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Review of the existing maximum residue levels for 1,4-dimethylnaphthalene according to Article 12 of Regulation (EC) No 396/2005

European Food Safety Authority (EFSA),
Maria Anastassiadou, Giulia Bellisai, Giovanni Bernasconi, Alba Brancato,
Luis Carrasco Cabrera, Lucien Ferreira, Luna Greco, Samira Jarrah, Aija Kazocina,
Renata Leuschner, Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnor Pedersen,
Hermine Reich, Miguel Santos, Alessia Pia Scarlato, Anne Theobald, Benedicte Vagenende and
Alessia Verani

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.

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

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Correspondence: pesticides.mrl@efsa.europa.eu

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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

[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	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, ethephon, 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[8] 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 DAT_1 and 30 DAT_6, 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_6, 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.

[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-dimathylnaphthalene, 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 methylnaphthalenes 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 spinaches 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 spinaches (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 available, 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 (1× 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	
				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
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

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	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[(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.

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Abbreviations

a.i.	active ingredient
a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose

BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
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	mass spectrometry detector
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

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 G or I[(a)]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)[(d)]	Remarks
				Type[(b)]	Conc. a.s.	Method kind	Range of growth stages & season[(c)]	Number min–max	Min interval between applications (days)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
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	[^{14}C]-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 DAT_1, 30 DAT_6	[^{14}C]-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 massspectrometry; 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
				Value	Unit		
	High water content	Potato (peel and pulp)	–18	5	Months	1,4-dimethylnaphthalene	Netherlands (2013), EFSA (2013)
			–18	9	Days	Metabolites 1-hydroxymethyl-4-naphthalene (M21) and 4-methyl-1-naphthoic 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 **RA:** –	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	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.
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	No study available and not required.

B.1.2.3. Processing factors

Processed commodity	Number of valid studies[(a)]	Processing Factor (PF)		CF_P[(b)]	Comment/Source
		Individual values	Median PF		
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); CF_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	Median	Maximum				
Cattle (all)	14.103	14.579	485.25	497.63	Dairy cattle	Potato, processed waste	Yes	–
Cattle (dairy only)	14.103	14.579	366.67	379.05	Dairy cattle	Potato, processed waste	Yes	–
Sheep (all)	16.170	16.583	485.10	497.48	Ram/Ewe	Potato, processed waste	Yes	–
Sheep (ewe only)	16.170	16.583	485.10	497.48	Ram/Ewe	Potato, processed waste	Yes	–
Swine (all)	5.887	6.363	255.11	275.73	Swine (breeding)	Potato, processed waste	Yes	Potatoes are only fed to swine and poultry after cooking and since no reliable processing and conversion factors could be derived, intakes were not refined.
Poultry (all)	4.599	4.891	65.16	69.28	Poultry broiler	Potato, dried pulp	Yes	
Poultry (layer only)	3.411	3.693	49.85	53.97	Poultry layer	Potato, dried pulp	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'.

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	[^{14}C]-1,4-dimethylnaphthalene (Netherlands, 2013; EFSA, 2013)
	Lactating goats	0.39	7	[^{14}C]-1,4-dimethylnaphthalene (Netherlands, 2013; EFSA, 2013)
	Pigs	–	–	Not available and not required.

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[9]

Animal commodity	Residues at the closest feeding level (mg/kg)		Estimated value at 1N		MRL proposal (mg/kg)
	Mean	Highest	$STMR_{Mo}$[(a)] (mg/kg)	HR_{Mo}[(b)] (mg/kg)	
Cattle (all) – Closest feeding level (19.14 mg/kg bw; 1.3 N rate)[(d)]					
Muscle	0.03	0.04	0.03	0.03	0.04 (tentative)[(c)]
Fat	0.78	1.27	0.57	0.95	1 (tentative)[(c)]
Liver	3.65	3.79	2.75	2.94	3 (tentative)[(c)]
Kidney	2.60	2.81	2.01	2.23	3 (tentative)[(c)]
Cattle (dairy only) – Closest feeding level (19.14 mg/kg bw; 1.3 N rate)[(d)]					
Milk[(e)]	0.52	0.52	0.38	0.40	0.4 (tentative)[(c)]
Sheep (all)[(f)] – Closest feeding level (19.14 mg/kg bw; 1.2 N rate)[(d)]					
Muscle	0.03	0.04	0.03	0.03	0.04 (tentative)[(c)]
Fat	0.78	1.27	0.65	1.09	1.5 (tentative)[(c)]
Liver	3.65	3.79	3.12	3.31	4 (tentative)[(c)]
Kidney	2.60	2.81	2.25	2.49	3 (tentative)[(c)]
Sheep (ewe only)[(f)] – Closest feeding level (19.14 mg/kg bw; 1.2 N rate)[(d)]					
Milk[(e)]	0.52	0.52	0.44	0.45	0.5 (tentative)[(c)]
Swine (all)[(f)] – Closest feeding level (3.97 mg/kg bw; 0.6 N rate)[(d)]					
Muscle	0.03	0.03	0.03	0.03	0.03 (tentative)[(c)]
Fat	0.13	0.20	0.22	0.38	0.4 (tentative)[(c)]
Liver	0.93	0.94	1.27	1.40	1.5 (tentative)[(c)]
Kidney	0.81	0.90	1.04	1.20	1.5 (tentative)[(c)]
Poultry (all) – Closest feeding level (2.4 mg/kg bw; 0.5 N rate)[(d)]					
Muscle	0.06	0.09	0.12	0.16	0.2 (tentative)[(c)]
Fat	0.34	0.38	0.62	0.69	0.7 (tentative)[(c)]
Liver	0.17	0.30	0.40	0.56	0.6 (tentative)[(c)]
Poultry (layer only) – Closest feeding level (2.4 mg/kg bw; 0.6 N rate)[(d)]					
Eggs[(g)]	0.04	0.05	0.10	0.13	0.15 (tentative)[(c)]

bw: body weight; $STMR_{Mo}$: median residue expressed according to the residue definition for monitoring; HR_{Mo}: 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).

[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.

ADI	0.1 mg/kg bw per day (European Commission, 2013)
TMDI according to EFSA PRIMo	Not assessed in this review.
NTMDI, according to (to be specified)	Not assessed in this review.
Highest IEDI, according to EFSA PRIMo (rev.3.1)	65% ADI (NL toddler)
NEDI (% ADI)	Not assessed in this review.
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).

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

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

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

B.4. Proposed MRLs

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				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

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				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[(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.

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	LOQ[a] (min–max)	Number of samples > LOQ[a]	Number of samples > MRL	Maximum residue level (mg/kg)
Cresses and other sprouts and shoots	1	0.01	0	0	–
Crops or parts of crops exclusively used for animal feed production	12	0.01	0	0	–
Cucumbers	168	0.005–0.01	0	0	–
Cultivated fungi	125	0.005–0.01	0	0	–
Currants (black, red and white)	52	0.005–0.01	0	0	–
Escaroles/broad-leaved endives	24	0.005–0.01	0	0	–
Figs	33	0.005–0.01		0	–
Florence fennels	28	0.005–0.01	0	0	–
Garlic	7	0.01	0	0	–
Gherkins	9	0.01	0	0	–
Ginger roots	8	0.005–0.01	0	0	–
Globe artichokes	15	0.01	0	0	–
Gooseberries (green, red and yellow)	26	0.005–0.01	0	0	–
Granate apples/pomegranates	60	0.005–0.01	0	0	–
Grape leaves and similar species	1	0.01	0	0	–
Grapefruits	47	0.005–0.01	0	0	–
Hazelnuts/cobnuts	2	0.01	0	0	–
Head cabbages	138	0.005–0.01	0	0	–
Hemp seeds	2	0.01	0	0	–
Herbal infusions (leaves)	2	0.01	0	0	–
Honey and other apicultural products	50	0.01	0	0	–
Kaki/Japanese persimmons	29	0.005–0.01	0	0	–
Kales	10	0.01	0	0	–
Kiwi fruits (green, red, yellow)	59	0.005–0.01	0	0	–
Kohlrabies	28	0.005–0.01	0	0	–
Kumquats	4	0.005–0.01	0	0	–
Lamb's lettuces/corn salads	40	0.005–0.01		0	–
Leaf vegetables, herbs and edible flowers	2	0.01	0	0	–
Leeks	75	0.005–0.01	0	0	–
Lemons	65	0.005–0.01	0	0	–
Lentils (dry)	19	0.025	0	0	–
Lettuces	310	0.005–0.01	0	0	–
Limes	17	0.005–0.01	0	0	–
Linseeds	15	0.01	0	0	–
Litchis/lychees	3	0.01	0	0	–
Maize/corn	13	0.01	0	0	–
Mandarins	92	0.005–0.01	0	0	–
Mangoes	57	0.005–0.01	0	0	–
Maté	1	0.01	0	0	–
Medlars	1	0.01	0	0	–
Melons	90	0.005–0.01	0	0	–
Millet	12	0.01	0	0	–
Oat	40	0.01	0	0	–
Oilseeds	2	0.01	0	0	–

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)
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	–
Pears	211	0.005–0.01	0	0	–
Peas (with pods)	23	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	–
Rapeseeds/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[a] (min–max)	Number of samples > LOQ[a]	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)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

1,4-Dimethylnaphthalene (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw per day):	0.1	ARfD (mg/kg bw):	Not necessary
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2013	Year of evaluation:	2013

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
65%	NL toddler	64.95	30%	Potatoes	23%	Milk: Cattle	2%	Apples		54%
42%	UK infant	41.59	23%	Potatoes	15%	Milk: Cattle	0.5%	Wheat		39%
41%	NL child	40.99	24%	Potatoes	9%	Milk: Cattle	2%	Sugar beet roots		35%
41%	PT general	40.88	38%	Potatoes	0.7%	Wheat	0.5%	Wine grapes		38%
38%	SE general	38.02	30%	Potatoes	5%	Milk: Cattle	0.6%	Wheat		35%
37%	UK toddler	36.59	25%	Potatoes	8%	Milk: Cattle	0.7%	Wheat		33%
36%	GEMS/Food G11	36.00	28%	Potatoes	3%	Milk: Cattle	0.7%	Soyabeans		31%
36%	FI 3 yr	35.84	34%	Potatoes	0.3%	Bananas	0.2%	Wheat		34%
35%	RO general	35.01	27%	Potatoes	4%	Milk: Cattle	1.0%	Wheat		31%
35%	GEMS/Food G08	34.94	28%	Potatoes	2%	Milk: Cattle	0.8%	Wheat		31%
35%	GEMS/Food G07	34.54	27%	Potatoes	2%	Milk: Cattle	0.8%	Wheat		30%
33%	DE child	33.24	19%	Potatoes	8%	Milk: Cattle	2%	Apples		26%
33%	GEMS/Food G15	33.11	25%	Potatoes	3%	Milk: Cattle	0.9%	Wheat		29%
29%	FI 6 yr	29.40	28%	Potatoes	0.2%	Wheat	0.1%	Bananas		28%
29%	FR toddler 2 3 yr	28.79	13%	Potatoes	11%	Milk: Cattle	0.6%	Apples		25%
28%	GEMS/Food G10	28.39	21%	Potatoes	2%	Milk: Cattle	0.7%	Wheat		24%
27%	DK child	26.77	17%	Potatoes	5%	Milk: Cattle	1%	Rye		23%
26%	LT adult	25.71	23%	Potatoes	2%	Milk: Cattle	0.4%	Apples		24%
26%	PL general	25.63	24%	Potatoes	0.4%	Apples	0.2%	Tomatoes		24%
25%	FR child 3 15 yr	24.69	11%	Potatoes	9%	Milk: Cattle	0.9%	Wheat		20%
24%	NL general	23.73	17%	Potatoes	3%	Milk: Cattle	0.5%	Sugar beet roots		21%
23%	IE adult	23.32	16%	Potatoes	2%	Milk: Cattle	0.7%	Sheep: Liver		19%
22%	FR infant	21.96	14%	Potatoes	6%	Milk: Cattle	0.3%	Apples		20%
22%	GEMS/Food G06	21.70	14%	Potatoes	1%	Wheat	1.0%	Milk: Cattle		16%
22%	ES child	21.65	13%	Potatoes	5%	Milk: Cattle	0.8%	Wheat		19%
17%	DE general	17.14	9%	Potatoes	5%	Milk: Cattle	0.8%	Sugar beet roots		14%
16%	DE women 14-50 yr	16.47	8%	Potatoes	5%	Milk: Cattle	0.9%	Sugar beet roots		13%
13%	DK adult	12.86	9%	Potatoes	2%	Milk: Cattle	0.2%	Wheat		11%
13%	UK vegetarian	12.84	10%	Potatoes	1%	Milk: Cattle	0.4%	Wheat		11%
13%	UK adult	12.78	10%	Potatoes	1%	Milk: Cattle	0.3%	Wheat		11%
11%	ES adult	11.04	7%	Potatoes	2%	Milk: Cattle	0.4%	Wheat		9%
11%	FI adult	10.59	8%	Potatoes	1%	Coffee beans	0.1%	Rye		8%
9%	FR adult	9.48	5%	Potatoes	2%	Milk: Cattle	0.4%	Wine grapes		7%
9%	FI toddler	9.32	6%	Potatoes	1%	Wheat	0.3%	Other cereals		6%
6%	IT adult	6.46	4%	Potatoes	0.8%	Wheat	0.2%	Tomatoes		4%
6%	IE child	6.41	4%	Potatoes	1%	Milk: Cattle	0.2%	Wheat		6%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of 1,4-Dimethylnaphthalene (F) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

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

Show results for all crops

Unprocessed commodities

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

Processed commodities

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

Conclusion:

Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of 1,4-dimethylnaphthalene, M21 and its conjugates, expressed as 1,4-dimethylnaphthalene				
Potato culls	7.11	$STMR_{Mo}$ × CF (1.9)[(a)]	15.36	HR_{Mo} × CF (1.9)[(a)]
Potato process waste	142.26	$STMR_{Mo}$ × CF (1.9) × default PF (20)[(b)]	142.26	$STMR_{Mo}$ × CF (1.9) × default PF (20)[(b)]
Potato dried pulp	270.29	$STMR_{Mo}$ × CF (1.9) × default PF (38)[(b)]	270.29	$STMR_{Mo}$ × CF (1.9) × default PF (38)[(b)]
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)[(b)]	0.48	Default value × CF (1.9) × default PF (2.5)[(b)]
Alfalfa meal	0.48	Default value × CF (1.9) × default PF (2.5)[(b)]	0.48	Default value × CF (1.9) × default PF (2.5)[(b)]
Alfalfa silage	0.21	Default value × CF (1.9) × default PF (1.1)[(b)]	0.21	Default value × CF (1.9) × default PF (1.1)[(b)]
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)[(b)]	0.25	Default value × CF (1.9) × default PF (1.3)[(b)]
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)[(b)]	0.57	Default value × CF (1.9) × default PF (3)[(b)]
Clover silage	0.19	Default value × CF (1.9) × default PF (1)[(b)]	0.19	Default value × CF (1.9) × default PF (1)[(b)]
Corn, field forage/silage	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Corn, field stover (fodder)	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)[(b)]	0.55	Default value × CF (1.9) × default PF (2.9)[(b)]
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)[(b)]	0.67	Default value × CF (1.9) × default PF (3.5)[(b)]
Grass 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)]

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Kale leaves (forage)	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Lespedeza forage	0.19	Default value × CF (1.9)	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)	0.19	Default value × CF (1.9)
Millet straw (fodder, dry)	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Oat forage	0.19	Default value × CF (1.9)	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)	0.19	Default value × CF (1.9)
Pea vines (green)	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Pea hay (hay or fodder)	0.67	Default value × CF (1.9) × default PF (3.5)[(b)]	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)	0.19	Default value × CF (1.9)
Rice straw	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Rye forage (greens)	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Rye straw	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Sorghum forage	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Sorghum, grain stover	0.19	Default value × CF (1.9)	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 (green)	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Soybean hay (fodder)	0.29	Default value × CF (1.9) × default PF (1.5)[(b)]	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)]
Trefoil forage	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Trefoil hay	0.53	Default value × CF (1.9) × default PF (2.8)[(b)]	0.53	Default value × CF (1.9) x default PF (2.8)[(b)]
Triticale forage	0.19	Default value × CF (1.9)	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)	0.19	Default value × CF (1.9)
Turnip tops (leaves)	0.19	Default value × CF (1.9)	0.19	Default value x CF (1.9)
Vetch forage	0.19	Default value × CF (1.9)	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)	0.19	Default value × CF (1.9)
Wheat hay (fodder dry)	0.67	Default value × CF (1.9) × default PF (3.5)[(b)]	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 × CF (1.9)	0.19	Default value × CF (1.9)
Carrot culls	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Cassava/tapioca roots	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Swede roots	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Turnip roots	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Barley grain	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Bean seed (dry)	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Corn, field (Maize) grain	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Corn, pop grain	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Cotton undelinted seed	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Cowpea seed	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Lupin seed	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Millet grain	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Oat grain	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Pea (Field pea) seed (dry)	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Rye grain	0.19	Default value x CF (1.9)	0.19	Default value × CF (1.9)
Sorghum grain	0.19	Default value × CF (1.9)	0.19	Default value x CF (1.9)
Soybean seed	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Triticale grain	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Wheat grain	0.19	Default value × CF (1.9)	0.19	Default value × CF (1.9)
Apple pomace, wet	0.95	Default value × CF (1.9) × default PF (5)[(b)]	0.95	Default value × CF (1.9) × default PF (5)[(b)]
Beet, sugar dried pulp	3.42	Default value × CF (1.9) × default PF (18)[(b)]	3.42	Default value × CF (1.9) × default PF (18)[(b)]
Beet, sugar ensiled pulp	0.57	Default value × CF (1.9) × default PF (3)[(b)]	0.57	Default value × CF (1.9) × default PF (3)[(b)]
Beet, sugar molasses	5.32	Default value × CF (1.9) × default PF (28)[(b)]	5.32	Default value × CF (1.9) × default PF (28)[(b)]
Brewer's grain dried	0.63	Default value × CF (1.9) × default PF (3.3)[(b)]	0.63	Default value × CF (1.9) × default PF (3.3)[(b)]
Canola (Rape seed) meal	0.38	Default value × CF (1.9) × default PF (2)[(b)]	0.38	Default value × CF (1.9) × default PF (2)[(b)]
Citrus dried pulp	1.9	Default value × CF (1.9) × default PF (10)[(b)]	1.9	Default value × CF (1.9) × default PF (10)[(b)]
Coconut meal	0.29	Default value × CF (1.9) × default PF (1.5)[(b)]	0.29	Default value × CF (1.9) × default PF (1.5)[(b)]
Corn, field milled by-pdts	0.19	Default value × CF (1.9) × default PF (1)[(b)]	0.19	Default value × CF (1.9) × default PF (1)[(b)]
Corn, field hominy meal	1.14	Default value × CF (1.9) × default PF (6)[(b)]	1.14	Default value × CF (1.9) × default PF (6)[(b)]
Corn, field gluten feed	0.48	Default value × CF (1.9) × default PF (2.5)[(b)]	0.48	Default value × CF (1.9) × default PF (2.5)[(b)]
Corn, field gluten, meal	0.19	Default value × CF (1.9) × default PF (1)[(b)]	0.19	Default value × CF (1.9) × default PF (1)[(b)]

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Cotton meal	0.25	Default value × CF (1.9) × default PF (1.3)[(b)]	0.25	Default value × CF (1.9) × default PF (1.3)[(b)]
Distiller's grain dried	0.63	Default value × CF (1.9) × default PF (3.3)[(b)]	0.63	Default value × CF (1.9) × default PF (3.3)[(b)]
Flaxseed/ Linseed meal	0.38	Default value × CF (1.9) × default PF (2)[(b)]	0.38	Default value × CF (1.9) × default PF (2)[(b)]
Lupin seed meal	0.21	Default value × CF (1.9) × default PF (1.1)[(b)]	0.21	Default value × CF (1.9) × default PF (1.1)[(b)]
Palm (hearts) kernel meal	0.38	Default value × CF (1.9) × default PF (2)[(b)]	0.38	Default value × CF (1.9) × default PF (2)[(b)]
Peanut meal	0.38	Default value × CF (1.9) × default PF (2)[(b)]	0.38	Default value × CF (1.9) × default PF (2)[(b)]
Rape meal	0.38	Default value × CF (1.9) × default PF (2)[(b)]	0.38	Default value × CF (1.9) × default PF (2)[(b)]
Rice bran/ pollard	1.9	Default value × CF (1.9) × default PF (10)[(b)]	1.9	Default value × CF (1.9) × default PF (10)[(b)]
Safflower meal	0.38	Default value × CF (1.9) × default PF (2)[(b)]	0.38	Default value × CF (1.9) × default PF (2)[(b)]
Soybean meal	0.25	Default value × CF (1.9) × default PF (1.3)[(b)]	0.25	Default value × CF (1.9) × default PF (1.3)[(b)]
Soybean hulls	2.47	Default value × CF (1.9) × default PF (13)[(b)]	2.47	Default value × CF (1.9) × default PF (13)[(b)]
Sugarcane molasses	6.08	Default value × CF (1.9) × default PF (32)[(b)]	6.08	Default value × CF (1.9) × default PF (32)[(b)]
Sunflower meal	0.38	Default value × CF (1.9) × default PF (2)[(b)]	0.38	Default value × CF (1.9) × default PF (2)[(b)]
Wheat gluten meal	0.34	Default value × CF (1.9) × default PF (1.8)[(b)]	0.34	Default value × CF (1.9) × default PF (1.8)[(b)]
Wheat milled by-pdts	1.33	Default value × CF (1.9) × default PF (7)[(b)]	1.33	Default value × CF (1.9) × default PF (7)[(b)]

$STMR_{Mo}$: median residue expressed according to the residue definition for monitoring; HR_{Mo}: 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.

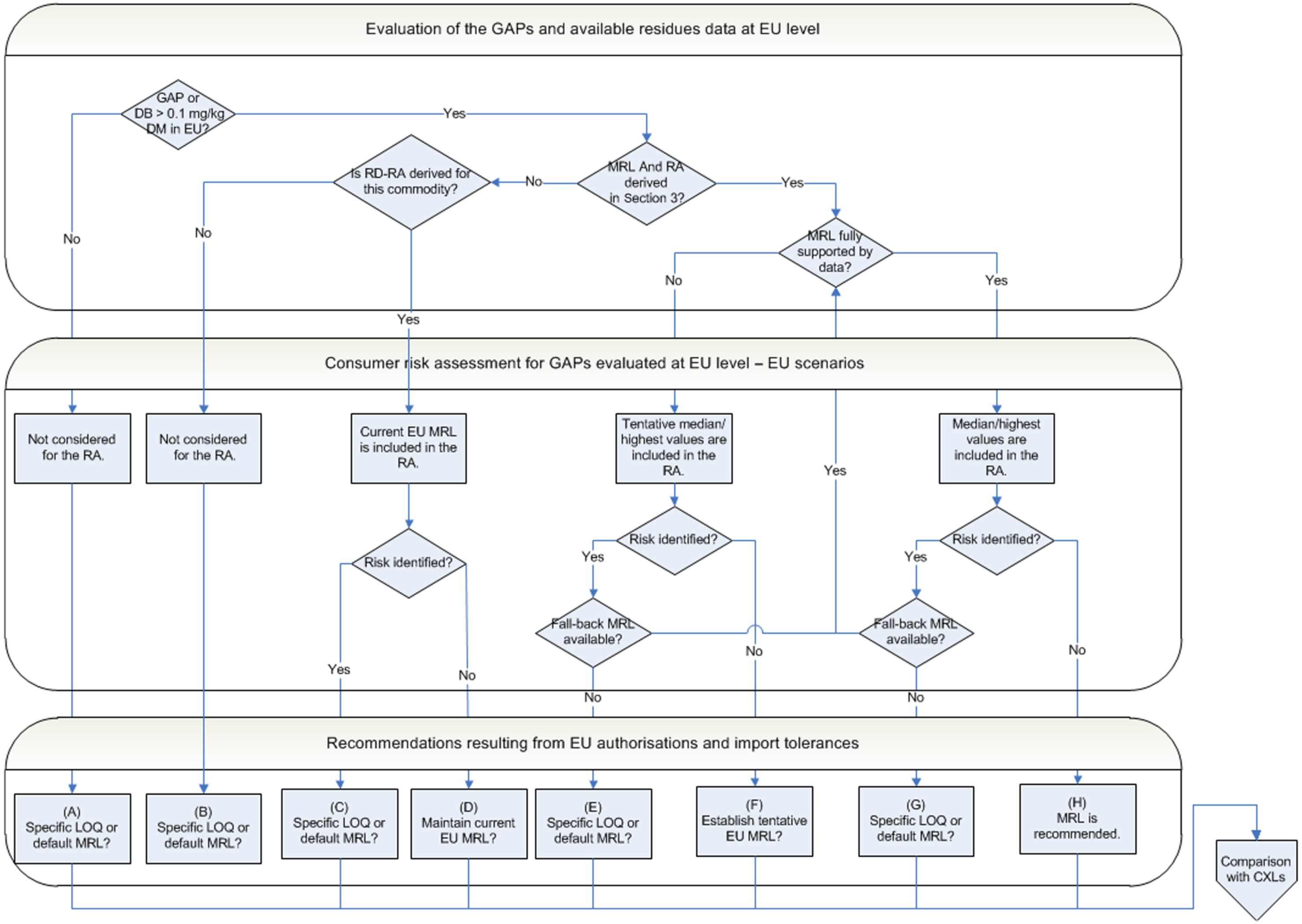
D.2. Consumer risk assessment

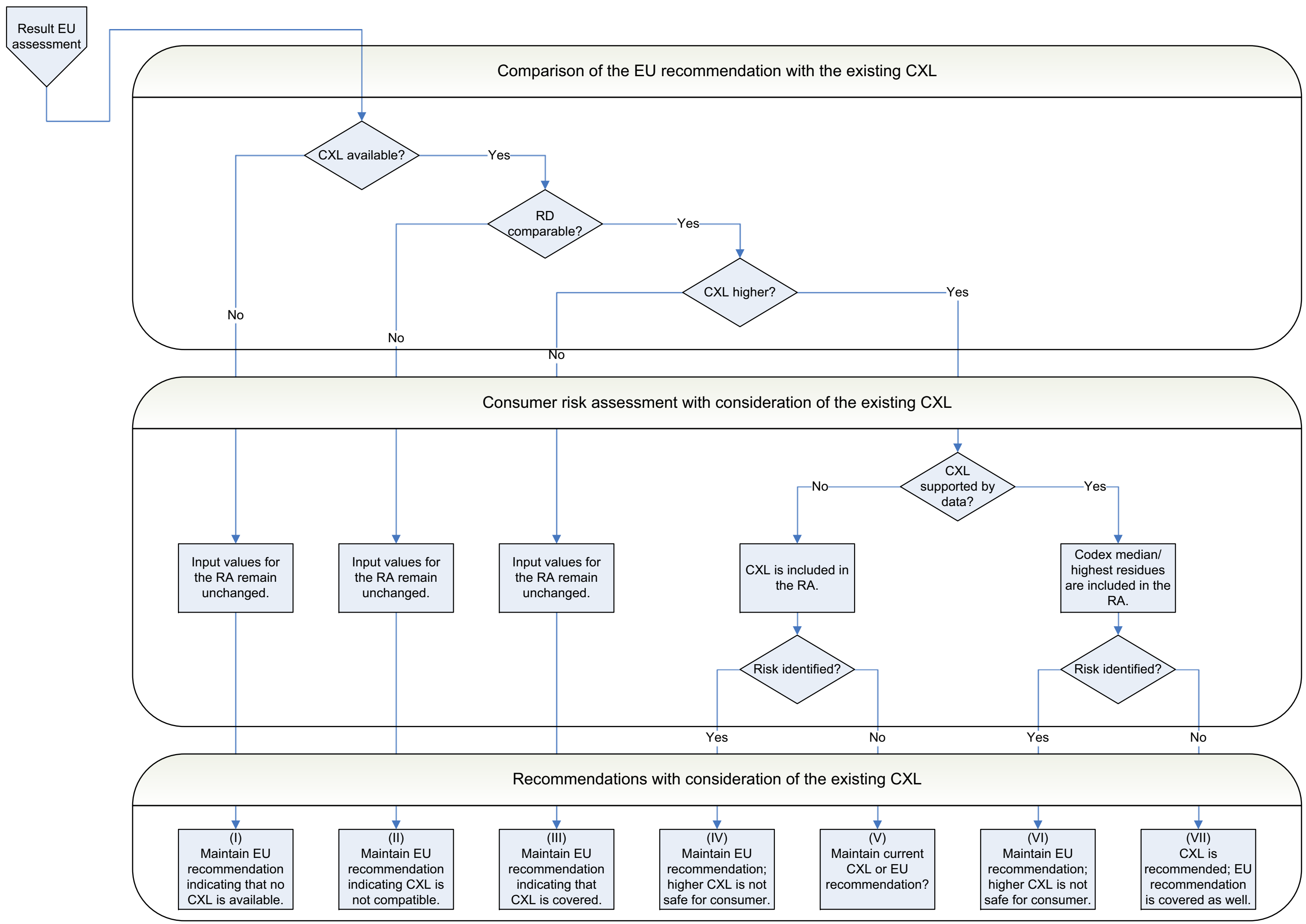
Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition 1: sum of 1,4-dimethylnaphthalene, M21 and its conjugates, expressed as 1,4-dimethylnaphthalene		
Potato	7.11	$STMR_{Mo}$ × CF (1.9) (tentative)
All other commodities included in Annex I of Reg. (EC) 396/2005	0.19	Default value[(a)] × 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	Chronic risk assessment	
	Input value (mg/kg)	**Comment**
Swine meat	0.06	0.8 × STMR muscle (tentative) + 0.2 × 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 × STMR muscle (tentative) + 0.2 × 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 × STMR muscle (tentative) + 0.2 × 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 × STMR muscle (tentative) + 0.1 × 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)

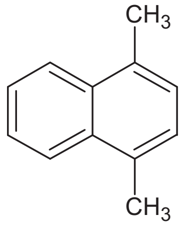
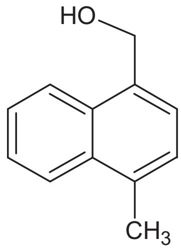
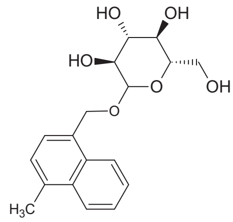
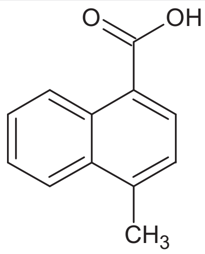
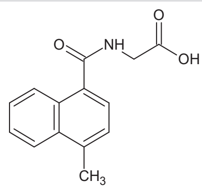
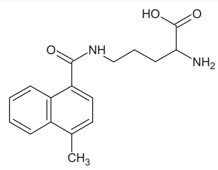
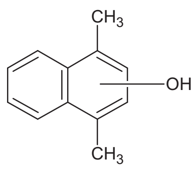
STMR: supervised trials median residue; $STMR_{Mo}$: median residues expressed according to the residue definition for monitoring; CF: conversion factor.
(a): Default value used to cover the possible natural background levels of 1,4-dimethylnaphthalene in plants (EFSA, 2014).

Appendix E – Decision tree for deriving MRL recommendations




Result EU assessment
Comparison of the EU recommendation with the existing CXL
CXL available?
Yes
No
RD comparable?
Yes
No
CXL higher?
Yes
No
Consumer risk assessment with consideration of the existing CXL
CXL supported by data?
No
Yes
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
CXL is included in the RA.
Codex median/ highest residues are included in the RA.
Risk identified?
Risk identified?
Yes
No
Yes
No
Recommendations with consideration of the existing CXL
(I) Maintain EU recommendation indicating that no CXL is available.
(II) Maintain EU recommendation indicating CXL is not compatible.
(III) Maintain EU recommendation indicating that CXL is covered.
(IV) Maintain EU recommendation; higher CXL is not safe for consumer.
(V) Maintain current CXL or EU recommendation?
(VI) Maintain EU recommendation; higher CXL is not safe for consumer.
(VII) 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 APQSQLNWAIULLK-UHFFFAOYSA-N Cc1ccc(C)c2ccccc12	
M21 1-hydroxymethyl-4-methylnaphthalene	(4-methylnaphthalen-1-yl)methanol RRSGUDDGNKMFRY-UHFFFAOYSA-N Cc1ccc(CO)c2ccccc12	
Glycoside conjugates of M21	One example of several possible glycoside structures: (4-methylnaphthalen-1-yl)methyl L-glucopyranoside VXPLOPHXPXEBSS-KYLYMASSSA-N Cc1ccc(COC2O[C@@H](CO)[C@H](O)[C@@H](O)[C@@H]2O)c2ccccc21	
M23 4-methyl-1-naphthoic acid	4-methylnaphthalene-1-carboxylic acid SIVYRLBDAPKADZ-UHFFFAOYSA-N O=C(O)c1ccc(C)c2ccccc21	
Gly-M23 glycine conjugate of M23	*N*-(4-methylnaphthalene-1-carbonyl)glycine ONRMQUIJXGTWIZ-UHFFFAOYSA-N O=C(O)CNC(=O)c1ccc(C)c2ccccc21	
Orn-M23 ornithine conjugate of M23	One possible structures of the conjugate: N^5-(4-methylnaphthalene-1-carbonyl)ornithine NYTODGAWHRBOAO-UHFFFAOYSA-N O=C(O)C(N)CCCNC(=O)c1ccc(C)c2ccccc21	
1,4-dimethylnaphthol	One example of several possible structures (position of OH group not determined): 1,4-dimethylnaphthalen-2-ol INBDACYHPDXEOQ-UHFFFAOYSA-N Cc1cc(O)c(C)c2ccccc12	

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

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 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).