Review of the existing maximum residue levels for 1,4-dimethylnaphthalene 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 1,4-dimethylnaphthalene. To assess the occurrence of 1,4-dimethylnaphthalene residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Commission Regulation (EU) No 188/2011, as well as the European authorisations reported by Member States and the UK (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 all MRL proposals derived by EFSA still require further consideration by risk managers.

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Keywords: 1,4-dimethylnaphthalene, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, plant growth regulator

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Summary

1,4-dimethylnaphthalene was approved on 1 July 2014 by means of Commission Implementing Regulation (EU) No 192/2014 in the framework of Regulation (EC) No 1107/2009 as amended by Commission Implementing Regulations (EU) No 540/2011 and 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 20 March 2020, EFSA initiated the collection of data for this active substance. In a first step, Member States and the UK were invited to submit by 20 April 2020 their national Good Agricultural Practices (GAPs) in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State, the Netherlands, to identify the critical GAPs in the format of a specific GAP overview file. Subsequently, Member States and the UK were requested to provide residue data supporting the critical GAPs, within a period of 1 month, by 25 June 2020.

On the basis of all the data submitted by Member States and the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked the RMS to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report, together with Pesticide Residues Intake Model (PRIMO) calculations and an updated GAP overview file were provided by the RMS to EFSA on 23 October 2020. 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 information provided by the RMS, Member States and the EURLs, and taking into account the conclusions derived by EFSA in the framework of Commission Regulation (EU) No 188/2011, EFSA prepared in March 2021 a draft reasoned opinion, which was circulated to Member States and EURLs for consultation via a written procedure. Comments received by 24 March 2021 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of 1,4-dimethylnaphthalene in plant was investigated in primary crops belonging to root crops group. According to the results of the metabolism studies, the residue definitions in root crops can be proposed as 1,4-dimethylnaphthalene for enforcement, and as the 'sum of 1,4-dimethylnaphthalene, M21 and its conjugates, expressed as 1,4-dimethylnaphthalene' for risk assessment. These residue definitions are also tentatively applicable to processed commodities pending the submission of additional studies confirming the nature of the residues observed in processed commodities. A specific residue definition for rotational crops is not deemed necessary considering that this active substance is only authorised for indoor post-harvest treatment of stored potatoes. Fully validated analytical methods are available for the enforcement of the proposed residue definition in high water commodity crops at the limit of quantification (LOQ) of 1 mg/kg. According to the EURLs, a default LOQ of 0.01 mg/kg is achievable in all matrix groups by using multiresidue QuEChERS in routine analyses.

Available residue trials data were considered sufficient to derive tentative MRL proposal as well as risk assessment values for the commodity under evaluation, considering the data gaps identified in the processing studies and for additional residue trials on potato. For the crops other than potato and having regard to the possible background levels of 1,4-dimethylnaphthalene, in a previous EFSA assessment a default value of 0.1 mg/kg was considered appropriate to cover the natural background levels in plants, although based on limited data. Results from the last three annual monitoring programmes suggest that for most of the crops for which monitoring data are available, the default MRL of 0.01 mg/kg would still be appropriate.

1,4-dimethylnaphthalene is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance and considering the possible natural background levels of this active substance present in feed items. The dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg dry matter. Behaviour of residues was therefore assessed in all commodities of animal origin.

The metabolism of 1,4-dimethylnaphthalene residues in livestock was investigated in lactating goats and laying hens at dose rates not covering the maximum dietary burdens calculated in this review; however, the metabolism was considered to be sufficiently elucidated, also in view of the results of the feeding studies. Accordingly, the residue definition for enforcement and risk assessment in livestock commodities was proposed as the 'sum of 1,4-dimethylnaphthalene and its metabolite M23 free and.
conjugated, expressed as 1,4-dimethylnaphthalene. An analytical method for the enforcement of the proposed residue definition is not available in any animal matrices. Nevertheless, according to the EURLs, a default LOQ of 0.01 mg/kg is achievable for 1,4-dimethylnaphthalene and free M23 in livestock matrices (combined LOQ 0.02 mg/kg) by using the QuEChERS method in routine analyses. It is assumed that the LOQ of 0.01 mg/kg is also achievable for the sum of free and conjugated M23 in animal products.

Livestock feeding studies on lactating cows and laying hens were used to derive MRL and risk assessment values in milk, eggs and tissues of ruminants and poultry. Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs. Considering the general data gap on the analytical method, all MRLs are tentative.

Chronic consumer exposure resulting from the authorised use reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMo. Under a worst-case scenario considering also the possible natural background levels of 1,4-dimethylnaphthalene in plants in the calculation, the highest chronic exposure represented 65% of the acceptable daily intake (ADI) (Dutch toddler). Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance.
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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 1,4-dimethylnaphthalene was approved on 1 July 2014 by means of Commission Implementing Regulation (EU) No 192/2014\(^3\) in the framework of Regulation (EC) No 1107/2009\(^4\) as amended by Commission Implementing Regulations (EU) No 540/2011\(^5\) and 541/2011\(^6\), EFSA initiated the review of all existing MRLs for that active substance.

By way of background information, in the framework of Directive 91/414/EEC 1,4-dimethylnaphthalene was evaluated by the Netherlands, designated as rapporteur Member State (RMS). Subsequently, a peer review on the initial evaluation of the RMS was conducted by EFSA, leading to the conclusions as set out in the EFSA scientific output (EFSA, 2013). Furthermore, according to the provisions of the approval regulation, confirmatory information was requested, among others, as regards the residue definition for the active substance, to be submitted by 30 June 2016. The confirmatory data submitted were assessed in a technical report (EFSA, 2017).

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC repealed by Regulation (EC) No 1107/2009. It should be noted, however, that, in the framework of Regulation (EC) No 1107/2009, 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 Regulation (EC) No 1107/2009 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 20 March 2020, EFSA initiated the collection of data for this active substance. In a first step, Member States and the UK\(^7\) were invited to submit by 20 April 2020 their Good Agricultural Practices (GAPs) that are authorised nationally, in a standardised way, in the format of specific GAP forms. In the framework of this consultation, 12 Member States and the UK provided feedback on their national authorisations of 1,4-dimethylnaphthalene. Based on the GAP data collected until 31 December 2020.

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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 Implementing Regulation (EU) No 192/2014 of 27 February 2014 approving the active substance 1,4-dimethylnaphthalene, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011. OJ L 59, 28.2.2014, p. 20–24.

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.

7. The United Kingdom withdrew from EU on 1 February 2020. In accordance with the agreement on the withdrawal of the UK from the EU, and with the established transition period, the EU requirements on data reporting also apply to the UK data collected until 31 December 2020.
submitted, the designated RMS, the Netherlands, was asked to identify the critical GAPs to be further considered in the assessment, in the format of a specific GAP overview file. Subsequently, in a second step, Member States and the UK were requested to provide residue data supporting the critical GAPs by 25 June 2020.

On the basis of all the data submitted by Member States and the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked the Netherlands to complete the PROFile and to prepare a supporting evaluation report. The PROFile and the supporting evaluation report, together with the Pesticide Residues Intake Model (PRIMo) calculations and an updated GAP overview file, were submitted to EFSA on 23 October 2020. 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.

Considering all the available information, EFSA prepared in March 2021 a draft reasoned opinion, which was circulated to Member States and the EURLs for commenting via a written procedure. All comments received by 24 March 2021 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Netherlands, 2020), taking into account also the information provided by Member States and the UK during the collection of data, and the EURLs report on analytical methods (EURLs, 2020) are considered as main supporting documents to this reasoned opinion and, thus, made publicly available.

In addition, further supporting documents to this reasoned opinion are the completeness check report (EFSA, 2021a) and the Member States consultation report (EFSA, 2021c). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Furthermore, the 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. 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

There is no ISO common name for the active substance 1,4-dimethylnaphthalene. 1,4-dimethylnaphthalene is a naturally occurring component, endogenous to many plants, of which potatoes, and used in plant protection products as sprout inhibitor. The chemical structure of this active substance and its main metabolites are reported in Appendix F.

The EU MRLs for 1,4-dimethylnaphthalene are established in Annexes IIIA of Regulation (EC) No 396/2005. Codex maximum residue limits (CXLs) for 1,4-dimethylnaphthalene are not available. An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below (Table 1).

**Table 1: Overview of the MRL changes since the entry into force of Regulation (EC) No 396/2005**

| Procedure application | Legal implementation | Remarks |
|-----------------------|----------------------|---------|
| MRL application       | Commission Regulation (EU) 2015/399(a) | Potatoes (EFSA, 2014) |

(a): Commission Regulation (EU) 2015/399 of 25 February 2015 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1,4-dimethylnaphthalene, benfuracarb, carbofuran, carbosulfan, ethenphon, fenamidone, fenvalerate, fenhexamid, furathiocarb, imazapyr, malathion, picoxystrobin, spirotetramat, tepraloxydim and trifloxystrobin in or on certain products. OJ L 71, 14.3.2015, p. 1–55.

For the purpose of this MRL review, all the uses of 1,4-dimethylnaphthalene currently authorised within the EU as submitted by the Member States and the UK during the GAP collection, have been
reported by the RMS in the GAP overview file. The critical GAP identified in the GAP overview file was then summarised in the PROFile and considered in the assessment. The details of the authorised critical GAP for 1,4-dimethylnaphthalene 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 following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (Netherlands, 2020);
- the draft assessment report (DAR) and its addendum prepared under Council Directive 91/414/EEC (Netherlands, 2012, 2013);
- the conclusion on the peer review of the pesticide risk assessment of the active substance 1,4-dimethylnaphthalene (EFSA, 2013);
- the previous reasoned opinion on 1,4-dimethylnaphthalene (EFSA, 2014);
- the addendum to the draft assessment report on 1,4-dimethylnaphthalene in light of confirmatory data (Netherlands, 2017);
- the technical report on the outcome of the consultation on the pesticide risk assessment for 1,4-dimethylnaphthalene in light of confirmatory data (EFSA, 2017).

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, 2008, 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 1,4-dimethylnaphthalene was first investigated and assessed in the framework of the peer review (EFSA, 2013; Netherlands, 2013). However, with one single application, the experimental design of this study was not representative of the GAP and was not considered sufficient to elucidate the metabolic pathway of 1,4-dimethylnaphthalene. A metabolism study representative of the use pattern (covering at least 6 months of storage period) was therefore required as specific provision for the approval.3

An additional study representative of the GAP was submitted as confirmatory data and assessed in accordance with the specific provision of the approval (EFSA, 2017; Netherlands, 2017). In this study, radiolabelled 1,4-dimethylnaphthalene was applied to potatoes in six post-harvest treatments (one-month interval) at 20 g a.s./ton. After one or six applications (30 DAT1 and 30 DAT6, respectively), the major component identified in the whole tuber was parent 1,4-dimethylnaphthalene, representing 79–93% total radioactive residue (TRR) (2.66–19.66 mg eq/kg). Parent compound was also predominant in peeled potato and potato peel (57–94% TRR; 0.22–137 mg eq/kg). In peeled potato, metabolite M21 was accounting for up to 20% TRR (1.31 mg eq/kg) 30 DAT, while M23 was not detected or only in low proportions (< 3% TRR). Minor more polar compounds were detected after six applications (7–10% TRR; 0.48–0.65 mg eq/kg) and were further identified as 1,4-dimethylnaphtol and glycoside conjugates of metabolite M21.

It can be concluded that the metabolism of 1,4-dimethylnaphthalene in roots is sufficiently elucidated.

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8 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
1.1.2. Nature of residues in rotational crops

1,4-dimethylnaphthalene is only authorised for indoor post-harvest treatment of stored potatoes (excluding seed potatoes). Therefore, studies investigating the nature of 1,4-dimethylnaphthalene on rotational crops were not reported and are not required.

1.1.3. Nature of residues in processed commodities

Studies investigating the nature of 1,4-dimethylnaphthalene residues under standard hydrolysis conditions simulating pasteurisation, baking/boiling and sterilisation were not provided. Although the physical and chemical properties suggest that 1,4-dimethylnaphthalene, M21 and M23 are probably not vulnerable to hydrolysis, this was identified as a data gap during the peer review (EFSA, 2013) and such studies would be still required, considering the significant residue levels expected in potato tubers.

Additional processing studies conducted on potatoes were provided under this review (Netherlands, 2020), simulating typical household methods (boiling, baking and frying). Even though these studies were not performed as standard hydrolysis studies according to the applicable guidance, since the use on potatoes is the only authorised one, they could be considered acceptable under this review. The studies were conducted with radiolabelled 1,4-dimethylnaphthalene. In unprocessed potato, the main compounds identified are parent 1,4-dimethylnaphthalene (61% TRR) and M21 (17% TRR). In all samples of processed potatoes, 1,4-dimethylnaphthalene was also the major compound identified (47–58% TRR; 5.5–7.7 mg eq/kg), while M21 and M23 were identified at 0.5–7.2% TRR and < 0.6–5.6% TRR, respectively. Analyses showed the formation of several minor degradation products. Some of these metabolites, present at up to 15% TRR (2.42 mg eq/kg), were tentatively identified as glycoside conjugates of M21 and 1,4-dimethylnaphthol (metabolites which were already identified in the metabolism study on primary crops, see Section 1.1.1). In processed products, there is no evidence of new degradation products not already present in unprocessed potatoes.

It is concluded that even though processing is not expected to impact the metabolism of 1,4-dimethylnaphthalene, the new studies provided under this review are not fully addressing the nature of 1,4-dimethylnaphthalene residues since an unambiguous identification of some metabolites measured at significant levels is still required and the data gap identified during the peer review is still open.

1.1.4. Methods of analysis in plants

During the peer review, a QuEChERS multiresidue method based on gas chromatography coupled to mass spectrometry detection (GC-MSD) was validated for parent 1,4-dimethylnaphthalene in high water content commodities, with a limit of quantification (LOQ) of 0.01 mg/kg. This primary method is supported by an independent laboratory validation (ILV), with an LOQ of 0.03 mg/kg. The confirmation method using high-performance liquid chromatography with fluorescence detection (HPLC-FLD) was validated at the LOQ of 1 mg/kg. It was concluded that this analytical method was sufficiently validated for enforcing 1,4-dimethylnaphthalene residues in potato at the LOQ of 1 mg/kg. However, a data gap for additional extraction efficiency data was identified (EFSA, 2013).

Under the current review, the RMS considers that the data gap set on the extraction efficiency during the peer review was addressed by making cross reference to the metabolism study on potatoes after repeated exposure submitted as part of the confirmatory data (EFSA, 2017). It was concluded that acetonitrile:water (1:1) is the right solvent which efficiently extracts residues of 1,4-dimethylnaphthalene, M21 and M23 in plant matrices with high water content (Netherlands, 2020). EFSA is therefore of the opinion that additional extraction efficiency data are not required under this review.

During the completeness check, the EURLs provided a QuEChERS multi-residue analytical method using GC-MS/MS and GC-HRMS techniques, with a default LOQ of 0.01 mg/kg for the routine analysis of 1,4-dimethylnaphthalene in high water content, high acid content, dry and high oil content commodities. In high water content and high acid content commodities, lower levels (down to 0.005 mg/kg) were successfully validated, and for cereal based dry commodities, it was validated at even lower levels. In its evaluation report, the EURLs highlighted that 1,4-dimethylnaphthalene is one of 10 dimethylnaphthalene isomers and chromatographic separation of these isomers may not be achievable using routine methodologies; thus, this could affect specificity and introduce bias (EURLs, 2020).
EFSA concludes that sufficient analytical methods are available for the enforcement of all commodities under assessment.

1.1.5. Stability of residues in plants

The storage stability of parent 1,4-dimethylnaphthalene and its metabolites M21 and M23 in high water content commodities was investigated in the framework of the peer review (Netherlands, 2013; EFSA, 2013).

In high water content commodities (potato peel and pulp), the available studies demonstrated a storage stability for 1,4-dimethylnaphthalene for a period of 5 months when stored at –18°C, and for at least 9 days for metabolites M21 and M23.

1.1.6. Proposed residue definitions

The metabolism of 1,4-dimethylnaphthalene was investigated in root crops only but it was considered sufficient to address the nature of residues for the only use authorised under this assessment (potato). No studies were available in rotational crops, but no residue definition is required (see Section 1.1.2). Although the physical and chemical properties of 1,4-dimethylnaphthalene, M21 and M23 suggest that these compounds are probably not vulnerable to hydrolysis, the metabolism in processed commodities was not fully elucidated (see Section 1.1.3) and under this review, it is tentatively proposed to set the residue definitions for enforcement and risk assessment for processed commodities in line with the ones for primary crops.

As the parent compound was found to be a sufficient marker in roots, the residue definition for enforcement is proposed as 1,4-dimethylnaphthalene only. It is restricted to root crops and is the same as the one derived during the peer review and adopted in Regulation (EC) 396/2005. This residue definition is also applicable to processed commodities on a tentative basis.

An analytical method for the enforcement of the proposed residue definition at the LOQ of 1 mg/kg in high water content matrices is available (EFSA, 2013). According to the EURLs, a default LOQ of 0.01 mg/kg is achievable by using multiresidue QuEChERS in routine analyses (EURLs, 2020).

For risk assessment, in the framework of the peer review, a provisional residue definition was set (as the sum of 1,4-dimethylnaphthalene, M21, and M23, expressed as 1,4-dimethylnaphthalene) pending the submission of adequate metabolism studies. Considering the new metabolism study provided as confirmatory data (EFSA, 2017), parent and metabolite M21 and its conjugates are toxicologically relevant and should be considered in the consumer exposure. It was also concluded that metabolites M21 and M23 are of similar toxicity as the parent compound; however, M23 is very minor compared to the amount of 1,4-dimethylnaphthalene and M21 (including conjugates); thus, M23 does not need to be included in the residue definition for risk assessment (EFSA, 2017). These conclusions are still valid under the current review; therefore, the residue definition for risk assessment for root crops is proposed as the 'sum of 1,4-dimethylnaphthalene, M21 and its conjugates, expressed as 1,4-dimethylnaphthalene', in line with the proposal from the assessment of the confirmatory data.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of 1,4-dimethylnaphthalene residues resulting from the reported GAP, EFSA considered the residue trials evaluated in the framework of a previous MRL application (EFSA, 2014) and reported by the RMS in its evaluation report.

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).

All residue trial samples considered in this framework were stored in compliance with the conditions for which storage stability of 1,4-dimethylnaphthalene residues was demonstrated. Even though stability of M21 was investigated on 9 days only (see Section 1.1.5), this was concluded appropriate as samples were extracted and analysed within 48 h of receipt (EFSA, 2014). Decline of residues during storage of the trial samples is therefore not expected.

Residue trials analysing simultaneously for enforcement and risk assessment residue definitions were not available. Although the conversion factor (1.9) established on the basis of the metabolism study following the evaluation of confirmatory data (EFSA, 2017) could be applied for risk assessment,
eight additional trials on potato compliant with the GAP and analysing simultaneously for enforcement and risk assessment residue definitions are still required. Pending the submission of these additional trials and of additional information on the compounds identified in the processing studies, the MRL and risk assessment values are considered as tentative only.

It is noted that new supervised residue trials in which the relevant residues are analysed, are currently under evaluation in a recently submitted Article 6 MRL application for which the assessment is ongoing at MS level however; these trials could not be considered yet under this review.

1.2.2. Natural background levels of 1,4-dimethylnaphthalene

1,4-dimethylnaphthalene is a naturally occurring plant compound and various crop commodities may contain natural background levels of 1,4-dimethylnaphthalene and of similar methylated naphthalene compounds. It should also be noted that 1,4-dimethylnaphthalene residues may be originating from other sources than the use of plant protection products containing this active substance (e.g. plant protection products containing petroleum products, food contact materials containing residues of mineral oils where dimethylnaphthalenes are part of the aromatic hydrocarbons fraction). This was supported by the EURLs (EURLs, 2020).

In the framework of the peer review, the DAR (Netherlands, 2013) reported data from the literature review showing that dimethylnaphthalenes or methylated naphthalene compounds were identified in a wide range of plant commodities (apple, coffee, beans, grape, maize, tomato, poppy, rhubarb, etc.). However, limited quantitative information on the natural background levels is available. For instance, 1,4-dimethylnaphthalene natural levels were reported up to 60 µg/kg in potato peel, 1 µg/kg in tobacco, 0.4 µg/kg in poppy and dimethylnaphthalenes, up to 12 µg/kg poppy tops and 14 µg/kg in potato tuber (Netherlands, 2013; EFSA, 2014).

In addition, in supervised residue trials where samples were analysed for 1,4-dimethylnaphthalene prior to applications, natural background levels in whole potatoes were reported up to 0.061 mg/kg.

Therefore, in its previous MRL assessment, EFSA concluded that for the rest of the plant commodities, a default value of 0.01 mg/kg could not be considered and a default value of 0.1 mg/kg would be more appropriate to cover the possible natural background levels of 1,4-dimethylnaphthalene in plants, although this proposal is not supported by a sufficient number of data (EFSA, 2014).

As agreed with the RMS during the completeness check (EFSA, 2021a), the same approach as in the previous assessment is followed under the current review, and the agreed default value of 0.1 mg/kg is used on a tentative basis to perform indicative calculations for the dietary burden and the risk assessment (see Sections 2 and 3).

Since the publication of this last reasoned opinion, additional data from the annual monitoring reports, analysing pesticide residue levels in foods are available (EFSA, 2019b, 2020, 2021b). According to the monitoring data in almost all crop samples analysed (except spinach and potatoes), 1,4-dimethylnaphthalene was never quantified for three consecutive years (2017, 2018, 2019). This means that, at least for these specific crops, the default value of 0.01 mg/kg could still be appropriate. Residues above LOQ (0.01 mg/kg) were reported only for spinach (maximum residues of 0.017 mg/kg; residues above the LOQ were found only in one out of 159 samples analysed) and for potatoes (maximum residues of 1.62 mg/kg); for beans (dry), rice and thyme, uncertainties remain since results fall between LOQs of 0.01 and 0.025 mg/kg. Data collected on the crops analysed and residue levels are reported in Appendix B.5. It should be highlighted that 1,4-dimethylnaphthalene was analysed for in a limited number of crops, but covering all four main matrices groups. These data are reported as additional information in support of risk management decisions.

1.2.3. Magnitude of residues in rotational crops

No studies are available and are not required (see also Section 1.1.2).

1.2.4. Magnitude of residues in processed commodities

The effect of industrial processing and/or household preparation was assessed during the peer review and in a previous MRL application on studies conducted on potato (EFSA, 2013, 2014; Netherlands, 2013). However, these studies were not considered appropriate to derive robust processing factors and a data gap was set for new processing studies considering washing, boiling and frying, representative of the residues observed in potato following a total of six applications (EFSA, 2014).
Non-standard studies investigating the processing of potatoes according to typical household methods and considering parent compound and relevant metabolites (M21 and its conjugates, M23, 1,4-dimethylnaphtol), were provided under this review (Netherlands, 2020). Tentative processing factors (not fully supported by data) could be derived for unpeeled boiled, unpeeled baked and unpeeled fried potatoes. These studies showed that residues tend to decrease with processing. An overview of all available processing studies is available in Appendix B.1.2.3.

Further processing studies to investigate the magnitude of residues are not required under this review as they are not expected to affect the outcome of the risk assessment. However, if more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

1.2.5. Proposed MRLs

The available data are considered sufficient to derive tentative MRL proposal as well as risk assessment values for the commodity under evaluation. The MRL for potato is tentative considering the data gaps identified in the processing studies and for additional residue trials analysing simultaneously for the enforcement and risk assessment residue definitions (see Appendix B.4).

For the crops other than potato and having regard to the possible background levels of 1,4-dimethylnaphthalene, a default value of 0.1 mg/kg was considered appropriate to cover the natural background levels in plants, although based on limited data (EFSA, 2014). Results from the last three annual monitoring programmes suggest that for most of the crops for which monitoring data are available, the default MRL of 0.01 mg/kg would still be appropriate (see Appendix B.5).

2. Residues in livestock

1,4-dimethylnaphthalene is authorised for use on potato 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. The dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). Behaviour of residues was therefore assessed in all commodities of animal origin.

It is highlighted that the possible natural background levels of 1,4-dimethylnaphthalene in feed products were considered in the dietary burden calculation, using the default value of 0.10 mg/kg for other crops than potato, as proposed in the previous MRL assessment (EFSA, 2014). The comparison between the calculation performed with and without considering this default value of 0.1 mg/kg covering the possible background levels in plants, confirms the high contribution of potatoes (and negligible contribution of other crops) to livestock exposure. Despite this, and in accordance with the outcome of the completeness check (EFSA, 2021a), this more conservative scenario using the default value of 0.1 mg/kg was retained under the current assessment.

Since potatoes are only fed to poultries and pigs after cooking, the residue levels expected in unpeeled boiled potatoes would need to be considered for the estimation of the dietary animal burden (EFSA, 2014). As no reliable processing and conversion factors could be derived for processed potatoes (see Section 1.2.4), intakes were not refined. However, it should be highlighted that considering the major contributors to all diets (processed waste and dried pulp of potatoes, for which default processing factors were used), the use of processing factors to recalculate the ‘potato culls’ input value for poultry and swine is not expected to impact the outcome of the dietary burden estimation.

2.1. Nature of residues and methods of analysis in livestock

The metabolism of 1,4-dimethylnaphthalene residues in livestock was investigated in lactating goats and laying hens. These studies were assessed in the framework of the peer review (EFSA, 2013; Netherlands, 2013). All studies were performed using radiolabelled 1,4-dimethylnaphthalene with dose rates that are not covering the maximum dietary burdens calculated in this review. However, the identification rate of the compounds was satisfactory, and the metabolic pathway was confirmed by the feeding studies provided under this review.

The study performed on lactating goats indicates that 1,4-dimethylnaphthalene is rapidly absorbed and excreted. It is not detected in goat matrices, except in muscle but at a very low concentration
(0.001 mg eq/kg, 0.04% TRR). The only major metabolite was identified as conjugate of M23, accounting for 18% and 16% TRR in milk and in kidney (0.006 and 0.05 mg eq/kg, respectively).

In the study performed on laying hens, 1,4-dimethylnaphthalene is less extensively degraded. The major component of the residues was metabolite M23 (free and conjugated) accounting for 34% to 71% TRR (0.02–0.11 mg eq/kg) in all matrices, with the exception of the fat where it is not detected while 94% TRR (0.47 mg eq/kg) was identified as 1,4-dimethylnaphthalene. The parent 1,4-dimethylnaphthalene was also present in significant proportions in egg and muscle (29–35% TRR; 0.02–0.03 mg eq/kg).

An additional metabolism study in rats was submitted and assessed in the framework of a previous MRL application (EFSA, 2014), allowing to conclude that the metabolism in rats and ruminants is similar. It should be noted that these animal studies were performed using the 1,4-dimethylnaphthalene, whereas M21 was also identified as a major component of the residues in potato tubers. It can be assumed that M21 is an intermediate in the formation of the metabolite M23, found as a major component of the residues in rat, goat and hen. It is therefore concluded that the animal metabolism studies conducted with the parent 1,4-dimethylnaphthalene are relevant to address the fate of M21 in livestock (EFSA, 2013).

During the peer review and the previous MRL assessment, EFSA concluded that the metabolism of 1,4-dimethylnaphthalene in livestock was adequately elucidated, but that the metabolic pathway observed in ruminants and hens should be confirmed by the submission of feeding studies. Although not peer reviewed, the feeding studies submitted under this review (see Section 2.2) confirmed the metabolic pathway observed, with parent and metabolite M23 (free and conjugated) being the most relevant components of the residues in livestock commodities.

It is concluded that the parent compound is not a sufficient marker in livestock commodities, and parent and metabolite M23 (free and conjugated) should both be considered in the consumer exposure. Therefore, the residue definition for enforcement and risk assessment that was provisionally proposed during the peer review, is confirmed as the sum of 1,4-dimethylnaphthalene and its metabolite M23 free and conjugated, expressed as 1,4-dimethylnaphthalene. Considering both the metabolism and feeding studies, the residue definition is considered fat soluble.

An analytical method using HPLC-FLD was provided in the framework of the peer review for the determination of 1,4-dimethylnaphthalene in animal tissues and eggs, with an LOQ of 0.01 mg/kg. However, a confirmatory method, an ILV and extraction efficiency data were required. Full validation data were also needed for milk and metabolite M23 (EFSA, 2013).

In the framework of this MRL review, new independent method validations in all animal matrices and considering all relevant compounds were available, but not considered fit for purpose due to several data gaps. These studies including additional data and an ongoing ILV will be assessed in a recently submitted Article 6 MRL application for which the assessment is ongoing at MS level (Netherlands, 2020). For what regards the extraction efficiency, the RMS concluded that this data gap is addressed. Considering the new analytical method provided under this review and making cross reference to the metabolism studies already assessed under the peer review, it is concluded that acetonitrile is the right solvent which efficiently extracts residues of 1,4-dimethylnaphthalene, M23 and M23 conjugates in animal matrices including those with high fat content.

Although a fully validated analytical method for the enforcement of the proposed residue definition is not established, the EURLs informed EFSA that for 1,4-dimethylnaphthalene and free M23, a default LOQ of 0.01 mg/kg (combined LOQ of 0.02 mg/kg) is achievable in milk and liver, and would be also achievable for other animal products (e.g. muscle, eggs, kidney, fat) by using QuEChERS-based methods in routine analyses. The EURLs could not conduct validation experiments on M23 conjugates; however, based on the analytical behaviour of free M23, it can be assumed that the LOQ of 0.01 mg/kg is achievable for the sum of free and conjugated M23 in milk, as well as in other animal products (e.g. muscle, eggs, kidney, fat) (EURLs, 2020).

No storage stability studies are available; however, all samples were analysed within 30 days and additional data are therefore not required.

2.2. **Magnitude of residues in livestock**

In the framework of the peer review, no feeding study performed on ruminants was provided and the available feeding study on poultry was considered inconclusive (EFSA, 2013). New feeding studies were submitted in the framework of this review (Netherlands, 2020).
In these new studies, a mixture of the parent compound 1,4-dimethylnaphthalene and metabolites M21 and M23 was administered. In both studies, the storage period of the samples was covered by the conditions for which storage stability was demonstrated, thus decline of residues during storage of the trial samples is not expected.

The study on dairy cows was performed using different dosing levels, ranging from 1.31 mg/kg body weight (bw) per day (1x) to 19.14 mg/kg bw/day (15x). This study was used to derive MRL and risk assessment values in milk and tissues of ruminants. Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs. In this study, all samples were analysed for 1,4-dimethylnaphthalene, M21, M23 and Gly-M23 (relevant conjugate in ruminants).

The study on laying hens was performed with dose levels ranging from 1.81 to 8.1 mg/kg bw per day (1x to 10x) and used to derive MRL and risk assessment values in eggs and tissues of poultry. Tissues and egg samples were analysed for 1,4-dimethylnaphthalene, M21, M23 and Orn-M23 (relevant conjugate in poultry).

In both studies, total residues were expressed considering the residue definition for risk assessment, with each analyte having an LOQ of 0.01 mg/kg in all matrices, except for M23 in liver which has an LOQ of 0.04 mg/kg. Most of the time residues of M21 were not quantified in any matrices, while quantifications of 1,4-dimethylnaphthalene, M23 and its conjugates were significant (from 0.03 to 3.5 mg eq/kg) in all cow and hen matrices.

Based on these studies, MRL and risk assessment values were derived for all commodities of animal origin, in compliance with the latest recommendations on this matter (FAO, 2009). Considering the data gaps on the analytical methods for enforcement purposes (see Section 2.1), these MRLs are considered tentative.

3. Consumer risk assessment

Chronic exposure calculations for all crops reported in the framework of this review were performed using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019a). 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).

Since 1,4-dimethylnaphthalene is a naturally occurring component endogenous to many plants, possible natural background levels should be taken into consideration in the calculation (see also Section 1.2.2). In the previous assessment (EFSA, 2014), the default value of 0.1 mg/kg for plant commodities other than potatoes was proposed to cover these natural background levels in plants. Since annual monitoring data confirm that this default value is sufficiently high, the worst-case default value of 0.1 mg/kg was considered to perform the indicative chronic consumer intake calculations. All input values included in the exposure calculations are summarised in Appendix D.

The calculated exposure values were compared with the toxicological reference value derived for 1,4-dimethylnaphthalene (European Commission, 2013). In this worst-case scenario, the highest chronic exposure was calculated for the Dutch toddlers, representing 65% of the acceptable daily intake (ADI). This calculation indicates that the use assessed under this review results in a consumer exposure lower than the toxicological reference value. Although major uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumer’s health.

Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance.

Conclusions

The metabolism of 1,4-dimethylnaphthalene in plant was investigated in primary crops belonging to root crops group. According to the results of the metabolism studies, the residue definitions in root crops can be proposed as 1,4-dimethylnaphthalene for enforcement, and as the 'sum of 1,4-dimethylnaphthalene, M21 and its conjugates, expressed as 1,4-dimethylnaphthalene' for risk assessment. These residue definitions are also tentatively applicable to processed commodities pending the submission of additional studies confirming the nature of the residues observed in processed commodities. A specific residue definition for rotational crops is not deemed necessary considering that this active substance is only authorised for indoor post-harvest treatment of stored potatoes. Fully
validated analytical methods are available for the enforcement of the proposed residue definition in high water commodity crops at the limit of quantification (LOQ) of 1 mg/kg. According to the EURLs, a default LOQ of 0.01 mg/kg is achievable in all matrix groups by using multiresidue QuEChERS in routine analyses.

Available residue trials data were considered sufficient to derive tentative MRL proposal as well as risk assessment values for the commodity under evaluation, considering the data gaps identified in the processing studies and for additional residue trials on potato. For the crops other than potato and having regard to the possible background levels of 1,4-dimethylnaphthalene, in a previous EFSA assessment, a default value of 0.1 mg/kg was considered appropriate to cover the natural background levels in plants, although based on limited data. Results from the last three annual monitoring programmes suggest that for most of the crops for which monitoring data are available, the default MRL of 0.01 mg/kg would still be appropriate.

1,4-dimethylnaphthalene is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance and considering the possible natural background levels of this active substance present in feed items. The dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg dry matter. Behaviour of residues was therefore assessed in all commodities of animal origin.

The metabolism of 1,4-dimethylnaphthalene residues in livestock was investigated in lactating goats and laying hens at dose rates not covering the maximum dietary burdens calculated in this review; however, the metabolism was considered to be sufficiently elucidated, also in view of the results of the feeding studies. Accordingly, the residue definition for enforcement and risk assessment in livestock commodities was proposed as the 'sum of 1,4-dimethylnaphthalene and its metabolite M23 free and conjugated, expressed as 1,4-dimethylnaphthalene'. An analytical method for the enforcement of the proposed residue definition is not available in any animal matrices. Nevertheless, according to the EURLs, a default LOQ of 0.01 mg/kg is achievable for 1,4-dimethylnaphthalene and free M23 in livestock matrices (combined LOQ 0.02 mg/kg) by using the QuEChERS method in routine analyses. It is assumed that the LOQ of 0.01 mg/kg is also achievable for the sum of free and conjugated M23 in animal products.

Livestock feeding studies on lactating cows and laying hens were used to derive MRL and risk assessment values in milk, eggs and tissues of ruminants and poultry. Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs. Considering the general data gap on the analytical method, all MRLs are tentative.

Chronic consumer exposure resulting from the authorised use reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMo. Under a worst-case scenario considering also the possible natural background levels of 1,4-dimethylnaphthalene in plants in the calculation, the highest chronic exposure represented 65% of the acceptable daily intake (ADI) (Dutch toddler). Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance.

**Recommendations**

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 2). None of the MRL values listed in the table are recommended for inclusion in Annex II to the Regulation as they are not sufficiently supported by data. In particular, all tentative MRLs need to be confirmed by the following data:

1) Eight residue trials on potato compliant with the GAP and analysing simultaneously for enforcement and risk assessment residue definitions.
2) Additional information allowing to unambiguously identify the metabolites found at significant levels in the processing studies.
3) Sufficiently validated analytical methods for the enforcement of the proposed residue definition in livestock commodities (a confirmatory method and an ILV are required for 1,4-dimethylnaphthalene on animal tissues and egg, as well as fully validated method in milk, and for metabolite M23 in all animal matrices).
Considering the multiple sources of 1,4-dimethylnaphthalene and the lack of comprehensive data on the actual natural background levels of 1,4-dimethylnaphthalene in plants, EFSA recommends Members States to continue monitoring 1,4-dimethylnaphthalene in commodities of plant origin.

**Table 2:** Summary table

| Code number | Commodity         | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment                  |
|-------------|-------------------|-------------------------|----------------------|-----------------------|--------------------------|
|             |                   |                         |                      |                       |                          |
| **Enforcement residue definition 1: 1,4-dimethylnaphthalene** |  |  |  |  |  |
| 211000      | Potatoes          | 15                      | –                    | 15                    | Further consideration needed<sup>(a)</sup> Data gaps #1, 2 |
|             |                   |                         |                      |                       |                          |
| **Enforcement residue definition 2: sum of 1,4-dimethylnaphthalene and its metabolite M23 free and conjugated, expressed as 1,4-dimethylnaphthalene (F)** | | | | | |
| 1011010     | Swine meat        | –                       | –                    | 0.03                  | Further consideration needed<sup>(a)</sup> Data gap #3 |
| 1011020     | Swine fat (free of lean meat) | – | – | 0.4 | Further consideration needed<sup>(a)</sup> Data gap #3 |
| 1011030     | Swine liver       | –                       | –                    | 1.5                   | Further consideration needed<sup>(a)</sup> Data gap #3 |
| 1011040     | Swine kidney      | –                       | –                    | 1.5                   | Further consideration needed<sup>(a)</sup> Data gap #3 |
| 1012010     | Bovine meat       | –                       | –                    | 0.04                  | Further consideration needed<sup>(a)</sup> Data gap #3 |
| 1012020     | Bovine fat        | –                       | –                    | 1                     | Further consideration needed<sup>(a)</sup> Data gap #3 |
| 1012030     | Bovine liver      | –                       | –                    | 3                     | Further consideration needed<sup>(a)</sup> Data gap #3 |
| 1012040     | Bovine kidney     | –                       | –                    | 3                     | Further consideration needed<sup>(a)</sup> Data gap #3 |
| 1013010     | Sheep meat        | –                       | –                    | 0.04                  | Further consideration needed<sup>(a)</sup> Data gap #3 |
| 1013020     | Sheep fat         | –                       | –                    | 1.5                   | Further consideration needed<sup>(a)</sup> Data gap #3 |
| 1013030     | Sheep liver       | –                       | –                    | 4                     | Further consideration needed<sup>(a)</sup> Data gap #3 |
| 1013040     | Sheep kidney      | –                       | –                    | 3                     | Further consideration needed<sup>(a)</sup> Data gap #3 |
| 1014010     | Goat meat         | –                       | –                    | 0.04                  | Further consideration needed<sup>(a)</sup> Data gap #3 |
| 1014020     | Goat fat          | –                       | –                    | 1.5                   | Further consideration needed<sup>(a)</sup> Data gap #3 |
| 1014030     | Goat liver        | –                       | –                    | 4                     | Further consideration needed<sup>(a)</sup> Data gap #3 |
| 1014040     | Goat kidney       | –                       | –                    | 3                     | Further consideration needed<sup>(a)</sup> Data gap #3 |
| 1015010     | Horse meat        | –                       | –                    | 0.04                  | Further consideration needed<sup>(a)</sup> Data gap #3 |
| 1015020     | Horse fat         | –                       | –                    | 1                     | Further consideration needed<sup>(a)</sup> Data gap #3 |
| 1015030     | Horse liver       | –                       | –                    | 3                     | Further consideration needed<sup>(a)</sup> Data gap #3 |
| 1015040     | Horse kidney      | –                       | –                    | 3                     | Further consideration needed<sup>(a)</sup> Data gap #3 |
| 1016010     | Poultry meat      | –                       | –                    | 0.2                   | Further consideration needed<sup>(a)</sup> Data gap #3 |
### Code number | Commodity        | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | MRL (mg/kg) | Comment |
|---------------|------------------|-------------------------|----------------------|-----------------------|-------------|---------|
| 1016020       | Poultry fat      | –                       | –                    | **0.7**               | **0.7**     | Further consideration needed (a) Data gap #3 |
| 1016030       | Poultry liver    | –                       | –                    | **0.6**               | **0.6**     | Further consideration needed (a) Data gap #3 |
| 1020010       | Cattle milk      | –                       | –                    | **0.4**               | **0.4**     | Further consideration needed (a) Data gap #3 |
| 1020020       | Sheep milk       | –                       | –                    | **0.5**               | **0.5**     | Further consideration needed (a) Data gap #3 |
| 1020030       | Goat milk        | –                       | –                    | **0.5**               | **0.5**     | Further consideration needed (a) Data gap #3 |
| 1020040       | Horse milk       | –                       | –                    | **0.4**               | **0.4**     | Further consideration needed (a) Data gap #3 |
| 1030000       | Birds’ eggs      | –                       | –                    | **0.15**              | **0.15**    | Further consideration needed (a) Data gap #3 |
| –             | Other commodities of plant origin | See Reg. 2015/399 | –                    | –                     | –           | Further consideration needed (b) |

**MRL:** maximum residue level; **CXL:** codex maximum residue limit.

(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 F-I in Appendix E).

(b): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either an MRL of 0.1 mg/kg or the default MRL of 0.01 mg/kg may be considered by risk managers to cover the natural background levels of 1,4-dimethylnaphthalene in plants.

(F): The residue definition is fat soluble.

### References

EFSA (European Food Safety Authority), 2013. Conclusion on the peer review of the pesticide risk assessment of the active substance 1,4-dimethylnaphthalene. EFSA Journal 2013;11(10):3229, 43 pp. [https://doi.org/10.2903/j.efsa.2013.3229](https://doi.org/10.2903/j.efsa.2013.3229)

EFSA (European Food Safety Authority), 2014. Reasoned opinion on the setting of a new MRL for 1,4-dimethylnaphthalene in potatoes. EFSA Journal 2014;12(6):3735, 24 pp. [https://doi.org/10.2903/j.efsa.2014.3735](https://doi.org/10.2903/j.efsa.2014.3735)

EFSA (European Food Safety Authority), 2017. Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for 1,4-dimethylnaphthalene in light of confirmatory data. EFSA supporting publication 2017;EN-1225, 17 pp. [https://doi.org/10.2903/sp.efsa.2017.EN-1225](https://doi.org/10.2903/sp.efsa.2017.EN-1225)

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

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

EFSA (European Food Safety Authority), 2019b. Scientific report on the 2017 European Union report on pesticide residues in food. EFSA Journal 2019;17(6):5743, 152 pp. [https://doi.org/10.2903/j.efsa.2019.5743](https://doi.org/10.2903/j.efsa.2019.5743)

EFSA (European Food Safety Authority), Medina-Pastor P and Triacchini G, 2020. The 2018 European Union report on pesticide residues in food. EFSA Journal 2020;18(4):6057, 103 pp. [https://doi.org/10.2903/j.efsa.2020.6057](https://doi.org/10.2903/j.efsa.2020.6057)

EFSA (European Food Safety Authority), 2021a. Completeness check report on the review of the existing MRLs of 1,4-dimethylnaphthalene prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 2 February 2021. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

EFSA (European Food Safety Authority), Carrasco Cabrera L and Medina Pastor P, 2021b. The 2019 European Union report on pesticide residues in food. EFSA Journal 2021;19(4):6491, 89 pp. [https://doi.org/10.2903/j.efsa.2021.6491](https://doi.org/10.2903/j.efsa.2021.6491)
EFSA (European Food Safety Authority), 2021c. Member States consultation report on the review of the existing MRLs of 1,4-dimethylnaphthalene prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 14 April 2021. Available online: www.efsa.europa.eu

EURLs (European Union Reference Laboratories for Pesticide Residues), 2020. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Analytical validations by the EURLs and capability of official laboratories to be considered for the review of the existing MRLs for 1,4-dimethylnaphthalene. 25 June 2020, revised in March 2021. Available online: www.efsa.europa.eu

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

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

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

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

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

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

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

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

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

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

European Commission, 2013. Review report for the active substance 1,4-dimethylnaphthalene. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 13 December 2013 in view of the approval of 1,4-dimethylnaphthalene as active substance in accordance with Regulation (EC) No 1107/2009. SANCO/12596/2013 rev 2, 13 December 2013.

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

FAO (Food and Agriculture Organization of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Edition. FAO Plant Production and Protection Paper 197, 264 pp.

Netherlands, 2012. Draft assessment report on the active substance 1,4-dimethylnaphthalene prepared by the rapporteur Member State The Netherlands in the framework of Council Directive 91/414/EEC, March 2012. Available online: www.efsa.europa.eu

Netherlands, 2013. Final addendum to the draft assessment report on the active substance 1,4-dimethylnaphthalene, compiled by EFSA, April 2013. Available online: www.efsa.europa.eu

Netherlands, 2017. Addendum to the assessment report on 1,4-dimethylnaphthalene, confirmary data, January 2017; revised in March 2017. Available online: www.efsa.europa.eu.

Netherlands, 2020. Evaluation report prepared under Article 12.1 of Regulation (EC) No 396/2005. Review of the existing MRLs for 1,4-dimethylnaphthalene, 23 October 2020. Available online: www.efsa.europa.eu

OECD (Organisation for Economic Co-operation and Development), 2008. Guidance document on the magnitude of pesticide residues in processed commodities. In: Series of Testing and Assessment No 96. ENV/JM/MONO(2008)23, 29 July 2008.

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org

OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 4 September 2013.

Abbreviations

a.i. active ingredient
a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
ARfD acute reference dose
| Acronym | Description |
|---------|-------------|
| BBCH    | growth stages of mono- and dicotyledonous plants |
| bw      | body weight |
| CAS     | Chemical Abstract Service |
| CF      | conversion factor for enforcement residue definition to risk assessment residue definition |
| CIRCA   | (EU) Communication & Information Resource Centre Administrator |
| CS      | capsule suspension |
| CV      | coefficient of variation (relative standard deviation) |
| CXL     | codex maximum residue limit |
| DAR     | draft assessment report |
| DAT     | days after treatment |
| DB      | dietary burden |
| DM      | dry matter |
| DS      | powder for dry seed treatment |
| EMS     | evaluating Member State |
| 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 |
| FID     | flame ionisation detector |
| GAP     | Good Agricultural Practice |
| GC      | gas chromatography |
| GC-FID  | gas chromatography with flame ionisation detector |
| GC-HRMS | gas chromatography with high resolution mass spectrometry |
| GC-MS   | gas chromatography with mass spectrometry |
| GC-MS/MS| gas chromatography with tandem mass spectrometry |
| GS      | growth stage |
| HN      | hot fogging concentrate |
| HPLC-FLD| high-performance liquid chromatography with fluorescence detection |
| HPLC-MS | high-performance liquid chromatography with mass spectrometry |
| HPLC-MS/MS| high-performance liquid chromatography with tandem mass spectrometry |
| HR      | highest residue |
| IEDI    | international estimated daily intake |
| ILV     | independent laboratory validation |
| ISO     | International Organisation for Standardization |
| IUPAC   | International Union of Pure and Applied Chemistry |
| KN      | cold fogging concentrate |
| LC-MS/MS| liquid chromatography with tandem mass spectrometry |
| LOQ     | limit of quantification |
| Mo      | monitoring |
| MRL     | maximum residue level |
| MS      | Member States |
| MS/MS   | tandem mass spectrometry detector |
| MW      | molecular weight |
| NTMDI   | national theoretical maximum daily intake |
| OECD    | Organisation for Economic Co-operation and Development |
| PBI     | plant back interval |
| PF      | processing factor |
| PHI     | preharvest interval |
| P_{ow}  | partition coefficient between n-octanol and water |
| ppm     | parts per million (10^{-6}) |
| PRIMo   | (EFSA) Pesticide Residues Intake Model |
| PROFile | (EFSA) Pesticide Residues Overview File |
| QuEChERS| Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method) |
| RA      | risk assessment |
| RD      | residue definition |
| RAC     | raw agricultural commodity |
| RD      | residue definition |
| Acronym | Description                                      |
|---------|--------------------------------------------------|
| 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     |
| SL      | soluble concentrate                              |
| SP      | water soluble powder                             |
| STMR    | supervised trials median residue                 |
| TAR     | total applied radioactivity                       |
| TMDI    | theoretical maximum daily intake                 |
| TRR     | total radioactive residue                         |
| WHO     | World Health Organization                        |
Appendix A – Summary of authorised uses considered for the review of MRLs

A.1. Authorised indoor uses (post-harvest uses) in EU

| Crop and/or situation | MS or country | F or G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|----------------|-----------------------------------|-------------|------------|------------------------------|--------------|---------|
| Potatoes              | AT, BE, DE, FI, FR, IE, NL, PL | I | Growth regulator/dormancy enhancement/sprout control | HN | 980 g/kg | Post-harvest treatment – fogging | 99–99 | 1–6 | 28 | – | – | 19.87 g a.s./ton | 30 | Formulation type: HN or KN |

MS: Member State; a.s.: active substance; HN: Hot fogging concentrate; KN: cold fogging concentrate.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system. 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.
(c): PHI – minimum preharvest interval.
### Appendix B – List of end points

#### B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|-----------------------------------|-------------|---------|----------------|----------------|----------------|
| Root crops                        | Potato      |         | Post-harvest thermal fogging, 1 × 20 g a.s./ton, BBCH 99 | 1, 30          | [14C]-1,4-dimethylnaphthalene. Study not representative of the GAP (EFSA, 2013; Netherlands, 2013) |
|                                   | Potato      |         | Post-harvest thermal fogging, 6 × 20 g a.s./ton (1-month interval), BBCH 99 | 30 DAT₁, 30 DAT₆ | [14C]-1,4-dimethylnaphthalene (EFSA, 2017; Netherlands, 2017) |
| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|                                   |             |         |                |           | Not available and not required as 1,4-dimethylnaphthalene is used as indoor post-harvest treatment only. |
| Processed commodities (hydrolysis study) | Conditions |          |                | Stable? | Comment/Source |
|                                   | Pasteurisation (20 min, 90°C, pH 4) | Inconclusive | Standard hydrolysis studies not available (EFSA, 2013) |
|                                   | Baking, brewing and boiling (60 min, 100°C, pH 5) | Inconclusive | Standard hydrolysis studies not available (EFSA, 2013) |
|                                   | Sterilisation (20 min, 120°C, pH 6) | Inconclusive | Standard hydrolysis studies not available (EFSA, 2013) |
|                                   | Other processing conditions: boiling (30 min, 100°C) | Yes | Non-standard study, following typical household method. Formation of unknown metabolites tentatively identified as glycoside conjugates of M21 (Netherlands, 2020) |
|                                   | Other processing conditions: baking (45 min, 180°C) | Yes | Non-standard study, following typical household method. Formation of unknown metabolites tentatively identified as glycoside conjugates of M21 (Netherlands, 2020) |
|                                   | Other processing conditions: frying (5 min, 190°C) | Yes | Non-standard study, following typical household method. Formation of unknown metabolites tentatively identified as glycoside conjugates of M21 (Netherlands, 2020) |
Can a general residue definition be proposed for primary crops?  
No  
Only one crop group investigated (roots)

Rotational crop and primary crop metabolism similar?  
Not applicable  
No study available and not required.

Residue pattern in processed commodities similar to residue pattern in raw commodities?  
Inconclusive  
Available processing studies not sufficient to conclude on the nature of the residues in processed commodities (data gap).

Plant residue definition for monitoring (RD-Mo)  
Root crops: 1,4-dimethylnaphthalene.

Processed potato (tentative): 1,4-dimethylnaphthalene.

Plant residue definition for risk assessment (RD-RA)  
Root crops: sum of 1,4-dimethylnaphthalene, M21 and its conjugates, expressed as 1,4-dimethylnaphthalene.

Processed potato (tentative): sum of 1,4-dimethylnaphthalene, M21 and its conjugates, expressed as 1,4-dimethylnaphthalene.

Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)  
Matrices with high water content (EFSA, 2013):
- QuEChERS, GC-MSD (primary method), LOQ 0.01 mg/kg.
- HPLC-FLD (confirmatory method), LOQ 1 mg/kg. ILV available (LOQ 0.03 mg/kg).
- Overall, LOQ for enforcement of 1,4-dimethylnaphthalene set at 1 mg/kg.

Matrices with high water content, high oil content, high acid content and dry matrices (EURLs, 2020):
- QuEChERS method using GC–MS/MS and GC-HRMS techniques, LOQ 0.01 mg/kg in routine analysis.
  Lower levels were achieved in high water content and high acid content commodities (down to 0.005 mg/kg), and even lower in dry matrices.

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; GC-MSD: gas chromatography with mass spectrometry detection; HPLC-FLD: high performance liquid chromatography with fluorescence detection; GC–MS/MS: gas chromatography with tandem mass spectrometry; GC-HRMS: gas chromatography with high resolution 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 period | Compounds covered                                                                 | Comment/Source                                      |
|------------------------------------|------------------------|--------------------------|-------|-----------------|-----------------------------------------------------------------------------------|-----------------------------------------------------|
|                                    | High water content     | Potato (peel and pulp)   | –18   | Months          | 1,4-dimethylnaphthalene                                                           | Netherlands (2013), EFSA (2013)                      |
|                                    |                       |                          | –18   | Days            | Metabolites 1-hydroxymethyl-4-naphthalene (M21) and 4-methyl-1-napthoic acid (M23) | Netherlands (2013), EFSA (2013)                      |

B.1.2. Magnitude of residues in plants

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

| Commodity | Region(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|-----------|-----------|---------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|--------------|----------------|-------|
| Potato    | Indoor EU | Mo: 1.8; 1.9; 2.8; 2.9; 3.0; 3.5; 3.6; 3.7; 3.8; 4.5; 4.9; 5.1; 5.7; 6.8; 7.1; 8.1 | Trials on potatoes compliant with GAP (EFSA, 2014; Netherlands, 2020). MRL_{OECD} = 12.98 | 15 (tentative)(e)     | 8.10         | 3.75           | 1.90  |

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level; Mo: residue levels expressed according to the monitoring residue definition; RA: residue levels expressed according to risk assessment residue definition. (a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: indoor EU trials or Country code: if non-EU trials. (b): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion. (c): Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion. (d): Conversion factor calculated based on the available metabolism study according to the residue definitions for monitoring and risk assessment, in light of confirmatory data (EFSA, 2017). (e): MRL is tentative pending additional information to conclude on the nature of residues in processed commodities and additional residue trials analysing simultaneously for enforcement and risk assessment residue definitions are required.

B.1.2.2. Residues in rotational crops

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | Not triggered                                                                 |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | Not triggered                                                                 |

Studies investigating the nature of 1,4-dimethylnaphthalene on rotational crops are not required, as this active substance is only authorised for indoor post-harvest treatment of stored potatoes. No study available and not required.
B.1.2.3. Processing factors

| Processed commodity                  | Number of valid studies\(^{(a)}\) | Processing Factor (PF) Individual values | Median PF | \(\text{CF}_{\text{p}}\)\(^{(b)}\) | Comment/Source                                                                 |
|-------------------------------------|-----------------------------------|------------------------------------------|-----------|----------------------------|--------------------------------------------------------------------------------|
| Potato, unpeeled boiled             | 1                                 | 0.5                                      | 0.5 (tentative)\(^{(c)}\) | 1.43                      | Non-standard study following typical household method (Netherlands, 2020)      |
| Potato, unpeeled baked              | 1                                 | 0.69                                     | 0.69 (tentative)\(^{(c)}\) | 1.72                      | Non-standard study following typical household method (Netherlands, 2020)      |
| Potato, unpeeled fried              | 1                                 | 0.71                                     | 0.71 (tentative)\(^{(c)}\) | 1.70                      | Non-standard study following typical household method (Netherlands, 2020)      |

PF: Processing factor (Residue level in processed commodity expressed according to RD-Mo/Residue level in raw commodity expressed according to RD-Mo); \(\text{CF}_{\text{p}}\): Conversion factor for risk assessment in processed commodity (Residue level in processed commodity expressed according to RD-RA/Residue level in processed commodity expressed according to RD-Mo).

\((a)\): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

\((b)\): Median of the individual conversion factors for each processing residues trial.

\((c)\): A tentative PF is derived based on a limited data set and pending additional information to conclude on the nature of residues in processed commodities.

B.2. Residues in livestock

Possible natural background levels of 1,4-dimethylnaphthalene in feed products other than potato were considered for the calculation, with a default value of 0.10 mg/kg (EFSA, 2014).

| Relevant groups (subgroups) | Dietary burden expressed in | Most critical subgroup\(^{(a)}\) | Most critical commodity\(^{(b)}\) | Trigger exceeded (Yes/No) | Comments |
|----------------------------|-----------------------------|----------------------------------|----------------------------------|--------------------------|----------|
|                            | mg/kg bw per day            | mg/kg DM                         | Median                           | Maximum                  |          |
| Cattle (all)               | 14.103                      | 14.579                           | 485.25                           | 497.63                   | Yes      |
| Cattle (dairy only)        | 14.103                      | 14.579                           | 366.67                           | 379.05                   | Yes      |
| Sheep (all)                | 16.170                      | 16.583                           | 485.10                           | 497.48                   | Yes      |
| Sheep (ewe only)           | 16.170                      | 16.583                           | 485.10                           | 497.48                   | Yes      |
| Swine (all)                | 5.887                       | 6.363                            | 255.11                           | 275.73                   | Yes      |
| Poultry (all)              | 4.599                       | 4.891                            | 65.16                            | 69.28                    | Yes      |
| Poultry (layer only)       | 3.411                       | 3.693                            | 49.85                            | 53.97                    | Yes      |

bw: body weight; DM: dry matter.

\((a)\): When one group of livestock includes several subgroups (e.g. poultry 'all' including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.

\((b)\): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

Swines are only fed to swine and poultry after cooking and since no reliable processing and conversion factors could be derived, intakes were not refined.
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/day) | Duration (days) | Comment/Source                                             |
|-------------------------------|----------------|---------------------|-----------------|------------------------------------------------------------|
|                               | Laying hen     | 0.83                | 7               | \[^{13}C\]-1,4-dimethylnaphthalene (Netherlands, 2013; EFSA, 2013) |
|                               | Lactating goats| 0.39                | 7               | \[^{13}C\]-1,4-dimethylnaphthalene (Netherlands, 2013; EFSA, 2013) |
|                               | Pigs           | –                   | –               | Not available and not required.                           |

Review of the existing MRLs for 1,4-dimethylnaphthalene
Time needed to reach a plateau concentration in milk and eggs (days)

|               | Milk: 2 | Data from the metabolism study. |
|---------------|---------|---------------------------------|
| Eggs: 7       |         | Data from the feeding study (Netherlands, 2020). |
| Metabolism in rat and ruminant similar | Yes | Metabolism study in rat (EFSA, 2014). |
| Can a general residue definition be proposed for animals? | Yes | - |
| Animal residue definition for monitoring (RD-Mo) | Sum of 1,4-dimethylnaphthalene and its metabolite M23 free and conjugated, expressed as 1,4-dimethylnaphthalene. |
| Animal residue definition for risk assessment (RD-RA) | Sum of 1,4-dimethylnaphthalene and its metabolite M23 free and conjugated, expressed as 1,4-dimethylnaphthalene. |
| Fat soluble residues | Yes | Log P_{ow} (1,4-dimethylnaphthalene) = 4.37 > 3. Accumulation in fat was demonstrated. |
| Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs) | Animal tissues and eggs, (EFSA, 2013): |• HPLC–FLD, LOQ 0.01 mg/kg, validated for 1,4-dimethylnaphthalene only. |
| | |• Confirmatory method and ILV for 1,4-dimethylnaphthalene in animal tissues and eggs and full validation data for milk and metabolite M23 in all animal matrices required (data gap). |
| | Milk, Liver in routine analysis (EURLs, 2020): |• Method validated for 1,4-dimethylnaphthalene and metabolite M23 (free). |
| | |• QuEChERS method using LC–MS/MS technique, default LOQ 0.01 mg/kg for each analyte. A combined LOQ is calculated to 0.02 mg/kg, considering the molecular weights of each compound. It is furthermore supposed that the default LOQ of 0.01 mg/kg would be also achievable for other animal products (e.g. muscle, eggs, kidney, fat). |
| | |• Based on the analytical behaviour of free M23, it can be assumed that the LOQ of 0.01 mg/kg is achievable for the sum of free and conjugated M23 in milk, as well as in other animal products (e.g. muscle, eggs, kidney, fat). |

bw: body weight; P_{ow}: partition coefficient between n-octanol and water; HPLC–FLD: high-performance liquid chromatography with fluorescence detection; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe.

B.2.1.2. Stability of residues in livestock

Studies were not available. However, analysed samples were stored for less than 30 days (Netherlands, 2020), and thus, residue decline is not expected.
### B.2.2. Magnitude of residues in livestock

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

Calculations performed with Animal model 2017

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N MRL proposal (mg/kg) | MRL proposal (mg/kg) |
|------------------|---------------------------------------------|-------------------------------------------|----------------------|
|                  | Mean Highest STMR<sub>Mo</sub> (a) (mg/kg) | HR<sub>Mo</sub> (b) (mg/kg)               |                      |
| **Cattle (all)** |                                            |                                           |                      |
| Muscle           | 0.03 0.04                                  | 0.03                                      | 0.04 (tentative)<sup>(c)</sup> |
| Fat              | 0.78 1.27                                  | 0.57                                      | 0.95 1 (tentative)<sup>(c)</sup> |
| Liver            | 3.65 3.79                                  | 2.75                                      | 2.94 3 (tentative)<sup>(c)</sup> |
| Kidney           | 2.60 2.81                                  | 2.01                                      | 2.23 3 (tentative)<sup>(c)</sup> |
| **Cattle (dairy only)** |                                            |                                           |                      |
| Milk<sup>(e)</sup> | 0.52 0.52                                  | 0.38                                      | 0.40 0.4 (tentative)<sup>(c)</sup> |
| **Sheep (all)**<sup>(f)</sup> |                                            |                                           |                      |
| Muscle           | 0.03 0.04                                  | 0.03                                      | 0.03 0.04 (tentative)<sup>(c)</sup> |
| Fat              | 0.78 1.27                                  | 0.65                                      | 1.09 1.5 (tentative)<sup>(c)</sup> |
| Liver            | 3.65 3.79                                  | 3.12                                      | 3.31 4 (tentative)<sup>(c)</sup> |
| Kidney           | 2.60 2.81                                  | 2.25                                      | 2.49 3 (tentative)<sup>(c)</sup> |
| **Sheep (ewe only)**<sup>(f)</sup> |                                            |                                           |                      |
| Milk<sup>(e)</sup> | 0.52 0.52                                  | 0.44                                      | 0.45 0.5 (tentative)<sup>(c)</sup> |
| **Swine (all)**<sup>(g)</sup> |                                            |                                           |                      |
| Muscle           | 0.03 0.03                                  | 0.03                                      | 0.03 0.03 (tentative)<sup>(c)</sup> |
| Fat              | 0.13 0.20                                  | 0.22                                      | 0.38 0.4 (tentative)<sup>(c)</sup> |
| Liver            | 0.93 0.94                                  | 1.27                                      | 1.40 1.5 (tentative)<sup>(c)</sup> |
| Kidney           | 0.81 0.90                                  | 1.04                                      | 1.20 1.5 (tentative)<sup>(c)</sup> |
| **Poultry (all)** |                                            |                                           |                      |
| Muscle           | 0.06 0.09                                  | 0.12                                      | 0.16 0.2 (tentative)<sup>(c)</sup> |
| Fat              | 0.34 0.38                                  | 0.62                                      | 0.69 0.7 (tentative)<sup>(c)</sup> |
| Liver            | 0.17 0.30                                  | 0.40                                      | 0.56 0.6 (tentative)<sup>(c)</sup> |
| **Poultry (layer only)** |                                            |                                           |                      |
| Eggs<sup>(g)</sup> | 0.04 0.05                                  | 0.10                                      | 0.13 0.15 (tentative)<sup>(c)</sup> |

bw: body weight; STMR<sub>Mo</sub>: median residue expressed according to the residue definition for monitoring; HR<sub>Mo</sub>: highest residue expressed according to the residue definition for monitoring.

(a): Median residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the median dietary burden.

(b): Highest residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the maximum dietary burden.

(c): MRL is tentative because an analytical method sufficiently validated for enforcement is not available.

(d): Closest feeding level and N dose rate related to the maximum dietary burden.

(e): For milk, mean was derived from samplings performed from day –1 to day 28 (daily mean of 6 cows).

(f): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.

(g): For eggs, mean and highest residues were derived from samplings performed from day –1 to day 28 (daily mean or daily highest of 12 laying hens).

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9 https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en
B.3. Consumer risk assessment

No acute consumer exposure was calculated, as an ARfD was not deemed necessary.

| Assumptions made for the calculations |
|---------------------------------------|
| The calculation is based on the median residue levels derived for the raw agricultural commodity under assessment (potato), multiplied by the conversion factor for risk assessment (1.9). |
| A default value of 0.1 mg/kg (multiplied by the conversion factor for risk assessment, 1.9) was used for all plant commodities other than potato, to consider the worst-case possible natural background levels of 1,4-dimethylnaphthalene in plants (EFSA, 2014). |

Consumer exposure assessment through drinking water resulting from groundwater metabolite(s) according to SANCO/221/2000 rev.10 Final (25/2/2003).

| Metabolite(s) | ADI (mg/kg bw per day) | Intake of groundwater metabolites (% ADI) |
|---------------|------------------------|------------------------------------------|
| Not assessed in this review. | Not assessed in this review. | Not assessed in this review. |

B.4. Proposed MRLs

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment |
|-------------|-----------|-------------------------|----------------------|-------------|---------|
| Enforcement residue definition 1: 1,4-dimethylnaphthalene |
| 211000 | Potatoes | 15 | – | 15 | Further consideration needed(a) |
| | | | | | Data gaps #1, 2 |
| Enforcement residue definition 2: sum of 1,4-dimethylnaphthalene and its metabolite M23 free and conjugated, expressed as 1,4-dimethylnaphthalene (F) |
| 1011010 | Swine meat | – | – | 0.03 | Further consideration needed(a) |
| | | | | | Data gap #3 |
| 1011020 | Swine fat (free of lean meat) | – | – | 0.4 | Further consideration needed(a) |
| | | | | | Data gap #3 |
| 1011030 | Swine liver | – | – | 1.5 | Further consideration needed(a) |
| | | | | | Data gap #3 |
| 1011040 | Swine kidney | – | – | 1.5 | Further consideration needed(a) |
| | | | | | Data gap #3 |

ADI: acceptable daily intake; bw: body weight; NEDI: national estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; TMDI: theoretical maximum daily intake; NTMDI: national theoretical maximum daily intake; international estimated daily intake.
| Code number | Commodity       | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment                                      |
|------------|----------------|------------------------|---------------------|-------------|----------------------------------------------|
| 1012010    | Bovine meat    | –                      | –                   | 0.04        | Further consideration needed (a) Data gap #3 |
| 1012020    | Bovine fat     | –                      | –                   | 1           | Further consideration needed (a) Data gap #3 |
| 1012030    | Bovine liver   | –                      | –                   | 3           | Further consideration needed (a) Data gap #3 |
| 1012040    | Bovine kidney  | –                      | –                   | 3           | Further consideration needed (a) Data gap #3 |
| 1013010    | Sheep meat     | –                      | –                   | 0.04        | Further consideration needed (a) Data gap #3 |
| 1013020    | Sheep fat      | –                      | –                   | 1.5         | Further consideration needed (a) Data gap #3 |
| 1013030    | Sheep liver    | –                      | –                   | 4           | Further consideration needed (a) Data gap #3 |
| 1013040    | Sheep kidney   | –                      | –                   | 3           | Further consideration needed (a) Data gap #3 |
| 1014010    | Goat meat      | –                      | –                   | 0.04        | Further consideration needed (a) Data gap #3 |
| 1014020    | Goat fat       | –                      | –                   | 1.5         | Further consideration needed (a) Data gap #3 |
| 1014030    | Goat liver     | –                      | –                   | 4           | Further consideration needed (a) Data gap #3 |
| 1014040    | Goat kidney    | –                      | –                   | 3           | Further consideration needed (a) Data gap #3 |
| 1015010    | Horse meat     | –                      | –                   | 0.04        | Further consideration needed (a) Data gap #3 |
| 1015020    | Horse fat      | –                      | –                   | 1           | Further consideration needed (a) Data gap #3 |
| 1015030    | Horse liver    | –                      | –                   | 3           | Further consideration needed (a) Data gap #3 |
| 1015040    | Horse kidney   | –                      | –                   | 3           | Further consideration needed (a) Data gap #3 |
| 1016010    | Poultry meat   | –                      | –                   | 0.2         | Further consideration needed (a) Data gap #3 |
| 1016020    | Poultry fat    | –                      | –                   | 0.7         | Further consideration needed (a) Data gap #3 |
| 1016030    | Poultry liver  | –                      | –                   | 0.6         | Further consideration needed (a) Data gap #3 |
| 1020010    | Cattle milk    | –                      | –                   | 0.4         | Further consideration needed (a) Data gap #3 |
| 1020020    | Sheep milk     | –                      | –                   | 0.5         | Further consideration needed (a) Data gap #3 |
| 1020030    | Goat milk      | –                      | –                   | 0.5         | Further consideration needed (a) Data gap #3 |
| 1020040    | Horse milk     | –                      | –                   | 0.4         | Further consideration needed (a) Data gap #3 |
| 1030000    | Birds’ eggs    | –                      | –                   | 0.15        | Further consideration needed (a) Data gap #3 |
| –          | Other commodities of plant origin | See Reg. 2015/399 | –               | –           | Further consideration needed (a) |

MRL: maximum residue level; CXL: codex maximum residue limit.

(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 F-I in Appendix E).
There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either an MRL of 0.1 mg/kg or the default MRL of 0.01 mg/kg may be considered by risk managers to cover the natural background levels of 1,4-dimethylnaphthalene in plants.

(F): The residue definition is fat soluble.

### B.5. Annual monitoring data on pesticide residues

Annual monitoring data on pesticide residues collected in 2017, 2018 and 2019 from the official national control activities carried out by EU Member States, Iceland and Norway.

| Crop (raw commodities)                      | Number of samples analysed | LOQ(a) (min–max) | Number of samples > LOQ(a) | Number of samples > MRL | Maximum residue level (mg/kg) |
|---------------------------------------------|----------------------------|------------------|----------------------------|------------------------|-------------------------------|
| Almonds                                     | 6                          | 0.01             | 0                          | 0                      | –                             |
| Apples                                      | 178                        | 0.005–0.01       | 0                          | 0                      | –                             |
| Apricots                                    | 42                         | 0.005–0.01       | 0                          | 0                      | –                             |
| Asparagus                                   | 54                         | 0.01             | 0                          | 0                      | –                             |
| Aubergines/eggplants                        | 74                         | 0.005–0.01       | 0                          | 0                      | –                             |
| Avocados                                    | 60                         | 0.01             | 0                          | 0                      | –                             |
| Baby leaf crops (including brassica species)| 3                          | 0.01             | 0                          | 0                      | –                             |
| Bananas                                     | 75                         | 0.005–0.01       | 0                          | 0                      | –                             |
| Barley                                      | 51                         | 0.01             | 0                          | 0                      | –                             |
| Basil and edible flowers                    | 66                         | 0.005–0.01       | 0                          | 0                      | –                             |
| Beans (dry)                                 | 31                         | 0.01–0.025       | 0                          | 0                      | –                             |
| Beans (with pods)                           | 51                         | 0.005–0.01       | 0                          | 0                      | –                             |
| Beetroots                                   | 7                          | 0.005–0.01       | 0                          | 0                      | –                             |
| Blackberries                                | 24                         | 0.005–0.01       | 0                          | 0                      | –                             |
| Blueberries                                  | 78                         | 0.005–0.01       | 0                          | 0                      | –                             |
| Broccoli                                    | 33                         | 0.005–0.01       | 0                          | 0                      | –                             |
| Brussels sprouts                            | 43                         | 0.005–0.01       | 0                          | 0                      | –                             |
| Buckwheat and other pseudo-cereals          | 55                         | 0.01             | 0                          | 0                      | –                             |
| Carambolas                                   | 8                          | 0.005–0.01       | 0                          | 0                      | –                             |
| Carrots                                     | 112                        | 0.005–0.01       | 0                          | 0                      | –                             |
| Cassava roots/manioc                        | 9                          | 0.01             | 0                          | 0                      | –                             |
| Cauliflowers                                | 17                         | 0.005–0.01       | 0                          | 0                      | –                             |
| Celeriacs/turnip rooted celeries            | 26                         | 0.005–0.01       | 0                          | 0                      | –                             |
| Celeries                                    | 86                         | 0.005–0.01       | 0                          | 0                      | –                             |
| Celery leaves                               | 6                          | 0.005–0.01       | 0                          | 0                      | –                             |
| Chards/beet leaves                          | 22                         | 0.005–0.01       | 0                          | 0                      | –                             |
| Cherimoyas                                  | 4                          | 0.01             | 0                          | 0                      | –                             |
| Cherries (sweet)                            | 149                        | 0.005–0.01       | 0                          | 0                      | –                             |
| Chestnuts                                   | 3                          | 0.005–0.01       | 0                          | 0                      | –                             |
| Chili peppers                               | 11                         | 0.005–0.01       | 0                          | 0                      | –                             |
| Chinese cabbages/pe-tsai                    | 26                         | 0.005–0.01       | 0                          | 0                      | –                             |
| Chives                                      | 12                         | 0.005–0.01       | 0                          | 0                      | –                             |
| Cocoa beans                                 | 1                          | 0.01             | 0                          | 0                      | –                             |
| Coconuts                                    | 1                          | 0.005            | 0                          | 0                      | –                             |
| Common millet/proso millet                  | 2                          | 0.01             | 0                          | 0                      | –                             |
| Coriander leaves                            | 8                          | 0.005–0.01       | 0                          | 0                      | –                             |
| Coriander seed                              | 2                          | 0.01             | 0                          | 0                      | –                             |
| Courgettes                                  | 89                         | 0.005–0.01       | 0                          | 0                      | –                             |
| Crop (raw commodities)                                                                 | Number of samples analysed | Number of samples > LOQ(a) | Number of samples > MRL | Maximum residue level (mg/kg) |
|-----------------------------------------------------------------------------------------|-----------------------------|-----------------------------|-------------------------|-------------------------------|
| Cresses and other sprouts and shoots                                                    | 1                           | 0                           | 0                       | –                             |
| Crops or parts of crops exclusively used for animal feed production                     | 12                          | 0                           | 0                       | –                             |
| Cucumbers                                                                               | 168                         | 0.005-0.01                  | 0                       | –                             |
| Cultivated fungi                                                                        | 125                         | 0.005-0.01                  | 0                       | –                             |
| Currants (black, red and white)                                                         | 52                          | 0.005-0.01                  | 0                       | –                             |
| Escaroles/broad-leaved endives                                                          | 24                          | 0.005-0.01                  | 0                       | –                             |
| Figs                                                                                    | 33                          | 0.005-0.01                  | 0                       | –                             |
| Florence fennels                                                                       | 28                          | 0.005-0.01                  | 0                       | –                             |
| Garlic                                                                                  | 7                           | 0.01                        | 0                       | –                             |
| Gherkins                                                                                | 9                           | 0.01                        | 0                       | –                             |
| Ginger roots                                                                            | 8                           | 0.005-0.01                  | 0                       | –                             |
| Globe artichokes                                                                        | 15                          | 0.01                        | 0                       | –                             |
| Gooseberries (green, red and yellow)                                                    | 26                          | 0.005-0.01                  | 0                       | –                             |
| Granate apples/pomegranates                                                             | 60                          | 0.005-0.01                  | 0                       | –                             |
| Grape leaves and similar species                                                       | 1                           | 0.01                        | 0                       | –                             |
| Grapefruits                                                                             | 47                          | 0.005-0.01                  | 0                       | –                             |
| Hazelnuts/cobnuts                                                                       | 2                           | 0.01                        | 0                       | –                             |
| Head cabbages                                                                           | 138                         | 0.005-0.01                  | 0                       | –                             |
| Hemp seeds                                                                              | 2                           | 0.01                        | 0                       | –                             |
| Herbal infusions (leaves)                                                               | 2                           | 0.01                        | 0                       | –                             |
| Honey and other apicultural products                                                    | 50                          | 0.01                        | 0                       | –                             |
| Kaki/Japanese persimmons                                                                | 29                          | 0.005-0.01                  | 0                       | –                             |
| Kales                                                                                  | 10                          | 0.01                        | 0                       | –                             |
| Kiwi fruits (green, red, yellow)                                                        | 59                          | 0.005-0.01                  | 0                       | –                             |
| Kohlrabies                                                                              | 28                          | 0.005-0.01                  | 0                       | –                             |
| Kumquats                                                                                | 4                           | 0.005-0.01                  | 0                       | –                             |
| Lamb’s lettuces/corn salads                                                             | 40                          | 0.005-0.01                  | 0                       | –                             |
| Leaf vegetables, herbs and edible flowers                                               | 2                           | 0.01                        | 0                       | –                             |
| Leeks                                                                                  | 75                          | 0.005-0.01                  | 0                       | –                             |
| Lemons                                                                                 | 65                          | 0.005-0.01                  | 0                       | –                             |
| Lentils (dry)                                                                           | 19                          | 0.025                       | 0                       | –                             |
| Lettuces                                                                               | 310                         | 0.005-0.01                  | 0                       | –                             |
| Limes                                                                                  | 17                          | 0.005-0.01                  | 0                       | –                             |
| Linseeds                                                                               | 15                          | 0.01                        | 0                       | –                             |
| Litchis/lychees                                                                         | 3                           | 0.01                        | 0                       | –                             |
| Maize/corn                                                                              | 13                          | 0.01                        | 0                       | –                             |
| Mandarinis                                                                              | 92                          | 0.005-0.01                  | 0                       | –                             |
| Mangement                                                                              | 57                          | 0.005-0.01                  | 0                       | –                             |
| Maté                                                                                   | 1                           | 0.01                        | 0                       | –                             |
| Medlars                                                                                 | 1                           | 0.01                        | 0                       | –                             |
| Melons                                                                                 | 90                          | 0.005-0.01                  | 0                       | –                             |
| Millet                                                                                 | 12                          | 0.01                        | 0                       | –                             |
| Oat                                                                                    | 40                          | 0.01                        | 0                       | –                             |
| Oileseeds                                                                               | 2                           | 0.01                        | 0                       | –                             |
| Crop (raw commodities)                                      | Number of samples analysed | LOQ<sup>(a)</sup> (min–max) | Number of samples > LOQ<sup>(a)</sup> | Number of samples > MRL | Maximum residue level (mg/kg) |
|-------------------------------------------------------------|-----------------------------|-------------------------------|----------------------------------------|--------------------------|--------------------------------|
| Okra (lady’s fingers)                                       | 8                           | 0.005–0.01                    | 0                                      | 0                        | –                              |
| Onions                                                      | 25                          | 0.005–0.01                    | 0                                      | 0                        | –                              |
| Oranges                                                     | 75                          | 0.005–0.01                    | 0                                      | 0                        | –                              |
| Other cucurbits with inedible peel                         | 1                           | 0.01                          | 0                                      | 0                        | –                              |
| Other fresh herbs and edible flowers                        | 1                           | 0.01                          | 0                                      | 0                        | –                              |
| Other kinds of spinaches and similar leaves                 | 1                           | 0.01                          | 0                                      | 0                        | –                              |
| Papayas                                                     | 17                          | 0.005–0.01                    | 0                                      | 0                        | –                              |
| Parsley                                                     | 20                          | 0.005–0.01                    | 0                                      | 0                        | –                              |
| Parsley roots/Hamburg roots parsley                         | 5                           | 0.005–0.01                    | 0                                      | 0                        | –                              |
| Parsnips                                                    | 8                           | 0.01                          | 0                                      | 0                        | –                              |
| Passion fruits/maracujas                                   | 15                          | 0.005–0.01                    | 0                                      | 0                        | –                              |
| Peaches                                                     | 191                         | 0.005–0.01                    | 0                                      | 0                        | –                              |
| Peanuts/groundnuts                                          | 1                           | 0.01                          | 0                                      | 0                        | –                              |
| Peas (with peanuts)                                        | 211                         | 0.005–0.01                    | 0                                      | 0                        | –                              |
| Peppercorn (black, green and white)                         | 1                           | 0.01                          | 0                                      | 0                        | –                              |
| Persimmon                                                   | 5                           | 0.01                          | 0                                      | 0                        | –                              |
| Pineapples                                                  | 92                          | 0.005–0.01                    | 0                                      | 0                        | –                              |
| Pistachios                                                  | 2                           | 0.01                          | 0                                      | 0                        | –                              |
| Pitahaya (dragon fruit)                                     | 8                           | 0.01                          | 0                                      | 0                        | –                              |
| Plums                                                       | 100                         | 0.005–0.01                    | 0                                      | 0                        | –                              |
| Poppy seeds                                                 | 3                           | 0.01                          | 0                                      | 0                        | –                              |
| Potatoes                                                    | 256                         | 0.005–0.01                    | 21                                     | 0                        | 1.62                           |
| Prickly pears/cactus fruits                                 | 5                           | 0.005–0.01                    | 0                                      | 0                        | –                              |
| Pumpkin seeds                                               | 49                          | 0.01                          | 0                                      | 0                        | –                              |
| Pumpkins                                                    | 52                          | 0.005–0.01                    | 0                                      | 0                        | –                              |
| Quinces                                                     | 4                            | 0.005–0.01                    | 0                                      | 0                        | –                              |
| Radishes                                                    | 50                          | 0.005–0.01                    | 0                                      | 0                        | –                              |
| Rape seedseans/canola seeds                                 | 31                          | 0.01                          | 0                                      | 0                        | –                              |
| Raspberries (red and yellow)                                | 34                          | 0.005–0.01                    | 0                                      | 0                        | –                              |
| Rhubarbs                                                    | 1                            | 0.005                         | 0                                      | 0                        | –                              |
| Rice                                                        | 41                           | 0.01–0.025                    | 0                                      | 0                        | –                              |
| Roman rocket/rucola                                         | 45                           | 0.005–0.01                    | 0                                      | 0                        | –                              |
| Rose hips                                                   | 1                            | 0.01                          | 0                                      | 0                        | –                              |
| Rosemary                                                    | 2                            | 0.01                          | 0                                      | 0                        | –                              |
| Rye                                                         | 12                           | 0.01                          | 0                                      | 0                        | –                              |
| Sesame seeds                                                | 12                           | 0.01                          | 0                                      | 0                        | –                              |
| Shallots                                                    | 5                            | 0.01                          | 0                                      | 0                        | –                              |
| Sorghum                                                     | 12                           | 0.01                          | 0                                      | 0                        | –                              |
| Spices (seeds)                                              | 1                            | 0.01                          | 0                                      | 0                        | –                              |
| Spinaches                                                   | 159                          | 0.005–0.01                    | 1                                      | 1                        | 0.017                          |
| Spring onions/green onions and Welsh onions                 | 5                            | 0.005–0.01                    | 0                                      | 0                        | –                              |
| Strawberries                                                | 224                          | 0.005–0.01                    | 0                                      | 0                        | –                              |
| Strawberry leaves                                           | 1                            | 0.01                          | 0                                      | 0                        | –                              |
| Crop (raw commodities) | Number of samples analysed | LOQ<sup>(a)</sup> (min–max) | Number of samples > LOQ<sup>(a)</sup> | Number of samples > MRL | Maximum residue level (mg/kg) |
|------------------------|---------------------------|-----------------------------|-----------------------------------|------------------------|--------------------------------|
| Sugar beet roots       | 9                         | 0.01                        | 0                                 | 0                      | –                             |
| Sunflower seeds        | 14                        | 0.01                        | 0                                 | 0                      | –                             |
| Swedes/rutabagas       | 2                         | 0.01                        | 0                                 | 0                      | –                             |
| Sweet corn             | 2                         | 0.005                       | 0                                 | 0                      | –                             |
| Sweet peppers/bell peppers | 219                  | 0.005–0.01                  | 0                                 | 0                      | –                             |
| Sweet potatoes         | 22                        | 0.01                        | 0                                 | 0                      | –                             |
| Table grapes           | 224                       | 0.005–0.01                  | 0                                 | 0                      | –                             |
| Tarragon               | 5                         | 0.01                        | 0                                 | 0                      | –                             |
| Teas                   | 44                        | 0.01                        | 0                                 | 0                      | –                             |
| Thyme                  | 13                        | 0.01–0.025                  | 0                                 | 0                      | –                             |
| Tomatoes               | 215                       | 0.005–0.01                  | 0                                 | 0                      | –                             |
| Turnips                | 13                        | 0.01                        | 0                                 | 0                      | –                             |
| Walnuts                | 3                         | 0.01                        | 0                                 | 0                      | –                             |
| Watercresses           | 8                         | 0.01                        | 0                                 | 0                      | –                             |
| Watermelons            | 9                         | 0.005–0.01                  | 0                                 | 0                      | –                             |
| Wheat                  | 123                       | 0.01                        | 0                                 | 0                      | –                             |
| Wild fungi             | 22                        | 0.005–0.01                  | 0                                 | 0                      | –                             |
| Wine grapes            | 31                        | 0.01                        | 0                                 | 0                      | –                             |
| Yams                   | 1                         | 0.01                        | 0                                 | 0                      | –                             |

LOQ: limit of quantification; MRL: maximum residue levels.
(a): LOQ (mg/kg) of the reporting laboratories.
## Appendix C – Pesticide Residue Intake Model (PRIMo)

### 1,4-Dimethylnaphthalene (F)

| Commodity/group of commodities | MRLs set at the LOQ (%) | Commodity/group of commodities | MRLs set at the LOQ (%) |
|--------------------------------|------------------------|--------------------------------|------------------------|
| Wheat                          | 39%                    | Wine grapes                    | 38%                    |
| Sugar beet roots               | 35%                    | Sugar beet roots               | 35%                    |
| Apples                         | 54%                    | Other cereals                  | 28%                    |

### Normal mode

**Chronic risk assessment:** JMPR methodology (IEDI/TMDI)

| Calculated exposure (% of ADI) | Exposure resulting from MS diet (µg/kg bw per day) | Highest contributor to MS diet (in % of ADI) | 2nd contributor to MS diet (in % of ADI) | 3rd contributor to MS diet (in % of ADI) |
|--------------------------------|---------------------------------------------------|---------------------------------------------|------------------------------------------|------------------------------------------|
| USA infant                     | 11.04                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| Canada infant                  | 10.89                                             | 10% Wheat                                   | 9% Sugar beet roots                      | 8% Other cereals                         |
| NL infant                      | 11.28                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| NL child                       | 11.62                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| NL adult                       | 11.75                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| NL toddler                     | 12.03                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| PT infant                      | 11.92                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| PT child                       | 12.24                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| PT toddler                     | 12.56                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| FR infant                      | 12.03                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| FR child                       | 12.24                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| FR toddler                     | 12.56                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| DE infant                      | 12.03                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| DE child                       | 12.24                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| DE toddler                     | 12.56                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| IT infant                      | 12.03                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| IT child                       | 12.24                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| IT toddler                     | 12.56                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| IE infant                      | 12.03                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| IE child                       | 12.24                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| IE toddler                     | 12.56                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| SE infant                      | 12.03                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| SE child                       | 12.24                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| SE toddler                     | 12.56                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| ES infant                      | 12.03                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| ES child                       | 12.24                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| ES toddler                     | 12.56                                             | 11% Wheat                                   | 10% Sugar beet roots                     | 9% Other cereals                         |
| FR adult                       | 17.14                                             | 17% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |
| DE adult                       | 17.97                                             | 17% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |
| PT adult                       | 18.14                                             | 18% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |
| NL adult                       | 18.52                                             | 18% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |
| NL infant                      | 18.77                                             | 18% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |
| NL child                       | 19.06                                             | 19% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |
| NL toddler                     | 19.35                                             | 19% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |
| PT infant                      | 19.44                                             | 19% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |
| PT child                       | 19.74                                             | 19% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |
| PT toddler                     | 20.03                                             | 19% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |
| FR infant                      | 20.12                                             | 19% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |
| FR child                       | 20.42                                             | 19% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |
| FR toddler                     | 20.72                                             | 19% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |
| DE infant                      | 20.12                                             | 19% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |
| DE child                       | 20.42                                             | 19% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |
| DE toddler                     | 20.72                                             | 19% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |
| IT infant                      | 20.21                                             | 19% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |
| IT child                       | 20.51                                             | 19% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |
| IT toddler                     | 20.81                                             | 19% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |
| IE infant                      | 20.31                                             | 19% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |
| IE child                       | 20.61                                             | 19% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |
| IE toddler                     | 20.91                                             | 19% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |
| SE infant                      | 20.41                                             | 19% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |
| SE child                       | 20.71                                             | 19% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |
| SE toddler                     | 21.01                                             | 19% Sheep Liver                           | 15% Milk: Cattle                      | 13% Milk: Cattle                        |

### Conclusion

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of 1,4-Dimethylnaphthalene is unlikely to present a public health concern.

**DISCLAIMER:** Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.
As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

### Show results for all crops

#### Unprocessed commodities

| IESTI | Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|-------|------------------------|-------------|--------------------------|---------------------|------------------------|-------------|--------------------------|---------------------|

#### Processed commodities

| IESTI | Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|-------|------------------------|-------------|--------------------------|---------------------|------------------------|-------------|--------------------------|---------------------|

### Conclusion:

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

Results for children

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

Results for adults

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

Details – acute risk assessment/children

Details – acute risk assessment/adults
### 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                |
|                                 |                       |                        |
| **Risk assessment residue definition:** sum of 1,4-dimethylnaphthalene, M21 and its conjugates, expressed as 1,4-dimethylnaphthalene. |
| Potato culls                    | 7.11                  | **STMR**<sub>Mo</sub> × CF (1.9)<sup>(a)</sup> | 15.36 | **HR**<sub>Mo</sub> × CF (1.9)<sup>(a)</sup> |
| Potato process waste            | 142.26                | **STMR**<sub>Mo</sub> × CF (1.9) × default PF (20)<sup>(b)</sup> | 142.26 | **STMR**<sub>Mo</sub> × CF (1.9) × default PF (20)<sup>(b)</sup> |
| Potato dried pulp               | 270.29                | **STMR**<sub>Mo</sub> × CF (1.9) × default PF (38)<sup>(b)</sup> | 270.29 | **STMR**<sub>Mo</sub> × CF (1.9) × default PF (38)<sup>(b)</sup> |
| Alfalfa forage (green)          | 0.19                  | Default value × CF (1.9) | 0.19  | Default value × CF (1.9) |
| Alfalfa hay (fodder)            | 0.48                  | Default value × CF (1.9) × default PF (2.5)<sup>(b)</sup> | 0.48  | Default value × CF (1.9) × default PF (2.5)<sup>(b)</sup> |
| Alfalfa meal                    | 0.48                  | Default value × CF (1.9) × default PF (2.5)<sup>(b)</sup> | 0.48  | Default value × CF (1.9) × default PF (2.5)<sup>(b)</sup> |
| Alfalfa silage                  | 0.21                  | Default value × CF (1.9) × default PF (1.1)<sup>(b)</sup> | 0.21  | Default value × CF (1.9) × default PF (1.1)<sup>(b)</sup> |
| Barley forage                   | 0.19                  | Default value × CF (1.9) | 0.19  | Default value × CF (1.9) |
| Barley straw                    | 0.19                  | Default value × CF (1.9) | 0.19  | Default value × CF (1.9) |
| Barley silage                   | 0.25                  | Default value × CF (1.9) × default PF (1.3)<sup>(b)</sup> | 0.25  | Default value × CF (1.9) × default PF (1.3)<sup>(b)</sup> |
| Bean vines (fodder green)       | 0.19                  | Default value × CF (1.9) | 0.19  | Default value × CF (1.9) |
| Beet, mangel fodder             | 0.19                  | Default value × CF (1.9) | 0.19  | Default value × CF (1.9) |
| Beet, sugar tops                | 0.19                  | Default value × CF (1.9) | 0.19  | Default value × CF (1.9) |
| Cabbage, heads leaves           | 0.19                  | Default value × CF (1.9) | 0.19  | Default value × CF (1.9) |
| Clover forage                   | 0.19                  | Default value × CF (1.9) | 0.19  | Default value × CF (1.9) |
| Clover hay                      | 0.57                  | Default value × CF (1.9) × default PF (3)<sup>(b)</sup> | 0.57  | Default value × CF (1.9) × default PF (3)<sup>(b)</sup> |
| Clover silage                   | 0.19                  | Default value × CF (1.9) × default PF (1)<sup>(b)</sup> | 0.19  | Default value × CF (1.9) × default PF (1)<sup>(b)</sup> |
| Corn, field forage/silage       | 0.19                  | Default value × CF (1.9) | 0.19  | Default value × CF (1.9) |
| Corn, pop stover (fodder)       | 0.19                  | Default value × CF (1.9) | 0.19  | Default value × CF (1.9) |
| Cowpea forage                   | 0.19                  | Default value × CF (1.9) | 0.19  | Default value × CF (1.9) |
| Cowpea hay                      | 0.55                  | Default value × CF (1.9) × default PF (2.9)<sup>(b)</sup> | 0.55  | Default value × CF (1.9) × default PF (2.9)<sup>(b)</sup> |
| Grass forage (fresh)            | 0.19                  | Default value × CF (1.9) | 0.19  | Default value × CF (1.9) |
| Grass hay                       | 0.67                  | Default value × CF (1.9) × default PF (3.5)<sup>(b)</sup> | 0.67  | Default value × CF (1.9) × default PF (3.5)<sup>(b)</sup> |
| Grass silage                    | 0.3                   | Default value × CF (1.9) × default PF (1.6)<sup>(b)</sup> | 0.3   | Default value × CF (1.9) × default PF (1.6)<sup>(b)</sup> |
| Feed commodity        | Median dietary burden | Maximum dietary burden |
|----------------------|-----------------------|------------------------|
|                      | Input value (mg/kg)   | Comment (mg/kg)        |
|                      |                       | Comment (mg/kg)        |
| **Kale leaves**      | 0.19                  | Default value × CF (1.9) |
| (forage)             |                       | 0.19 Default value × CF (1.9) |
| **Lespedeza forage** | 0.19                  | Default value × CF (1.9) |
| **Lespedeza hay**    | 0.76                  | Default value × CF (1.9) × default PF (4)(b) |
|                      | 0.76                  | Default value × CF (1.9) × default PF (4)(b) |
| **Millet forage**    | 0.19                  | Default value × CF (1.9) |
| **Millet straw**     | 0.19                  | Default value × CF (1.9) |
| (fodder, dry)        | 0.19                  | Default value × CF (1.9) |
| **Oat forage**       | 0.19                  | Default value × CF (1.9) |
| **Oat hay**          | 0.57                  | Default value × CF (1.9) × default PF (3)(b) |
|                      | 0.57                  | Default value × CF (1.9) × default PF (3)(b) |
| **Oat straw**        | 0.19                  | Default value × CF (1.9) |
| **Pea vines**        | 0.19                  | Default value × CF (1.9) |
| (green)              | 0.19                  | Default value × CF (1.9) |
| **Pea hay**          | 0.67                  | Default value × CF (1.9) × default PF (3.5)(b) |
| (hay or fodder)      | 0.67                  | Default value × CF (1.9) × default PF (3.5)(b) |
| **Pea silage**       | 0.3                   | Default value × CF (1.9) × default PF (1.6)(b) |
|                      | 0.3                   | Default value × CF (1.9) × default PF (1.6)(b) |
| **Rape forage**      | 0.19                  | Default value × CF (1.9) |
| **Rice straw**       | 0.19                  | Default value × CF (1.9) |
| **Rye forage**       | 0.19                  | Default value × CF (1.9) |
| (greens)             | 0.19                  | Default value × CF (1.9) |
| **Rye straw**        | 0.19                  | Default value × CF (1.9) |
| **Sorghum forage**   | 0.19                  | Default value × CF (1.9) |
| **Sorghum, grain**   | 0.19                  | Default value × CF (1.9) |
| stover               | 0.19                  | Default value × CF (1.9) |
| **Sorghum silage**   | 0.11                  | Default value × CF (1.9) × default PF (0.6)(b) |
|                      | 0.11                  | Default value × CF (1.9) × default PF (0.6)(b) |
| **Soybean forage**   | 0.19                  | Default value × CF (1.9) |
| (green)              | 0.19                  | Default value × CF (1.9) |
| **Soybean hay**      | 0.29                  | Default value × CF (1.9) × default PF (1.5)(b) |
| (fodder)             | 0.29                  | Default value × CF (1.9) × default PF (1.5)(b) |
| **Soybean silage**   | 0.1                   | Default value × CF (1.9) × default PF (0.5)(b) |
|                      | 0.1                   | Default value × CF (1.9) × default PF (0.5)(b) |
| **Trefol hay**       | 0.19                  | Default value × CF (1.9) |
| **Trefol forage**    | 0.19                  | Default value × CF (1.9) |
| **Triticale forage** | 0.19                  | Default value × CF (1.9) |
| **Triticale hay**    | 0.55                  | Default value × CF (1.9) × default PF (2.9)(b) |
|                      | 0.55                  | Default value × CF (1.9) × default PF (2.9)(b) |
| **Triticale straw**  | 0.19                  | Default value × CF (1.9) |
| **Turnip tops**      | 0.19                  | Default value × CF (1.9) |
| (leaves)             | 0.19                  | Default value × CF (1.9) |
| **Vetch forage**     | 0.19                  | Default value × CF (1.9) |
| **Vetch hay**        | 0.53                  | Default value × CF (1.9) × default PF (2.8)(b) |
|                      | 0.53                  | Default value × CF (1.9) × default PF (2.8)(b) |
| **Wheat forage**     | 0.19                  | Default value × CF (1.9) |
| **Wheat hay**        | 0.67                  | Default value × CF (1.9) × default PF (3.5)(b) |
| (fodder dry)         | 0.67                  | Default value × CF (1.9) × default PF (3.5)(b) |
| Feed commodity                        | Median dietary burden | Maximum dietary burden |
|---------------------------------------|-----------------------|------------------------|
| **Input value** (mg/kg)               | **Comment**           | **Input value** (mg/kg) | **Comment** |
| Wheat straw                          | 0.19                  | Default value $\times$ CF (1.9) | 0.19         | Default value $\times$ CF (1.9) |
| Carrot culls                         | 0.19                  | Default value $\times$ CF (1.9) | 0.19         | Default value $\times$ CF (1.9) |
| Cassava/tapioca roots                | 0.19                  | Default value $\times$ CF (1.9) | 0.19         | Default value $\times$ CF (1.9) |
| Swede roots                          | 0.19                  | Default value $\times$ CF (1.9) | 0.19         | Default value $\times$ CF (1.9) |
| Turnip roots                         | 0.19                  | Default value $\times$ CF (1.9) | 0.19         | Default value $\times$ CF (1.9) |
| Barley grain                         | 0.19                  | Default value $\times$ CF (1.9) | 0.19         | Default value $\times$ CF (1.9) |
| Bean seed (dry)                      | 0.19                  | Default value $\times$ CF (1.9) | 0.19         | Default value $\times$ CF (1.9) |
| Corn, field grain (Maize)            | 0.19                  | Default value $\times$ CF (1.9) | 0.19         | Default value $\times$ CF (1.9) |
| Corn, pop grain                      | 0.19                  | Default value $\times$ CF (1.9) | 0.19         | Default value $\times$ CF (1.9) |
| Cotton undelinted seed               | 0.19                  | Default value $\times$ CF (1.9) | 0.19         | Default value $\times$ CF (1.9) |
| Cowpea seed                          | 0.19                  | Default value $\times$ CF (1.9) | 0.19         | Default value $\times$ CF (1.9) |
| Lupin seed                           | 0.19                  | Default value $\times$ CF (1.9) | 0.19         | Default value $\times$ CF (1.9) |
| Millet grain                         | 0.19                  | Default value $\times$ CF (1.9) | 0.19         | Default value $\times$ CF (1.9) |
| Oat grain                            | 0.19                  | Default value $\times$ CF (1.9) | 0.19         | Default value $\times$ CF (1.9) |
| Pea (Field pea) seed (dry)           | 0.19                  | Default value $\times$ CF (1.9) | 0.19         | Default value $\times$ CF (1.9) |
| Rye grain                            | 0.19                  | Default value $\times$ CF (1.9) | 0.19         | Default value $\times$ CF (1.9) |
| Sorghum grain                        | 0.19                  | Default value $\times$ CF (1.9) | 0.19         | Default value $\times$ CF (1.9) |
| Soybean seed                         | 0.19                  | Default value $\times$ CF (1.9) | 0.19         | Default value $\times$ CF (1.9) |
| Triticale grain                      | 0.19                  | Default value $\times$ CF (1.9) | 0.19         | Default value $\times$ CF (1.9) |
| Wheat grain                          | 0.19                  | Default value $\times$ CF (1.9) | 0.19         | Default value $\times$ CF (1.9) |
| Apple pomace, wet                    | 0.95                  | Default value $\times$ CF (1.9) $\times$ default PF (5)\(^{(b)}\) | 0.95         | Default value $\times$ CF (1.9) $\times$ default PF (5)\(^{(b)}\) |
| Beet, sugar dried pulp               | 3.42                  | Default value $\times$ CF (1.9) $\times$ default PF (18)\(^{(b)}\) | 3.42         | Default value $\times$ CF (1.9) $\times$ default PF (18)\(^{(b)}\) |
| Beet, sugar ensiled pulp             | 0.57                  | Default value $\times$ CF (1.9) $\times$ default PF (3)\(^{(b)}\) | 0.57         | Default value $\times$ CF (1.9) $\times$ default PF (3)\(^{(b)}\) |
| Beet, sugar molasses                 | 5.32                  | Default value $\times$ CF (1.9) $\times$ default PF (28)\(^{(b)}\) | 5.32         | Default value $\times$ CF (1.9) $\times$ default PF (28)\(^{(b)}\) |
| Brewer’s grain dried                 | 0.63                  | Default value $\times$ CF (1.9) $\times$ default PF (3.3)\(^{(b)}\) | 0.63         | Default value $\times$ CF (1.9) $\times$ default PF (3.3)\(^{(b)}\) |
| Canola (Rape seed) meal              | 0.38                  | Default value $\times$ CF (1.9) $\times$ default PF (2)\(^{(b)}\) | 0.38         | Default value $\times$ CF (1.9) $\times$ default PF (2)\(^{(b)}\) |
| Citrus dried pulp                    | 1.9                   | Default value $\times$ CF (1.9) $\times$ default PF (10)\(^{(b)}\) | 1.9          | Default value $\times$ CF (1.9) $\times$ default PF (10)\(^{(b)}\) |
| Coconut meal                         | 0.29                  | Default value $\times$ CF (1.9) $\times$ default PF (1.5)\(^{(b)}\) | 0.29         | Default value $\times$ CF (1.9) $\times$ default PF (1.5)\(^{(b)}\) |
| Corn, field milled by-pdts           | 0.19                  | Default value $\times$ CF (1.9) $\times$ default PF (1)\(^{(b)}\) | 0.19         | Default value $\times$ CF (1.9) $\times$ default PF (1)\(^{(b)}\) |
| Corn, field hominy meal              | 1.14                  | Default value $\times$ CF (1.9) $\times$ default PF (6)\(^{(b)}\) | 1.14         | Default value $\times$ CF (1.9) $\times$ default PF (6)\(^{(b)}\) |
| Corn, field gluten feed              | 0.48                  | Default value $\times$ CF (1.9) $\times$ default PF (2.5)\(^{(b)}\) | 0.48         | Default value $\times$ CF (1.9) $\times$ default PF (2.5)\(^{(b)}\) |
| Corn, field gluten, meal             | 0.19                  | Default value $\times$ CF (1.9) $\times$ default PF (1)\(^{(b)}\) | 0.19         | Default value $\times$ CF (1.9) $\times$ default PF (1)\(^{(b)}\) |
### D.2. Consumer risk assessment

| Commodity                     | Chronic risk assessment |
|-------------------------------|-------------------------|
| **Risk assessment residue definition 1**: sum of 1,4-dimethylnaphthalene, M21 and its conjugates, expressed as 1,4-dimethylnaphthalene |                      |
| Potato                        | 7.11 STMR<sub>Mo</sub> × CF (1.9) (tentative) |
| All other commodities included in Annex I of Reg. (EC) 396/2005 | 0.19 Default value<sup>(a)</sup> × CF (1.9) (tentative) |

**Risk assessment residue definition 2**: sum of 1,4-dimethylnaphthalene and its metabolite M23 free and conjugated, expressed as 1,4-dimethylnaphthalene

| Commodity                     | Input value (mg/kg) | Comment                              |
|-------------------------------|--------------------|--------------------------------------|
| Potato                        | 7.11               | STMR<sub>Mo</sub> × CF (1.9) (tentative) |
| All other commodities included in Annex I of Reg. (EC) 396/2005 | 0.19               | Default value<sup>(a)</sup> × CF (1.9) (tentative) |

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STMR<sub>Mo</sub>: median residue expressed according to the residue definition for monitoring; HR<sub>Mo</sub>: highest residue expressed according to the residue definition for monitoring; CF: conversion factor; PF: processing factor.

(a): Since potatoes are only fed to swine and poultry after cooking, processing factors for unpeeled boiled potatoes should have been used to recalculate the potato culls input values. As no reliable processing factors are available, these values were not refined.

(b): In the absence of processing factors supported by data, default processing factors were included in the calculation to consider the potential concentration of residues in these commodities.
| Commodity                  | Input value (mg/kg) | Chronic risk assessment                                                                 |
|----------------------------|---------------------|----------------------------------------------------------------------------------------|
| Swine meat                 | 0.06                | $0.8 \times \text{STMR muscle (tentative)} + 0.2 \times \text{STMR fat (tentative)}$     |
| Swine fat                  | 0.22                | STMR (tentative)                                                                        |
| Swine liver                | 1.27                | STMR (tentative)                                                                        |
| Swine kidney               | 1.04                | STMR (tentative)                                                                        |
| Bovine and equine meat     | 0.14                | $0.8 \times \text{STMR muscle (tentative)} + 0.2 \times \text{STMR fat (tentative)}$     |
| Bovine and equine fat      | 0.57                | STMR (tentative)                                                                        |
| Bovine and equine liver    | 2.75                | STMR (tentative)                                                                        |
| Bovine and equine kidney   | 2.01                | STMR (tentative)                                                                        |
| Sheep and goat meat       | 0.16                | $0.8 \times \text{STMR muscle (tentative)} + 0.2 \times \text{STMR fat (tentative)}$     |
| Sheep and goat fat        | 0.65                | STMR (tentative)                                                                        |
| Sheep and goat liver      | 3.12                | STMR (tentative)                                                                        |
| Sheep and goat kidney     | 2.25                | STMR (tentative)                                                                        |
| Poultry meat              | 0.17                | $0.9 \times \text{STMR muscle (tentative)} + 0.1 \times \text{STMR fat (tentative)}$      |
| Poultry fat               | 0.62                | STMR (tentative)                                                                        |
| Poultry liver             | 0.40                | STMR (tentative)                                                                        |
| Cattle and horse milk     | 0.38                | STMR (tentative)                                                                        |
| Sheep and goat milk       | 0.44                | STMR (tentative)                                                                        |
| Birds eggs                | 0.10                | STMR (tentative)                                                                        |

STMR: supervised trials median residue; STMR$_{Mo}$: median residues expressed according to the residue definition for monitoring; CF: conversion factor.
(a): Default value used to cover the possible natural background levels of 1,4-dimethylnaphthalene in plants (EFSA, 2014).
Appendix E – Decision tree for deriving MRL recommendations

Evaluation of the GAPs and available residues data at EU level

- GAP of DB ≥ 0.1 mg/kg DM in EU
  - Yes
  - No
  - No

- RD-RA derived for this commodity?
  - Yes
  - No
  - No

- MRL And RA derived in Section 3?
  - Yes
  - No
  - No

- MRL fully supported by data?
  - Yes
  - No
  - No

Consumer risk assessment for GAPs evaluated at EU level – EU scenarios

- Not considered for the RA.
- Not considered for the RA.
- Current EU MRL is included in the RA.
- Tentative median/highest values are included in the RA.
- Median/highest values are included in the RA.

- Risk identified?
  - Yes
  - No
  - No

- Fall-back MRL available?
  - Yes
  - No
  - No

Recommendations resulting from EU authorisations and import tolerances

- Specific LOQ or default MRL?
- Specific LOQ or default MRL?
- Specific LOQ or default MRL?
- Maintain current EU MRL?
- Specific LOQ or default MRL?
- Establish tentative EU MRL?
- Specific LOQ or default MRL?
- MRL is recommended.
Comparison of the EU recommendation with the existing CXL

- CXL available?
  - Yes
    - RD comparable?
      - Yes
        - CXL higher?
          - Yes
    - No
      - No

- CXL higher?
  - Yes
    - RD comparable?
      - Yes
  - No
    - No

Consumer risk assessment with consideration of the existing CXL

- CXL supported by data?
  - Yes
    - Risk identified?
      - Yes
    - No
    - No
  - No
    - Risk identified?
      - Yes
    - No

Recommendations with consideration of the existing CXL

- CXL higher?
  - Yes
    - RD comparable?
      - Yes
    - No
      - No
    - No
  - No
    - RD comparable?
      - Yes
    - No
      - No

- Input values for the RA remain unchanged.
- CXL is included in the RA.
- Codex median/ highest residues are included in the RA.
- Risk identified?
  - Yes
  - No

- Maintain EU recommendation indicating that no CXL is available.
- Maintain EU recommendation indicating CXL is not compatible.
- Maintain EU recommendation indicating that CXL is covered.
- Maintain EU recommendation; higher CXL is not safe for consumer.
- Maintain current CXL or EU recommendation?
- Maintain EU recommendation; higher CXL is not safe for consumer.
- CXL is recommended; EU recommendation is covered as well.
## Appendix F – Used compound codes

| Code/trivial name(a)         | IUPAC name/SMILES notation/InChiKey(b)                                                                 | Structural formula(c) |
|-----------------------------|------------------------------------------------------------------------------------------------------|-----------------------|
| 1,4-dimethylnaphthalene     | 1,4-dimethylnaphthalene<br>APQSQLNWAILLK-UHFFFAOYSA-N<br>Cc1ccc(C)c2cccc12                         | ![1,4-dimethylnaphthalene](image) |
| **M21**                     | 1-hydroxymethyl-1-methylnaphthalene<br>(4-methylnaphthalen-1-yl)methanol<br>RRSGUDDGNKMFRY-UHFFFAOYSA-N<br>Cc1ccc(CO)c2cccc12 | ![1-hydroxymethyl-1-methylnaphthalene](image) |
| Glycoside conjugates of M21 | One example of several possible glycoside structures: (4-methylnaphthalen-1-yl)methyl L-glucopyranoside<br>VXPLOPHXPXBSS-KYLMASSSA-N<br>Cc1ccc(COC2O[C@@H](CO)[C@H](O)[C@@H](O)[C@@H]2O)c2cccc12 | ![Glycoside conjugates of M21](image) |
| **M23**                     | 4-methylnaphthalene-1-carboxylic acid<br>SIVYRLBDAPKADZ-UHFFFAOYSA-N<br>O=C(O)c1ccc(C)c2cccc12   | ![4-methylnaphthalene-1-carboxylic acid](image) |
| Gly-M23                     | N-(4-methylnaphthalene-1-carbonyl)glycine<br>ONRMQUIJXGTWIZ-UHFFFAOYSA-N<br>O=C(O)CNC(=O)c1ccc(C)c2cccc12 | ![Gly-M23](image) |
| Orn-M23                     | One possible structures of the conjugate: N\(^5\)-(4-methylnaphthalene-1-carbonyl)ornithine<br>NYTODGAWHRBOAO-UHFFFAOYSA-N<br>O=C(O)C(N)CCCNC(=O)c1ccc(C)c2cccc12 | ![Orn-M23](image) |
| 1,4-dimethylnaphthol        | One example of several possible structures (position of OH group not determined):<br>1,4-dimethylnaphthalen-2-ol<br>INBDACYHPDXEOQ-UHFFFAOYSA-N<br>Cc1ccc(O)c(C)c2cccc12 | ![1,4-dimethylnaphthol](image) |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
Review of the existing MRLs for 1,4-dimethylnaphthalene

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2019.1.3 ACD/Labs 2019 Release (File version N05E41, Build 111418, 3 September 2019).
(c): ACD/ChemSketch 2019.1.3 ACD/Labs 2019 Release (File version C05H41, Build 111302, 27 August 2019).