponding to a mean rate of 8.3 mg/kg feed (equivalent to 0.52 mg/kg bw per day). Napropamide was rapidly metabolised and excreted by hens with 92.1% of the dose being excreted during the dosing period. The only relevant residue was detected in egg yolk where napropamide was present at 5.2% TRR (0.0018 mg/kg). No other single components or fractions occurred at levels above 0.01 mg/kg in any tissues.

In the framework of the peer review, a residue definition for risk assessment or enforcement was not deemed necessary (EFSA, 2010). For this MRL, no residue definition for livestock is necessary.

If a residue definition for livestock is set in the future based on additional uses, then a residue definition for enforcement and risk assessment could be proposed as napropamide (sum of isomers) based on the results of the metabolism studies assessed above.

No feeding studies were available or required for this MRL review. In addition, no validated analytical methods for animal matrices were reported.

### 3. Consumer risk assessment

Chronic exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA PRIMo (EFSA, 2007). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where a (tentative) MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). For those commodities where data were insufficient to derive an MRL in Section 1, EFSA considered the existing EU MRL for an indicative calculation.

Regarding rotational crops, there are indications that levels of napropamide would remain below 0.01 mg/kg when using a PBI longer that 180 DAT. Therefore, the calculations were done assuming that mitigation measures (e.g. restriction with a PBI of minimum 180 DAT) would be implemented by risk managers and be sufficient to avoid any significant residues in rotational crops.
All input values included in the exposure calculations are summarised in Appendix D. Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance.

The exposures calculated were compared with the reference value for napropamide, derived by EFSA (2010) under Directive 91/414/EEC. The highest chronic exposure was calculated for France, all population, representing 0.2% of the ADI. Although some uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumers.

Since the exposure to napropamide is marginal, representing 0.2% of the ADI, EFSA concludes that a potential change of isomer ratios in the final residue will not be of concern for the authorised uses reported in the framework of this review. 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.

Conclusions

The metabolism of napropamide following soil treatment in fruits, leafy vegetables, root crops and pulses/oilseeds is similar. A residue definition for risk assessment common to all commodities is proposed as napropamide (sum of isomers); this residue definition is restricted to soil treatments. As no metabolism studies following foliar treatments were available, the same residue definition was applied on a tentative basis to this type of treatment. A residue definition for enforcement for all crops under review is proposed as napropamide (sum of isomers). A validated analytical method for the main four plant matrices with a limit of quantification (LOQ) of 0.01 mg/kg is available.

The data on metabolism and distribution of napropamide in rotational crops indicated that the metabolism in rotational crops is similar to the pathway observed in primary crops. According to the confined rotational crop study, significant residues are not expected in rotational crops planted with PBI of 180 days.

Storage stability data is available for high water and high oil content matrices, but no data is available for high acid and dry content matrices.

Studies investigating the stability of napropamide to hydrolysis under standard conditions of pasteurisation, baking/brewing/boiling and sterilisation were not available for this review. Nevertheless, these studies are not necessary since residue levels are expected to remain below 0.1 mg/kg in raw commodities and overall chronic exposure is very low. Studies investigating the magnitude of residues in processed commodities are not required.

The available data are considered sufficient to derive appropriate MRL proposals as well as risk assessment values for all crops under review, except for table/wine grapes, figs, granate apples/pomegranate, sweet peppers/bell peppers, watermelons, turnip tops, fresh herbs, herbal infusions and fresh spices where the available data were insufficient to derive tentative MRLs.

Studies investigating the metabolism in livestock were conducted on lactating goats and laying hens. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM, further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure was calculated for France, all population representing 0.2% of the ADI. Although some uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumers. Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance. Considering the very low exposure derived from the authorised uses, it was concluded 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.

Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 2). All MRL values listed as ‘Recommended’ in the table are sufficiently
supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see Table 2 footnotes for details). In particular, some tentative MRLs and/or existing EU MRLs need to be confirmed by the following data:

- 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);
- Residue trials are needed 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.
- A storage stability study on high acid content (data gap relevant for citrus fruit and for berries and small fruits);
- An analytical method for matrices difficult to analyse (data gap relevant for herbal infusions from flowers, leaves and herbs, roots and fruit spices).

It is highlighted, however, that some of the MRLs derived result from a GAP in one climatic zone only whereas other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gaps which are not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- Additional trials on rocket/rucola, sesame seeds, rapeseeds, borage seeds, gold of pleasure seeds and hemp seeds are required.

If the above-reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

A minor deficiency was also identified in the assessment but this deficiency is not expected to impact either on the validity of the MRL derived or on the national authorisation. The following data is therefore considered desirable but not essential:

- A storage stability study on dry content commodities (relevant for chestnuts).
- Trials with analysis performed on turnip tops.

Regarding residues in rotational crops, there are indications that levels of napropamide would remain below 0.01 mg/kg when using a PBI longer that 180 DAT. Therefore, MRLs were derived considering that significant residues uptakes in rotational crops can be avoided. This information should be considered by risk managers for the adoption of possible mitigation measures.

It should be noted that the R-isomer of napropamide (napropamide-M) is currently under assessment under the peer-review process for approval as a new active substance. If new information provided during the peer review of napropamide-M has an impact on the current assessment of napropamide, this new information should deserve further consideration by risk managers (Table 1).

Table 1: Summary table

| Code number | Commodity       | Existing EU MRL (mg/kg) | Outcome of the review | Comment                      |
|-------------|-----------------|-------------------------|-----------------------|------------------------------|
|             |                 | **Existing EU MRL**     | **MRL**               |                              |
|             |                 | **(mg/kg)**             | **(mg/kg)**           |                              |
|             |                 | **Existing EU MRL**     | **MRL**               |                              |
|             |                 | **(mg/kg)**             | **(mg/kg)**           |                              |
| **Enforcement residue definition (existing):** | napropamide | | | |
| 110010 | Grapefruits | 0.05* | 0.01* | Further consideration needed<sup>(a)</sup> |
| 110020 | Oranges | 0.05* | 0.01* | Further consideration needed<sup>(a)</sup> |
| 110030 | Lemons | 0.05* | 0.01* | Further consideration needed<sup>(a)</sup> |
| 110040 | Limes | 0.05* | 0.01* | Further consideration needed<sup>(a)</sup> |
| 110050 | Mandarins | 0.05* | 0.01* | Further consideration needed<sup>(a)</sup> |
| 120010 | Almonds | 0.05* | 0.01* | Recommended<sup>(b)</sup> |
| 120040 | Chestnuts | 0.05* | 0.01* | Recommended<sup>(b)</sup> |
| 120060 | Hazelnuts/cobnuts | 0.05* | 0.01* | Recommended<sup>(b)</sup> |
| 120080 | Pecans | 0.05* | 0.01* | Recommended<sup>(b)</sup> |
| Code number | Commodity                                | Existing EU MRL (mg/kg) | Outcome of the review |
|------------|------------------------------------------|------------------------|-----------------------|
|            |                                          | MRL (mg/kg)            | Comment               |
| 120090     | Pine nut kernels                         | 0.05*                  | 0.01*                 | Recommended (b) |
| 120100     | Pistachios                               | 0.05*                  | 0.01*                 | Recommended (b) |
| 120110     | Walnuts                                  | 0.05*                  | 0.01*                 | Recommended (b) |
| 130010     | Apples                                   | 0.1                    | 0.01*                 | Recommended (b) |
| 130020     | Pears                                    | 0.1                    | 0.01*                 | Recommended (b) |
| 130030     | Quinces                                  | 0.1                    | 0.01*                 | Recommended (b) |
| 130040     | Medlars                                  | 0.1                    | 0.01*                 | Recommended (b) |
| 130050     | Loquats/Japanese medlars                  | 0.1                    | 0.01*                 | Recommended (b) |
| 140010     | Apricots                                 | 0.1                    | 0.01*                 | Recommended (b) |
| 140020     | Cherries (sweet)                         | 0.1                    | 0.01*                 | Recommended (b) |
| 140030     | Peaches                                  | 0.1                    | 0.01*                 | Recommended (b) |
| 140040     | Plums                                    | 0.1                    | 0.01*                 | Recommended (b) |
| 151010     | Table grapes                             | 0.1                    | 0.1                   | Further consideration needed (c) |
| 151020     | Wine grapes                              | 0.1                    | 0.1                   | Further consideration needed (c) |
| 152000     | Strawberries                             | 0.2                    | 0.01*                 | Further consideration needed (a) |
| 153010     | Blackberries                            | 0.1                    | 0.01*                 | Further consideration needed (a) |
| 153020     | Dewberries                              | 0.1                    | 0.01*                 | Further consideration needed (a) |
| 153030     | Raspberries (red and yellow)             | 0.1                    | 0.01*                 | Further consideration needed (a) |
| 154010     | Blueberries                             | 0.1                    | 0.02                  | Further consideration needed (a) |
| 154020     | Cranberries                             | 0.1                    | 0.02                  | Further consideration needed (a) |
| 154030     | Currants (black, red and white)          | 0.1                    | 0.02                  | Further consideration needed (a) |
| 154040     | Gooseberries (green, red and yellow)     | 0.1                    | 0.02                  | Further consideration needed (a) |
| 154050     | Rose hips                               | 0.1                    | 0.02                  | Further consideration needed (a) |
| 154080     | Elderberries                            | 0.1                    | 0.02                  | Further consideration needed (a) |
| 161020     | Figs                                     | 0.05*                  | 0.05                  | Further consideration needed (a) |
| 163050     | Granate apples/pomegranates              | 0.05*                  | 0.05                  | Further consideration needed (a) |
| 211000     | Potatoes                                 | 0.1                    | 0.01*                 | Recommended (b) |
| 213030     | Celeriacs/turnip rooted celeries         | 0.05*                  | 0.01*                 | Recommended (b) |
| 213040     | Horseradishes                            | 0.05*                  | 0.01*                 | Recommended (b) |
| 213080     | Radishes                                 | 0.05*                  | 0.01*                 | Recommended (b) |
| 213100     | Sweeds/rutabagas                         | 0.05*                  | 0.01*                 | Recommended (b) |
| 213110     | Turnips                                  | 0.05*                  | 0.01*                 | Recommended (b) |
| 231010     | Tomatoes                                 | 0.1                    | 0.01*                 | Recommended (b) |
| 231020     | Sweet peppers/bell peppers              | 0.1                    | 0.1                   | Further consideration needed (c) |
| 231030     | Aubergines/eggplants                     | 0.1                    | 0.01*                 | Recommended (b) |
| 233030     | Watermelons                              | 0.05*                  | 0.05                  | Further consideration needed (c) |
| 241010     | Broccoli                                 | 0.05*                  | 0.01*                 | Recommended (b) |
| 241020     | Cauliflowers                             | 0.1                    | 0.01*                 | Recommended (b) |
| 242010     | Brussels sprouts                         | 0.1                    | 0.01*                 | Recommended (b) |
| 242020     | Head cabbages                            | 0.1                    | 0.01*                 | Recommended (b) |
| 243010     | Chinese cabbages/pe-tsai                 | 0.05*                  | 0.05                  | Further consideration needed (c) |
| 243020     | Kales                                    | 0.05*                  | 0.05                  | Further consideration needed (c) |
| 244000     | Kohlrabies                               | 0.05*                  | 0.05                  | Further consideration needed (c) |
| 251010     | Lamb's lettuce/corn salads               | 0.2                    | 0.05                  | Recommended (b) |
| 251060     | Roman rocket/rucola                      | 0.2                    | 0.05                  | Recommended (b) |
| 251070     | Red mustards                             | 0.05*                  | 0.05                  | Recommended (b) |
Austria, 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for napropamide, October 2017. Available online: www.efsa.europa.eu

| Code number | Commodity                                  | Existing EU MRL (mg/kg) | Outcome of the review |
|-------------|--------------------------------------------|-------------------------|-----------------------|
| 251080      | Baby leaf crops (including brassica species) | 0.05*                   | 0.05                  | Recommended (b) |
| 256010      | Chervil                                    | 0.05*                   | 0.05                  | Further consideration needed (c) |
| 256020      | Chives                                     | 0.05*                   | 0.05                  | Further consideration needed (c) |
| 256030      | Celery leaves                              | 0.05*                   | 0.05                  | Further consideration needed (c) |
| 256040      | Parsley                                    | 0.05*                   | 0.05                  | Further consideration needed (c) |
| 256050      | Sage                                       | 0.05*                   | 0.05                  | Further consideration needed (c) |
| 256060      | Rosemary                                   | 0.05*                   | 0.05                  | Further consideration needed (c) |
| 256070      | Thyme                                      | 0.05*                   | 0.05                  | Further consideration needed (c) |
| 256080      | Basil and edible flowers                   | 0.05*                   | 0.05                  | Further consideration needed (c) |
| 256090      | Laurel/bay leave                           | 0.05*                   | 0.05                  | Further consideration needed (c) |
| 256100      | Tarragon                                   | 0.05*                   | 0.05                  | Further consideration needed (c) |
| 260010      | Beans (with pods)                          | 0.05*                   | 0.01*                 | Recommended (b) |
| 401010      | Linseeds                                   | 0.05*                   | 0.02                  | Recommended (b) |
| 401030      | Poppy seeds                                | 0.05*                   | 0.02                  | Recommended (b) |
| 401040      | Sesame seeds                               | 0.05*                   | 0.02                  | Recommended (b) |
| 401050      | Sunflower seeds                            | 0.05*                   | 0.02                  | Recommended (b) |
| 401060      | Rapeseeds/canola seeds                     | 0.1                     | 0.02                  | Recommended (b) |
| 401070      | Soya beans                                 | 0.05*                   | 0.02                  | Recommended (b) |
| 401080      | Mustard seeds                              | 0.05*                   | 0.02                  | Recommended (b) |
| 401090      | Cotton seeds                               | 0.05*                   | 0.02                  | Recommended (b) |
| 401100      | Pumpkin seeds                              | 0.05*                   | 0.02                  | Recommended (b) |
| 401110      | Safflower seeds                            | 0.05*                   | 0.02                  | Recommended (b) |
| 401120      | Borage seeds                               | 0.05*                   | 0.02                  | Recommended (b) |
| 401130      | Gold of pleasure seeds                     | 0.05*                   | 0.02                  | Recommended (b) |
| 401140      | Hemp seeds                                 | 0.05*                   | 0.02                  | Recommended (b) |
| 401150      | Castor beans                               | 0.05*                   | 0.02                  | Recommended (b) |
| 631000      | Herbal infusions from flowers              | 0.05*                   | 0.05                  | Further consideration needed (c) |
| 632000      | Herbal infusions from leaves and herbs      | 0.05*                   | 0.05                  | Further consideration needed (c) |
| 633000      | Herbal infusions from roots                | 0.05*                   | 0.05                  | Further consideration needed (c) |
| 820000      | Fruit spices                               | 0.05*                   | 0.05                  | Further consideration needed (c) |
| –           | Other commodities of plant/animal origin   | See Reg. 149/2008       | –                     | Further consideration needed (b) |

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(a): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination E-I in Appendix E).
(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix E).
(c): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination C-I in Appendix E).
(d): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).

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Abbreviations

- a.i. active ingredient
- a.s. active substance
- ADI acceptable daily intake
- AR applied radioactivity
- ARfD acute reference dose
- BBCH growth stages of mono- and dicotyledonous plants
- bw body weight
- CXL codex maximum residue limit
- DAR draft assessment report
- DAT days after treatment
- DB dietary burden
- DM dry matter
- DT$_{90}$ period required for 90% dissipation (define method of estimation)
- EC emulsifiable concentrate
- eq residue expressed as a.s. equivalent
- EURLs European Union Reference Laboratories for Pesticide Residues (former CRLs)
- FAO Food and Agriculture Organization of the United Nations
- GAP Good Agricultural Practice
- GC-MSD gas chromatography with mass selective detector
- GC-MS/MS gas 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 Standardization
- IUPAC International Union of Pure and Applied Chemistry
- LOQ limit of quantification
- Mo monitoring
- MRL maximum residue level
- NEU northern European Union
- OECD Organisation for Economic Co-operation and Development
- PBI plant-back interval
- PEC predicted environmental concentration
- PF processing factor
- PHI preharvest interval
- PRIMO (EFSA) Pesticide Residues Intake Model
- PROFile (EFSA) Pesticide Residues Overview File
| Acronym | Definition                                    |
|---------|-----------------------------------------------|
| RA      | risk assessment                               |
| RD      | residue definition                            |
| RMS     | rapporteur Member State                       |
| SANCO   | Directorate-General for Health and Consumers   |
| SC      | suspension concentrate                        |
| SEU     | southern European Union                       |
| SMILES  | simplified molecular-input line-entry system  |
| STMR    | supervised trials median residue              |
| TRR     | total radioactive residue                      |
| WG      | water-dispersible granule                     |
| WHO     | World Health Organization                      |
| WP      | wettable powder                               |
### Appendix A – Summary of authorised uses considered for the review of MRLs

#### A.1. Authorised uses in northern outdoor EU

| Crop and/or situation | Country | F (or I) | Pests or group of pests controlled | Preparation | Method kind | Range of growth stages and season | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------|----------|----------------------------------|-------------|------------|----------------------------------|-------------|-------------------------------|------------|---------|
| Almonds               | AT      | F        | Monocotyledonous and dicotyledonous weeds | SC 450 g/L  | Soil treatment – spraying | 0–1                 | – | 2.25 | n.a. |
| Chestnuts             | AT      | F        | Monocotyledonous and dicotyledonous weeds | SC 450 g/L  | Soil treatment – spraying | 0–1                 | – | 2.25 | n.a. |
| Hazelnuts             | AT      | F        | Monocotyledonous and dicotyledonous weeds | SC 450 g/L  | Soil treatment – spraying | 0–1                 | – | 2.25 | n.a. |
| Pine nut kernels      | AT      | F        | Monocotyledonous and dicotyledonous weeds | SC 450 g/L  | Soil treatment – spraying | 0–1                 | – | 2.25 | n.a. |
| Walnuts               | AT      | F        | Monocotyledonous and dicotyledonous weeds | SC 450 g/L  | Soil treatment – spraying | 0–1                 | – | 2.25 | n.a. |
| Apples                | FR      | F        | Annual grasses and broad | SC 450 g/L  | Soil treatment – general | 59–1                | – | 4.05 | n.a. |
| Pears                 | FR      | F        | Annual grasses and broad | SC 450 g/L  | Soil treatment – general | 59–1                | – | 4.05 | n.a. |
| Quinces               | FR      | F        | Annual grasses and broad | SC 450 g/L  | Soil treatment – general | 59–1                | – | 4.05 | n.a. |
| Crop and/or situation | Country | FG or I<sup>(a)</sup> | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)<sup>(d)</sup> | Remarks |
|-----------------------|---------|------------------------|-----------------------------------|-------------|-------------|-------------------------------|------------------------|---------|
| Medlars               | FR      | F                      | Annual grasses and broad          | SC 450 g/L  | Soil treatment – general      | 59 1                       | 4.05 n.a.             |
| Loquats               | FR      | F                      | Annual grasses and broad          | SC 450 g/L  | Soil treatment – general      | 59 1                       | 4.05 n.a.             |
| Apricots              | AT      | F                      | Monocotyledonous and dicotyledonous weeds | SC 450 g/L  | Soil treatment – spraying     | 0 1                        | 2.25 n.a.             |
| Cherries              | AT      | F                      | Monocotyledonous and dicotyledonous weeds | SC 450 g/L  | Soil treatment – spraying     | 0 1                        | 2.25 n.a.             |
| Peaches               | AT      | F                      | Monocotyledonous and dicotyledonous weeds | SC 450 g/L  | Soil treatment – spraying     | 0 1                        | 2.25 n.a.             |
| Plums                 | AT      | F                      | Monocotyledonous and dicotyledonous weeds | SC 450 g/L  | Soil treatment – spraying     | 0 1                        | 2.25 n.a.             |
| Wine grapes           | FR      | F                      | Annual grasses and broad          | SC 450 g/L  | Soil treatment – spraying     | 59 1                       | 4.05 n.a.             |
| Strawberries          | AT      | F                      | Annual grasses                   | SC 423 g/L  | Soil treatment – spraying     | 0 1                        | 1.06 n.a.             |
| Blackberries          | AT      | F                      | Monocotyledonous and dicotyledonous weeds | SC 450 g/L  | Soil treatment – spraying     | 0 1                        | 2.25 n.a.             |

<sup>(a)</sup> FG or I: Crop protection strategy

<sup>(b)</sup> Type: SC (Soluble concentrate)

<sup>(c)</sup> Method kind:
- Soil treatment – general
- Soil treatment – spraying

<sup>(d)</sup> PHI (days): PHI = Pre-Application Interval

Remarks:
- Nursery production, pre-emergence after planting in late autumn or late winter
| Crop and/or situation | Country | F G or I | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------|---------|----------------------------------|-------------|------------|-------------------------------|------------|---------|
| Dewberries            | AT      | F       | Monocotyledonous and dicotyledonous weeds | SC 450 g/L  | Soil treatment – spraying | 0 – 1 | 2.25 | n.a. | Nursery production, pre-emergence after planting in late autumn or late winter |
| Raspberries           | AT      | F       | Monocotyledonous and dicotyledonous weeds | SC 450 g/L  | Soil treatment – spraying | 0 – 1 | 2.25 | n.a. | Nursery production, pre-emergence after planting in late autumn or late winter |
| Blueberries           | DE      | F       | Blackgrass, annual bluegrass, annual dicotyledonous weeds (except: catchweed bedstraw) | SC 450 g/L  | Foliar treatment – broadcast spraying | 54 – 1 | 1.13 | n.a. | Before sprouting, at beginning of vegetation |
| Cranberries           | DE      | F       | Blackgrass, annual bluegrass, annual dicotyledonous weeds (except: catchweed bedstraw) | SC 450 g/L  | Foliar treatment – broadcast spraying | 54 – 1 | 1.13 | n.a. | Before sprouting, at beginning of vegetation |
| Currants              | DE      | F       | Blackgrass, annual bluegrass, annual dicotyledonous weeds (except: catchweed bedstraw) | SC 450 g/L  | Foliar treatment – broadcast spraying | 54 – 1 | 1.13 | n.a. | Before sprouting, at beginning of vegetation |
| Crop and/or situation | Country | F | G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------|---|-----------|-----------------------------------|-------------|------------|--------------------------------|--------------|---------|
| Gooseberries          | DE      | F | G or I    | Blackgrass, annual bluegrass, annual dicotyledonous weeds (except: catchweed bedstraw) | SC 450 g/L Foliar treatment – broadcast spraying | 54 1 | – – 1.13 n.a. | Before sprouting, at beginning of vegetation |
| Rose hips             | DE      | F | G or I    | Blackgrass, annual bluegrass, annual dicotyledonous weeds (except: catchweed bedstraw) | SC 450 g/L Foliar treatment – broadcast spraying | 54 1 | – – 1.13 n.a. | Before sprouting, at beginning of vegetation |
| Elderberries          | DE      | F | G or I    | Blackgrass, annual bluegrass, annual dicotyledonous weeds (except: catchweed bedstraw) | SC 450 g/L Foliar treatment – broadcast spraying | 54 1 | – – 1.13 n.a. | Before sprouting, at beginning of vegetation |
| Celeriacs             | UK      | F | G or I    | Soil treatment – general (see also comment field) | 0 1 | – – 0.56 n.a. | Pre-emergence of crop |
| Horseradishes         | UK      | F | G or I    | Soil treatment – general (see also comment field) | 0 1 | – – 0.56 n.a. | Pre-emergence of crop |

Notes:
(a) F, G or I: Footnotes for the table.
(b) Type: Formulation.
(c) Method: Kind of application.
(d) PHI: Pre-harvest interval.
| Crop and/or situation | Country | FG or I | Pests or group of pests controlled | Preparation | Application | PHII (days) | Remarks |
|-----------------------|---------|---------|-----------------------------------|-------------|-------------|------------|---------|
| Radishes              | DE      | F       | Annual bluegrass, annual dicotyledonous weeds (except: catchweed bedstraw) | SC 450 g/L | Soil treatment – general (see also comment field) | 0 1 | 0.38 n.a. Before sowing or before planting; with incorporation in a depth of 5 cm |
| Swedes                | FI      | F       | g/L                               | 0 1         | – –         | 0.95 n.a. | All crops: sprayed before sowing/planting |
| Turnips               | FI      | F       | g/L                               | 0 1         | – –         | 0.95 n.a. | All crops: sprayed before sowing/planting |
| Tomatoes              | SI      | F       | Annual grasses and BLW            | SC 450 g/L | Soil treatment – spraying | 0 1 | 1.8 72 Spraying on soil/ Spraying on soil followed by incorporation. Before transplanting |
| Sweet peppers         | SI      | F       | Annual grasses and BLW            | SC 450 g/L | Soil treatment – spraying | 0 1 | 1.8 72 Spraying on soil/ Spraying on soil followed by incorporation. Before transplanting |
| Broccoli              | NL      | F       | Poa annua, annual broadleaved weeds | SC 450 g/L | Soil treatment – spraying | 0 1 | 1.26 n.a. Soil treatment before transplanting |
| Cauliflowers          | NL      | F       | Poa annua, annual broadleaved weeds | SC 450 g/L | Soil treatment – spraying | 0 1 | 1.26 n.a. Soil treatment before transplanting |
| Crop and/or situation | Country | F or G or I | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------|-------------|-----------------------------------|-------------|-------------|-------------------------------|------------|---------|
| Brussels sprouts      | NL      | F           | Poa annua, annual broadleaved weeds | SC         | 450 g/L     | Soil treatment – spraying      | 0          | 1       | 1.26  | n.a.  | Soil treatment before transplanting |
| Head cabbages         | NL      | F           | Poa annua, annual broadleaved weeds | SC         | 450 g/L     | Soil treatment – spraying      | 0          | 1       | 1.26  | n.a.  | Soil treatment before transplanting |
| Chinese cabbages      | UK      | F           |                                    |            |             | Soil treatment – general       | 0          | 1       | 1.26  | n.a.  | Before transplanting or drilling    |
| Kales                 | UK      | F           |                                    |            |             | Soil treatment – general       | 0          | 1       | 1.26  | n.a.  | Before transplanting or drilling    |
| Kohlrabies            | DE      | F           | Blackgrass, annual bluegrass, annual dicotyledonous weeds (except: catchweed bedstraw) | SC         | 450 g/L     | Soil treatment – general       | 0          | 1       | 1.13  | n.a.  | Before sowing or before planting; with incorporation in a depth of 5 cm |
| Lamb’s lettuces       | FR      | F           | Annual grasses and broadleaved weeds | SC         | 450 g/L     | Soil treatment – general       | 1          | –       | 0.81  | 26    | Application to soil surface under crop followed by incorporation |
| Crop and/or situation | Country | FG or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------|------------|------------------------------------|-------------|-------------|-------------------------------|---------------|---------|
|                       |         |            |                                    |             |             |                               |               |         |
| **Roman rocket**      | FR      | F          | Annual grasses and broadleaved weeds | SC          | 450 g/L     | Soil treatment – general (see also comment field) | 0–1           | 0.81 26 | Application to soil surface under crop followed by incorporation |
| **Red mustards**      | UK      | F          |                                    | SC          | 450 g/L     | Soil treatment – general (see also comment field) | 0–1           | 0.38 n.a. | Before transplanting or drilling |
| **Baby leaf crops**   | UK      | F          |                                    | SC          | 450 g/L     | Soil treatment – general (see also comment field) | 0–1           | 0.38 n.a. | Before transplanting or drilling |
| **Sage**              | FR      | F          | Annual grasses and broadleaved weeds | SC          | 450 g/L     | Soil treatment – spraying | 9–1           | 1.13 n.a. | Spraying on soil followed by incorporation |
| **Thyme**             | FR      | F          | Annual grasses and broadleaved weeds | SC          | 450 g/L     | Soil treatment – spraying | 9–1           | 1.13 n.a. | Spraying on soil followed by incorporation |
| **Basil**             | FR      | F          | Annual grasses and broadleaved weeds | SC          | 450 g/L     | Soil treatment – spraying | 9–1           | 1.13 n.a. | Spraying on soil followed by incorporation |
| **Tarragon**          | FR      | F          | Annual grasses and broadleaved weeds | SC          | 450 g/L     | Soil treatment – spraying | 9–1           | 1.13 n.a. | Spraying on soil followed by incorporation |
| Crop and/or situation | Country | F G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------|------------|------------------------------------|-------------|-------------|------------------------|--------------|---------|
| Beans (with pods)     | DE      | F          | Annual bluegrass, annual dicotyledonous weeds (except: catchweed bedstraw) | SC 450 g/L  | Soil treatment – general (see also comment field) | 0 – 1 | 0.72 | n.a. | Growth stage: before sowing |
| Linseeds              | FR      | F          | Annual grasses and broadleaved weeds | SC 450 g/L  | Soil treatment – general (see also comment field) | 9 – 1 | 1.26 | n.a. | Application to soil surface under crop followed by incorporation |
| Poppy seeds           | BE      | F          | Annual monocotyledonous and dicotyledonous weeds | WG 40% (w/w) | Soil treatment – general (see also comment field) | 7 – 1 | 1.2 | n.a. | 2nd active substance in the formulation: clomazone (105 g/ha) |
| Sesame seeds          | BE      | F          | Annual monocotyledonous and dicotyledonous weeds | WG 40% (w/w) | Soil treatment – general (see also comment field) | 7 – 1 | 1.2 | n.a. | 2nd active substance in the formulation: clomazone (105 g/ha) |
| Sunflower seeds       | BE      | F          | Annual monocotyledonous and dicotyledonous weeds | WG 40% (w/w) | Soil treatment – general (see also comment field) | 7 – 1 | 1.2 | n.a. | 2nd active substance in the formulation: clomazone (105 g/ha) |

(a) F = France, G = Germany, I = Italy

(b) Type: SC = Suspension concentrate, WG = Wettable granule

(c) Range of growth stages and season:

(d) PHI (Days) = Preharvest interval

(e) Number between application (min)
| Crop and/or situation | Country | FG or I | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------|---------|------------------------------------|-------------|-------------|-----------------------------|-----------|---------|
|                       |         |         |                                    |                      |             |                             |           |         |
| Rapeseeds             | FR      | F       | Annual grasses and broadleaved weeds | SC 450 g/L      | Soil treatment – general (see also comment field) | 9 1 | – – | 1.26 n.a. | Application to soil surface under crop followed by incorporation |
| Soya beans            | BE      | F       | Annual monocotyledonous and dicotyledonous weeds | WG 40% (w/w)   | Soil treatment – general (see also comment field) | 7 1 | – – | 1.2 n.a. | 2nd active substance in the formulation: clomazone (105 g/ha) |
| Mustard seeds         | FR      | F       | Annual grasses and broadleaved weeds | SC 450 g/L      | Soil treatment – general (see also comment field) | 9 1 | – – | 1.26 n.a. | Application to soil surface under crop followed by incorporation |
| Cotton seeds          | BE      | F       | Annual monocotyledonous and dicotyledonous weeds | WG 40% (w/w)   | Soil treatment – general (see also comment field) | 7 1 | – – | 1.2 n.a. | 2nd active substance in the formulation: clomazone (105 g/ha) |
| Pumpkin seeds         | BE      | F       | Annual monocotyledonous and dicotyledonous weeds | WG 40% (w/w)   | Soil treatment – general (see also comment field) | 7 1 | – – | 1.2 n.a. | 2nd active substance in the formulation: clomazone (105 g/ha) |
| Crop and/or situation | Country | F or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------|-----------|-----------------------------------|-------------|-------------|-------------------------------|--------------|---------|
|                       |         |           |                                    |             |             |                               |              |         |
| Safflower seeds       | BE      | F         | Annual monocotyledonous and dicotyledonous weeds | WG 40% (w/w) | Soil treatment – general (see also comment field) | 7               | 1               | –        | 1.2     | n.a.     | 2nd active substance in the formulation: clomazone (105 g/ha) |
| Borage seeds          | FR      | F         | Annual grasses and broadleaved weeds | SC 450 g/L  | Soil treatment – general (see also comment field) | 9               | 1               | –        | 1.26    | n.a.     | Application to soil surface under crop followed by incorporation |
| Gold of pleasure seeds| FR      | F         | Annual grasses and broadleaved weeds | SC 450 g/L  | Soil treatment – general (see also comment field) | 9               | 1               | –        | 1.26    | n.a.     | Application to soil surface under crop followed by incorporation |
| Hemp seeds            | FR      | F         | Annual grasses and broadleaved weeds | SC 450 g/L  | Soil treatment – general (see also comment field) | 9               | 1               | –        | 1.26    | n.a.     | Application to soil surface under crop followed by incorporation |
| Castor beans          | BE      | F         | Annual monocotyledonous and dicotyledonous weeds | WG 40% (w/w) | Soil treatment – general (see also comment field) | 7               | 1               | –        | 1.2     | n.a.     | 2nd active substance in the formulation: clomazone (105 g/ha) |
| Crop and/or situation                        | Country | F  | G  | I (a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) (d) | Remarks |
|---------------------------------------------|---------|----|----|-------|-----------------------------------|-------------|-------------|---------------------------------|----------------|---------|
| Herbal infusions from flowers               | FR      | F  |    |       | Annual grasses and broadleaved weeds | SC 450 g/L  | Soil treatment – spraying        | –                 | 1.13 n.a.      | Application method: spraying on soil/spraying on soil followed by incorporation |
| Herbal infusions from leaves and herbs      | FR      | F  |    |       | Annual grasses and broadleaved weeds | SC 450 g/L  | Soil treatment – spraying        | –                 | 1.13 n.a.      | Application method: spraying on soil/spraying on soil followed by incorporation |
| Herbal infusions from roots                 | FR      | F  |    |       | Annual grasses and broadleaved weeds | SC 450 g/L  | Soil treatment – spraying        | –                 | 1.13 n.a.      | Application method: Spraying on soil/Spraying on soil followed by incorporation |
| Fruit spices                                | FR      | F  |    |       | Annual grasses and broadleaved weeds | SC 450 g/L  | Soil treatment – spraying        | –                 | 1.13 n.a.      | Application method: Spraying on soil/Spraying on soil followed by incorporation |

NEU: northern European Union; SEU: southern European Union; MS: Member State; GAP: Good Agricultural Practice; BBCH: growth stages of mono- and dicotyledonous plants; a.s.: active substance; SC: suspension concentrate; WG: water-dispersible granule.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI: minimum preharvest interval.
## A.2. Authorised uses in southern outdoor EU

| Crop and/or situation | Country | FG or I(a) | Pests or group of pests controlled | Preparation Type(b) | Conc. a.s. | Method kind | Range of growth stages and season(c) | Number min–max | Interval between application (min) | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------|------------|-----------------------------------|---------------------|-----------|------------|--------------------------------------|---------------|-----------------------------------|--------------------------|--------------|---------|
| Grapefruits EL        | F       | Annual & perennial weeds and grasses | SC 450 g/L Soil treatment – spraying | 9                   | 1         | –          | –                                    | 4.5           | n.a.                               | During winter before weeds emerge |
| Oranges EL            | F       | Annual & perennial weeds and grasses | SC 450 g/L Soil treatment – spraying | 9                   | 1         | –          | –                                    | 4.5           | n.a.                               | During winter before weeds emerge |
| Lemons EL             | F       | Annual & perennial weeds and grasses | SC 450 g/L Soil treatment – spraying | 9                   | 1         | –          | –                                    | 4.5           | n.a.                               | During winter before weeds emerge |
| Limes ES              | F       | Annual weeds (Pre-emergence)       | SC 450 g/L Soil treatment – spraying | 9                   | 1         | –          | –                                    | 2.48          | n.a.                               | Spraying on soil followed by incorporation by labour or irrigation within the following 48 h |
| Mandarins EL          | F       | Annual & perennial weeds and grasses | SC 450 g/L Soil treatment – spraying | 9                   | 1         | –          | –                                    | 4.5           | n.a.                               | During winter before weeds emerge |
| Chestnuts ES          | F       | Annual weeds (Pre-emergence)       | SC 450 g/L Soil treatment – spraying | 0                   | 1         | –          | –                                    | 2.48          | n.a.                               | Spraying on soil followed by incorporation by labour or irrigation within the following 48 h |
| Crop and/or situation | Country | FG or I | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------|---------|----------------------------------|-------------|------------|-------------------------------|-----------|---------|
|                       |         |         |                                  |             |            |                               |           |         |
| **Hazelnuts**         | ES      | F       | Annual weeds (Pre-emergence)     | SC          | 450 g/L   | Soil treatment – spraying     | 0 – 1     | 2.48 n.a. Spraying on soil followed by incorporation by labour or irrigation within the following 48 h |
| **Pecans**            | ES      | F       | Annual weeds (Pre-emergence)     | SC          | 450 g/L   | Soil treatment – spraying     | 0 – 1     | 2.48 n.a. Spraying on soil followed by incorporation by labour or irrigation within the following 48 h |
| **Pistachios**        | ES      | F       | Annual weeds (Pre-emergence)     | SC          | 450 g/L   | Soil treatment – spraying     | 0 – 1     | 2.48 n.a. Spraying on soil followed by incorporation by labour or irrigation within the following 48 h |
| **Walnuts**           | ES      | F       | Annual weeds (Pre-emergence)     | SC          | 450 g/L   | Soil treatment – spraying     | 0 – 1     | 2.48 n.a. Spraying on soil followed by incorporation by labour or irrigation within the following 48 h |
| **Apples**            | FR      | F       | Annual grasses and broad         | SC          | 450 g/L   | Soil treatment – general (see also comment field) | 59 – 1   | 4.05 n.a. Application to soil surface under crop followed by incorporation |
| Crop and/or situation | Country | F or G or I(a) | Pests or group of pests controlled | Preparation | Method kind | Range of growth stages and season(b) | Number min-max | Interval between application (min) | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------|----------------|----------------------------------|------------|------------|------------------------------------|----------------|-----------------------------|--------------------------------|-------------|---------|
| Pears FR F            |         | Annual grasses and broad | SC 450 g/L                      | Soil treatment – general (see also comment field) | 59 1          | – – 4.05 | n.a. | Application to soil surface under crop followed by incorporation |
| Quinces FR F          |         | Annual grasses and broad | SC 450 g/L                      | Soil treatment – general (see also comment field) | 59 1          | – – 4.05 | n.a. | Application to soil surface under crop followed by incorporation |
| Medlars FR F          |         | Annual grasses and broad | SC 450 g/L                      | Soil treatment – general (see also comment field) | 59 1          | – – 4.05 | n.a. | Application to soil surface under crop followed by incorporation |
| Loquats FR F          |         | Annual grasses and broad | SC 450 g/L                      | Soil treatment – general (see also comment field) | 59 1          | – – 4.05 | n.a. | Application to soil surface under crop followed by incorporation |
| Apricots FR F         |         | Annual grasses and broad | SC 450 g/L                      | Soil treatment – general (see also comment field) | 59 1          | – – 4.05 | n.a. | Application to soil surface under crop followed by incorporation |
| Crop and/or situation | Country | F or G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | Remarks |
|-----------------------|---------|----------------|-----------------------------------|-------------|-------------|------------------------------|---------|
|                       |         |                |                                   | Type(b) | Conc. a.s. | Method kind                  | g a.s./ha | Water L/ha | kg a.s./ha | PHI (days)(d) |          |
|                       |         |                |                                   | Range of growth stages and season(e) | Number min–max | Interval between application (min) | min–max | min–max | min–max | |
| Cherries              | FR      | F              | Annual grasses and broad         | SC        | 450 g/L   | Soil treatment – general (see also comment field) | 59      | 1      | –       | –       | 4.05     | n.a. | Application to soil surface under crop followed by incorporation |
| Peaches               | FR      | F              | Annual grasses and broad         | SC        | 450 g/L   | Soil treatment – general (see also comment field) | 59      | 1      | –       | –       | 4.05     | n.a. | Application to soil surface under crop followed by incorporation |
| Plums                 | FR      | F              | Annual grasses and broad         | SC        | 450 g/L   | Soil treatment – general (see also comment field) | 59      | 1      | –       | –       | 4.05     | n.a. | Application to soil surface under crop followed by incorporation |
| Table grapes          | FR      | F              | Annual grasses and broad         | SC        | 450 g/L   | Soil treatment – general (see also comment field) | 59      | 1      | –       | –       | 4.05     | n.a. | Application to soil surface under crop followed by incorporation |
| Wine grapes           | FR      | F              | Annual grasses and broad         | SC        | 450 g/L   | Soil treatment – general (see also comment field) | 59      | 1      | –       | –       | 4.05     | n.a. | Application to soil surface under crop followed by incorporation |
| Crop and/or situation | Country | FG or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | Remarks |
|-----------------------|---------|------------|-----------------------------------|-------------|------------|-----------------------------|---------|
|                       |         |            |                                   |             |            | g a.s./hL | Water L/ha | kg a.s./ha | PHI (days)(d) |         |
|                       |         |            |                                   |             |            | min-max | min-max | min-max |         |         |
| Strawberries          | EL      | F          | Annual & perennial weeds and grasses | SC          | 450 g/L    | Soil treatment – spraying | 9     | 1     | –       | –       | 4.5     | n.a.    | Preplant, during spring |
| Figs                  | ES      | F          | Annual weeds (Pre-emergence)      | SC          | 450 g/L    | Soil treatment – spraying | 0     | 1     | –       | –       | 2.48    | n.a.    | Spraying on soil followed by incorporation by labour or irrigation within the following 48 h |
| Granate apples        | ES      | F          | Annual weeds (Pre-emergence)      | SC          | 450 g/L    | Soil treatment – spraying | 0     | 1     | –       | –       | 2.48    | n.a.    | Spraying on soil followed by incorporation by labour or irrigation within the following 48 h |
| Potatoes              | IT      | F          | Annual and perennial weeds        | WP          | 500 g/kg   | Soil treatment – injection | 0     | 1     | –       | –       | 1.8     | n.a.    | Presowing or pretransplanting on soil (mechanical incorporation, irrigation or drop casted followed by rain falls). Currently in zonal evaluation for Step 2 reregistration |
| Tomatoes              | EL      | F          | Annual & perennial weeds and grasses | SC          | 450 g/L    | Soil treatment – spraying | 9     | 1     | –       | –       | 2.25    | n.a.    | Pre-emergence |
| Crop and/or situation | Country | F | G or I (a) | Pests or group of pests controlled | Preparation | Method kind | Range of growth stages and season (c) | Number min–max | Interval between application (min) | Application rate per treatment g a.s./ha min–max | Water L/ha min–max | kg a.s./ha min–max | PHI (days) (d) | Remarks |
|-----------------------|---------|---|------------|----------------------------------|-------------|------------|------------------------------------|--------------|-----------------------------------|---------------------------------|-------------|----------------|-------------|---------|
| Sweet peppers         | EL      | F | F          | Annual & perennial weeds and grasses | SC 450 g/L  | Soil treatment – spraying         | 9 1                  | – –                                  | 2.25                           | n.a.             | –              | 2.25        | n.a.    |
| Aubergines            | EL      | F | F          | Annual & perennial weeds and grasses | SC 450 g/L  | Soil treatment – spraying         | 9 1                  | – –                                  | 2.25                           | n.a.             | –              | 2.25        | n.a.    |
| Watermelons           | EL      | F | F          | Annual & perennial weeds and grasses | SC 450 g/L  | Soil treatment – spraying         | 9 1                  | – –                                  | 1.8                             | n.a.             | –              | 1.25        | n.a.    |
| Broccoli              | EL      | F | F          | Annual & perennial weeds and grasses | SC 450 g/L  | Soil treatment – spraying         | 9 1                  | – –                                  | 1.25                           | n.a.             | –              | 1.25        | n.a.    |
| Cauliflowers          | EL      | F | F          | Annual & perennial weeds and grasses | SC 450 g/L  | Soil treatment – injection        | 9 1                  | – –                                  | 1.25                           | n.a.             | –              | 1.25        | n.a.    |
| Brussels sprouts      | EL      | F | F          | Annual & perennial weeds and grasses | SC 450 g/L  | Soil treatment – spraying         | 9 1                  | – –                                  | 1.25                           | n.a.             | –              | 1.25        | n.a.    |
| Head cabbages         | EL      | F | F          | Annual & perennial weeds and grasses | SC 450 g/L  | Soil treatment – injection        | 9 1                  | – –                                  | 1.25                           | n.a.             | –              | 1.25        | n.a.    |
| Crop and/or situation | Country | F or G or I<sup>(a)</sup> | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | Remarks |
|-----------------------|---------|-----------------|--------------------------------------|-------------|----------------|--------------------------------|---------|
|                       |         |                 |                                      | Type<sup>(b)</sup> | Conc. a.s. | Method kind | Range of growth stages and season<sup>(c)</sup> | Number min–max | Interval between application (min) | g a.s./hL min–max | Water L/ha min–max | kg a.s./ha min–max | PHI (days)<sup>(d)</sup> | |
| Chinese cabbages      | EL      | F               | Annual & perennial weeds and grasses | SC          | 450 g/L   | Soil treatment – general (see also comment field) | 9          | 1                      |                          | –                | –                | 1.25                | n.a.                | Pretransplant (submitted for zonal Step 2, zRMS France) |
| Kales                 | EL      | F               | Annual & perennial weeds and grasses | SC          | 450 g/L   | Soil treatment – spraying                         | 9          | 1                      |                          | –                | –                | 1.25                | n.a.                | Pretransplant (submitted for zonal Step 2, zRMS France) |
| Kohlrabies            | EL      | F               | Annual & perennial weeds and grasses | SC          | 450 g/L   | Soil treatment – spraying                         | 9          | 1                      |                          | –                | –                | 1.25                | n.a.                | Pretransplant (submitted for zonal Step 2, zRMS France) |
| Roman rocket          | FR      | F               | Annual grasses and broadleaved weeds | SC          | 450 g/L   | Soil treatment – general (see also comment field) | 1          |                        |                          | –                | –                | 0.81                | 26                  | Application to soil surface under crop followed by incorporation |
| Chervil               | EL      | F               | Annual & perennial weeds and grasses | SC          | 450 g/L   | Soil treatment – spraying                         | 9          | 1                      |                          | –                | –                | 1.13                | n.a.                | Pre-emergence (submitted for zonal Step 2, zRMS France) |
| Chives                | EL      | F               | Annual & perennial weeds and grasses | SC          | 450 g/L   | Soil treatment – spraying                         | 9          | 1                      |                          | –                | –                | 1.13                | n.a.                | Pre-emergence (submitted for zonal Step 2, zRMS France) |
| Crop and/or situation | Country | F | G or I | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------|---|--------|-----------------------------------|-------------|-------------|--------------------------------|-----------|---------|
| Celery leaves         | EL      | F |        | Annual & perennial weeds and grasses | SC 450 g/L  | Soil treatment – spraying       | 9                  | 1         | 1.13  n.a. | Pre-emergence (submitted for zonal Step 2, zRMS France) |
| Parsley               | EL      | F |        | Annual & perennial weeds and grasses | SC 450 g/L  | Soil treatment – spraying       | 9                  | 1         | 1.13  n.a. | Pre-emergence (submitted for zonal Step 2, zRMS France) |
| Sage                  | EL      | F |        | Annual & perennial weeds and grasses | SC 450 g/L  | Soil treatment – spraying       | 9                  | 1         | 1.13  n.a. | Pre-emergence (submitted for zonal Step 2, zRMS France) |
| Rosemary              | EL      | F |        | Annual & perennial weeds and grasses | SC 450 g/L  | Soil treatment – spraying       | 9                  | 1         | 1.13  n.a. | Pre-emergence (submitted for zonal Step 2, zRMS France) |
| Thyme                 | FR      | F |        | Annual grasses and broadleaved weeds | SC 450 g/L  | Soil treatment – spraying       | 9                  | 1         | 1.13  n.a. | Application method: Spraying on soil/Spraying on soil followed by incorporation |
| Basil                 | FR      | F |        | Annual grasses and broadleaved weeds | SC 450 g/L  | Soil treatment – spraying       | 9                  | 1         | 1.13  n.a. | Application method: Spraying on soil/Spraying on soil followed by incorporation |
| Laurel                | EL      | F |        | Annual & perennial weeds and grasses | SC 450 g/L  | Soil treatment – spraying       | 9                  | 1         | 1.13  n.a. | Presowing (submitted for zonal Step 2, zRMS France) |
| Crop and/or situation | Country | F or G | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------|--------|----------------------------------|-------------|------------|--------------------------------|-----------|---------|
|                       |         |        |                                  | Type(b) Conc. a.s. Method kind Range of growth stages and season(c) Number min-max Interval between application (min) g a.s./hL min-max Water L/ha min-max kg a.s./ha min-max |           |           |
| Tarragon              | FR      | F      | Annual grasses and broadleaved weeds | SC 450 g/L Soil treatment – spraying 9 1 | – – 1.13 | n.a. Application method: spraying on soil/spraying on soil followed by incorporation |
| Sesame seeds          | FR      | F      | Annual grasses and broadleaved weeds | SC 450 g/L Soil treatment – general (see also comment field) 9 1 | – – 1.26 | n.a. Application to soil surface under crop followed by incorporation |
| Rapeseeds             | FR      | F      | Annual grasses and broadleaved weeds | SC 450 g/L Soil treatment – general (see also comment field) 9 1 | – – 1.26 | n.a. Application to soil surface under crop followed by incorporation |
| Borage seeds          | FR      | F      | Annual grasses and broadleaved weeds | SC 450 g/L Soil treatment – general (see also comment field) 9 1 | – – 1.26 | n.a. Application to soil surface under crop followed by incorporation |
| Gold of pleasure seeds| FR      | F      | Annual grasses and broadleaved weeds | SC 450 g/L Soil treatment – general (see also comment field) 9 1 | – – 1.26 | n.a. Application to soil surface under crop followed by incorporation |
| Crop and/or situation | Country | F | G or I | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | Remarks |
|-----------------------|---------|---|--------|-------------------------------|-------------|-------------|-------------------------------|---------|
|                       |         |   |        |                               |             |                         | g a.s./hL min-max | Water L/ha min-max | kg a.s./ha min-max | PH (days) (d) | |
| Hemp seeds            | FR      | F |        | Annual grasses and broadleaved weeds | SC 450 g/L | Soil treatment – general (see also comment field) | 9 1 | – | – | 1.26 | n.a. |
| Herbal infusions from flowers | FR      | F |        | Annual grasses and broadleaved weeds | SC 450 g/L | Soil treatment – spraying | 9 1 | – | – | 1.13 | n.a. |
| Herbal infusions from leaves and herbs | FR      | F |        | Annual grasses and broadleaved weeds | SC 450 g/L | Soil treatment – spraying | 9 1 | – | – | 1.13 | n.a. |
| Herbal infusions from roots | FR      | F |        | Annual grasses and broadleaved weeds | SC 450 g/L | Soil treatment – spraying | 9 1 | – | – | 1.13 | n.a. |
| Fruit spices          | FR      | F |        | Annual grasses and broadleaved weeds | SC 450 g/L | Soil treatment – spraying | 9 1 | – | – | 1.13 | n.a. |

NEU: northern European Union; SEU: southern European Union; MS: Member State; GAP: Good Agricultural Practice; BBCH: growth stages of mono- and dicotyledonous plants; a.s.: active substance; SC: suspension concentrate; WG: water-dispersible granule.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
## A.3. Authorised indoor uses in the EU

| Crop and/or situation | Country | F G or I (a) | Pests or group of pests controlled | Preparation | Method kind | Range of growth stages and season (c) | Number min–max | Interval between application (min) | Application rate per treatment | PHI (days) (d) | Remarks |
|-----------------------|---------|-------------|------------------------------------|-------------|------------|-------------------------------------|----------------|-------------------------------|--------------------------------|----------------|---------|
| Lamb’s lettuces       | BE      | I           | Annual dicots and meadow grass      | SC          | 450 g/L    | Soil treatment – general             | 0 1            | –                             | g a.s./ha; L/ha; kg a.s./ha    | 0.72           | n.a.    |
|                       |         |             |                                    |             |            | (see also comment field)             |                |                               |                                |                | Treatment before sowing. Superficial incorporation |
| Roman rocket          | UK      | I           |                                    |             |            | Soil treatment – general             | 0 1            | –                             | g a.s./ha; L/ha; kg a.s./ha    | 0.38           | n.a.    |
|                       |         |             |                                    |             |            | (see also comment field)             |                |                               |                                |                | Before transplanting or drilling |
| Red mustards          | UK      | I           |                                    |             |            | Soil treatment – general             | 0 1            | –                             | g a.s./ha; L/ha; kg a.s./ha    | 0.38           | n.a.    |
|                       |         |             |                                    |             |            | (see also comment field)             |                |                               |                                |                | Before transplanting or drilling |
| Baby leaf crops       | UK      | I           |                                    |             |            | Soil treatment – general             | 0 1            | –                             | g a.s./ha; L/ha; kg a.s./ha    | 0.38           | n.a.    |
|                       |         |             |                                    |             |            | (see also comment field)             |                |                               |                                |                | Before transplanting or drilling |

NEU: northern European Union; SEU: southern European Union; MS: Member State; GAP: Good Agricultural Practice; BBCH: growth stages of mono- and dicotyledonous plants; a.s.: active substance; SC: suspension concentrate; WG: water-dispersible granule.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
Appendix B – List of end points

B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) |
|----------------------------------|-------------|---------|----------------|----------------|
| 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 |
|                                  | 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 |
|                                  | 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 |

Source: Denmark (2005)

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) |
|--------------------------------------|-------------|---------|----------------|-----------|
| Root/tuber crops                     | Carrot      | Bare soil, 4.8 kg a.s./ha | 60, 180 and 364 |
| Leafy crops                          | Lettuce     | Bare soil, 4.8 kg a.s./ha | 60, 180 and 364 |
| Cereal (small grain)                 | Spring wheat| Bare soil, 4.8 kg a.s./ha | 60, 180 and 364 |

Source: Denmark (2005)

| Processed commodities (hydrolysis study) | Conditions                                           | Investigated? |
|-------------------------------------------|------------------------------------------------------|---------------|
|                                           | Pasteurisation (20 min, 90°C, pH 4)                   | No            |
|                                           | Baking, brewing and boiling (60 min, 100°C, pH 5)     | No            |
|                                           | Sterilisation (20 min, 120°C, pH 6)                   | No            |
|                                           | Not available and not required                        |               |

Can a general residue definition be proposed for primary crops? No (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] Napropamide (sum of isomers) [tentative for fruits following foliar treatment]

Plant residue definition for risk assessment (RD-RA) Napropamide (sum of isomers) [for soil treatments only] Napropamide (sum of isomers) [tentative for fruits following foliar treatment]

Conversion factor (monitoring to risk assessment) Not applicable
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

| Method                        | LOQs                      |
|-------------------------------|---------------------------|
| GC–MS/MS (European Union Reference Laboratories for Pesticide Residues, 2018): | LOQ 0.01 mg/kg |
|                               | Fully validated in high water, high acid, high oil and dry commodities |

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; GC–MS/MS: gas chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category          | Commodity     | T (°C) | Stability (months/years) |
|------------------------------------|-------------------|---------------|--------|--------------------------|
|                                    | High water content| Cabbages      | −18    | 11 months                |
|                                    | High oil content  | Oilseed rape  | −18    | 12 months                |

Source: EFSA (2010)
Studies are missing and are required for high acid content (data gap) and dry content commodities (minor deficiency in the present review)
### B.1.2. Magnitude of residues in plants

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

| Crop | Region/indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg)<sup>(b)</sup> | STMR (mg/kg)<sup>(c)</sup> |
|------|-----------------------------|-------------------------------------------------------------------------------------------------|-----------------------------------------------|-----------------------|-------------------------|--------------------------|
| Grapefruits  Oranges  Lemons  Mandarins | SEU | 4 × < 0.01 | Combined data set of trials on apples (1), pears (1), oranges (1) and mandarins (1) compliant with GAP (Denmark, 2018). A no-residue situation is expected. Extrapolation to all pome fruits, grapefruits, oranges, lemons and mandarins is applicable | 0.01*<sup>(tentative)</sup> | < 0.01 | < 0.01 |
| Limes | SEU | 4 × < 0.01 | Combined data set of overdosed trials on apples (1), pears (1), oranges (1) and mandarins (1) is considered acceptable (Denmark, 2018). A no-residue situation is expected | 0.01*<sup>(tentative)</sup> | < 0.01 | < 0.01 |
| Almonds  Chestnuts  Hazelnuts  Pecans  Pine nut kernels  Pistachios  Walnuts | NEU | 12 × < 0.01 | Combined data set of overdosed trials on apples (4), pears (4) and plums (4) (Denmark, 2018). A no-residue situation is expected. Extrapolation to the whole group tree nuts is applicable. GAP authorised for almonds, chestnuts, hazelnuts/cobnuts, pine nut kernels and walnuts only | 0.01* | < 0.01 | < 0.01 |
| SEU | 4 × < 0.01 | Combined data set of overdosed (1.8N) trials on apples (1), pears (1), oranges (1) and mandarins (1) (Denmark, 2018). A no-residue situation is expected. Extrapolation to tree nuts is applicable. GAP authorised for chestnuts, hazelnuts/cobnuts, pecans, pistachios and walnuts only | 0.01* | < 0.01 | < 0.01 |
| Pome fruits | NEU | 8 × < 0.01 | Combined data set of trials on apples (4) and pears (4) compliant with GAP (Denmark, 2018). A no-residue situation is expected. Extrapolation to whole pome fruits group is applicable | 0.01* | < 0.01 | < 0.01 |
| SEU | 4 × < 0.01 | Combined data set of trials on apples (1), pears (1), oranges (1) and mandarins (1) (Denmark, 2018). Extrapolation to all pome fruits, grapefruits, oranges, lemons and mandarins is applicable | 0.01* | < 0.01 | < 0.01 |

<sup>(a)</sup> Region/indoor: SEU = South Europe

<sup>(b)</sup> HR: Hazard Quotient

<sup>(c)</sup> STMR: Short Term Maximum Residue Level
| Crop                                      | Region/indoor(a) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg)(b) | STMR (mg/kg)(c) |
|-------------------------------------------|------------------|------------------------------------------------------------------------------------------------|---------------------------------------------|-----------------------|---------------|----------------|
| Stone fruits                              | NEU              | 12 × 0.01                                                                                     | Extrapolation from a combined data set of overdosed trials on apples (4), pears (4) and plums (4) compliant with GAP (Denmark, 2018). A no-residue situation is expected | 0.01*                | < 0.01        | < 0.01         |
|                                            | SEU              | 4 × 0.01                                                                                     | Extrapolation from a combined data set of trials on apples (1), pears (1), oranges (1) and mandarins (1) (Denmark, 2018). A no-residue situation is expected | 0.01*                | < 0.01        | < 0.01         |
| Table grapes                              | NEU              | –                                                                                             | No data available. GAP authorised for wine grapes only | –                    | –             | –              |
|                                            | SEU              | –                                                                                             | No data available                           | –                    | –             | –              |
| Table grapes                              | NEU              | –                                                                                             | No data available. GAP authorised for wine grapes only | –                    | –             | –              |
|                                            | SEU              | –                                                                                             | No data available                           | –                    | –             | –              |
| Strawberries                              | NEU              | 2 × 0.01                                                                                     | Two overdosed trials are considered acceptable (Denmark, 2018). A no-residue situation is expected | 0.01* (tentative)(d) | < 0.01        | < 0.01         |
|                                            | SEU              | 2 × 0.01                                                                                     | Residue trials compliant with GAP (Denmark, 2018). A no-residue situation is expected | 0.01* (tentative)(d) | < 0.01        | < 0.01         |
| Raspberries (red and yellow)              | NEU              | 4 × 0.01                                                                                     | Overdosed trials on raspberries are considered acceptable (Denmark, 2018). Extrapolation to blackberries and dewberries is applicable | 0.01* (tentative)(d) | < 0.01        | < 0.01         |
| Blackberries                             | NEU              | < 0.01; 3 × 0.02                                                                               | Trials on currants compliant with GAP (Denmark, 2018). Extrapolation to blueberries, cranberries, gooseberries, rose hips and elderberries is applicable \(\text{MRL}_{\text{OECD}} = 0.02\) | 0.02 (tentative)(d,e) | < 0.02        | < 0.02         |
| Dewberries                                | NEU              | –                                                                                             | No data available                           | –                    | –             | –              |
| Blueberries                               | SEU              | –                                                                                             | No data available                           | –                    | –             | –              |
| Cranberries                              | SEU              | –                                                                                             | No data available                           | –                    | –             | –              |
| Currants (black, red and white)           | SEU              | –                                                                                             | No data available                           | –                    | –             | –              |
| Gooseberries (green, red and yellow)      | SEU              | –                                                                                             | No data available                           | –                    | –             | –              |
| Rose hips                                 | SEU              | –                                                                                             | No data available                           | –                    | –             | –              |
| Elderberries                              | SEU              | –                                                                                             | No data available                           | –                    | –             | –              |
| Figs                                      | SEU              | –                                                                                             | No data available                           | –                    | –             | –              |
| Granate apples/pomegranates               | SEU              | –                                                                                             | No data available                           | –                    | –             | –              |
| Potatoes                                  | SEU              | 4 × 0.01                                                                                     | Overdosed trials on potatoes are considered acceptable. A no-residue situation is expected (Denmark, 2018) | 0.01*                | < 0.01        | < 0.01         |
| Crop                        | Region/indoor | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg)(b) | STMR (mg/kg)(c) |
|-----------------------------|---------------|------------------------------------------------------------------------------------------|----------------------------------------------|-----------------------|---------------|-----------------|
| Celeriacs/turnip rooted celeries, horseradishes, radishes | NEU           | 4 × < 0.01                                                                              | Trials on swedes compliant with GAP (Denmark, 2018). Extrapolation to celeriacs, horseradishes and radishes is applicable. A no-residue situation is expected | 0.01*                | < 0.01        | < 0.01          |
| Swedes/rutabagas, turnips   | NEU           | 4 × < 0.01                                                                              | Only under dosed trials (0.563 kg a.s./ha instead of 0.95 kg a.s./ha, outside the 25% deviation rule) on swedes roots (Denmark, 2018) are available. However, a no-residue situation is foreseen for root crops, since a clearly more critical GAP on potatoes, which is supported by trials done with three times the application rate reported for the GAP on swedes/rutabagas, showed a no-residue situation. In addition, the metabolism study performed on potatoes with twice the application rate reported for the GAP on swedes/rutabagas indicated that no residues are expected | 0.01*                | < 0.01        | < 0.01          |
| Turnip tops                 | NEU           | –                                                                                        | No data available                           | –                     | –             | –               |
| Tomatoes                    | NEU           | –                                                                                        | No data available. GAP authorised for tomatoes only. SEU data set is sufficient to confirm that a no-residue situation is expected | –                     | –             | –               |
| Aubergines/eggplants        | SEU           | 8 × < 0.01                                                                              | Trials on tomatoes compliant with GAP (Denmark, 2018). Extrapolation to aubergines is applicable | 0.01*                | < 0.01        | < 0.01          |
| Sweet peppers/bell peppers  | NEU           | –                                                                                        | No data is available                        | –                     | –             | –               |
|                            | SEU           | –                                                                                        | No data is available                        | –                     | –             | –               |
| Watermelons                 | SEU           | –                                                                                        | No data available                          | –                     | –             | –               |

Review of the existing MRLs for napropamide
| Crop                                      | Region/indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg)<sup>(b)</sup> | STMR (mg/kg)<sup>(c)</sup> |
|-------------------------------------------|-------------------------------|---------------------------------------------------------------------------------------------|------------------------------------------------|-----------------------|--------------------------|--------------------------|
| Broccoli                                 | NEU                           | 23 × < 0.01                                                                               | Combined data set of trials on head cabbages (8), Brussels sprouts (8) and cauliflower (7) compliant with GAP (EFSA, 2010). A no-residue situation is expected. Extrapolation to flowering and head brassicas is applicable | 0.01*                 | < 0.01                   | < 0.01                   |
| Cauliflowers                              | SEU                           | 4 × < 0.01                                                                               | Combined data set of GAP-compliant trials on cauliflower (2) and head cabbages (2) (Denmark, 2018). A no-residue situation is expected. Extrapolation to flowering and head brassicas is applicable | 0.01*                 | < 0.01                   | < 0.01                   |
| Brussels sprouts                          |                               |                                              |                                                |                       |                          |                          |
| Head cabbages                             |                               |                                              |                                                |                       |                          |                          |
| Cauliflowers                              | NEU                           |                                              |                                                |                       |                          |                          |
| Chinese cabbages/pe-tsai                   | NEU                           | –                                            | No data available                              | –                     | –                        | –                        |
| Kale                                       | SEU                           | –                                            | No data available                              | –                     | –                        | –                        |
| Kohlrabies                                 |                               |                                              |                                                |                       |                          |                          |
| Lamb’s lettuces/corn salads                | NEU                           | 3 × < 0.01; 0.01                                                                         | Trials on lamb’s lettuce compliant with GAP (Denmark, 2018). Extrapolation to red mustard, roman rocket/rucola and baby leaf crops is applicable \[MRL_{OECD} = 0.02\] | 0.02                  | < 0.01                   | 0.01                     |
| Red mustards                               | SEU                           | –                                            | No data available. GAP authorised for roman rocket/rucola only | –                     | –                        | –                        |
| Baby leaf crops (including brassica species)|                               |                                              |                                                |                       |                          |                          |
| EU                                        | 4 × < 0.05                    |                                              | Overdosed trials on lamb’s lettuce are considered acceptable (Denmark, 2018). Extrapolation to red mustard, roman rocket/rucola and baby leaf crops is applicable \[MRL_{OECD} = 0.05\] | 0.05                  | < 0.05                   | < 0.05                   |
| Crop                        | Region/indoor | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg) | STMR (mg/kg) |
|-----------------------------|---------------|-----------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|------------|-------------|
| Chervil                     | NEU           | —                                                                                             | No data available. GAP authorised for sage, thyme, basil and tarragon only | —                    | —          | —           |
| Chives                      | SEU           | —                                                                                             | No data available                          | —                    | —          | —           |
| Celery leaves               |               |                                                                                               |                                             |                      |            |             |
| Parsley                     |               |                                                                                               |                                             |                      |            |             |
| Sage                        |               |                                                                                               |                                             |                      |            |             |
| Rosemary                    |               |                                                                                               |                                             |                      |            |             |
| Thyme                       |               |                                                                                               |                                             |                      |            |             |
| Basil                       |               |                                                                                               |                                             |                      |            |             |
| Laurel                      |               |                                                                                               |                                             |                      |            |             |
| Tarragon                    |               |                                                                                               |                                             |                      |            |             |
| Herbal infusions from flowers | NEU         | —                                                                                             | No data available                          | —                    | —          | —           |
| Herbal infusion from leaves and herbs | SEU | —                                                                                             | No data available                          | —                    | —          | —           |
| Herbal infusion from roots  |               |                                                                                               |                                             |                      |            |             |
| Fresh spices                | NEU           | —                                                                                             | No data available                          | —                    | —          | —           |
| SEU                         |               |                                                                                               |                                             |                      |            |             |
| Beans (with pods)           | NEU           | $6 \times < 0.02$                                                                                | Trials compliant with GAP (Denmark, 2018). A no-residue situation is expected | $0.01^*$             | < 0.01     | < 0.01
| Crop                        | Region/in indoor\(^{(a)}\) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations)                                                                 | MRL proposals (mg/kg) | HR (mg/kg)\(^{(b)}\) | STMR (mg/kg)\(^{(c)}\) |
|-----------------------------|-----------------------------|-----------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|------------------------|----------------------|------------------------|
| Linseeds Poppy seeds        | NEU                         | 7 × < 0.01; 0.01                                                                              | Trials on rapeseeds compliant with GAP (Denmark, 2005). An extrapolation to the whole group oilseeds is proposed MRL\(_{OECD} = 0.02\) | 0.02                   | 0.01                 | < 0.01                 |
| Sesame seeds Sunflower seeds Sunflower seeds Rapeseeds/canola seeds Soya beans Mustard seeds Cotton seeds Pumpkin seeds Safflower seeds Borage seeds Gold of pleasure seeds Hemp seeds Castor beans | SEU                         | 3 × < 0.01                                                                                   | Trials on rapeseeds compliant with GAP (Denmark, 2018). GAP authorised for sesame seeds, rapeseeds/canola seeds, borage seeds, hemp seeds and gold of pleasure seeds only | 0.01* (tentative)     | < 0.01               | < 0.01                 |

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

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

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe; Indoor: indoor EU trials or Country code: if non-EU trials.

(b): Highest residue.

(c): Supervised trials median residue.

(d): MRL is tentative because a storage stability study on high acid content commodities is needed.

(e): MRL is tentative because a metabolism study following foliar treatments on fruit crops is needed.

(f): MRL is tentative because residue trials are missing.
B.1.2.2. Residues in succeeding crops

| Confined rotational crop study (quantitative aspect) | Sowing/planting of succeeding crops 180 days after last application would not lead to a potential uptake of napropamide (residues are below the LOQ of 0.01 mg/kg) |
| Field rotational crop study                    | When wheat was grown as a rotational crop to oilseed rape treated with 0.95 kg a.s./ha, residues of napropamide in wheat straw and grains were below the LOQ of 0.01 mg/kg |

B.1.2.3. Processing factors

| Processed commodity | Number of studies | Processing factor (PF) |
|---------------------|-------------------|------------------------|
|                     |                   | Individual values | Median PF |
| No studies available and not required |

B.2. Residues in livestock

| Relevant groups | Dietary burden expressed in | Most critical diet\(^{(a)}\) | Most critical commodity\(^{(a)}\) | Trigger exceeded (Y/N) |
|-----------------|-----------------------------|-----------------------------|-------------------------------|------------------------|
|                 | mg/kg bw per day | mg/kg DM | Med. | Max. | Med. | Max. |                |                        |
| Cattle (all diets) | 0.0023 | 0.0023 | 0.09 | 0.09 | Cattle (dairy) | Swede, roots | No |
| Cattle (dairy only) | 0.0023 | 0.0023 | 0.06 | 0.06 | Cattle (dairy) | Swede, roots | No |
| Sheep (all diets) | 0.0024 | 0.0024 | 0.07 | 0.07 | Sheep (ram/ewe) | Swede, roots | No |
| Sheep (ewe only) | 0.0024 | 0.0024 | 0.07 | 0.07 | Sheep (ram/ewe) | Swede, roots | No |
| Swine (all diets) | 0.0015 | 0.0015 | 0.06 | 0.06 | Swine (breeding) | Swede, roots | No |
| Poultry (all diets) | 0.0012 | 0.0012 | 0.02 | 0.02 | Poultry (layer) | Swede, roots | No |
| Poultry (layer only) | 0.0012 | 0.0012 | 0.02 | 0.02 | Poultry (layer) | Swede, roots | No |

bw: body weight; DM: dry matter.

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

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

| Livestock (available studies) | Animal | Dose (mg/kg bw per day) | Duration (days) | N rate/comment |
|--------------------------------|--------|-------------------------|-----------------|----------------|
| Laying hen                    | 0.52   | 10                      | 433N (compared to poultry) |
| Lactating goat                | 0.28   | 4                       | 117N (compared to sheep all diets) |

bw: body weight.

Time needed to reach a plateau concentration in milk and eggs (days)

- Eggs: Not reported
- Milk: 2 days

Metabolism in rat and ruminant similar (Yes/No)

- Yes

Animal residue definition for monitoring (RD-Mo)

- Not required

Animal residue definition for risk assessment (RD-RA)

- Not required

Conversion factor (monitoring to risk assessment)

- Not applicable

Fat soluble residues (Yes/No)

- Not applicable

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

- Not available and not required
B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability (Months/years) |
|-------------------------------------|--------|-----------|--------|-------------------------|
|                                     | –      | Muscle    | –      | –                       |
|                                     | –      | Liver     | –      | –                       |
|                                     | –      | Kidney    | –      | –                       |
|                                     | –      | Milk      | –      | –                       |
|                                     | –      | Egg       | –      | –                       |

No studies available and not required

B.2. Magnitude of residues in livestock

B.2.2.1. Summary of the residue data from livestock feeding studies

MRLs are not necessary as the dietary burdens were found to be below the trigger value.

B.3. Consumer risk assessment

| Consumer risk assessment | 0.3 mg/kg bw per day (EFSA, 2010) |
|--------------------------|-----------------------------------|
| Highest IEDI, according to EFSA PRIMo | 0.2% ADI (FR, all population) |
| Assumptions made for the calculations |

The calculation is based on the median residue levels in the raw agricultural commodities
For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation
The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation
The calculations were done assuming that sufficient restriction measures (e.g. PBI of minimum 180 DAT) would be implemented to avoid significant residue levels in rotational crops

B.4. Proposed MRLs

| Code number | Commodity       | Existing EU MRL (mg/kg) | Outcome of the review | Comment             |
|-------------|----------------|-------------------------|-----------------------|---------------------|
|             | Enf. residue def. (existing): napropamide | napropamide (sum of isomers) |                      |                     |
| 110010      | Grapefruits    | 0.05*                   | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 110020      | Oranges        | 0.05*                   | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 110030      | Lemons         | 0.05*                   | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 110040      | Limes          | 0.05*                   | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 110050      | Mandarins      | 0.05*                   | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 120010      | Almonds        | 0.05*                   | 0.01*                 | Recommended<sup>(b)</sup> |
| 120040      | Chestnuts      | 0.05*                   | 0.01*                 | Recommended<sup>(b)</sup> |

ARfD Not necessary (EFSA, 2010)
Highest IESTI, according to EFSA PRIMo
Assumptions made for the calculations

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; MRL: maximum residue level; WHO: World Health Organization; ARfD: acute reference dose; IESTI: international estimated short-term intake.
| Code number | Commodity                              | Existing EU MRL (mg/kg) | Outcome of the review | Comment               |
|-------------|----------------------------------------|-------------------------|-----------------------|-----------------------|
| 120060      | Hazelnuts/cobnuts                       | 0.05*                   | 0.01*                 | Recommended<sup>(b)</sup> |
| 120080      | Pecans                                 | 0.05*                   | 0.01*                 | Recommended<sup>(b)</sup> |
| 120090      | Pine nut kernels                        | 0.05*                   | 0.01*                 | Recommended<sup>(b)</sup> |
| 120100      | Pistachios                              | 0.05*                   | 0.01*                 | Recommended<sup>(b)</sup> |
| 120110      | Walnuts                                 | 0.05*                   | 0.01*                 | Recommended<sup>(b)</sup> |
| 130010      | Apples                                  | 0.1                     | 0.01*                 | Recommended<sup>(b)</sup> |
| 130020      | Pears                                   | 0.1                     | 0.01*                 | Recommended<sup>(b)</sup> |
| 130030      | Quinces                                 | 0.1                     | 0.01*                 | Recommended<sup>(b)</sup> |
| 130040      | Medlars                                 | 0.1                     | 0.01*                 | Recommended<sup>(b)</sup> |
| 130050      | Loquats/Japanese medlars                | 0.1                     | 0.01*                 | Recommended<sup>(b)</sup> |
| 140010      | Apricots                                | 0.1                     | 0.01*                 | Recommended<sup>(b)</sup> |
| 140020      | Cherries (sweet)                        | 0.1                     | 0.01*                 | Recommended<sup>(b)</sup> |
| 140030      | Peaches                                 | 0.1                     | 0.01*                 | Recommended<sup>(b)</sup> |
| 140040      | Plums                                   | 0.1                     | 0.01*                 | Recommended<sup>(b)</sup> |
| 151010      | Table grapes                            | 0.1                     | 0.1                   | Further consideration needed<sup>(c)</sup> |
| 151020      | Wine grapes                             | 0.1                     | 0.1                   | Further consideration needed<sup>(c)</sup> |
| 152000      | Strawberries                            | 0.2                     | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 153010      | Blackberries                            | 0.1                     | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 153020      | Dewberries                              | 0.1                     | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 153030      | Raspberries (red and yellow)            | 0.1                     | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 154010      | Blueberries                             | 0.1                     | 0.02                  | Further consideration needed<sup>(a)</sup> |
| 154020      | Cranberries                             | 0.1                     | 0.02                  | Further consideration needed<sup>(a)</sup> |
| 154030      | Currants (black, red and white)         | 0.1                     | 0.02                  | Further consideration needed<sup>(a)</sup> |
| 154040      | Gooseberries (green, red and yellow)    | 0.1                     | 0.02                  | Further consideration needed<sup>(a)</sup> |
| 154050      | Rose hips                               | 0.1                     | 0.02                  | Further consideration needed<sup>(a)</sup> |
| 154080      | Elderberries                            | 0.1                     | 0.02                  | Further consideration needed<sup>(a)</sup> |
| 161020      | Figs                                    | 0.05*                   | 0.05                  | Further consideration needed<sup>(c)</sup> |
| 163050      | Granate apples/pomegranates             | 0.05*                   | 0.05                  | Further consideration needed<sup>(c)</sup> |
| 211000      | Potatoes                                | 0.1                     | 0.01*                 | Recommended<sup>(b)</sup> |
| 213030      | Celeriacs/turnip rooted celeres         | 0.05*                   | 0.01*                 | Recommended<sup>(b)</sup> |
| 213040      | Horseradishes                           | 0.05*                   | 0.01*                 | Recommended<sup>(b)</sup> |
| 213080      | Radishes                                | 0.05*                   | 0.01*                 | Recommended<sup>(b)</sup> |
| 213100      | Swedes/rutabagas                        | 0.05*                   | 0.01*                 | Recommended<sup>(b)</sup> |
| 213110      | Turnips                                 | 0.05*                   | 0.01*                 | Recommended<sup>(b)</sup> |
| 231010      | Tomatoes                                | 0.1                     | 0.01*                 | Recommended<sup>(b)</sup> |
| 231020      | Sweet peppers/bell peppers             | 0.1                     | 0.1                   | Further consideration needed<sup>(c)</sup> |
| 231030      | Aubergines/eggplants                    | 0.1                     | 0.01*                 | Recommended<sup>(b)</sup> |
| 233030      | Watermelons                             | 0.05*                   | 0.05                  | Further consideration needed<sup>(c)</sup> |
| 241010      | Broccoli                                | 0.05*                   | 0.01*                 | Recommended<sup>(b)</sup> |
| 241020      | Cauliflowers                            | 0.1                     | 0.01*                 | Recommended<sup>(b)</sup> |
| 242010      | Brussels sprouts                        | 0.1                     | 0.01*                 | Recommended<sup>(b)</sup> |
| 242020      | Head cabbages                           | 0.1                     | 0.01*                 | Recommended<sup>(b)</sup> |
| 243010      | Chinese cabbages/pe-tsai                | 0.05*                   | 0.05                  | Further consideration needed<sup>(c)</sup> |
| 243020      | Kales                                   | 0.05*                   | 0.05                  | Further consideration needed<sup>(c)</sup> |
| Code number | Commodity | Existing EU MRL (mg/kg) | Outcome of the review | Comment |
|-------------|-----------|------------------------|-----------------------|---------|
| 244000      | Kohlrabies | 0.05*                  | MRL (mg/kg)          | 0.05    |
| 251010      | Lamb’s lettuces/corn salads | 0.2                   | Recommended          | (b)     |
| 251060      | Roman rocket/rucola | 0.2                   | Recommended          | (b)     |
| 251070      | Red mustards | 0.05*                  | Recommended          | (b)     |
| 251080      | Baby leaf crops (including brassica species) | 0.05*                 | Recommended          | (b)     |
| 256010      | Chervil    | 0.05*                  | Further consideration needed | (c) |
| 256020      | Chives     | 0.05*                  | Further consideration needed | (c) |
| 256030      | Celery leaves | 0.05*                 | Further consideration needed | (c) |
| 256040      | Parsley    | 0.05*                  | Further consideration needed | (c) |
| 256050      | Sage       | 0.05*                  | Further consideration needed | (c) |
| 256060      | Rosemary   | 0.05*                  | Further consideration needed | (c) |
| 256070      | Thyme      | 0.05*                  | Further consideration needed | (c) |
| 256080      | Basil and edible flowers | 0.05*                | Further consideration needed | (c) |
| 256090      | Laurel/bay leaf | 0.05*               | Further consideration needed | (c) |
| 256100      | Tarragon   | 0.05*                  | Further consideration needed | (c) |
| 260010      | Beans (with pods) | 0.05*               | 0.01* Recommended | (b) |
| 401010      | Linseeds   | 0.05*                  | Recommended          | (b)     |
| 401030      | Poppy seeds | 0.05*                 | Recommended          | (b)     |
| 401040      | Sesame seeds | 0.05*                | Recommended          | (b)     |
| 401050      | Sunflower seeds | 0.05*            | Recommended          | (b)     |
| 401060      | Rapeseeds/canola seeds | 0.1                  | 0.02 Recommended    | (b)     |
| 401070      | Soya beans | 0.05*                  | Recommended          | (b)     |
| 401080      | Mustard seeds | 0.05*               | 0.02 Recommended    | (b)     |
| 401090      | Cotton seeds | 0.05*                | Recommended          | (b)     |
| 401100      | Pumpkin seeds | 0.05*               | Recommended          | (b)     |
| 401110      | Safflower seeds | 0.05*             | Recommended          | (b)     |
| 401120      | Borage seeds | 0.05*                | Recommended          | (b)     |
| 401130      | Gold of pleasure seeds | 0.05*          | 0.02 Recommended    | (b)     |
| 401140      | Hemp seeds | 0.05*                  | Recommended          | (b)     |
| 401150      | Castor beans | 0.05*               | 0.02 Recommended    | (b)     |
| 631000      | Herbal infusions from flowers | 0.05*       | 0.05 Further consideration needed | (c) |
| 632000      | Herbal infusions from leaves and herbs | 0.05*      | 0.05 Further consideration needed | (c) |
| 633000      | Herbal infusions from roots | 0.05*       | 0.05 Further consideration needed | (c) |
| 820000      | Fruit spices | 0.05*               | 0.05 Further consideration needed | (c) |
|            | Other commodities of plant/animal origin | See Reg. 149/2008 | – | Further consideration needed | (d) |

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(a): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination E-I in Appendix E).
(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix E).
(c): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination C-I in Appendix E).
(d): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).
Appendix C – Pesticide Residue Intake Model (PRIMo)

• PRIMo(EU)

### Napropamide

| Toxicological end points | ADI (range (mg/kg bw)) | ARfD (mg/kg bw) | Source of ADI | Source of ARfD | Year of evaluation | Year of evaluation |
|-------------------------|------------------------|----------------|--------------|----------------|-------------------|-------------------|
|                         | 0.3                    | n.n.           | EFSA         | EFSA           | 2010              | 2010              |

| Source of ADI | Source of ARfD | Year of evaluation |
|---------------|----------------|--------------------|
| EFSA          | EFSA           | 2010               |

| No. of diets exceeding ADI |
|----------------------------|
|                            |

| Commodity/group of commodities     |
|------------------------------------|
| Potatoes                          |
| Peppers                           |
| Watermelons                       |
| Table grapes                      |
| Apples                            |
| Oranges                           |

| Estimated TMDI values in % of ADI |
|-----------------------------------|
| minimum - maximum                 |
|                                  |

| Commodity/group of commodities     |
|------------------------------------|
| Potatoes                          |
| Peppers                           |
| Watermelons                       |
| Table grapes                      |
| Apples                            |
| Oranges                           |

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

### Table grapes

| Commodity/group of commodities     |
|------------------------------------|
| Potatoes                          |
| Peppers                           |
| Watermelons                       |
| Table grapes                      |
| Apples                            |
| Oranges                           |

### Peppers

| Commodity/group of commodities     |
|------------------------------------|
| Potatoes                          |
| Peppers                           |
| Watermelons                       |
| Table grapes                      |
| Apples                            |
| Oranges                           |

### Apples

| Commodity/group of commodities     |
|------------------------------------|
| Potatoes                          |
| Peppers                           |
| Watermelons                       |
| Table grapes                      |
| Apples                            |
| Oranges                           |

### Potatoes

| Commodity/group of commodities     |
|------------------------------------|
| Potatoes                          |
| Peppers                           |
| Watermelons                       |
| Table grapes                      |
| Apples                            |
| Oranges                           |

### Oranges

| Commodity/group of commodities     |
|------------------------------------|
| Potatoes                          |
| Peppers                           |
| Watermelons                       |
| Table grapes                      |
| Apples                            |
| Oranges                           |

### Watermelons

| Commodity/group of commodities     |
|------------------------------------|
| Potatoes                          |
| Peppers                           |
| Watermelons                       |
| Table grapes                      |
| Apples                            |
| Oranges                           |

### Table grapes

| Commodity/group of commodities     |
|------------------------------------|
| Potatoes                          |
| Peppers                           |
| Watermelons                       |
| Table grapes                      |
| Apples                            |
| Oranges                           |

### Wine grapes

| Commodity/group of commodities     |
|------------------------------------|
| Potatoes                          |
| Peppers                           |
| Watermelons                       |
| Table grapes                      |
| Apples                            |
| Oranges                           |

### Tomatoes

| Commodity/group of commodities     |
|------------------------------------|
| Potatoes                          |
| Peppers                           |
| Watermelons                       |
| Table grapes                      |
| Apples                            |
| Oranges                           |

### Wine grapes

| Commodity/group of commodities     |
|------------------------------------|
| Potatoes                          |
| Peppers                           |
| Watermelons                       |
| Table grapes                      |
| Apples                            |
| Oranges                           |

### Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs, were below the ADI. A long-term intake of residues of napropamide is unlikely to present a public health concern.
### Acute risk assessment/children – refined calculations

| No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): | No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): |
|---|---|---|---|
| --- | --- | --- | --- |

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

| No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): | No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): |
|---|---|---|---|
| --- | --- | --- | --- |

---

*The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.*

**pTMRL: provisional temporary MRL.

***) pTMRL: provisional temporary MRL for unprocessed commodity.

---

**Conclusion:**

As no ARfD was considered necessary, it is concluded that the short-term intake of napropamide residues is unlikely to present a public health concern.

---

**Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.**

---

**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

---

**Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.**

---

**No of critical MRLs (IESTI 1):**

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

---

**No of commodities for which ARfD/ADI is exceeded:**

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

---

**No of critical MRLs (IESTI 2):**

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.
Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

| Feed commodity                  | Median dietary burden | Maximum dietary burden |
|---------------------------------|-----------------------|------------------------|
|                                 | Input value (mg/kg)   | Comment                | Input value (mg/kg) | Comment                |
| **Risk assessment residue definition – napropamide (sum of isomers)** |                       |                        |                       |                        |
| Grapefruits, dried pulp        | 0.01*                 | STMR (default PF not applied) | 0.01                 | STMR (default PF not applied) |
| Oranges, dried pulp            | 0.01*                 | STMR (default PF not applied) | 0.01                 | STMR (default PF not applied) |
| Lemons, dried pulp             | 0.01*                 | STMR (default PF not applied) | 0.01                 | STMR (default PF not applied) |
| Limes, dried pulp              | 0.01*                 | STMR (default PF not applied) | 0.01                 | STMR (default PF not applied) |
| Mandarins, dried pulp          | 0.01*                 | STMR (default PF not applied) | 0.01                 | STMR (default PF not applied) |
| Apple, pomace, wet             | 0.01*                 | STMR (default PF not applied) | 0.01                 | STMR (default PF not applied) |
| Potato, culls                  | 0.01*                 | STMR                   | 0.01                 | HR                     |
| Potato, process waste          | 0.01*                 | STMR (default PF not applied) | 0.01                 | STMR (default PF not applied) |
| Potato, dried pulp             | 0.01*                 | STMR (default PF not applied) | 0.01                 | STMR (default PF not applied) |
| Swede, roots                   | 0.01*                 | STMR                   | 0.01                 | HR                     |
| Turnip, roots                  | 0.01*                 | STMR                   | 0.01                 | HR                     |
| Cabbage, heads, leaves         | 0.01*                 | STMR                   | 0.01                 | HR                     |
| Flaxseed/Linseed, meal         | 0.01*                 | STMR (default PF not applied) | 0.01                 | STMR (default PF not applied) |
| Sunflower, meal                | 0.01*                 | STMR (default PF not applied) | 0.01                 | STMR (default PF not applied) |
| Canola (Rape seed), meal       | 0.01*                 | STMR (default PF not applied) | 0.01                 | STMR (default PF not applied) |
| Rape, meal                     | 0.01*                 | STMR (default PF not applied) | 0.01                 | STMR (default PF not applied) |
| Soybean, seed                  | 0.01*                 | STMR                   | 0.01                 | STMR                   |
| Soybean, meal                  | 0.01*                 | STMR (default PF not applied) | 0.01                 | STMR (default PF not applied) |
| Soybean, hulls                 | 0.01*                 | STMR (default PF not applied) | 0.01                 | STMR (default PF not applied) |
| Cotton, undelinted seed        | 0.01*                 | STMR                   | 0.01                 | STMR                   |
| Cotton, meal                   | 0.01*                 | STMR (default PF not applied) | 0.01                 | STMR (default PF not applied) |
| Safflower, meal                | 0.01*                 | STMR (default PF not applied) | 0.01                 | STMR (default PF not applied) |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
*#: Indicates that the input value is proposed at the limit of quantification.
(a): For fruit pomace, potatoes waste/pulp and oilseed meals no default processing factor was applied because napropamide is applied early in the growing season and residues are expected to be below or equal to the LOQ. Concentration of residues in these commodities is therefore not expected.
## D.2. Consumer risk assessment

| Commodity                  | Chronic risk assessment | Input value (mg/kg) | Comment         |
|----------------------------|-------------------------|---------------------|-----------------|
| **Risk assessment residue definition** – napropamide (sum of isomers) | | | |
| Grapefruits                |                         | 0.01*               | STMR (tentative) |
| Oranges                    |                         | 0.01*               | STMR (tentative) |
| Lemons                     |                         | 0.01*               | STMR (tentative) |
| Limes                      |                         | 0.01*               | STMR (tentative) |
| Mandarins                  |                         | 0.01*               | STMR (tentative) |
| Almonds                    |                         | 0.01*               | STMR             |
| Chestnuts                  |                         | 0.01*               | STMR             |
| Hazelnuts/cobnuts          |                         | 0.01*               | STMR             |
| Pecans                     |                         | 0.01*               | STMR             |
| Pine nut kernels           |                         | 0.01*               | STMR             |
| Pistachios                 |                         | 0.01*               | STMR             |
| Walnuts                    |                         | 0.01*               | STMR             |
| Apples                     |                         | 0.01*               | STMR             |
| Pears                      |                         | 0.01*               | STMR             |
| Quinces                    |                         | 0.01*               | STMR             |
| Medlars                    |                         | 0.01*               | STMR             |
| Loquats/Japanese medlars   |                         | 0.01*               | STMR             |
| Apricots                   |                         | 0.01*               | STMR             |
| Cherries (sweet)           |                         | 0.01*               | STMR             |
| Peaches                    |                         | 0.01*               | STMR             |
| Plums                      |                         | 0.01*               | STMR             |
| Table grapes               |                         | 0.1                 | EU MRL          |
| Wine grapes                |                         | 0.1                 | EU MRL          |
| Strawberries               |                         | 0.01*               | STMR (tentative) |
| Blackberries               |                         | 0.01*               | STMR (tentative) |
| Dewberries                 |                         | 0.01*               | STMR (tentative) |
| Raspberries (red and yellow)|                         | 0.01*               | STMR (tentative) |
| Blueberries                |                         | 0.02                | STMR (tentative) |
| Commodity                                      | Input value (mg/kg) | Comment       |
|-----------------------------------------------|--------------------|---------------|
| Cranberries                                  | 0.02               | STMR (tentative) |
| Currants (black, red and white)              | 0.02               | STMR (tentative) |
| Gooseberries (green, red and yellow)         | 0.02               | STMR (tentative) |
| Rose hips                                    | 0.02               | STMR (tentative) |
| Elderberries                                 | 0.02               | STMR (tentative) |
| Figs                                          | 0.05               | EU MRL        |
| Granate apples/pomegranates                  | 0.05               | EU MRL        |
| Potatoes                                      | 0.01*              | STMR          |
| Celeriacs/turnip rooted celeries             | 0.01*              | STMR          |
| Horseradishes                                | 0.01*              | STMR          |
| Radishes                                     | 0.01*              | STMR          |
| Swedes/rutabagas                             | 0.01*              | STMR          |
| Turnips                                      | 0.01*              | STMR          |
| Tomatoes                                     | 0.01*              | STMR          |
| Sweet peppers/bell peppers                   | 0.1                | EU MRL        |
| Aubergines/eggplants                         | 0.01*              | STMR          |
| Watermelons                                  | 0.05               | EU MRL        |
| Broccoli                                     | 0.01*              | STMR          |
| Cauliflowers                                 | 0.01*              | STMR          |
| Brussels sprouts                             | 0.01*              | STMR          |
| Head cabbages                                | 0.01*              | STMR          |
| Chinese cabbages/pe-tsai                     | 0.05               | EU MRL        |
| Kales                                        | 0.05               | EU MRL        |
| Kohlrabies                                    | 0.05               | EU MRL        |
| Lamb’s lettuces/corn salads                  | 0.05               | STMR          |
| Roman rocket/rucola                          | 0.05               | STMR          |
| Red mustards                                 | 0.05               | STMR          |
| Baby leaf crops (including brassica species) | 0.05               | STMR          |
| Chervil                                      | 0.05               | EU MRL        |
| Chives                                       | 0.05               | EU MRL        |
| Celery leaves                                | 0.05               | EU MRL        |
### Commodity
### Chronic risk assessment

| Commodity                  | Input value (mg/kg) | Comment          |
|----------------------------|--------------------|------------------|
| Parsley                    | 0.05               | EU MRL          |
| Sage                       | 0.05               | EU MRL          |
| Rosemary                   | 0.05               | EU MRL          |
| Thyme                      | 0.05               | EU MRL          |
| Basil and edible flowers   | 0.05               | EU MRL          |
| Laurel/bay leave           | 0.05               | EU MRL          |
| Tarragon                   | 0.05               | EU MRL          |
| Beans (with pods)          | 0.01*              | STMR            |
| Linseeds                   | 0.01*              | STMR            |
| Poppy seeds                | 0.01*              | STMR            |
| Sesame seeds               | 0.01*              | STMR            |
| Sunflower seeds            | 0.01*              | STMR            |
| Rapeseeds/canola seeds     | 0.01*              | STMR            |
| Soya beans                 | 0.01*              | STMR            |
| Mustard seeds              | 0.01*              | STMR            |
| Cotton seeds               | 0.01*              | STMR            |
| Pumpkin seeds              | 0.01*              | STMR            |
| Safflower seeds            | 0.01*              | STMR            |
| Borage seeds               | 0.01*              | STMR            |
| Gold of pleasure seeds     | 0.01*              | STMR            |
| Hemp seeds                 | 0.01*              | STMR            |
| Castor beans               | 0.01*              | STMR            |
| Herbal infusions from flowers | 0.05         | EU MRL          |
| Herbal infusions from leaves and herbs | 0.05 | EU MRL       |
| Herbal infusions from roots | 0.05               | EU MRL          |
| Fruit spices               | 0.05               | EU MRL          |

STMR: supervised trials median residue; MRL: maximum residue level.

*: Indicates that the input value is proposed at the limit of quantification.
Appendix E – Decision tree for deriving MRL recommendations

Evaluation of the GAPs and available residues data at EU level

- GAP or DM >0.1 mg/kg QM in EU?
  - No
  - Yes
    - MRL derived in section 3?
      - No
      - Yes
        - MRL fully supported by data?
          - No
          - Yes
  
Consumer risk assessment for GAPs evaluated at EU level - EU scenarios

- Not considered for the RA
  - Yes
  - No
- Current EU MRL is included in the RA?
  - Yes
  - No
- Tentative median/highest values are included in the RA?
  - Yes
  - No
- Median/highest values are included in the RA?
  - Yes
  - No
- Risk identified?
  - Yes
  - No
- Fall-back MRL available?
  - Yes
  - No

Recommendations resulting from EU authorisations and import tolerances

(A) Specific LOQ or default MRL?
(B) Specific LOQ or default MRL?
(C) Maintain current EU MRL?
(D) Establish tentative EU MRL?
(E) Specific LOQ or default MRL?
(F) MRL is recommended?

Comparison with CXLs
Review of the existing MRLs for napropamide

Comparison of the EU recommendation with the existing CXL

- CXL available?
  - Yes
    - RD comparable?
      - Yes
        - CXL higher?
          - Yes
            - Maintain EU recommendation; higher CXL is not safe for consumer.
          - No
            - CXL supported by data?
              - Yes
                - CXL is included in the RA.
              - No
                - Risk identified?
                  - Yes
                    - CXL is recommended; EU recommendation is covered as well.
                  - No
                    - (VII) CXL is recommended; EU recommendation is covered as well.
        - No
          - CXL is included in the RA.
          - Risk identified?
            - Yes
              - CXL is recommended; EU recommendation is covered as well.
            - No
              - Input values for the RA remain unchanged.
  - No
    - CXL supported by data?
      - Yes
        - CXL is included in the RA.
        - Risk identified?
          - Yes
            - CXL is recommended; EU recommendation is covered as well.
          - No
            - Input values for the RA remain unchanged.
      - No
        - Risk identified?
          - Yes
            - CXL is recommended; EU recommendation is covered as well.
          - No
            - Input values for the RA remain unchanged.

Consumer risk assessment with consideration of the existing CXL

- CXL supported by data?
  - Yes
    - CXL is included in the RA.
    - Risk identified?
      - Yes
        - CXL is recommended; EU recommendation is covered as well.
      - No
        - Input values for the RA remain unchanged.
  - No
    - Risk identified?
      - Yes
        - CXL is recommended; EU recommendation is covered as well.
      - No
        - Input values for the RA remain unchanged.

Recommendations with consideration of the existing CXL

1. Maintain EU recommendation indicating that no CXL is available.
2. Maintain EU recommendation indicating CXL is not compatible.
3. Maintain EU recommendation indicating CXL is not safe for consumer.
4. Maintain current CXL or EU recommendation?
5. Maintain EU recommendation; higher CXL is not safe for consumer.
6. Maintain EU recommendation; higher CXL is not safe for consumer.
7. CXL is recommended; EU recommendation is covered as well.
### Appendix F – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-------------------------------|-----------------------------------------------|---------------------------------|
| napropamide                   | (RS)-N,N-diethyl-2-(1-naphthyloxy)propionamide CCN(CC)C(=O)C (C)Oc1cccc2cccccc21 WXZVAROIGSCFJ-UHFFFAOYSA-N | ![napropamide Structural Formula](image) |
| Napropamide-M                 | (R)-N,N-diethyl-2-(1-naphthyloxy)propionamide CCN(CC)C(=O)[C@@H](C)Oc1cccc2cccccc21 WXZVAROIGSCFJ-CY8MUJFWSA-N | ![Napropamide-M Structural Formula](image) |

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 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).

(c): ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).