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Modification of the existing maximum residue levels for copper compounds in other small fruits and berries

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Spiess-Urania Chemicals GmbH submitted a request to the competent national authority in Austria to modify the existing maximum residue levels (MRLs) for the active substance copper compounds in the whole group of other small fruits and berries. The data submitted in support of the request were found to be sufficient to derive MRL proposals for the whole subgroup of other small fruits and berries. Adequate analytical methods for enforcement of mineral copper independently from its chemical form are available for matrices under consideration at the validated limit of quantification (LOQ) of 5 mg/kg. Based on indicative risk assessment results, EFSA concluded that the long-term intake of copper residues resulting from the intended and existing uses, natural background levels and monitoring levels might present a risk to consumer health. Although residues in other small fruits and berries are minor contributors to the overall consumer exposure, a risk management decision has to be taken on whether it is appropriate to increase the existing MRLs for these crops, given that a potential consumer intake concern could not be excluded.

Keywords: copper compounds, copper hydroxide, other small fruits and berries, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Spiess-Urania Chemicals GmbH submitted an application to the competent national authority in Austria (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance copper compounds in other small fruits and berries application.

The application, alongside the dossier containing the supporting data using the IUCLID format was submitted through the EFSA Central Submission System on 12 May 2021. The appointed EMS (Austria) assessed the dossier and declared its admissibility on 12 August 2021. Subsequently, following the implementation of the EFSA's confidentiality decision, the dossier was published by EFSA, and a public consultation was launched on the dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The consultation run from 13 October 2021 to 3 November 2021. No additional data nor comments were submitted in the framework of the consultation. At the end of the commenting period, the EMS proceeded with drafting the evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005. The report was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 28 February 2022. To accommodate for the intended uses of copper compounds, the EMS proposed to raise the existing MRLs for other small fruits and berries from the limit of quantification (LOQ) of 5–15 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 25 May 2022, the applicant provided the requested information in an updated IUCLID dossier. The additional information was duly considered by the EMS who submitted a revised evaluation report to EFSA on 30 May 2022, which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of Regulation (EC) No 1107/2009, 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.

Specific studies evaluating the metabolism and distribution of residues in plants following the use of copper compounds as a plant protection product are not available. According to the public scientific literature, in plants, copper ions are absorbed from the soil through the roots and then further transported to the rest of the plant. Upon foliar application, transportation and distribution of copper in plants are limited. As no metabolites are expected, the nature of residues in primary crops, rotational crops and processed commodities as well as the storage stability are considered addressed and specific studies are not required.

The relevant residue for monitoring and risk assessment was defined as total copper, including copper residues arising from all forms of copper. Analytical methods for enforcement of mineral copper independently from its chemical form are available for matrices under consideration (high acid content commodities) at the validated limit of quantification (LOQ) of 5 mg/kg.

The available data are considered sufficient to derive an MRL proposal of 15 mg/kg as well as risk assessment values for other small fruits and berries in support of the intended northern outdoor use of copper hydroxide.

Specific studies investigating the magnitude of copper residues in processed commodities from the group of other small fruits and berries were not submitted and are not required considering very low contribution of residues in these crops to the total theoretical maximum daily intake (TMDI).

Since the intended use of copper hydroxide is on permanent crops, investigations of residues in rotational crops are not required. However, copper being an essential nutrient for plant growth development, it is normally taken up from the soil where it occurs naturally or after applications of pesticide products and fertilisers. The uptake of copper is regulated by plants to provide the essential nutritional amount. Therefore, copper can be present in succeeding crops (annual and permanent) as an endogenous compound, following natural soil absorption as a micronutrient. Based on the literature data on the copper background levels in plant commodities and based on the copper levels measured in the untreated samples of the residue trials submitted in the present opinion, it could be concluded the MRL derived in the present opinion largely covers the potential uptake of copper from the soil in succeeding years of applications.

Residues of copper in commodities of animal origin were not assessed since other small fruits and berries are normally not fed to livestock.

The toxicological profile of copper was assessed in the framework of the EU pesticides peer review under Regulation (EC) No 1107/2009 and the data were considered sufficient at the time to derive an acceptable daily intake (ADI) of 0.15 mg/kg body weight (bw) per day. An acute reference dose (ARfD) was not deemed necessary. It is noted that EFSA's Scientific Committee has recently prepared a scientific opinion under an European Commission mandate to harmonise previous divergent HBGVs for copper, where a replacement of this ADI is proposed and an updated exposure assessment from all sources of copper was performed (EFSA-Q-2020-00399). The draft scientific opinion of the Scientific Committee is currently under public consultation. Should the proposed revised ADI be established as a result of the scientific opinion of the Scientific Committee, the risk assessment in this reasoned opinion shall be reconsidered.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). An indicative exposure to copper residues was calculated based on all critical GAPs authorised in the EU and the background levels (from survey or monitoring data) expected in all commodities of plant and animal origin in the EFSA review of the existing MRLs for copper under Article 12 of Regulation 396/2005 (MRL review). For the long-term consumer exposure, an update of scenario 1 (considering all commodities of plant and animal origin) and scenario 2 (considering risk mitigation measures to reduce the exposure) performed in the MRL review was done considering the input values derived from the intended uses. In both scenarios, the maximum exposure exceeded the ADI (166% and 162% of the ADI for the Dutch toddler diet, respectively). It is noted that, in the MRL review, using revision 2 of PRIMo, an exceedance of the ADI was identified for scenario 1 but not for scenario 2. The significant increase in the calculated exposure derived in the current assessment compared with the risk assessment performed in the framework of the MRL review is related to the use of the new version of EFSA PRIMo (revision 3.1) which contains updated food consumption data. Nevertheless, the contribution of copper residues in other small fruits and berries to the actual long-term consumer exposure is very low (1.08% of the ADI considering the contribution of the whole group of other small fruit and berries; individually, maximum of 0.46% of the ADI for currants).

EFSA concluded that the long-term consumer intake concerns cannot be excluded for the intake of copper residues resulting from the intended uses, existing uses and background/monitoring levels. Although residues in other small fruits and berries from the new intended uses result in a very low contribution to the overall consumer exposure, a risk management decision needs to be taken on whether it is appropriate to increase the existing MRL for these commodities from 5 to 15 mg/kg, given that, based on the currently available information, potential consumer intake concerns cannot be excluded. It is noted that EFSA is also currently working on a mandate to review the ADI for copper and to perform exposure calculations from all sources of copper (EFSA-Q-2020-00399). The draft opinion is currently under public consultation. Therefore, the conclusions reported in this reasoned opinion may need to be reconsidered following the outcome of the review of the ADI for copper and exposure assessment considering all sources of copper.

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/ MRL proposed in the MRL review (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Copper compounds (Copper)				
0154010	Blueberries	5/5*	Further risk management considerations required	The submitted data are sufficient to derive an MRL proposal of 15 mg/kg in support of the intended norther outdoor use of copper hydroxide. Long-term consumer intake concerns cannot be excluded for the intake of copper residues resulting from the intended and existing uses of copper compounds and background/ monitoring levels. Residues in the group of other small fruits and berries contribute to a very low extent to the overall consumer exposure (1.08% of the ADI).
0154020	Cranberries	5/5*		
0154030	Currants (black, red and white)	5/5*		
0154040	Gooseberries (green, red and yellow)	5/5*		
0154050	Rose hips	5/5*		
0154060	Mulberries (black and white)	5/5*		
0154070	Azaroles/ Mediterranean medlars	5/5*		

Code[(a)]	Commodity	Existing EU MRL/ MRL proposed in the MRL review (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0154080	Elderberries	5/5*		A risk management decision has to be taken whether it is appropriate to raise the existing MRL, given that based on the currently available information, a potential consumer intake concern cannot be excluded.
0154990	Others	5/5*		

MRL: maximum residue level; EU: European Union; ADI: acceptable daily intake.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue levels (MRLs) for copper compounds in other small fruits and berries. The detailed description of the intended uses of copper hydroxide which are the basis for the current MRL application is reported in Appendix A.

Copper hydroxide is the common name for copper (II) hydroxide (or copper (2+) hydroxide or cupric hydroxide) (IUPAC). The active substances are copper(I) and copper (II) ions.

Copper compounds[1] have been evaluated for renewal of the approval in the framework of Regulation (EC) No 1107/2009[2] with France designated as rapporteur Member State (RMS) for the representative uses as fungicide/bactericide on field applications on grapes and field and greenhouse applications on tomatoes and cucurbits. The renewal assessment report (RAR) prepared by the RMS has been peer reviewed by EFSA (2018b). The peer review conclusions of EFSA published in 2018 (EFSA, 2018b) supersede the previous EFSA assessments (EFSA, 2008, 2013). The decision on the renewal of copper compounds entered into force on 1 January 2019.[3] The use of plant protection products containing copper compounds is restricted to a maximum application rate of 28 kg/ha of copper over a period of 7 years (i.e. on average 4 kg/ha per year).[4]

The EU MRLs covering the uses of the different copper compounds are established in Annex III of Regulation (EC) No 396/2005[5]; the MRLs are expressed on the basis of copper ions (all forms of copper present in the plant converted to Cu^{2+}). The review of existing EU MRLs for copper compounds according to Article12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2018c). The MRL proposals have not yet been implemented in the EU MRL regulation.

In accordance with Article 6 of Regulation (EC) No 396/2005 and following the provisions set by the 'Transparency Regulation' (EU) 2019/1381[6], the applicant Spiess-Urania Chemicals GmbH submitted on 12 May 2021 an application to the competent national authority in Austria, alongside the dossier containing the supporting data using the IUCLID format.

It is noted that for the current application, no general presubmission advice (GPSA) from EFSA was sought by the applicant in accordance with Article 32a(1) of the General Food Law GFL Regulation,[7] prior to submission of this dossier.

Furthermore, none of the studies submitted to support this MRL application were subject to the obligation of study notifications in accordance with Article 32b of the GFL Regulation,[8] since they were all commissioned or carried out before 27 March 2021.

The EMS assessed the dossier and declared its admissibility on 12 August 2021. Subsequently, following the implementation of the EFSA's confidentiality decision, the dossier was published by EFSA, and a public consultation was launched on the dossier. The consultation aimed to consult stakeholders

[1] Copper hydroxide, copper oxychloride, Bordeaux mixture, tribasic copper sulfate and copper(I) oxide.

[2] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

[3] Commission Implementing Regulation (EU) 2018/1981 of 13 December 2018 renewing the approval of the active substances copper compounds, as candidates for substitution, 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 Commission Implementing Regulation (EU) No 540/2011. C/2018/8449 OJ L 317, 14.12.2018, p. 16–20.

[4] In order to minimise the potential accumulation in soil and the exposure for not target organisms, while taking into account agro-climatic conditions occurring periodically in Member States leading to an increase of the fungal pressure. When authorising products, Member States should pay attention to certain issues and strive for the minimisation of application rates.

[5] 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 9. OJ L 70, 16.03.2005, p. 1–16.

[6] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, PE/41/2019/REV/1. OJ L 231, 6.9.2019, p. 1–28.

[7] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying own procedures in matters of food safety, as amended by Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, PE/41/2019/REV/1. OJ L 231, 6.9.2019, p. 1–28.

[8] 'In accordance with Article 32b of the GFL Regulation, both potential applicants and laboratories/testing facilities commissioning or carrying out studies as of 27 March 2021 in view of an MRL application have the obligation to notify EFSA' (For further details, see EFSA administrative guidance on peer review of pesticide active substances and MRL applications; EFSA, 2021).

and the public on the scientific data, studies and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The consultation run from 13 October 2021 to 3 November 2021. No additional data nor comments were submitted in the framework of the consultation. At the end of the commenting period, the EMS proceeded with drafting the evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005. The report was submitted to the European Commission and forwarded to the EFSA on 28 February 2022. To accommodate for the intended uses of copper compounds, the EMS proposed to raise the existing MRLs for other small fruits and berries from the limit of quantification (LOQ) of 5–15 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 25 May 2022, the applicant provided the requested information in an updated IUCLID dossier. The additional information was duly considered by the EMS who submitted a revised evaluation report to EFSA on 30 May 2022 (Austria, 2022), which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (Austria, 2022), the draft renewal assessment report (RAR) (and its addendum) (France, 2016, 2017) prepared under Regulation (EC) 1107/2009, the Commission review report on copper compounds (European Commission, 2018), the conclusion on the peer review of the pesticide risk assessment of the active substance copper compounds (EFSA, 2018b), as well as the conclusions from previous EFSA opinions on copper compounds, including the reasoned opinion on the MRL review according to Article 12 of Regulation No 396/2005 (EFSA, 2018c, 2020).

For this application, the data requirements established in Regulation (EU) No 283/2013[9] and the guidance documents applicable at the date of submission of the IUCLID application are applicable (European Commission, 2010, 2017, 2020, 2021; OECD, 2007a,b, 2009a,b, 2011, 2016). 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[10].

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 (Austria, 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.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

Specific studies evaluating the metabolism and distribution of residues in plants following the use of copper as a plant protection product are not available. However, the public scientific literature reported in the framework of the first peer review provided enough information on the uptake, translocation and effects of copper in plants (EFSA, 2018b,c).

In plants, copper is absorbed from the soil through the roots. From the roots, copper is transported in the sap to the rest of the plant. Upon foliar application, transportation and distribution of copper in plants are limited.

For the intended use, the metabolic behaviour in primary crops is thus considered addressed.

1.1.2. Nature of residues in rotational crops

Copper is extremely stable in soil and since no degradation is expected, no DT_{50}/DT_{90} values were derived during the EU pesticides peer review and the MRL review (EFSA, 2018b,c). However, for the

[9] Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, 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. OJ L 93, 3.4.2013, p. 1–84.

[10] 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.

same reason as mentioned in Section 1.1.1, specific studies to evaluate the nature of residues in succeeding crops are not necessary.

Copper hydroxide is proposed to be used on permanent crops that are not grown in rotation with other crops. Nevertheless, all soil-grown crops may contain copper (EFSA, 2018c), which is absorbed from the soil and can be transported to the rest of the plant, residue uptake in succeeding crops is a relevant issue. This point is further discussed under Section 1.2.2.

1.1.3. Nature of residues in processed commodities

Studies investigating the effects of industrial processing or household preparation on the nature of copper residues are not available. However, such studies are not necessary as copper is known to be inherently stable (see also Section 1.1.1) (EFSA, 2018a,c).

1.1.4. Analytical methods for enforcement purposes in plant commodities

Analytical methods for the determination of copper residues in plant matrices were provided and evaluated in the framework of the initial EU pesticides peer review (EFSA, 2008) and the MRL review (2018c). The available methods involve atomic absorption spectrometry (AAS) and were validated in commodities with high water content (limit of quantification (LOQ) of 2 mg/kg) and high acid content (LOQ of 5 mg/kg) (EFSA, 2018c).

It is noted that in the framework of the renewal of the approval of copper compounds under Regulation (EC) No 1107/2009, similar methods were reassessed and there are indications that a lower LOQ of 0.2 mg/kg could be achieved in these crops. Data gaps were identified for additional validation data for high oil content commodities, dry commodities and for an independent laboratory validation (ILV) for plants (EFSA, 2018b). The MRL review concluded that the ILV is not deemed necessary since AAS are recognised as standard methods of analysis for inorganic elements (EFSA, 2018c).

With regard to the crops under consideration (high acid content commodities), EFSA concludes that sufficiently validated analytical enforcement methods are available.

1.1.5. Storage stability of residues in plants

Since copper cannot degrade and since the analytical techniques measure total copper content, storage stability studies are not required (EFSA, 2018b,c).

1.1.6. Proposed residue definitions

The nature of copper residues in primary crops, rotational crops and processed commodities as well as its stability during storage are considered sufficiently addressed. The relevant residue for monitoring and risk assessment was defined as total copper, including copper residues arising from the different variants of copper (EFSA, 2018b). This definition is expected to include copper residues arising from all forms of copper as they would be converted to Cu^{2+} during the analytical phase (EFSA, 2018c).

The current residue definition for enforcement set in Regulation (EC) No 396/2005 is 'Copper compounds (copper)', therefore identifying the same marker compound for enforcement as the above-mentioned residue definition, but with a slightly different wording.

EFSA concluded that these residue definitions are appropriate for the current assessment and no further information is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted six residue trials performed in currants. The samples were analysed for total copper as per residue definition for enforcement and risk assessment. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose. Since copper is a nutrient, naturally present in plants, copper residues were also found in untreated control samples (see Section 1.2.2).

The six residue trials were performed in 2020 in various Member States of northern Europe (Austria, Northern France, Germany, Hungary and Poland). All trials were conducted according to the GAP, with three foliar spray applications at an application rate of 1 kg a.s./ha. The interval between the applications was 5 days. No PHI is specified in the intended GAP as the timing of application is defined by the growth stage of the plant.

In three residue trials, the growth stage at last application was reported as BBCH 59 (before flowering) in perfect accordance with the intended GAP. In the three other trials however, the growth stage at the last application was reported as BBCH 61 (10% of flowers open). In both cases, no consumable parts of the crop were present at last application. Nevertheless, it was noted that residues in samples treated at BBCH 59 were < 0.8 (LOQ), 1.08, 1.36 mg/kg while residues of samples treated at BBCH 61 were 2.73, 3.23 and 6.22 mg/kg. A robust statistical correlation between crop stage at last application and the residue levels measured in currants is not possible based on six samples. However, upon EFSA's request, the applicant was invited to provide further clarifications on the trials performed with the last application at BBCH 61. The applicant clarified that while the growth stage at the last application was reported as BBCH 61, the crop development of the plant bushes of the same plot can be inhomogeneous. For example, in the trial leading to the highest value of the data set (6.22 mg/kg), individual samples were taken from at least six separate bushes, where the BBCH at last application varied between 55 and 61.

It should be noted that inhomogeneous development of bushes is also happening in real agricultural conditions as it is very unlikely that all bushes reach the same growth stage on the same day. Consequently, the single plants that have been treated at growth stages slightly exceeding BBCH 59 (e.g. BBCH 61) in those trials might also be present in real conditions. Therefore, EFSA agrees with the conclusion of the EMS that the six available residue trials can be considered as GAP compliant.

According to the current technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation on residue data on products from plant and animal origin – SANTE/2019/12752 (European Commission, 2020), six trials are sufficient to support the northern GAP on currants and the extrapolation of results in currants to the whole subgroup of other small fruits and berries (0154000) is possible.

1.2.2. Magnitude of residues in rotational crops

Copper is an essential nutrient for plant growth development and is normally taken up from soil where it occurs naturally or after succeeding applications. Considering information published in scientific literature, the peer review concluded that the uptake of copper is regulated by plants to provide the essential nutritional amount. Therefore, copper can be present in succeeding crops (annual and permanent) as an endogenous compound, following natural soil absorption as a micronutrient (EFSA, 2018b).

A comprehensive survey on the copper background levels in plant commodities was reported in the framework of the MRL review (full report available in Annex A of the EFSA reasoned opinion on the review of existing MRLs for copper compounds; EFSA, 2018c). According to this survey, the maximum natural background level of copper in the group of other small fruits and berries is 1.8 mg/kg (found in rose hips). The maximum for all berries (including cane fruits) is 2.2 mg/kg. In addition, copper levels in the untreated samples of the residue trials submitted in the present opinion range between < 0.8 mg/kg (LOQ) and 2.09 mg/kg. This information gives an indication of the background levels of copper that are expected in the commodities belonging to the group of other small fruits and berries. The assessment performed in Section 1.2.1 indicates that the MRL proposal derived in the present opinion (15 mg/kg) largely covers the potential uptake of copper from the soil, which is regulated by the plant depending on its nutritional needs.

Since the intended use of copper hydroxide is on permanent crops, investigations of residues in rotational crops are not required. Furthermore, the intended use of copper hydroxide on the group of other small fruits and berries is in line with the provisions of the Commission Implementing Regulation EU 2018/1981[11] (restricted annual application rate of average 4 kg copper/ha and maximum total application of 28 kg copper/ha over a period of 7 years) and is below the application rates assessed for the representative uses in the renewal of the approval of copper compounds (EFSA, 2018b).

1.2.3. Magnitude of residues in processed commodities

New studies investigating the effect on the magnitude of copper residues in processed crops under consideration were not submitted in the framework of this assessment and are not requested since the

[11] Commission Implementing Regulation (EU) 2018/1981 of 13 December 2018 renewing the approval of the active substances copper compounds, as candidates for substitution, 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 Commission Implementing Regulation (EU) No 540/201. OJ L 317, 14.12.2018, p. 16–20.

contribution of other small fruits and berries to the consumer intake is very low (see Section 3) and further refinements would not have major impact on reducing the total exposure to copper residues.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive an MRL proposal of 15 mg/kg as well as risk assessment values for crops belonging to the group of other small fruits and berries in support of the intended northern outdoor use of copper hydroxide.

EFSA notes that a different MRL proposal (LOQ of 5 mg/kg) was recommended by the MRL review (EFSA, 2018c). In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as crops under consideration are not used for feed purposes.

3. Consumer risk assessment

In the framework of the MRL review (EFSA, 2018c), a comprehensive long-term exposure assessment was performed using revision 2 of EFSA Pesticide Residues Intake Model (PRIMo), taking into account the exposure to copper from authorised (existing) uses as well as from any other sources (background concentrations, uptake from the soil, etc.). The commodities on which no uses were reported in the MRL review were therefore also included in the calculation.

Two scenarios of exposure calculation were performed in the MRL review:

- scenario 1, including all commodities of plant and animal origin;
- scenario 2, considering a proposal for risk mitigation measures to reduce the exposure based on the main contributors to the chronic exposures identified using the revision 2 of PRIMo.

In the context of an MRL assessment performed in 2020 for fresh herbs and edible flowers, EFSA has updated these exposure calculations using revision 3.1 of the EFSA PRIMo and new STMR values derived from fresh herbs and edible flowers (EFSA, 2020). For the current assessment, EFSA now updated the calculations performed in EFSA (2020), adding the new STMR derived for currants and extrapolated to the other commodities included in the group other small fruits and berries. Calculations were done assuming that the recommendations of the MRL review will be taken over in the EU legislation and are indicative considering the data gaps identified in the MRL review (EFSA, 2018c). The detailed input values used for each crop are available in Appendix D.1 of the present opinion.

The revision 3.1 of the EFSA PRIMo is still used in the current assessment. This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population (EFSA, 2018a, 2019).

The toxicological reference value for copper compounds used in the risk assessment (i.e. ADI value of 0.15 mg/kg bw day) was derived in the framework of the EU pesticides peer review (European Commission, 2018).[12] The setting of the ARfD was considered not necessary.

The calculated long-term dietary exposure to copper residues considering all commodities of plant and animal origin (scenario 1) and the new STMR for other small fruit and berries exceeded the ADI. In scenario 1, the maximum exposure accounted for 166% of the ADI for the Dutch toddler diet. It is noted that an exceedance of the ADI (108.9%; WHO Cluster diet B) was also identified in the MRL review for scenario 1 (EFSA, 2018c) using revision 2 of PRIMo. However, the food contributors identified in the MRL review to propose risk mitigation measures (wine grapes, tomatoes, potatoes and lettuce) are not significantly contributing to the exposure calculated for the Dutch toddler diet with PRIMo rev. 3.1. Therefore, scenario 2 (risk mitigation measures as defined in the MRL review) does not have a significant impact on the chronic exposure calculated for Dutch toddler. When assessing scenario 2 with PRIMo 3.1, the calculated exposure still accounts for 162% of the ADI for the Dutch toddler diet. EFSA notes that in the MRL review, the exposure calculated in scenario 2 with PRIMo 2 resulted in a chronic exposure below the ADI (93.4% of the ADI) (EFSA, 2018c).

The significant increase of the calculated exposure derived in the current assessment compared with the risk assessment performed in the framework of the MRL review is related to the use of the

[12] EFSA has received a mandate to review the ADI for copper and to perform exposure calculations from all sources of copper (EFSA-Q-2020-00399).

new version of EFSA PRIMo (revision 3.1) which contains updated food consumption data. Nevertheless, the contribution of copper residues from the whole group of other small fruits and berries to the actual long-term consumer exposure is very low (1.08% of the ADI considering the contribution of the whole group of other small fruit and berries; individually, maximum of 0.46% of the ADI for currants).

The MRL review EFSA also assessed potential exposure via drinking water (EFSA, 2018c).

It is noted that in the evaluation report of the EMS, an additional calculation of the chronic exposure performed by the applicant was reported. This calculation resulted in a non-exceedance of the ADI (Austria, 2022). However, this calculation seems to be based on different input values for several crops, most of them not fully justified. For many crops where authorised GAPs were reported and assessed during the MRL review (e.g. pome fruits, grapes, lettuces and similar, spinach and similar), the STMR values derived in the MRL review were not considered. Instead, the medians of the background levels were considered without justification. Furthermore, for maize grain, sunflower seed and sugar beet, a dilution factor of 10 was applied based on the rational that these crops are mainly eaten as processed. While it is noted that a processing factor of 10 was supported for oil processing of rapeseed (EFSA, 2018c), the use of this dilution factor of 10 for maize, sunflower and sugar beet is not justified. For maize, processing to oil is not the only possible process and there is no evidence that the dilution factor of 10 would also apply to maize oil and to other maize products. Furthermore, for maize grain, a median background level of 2.4 mg/kg was considered while a median background level of 4.15 mg/kg was used in the MRL review (EFSA, 2018c). For sugar beet, EFSA agrees that a dilution might be expected through the sugar production, but the factor of 10 is not supported by any data. For sunflower oil, a dilution factor of 10 could indeed be extrapolated but EFSA already considered in the MRL review that this crop is not exclusively consumed as oil (in the contrary to rapeseed). Consequently, EFSA agrees with the EMS that the calculation performed by the applicant is not reliable. Therefore, the concerns identified by the EMS and EFSA regarding the chronic exposure of the Dutch toddler diet are still relevant.

In addition, it should be noted that EFSA has received a mandate to review the hazard assessment (ADI) and to update the exposure assessment for copper compounds considering all sources of copper (EFSA-Q-2020-00399). The draft opinion is currently under public consultation.

EFSA concluded that the long-term consumer intake concerns cannot be excluded for the intake of copper residues resulting from the intended uses, existing uses and background/monitoring levels. Although residues in the group of other small fruits and berries from the new intended use contribute to a very low extent to the overall consumer exposure, a risk management decision needs to be taken whether it is appropriate to increase the existing MRL for these commodities from 5 to 15 mg/kg, given that, based on the currently available information, potential consumer intake concerns cannot be excluded. The ongoing assessment performed by EFSA upon European Commission mandate (EFSA-Q-2020-00399) may provide further new elements to assist risk managers in this decision process.

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 of 15 mg/kg for copper for the whole group of other small fruits and berries in support of the intended use of copper hydroxide. The intended NEU use results in a more critical residue situation in these crops compared to the GAPs assessment in the MRL review, which proposed to set the MRL at the LOQ of 5 mg/kg.

Based on an indicative risk assessment, EFSA concluded that the long-term consumer intake concerns cannot be excluded for the intake of copper residues resulting from all existing uses and considering the background copper levels present in food of plant and animal origin. Residues in the group of other small fruits and berries resulting from the new intended uses contribute to a very low extent to the overall consumer exposure. A risk management decision has to be taken on whether it is appropriate to increase the existing MRL in these crops to 15 mg/kg, given that, based on the currently available information, potential consumer intake concerns cannot be excluded and considering that EFSA is also currently working on a mandate to review the ADI for copper and to perform exposure calculations from all sources of copper (EFSA-Q-2020-00399). Since the draft opinion is currently under public consultation, the conclusions reported in this reasoned opinion may need to

be reconsidered following the outcome of the review of the ADI for copper and exposure assessment considering all sources of copper.

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
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CCPR	Codex Committee on Pesticide Residues
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
CF	conversion factor for enforcement to risk assessment residue definition
cGAP	critical GAP
CIPAC	Collaborative International Pesticide Analytical Council
CIRCA	(EU) Communication & Information Resource Centre Administrator
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
CS	capsule suspension
CV	coefficient of variation (relative standard deviation)
CXL	Codex maximum residue limit
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DP	dustable powder
DS	powder for dry seed treatment
DT90	period required for 90% dissipation (define method of estimation)
dw	dry weight
EC	emulsifiable concentrate
ECD	electron capture detector
EDI	estimated daily intake
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
ESI	electrospray ionisation
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organization of the United Nations
FID	flame ionisation detector

FLD	fluorescence detector
FPD	flame photometric detector
GAP	Good Agricultural Practice
GC	gas chromatography
GC-ECD	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-FPD	gas chromatography with flame photometric detector
GC–MS	gas chromatography with mass spectrometry
GC–MS/MS	gas chromatography with tandem mass spectrometry
GC-NPD	gas chromatography with nitrogen/phosphorous detector
GCPF	Global Crop Protection Federation (formerly International Group of National Associations of Manufacturers of Agrochemical Products (GIFAP))
GLP	good laboratory practice
GR	granule
GS	growth stage
HPLC	high performance liquid chromatography
HPLC-MS	high performance liquid chromatography with mass spectrometry
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HPLC-UVD	high performance liquid chromatography with ultra-violet detector
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
IPCS	International Programme of Chemical Safety
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
Koc	organic carbon adsorption coefficient
LC	liquid chromatography
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue level
MS	mass spectrometry detector
MS	Member States
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
NOAEL	no observed adverse effect level
NPD	nitrogen/phosphorous detector
OECD	Organisation for Economic Co-operation and Development
PAFF	Standing Committee on Plants, Animals, Food and Feed
PBI	plant back interval
PF	processing factor
PHI	pre-harvest interval
Pow	partition coefficient between n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RAC	raw agricultural commodity
Rber	statistical calculation of the MRL by using a non-parametric method
RD	residue definition
Rmax	statistical calculation of the MRL by using a parametric method
RMS	rapporteur Member State
RPF	relative potency factor
SANCO	Directorate-General for Health and Consumers

SC	suspension concentrate
SCPAFF	Standing Committee on Plants, Animals, Food and Feed (formerly: Standing Committee on the Food Chain and Animal Health; SCFCAH)
SEU	southern Europe
SG	water-soluble granule
SL	soluble concentrate
SP	water-soluble powder
STMR	supervised trials median residue
TAR	total applied radioactivity
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UV	ultraviolet (detector)
WG	water-dispersible granule
WHO	World Health Organization
WP	wettable powder
YF	yield factor
ZC	mixed CS and SC formulation

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

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				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s. (g/L)	Method kind	Range of growth stages & 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		
Small fruit crops (3RIBC, 3VACC, 3MULC, ROSSS, CSCAZ, SAMNI)[e]	NEU (AT, CZ, PL, HU, SK, DE)	F	*Drepanopeziza ribis* (Leaf spot) (DREPRI) *Cronartium ribicola* (Rust of gooseberry) (CRONRI)	SC	250 g Cu/L 384 g CuOH/L	Foliar treatment – broadcast spraying	After harvest until flowering (BBCH 91–59)	3	5–7	4	500–1,000	1	kg a.s./ha	n.a.	In case of treatments with low doses (with less effectiveness, e.g. in organic farming), the maximal number of applications could be increased as far as the acceptable annual active ingredient amount of the product is not exceeded.

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; SC: suspension concentrate, n.a.: not applicable.
(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): PHI: minimum preharvest interval.
(e): Reference is made to the EPPO codes used for crop groups (https://gd.eppo.int/taxon/3CRGK).

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**
	–	–	–	–	–
	Copper is a monoatomic element and inherently stable. Therefore, it is not expected to metabolise or to form degradation products (EFSA, 2018b,c)				
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	–	–	–	–	–
	Copper is a monoatomic element and inherently stable. Therefore, it is not expected to metabolise or to form degradation products (EFSA, 2018b,c).				

Processed commodities (hydrolysis study)	**Conditions**	**Stable?**	**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)	Yes	No hydrolysis study available and not required. Copper is inherently stable. Therefore, it is not expected to metabolise or to form degradation products (EFSA, 2018b,c)
	Baking, brewing and boiling (60 min, 100°C, pH 5)	Yes	
	Sterilisation (20 min, 120°C, pH 6)	Yes	
	Other processing conditions	Yes	

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2018b,c)
Rotational crop and primary crop metabolism similar?	Yes	EFSA (2018b,c)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2018b,c)
Plant residue definition for monitoring (RD-Mo)	Total copper (EFSA 2018b,c) Copper compounds (copper) (Regulation (EC) No 396/2005)	
Plant residue definition for risk assessment (RD-RA)	Total copper (EFSA 2018b,c)	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	AAS – atomic absorption spectrometry (EFSA, 2018c): •High water content commodities, LOQ: 2 mg/kg •High acid content commodities, LOQ: 5 mg/kg •ILV not required since determination by AAS is recognised as standard methods of analysis for inorganic elements (EFSA, 2018c)	

DAT: days after treatment; PBI: plant-back interval; 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		
	Since copper cannot degrade and since the analytical techniques measure total copper content, storage stability studies are not required (EFSA, 2018b,c).						

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)
Blueberries Cranberries Currants (black, red and white) Gooseberries (green, red and yellow) Rose hips Mulberries (black and white) Azaroles/ Mediterranean medlars Elderberries	NEU	< 0.8 (LOQ); 1.08; 1.36; 2.73; 3.23; 6.22	Six trials performed on currants, all deemed compliant with GAP (last application performed between BBCH 57 and BBCH 61). Extrapolation from currants to the whole subgroup of other small fruits and berries is possible.	15	6.22	2.05

MRL: maximum residue level; GAP: Good Agricultural Practice; BBCH: growth stages of mono- and dicotyledonous plants.
(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.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	No study available and not required.
Residues in rotational and succeeding crops expected based on field rotational crop study?	No study available and not required. Copper is an essential nutrient for plant growth development and is normally taken up from soil where it occurs naturally. The uptake of copper is regulated by plants to provide the essential nutritional amount. Therefore, the survey on the endogenous copper levels in all plant commodities as reported in the MRL review was considered as a surrogate to rotational crop studies (EFSA, 2018c). Based on these data, the MRL review derived MRLs and risk assessment values for all plant commodities (EFSA, 2018c). The residue data on currants submitted also confirm that natural levels of copper is expected in other small fruits and berries (max 2.09 mg/kg).

B.1.2.3. Processing factors

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

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

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

ADI	0.15 mg/kg bw per day (European Commission, 2018)
Highest IEDI, according to EFSA PRIMo	**Scenario 1 without risk mitigation measures:** 166% ADI (NL toddler diet) Contribution of crops assessed: – Whole group of 'other and small fruit': 1.08% of ADI (Maximum for currants: 0.46 % of ADI) **Scenario 2 with risk mitigation measures:** 162% ADI (NL toddler diet) Contribution of crops assessed: – Whole group of 'other and small fruits': 1.08% of ADI (Maximum for currants: 0.46 % of ADI)
Assumptions made for the calculations	**Scenario 1 without risk mitigation measures:** The calculation updates the consumer exposure calculated for copper compounds in the framework of the MRL review (EFSA, 2018c) with the STMR values for the group of other small fruits and berries as derived in the framework of the current assessment and with input value derived in a reasoned opinion issued in the meantime (EFSA, 2020). The calculation takes into account residues arising from authorised uses (reported in the MRL review) as well as from any other sources (background concentrations, uptake from soil, etc.) (EFSA, 2020). For commodities where no GAP was reported in the framework of the MRL review or in the reasoned opinion issued after (EFSA, 2020), input values were also derived based on the monitoring and background levels.

For all commodities where MRL proposals were derived in the MRL review, the input values were derived as follow:
–If the MRL was derived from an authorised GAP supported by data: input values were based on the median values of the supporting residue trials;
–If the MRL was derived from the monitoring data: input values were based on mean values of the monitoring results;
–If the MRL was derived from the background levels data: input values were based on median values of the survey on background levels.
For citrus fruits, kiwi fruits, cucurbits with inedible peel, the relevant peeling factors were applied. For wine grapes, the yield and the processing factors of juice were applied. For rapeseed and olives for oil production, the processing factor for oil production was applied. For those commodities where data were insufficient to derive an MRL - oil palm kernels, oil palm fruits, kapok - EFSA considered the existing EU MRL for an indicative calculation (EFSA, 2018c).

Scenario 2 with risk mitigation measures:
The same approach as in scenario 1 was applied, including the following assumptions by the MRL review:
–NEU GAP on potatoes will be withdrawn; a fall-back option is identified with the southern GAP (MRL of 4 mg/kg);
– the critical GAPs authorised on wine grapes will be withdrawn (no fall-back GAP identified); exposure assessed with the background levels;
–the critical GAPs authorised on tomatoes will be withdrawn (no fall-back GAP identified); exposure assessed with the background levels;
– the critical GAPs authorised on lettuces will be withdrawn (no fall-back GAP identified); exposure assessed with the background levels.

Calculations performed with PRIMo revision 3.1

ARfD: acute reference dose; bw: body weight; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; STMR: supervised trials median residue; GAP: Good Agricultural Practice; NEU: northern European Union.

B.4. Recommended MRLs

Appendix C – Code[(a)]	Commodity	Existing EU MRL/MRL proposed in the MRL review (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Copper compounds (Copper)				
0154010	Blueberries	5/5*	Further risk management considerations required	The submitted data are sufficient to derive an MRL proposal of 15 mg/kg in support of the intended northern outdoor use of copper hydroxide. Long-term consumer intake concerns cannot be excluded for the intake of copper residues resulting from the
0154020	Cranberries	5/5*		
0154030	Currants (black, red and white)	5/5*		
0154040	Gooseberries (green, red and yellow)	5/5*		
0154050	Rose hips	5/5*		
0154060		5/5*		

Appendix C – Code[(a)]	Commodity	Existing EU MRL/MRL proposed in the MRL review (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
	Mulberries (black and white)			intended and existing uses of copper compounds and background/monitoring levels. Residues in the group of other small fruits and berries contribute to a very low extent to the overall consumer exposure (1.08% of the ADI). A risk management decision has to be taken whether it is appropriate to raise the existing MRL, given that based on the currently available information, a potential consumer intake concern cannot be excluded.
0154070	Azaroles/ Mediterranean medlars	5/5*		
0154080	Elderberries	5/5*		
0154990	Others	5/5*		

MRL: maximum residue level; EU: European Union; ADI: acceptable daily intake.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

Appendix C – Pesticide Residue Intake Model (PRIMo)

- EFSA_Q_2021_00463_Copper hydroxide_PRIMo_rev.3.1_scenario 1.xlsm

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Copper compound

LOQs (mg/kg) range from: 0.6 to: 5.0

Toxicological reference values

ADI (mg/kg bw per day):	0.15	ARfD (mg/kg bw):	insert valid entry
Source of ADI:	EC	Source of ARfD:	
Year of evaluation:	2018	Year of evaluation:	

Input values

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

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

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 1

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)
166%	NL toddler	248.42	19%	Maize/corn	17%	Spinaches	12%	Oil palm kernels		166%
98%	NL child	147.63	16%	Oil palm fruits	11%	Wheat	7%	Sugar beet roots		98%
98%	GEMS/Food G06	147.18	20%	Wheat	10%	Soyabeans	6%	Table grapes		98%
96%	GEMS/Food G11	143.41	30%	Soyabeans	10%	Wheat	5%	Potatoes		96%
95%	GEMS/Food G10	142.90	26%	Soyabeans	11%	Wheat	7%	Lettuces		95%
90%	GEMS/Food G07	135.40	14%	Soyabeans	12%	Wheat	8%	Bovine: Liver		90%
84%	GEMS/Food G08	125.43	16%	Soyabeans	11%	Wheat	6%	Sunflower seeds		84%
79%	GEMS/Food G15	118.45	14%	Soyabeans	13%	Wheat	7%	Sunflower seeds		79%
78%	DE child	116.92	12%	Apples	12%	Wheat	8%	Table grapes		78%
76%	FI adult	113.89	60%	Coffee beans	3%	Lettuces	2%	Rye		76%
72%	IE adult	107.97	14%	Sheep: Liver	6%	Wheat	3%	Sweet potatoes		72%
63%	FR child 3 15 yr	95.05	13%	Wheat	4%	Other oilseeds	4%	Milk: Cattle		63%
56%	NL general	84.08	9%	Oil palm fruits	5%	Wheat	4%	Spinaches		56%
56%	DK child	83.60	15%	Rye	12%	Wheat	3%	Lettuces		56%
54%	ES child	80.91	12%	Wheat	10%	Lettuces	3%	Poultry: Muscle/meat		54%
52%	FR toddler 2 3 yr	78.41	9%	Wheat	5%	Milk: Cattle	4%	Spinaches		52%
52%	RO general	77.94	14%	Wheat	8%	Sunflower seeds	5%	Potatoes		52%
45%	PT general	68.08	11%	Wheat	7%	Potatoes	4%	Wine grapes		45%
45%	IT toddler	66.81	18%	Wheat	7%	Lettuces	3%	Other lettuce and other salad plants		45%
45%	SE general	66.80	9%	Lettuces	9%	Wheat	6%	Potatoes		45%
44%	DE women 14-50 yr	65.29	6%	Wheat	5%	Coffee beans	4%	Sugar beet roots		44%
43%	UK infant	64.94	7%	Wheat	6%	Milk: Cattle	5%	Bovine: Liver		43%
43%	DE general	64.67	5%	Wheat	5%	Coffee beans	4%	Sugar beet roots		43%
42%	ES adult	63.68	12%	Lettuces	6%	Wheat	2%	Chards/beet leaves		42%
42%	UK toddler	63.45	11%	Wheat	5%	Potatoes	4%	Beans		42%
41%	IT adult	61.24	11%	Wheat	9%	Lettuces	4%	Other lettuce and other salad plants		41%
40%	FR adult	59.88	6%	Wheat	4%	Coffee beans	4%	Wine grapes		40%
30%	FI 3 yr	44.78	6%	Potatoes	3%	Wheat	2%	Rye		30%
28%	FR infant	42.42	6%	Spinaches	3%	Milk: Cattle	3%	Potatoes		28%
26%	FI 6 yr	38.61	5%	Potatoes	3%	Wheat	2%	Lettuces		26%
26%	UK vegetarian	38.49	6%	Wheat	3%	Lettuces	2%	Potatoes		26%
24%	UK adult	35.51	5%	Wheat	3%	Lettuces	2%	Potatoes		24%
22%	LT adult	33.17	4%	Potatoes	3%	Rye	3%	Wheat		22%
20%	DK adult	30.65	3%	Wheat	2%	Lettuces	2%	Potatoes		20%
14%	PL general	21.06	5%	Potatoes	2%	Apples	2%	Table grapes		14%
8%	IE child	12.33	3%	Wheat	0.8%	Rice	0.8%	Potatoes		8%

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 165.6 % of the ADI.
For 1 diet(s) the ADI is exceeded.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

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

Processed commodities

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

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

- EFSA_Q_2021_00463_Copper hydroxide_PRIMo_rev.3.1_scenario 2.xlsm

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Copper compound

LOQs (mg/kg) range from: 0.6 to: 5.0

Toxicological reference values

ADI (mg/kg bw per day):	0.15	ARfD (mg/kg bw):	insert valid entry
Source of ADI:	EC	Source of ARfD:	
Year of evaluation:	2018	Year of evaluation:	

Input values | Details – chronic risk assessment | Supplementary results – chronic risk assessment | Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 1

TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
	162%	NL toddler	243.32	19%	Maize/corn	17%	Spinaches	12%	Oil palm kernels		162%
	95%	NL child	141.77	16%	Oil palm fruits	11%	Wheat	7%	Sugar beet roots		95%
	91%	GEMS/Food G06	135.98	20%	Wheat	10%	Soyabeans	6%	Table grapes		91%
	89%	GEMS/Food G11	134.14	30%	Soyabeans	10%	Wheat	5%	Kapok		89%
	84%	GEMS/Food G10	126.56	26%	Soyabeans	11%	Wheat	3%	Rice		84%
	80%	GEMS/Food G07	119.49	14%	Soyabeans	12%	Wheat	8%	Bovine: Liver		80%
	75%	GEMS/Food G08	111.81	16%	Soyabeans	11%	Wheat	6%	Sunflower seeds		75%
	74%	DE child	110.64	12%	Apples	12%	Wheat	8%	Table grapes		74%
	72%	GEMS/Food G15	107.89	14%	Soyabeans	13%	Wheat	7%	Sunflower seeds		72%
	71%	FI adult	106.64	60%	Coffee beans	2%	Rye	1%	Other oilseeds		71%
	67%	IE adult	100.05	14%	Sheep: Liver	6%	Wheat	3%	Sweet potatoes		67%
	61%	FR child 3 15 yr	91.53	13%	Wheat	4%	Other oilseeds	4%	Milk: Cattle		61%
	51%	NL general	77.22	9%	Oil palm fruits	5%	Wheat	4%	Spinaches		51%
	51%	DK child	76.22	15%	Rye	12%	Wheat	2%	Apples		51%
	51%	FR toddler 2 3 yr	75.75	9%	Wheat	5%	Milk: Cattle	4%	Spinaches		51%
	46%	RO general	68.25	14%	Wheat	8%	Sunflower seeds	3%	Potatoes		46%
	43%	ES child	63.81	12%	Wheat	3%	Poultry: Muscle/meat	2%	Milk: Cattle		43%
	41%	UK infant	61.98	7%	Wheat	6%	Milk: Cattle	5%	Bovine: Liver		41%
	39%	UK toddler	59.20	11%	Wheat	4%	Beans	3%	Milk: Cattle		39%
	38%	DE general	57.59	5%	Wheat	5%	Coffee beans	4%	Sugar beet roots		38%
	38%	DE women 14-50 yr	57.48	6%	Wheat	5%	Coffee beans	4%	Sugar beet roots		38%
	36%	IT toddler	53.89	18%	Wheat	3%	Other lettuce and other salad plants	1%	Chards/beet leaves		36%
	36%	PT general	53.78	11%	Wheat	5%	Potatoes	4%	Sunflower seeds		36%
	35%	FR adult	53.19	6%	Wheat	4%	Coffee beans	3%	Other lettuce and other salad plants		35%
	33%	SE general	48.94	9%	Wheat	4%	Potatoes	3%	Bovine: Muscle/meat		33%
	31%	IT adult	46.06	11%	Wheat	4%	Other lettuce and other salad plants	2%	Spinaches		31%
	28%	ES adult	42.68	6%	Wheat	2%	Chards/beet leaves	2%	Spinaches		28%
	27%	FR infant	40.84	6%	Spinaches	3%	Milk: Cattle	3%	Leeks		27%
	26%	FI 3 yr	39.28	4%	Potatoes	3%	Wheat	2%	Rye		26%
	22%	FI 6 yr	32.32	3%	Potatoes	3%	Wheat	2%	Rye		22%
	20%	UK vegetarian	29.91	6%	Wheat	2%	Beans	1%	Potatoes		20%
	18%	LT adult	27.72	3%	Rye	3%	Wheat	3%	Potatoes		18%
	18%	UK adult	27.44	5%	Wheat	1%	HOPS (dried)	1%	Potatoes		18%
	16%	DK adult	23.72	3%	Wheat	1%	Rye	1%	Potatoes		16%
	11%	PL general	16.66	3%	Potatoes	2%	Apples	2%	Table grapes		11%
	8%	IE child	11.57	3%	Wheat	0.8%	Rice	0.6%	Milk: Cattle		8%

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 162.2 % of the ADI.
For 1 diet(s) the ADI is exceeded.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

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

Processed commodities

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

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of copper compound is unlikely to present a public health risk.

For processed commodities, no exceedance of the ARfD/ADI was identified.

Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

Commodity	Proposed MRL[a] (mg/kg)	Source	Chronic risk assessment		Acute risk assessment
			Input value (mg/kg)	Comment	
Risk assessment residue definition: Total copper					
Grapefruits	15	EFSA (2018c)	1.22	STMR-RAC × PeF	Acute exposure not calculated since setting of the ARfD was considered not necessary.
Oranges	15	EFSA (2018c)	1.22	STMR-RAC × PeF	
Lemons	15	EFSA (2018c)	1.18	STMR-RAC × PeF	
Limes	15	EFSA (2018c)	1.18	STMR-RAC × PeF	
Mandarins	15	EFSA (2018c)	1.18	STMR-RAC × PeF	
Other citrus fruit	15	EFSA (2018c)	1.22	STMR-RAC × PeF	
Almonds	40	EFSA (2018c)	11.7	STMR-RAC	
Brazil nuts	40	EFSA (2018c)	11.7	STMR-RAC	
Cashew nuts	40	EFSA (2018c)	13.3	Median background levels	
Chestnuts	40	EFSA (2018c)	11.7	STMR-RAC	
Coconuts	5	EFSA (2018c)	4.50	Median background levels	
Hazelnuts/cobnuts	40	EFSA (2018c)	11.7	STMR-RAC	
Macadamia	40	EFSA (2018c)	11.7	STMR-RAC	
Pecans	40	EFSA (2018c)	11.7	STMR-RAC	
Pine nut kernels	40	EFSA (2018c)	16.0	Mean monitoring data	
Pistachios	40	EFSA (2018c)	11.7	STMR-RAC	
Walnuts	40	EFSA (2018c)	11.7	STMR-RAC	
Apples	6	EFSA (2018c)	1.41	STMR-RAC	
Pears	6	EFSA (2018c)	1.41	STMR-RAC	
Quinces	6	EFSA (2018c)	1.41	STMR-RAC	
Medlar	6	EFSA (2018c)	1.41	STMR-RAC	
Loquats/Japanese medlars	6	EFSA (2018c)	1.41	STMR-RAC	
Apricots	3	EFSA (2018c)	1.5	STMR-RAC	
Cherries (sweet)	10	EFSA (2018c)	2.69	STMR-RAC	
Peaches	8	EFSA (2018c)	2.35	STMR-RAC	
Plums	4	EFSA (2018c)	1.15	STMR-RAC	
Table grapes	100	EFSA (2018c)	8.70	STMR-RAC	
Wine grapes	100	EFSA (2018c) (Scenario 1)	2.55	STMR-RAC × 0.75 (yield factor for juice) × PF (juice)[b]	
	2	EFSA (2018c) (Scenario 2)	0.35	Median background levels × 0.75 (yield factor for juice) × PF (juice)[b]	
Strawberries	15	EFSA (2018c)	2.29	STMR-RAC	
Blackberries	5	EFSA (2018c)	0.99	STMR-RAC	
Dewberries	5	EFSA (2018c)	0.99	STMR-RAC	
Raspberries (red and yellow)	5	EFSA (2018c)	0.99	STMR-RAC	
Other cane fruit	5	EFSA (2018c)	0.99	STMR-RAC	
Blueberries	**15**	**Intended**	**2.05**	**STMR-RAC**	

Commodity	Proposed MRL[a] (mg/kg)	Source	Chronic risk assessment		Acute risk assessment
			Input value (mg/kg)	Comment	
Cranberries	**15**	**Intended**	**2.05**	**STMR-RAC**	
Currants (red, black and white)	**15**	**Intended**	**2.05**	**STMR-RAC**	
Gooseberries (green, red and yellow)	**15**	**Intended**	**2.05**	**STMR-RAC**	
Rose hips	**15**	**Intended**	**2.05**	**STMR-RAC**	
Mulberries (black and white)	**15**	**Intended**	**2.05**	**STMR-RAC**	
Azaroles/ Mediterranean medlar	**15**	**Intended**	**2.05**	**STMR-RAC**	
Elderberries	**15**	**Intended**	**2.05**	**STMR-RAC**	
Dates	2	EFSA (2018c)	0.86	Median background levels	
Figs	30	EFSA (2018c)	7.85	Mean monitoring data	
Table olives	20	EFSA (2018c)	6.23	STMR-RAC	
Kumquats	2	EFSA (2018c)	0.86	Median background levels	
Carambolas	2	EFSA (2018c)	0.86	Median background levels	
Kaki/Japanese persimmons	2	EFSA (2018c)	0.86	Median background levels	
Jambuls/jambolans	10	EFSA (2018c)	2.69	STMR-RAC	
Kiwi fruits (green, red, yellow)	30	EFSA (2018c)	6.94	STMR-RAC × PeF	
Litchis/lychees	2	EFSA (2018c)	1.48	Median background levels	
Passion fruits/maracujas	4	EFSA (2018c)	3.55	Mean monitoring data	
Prickly pears/cactus fruits	2	EFSA (2018c)	1.48	Median background levels	
Star apples/cainitos	2	EFSA (2018c)	1.48	Median background levels	
American persimmon/ Virginia kaki	2	EFSA (2018c)	1.48	Median background levels	
Avocados	6	EFSA (2018c)	0.96	Median background levels	
Bananas	6	EFSA (2018c)	0.96	Median background levels	
Mangoes	6	EFSA (2018c)	0.96	Median background levels	
Papayas	6	EFSA (2018c)	0.96	Median background levels	
Granate apples/ pomegranates	6	EFSA (2018c)	0.96	Median background levels	
Cherimoyas	6	EFSA (2018c)	0.96	Median background levels	
Guavas	6	EFSA (2018c)	0.96	Median background levels	

Commodity	Proposed MRL[a] (mg/kg)	Source	Chronic risk assessment		Acute risk assessment
			Input value (mg/kg)	Comment	
Pineapples	6	EFSA (2018c)	0.96	Median background levels	
Breadfruits	6	EFSA (2018c)	0.96	Median background levels	
Durians	6	EFSA (2018c)	0.96	Median background levels	
Soursops/guanabanas	6	EFSA (2018c)	0.96	Median background levels	
Other miscellaneous fruit (inedible peel, large)	6	EFSA (2018c)	0.96	STMR-RAC	
Potatoes	7	EFSA (2018c) (Scenario 1)	2.00	STMR-RAC	
	4	EFSA (2018c) (Scenario 2)	1.30	STMR-RAC	
Cassava roots/manioc	4	EFSA (2018c)	1.30	STMR-RAC	
Sweet potatoes	4	EFSA (2018c)	1.30	STMR-RAC	
Yams	4	EFSA (2018c)	1.30	STMR-RAC	
Arrowroots	4	EFSA (2018c)	1.30	STMR-RAC	
Other tropical root and tuber vegetables	4	EFSA (2018c)	1.30	STMR-RAC	
Beetroots	3	EFSA (2018c)	0.74	STMR-RAC	
Carrots	3	EFSA (2018c)	0.74	STMR-RAC	
Celeriacs/turnip-rooted celeries	3	EFSA (2018c)	0.74	STMR-RAC	
Horseradishes	3	EFSA (2018c)	0.74	STMR-RAC	
Jerusalem artichokes	3	EFSA (2018c)	0.74	STMR-RAC	
Parsnips	3	EFSA (2018c)	0.74	STMR-RAC	
Parsley roots/Hamburg roots parsley	3	EFSA (2018c)	0.74	STMR-RAC	
Radishes	3	EFSA (2018c)	0.74	STMR-RAC	
Salsifies	3	EFSA (2018c)	0.74	STMR-RAC	
Swedes/rutabagas	3	EFSA (2018c)	0.74	STMR-RAC	
Turnips	3	EFSA (2018c)	0.74	STMR-RAC	
Other root and tuber vegetables	3	EFSA (2018c)	0.74	STMR-RAC	
Garlic	4	EFSA (2018c)	1.93	Mean monitoring data	
Onions	2	EFSA (2018c)	0.60	STMR-RAC	
Shallots	2	EFSA (2018c)	0.60	STMR-RAC	
Spring onions/green onions and Welsh onions	70	EFSA (2018c)	14.6	STMR-RAC	
Tomatoes	10	EFSA (2018c) (Scenario 1)	2.5	STMR-RAC	
	2	EFSA (2018c) (Scenario 2)	0.75	Median background levels	
Sweet peppers/bell peppers	20	EFSA (2018c)	3.45	STMR-RAC	
Aubergines/egg plants	10	EFSA (2018c)	2.5	STMR-RAC	

Commodity	Proposed MRL[a] (mg/kg)	Source	Chronic risk assessment		Acute risk assessment
			Input value (mg/kg)	Comment	
Okra/lady's fingers	2	EFSA (2018c)	0.94	Median background levels	
Cucumbers	5	EFSA (2018c)	2.0	STMR-RAC	
Gherkins	5	EFSA (2018c)	2.0	STMR-RAC	
Courgettes	5	EFSA (2018c)	2.0	STMR-RAC	
Other cucurbits – edible peel	5	EFSA (2018c)	2.0	STMR-RAC	
Melons	10	EFSA (2018c)	4.20	STMR-RAC × PeF	
Pumpkins	10	EFSA (2018c)	4.20	STMR-RAC × PeF	
Watermelons	10	EFSA (2018c)	4.20	STMR-RAC × PeF	
Other cucurbits – inedible peel	10	EFSA (2018c)	4.20	STMR-RAC × PeF	
Sweet corn	2	EFSA (2018c)	0.48	Median background levels	
Broccoli	5	EFSA (2018c)	1.25	STMR-RAC	
Cauliflowers	5	EFSA (2018c)	1.25	STMR-RAC	
Other flowering brassica	5	EFSA (2018c)	1.25	STMR-RAC	
Brussels sprouts	2	EFSA (2018c)	0.41	Median background levels	
Head cabbages	2	EFSA (2018c)	0.26	Mean monitoring data	
Other head brassica	2	EFSA (2018c)	0.41	STMR-RAC	
Chinese cabbages/pe-tsai	3	EFSA (2018c)	0.56	Median background levels	
Kales	3	EFSA (2018c)	0.56	Median background levels	
Other leafy brassica	3	EFSA (2018c)	0.56	Median background levels	
Kohlrabies	3	EFSA (2018c)	0.56	Median background levels	
Lamb's lettuce/corn salads	150	EFSA (2018c)	34.6	STMR-RAC	
Lettuces	150	EFSA (2018c) (Scenario 1)	34.6	STMR-RAC	
	4	EFSA (2018c) (Scenario 2)	0.83	Median background levels	
Escaroles/broad-leaved endives	150	EFSA (2018c)	34.6	STMR-RAC	
Cress and other sprouts and shoots	150	EFSA (2018c)	34.6	STMR-RAC	
Land cress	150	EFSA (2018c)	34.6	STMR-RAC	
Roman rocket/rucola	150	EFSA (2018c)	34.6	STMR-RAC	
Red mustards	150	EFSA (2018c)	34.6	STMR-RAC	
Baby leaf crops (including brassica species)	150	EFSA (2018c)	34.6	STMR-RAC	
Other lettuce and other salad plants	150	EFSA (2018c)	34.6	STMR-RAC	
Spinaches	150	EFSA (2018c)	34.6	STMR-RAC	
Purslanes	150	EFSA (2018c)	34.6	STMR-RAC	

Commodity	Proposed MRL[a] (mg/kg)	Source	Chronic risk assessment		Acute risk assessment
			Input value (mg/kg)	Comment	
Chards/beet leaves	150	EFSA (2018c)	34.6	STMR-RAC	
Other spinach and similar	150	EFSA (2018c)	34.6	STMR-RAC	
Grape leaves and similar species	5	EFSA (2018c)	4.15	Median background levels	
Watercress	150	EFSA (2018c)	11.7	STMR-RAC	
Witloofs/Belgian endives	2	EFSA (2018c)	0.51	Median background levels	
Chervil	150	EFSA (2020)	38	STMR-RAC	
Chives	150	EFSA (2020)	38	STMR-RAC	
Celery leaves	150	EFSA (2020)	38	STMR-RAC	
Parsley	150	EFSA (2020)	38	STMR-RAC	
Sage	150	EFSA (2020)	38	STMR-RAC	
Rosemary	150	EFSA (2020)	38	STMR-RAC	
Thyme	150	EFSA (2020)	38	STMR-RAC	
Basil and edible flowers	150	EFSA (2020)	38	STMR-RAC	
Laurel/bay leaves	150	EFSA (2020)	38	STMR-RAC	
Tarragon	150	EFSA (2020)	38	STMR-RAC	
Other herbs	150	EFSA (2020)	38	STMR-RAC	
Beans (with pods)	10	EFSA (2018c)	3.25	STMR-RAC	
Beans (without pods)	4	EFSA (2018c)	3.18	Median background levels	
Peas (with pods)	10	EFSA (2018c)	3.25	STMR-RAC	
Peas (without pods)	7	EFSA (2018c)	2.39	STMR-RAC	
Lentils (fresh)	4	EFSA (2018c)	3.18	Median background levels	
Asparagus	7	EFSA (2018c)	0.65	Median background levels	
Cardoons	7	EFSA (2018c)	0.65	Median background levels	
Celeries	7	EFSA (2018c)	0.65	Median background levels	
Florence fennels	7	EFSA (2018c)	0.65	Median background levels	
Globe artichokes	30	EFSA (2018c)	7.44	STMR-RAC	
Leeks	70	EFSA (2018c)	14.6	STMR-RAC	
Rhubarbs	7	EFSA (2018c)	0.65	Median background levels	
Bamboo shoots	7	EFSA (2018c)	0.65	Median background levels	
Palm hearts	7	EFSA (2018c)	0.65	Median background levels	
Cultivated fungi	6	EFSA (2018c)	2.86	Median background levels	
Wild fungi	6	EFSA (2018c)	2.86	Median background levels	
Algae and prokaryotes organisms	3	EFSA (2018c)	0.44	Median background levels	

Commodity	Proposed MRL[a] (mg/kg)	Source	Chronic risk assessment		Acute risk assessment
			Input value (mg/kg)	Comment	
Beans	15	EFSA (2018c)	7.21	Mean monitoring data	
Lentils	15	EFSA (2018c)	9.19	Mean monitoring data	
Peas	15	EFSA (2018c)	7.30	Median background levels	
Lupins/lupini beans	15	EFSA (2018c)	7.30	Median background levels	
Other pulses	15	EFSA (2018c)	9.19	STMR-RAC	
Linseeds	30	EFSA (2018c)	12.02	Median background levels	
Peanuts/groundnuts	30	EFSA (2018c)	12.02	Median background levels	
Poppy seeds	30	EFSA (2018c)	12.02	Median background levels	
Sesame seeds	30	EFSA (2018c)	12.02	Median background levels	
Sunflower seeds	30	EFSA (2018c)	18.41	Mean monitoring data	
Rapeseeds/ canola seeds	30	EFSA (2018c)	1.20	Median background levels × PF (oil)	
Soybeans	30	EFSA (2018c)	12.02	Median background levels	
Mustard seeds	30	EFSA (2018c)	12.02	Median background levels	
Cotton seeds	30	EFSA (2018c)	12.02	Median background levels	
Pumpkin seeds	30	EFSA (2018c)	12.02	Median background levels	
Safflower seeds	30	EFSA (2018c)	12.02	Median background levels	
Borage seeds	30	EFSA (2018c)	12.02	Median background levels	
Gold of pleasure seeds	30	EFSA (2018c)	12.02	Median background levels	
Hemp seeds	30	EFSA (2018c)	12.02	Median background levels	
Castor beans	30	EFSA (2018c)	12.02	Median background levels	
Other oilseeds	30	EFSA (2018c)	18.4	Mean monitoring data	
Olives for oil production	20	EFSA (2018c)	0.62	STMR-RAC × PF (oil)	
Oil palm kernels	30	EFSA (2018c)	30	EU MRL	
Oil palm fruits	30	EFSA (2018c)	30	EU MRL	
Kapok	30	EFSA (2018c)	30	EU MRL	
Barley	10	EFSA (2018c)	4.15	Median background levels	
Buckwheat and other pseudo-cereals	15	EFSA (2018c)	8.42	Median background levels	
Maize/corn	10	EFSA (2018c)	4.15	Median background levels	
Common millet/proso millet	10	EFSA (2018c)	4.15	Median background levels	

Commodity	Proposed MRL[(a)] (mg/kg)	Source	Chronic risk assessment		Acute risk assessment
			Input value (mg/kg)	Comment	
Oat	10	EFSA (2018c)	4.15	Median background levels	
Rice	10	EFSA (2018c)	4.15	Median background levels	
Rye	10	EFSA (2018c)	4.15	Median background levels	
Sorghum	10	EFSA (2018c)	4.15	Median background levels	
Wheat	10	EFSA (2018c)	4.15	Median background levels	
Tea (dried leaves of Camellia sinensis)	30	EFSA (2018c)	25	Median background levels	
Coffee beans	20	EFSA (2018c)	16.3	Median background levels	
Herbal infusions (dried flowers)	5	EFSA (2018c)	0.3	Median background levels	
Chamomile	5	EFSA (2018c)	0.3	Median background levels	
Hibiscus/roselle	5	EFSA (2018c)	0.3	Median background levels	
Rose	5	EFSA (2018c)	0.3	Median background levels	
Jasmine	5	EFSA (2018c)	0.3	Median background levels	
Lime/linden	5	EFSA (2018c)	0.3	Median background levels	
Other herbal infusions (dried flowers)	5	EFSA (2018c)	0.3	Median background levels	
Herbal infusions (dried leaves)	5	EFSA (2018c)	0.3	Median background levels	
Strawberry leaves	5	EFSA (2018c)	0.3	Median background levels	
Rooibos	5	EFSA (2018c)	0.3	Median background levels	
Mate/maté	5	EFSA (2018c)	0.3	Median background levels	
Other herbal infusions (dried leaves)	5	EFSA (2018c)	0.3	Median background levels	
Herbal infusions (dried roots)	5	EFSA (2018c)	0.95	Median background levels	
Valerian root	5	EFSA (2018c)	0.95	Median background levels	
Ginseng root	5	EFSA (2018c)	0.95	Median background levels	
Other herbal infusions (dried roots)	5	EFSA (2018c)	0.95	Median background levels	
Cocoa beans	5	EFSA (2018c)	1.5	Median background levels	
Carobs/Staint John's bread	6	EFSA (2018c)	5.71	Median background levels	
HOPS (dried)	1,500	EFSA (2018c)	337.5	STMR-RAC	

Commodity	Proposed MRL[(a)] (mg/kg)	Source	Chronic risk assessment		Acute risk assessment
			Input value (mg/kg)	Comment	
Spices (seeds)	15	EFSA (2018c)	9.75	Median background levels	
Anise/aniseed	15	EFSA (2018c)	9.75	Median background levels	
Black caraway/black cumin	15	EFSA (2018c)	9.75	Median background levels	
Celery seed	15	EFSA (2018c)	9.75	Median background levels	
Coriander seed	15	EFSA (2018c)	9.75	Median background levels	
Cumin seed	15	EFSA (2018c)	9.75	Median background levels	
Dill seed	15	EFSA (2018c)	9.75	Median background levels	
Fennel seed	15	EFSA (2018c)	9.75	Median background levels	
Fenugreek	15	EFSA (2018c)	9.75	Median background levels	
Nutmeg	15	EFSA (2018c)	9.75	Median background levels	
Other spices (seeds)	15	EFSA (2018c)	9.75	Median background levels	
Spices (fruits)	15	EFSA (2018c)	11.3	Median background levels	
Allspice/pimento	15	EFSA (2018c)	11.3	Median background levels	
Sichuan pepper	15	EFSA (2018c)	11.3	Median background levels	
Caraway	15	EFSA (2018c)	11.3	Median background levels	
Cardamom	15	EFSA (2018c)	11.3	Median background levels	
Juniper berry	15	EFSA (2018c)	11.3	Median background levels	
Peppercorn (black, green and white)	15	EFSA (2018c)	11.3	Median background levels	
Vanilla pods	15	EFSA (2018c)	11.3	Median background levels	
Tamarind	15	EFSA (2018c)	11.3	Median background levels	
Other spices (fruits)	15	EFSA (2018c)	11.3	Median background levels	
Spices (bark)	5	EFSA (2018c)	3.39	Median background levels	
Cinnamon	5	EFSA (2018c)	3.39	Median background levels	
Other spices (bark)	5	EFSA (2018c)	3.39	Median background levels	
Spices (roots or rhizome)	5	EFSA (2018c)	2.13	Median background levels	

Commodity	Proposed MRL[a] (mg/kg)	Source	Chronic risk assessment		Acute risk assessment
			Input value (mg/kg)	Comment	
Liquorice	5	EFSA (2018c)	2.13	Median background levels	
Ginger	5	EFSA (2018c)	2.13	Median background levels	
Turmeric/curcuma	5	EFSA (2018c)	2.13	Median background levels	
Horseradish, root spices	5	EFSA (2018c)	2.13	Median background levels	
Other spices (roots)	5	EFSA (2018c)	2.13	Median background levels	
Spices (buds)	5	EFSA (2018c)	3.61	Median background levels	
Cloves	5	EFSA (2018c)	3.61	Median background levels	
Capers	5	EFSA (2018c)	3.61	Median background levels	
Other spices (buds)	5	EFSA (2018c)	3.61	Median background levels	
Spices (flower stigma)	5	EFSA (2018c)	3.28	Median background levels	
Saffron	5	EFSA (2018c)	3.28	Median background levels	
Other spices (flower stigma)	5	EFSA (2018c)	3.28	Median background levels	
Spices (aril)	30	EFSA (2018c)	24.7	Median background levels	
Mace	30	EFSA (2018c)	24.7	Median background levels	
Other spices (aril)	30	EFSA (2018c)	24.7	Median background levels	
Sugar beet roots	2	EFSA (2018c)	1.25	Median background levels	
Sugar canes	2	EFSA (2018c)	0.69	Median background levels	
Chicory roots	2	EFSA (2018c)	1.09	Median background levels	
Other sugar plants	2	EFSA (2018c)	1.25	Median background levels	
Swine: Muscle/meat	7	EFSA (2018c)	0.88	Median background levels	
Swine: Fat tissue	2	EFSA (2018c)	0.41	Median background levels	
Swine: Liver	90	EFSA (2018c)	11.6	Median background levels	
Swine: Kidney	10	EFSA (2018c)	7.28	Median background levels	
Bovine: Muscle/meat	3	EFSA (2018c)	0.9	Median background levels	
Bovine: Fat tissue	0.6	EFSA (2018c)	0.39	Median background levels	
Bovine: Liver	400	EFSA (2018c)	86.7	Mean monitoring data	

Commodity	Proposed MRL[(a)] (mg/kg)	Source	Chronic risk assessment		Acute risk assessment
			Input value (mg/kg)	Comment	
Bovine: Kidney	10	EFSA (2018c)	4.61	Median background levels	
Sheep: Muscle/meat	3	EFSA (2018c)	1.25	Median background levels	
Sheep: Fat tissue	0.6	EFSA (2018c)	0.3	Median background levels	
Sheep: Liver	150	EFSA (2018c)	90	Median background levels	
Sheep: Kidney	6	EFSA (2018c)	3.85	Median background levels	
Goat: Muscle/meat	3	EFSA (2018c)	1.25	Median background levels	
Goat: Fat tissue	0.6	EFSA (2018c)	0.3	Median background levels	
Goat: Liver	150	EFSA (2018c)	90	Median background levels	
Goat: Kidney	6	EFSA (2018c)	3.85	Median background levels	
Equine: Muscle/meat	3	EFSA (2018c)	0.9	Median background levels	
Equine: Fat tissue	0.6	EFSA (2018c)	0.39	Median background levels	
Equine: Liver	400	EFSA (2018c)	64.3	Median background levels	
Equine: Kidney	10	EFSA (2018c)	4.61	Median background levels	
Poultry: Muscle/meat	7	EFSA (2018c)	3.47	Mean monitoring data	
Poultry: Fat tissue	1	EFSA (2018c)	0.00	Median background levels	
Poultry: Liver	80	EFSA (2018c)	6.90	Median background levels	
Milk: Cattle	1	EFSA (2018c)	0.24	Mean monitoring data	
Milk: Sheep	1	EFSA (2018c)	0.24	Mean monitoring data	
Milk: Goat	1	EFSA (2018c)	0.24	Mean monitoring data	
Milk: Horse	1	EFSA (2018c)	0.24	Mean monitoring data	
Eggs: Chicken	1	EFSA (2018c)	0.58	Mean monitoring data	
Eggs: Duck	1	EFSA (2018c)	0.58	Mean monitoring data	
Eggs: Goose	1	EFSA (2018c)	0.58	Mean monitoring data	
Eggs: Quail	1	EFSA (2018c)	0.58	Mean monitoring data	
Wild terrestrial vertebrate animals	3	EFSA (2018c) MRL review	1.72	Mean monitoring data	

STMR-RAC: supervised trials median residue in raw agricultural commodity; PeF: Peeling factor.
(a): 'Proposed MRLs' come from the MRLs derived during the MRL review (EFSA, 2018c), not implemented in the EU legislation.
(b): The MRL review applied the median PF derived for grape juice (0.39) and the yield factor for juice (0.75) to refine the input value for wine grapes. It was noted that wine grapes consumption referred to grape juice (for children) and to wine (for adults). However, the PF for juice was retain (not the PF for wines (0.04) was not considered) to perform a more conservative assessment (EFSA, 2018c).