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Modification of the existing maximum residue levels for 1,4-dimethylnaphthalene in potatoes

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Dormfresh limited submitted a request to the competent national authority in the Netherlands to modify the existing maximum residue level (MRL) for the active substance 1,4-dimethylnaphthalene in potatoes. The data submitted in support of the request were found to be sufficient to derive an MRL proposal. Adequate analytical methods for enforcement are available to control the residues of 1,4-dimethylnaphthalene in potatoes and residues of 1,4-dimethylnaphthalene, M23 and M23 conjugates in animal matrices. The data gaps identified during the MRL review relevant to the identity of metabolites found at significant levels in the processing studies and the analytical methods for enforcement in animal matrices were considered satisfactorily addressed. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of 1,4-dimethylnaphthalene according to the reported agricultural practice is unlikely to present a risk to consumer health.

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Keywords: 1,4-dimethylnaphthalene, potatoes, plant growth regulator, MRL, consumer risk assessment

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EUROPEAN FOOD SAFETY AUTHORITY

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Dormfresh limited submitted an application to the competent national authority in the Netherlands (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance 1,4-dimethylnaphthalene in potatoes. The EMS drafted an evaluation report in accordance with Article 8 of the MRL Regulation, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 7 April 2022. To accommodate for the intended use of 1,4-dimethylnaphthalene, the EMS proposed to raise the existing MRL from 15 to 20 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps, which were requested from the EMS. On 12 May 2023, the EMS submitted a revised evaluation report, which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of 1,4-dimethylnaphthalene following post-harvest treatment has been investigated in potatoes. Studies investigating the effect of processing potatoes on the nature of 1,4-dimethylnaphthalene and its metabolite M21 that are present in the raw commodities demonstrated that both compounds are stable. During the MRL review, a data gap on the identification of relevant degradation products was highlighted. For the present MRL application, additional data were provided by the applicant, demonstrating that unknown metabolites/degradation products are unambiguously M21 conjugates and 1,4-dimethylnaphthol. EFSA considered the data gap as addressed.

Fully validated analytical methods are available for the enforcement of the residue definition in high water content commodities at the limit of quantification (LOQ) of 1 mg/kg. According to the European Union Reference Laboratories (EURLs), a default LOQ of 0.01 mg/kg is achievable in all matrix groups by using multiresidue analytical method Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) in routine analyses.

Based on the metabolic pattern identified in metabolism studies, processing studies, the toxicological relevance of metabolites and degradation products and capability of analytical methods, the residue definitions for plant products were proposed during the MRL review as '1,4-dimethylnaphthalene' for enforcement and 'sum of 1,4-dimethylnaphthalene, M21 and its conjugates, expressed as 1,4-dimethylnaphthalene' for risk assessment. These residue definitions are applicable to primary crops and to processed products, considering new data submitted in the present MRL application. The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition.

EFSA concluded that for the intended post-harvest use on potatoes, metabolism of 1,4-dimethylnaphthalene has been sufficiently addressed.

The available residue trials are sufficient to derive an MRL proposal of 20 mg/kg for potatoes. Conjugated M21 residues, which are included in the residue definition for risk assessment were not quantified. The applicant demonstrated that it is not technically feasible to accurately quantify conjugated residues of M21. For this reason, a conversion factor (1.9), as derived in a previous EFSA output, was considered appropriate to perform risk assessment for the new use.

Several processing factors (PF) for potatoes were derived from processing studies considering the residue definition for monitoring. During these trials, M21 conjugates were not determined, as not technically feasible. PF for potatoes process waste was used for animal burden calculations.

As potatoes and potato by-products can be used as feed products, a potential carry-over into the food of animal origin was assessed. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all relevant animal species. Therefore, the possible occurrence of 1,4-dimethylnaphthalene residues in commodities of animal origin was investigated. The nature of 1,4-dimethylnaphthalene residues in livestock has been investigated during the EU pesticides peer review and the MRL review and the residue definition for enforcement and risk assessment was proposed as 'sum of 1,4-dimethylnaphthalene and its metabolite M23 free and conjugated, expressed as 1,4-dimethylnaphthalene'. Livestock dietary burden was updated with the new processing factor for potato process waste, and the results of livestock feeding studies. MRLs were proposed for products of animal origin.

The toxicological profile of 1,4-dimethylnaphthalene was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.1 mg/kg bw per day. An acute reference dose (ARfD) was deemed

unnecessary for this compound. The metabolites included in the residue definitions for plants or livestock are of similar toxicity as the parent active substance.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). EFSA updated calculations performed during the MRL review, taking into consideration the intended use and existing MRLs in other plant commodities. Risk assessment was performed with the use of a conversion factor (1.9), to account for free and conjugated M21 residues. The estimated long-term dietary intake amounted up to 83% of the ADI (Dutch toddler diet). The contribution of residues expected in potatoes was 64% of the ADI for the same diet. EFSA concluded that the proposed post-harvest treatment of 1,4-dimethylnaphthalene on potatoes will not result in consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers' health.

EFSA proposes to amend the existing MRLs as reported in the summary table below.

Full details of all end points and the consumer risk assessment can be found in Appendices B–D.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: 1,4-dimethylnaphthalene[(F)]				
0211000	Potatoes	15 (ft 1)	20	The submitted data are sufficient to derive an MRL proposal for the intended post-harvest use. Uncertainty remains regarding the quantification of the conjugates of M21 in plant matrices but risk for consumers unlikely. The data gap identified by EFSA during the MRL review concerning information on the identity if metabolites found at significant levels in the processing studies has been addressed.
Enforcement residue definition: Sum of 1,4-dimethylnaphthalene and its metabolite M23 free and conjugated, expressed as 1,4-dimethylnaphthalene[(F)]				
1011010	Swine, muscle	0.03 (ft 2)	0.03	MRL proposal based on the updated calculated livestock exposure. Risk for consumers unlikely. The data gaps identified by EFSA during the MRL review concerning information on the analytical methods for the enforcement of the proposed residue definition in livestock commodities have been addressed.
1011020	Swine, fat	0.4 (ft 2)	0.3	MRL proposal based on the updated calculated livestock exposure. A lower MRL derives due to a new processing factor for potato process waste submitted under this MRL application. Risk for consumers unlikely. The data gaps identified by EFSA during the MRL review concerning information on the analytical methods for the enforcement of the proposed residue definition in livestock commodities have been addressed.
1011030	Swine, liver	1.5 (ft 2)	1.5	MRL proposal based on the updated calculated livestock exposure. Risk for consumers unlikely. The data gaps identified by EFSA during the MRL review concerning information on the analytical methods for the enforcement of the proposed residue definition in livestock commodities have been addressed.
1011040	Swine, kidney	1.5 (ft 2)	1.5	
1011050	Swine, edible offals (other than liver and kidney)	1.5 (ft 2)	1.5	

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
1012010	Bovine, muscle	0.04 (ft 2)	0.03	MRL proposal based on the updated calculated livestock exposure. A lower MRL derives due to a new processing factor for potato process waste submitted under this MRL application. Risk for consumers unlikely. The data gaps identified by EFSA during the MRL review concerning information on the analytical methods for the enforcement of the proposed residue definition in livestock commodities have been addressed.
1012020	Bovine, fat	1 (ft 2)	0.5	
1012030	Bovine, liver	3 (ft 2)	2	
1012040	Bovine, kidney	3 (ft 2)	2	
1012050	Bovine, edible offals (other than liver and kidney)	3 (ft 2)	2	
1013010	Sheep, muscle	0.04 (ft 2)	0.03	
1013020	Sheep, fat	1.5 (ft 2)	0.6	
1013030	Sheep, liver	4 (ft 2)	3	
1013040	Sheep, kidney	3 (ft 2)	3	MRL proposal based on the updated calculated livestock exposure. Risk for consumers unlikely. The data gaps identified by EFSA during the MRL review concerning information on the analytical methods for the enforcement of the proposed residue definition in livestock commodities have been addressed.
1013050	Sheep, edible offals (other than liver and kidney)	4 (ft 2)	3	MRL proposal based on the updated calculated livestock exposure. A lower MRL derives due to a new processing factor for potato process waste submitted under this MRL application. Risk for consumers unlikely. The data gaps identified by EFSA during the MRL review concerning information on the analytical methods for the enforcement of the proposed residue definition in livestock commodities have been addressed.
1014010	Goat, muscle	0.04 (ft 2)	0.03	
1014020	Goat, fat	1.5 (ft 2)	0.6	
1014030	Goat, liver	4 (ft 2)	3	
1014040	Goat, kidney	3 (ft 2)	3	MRL proposal based on the updated calculated livestock exposure. Risk for consumers unlikely. The data gaps identified by EFSA during the MRL review concerning information on the analytical methods for the enforcement of the proposed residue definition in livestock commodities have been addressed.
1014050	Goat, edible offals (other than liver and kidney)	4 (ft 2)	3	MRL proposal based on the updated calculated livestock exposure. A lower MRL derives due to a new processing factor for potato process waste submitted under this MRL application. Risk for consumers unlikely. The data gaps identified by EFSA during the MRL review concerning information on the analytical methods for the enforcement of the proposed residue definition in livestock commodities have been addressed.
1015010	Equine, muscle	0.04 (ft 2)	0.03	
1015020	Equine, fat	1 (ft 2)	0.5	
1015030	Equine, liver	3 (ft 2)	2	
1015040	Equine, kidney	3 (ft 2)	2	
1015050	Equine, edible offals (other than liver and kidney)	3 (ft 2)	2	

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
1016010	Poultry, muscle	0.2 (ft 2)	0.3	MRL proposal based on the updated calculated livestock exposure. Risk for consumers unlikely. The data gaps identified by EFSA during the MRL review concerning information on the analytical methods for the enforcement of the proposed residue definition in livestock commodities have been addressed.
1016020	Poultry, fat	0.7 (ft 2)	1.5	
1016030	Poultry, liver	0.6 (ft 2)	1.5	
1016040	Poultry, kidney	0.7 (ft 2)	1.5	
1016050	Poultry, edible offals (other than liver and kidney)	0.7 (ft 2)	1.5	
1020010	Cattle, milk	0.4 (ft 2)	0.3	MRL proposal based on the updated calculated livestock exposure. A lower MRL derives due to a new processing factor for potato process waste submitted under this MRL application. Risk for consumers unlikely. The data gaps identified by EFSA during the MRL review concerning information on the analytical methods for the enforcement of the proposed residue definition in livestock commodities have been addressed.
1020020	Sheep, milk	0.5 (ft 2)	0.3	
1020030	Goat, milk	0.5 (ft 2)	0.3	
1020040	Horse, milk	0.4 (ft 2)	0.3	
1030000	Eggs	0.15 (ft 2)	0.4	MRL proposal based on the updated calculated livestock exposure. Risk for consumers unlikely. The data gaps identified by EFSA during the MRL review concerning information on the analytical methods for the enforcement of the proposed residue definition in livestock commodities have been addressed.

MRL: maximum residue level.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.
ft 1: The European Food Safety Authority identified some information on residue trials and nature of the residue in processed commodities as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 2 August 2024, or, if that information is not submitted by that date, the lack of it.
ft 2: The European Food Safety Authority identified some information on analytical methods as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 2August 2024, or, if that information is not submitted by that date, the lack of it.

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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for 1,4-dimethylnaphthalene in potatoes. The detailed description of the intended use of 1,4-dimethylnaphthalene, which is the basis for the current MRL application, is reported in Appendix A.

1,4-dimethylnaphthalene is the ISO common name for 1,4-dimethylnaphthalene (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

1,4-dimethylnaphthalene was evaluated in the framework of Directive 91/414/EEC[1] with the Netherlands designated as rapporteur Member State (RMS) for the representative use as a sprout suppressor on potatoes.

The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (2013). 1,4-dimethylnaphthalene was approved[2] on 1 July 2014.

The EU MRLs for 1,4-dimethylnaphthalene are established in Annex IIIA of Regulation (EC) No 396/2005[3]. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2021) and the proposed modifications have been implemented in the MRL legislation. The current reasoned opinion is the first one being issued after the MRL review.

In accordance with Article 6 of Regulation (EC) No 396/2005, Dormfresh limited submitted an application to the competent national authority in the Netherlands (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance 1,4-dimethylnaphthalene in potatoes. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005 (Netherlands, 2022), which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 7 April 2022. To accommodate for the intended uses of 1,4-dimethylnaphthalene, the EMS proposed to raise the existing MRL from 15 to 20 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps, which were requested from the EMS. On 12 May 2023, the EMS submitted a revised evaluation report, which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (Netherlands, 2022), the draft assessment report (DAR) (and its addendum) (Netherlands, 2012, 2013) prepared under Council Directive 91/414/EEC, the Commission review report on 1,4-dimethylnaphthalene (European Commission, 2013), the conclusion on the peer review of the pesticide risk assessment of the active substance 1,4-dimethylnaphthalene (EFSA, 2013), as well as the conclusions from previous EFSA opinions on 1,4-dimethylnaphthalene (EFSA, 2014, 2017, 2021).

For this application, the data requirements established in Regulation (EU) No 544/2011[4] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[5].

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously is presented in Appendix B.

The evaluation report submitted by the EMS (Netherlands, 2022) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.[6]

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[1] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.

[2] 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.

[3] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

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

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

[6] Background documents to this reasoned opinion are published on OpenEFSA portal and are available at the following link: https://open.efsa.europa.eu/study-inventory/EFSA-Q-2022-00273

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 pesticides peer review (EFSA, 2013). Potatoes were treated once and sampled after 1 and 30 days. This experimental design is not representative of the intended use. However, the study submitted as confirmatory data and assessed in accordance with the specific provision of the approval (EFSA, 2017) is representative of the use. In this study, radiolabelled 1,4-dimethylnaphthalene was applied to potatoes in six post-harvest treatments (1-month interval) at 20 g a.s./ton. After one or six applications (30 days after treatment – DAT1 and 30 DAT6, respectively), the major component identified in the whole tuber was parent 1,4-dimethylnaphthalene, representing 79–93% total radiolabelled residue – TRR (2.66–19.66 mg eq/kg). Parent compound was also predominant in peeled potato (57–81% TRR; 0.22–3.64 mg eq/kg) and potato peel (86–94% TRR; 16–137 mg eq/kg). In peeled potato, metabolite M21 was accounting for up to 20% TRR (1.31 mg eq/kg) 30 DAT6, while M23 was not detected or only in low proportions (< 3% TRR). Minor more polar compounds were detected after six applications in peeled potatoes (7–10% TRR; 0.48–0.65 mg eq/kg) and at lower levels (< 2.4% TRR) in the whole tubers and were further identified as 1,4-dimethylnaphtol and glycoside conjugates of metabolite M21.

For the intended post-harvest use on potatoes, the metabolism of 1,4-dimethylnaphthalene is sufficiently elucidated.

1.1.2. Nature of residues in rotational crops

Not relevant for the post-harvest use on potato tubers.

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 are not available. 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).

Additional processing studies conducted on potatoes were assessed in the framework of the MRL review (EFSA, 2021), 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 only the use on potatoes is authorised, these were considered acceptable (EFSA, 2021). The studies were conducted with radiolabelled 1,4-dimethylnaphthalene. In unprocessed potato, the main compounds identified were 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 (EFSA, 2021).

During the MRL review, it was concluded that even though processing was not expected to impact the metabolism of 1,4-dimethylnaphthalene, the new studies did not fully address the nature of 1,4-dimethylnaphthalene residues. Consequently, additional information allowing to unambiguously identify the metabolites found at significant levels in the above studies was required and this was reported as a data gap of the MRL review by EFSA (EFSA, 2021).

In line with the MRL review, EFSA requested, in the framework of the present MRL application, further data on the identity of the minor metabolites/degradation products found in processed potatoes (four signals in chromatograms at retention time (RT) 19–23 min).

Applicant submitted additional data to elucidate the identity of the relevant degradation products.

Same samples were used in three different studies and compounds RT20 and RT21 were unambiguously identified by mass spectrometry as disaccharide conjugates of M21. Further hydrolysis experiments resulted in formation of M21, identified by comparison of retention times/patterns in two dissimilar chromatographic systems. Compound RT23 was unambiguously identified as 1,4-dimethylnaphthol by high-resolution mass spectrometry. Compound RT19 was characterised as M21 conjugate based on the retention time, however, being present in processed potatoes up to 8.7% was not further investigated. More than 90% of TRR was identified in processed potatoes. Based on all submitted data, EMS considered the identity of the above-mentioned compounds to be unambiguously identified as M21 conjugates and 1,4-dimethylnaphthol.

Under the present MRL application EFSA considered new data, submitted relevant to the identity of metabolites/degradation products during processing potatoes, as sufficient to address the data gap identified during the MRL review. Additional data are not required.

1.1.4. Analytical methods for enforcement purposes in plant commodities

During the peer review, a Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) multiresidue analytical method based on gas chromatography coupled to mass spectrometry detection (GC–MSD) was validated for parent 1,4-dimethylnaphthalene (compound relevant to the residue definition for monitoring) 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 potatoes at the LOQ of 1 mg/kg. The method efficiently extracts 1,4-dimethylnaphthalene, M21 and M23 from high water content matrices such as potatoes (EFSA, 2021).

In addition, during the MRL review, the EU reference laboratories (EURLs) provided a QuEChERS multiresidue analytical method using gas chromatography with tandem mass spectrometry (GC–MS/MS) and gas chromatography with high resolution mass spectrometry (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 method was successfully validated at lower levels (down to 0.005 mg/kg, 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, 2021).

EFSA concludes that sufficient analytical methods are available for the enforcement of potatoes.

1.1.5. Storage stability of residues in plants

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

Under the present MRL application, new experimental data on the storage stability of residues in potatoes were provided in a processing study. In this study, 1,4-dimethylnaphthalene and its metabolites M21 and M23 were proven to be stable in potatoes for a period of 400 days when stored frozen at −18°C (Netherlands, 2022).

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and degradation products, the capabilities of enforcement analytical methods, the following residue definitions were proposed in the framework of the MRL review (EFSA, 2021):

- residue definition for risk assessment: sum of 1,4-dimethylnaphthalene, M21 and its conjugates, expressed as 1,4-dimethylnaphthalene;
- residue definition for enforcement: 1,4-dimethylnaphthalene.

During the MRL review, these definitions were proposed by EFSA, on a tentative basis, for processed products (EFSA, 2021). In the present MRL application, the residue definitions are confirmed for processed products, since the data gap[7] relevant to the nature of residues in processed commodities was addressed.

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition.

EFSA concludes that these residue definitions are appropriate for the present MRL application.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant relied upon 16 residues trials in total. Four trials that were assessed during the peer review (Netherlands, 2012; EFSA, 2013) were considered by the EMS as GAP-compliant. In these trials, potato tubers, that were treated six times, were analysed at a withholding period (WHP) of 3 days for 1,4-dimethylnaphthalene only. In another study assessed under a previous MRL application (EFSA, 2014), two trials were also selected to support the intended use. Potato tubers were analysed for 1,4-dimethylnaphthalene, and its metabolites M21, and M23 at WHP of 3 days.

In addition, the applicant submitted 10 new residue trials performed on potatoes. In five trials, where potatoes were stored in boxes, sampling was performed from four different boxes. In the remaining five trials, potatoes were stored bulked on heaps when treated and collected for analysis from four spots from only the top of each heap. EMS considered method of sampling acceptable, since from a previous MRL assessment (EFSA, 2014), it was shown that residues in potatoes collected either from the top, the middle or the bottom of the heap, did not differ significantly (H test; a: 0.05%). When different potato varieties were treated in the same compartment, they were not considered as independent trials and thus the highest result found in the compartment was selected. Furthermore, when higher residues occurred at WHP longer that the one defined in the intended GAP (3 days), these values were selected for calculations.

The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated. Potatoes were analysed for 1,4-dimethylnaphthalene and its metabolite M21. Residues were extracted following steps of the multiresidues method QuEChERS, for which the efficiency has been demonstrated (see Section 1.1.4) and analysed with the use of GC–MSD (1,4-DMN and M21). It is to be noted that the conjugated forms of M21 that are included in the residue definition for risk assessment were not determined in any of the residue trials.

Regarding the determination of M21 conjugates, applicant demonstrated that acidic or enzymatic hydrolysis is not appropriate to properly release M21 conjugates. The conjugates can efficiently be hydrolysed using the acidic as well as the enzymatic conditions. However, it was not possible to certainly conclude that the hydrolysed conjugated are merely converted to M21. In addition, M21 is volatile at 50°C and not stable under acidic conditions. M21 is stable under enzymatic hydrolysis, however, the end product was influenced as a result of the occurrence of oxidative reaction in the process. An alkali hydrolysis was not performed as glycosides are fairly stable under basic conditions. In conclusion, enzymatic and acidic hydrolysis are suitable for releasing the conjugated form of the metabolite, but unsuitable to be included in analytical methods for risk assessment. Applicant also stated that the attempt to synthesise standards for the M21 conjugates (disaccharides) and perform direct analyses would not be successful, due to the chemical characteristics of the disaccharides. EMS considered the extensive efforts made by the applicant and concluded that it is not technically possible to accurately quantify conjugated residues of M21 (Netherlands, 2022).

For the purpose of the present MRL application, the conversion factor (CF) of 1.9 derived in previous assessments was used to consider the potential presence of conjugated forms of M21 in the dietary exposure. The specific CF was derived based on data from supervised residue trials, where only M21 was estimated, and taking into consideration an additional 50% for the conjugated residues based on the metabolism trials (potatoes treated six time and a WHP of 30 days) (EFSA, 2017). In the new trials conducted with a WHP of 3 days, M21 residues are of the same proportion of the parent compound to those considered previously (EFSA, 2017). When considering conjugated residues of M21, the CF of 1.9 is also applicable for the present residue data and therefore is considered conservative enough.

[7] Additional information allowing to unambiguously identify the metabolites found at significant levels in the processing studies (EFSA, 2021).

1.2.2. Magnitude of residues in rotational crops

Not relevant for the post-harvest use on potatoes.

1.2.3. Magnitude of residues in processed commodities

During the MRL review, tentative processing factors (PF) were calculated for unpeeled boiled, unpeeled baked, and unpeeled fried potatoes. These PF were tentative because were based on limited data (one trial) (EFSA, 2021). For these processing factors, since trials were performed with radiolabelled 1,4-dimethylnapthtalene, conjugated M21 residues (three signals at RT19, RT20 and RT21) were also determined and conversion factors could be estimated based on the residue definition for risk assessment being 'sum of 1,4-dimethylnaphthalene, M21 and its conjugates, expressed as 1,4-dimethylnaphthalen'.

Two new processing studies were submitted within the present application investigating the magnitude of residues during processing and deriving several robust PF. In one study, potatoes were treated two or three times when stored. EMS considered trials to be representative of the use, since residues concentration in raw commodities were high enough to allow calculation of PF. All new trials samples were analysed for 1,4-dimethylnaphthalene and its metabolites M21 and M23. Conjugated M21 residues, that are included in the residue definition for risk assessment, were not determined because not technically feasible (see Section 1.1.3). For this reason, a conversion factor (CF) for risk assessment could not be directly calculated in the absence of data for the conjugates of M21. Where data on the M21 conjugates were available for a same or similar process from a previous EFSA output, same CF was considered for the new processing trials.

Concentration of 1,4-dimethylnaphthalene residues occurs in potato wet peel, and dry pulp. The median PF for wet peel (potato process waste) is deemed robust and was considered in the livestock dietary burden (see Section 2). Regarding the PF for dry pulp, EMS expressed its concerns on the appropriateness of the values proposed by the applicant. This PF was calculated differently in the two studies and differed significantly. One was measured indirectly (PF = 40)[8], while the other (PF = 2.9) was calculated by trials after drying rasped potatoes by centrifugation. Since in the OECD guidance document (OECD, 2013) the process of production of dried pulp and estimation of a PF is not clearly defined, the default PF (38) included in the livestock burden calculator of 2017 was used for calculations in Section 2.

For monitoring purposes, available data from previous assessment were pooled with new data to derive more robust PF for the parent compound, as presented in Appendix B.1.2.3.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive an MRL proposal for potatoes at the level of 20 mg/kg.

In Section 3, EFSA assessed whether residues on/in potatoes resulting from the intended post-harvest use are likely to pose a consumer health risk.

2. Residues in livestock

Potatoes and potato by-products can be fed to livestock and therefore the possible carry-over of residues through feeding to commodities of animal origin should be examined.

The previous EU livestock dietary burden (EFSA, 2021) was updated with the higher residue levels derived from the new intended post-harvest use on potatoes and with the new PF for potato waste (4.7; significantly lower compared to the default (20) of the animal model), while for dry pulp the default PF was used (see Section 1.2.3). For the PF for potato waste, a CF of 1.9 was considered to perform a conservative calculation of the animal dietary burden.

In the framework of the MRL review (EFSA, 2021), possible background levels of 1,4-dimethylnapthtalene in feed items were considered for the livestock dietary burden (i.e. 0.1 mg/kg). In Reg. (EU) 2022/1346, the MRL value of 0.05 mg/kg was implemented for all feed commodities other than potatoes. Therefore, EFSA updated the previous calculation with the new value of 0.05 mg/kg (instead of 0.1 mg/kg). Since potatoes and potato by-products are the main contributors to the dietary burden, the impact of the possible background levels in the other feed items is negligible. However,

[8] PF for dry pulp estimated indirectly based on the PF for starch-extracted wet pulp multiplied to the PF to dry the wet potato pulp. ($PF_{dry\ pulp} = PF_{animal\ feed/wet\ pulp} \times PF_{wet\ pulp\ to\ dry\ pulp} = 9.2 \times 4.4$).

due to the new PF used for potato waste, the dietary burden estimations newly calculated are lower than the previous ones for ruminants and swine.

The input values for the exposure calculations for livestock are presented in Appendix D.1. The results of the dietary burden calculation are presented in Section B.2.1.2, in comparison with the results of the MRL review. For all livestock species included in the model threshold values are exceeded. Therefore, further investigations are needed and presented hereafter.

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). All studies were performed using radiolabelled 1,4-dimethylnaphthalene with dose rates that are not covering the maximum dietary burdens calculated in the MRL review or the present MRL application. However, the identification rate of the compounds was satisfactory, and the metabolic pathway was confirmed by the feeding studies (EFSA, 2021).

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 34–71% 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).

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

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 metabolism studies were performed using only 1,4-dimethylnaphthalene as test material, whereas M21 (and its conjugates) was also identified as a major component of the residues in potato tubers. It was noted that M21 is an intermediate in the formation of the metabolite M23 in livestock, 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).

In the framework of the MRL review the feeding studies that were assessed (EFSA, 2021) confirmed the metabolic pathway observed, with parent and metabolite M23 (free and conjugated) being the most relevant components of the residues in livestock commodities (see also Section 2.2).

During the MRL review, the proposed residue definition for monitoring and risk assessment was confirmed as '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 (EFSA, 2021).

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). The MRL review confirmed those data gaps[9] (EFSA, 2021).

Under the present MRL application, new method validations were submitted to address the above-mentioned data gap. A full validation of the peer reviewed method was submitted. 1,4-dimethylnaphthalene and M23 were extracted with acetonitrile and determined by HPLC-FLD in animal tissues, milk, and eggs at the LOQ of 0.01 mg/kg, except for M23 in liver at a higher LOQ of 0.04 mg/kg. M23 conjugates (Gly-M23, or Orn-M23) were also extracted with acetonitrile but determined with HPLC-MS/MS in the same matrices (Netherlands, 2022).

[9] 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) (EFSA, 2021).

Since the analyses with HPLC-FLD does not satisfy the requirements of the specificity a confirmatory method was also submitted. After extracting residues with acetonitrile, 1,4-dimethylnaphthalene and M23 were successfully determined at the LOQ of 0.01 mg/kg with two mass transitions by GC–MS/MS and HPLC-MS/MS, respectively, in animal tissues, milk, and eggs (Netherlands, 2022).

The monitoring method was validated by an independent laboratory (ILV) at the LOQ of 0.01 mg/kg for 1,4-dimethylnaphthalene and M23 by HPLC/FLD in animal tissues, and milk; for M-23 conjugates (Gly-M23, or Orn-M23) by HPLC-MS/MS in animal tissues, milk, and eggs (Netherlands, 2022).

Consequently, the data gaps identified in the framework of the MRL review (EFSA, 2021) for products of animal origin, that were implemented in the MRL Reg. (EU) 2022/1346 as footnotes, are considered as addressed.

Extraction efficiency of the post-authorisation method was addressed in the frame of the MRL review. Considering the new analytical methods 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 (EFSA, 2021).

2.2. Magnitude of residues in livestock

Feeding studies on dairy cows and laying hens were assessed in the framework of the MRL review. In these studies, a mixture of the parent compound 1,4-dimethylnaphthalene and metabolites M21 and M23 was administered. In both studies, total residues were expressed considering the residue definition for risk assessment in animal commodities (i.e. sum of 1,4-dimethylnaphthalene and its metabolite M23 free and conjugated, expressed as 1,4-dimethylnaphthalene), with each analyte having an LOQ of 0.01 mg/kg in all matrices, except for M23 in liver which had an LOQ of 0.04 mg/kg. In most of the samples, 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. The metabolite M21, which not in the residue definition for animal products was generally not quantified above the LOQ in the analysed samples (EFSA, 2021).

Based on these studies, and the updated livestock burden calculations of the present MRL assessment, MRLs and risk assessment values were derived for all commodities of animal origin. Due to the new PF on potato process waste (i.e. residues in wet peel) that replaced the default PF of the animal model a lower livestock dietary burden is calculated for all animal species except for poultry. New calculated MRLs for commodities of animal origin are presented in Appendices B.2.2.1 and B.4.

EFSA notes that data gaps identified in the framework of the MRL review (EFSA, 2021) for products of animal origin and implemented in the MRL regulation as footnotes are considered as addressed (see Section 2.1).

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference value for 1,4-dimethylnaphthalene used in the risk assessment (i.e. ADI) was derived in the framework of the EU pesticides peer review (European Commission, 2013). The metabolites included in the risk assessment residue definition were considered to be of similar toxicity the parent compound (EFSA, 2017). Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance.

In the framework of the MRL review (EFSA, 2021), a long-term exposure assessment was performed, taking into account the existing uses on potatoes at EU level, residue values in products of animal origin, and the possible natural background levels in the rest plant commodities. 1,4-dimethylnaphthalene is a naturally occurring component. To cover these natural background levels in plants, tentative MRLs with a footnote[10] were set at 0.05 mg/kg in Reg. (EU) 2022/1346 for all plant

[10] There is evidence that 1,4-dimethylnaphthalene could naturally occur in some plant compounds. Based on currently available monitoring data, a temporary MRL is set at a value of 0.05 mg/kg pending the submission of further monitoring data to confirm it. When reviewing the MRL, the Commission will take into account the information, if it is submitted by 2 August 2024, or, if that information is not submitted by that date, the lack of it.

commodities besides potatoes, hence, this value was considered for the present assessment. EFSA updated the calculations with the relevant STMR value derived from the residue trials submitted in support of this MRL application for potatoes. Risk assessment for the intended use was performed with the use of conversion factor (CF) of 1.9 derived in the framework of previous assessment (EFSA, 2017). The input values used in the exposure calculations are summarised in Appendix D.2.

The estimated long-term dietary intake amounted up to 83% of the ADI (Dutch toddler diet). The contribution of residues expected in potatoes was 64% of the ADI for this diet.

EFSA concluded that the long-term intake of residues of 1,4-dimethylnaphthalene resulting from the intended use and the possible background levels is unlikely to present a risk to consumer health. Although uncertainties remain as reported in the previous sections regarding determination of conjugated M21 residues in raw and processed potatoes, this exposure calculation did not indicate a risk to consumer health.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

4. Conclusion and recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for potatoes of 20 mg/kg. Potatoes can be fed to livestock. When estimating the possible carry-over of residues through feeding to commodities of animal origin, new MRLs for those commodities were calculated and proposed.

EFSA notes that data gaps identified in the framework of the MRL review (EFSA, 2021) relevant to the identity of metabolites/degradation products during processing potatoes, and to the analytical methods for products of animal origin, that were implemented in the MRL regulation as footnotes are now considered as addressed.

Uncertainty remains regarding the quantification of the conjugates of M21 in plant matrices, but conservative conversion factors were used to perform the risk assessment, EFSA concluded that the proposed use of 1,4-dimethylnaphthalene on potatoes will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

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
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
EC	emulsifiable concentrate
ECD	electron capture detector
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent

EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organisation of the United Nations
FLD	fluorescence detector
GAP	Good Agricultural Practice
GC	gas chromatography
GC–MS/MS	gas chromatography with tandem mass spectrometry
HPLC-MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS	mass spectrometry detector
MS	Member States
MS/MS	tandem mass spectrometry detector
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
P_{ow}	partition coefficient between n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SEU	southern Europe
STMR	supervised trials median residue
TRR	total radioactive residue
WHO	World Health Organization

Appendix A – Summary of intended GAP triggering the amendment of existing EU MRL

Crop and/or situation	NEU, SEU, MS or country	F, G or I[(a)]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment				WHP (days)[(d)]	Remarks
				Type[(b)]	Conc.a.s.	Method kind	Range of growth stages and season[(c)]	Number min–max	Interval between application (days)min-max	g a.s./hL min–max	Water (L/ha) min–max	Rate min–max	Unit		
Potatoes	EU	I	Sprouting inhibitor	HN	98%	Post-harvest treatment – fogging	99 (September–July)	1–6	30–40	–	–	9.8–19.6	g a.s./tonne	3	Not for use on seed potatoes.

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; HN: hot 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.

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3–8263–3152-4), including, where relevant, information on season at time of application.

(d): WHP: withholding period.

Appendix B – List of end points

B.1. Residues in plants

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

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

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling (DAT)**	**Comment/Source**
	Root crops	Potato	Post-harvest thermal fogging, 1 × 20 g a.s./ ton, BBCH 99	1, 30	[^{14}C]-1,4-dimethylnaphthalene (EFSA, 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)
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	–	–	–	–	Not available and not required as the intended use is an indoor post-harvest treatment.

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 with [^{14}C]-1,4-dimethylnaphthalene. Formation of unknown metabolites tentatively identified as glycoside conjugates of M21 (EFSA, 2021)
	Other processing conditions: baking (45 min, 180°C)	Yes	Non-standard study, following typical household method with [^{14}C]-1,4-dimethylnaphthalene. Formation of unknown metabolites tentatively identified as glycoside conjugates of M21 (EFSA, 2021)
	Other processing conditions: frying (5 min, 190°C)	Yes	Non-standard study, following typical household method with [^{14}C]-1,4-dimethylnaphthalene. Formation of unknown metabolites tentatively identified as glycoside conjugates of M21 (EFSA, 2021)

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 (Reg (EC) No 396/2003) Processed potato: 1,4-dimethylnaphthalene	
Plant residue definition for risk assessment (RD-RA)	Root crops (post-harvest treatment): sum of 1,4-dimethylnaphthalene, M21 and its conjugates, expressed as 1,4-dimethylnaphthalene (EFSA, 2021). Processed potato: 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 (default) in routine analysis. Method validated at lower levels in high water content and high acid content commodities (down to 0.005 mg/kg), and even lower in dry matrices (down to 0.0005 mg/kg).	

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; GC–MSD: gas chromatography with mass spectrometry detection; HPLC-FLD: high performance liquid chromatography with fluorescence detection; GC–MS/MS: gas chromatography with tandem mass spectrometry; GC–HRMS: gas chromatography with high-resolution mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.1.1.2. Stability of residues in plants

Plant products (available studies)	Category	Commodity	T(°C)	Stability period		Compounds covered	Comment/ Source
				Value	Unit		
	High water content	Potato	–18	400	Days	1,4-dimethylnaphthalene	Netherlands (2022)
			–18	400	Days	M21	Netherlands (2022)
			–18	400	Days	M23	Netherlands (2022)

B.1.2. Magnitude of residues in plants

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

Commodity	Region[(a)]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[(b)] (mg/kg)	STMR[(c)] (mg/kg)	CF[(d)]
Potatoes	Indoor (post-harvest), EU	**Mo:** 3.3; 3.8[(e)]; 4.0; 4.3; 5.6; 5.9; 6.3; 7.8; 8.0; 8.1; 8.2; 8.4[(e)]; 8.4; 8.7; 9.6; 10.9 **RA:** –	Trials on potatoes compliant with GAP (Netherlands, 2022). Residues underlined when occurred higher at longer withholding period. The available trials do not provide analyses for the conjugates of M21, results for RD-RA are not available. When considering the RD-RA without the M21 conjugates, the following residue levels were quantified: –; –; 5.8; 6.8; 8.9; 9.6; 10.7; 10.6; 11.9; –; 12.7; –; 14; 17.3; –; –	**20**	**10.9**	**7.9**	1.9

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment.

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

(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.

(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.

(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment. CF was derived from metabolism trials with potatoes treated six times and analysed after 30 days (EFSA, 2017).

(e): EFSA selected different values than those reported by the EMS. In peer reviewed trials 'R02-139-01' and 'rep 21158 (room 10)' higher residues occurred at longer WHP of 15 days.

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 the intended use is a post-harvest application.
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	Not relevant for a post-harvest application.

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 (EFSA, 2021)
Potato, unpeeled baked	1	0.69	0.69 (tentative)[(c)]	1.72	Non-standard study following typical household method (EFSA, 2021)
Potato, unpeeled fried	1	0.71	0.71 (tentative)[(c)]	1.70	Non-standard study following typical household method (EFSA, 2021)
Potato, wet peel	6	5.8; 7.4; 5.2; 3.4; 3.6; 4.2	4.7	1.5[(e)]	Six new trials (Netherlands, 2022). M21 conjugates are not expected in potato peel (EFSA, 2021).
Potato, baked unpeeled	4	0.69; 0.36; 0.46; 0.42	0.44	1.72[(d)]	PF (0.69) from the MRL review was also considered. (EFSA, 2021; Netherlands, 2022)
Potato, boiled unpeeled	4	0.5; 0.31; 0.28; 1.1	0.41	1.43[(d)]	PF (0.5) from the MRL review was also considered. (EFSA, 2021; Netherlands, 2022)
Potato, crisp (peeled)	3	0.05; 0.1; 0.1	0.1	1.70[(d)]	Netherlands (2022). CF for fried potatoes is applicable (EFSA, 2021).
Potato, starch	3	0.19; 0.18; 0.18	0.18	1.9[(f)]	Netherlands (2022)
Potato, starch-extracted wet pulp	3	9.2; 9.0; 9.4	9.2	1.9[(f)]	Netherlands (2022)
Potato, canned unpeeled	3	0.25; 0.25; 0.25	0.25	1.72[(d)]	Netherlands (2022). CF for baked potatoes is applicable (EFSA, 2021).
Potato, microwaved unpeeled	3	0.27; 0.27; 0.25	0.27	1.72[(d)]	Netherlands (2022). CF for baked potatoes is applicable (EFSA, 2021).
Potato, chips unpeeled	3	0.30; 0.25; 0.24	0.25	1.70[(d)]	Netherlands (2022). CF for fried potatoes is applicable (EFSA, 2021).
Potato, flakes	3	0.03; 0.04; 0.03	0.03	1.9[(f)]	Netherlands (2022)
Potato, dried pulp	3	2.6; 2.9; 3.1	2.9	1.9[(f)]	Netherlands (2022)

CF: conversion factor; PF: processing factor.
n.c.: not calculated; products were not analysed for al compounds included in the RD-RA (conjugated M21 was not determined).
CFp: 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): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial.
(c): A tentative PF is derived based on a limited data set (EFSA, 2021).
(d): CF from trials with radiolabelled 1,4-dimehtylnephthaline (EFSA, 2021) can be used for similar processing procedures.

(e): From metabolism trials M21 conjugates are not expected in potato peels (EFSA, 2017). CF calculated based on residues of parent and free M21.
(f): Residue data on conjugated M21 are not available. The CF from primary crops can be considered instead for risk assessment. However, if more information would be required by risk managers processing trials with radiolabelled 1,4-dimehtylnaphthaline should be performed.

B.2. Residues in livestock

Dietary burden calculation according to animal model 2017.[11]

Relevant groups (subgroups)	Dietary burden expressed in				Most critical subgroup[(a)]	Most critical commodity[(b)]		Trigger exceeded (Y/N)	Previous assessment (EFSA, 2021)
	mg/kg bw per day		mg/kg DM						Max burden (mg/kg DM)
	Median	Maximum	Median	Maximum					
Cattle (all)	7.643	7.971	257.43	265.96	Dairy cattle	Potato	Process waste	Yes	497.63
Cattle (dairy only)	7.643	7.971	198.72	207.26	Dairy cattle	Potato	Process waste	Yes	379.05
Sheep (all)	9.381	9.665	281.42	289.95	Ram/Ewe	Potato	Dried pulp	Yes	497.48
Sheep (ewe only)	9.381	9.665	281.42	289.95	Ram/Ewe	Potato	Dried pulp	Yes	497.48
Swine (all)	5.008	5.435	166.94	181.17	Swine (finishing)	Potato	Dried pulp	Yes	275.73
Poultry (all)	9.670	9.871	136.99	139.84	Poultry broiler	Potato	Dried pulp	Yes	69.28
Poultry (layer only)	7.161	7.356	104.66	107.51	Poultry layer	Potato	Dried pulp	Yes	53.97

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 per 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.

[11] https://food.ec.europa.eu/plants/pesticides/maximum-residue-levels/guidelines-maximum-residue-levels_en

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 (EFSA, 2021).
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 (Reg (EC) No 396/2003)	
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 (EFSA, 2021)	
Fat soluble residues	Yes	Log P_{ow} (1,4-dimethylnaphthalene) = 4.37 > 3. Accumulation in fat was demonstrated (EFSA, 2021)
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. Animal tissues, milk, and eggs (Netherlands, 2022): • Method validated for 1,4-dimethylnaphthalene, M23, and conjugated M23 (Gly-M23, Orn-M23) in animal tissues, milk, and eggs. 1,4-dimethylnaphthalene, M23: extraction with acetonitrile, analysis with HPLC-FLD, LOQ 0.01 mg/kg (liver: LOQ 0.04 mg/kg). M23 conjugates (Gly-M23, Orn-M23): extraction with acetonitrile, analysis with HPLC–MS/MS, LOQ 0.01 mg/kg. • Confirmatory method in animal tissues, milk, and eggs: 1,4-dimethylnaphthalene, M23: extraction with acetonitrile, analysis with GC–MS/MS, LOQ 0.01 mg/kg. M23 conjugates (Gly-M23, Orn-M23): extraction with acetonitrile, analysis with HPLC–MS/MS, LOQ 0.01 mg/kg. • ILV in animal tissues, milk, and eggs: 1,4-dimethylnaphthalene, M23: extraction with acetonitrile, analysis with HPLC-FLD, LOQ 0.01 mg/k. M23 conjugates (Gly-M23, Orn-M23): extraction with acetonitrile, analysis with HPLC–MS/MS, LOQ 0.01 mg/kg.	

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 and thus residue decline is not expected (EFSA, 2021).

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.[12]

Animal commodity	Residues at the closest feeding level[(a)] (mg/kg)		Estimated value at 1 N		MRL proposal (mg/kg)
	Mean	Highest	STMR[(b)] (mg/kg)	HR[(c)] (mg/kg)	
Cattle (all) Closest feeding level (3.97 mg/kg bw; 0.5 N rate (Dairy cattle))[(d)]					
Muscle	0.03	0.03	0.03	0.03	**0.03**
Fat	0.13	0.20	0.29	0.49	**0.5**
Liver	0.93	0.94	1.78	1.89	**2**
Kidney	0.81	0.90	1.56	1.80	**2**
Cattle (dairy only) Closest feeding level (3.97 mg/kg bw; 0.5 N rate)[(d)]					
Milk[(e)]	0.11	0.14	0.21	0.22	**0.3**
Sheep (all)[(f)] Closest feeding level (3.97 mg/kg bw; 0.5 N rate (Ram/Ewe))[(d)]					
Muscle	0.03	0.03	0.03	0.03	**0.03**
Fat	0.13	0.20	0.37	0.61	**0.6**
Liver	0.93	0.94	2.19	2.29	**3**
Kidney	0.81	0.90	1.92	2.18	**3**
Sheep (ewe only)[(f)] Closest feeding level (3.97 mg/kg bw; 0.5 N rate)[(d)]					
Milk[(d)]	0.11	0.14	0.26	0.27	**0.3**
Swine (all)[(f)] Closest feeding level (3.97 mg/kg bw; 0.8 N rate (Finishing))[(d)]					
Muscle	0.03	0.03	0.03	0.03	**0.03**
Fat	0.13	0.20	0.17	0.31	**0.3**
Liver	0.93	0.94	1.17	1.29	**1.5**
Kidney	0.81	0.90	1.03	1.23	**1.5**
Poultry (all) Closest feeding level (8.1 mg/kg bw; 0.9 N rate (Broiler))[(d)]					
Muscle	0.21	0.25	0.26	0.30	**0.3**
Fat	1.06	1.10	1.29	1.36	**1.5**
Liver	0.76	0.90	0.91	1.10	**1.5**
Poultry (layer only) Closest feeding level (8.1 mg/kg bw; 1.2 N rate)[(d)]					
Eggs[(g)]	0.32	0.37	0.28	0.34	**0.4**

bw: body weight; STMR: supervised trials median residue; HR: highest residue.
(a): Total residues are expressed considering the residue definition for risk assessment in animal commodities (i.e. sum of 1,4-dimethylnaphthalene and its metabolite M23 free and conjugated, expressed as 1,4-dimethylnaphthalene). For each analyte LOQ is 0.01 mg/kg. The combined LOQ for the RD-RA is 0.0248 mg/kg.
(b): The median residues were recalculated at the 1 N rate for the median dietary burden.
(c): The median residue level in milk and the highest residue levels in eggs and tissues were recalculated at the 1 N rate for the maximum dietary burden.
(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).

[12] https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en

B.3. Consumer risk assessment

Acute consumer exposure is not relevant since no ARfD has been considered necessary.

ADI	0.1 mg/kg bw per day (European Commission, 2013)
Highest IEDI, according to EFSA PRIMo	83% ADI (NL toddler diet) Contribution of crops assessed: Potatoes: 64% of ADI (NL toddler diet)
Assumptions made for the calculations	The calculation is based on the median residue levels derived for raw agricultural commodities, multiplied by the conversion factor for risk assessment (1.9). The contributions of possible background level of 1,4-dimethylnaphthalene as set in the MRL Regulation in all other plant commodities were also considered in the calculations considering the default background value of 0.05 mg/kg (Reg. (EU) 2022/1346). Calculations performed with PRIMo revision 3.1.

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; STMR: supervised trials median residue; CXL: codex maximum residue limit.

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: 1,4-dimethylnaphthalene[(F)]				
0211000	Potatoes	15 (ft 1)	20	The submitted data are sufficient to derive an MRL proposal for the intended post-harvest use. Uncertainty remains regarding the quantification of the conjugates of M21 in plant matrices but risk for consumers unlikely. The data gap identified by EFSA during the MRL review concerning information on the identity if metabolites found at significant levels in the processing studies has been addressed.
Enforcement residue definition: Sum of 1,4-dimethylnaphthalene and its metabolite M23 free and conjugated, expressed as 1,4-dimethylnaphthalene[(F)]				
1011010	Swine, muscle	0.03 (ft 2)	0.03	MRL proposal based on the updated calculated livestock exposure. Risk for consumers unlikely. The data gaps identified by EFSA during the MRL review concerning information on the analytical methods for the enforcement of the proposed residue definition in livestock commodities have been addressed.
1011020	Swine, fat	0.4 (ft 2)	0.3	MRL proposal based on the updated calculated livestock exposure. A lower MRL derives due to a new processing factor for potato process waste submitted under this MRL application. Risk for consumers unlikely. The data gaps identified by EFSA during the MRL review concerning information on the analytical methods for the enforcement of the proposed residue definition in livestock commodities have been addressed.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
1011030	Swine, liver	1.5 (ft 2)	1.5	MRL proposal based on the updated calculated livestock exposure. Risk for consumers unlikely. The data gaps identified by EFSA during the MRL review concerning information on the analytical methods for the enforcement of the proposed residue definition in livestock commodities have been addressed.
1011040	Swine, kidney	1.5 (ft 2)	1.5	
1011050	Swine, edible offals (other than liver and kidney)	1.5 (ft 2)	1.5	
1012010	Bovine, muscle	0.04 (ft 2)	0.03	MRL proposal based on the updated calculated livestock exposure. A lower MRL derives due to a new processing factor for potato process waste submitted under this MRL application. Risk for consumers unlikely. The data gaps identified by EFSA during the MRL review concerning information on the analytical methods for the enforcement of the proposed residue definition in livestock commodities have been addressed.
1012020	Bovine, fat	1 (ft 2)	0.5	
1012030	Bovine, liver	3 (ft 2)	2	
1012040	Bovine, kidney	3 (ft 2)	2	
1012050	Bovine, edible offals (other than liver and kidney)	3 (ft 2)	2	
1013010	Sheep, muscle	0.04 (ft 2)	0.03	
1013020	Sheep, fat	1.5 (ft 2)	0.6	
1013030	Sheep, liver	4 (ft 2)	3	
1013040	Sheep, kidney	3 (ft 2)	3	MRL proposal based on the updated calculated livestock exposure. Risk for consumers unlikely. The data gaps identified by EFSA during the MRL review concerning information on the analytical methods for the enforcement of the proposed residue definition in livestock commodities have been addressed.
1013050	Sheep, edible offals (other than liver and kidney)	4 (ft 2)	3	MRL proposal based on the updated calculated livestock exposure. A lower MRL derives due to a new processing factor for potato process waste submitted under this MRL application. Risk for consumers unlikely. The data gaps identified by EFSA during the MRL review concerning information on the analytical methods for the enforcement of the proposed residue definition in livestock commodities have been addressed.
1014010	Goat, muscle	0.04 (ft 2)	0.03	
1014020	Goat, fat	1.5 (ft 2)	0.6	
1014030	Goat, liver	4 (ft 2)	3	
1014040	Goat, kidney	3 (ft 2)	3	MRL proposal based on the updated calculated livestock exposure. Risk for consumers unlikely. The data gaps identified by EFSA during the MRL review concerning information on the analytical methods for the enforcement of the proposed residue definition in livestock commodities have been addressed.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
1014050	Goat, edible offals (other than liver and kidney)	4 (ft 2)	3	MRL proposal based on the updated calculated livestock exposure. A lower MRL derives due to a new processing factor for potato process waste submitted under this MRL application. Risk for consumers unlikely. The data gaps identified by EFSA during the MRL review concerning information on the analytical methods for the enforcement of the proposed residue definition in livestock commodities have been addressed.
1015010	Equine, muscle	0.04 (ft 2)	0.03	
1015020	Equine, fat	1 (ft 2)	0.5	
1015030	Equine, liver	3 (ft 2)	2	
1015040	Equine, kidney	3 (ft 2)	2	
1015050	Equine, edible offals (other than liver and kidney)	3 (ft 2)	2	
1016010	Poultry, muscle	0.2 (ft 2)	0.3	MRL proposal based on the updated calculated livestock exposure. Risk for consumers unlikely. The data gaps identified by EFSA during the MRL review concerning information on the analytical methods for the enforcement of the proposed residue definition in livestock commodities have been addressed.
1016020	Poultry, fat	0.7 (ft 2)	1.5	
1016030	Poultry, liver	0.6 (ft 2)	1.5	
1016040	Poultry, kidney	0.7 (ft 2)	1.5	
1016050	Poultry, edible offals (other than liver and kidney)	0.7 (ft 2)	1.5	
1020010	Cattle, milk	0.4 (ft 2)	0.3	MRL proposal based on the updated calculated livestock exposure. A lower MRL derives due to a new processing factor for potato process waste submitted under this MRL application. Risk for consumers unlikely. The data gaps identified by EFSA during the MRL review concerning information on the analytical methods for the enforcement of the proposed residue definition in livestock commodities have been addressed.
1020020	Sheep, milk	0.5 (ft 2)	0.3	
1020030	Goat, milk	0.5 (ft 2)	0.3	
1020040	Horse, milk	0.4 (ft 2)	0.3	
1030000	Eggs	0.15 (ft 2)	0.4	MRL proposal based on the updated calculated livestock exposure. Risk for consumers unlikely. The data gaps identified by EFSA during the MRL review concerning information on the analytical methods for the enforcement of the proposed residue definition in livestock commodities have been addressed.

MRL: maximum residue level.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.
ft 1: The European Food Safety Authority identified some information on residue trials and nature of the residue in processed commodities as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 2 August 2024, or, if that information is not submitted by that date, the lack of it.
ft 2: The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 2August 2024, or, if that information is not submitted by that date, the lack of it.

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 – acuterisk 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	Expsoure (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)
83%	NL toddler	82.74	64%	Potatoes	13%	Milk: Cattle	1%	Apples		77%
81%	PT general	81.39	80%	Potatoes	0.4%	Wheat	0.2%	Wine grapes		80%
72%	FI 3 yr	71.84	71%	Potatoes	0.1%	Bananas	0.1%	Wheat		71%
67%	SE general	67.11	62%	Potatoes	3%	Milk: Cattle	0.4%	Bovine: Muscle/meat		66%
63%	GEMS/Food G11	63.17	59%	Potatoes	2%	Milk: Cattle	0.4%	Soyabeans		61%
63%	GEMS/Food G08	62.56	59%	Potatoes	1%	Milk: Cattle	0.4%	Wheat		60%
61%	RO general	60.78	56%	Potatoes	2%	Milk: Cattle	0.5%	Wheat		59%
61%	GEMS/Food G07	60.77	56%	Potatoes	1%	Milk: Cattle	0.4%	Poultry: Muscle/meat		59%
61%	NL child	60.68	52%	Potatoes	5%	Milk: Cattle	0.8%	Sugar beet roots		57%
59%	UK infant	59.15	49%	Potatoes	8%	Milk: Cattle	0.4%	Eggs: Chicken		58%
59%	FI 6 yr	59.14	58%	Potatoes	0.1%	Wheat	0.1%	Bananas		58%
59%	UK toddler	58.95	52%	Potatoes	4%	Milk: Cattle	0.4%	Wheat		57%
58%	GEMS/Food G15	57.77	53%	Potatoes	1%	Milk: Cattle	0.4%	Wheat		56%
52%	PL general	52.07	51%	Potatoes	0.2%	Apples	0.1%	Tomatoes		51%
49%	LT adult	49.42	48%	Potatoes	0.8%	Milk: Cattle	0.2%	Apples		49%
49%	GEMS/Food G10	48.62	44%	Potatoes	1%	Milk: Cattle	0.5%	Poultry: Muscle/meat		46%
47%	DE child	47.29	39%	Potatoes	4%	Milk: Cattle	1%	Apples		44%
42%	DK child	41.90	36%	Potatoes	3%	Milk: Cattle	0.5%	Rye		40%
40%	NL general	40.03	36%	Potatoes	2%	Milk: Cattle	0.3%	Sugar beet roots		39%
38%	IE adult	38.25	34%	Potatoes	0.9%	Milk: Cattle	0.5%	Sheep: Liver		36%
37%	FR toddler 2 3 yr	36.59	28%	Potatoes	6%	Milk: Cattle	0.3%	Apples		35%
34%	GEMS/Food G06	33.94	30%	Potatoes	0.7%	Wheat	0.5%	Milk: Cattle		31%
33%	FR infant	33.24	29%	Potatoes	4%	Milk: Cattle	0.2%	Apples		32%
33%	ES child	32.71	28%	Potatoes	3%	Milk: Cattle	0.5%	Poultry: Muscle/meat		31%
31%	FR child 3 15 yr	30.60	23%	Potatoes	5%	Milk: Cattle	0.4%	Wheat		28%
23%	DE general	23.03	18%	Potatoes	3%	Milk: Cattle	0.4%	Sugar beet roots		21%
23%	UK adult	22.62	21%	Potatoes	0.6%	Milk: Cattle	0.2%	Wheat		22%
22%	UK vegetarian	22.23	21%	Potatoes	0.7%	Milk: Cattle	0.2%	Wheat		21%
21%	DK adult	21.25	19%	Potatoes	1%	Milk: Cattle	0.1%	Wheat		21%
21%	DE women 14-50 yr	21.22	16%	Potatoes	3%	Milk: Cattle	0.4%	Sugar beet roots		19%
19%	FI adult	18.84	18%	Potatoes	0.5%	Coffee beans	0.1%	Rye		18%
17%	ES adult	16.57	14%	Potatoes	1%	Milk: Cattle	0.2%	Poultry: Muscle/meat		16%
15%	IT toddler	14.91	13%	Potatoes	0.6%	Wheat	0.1%	Other cereals		13%
13%	FR adult	13.37	11%	Potatoes	0.9%	Milk: Cattle	0.2%	Wine grapes		12%
10%	IE child	10.37	9%	Potatoes	0.8%	Milk: Cattle	0.1%	Wheat		10%
10%	IT adult	10.09	9%	Potatoes	0.4%	Wheat	0.1%	Tomatoes		9%

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.

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)[(a)]	Comment	Input value (mg/kg)[(a)]	Comment
Risk assessment residue definition: sum of 1,4-dimethylnaphthalene, M21 and its conjugates, expressed as 1,4-dimethylnaphthalene				
Potato culls	14.98	$STMR_{Mo}$ × CF (1.9)	20.68	HR_{Mo} × CF (1.9)
Potato, process waste	70.43	$STMR_{Mo}$ × CF (1.9) × PF (4.7)	70.43	$STMR_{Mo}$ × CF (1.9) × PF (4.7)
Potato, dried pulp	569.42	$STMR_{Mo}$ × CF (1.9) × default PF (38)[(b)]	569.42	$STMR_{Mo}$ × CF (1.9) × default PF (38)[(b)]
Alfalfa forage (green)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Alfalfa hay (fodder)	0.24	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2.5)[(b)]	0.24	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2.5)[(b)]
Alfalfa meal	0.24	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2.5)[(b)]	0.24	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2.5)[(b)]
Alfalfa silage	0.1	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1.1)[(b)]	0.1	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1.1)[(b)]
Barley forage	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Barley straw	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Barley silage	0.12	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1.3)[(b)]	0.12	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1.3)[(b)]
Bean vines (fodder green)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Beet, mangel fodder	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Beet, sugar tops	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Cabbage, heads leaves	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Clover forage	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Clover hay	0.28	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (3)[(b)]	0.28	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (3)[(b)]
Clover silage	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1)[(b)]	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1)[(b)]
Corn, field forage/ silage	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Corn, field stover (fodder)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Corn, pop stover (fodder)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Cowpea forage	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)[(a)]	Comment	Input value (mg/kg)[(a)]	Comment
Cowpea hay	0.28	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2.9)[(b)]	0.28	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2.9)[(b)]
Grass forage (fresh)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Grass hay	0.33	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (3.5)[(b)]	0.33	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (3.5)[(b)]
Grass silage	0.15	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1.6)[(b)]	0.15	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1.6)[(b)]
Kale leaves (forage)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Lespedeza forage	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Lespedeza hay	0.38	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (4)[(b)]	0.38	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (4)[(b)]
Millet forage	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Millet straw (fodder, dry)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Oat forage	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Oat hay	0.28	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (3)[(b)]	0.28	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (3)[(b)]
Oat straw	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Pea vines (green)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Pea hay (hay or fodder)	0.33	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (3.5)[(b)]	0.33	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (3.5)[(b)]
Pea silage	0.15	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1.6)[(b)]	0.15	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1.6)[(b)]
Rape forage	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Rice straw	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Rye forage (greens)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Rye straw	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Sorghum forage	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Sorghum, grain stover	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Sorghum silage	0.06	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (0.6)[(b)]	0.06	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (0.6)[(b)]
Soybean forage (green)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)[(a)]	Comment	Input value (mg/kg)[(a)]	Comment
Soybean hay (fodder)	0.14	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1.5)[(b)]	0.14	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1.5)[(b)]
Soybean silage	0.05	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (0.5)[(b)]	0.05	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (0.5)[(b)]
Trefoil forage	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Trefoil hay	0.27	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2.8)[(b)]	0.27	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2.8)[(b)]
Triticale forage	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Triticale hay	0.28	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2.9)[(b)]	0.28	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2.9)[(b)]
Triticale straw	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Turnip tops (leaves)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Vetch forage	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Vetch hay	0.27	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2.8)[(b)]	0.27	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2.8)[(b)]
Wheat forage	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Wheat hay (fodder dry)	0.33	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (3.5)[(b)]	0.33	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (3.5)[(b)]
Wheat straw	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Carrot culls	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Cassava/tapioca roots	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Swede roots	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Turnip roots	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Barley grain	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Bean seed (dry)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Corn, field (Maize) grain	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Corn, pop grain	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Cotton undelinted seed	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Cowpea seed	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)[(a)]	Comment	Input value (mg/kg)[(a)]	Comment
Lupin seed	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Millet grain	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Oat grain	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Pea (Field pea) seed (dry)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Rye grain	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Sorghum grain	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Soybean seed	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Triticale grain	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Wheat grain	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9)
Apple pomace, wet	0.47	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (5)[(b)]	0.47	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (5)[(b)]
Beet, sugar dried pulp	1.71	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (18)[(b)]	1.71	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (18)[(b)]
Beet, sugar ensiled pulp	0.28	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (3)[(b)]	0.28	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (3)[(b)]
Beet, sugar molasses	2.66	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (28)[(b)]	2.66	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (28)[(b)]
Brewer's grain dried	0.31	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (3.3)[(b)]	0.31	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (3.3)[(b)]
Canola (Rape seed) meal	0.19	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2)[(b)]	0.19	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2)[(b)]
Citrus dried pulp	0.95	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (10)[(b)]	0.95	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (10)[(b)]
Coconut meal	0.14	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1.5)[(b)]	0.14	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1.5)[(b)]
Corn, field milled by-products	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1)[(b)]	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1)[(b)]
Corn, field hominy meal	0.57	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (6)[(b)]	0.57	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (6)[(b)]
Corn, field gluten feed	0.24	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2.5)[(b)]	0.24	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2.5)[(b)]
Corn, field gluten, meal	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1)[(b)]	0.09	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1)[(b)]
Cotton meal	0.12	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1.3)[(b)]	0.12	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1.3)[(b)]
Distiller's grain dried	0.31	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (3.3)[(b)]	0.31	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (3.3)[(b)]

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)[(a)]	Comment	Input value (mg/kg)[(a)]	Comment
Flaxseed/Linseed meal	0.19	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2)[(b)]	0.19	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2)[(b)]
Lupin seed meal	0.1	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1.1)[(b)]	0.1	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1.1)[(b)]
Palm (hearts) kernel meal	0.19	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2)[(b)]	0.19	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2)[(b)]
Peanut meal	0.19	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2)[(b)]	0.19	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2)[(b)]
Rape meal	0.19	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2)[(b)]	0.19	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2)[(b)]
Rice bran/pollard	0.95	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (10)[(b)]	0.95	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (10)[(b)]
Safflower meal	0.19	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2)[(b)]	0.19	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2)[(b)]
Soybean meal	0.12	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1.3)[(b)]	0.12	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1.3)[(b)]
Soybean hulls	1.23	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (13)[(b)]	1.23	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (13)[(b)]
Sugarcane molasses	3.03	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (32)[(b)]	3.03	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (32)[(b)]
Sunflower meal	0.19	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2)[(b)]	0.19	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (2)[(b)]
Wheat gluten meal	0.17	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1.8)[(b)]	0.17	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (1.8)[(b)]
Wheat milled by-products	0.66	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (7)[(b)]	0.66	MRL (Reg. (EU) 2022/1346) × CF (1.9) × default PF (7)[(b)]

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
(a): Figures in the table are rounded to 2 digits, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce dietary burden calculations, the unrounded values need to be used.
(b): In the absence of processing factors supported by data, default processing factors (in bracket) were, respectively, included in the calculation to consider the potential concentration of residues in these commodities.

D.2. Consumer risk assessment

Commodity	Existing/Proposed MRL (mg/kg)	Chronic risk assessment	
		Input value[(a)] (mg/kg)	Comment
Risk assessment residue definition 1: sum of 1,4-dimethylnaphthalene, M21 and its conjugates, expressed as 1,4-dimethylnaphthalene			
Potatoes	20	14.98	STMR-RAC × CF (1.9) (tentative) Intended use (Netherlands, 2022)
Other plant commodities	0.05	0.095	MRL (Reg. (EU) 2022/1346) × 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			
Swine: Muscle/ meat	0.03	0.058	0.8 × STMR muscle +0.2 × STMR fat[(b)] (B.2.2.1)
Swine: Fat tissue	0.3	0.17	STMR-RAC (B.2.2.1)
Swine: Liver	1.5	1.17	STMR-RAC (B.2.2.1)

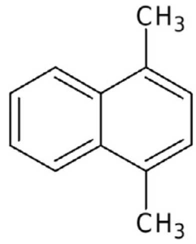
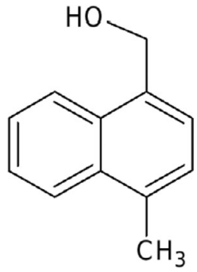
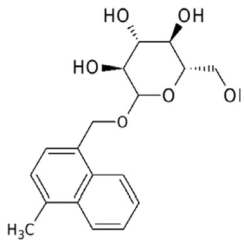
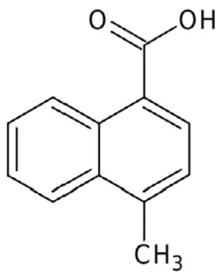
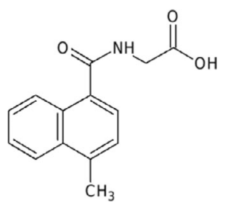
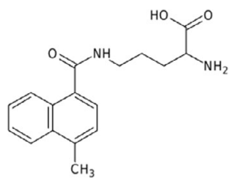
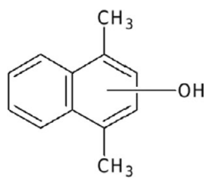
Commodity	Existing/Proposed MRL (mg/kg)	Chronic risk assessment	
		Input value[(a)] (mg/kg)	Comment
Swine: Kidney	1.5	1.03	STMR-RAC (B.2.2.1)
Bovine: Muscle/ meat	0.03	0.082	0.8 × STMR muscle +0.2 × STMR fat[(b)] (B.2.2.1)
Bovine: Fat tissue	0.5	0.29	STMR-RAC (B.2.2.1)
Bovine: Liver	2	1.78	STMR-RAC (B.2.2.1)
Bovine: Kidney	2	1.56	STMR-RAC (B.2.2.1)
Sheep: Muscle/ meat	0.03	0.098	0.8 × STMR muscle +0.2 × STMR fat[(b)] (B.2.2.1)
Sheep: Fat tissue	0.6	0.37	STMR-RAC (B.2.2.1)
Sheep: Liver	3	2.19	STMR-RAC (B.2.2.1)
Sheep: Kidney	3	1.92	STMR-RAC (B.2.2.1)
Goat: Muscle/ meat	0.03	0.098	0.8 × STMR muscle +0.2 × STMR fat[(b)] (B.2.2.1)
Goat: Fat tissue	0.6	0.37	STMR-RAC (B.2.2.1)
Goat: Liver	3	2.19	STMR-RAC (B.2.2.1)
Goat: Kidney	3	1.92	STMR-RAC (B.2.2.1)
Equine: Muscle/ meat	0.03	0.082	0.8 × STMR muscle +0.2 × STMR fat[(b)] (B.2.2.1)
Equine: Fat tissue	0.5	0.29	STMR-RAC (B.2.2.1)
Equine: Liver	2	1.78	STMR-RAC (B.2.2.1)
Equine: Kidney	2	1.56	STMR-RAC (B.2.2.1)
Poultry: Muscle/ meat	0.3	0.363	0.9 × STMR muscle +0.1 × STMR fat[(b)] (B.2.2.1)
Poultry: Fat tissue	1.5	1.29	STMR-RAC (B.2.2.1)
Poultry: Liver	1.5	0.91	STMR-RAC (B.2.2.1)
Milk: Cattle	0.3	0.21	STMR-RAC (B.2.2.1)
Milk: Sheep	0.3	0.26	STMR-RAC (B.2.2.1)
Milk: Goat	0.3	0.26	STMR-RAC (B.2.2.1)
Milk: Horse	0.3	0.21	STMR-RAC (B.2.2.1)
Bird eggs	0.4	0.28	STMR-RAC (B.2.2.1)

STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; CF: conversion factor.

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

(b): Consumption figures in the EFSA PRIMo are expressed as meat. Since the a.s. is a fat-soluble pesticides, STMR and HR residue values were calculated considering a 80%/90% muscle and 20%/10% fat content for mammal/poultry meat, respectively (FAO, 2016).

Appendix E – 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 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 7 July 2021).
(c): ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 28 August 2021).