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Modification of the existing maximum residue levels for copper compounds in fresh herbs and edible flowers

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant LLG Sachsen-Anhalt, Dez. Pflanzenschutz submitted a request to the competent national authority in Germany to modify the existing maximum residue levels (MRLs) for copper compounds in herbs and edible flowers. The data submitted in support of the request were found sufficient to derive an MRL proposal of 150 mg/kg, confirming the MRL proposal of the MRL review, for copper compounds in herbs and edible flowers in support of the intended indoor use. Based on the 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 herbs and edible flowers are minor contributors to the overall consumer exposure, a risk management decision has to be taken 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 hydroxide, fresh herbs and edible flowers, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant LLG Sachsen-Anhalt, Dez. Pflanzenschutz submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for copper compounds (hereafter copper) in fresh herbs and edible flowers. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 20 June 2019. To accommodate for the intended EU indoor and NEU outdoor uses of copper hydroxide on herbs and edible flowers, the EMS proposed to raise the existing MRLs in these commodities to 150 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification, which were requested from the EMS Germany. On 3 February 2020, the EMS submitted the requested information in a revised evaluation report, which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of Regulation (EC) No 1107/2009, the review of the existing EU MRLs under Article 12 of the Regulation (EC) No 396/2005 and the data provided by the EMS in the Evaluation report in the framework of this application, the following conclusions are derived.

Specific studies evaluating 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 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 at the validated limit of quantification (LOQ) of 2 mg/kg.

The available data are considered sufficient to derive an MRL proposal of 150 mg/kg as well as risk assessment values for fresh herbs and edible flowers in support of the intended EU indoor use of copper hydroxide. The intended NEU use is sufficiently supported by residue data, but results in a less critical residue situation for the crops under assessment. EFSA notes that the same MRL proposal (150 mg/kg) was recommended by the MRL review but has not yet been implemented.

Specific studies investigating the magnitude of copper residues in processed herbs and edible flowers were not submitted and are not required considering low contribution of residues in these crops to the total theoretical maximum daily intake (TMDI).

Since the intended new use of copper hydroxide on fresh herbs and edible flowers is in line with the restricted annual application rate and is below the application rates assessed in the renewal of the approval of copper compounds, EFSA concludes that the use on herbs and edible flowers is not the most critical with regard to residues in rotational crops. Moreover, the uptake of copper in succeeding crops is regulated by plant depending on its nutritional needs. It is noted that the MRL review derived MRLs for all plant commodities (also off-label crops) included in Annex I to Regulation (EC) No 396/2005, considering residues from authorised uses as well as taking into consideration endogenous occurrence of copper in soil and plant commodities. These MRL proposals cover possible residue uptakes that may occur in rotational crops.

Residues of copper in commodities of animal origin were not assessed since herbs and edible flowers 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 sufficient 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 has recently received a mandate to review the ADI for copper and to perform exposure calculations from all sources of copper (EFSA-Q-2020-00399).

In the framework of the MRL review, a comprehensive long-term consumer exposure was performed using revision 2 of EFSA Pesticide Residues Intake Model (PRIMo). The exposure to copper residues was calculated from the authorised (existing) uses as well as from any other sources (background concentrations, uptake from soil, etc.). Two scenarios of exposure calculation were performed in the MRL review:

- scenario 1, considering all commodities of plant and animal origin;
- scenario 2, considering risk mitigation measures to reduce the exposure (for wine grapes, tomatoes, lettuces, the supervised trials median residue (STMR) values used in scenario 1 were replaced by STMR values that reflect the background level only; for potatoes, an STMR for a fall-back GAP was used).

Assuming that conclusions of the MRL review will be taken over in the EU legislation, EFSA now updated both exposure scenarios of the MRL review with the relevant STMR values as derived from the residue trials on herbs and edible flowers. The consumer risk assessment was performed with revision 3.1 of the EFSA PRIMo.

The calculated long-term dietary exposure to copper residues in both calculation scenarios exceeded the ADI. In scenario 1, the maximum exposure accounted for 169% of the ADI for Dutch toddler diet and for 102% of the ADI for Dutch child diet. In the MRL review, EFSA also identified a slight exceedance of the ADI for this scenario (108.9%; WHO Cluster diet B).

In scenario 2, the calculated exposure accounted for a maximum of 166% of the ADI for Dutch toddler diet. EFSA notes that in the MRL review, the exposure calculated in scenario 2 identified no chronic consumer intake concern (93.4% of the ADI). 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. The contribution of copper residues in fresh herbs and edible flowers on the actual long-term consumer exposure is insignificant (0.11% of the ADI). Further refinements of the exposure calculation might be possible, once a decision is taken on the appropriate risk mitigation measures that will be implemented.

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 herbs and edible flowers are minor contributors to the overall consumer exposure, a risk management decision has to be taken whether it is appropriate to increase the existing MRLs for these crops, given that a potential consumer intake concern could not be excluded.

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

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

Code[(a)]	Commodity	Existing EU MRL/MRL proposals Art. 12 review (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Copper compounds (copper)				
0256000, except 0256030	Herbs and edible flowers (except celery leaves)	20/150	Further risk management considerations required	The submitted data are sufficient to derive an MRL proposal of 150 mg/kg in support of the intended indoor use of copper hydroxide. The NEU outdoor use is less critical Long-term consumer intake concerns cannot be excluded for the intake of copper residues resulting from the existing uses of copper compounds and background/monitoring levels. Residues in herbs and edible flowers contribute to a very low extent to the overall consumer exposure (0.11% of the ADI). A risk management decision has to be taken whether it is appropriate to raise the existing MRLs, given that based on the currently available information, a potential consumer intake concern cannot be excluded
0256030	Celery leaves	50/150		

NEU: northern Europe; MRL: maximum residue level; ADI: acceptable daily intake.
(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 level (MRL) for copper in fresh herbs and edible flowers. 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); the representative uses assessed were used 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 (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 Article 12 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, the applicant LLG Sachsen-Anhalt, Dez. Pflanzenschutz, submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for copper in fresh herbs and edible flowers. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 20 June 2019. To accommodate for the intended EU indoor and NEU outdoor uses of copper hydroxide on herbs and edible flowers, the EMS proposed to raise the existing MRLs in these commodities to 150 mg/kg. EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification, which were requested from the EMS. On 3 February 2020, the EMS submitted the requested information in a revised evaluation report, which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (Germany, 2018), the renewal assessment report (RAR) (and its addendum) (France, 2016, 2017) prepared under Regulation (EC) 1107/2009, the Commission renewal review report on copper compounds (European Commission, 2018), the conclusion on the peer review of the pesticide risk assessment of copper compounds (EFSA, 2018b), as well as the conclusions from the EFSA reasoned opinion on the review of the existing maximum residue levels for copper compounds according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2018c).

For this application, the data requirements established in Regulation (EU) No 283/2013[6] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 2010a,b, 2017; OECD, 2007a,b, 2009, 2011, 2016). The assessment is

[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.

[6] 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.

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[7].

The evaluation report submitted by the EMS (Germany, 2018) 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 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 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. The metabolic pathway of copper hydroxide in the crops under consideration 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 peer review (EFSA, 2018b,c). However, for the same reason as mentioned in Section 1.1.1, specific studies to evaluate the nature of residues in succeeding crops are not necessary.

As copper is absorbed from 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. Methods of analysis in plants

Analytical methods for the determination of copper residues in plant matrices were provided and evaluated in the framework of the initial 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 water content matrices), 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).

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

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 is 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).

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

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 intended indoor use, the applicant submitted in total 10 residue trials on lettuce (open leaf varieties) (seven trials), parsley (two) and basil (one). All trials were performed in Germany in 2013, 2014 and 2015. Four lettuce trials from two locations were considered not independent and thus the highest value per replicate trial was selected. Residue trial on basil was underdosed in terms of the number of applications (three applications instead of six) and was therefore disregarded. According to the information provided by the EMS, copper residues in the control samples of residue trials were below the respective LOQs (Germany, 2018). Finally, seven GAP compliant residue trials were selected for deriving an MRL proposal of 150 mg/kg. The applicant proposes to extrapolate residue data on lettuce and parsley to the whole group of herbs and edible flowers. According to EU guidance document (European Commission, 2017), such an extrapolation is acceptable. EFSA notes that the same MRL proposal of 150 mg/kg was recommended by the MRL review (EFSA, 2018c), but so far has not been implemented.

In support of the intended NEU outdoor use, the applicant submitted in total 16 GAP compliant residue trials on lettuce (open leaf varieties) (eight trials), parsley (four), sage (three) and savoury (one). Residue trials were performed in Germany in 2011, 2012, 2013 and 2014. The applicant proposes to extrapolate residue data on lettuce, sage, savoury and parsley to the whole group of fresh herbs and edible flowers. According to EU guidance document (European Commission, 2017), an extrapolation of residue data would be acceptable from parsley and lettuce, but not from sage and savoury. However, since a sufficient number of trials on lettuce and parsley are available, EFSA did not exclude sage and savoury from the data set, considering that these crops would add to the overall representativeness of residues in herbs. An MRL proposal of 100 mg/kg is thus derived for the whole group of fresh herbs and edible flowers.

According to the EMS, the analytical methods used to analyse residue trial samples were fit for purpose and were sufficiently validated (Germany, 2018).

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. The peer review experts agreed that, considering information published in scientific literature, the uptake of copper by plants is regulated to provide the essential nutritional amount. It was concluded that 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 by the RMS, France, in the framework of the MRL review (Annex A of the EFSA reasoned opinion on the review of existing MRLs for copper compounds) (EFSA, 2018c). According to this survey, in fresh herbs and edible flowers, the natural background levels of copper ranged from 0.59 mg/kg in chives to 6.77 mg/kg in tarragon.

Since the intended new use of copper hydroxide on fresh herbs and edible flowers is in line with the restricted annual application rate of average 4 kg copper/ha and is below the application rates assessed in the renewal of the approval of copper compounds, EFSA concludes that the use on herbs and edible flowers is not the most critical with regard to residues in rotational crops. Moreover, the uptake of copper in succeeding crops is regulated by plant depending on its nutritional needs (EFSA, 2018b).

It is noted that the MRL review derived MRLs for all plant commodities (also off-label crops) included in Annex I to Regulation (EC) No 396/2005, considering residues from authorised uses as well as taking into consideration endogenous occurrence of copper in soil and plant commodities. These MRL proposals cover possible residue uptakes that may occur in rotational crops (EFSA, 2018c).

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 contribution of herbs and edible flowers to the consumer intake is low 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 150 mg/kg as well as risk assessment values for fresh herbs and edible flowers in support of the intended EU indoor use of copper hydroxide. The intended NEU use is sufficiently supported by residue data, but results in a less critical residue situation the crops. EFSA notes that the same MRL proposal (150 mg/kg) was recommended by the MRL review, but has not yet been implemented. 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, 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 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 risk mitigation measures to reduce the exposure (for wine grapes, tomatoes, lettuces, the STMR values used in scenario 1 were replaced by STMR values that reflect the background level only; for potatoes, an STMR for a fall-back GAP was used).

Assuming that conclusions of the MRL review will be taken over in the EU legislation, EFSA now updated both exposure scenarios of the MRL review with the relevant STMR values as derived from the residue trials on herbs and edible flowers (Appendix B.1.2.1) as submitted in support of this MRL application; it is noted that the STMR value for fresh herbs and edible flowers used in the previous risk assessment was only slightly lower than the STMR value derived in the current assessment (34.6 mg/kg vs. 38 mg/kg). The summary of the input values for commodities other than fresh herbs and edible flowers is available in the Appendix D.2 of EFSA reasoned opinion on the review of the existing MRLs for copper compounds (EFSA, 2018c).

For the current assessment, EFSA used revision 3.1 of the EFSA PRIMo. 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).[8] The setting of the ARfD was considered not necessary.

The calculated long-term dietary exposure to copper residues in both calculation scenarios exceeded the ADI. In **scenario 1,** the maximum exposure accounted for 169% of the ADI for Dutch toddler diet and for 102% of the ADI for Dutch child 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).

[8] 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).

In **scenario 2**, which comprises the risk mitigation measures applied by the MRL review, the calculated exposure accounted for a maximum of 166% of the ADI for Dutch toddler diet. EFSA notes that in the MRL review, the exposure calculated in scenario 2 identified no chronic consumer intake concern (93.4% of the ADI) (EFSA, 2018c).

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. The contribution of copper residues in fresh herbs and edible flowers to the actual long-term consumer exposure is very low (0.11% of the ADI). Further refinements of the exposure calculation might be possible, once a decision is taken on the appropriate risk mitigation measures that will be implemented.

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 herbs and edible flowers from the new intended use contribute insignificantly to the overall consumer exposure, a risk management decision has to be taken whether it is appropriate to increase the existing MRL for herbs and edible flowers from 20 or 50 mg/kg[9] to 150 mg/kg, given that, based on the currently available information, potential consumer intake concerns cannot be excluded.

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 150 mg/kg for copper in fresh herbs and edible flowers in support of the intended indoor use of copper hydroxide. The intended NEU use is sufficiently supported by residue data, but results in a less critical residue situation in the crops. EFSA notes that the same MRL proposal (150 mg/kg) was recommended by the MRL review, but so far has not been implemented.

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. Residues in herbs and edible flowers resulting from the new intended use contribute to a very low extent to the overall consumer exposure. A risk management decision has to be taken whether it is appropriate to increase the existing MRL for herbs and edible flowers from 20 or 50 mg/kg[9] to 150 mg/kg, given that, based on the currently available information, potential consumer intake concerns cannot be excluded.

The MRL recommendations are summarised in Appendix B.4.

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[9] The existing EU MRL for celery leaves is set at 50 mg/kg; for other commodities classified the group of herbs and edible flowers, the existing MRL is 20 mg/kg.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CF	conversion factor for enforcement to risk assessment residue definition
CIRCA	(EU) Communication & Information Resource Centre Administrator
CS	capsule suspension
CV	coefficient of variation (relative standard deviation)
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DP	dustable powder
DS	powder for dry seed treatment
DT_{90}	period required for 90% dissipation (define method of estimation)

EC	emulsifiable concentrate
EDI	estimated daily intake
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
FID	flame ionisation detector
GAP	Good Agricultural Practice
GC	gas chromatography
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography with mass spectrometry
GC-MS/MS	gas chromatography with tandem mass spectrometry
GS	growth stage
HR	highest residue
IEDI	international estimated daily 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	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RAR	renewal assessment report
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe
SL	soluble concentrate
SP	water-soluble powder
STMR	supervised trials median residue
TAR	total applied radioactivity
TMDI	theoretical maximum daily intake
UV	ultraviolet (detector)
WHO	World Health Organization

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

Code	Crop name	NEU, SEU, MS or country	Outdoor/ Indoor[a]	Pests controlled	a.s.	Type[b]	Conc. a.s. (g/kg)	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application	Water L/ha min-max	Rate (g/ha)	PHI (days)[d]	Remarks
256010	Chervil	NEU	Outdoor	Downy mildew	Copper hydroxide	SC	383.0	Foliar treatment – broadcast spraying	13	6	7–10 days	200–400	766.00	7	Growth stage and season: at beginning of infestation and/or when first symptoms become visible Application rate refers to ca. 500 g Cu^{2+}/ha
256020	Chives	NEU	Outdoor	Downy mildew	Copper hydroxide	SC	383.0	Foliar treatment – broadcast spraying	13	6	7–10 days	200–400	766.00	7	
256030	Celery leaves	NEU	Outdoor	Downy mildew	Copper hydroxide	SC	383.0	Foliar treatment – broadcast spraying	13	6	7–10 days	200–400	766.00	7	
256040	Parsley	NEU	Outdoor	Downy mildew	Copper hydroxide	SC	383.0	Foliar treatment – broadcast spraying	13	6	7–10 days	200–400	766.00	7	
256050	Sage	NEU	Outdoor	Downy mildew	Copper hydroxide	SC	383.0	Foliar treatment – broadcast spraying	13	6	7–10 days	200–400	766.00	7	
256060	Rosemary	NEU	Outdoor	Downy mildew	Copper hydroxide	SC	383.0	Foliar treatment – broadcast spraying	13	6	7–10 days	200–400	766.00	7	
256070	Thyme	NEU	Outdoor	Downy mildew	Copper hydroxide	SC	383.0	Foliar treatment – broadcast spraying	13	6	7–10 days	200–400	766.00	7	
256080	Basil and edible flowers	NEU	Outdoor	Downy mildew	Copper hydroxide	SC	383.0	Foliar treatment – broadcast spraying	13	6	7–10 days	200–400	766.00	7	
256090	Laurel/ bay leaves	NEU	Outdoor	Downy mildew	Copper hydroxide	SC	383.0	Foliar treatment – broadcast spraying	13	6	7–10 days	200–400	766.00	7	
256100	Tarragon	NEU	Outdoor	Downy mildew	Copper hydroxide	SC	383.0	Foliar treatment– broadcast spraying	13	6	7–10 days	200–400	766.00	7	
256010	Chervil	NEU/SEU	Indoor	Downy mildew	Copper hydroxide	SC	383.0	Foliar treatment– broadcast spraying	13	6	7–10 days	200–400	766.00	7	
256020	Chives	NEU/SEU	Indoor	Downy mildew	Copper hydroxide	SC	383.0	Foliar treatment – broadcast spraying	13	6	7–10 days	200–400	766.00	7	
256030	Celery leaves	NEU/SEU	Indoor	Downy mildew	Copper hydroxide	SC	383.0	Foliar treatment– broadcast spraying	13	6	7–10 days	200–400	766.00	7	
256040	Parsley	NEU/SEU	Indoor	Downy mildew	Copper hydroxide	SC	383.0	Foliar treatment – broadcast spraying	13	6	7–10 days	200–400	766.00	7	
256050	Sage	NEU/SEU	Indoor	Downy mildew	Copper hydroxide	SC	383.0	Foliar treatment – broadcast spraying	13	6	7–10 days	200–400	766.00	7	
256060	Rosemary	NEU/SEU	Indoor	Downy mildew	Copper hydroxide	SC	383.0	Foliar treatment – broadcast spraying	13	6	7–10 days	200–400	766.00	7	
256070	Thyme	NEU/SEU	Indoor	Downy mildew	Copper hydroxide	SC	383.0	Foliar treatment – broadcast spraying	13	6	7–10 days	200–400	766.00	7	
256080	Basil and edible flowers	NEU/SEU	Indoor	Downy mildew	Copper hydroxide	SC	383.0	Foliar treatment – broadcast spraying	13	6	7–10 days	200–400	766.00	7	
256090	Laurel/ bay leaves	NEU/SEU	Indoor	Downy mildew	Copper hydroxide	SC	383.0	Foliar treatment – broadcast spraying	13	6	7–10 days	200–400	766.00	7	
256100	Tarragon	NEU/SEU	Indoor	Downy mildew	Copper hydroxide	SC	383.0	Foliar treatment – broadcast spraying	13	6	7–10 days	200–400	766.00	7	

NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; SC: suspension 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): PHI: minimum preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

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

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

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling (DAT)**	**Comment/Source**
	–	–	–	–	–
	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)	No	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)	No	
	Sterilisation (20 min, 120°C, pH 6)	No	
	Other processing conditions	No	

Can a general residue definition be proposed for primary crops?	Yes	
Rotational crop and primary crop metabolism similar?	Yes	
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	
Plant residue definition for monitoring (RD-Mo)	Total copper	
Plant residue definition for risk assessment (RD-RA)	Total copper	
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/Indoor[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)
Fresh herbs and edible flowers	EU (indoor)	Open leaf lettuce: 12; 2 × 32; 51; 71 Parsley: 38; 83	Residue trials on open leaf lettuce and parsley compliant with the GAP Extrapolation to the whole group of herbs and edible flowers acceptable	**150**	83	38
Fresh herbs and edible flowers	NEU	Open leaf lettuce: 4 × < 5; 6.8; 9.9; 12; 21 Parsley: 15; 16; 43; 56 Sage: 17; 40; 67 Savoury: 37	Residue trials on open leaf lettuce, parsley, sage and savoury compliant with GAP Extrapolation from a combined residue data set on lettuce, parsley, sage and savoury to the whole group of herbs and edible flowers acceptable	100	67	15.5

MRL: maximum residue level; GAP: Good Agricultural Practice.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. 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 micronutrient for plants and it is assumed that copper uptake in succeeding crop is auto regulated by the crops. Therefore, the survey on the endogenous copper levels in all plant commodities as reported by the RMS France 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 (reported in Appendix F.1. of the EFSA reasoned opinion on the review of existing MRLs for copper compounds (EFSA, 2018c))

MRL: maximum residue level.

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:** 169% ADI (NL toddler diet) 102% ADI (NL child diet) Contribution of crops assessed: Herbs and edible flowers: 0.11% of ADI **Scenario 2 with risk mitigation measures:** 166% ADI (NL toddler diet) Contribution of crops assessed: Herbs and edible flowers: 0.11% 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 herbs and edible flowers as derived in the framework of the current assessment The calculation takes into account residues arising from authorised uses as well as from any other sources (background concentrations, uptake from soil, etc.) Therefore, commodities where no GAP was reported in the framework of the MRL review were also included in the calculation. For those commodities where MRL proposals were derived in the Article 12 MRL review from: – the authorised GAPs: input values are based on the median values of the supporting residue trials; – the monitoring data: input values are based on mean values of the monitoring results; – the background levels data: input values are based on median values of the background levels. For citrus 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 fallback 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

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; STMR: supervised trials median residue; MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern Europe; SEU: southern Europe.

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL/MRL proposals Art. 12 review (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Copper compounds (copper)				
0256000, except 0256030	Herbs and edible flowers (except celery leaves)	20/150	Further risk management considerations required	The submitted data are sufficient to derive an MRL proposal of 150 mg/kg in support of the intended indoor use of copper hydroxide. The NEU outdoor use is less critical
0256030	Celery leaves	50/150		Long-term consumer intake concerns cannot be excluded for the intake of copper residues resulting from the existing uses of copper compounds and background/monitoring levels. Residues in herbs and edible flowers contribute to a very low extent to the overall consumer exposure (0.11% of the ADI). A risk management decision has to be taken whether it is appropriate to raise the existing MRLs, given that based on the currently available information a potential consumer intake concern cannot be excluded

NEU: northern Europe; MRL: maximum residue level; ADI: acceptable daily intake.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

Appendix C – Pesticide Residue Intake Model (PRIMo)

- PRIMo scenario 1

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Copper

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw per day):	0.15	ARfD (mg/kg bw):	not necessary
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:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 2

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)
169%	NL toddler	253.44	19%	Maize/corn	17%	Spinaches	12%	Oil palm kernels		
102%	NL child	152.87	16%	Oil palm fruits	11%	Wheat	7%	Sugar beet roots		
99%	GEMS/Food G06	148.14	20%	Wheat	10%	Soyabeans	6%	Table grapes		
97%	GEMS/Food G11	145.09	30%	Soyabeans	10%	Wheat	5%	Potatoes		
96%	GEMS/Food G10	144.19	26%	Soyabeans	11%	Wheat	7%	Lettuces		
91%	GEMS/Food G07	136.25	14%	Soyabeans	12%	Wheat	8%	Bovine: Liver		
84%	GEMS/Food G08	126.24	16%	Soyabeans	11%	Wheat	6%	Sunflower seeds		
79%	GEMS/Food G15	119.10	14%	Soyabeans	13%	Wheat	7%	Sunflower seeds		
79%	DE child	118.18	12%	Apples	12%	Wheat	8%	Table grapes		
76%	FI adult	113.92	60%	Coffee beans	3%	Lettuces	2%	Rye		
73%	IE adult	109.79	14%	Sheep: Liver	6%	Wheat	3%	Sweet potatoes		
64%	FR child 3 15 yr	96.18	13%	Wheat	4%	Other oilseeds	4%	Milk: Cattle		
58%	NL general	87.34	9%	Oil palm fruits	5%	Wheat	4%	Spinaches		
56%	DK child	83.65	15%	Rye	12%	Wheat	3%	Lettuces		
54%	ES child	81.05	12%	Wheat	10%	Lettuces	3%	Poultry: Muscle/meat		
53%	FR toddler 2 3 yr	78.98	9%	Wheat	5%	Milk: Cattle	4%	Spinaches		
52%	RO general	78.08	14%	Wheat	8%	Sunflower seeds	5%	Potatoes		
45%	PT general	68.08	11%	Wheat	7%	Potatoes	4%	Wine grapes		
45%	IT toddler	66.92	18%	Wheat	7%	Lettuces	3%	Other lettuce and other salad plants		
44%	SE general	66.74	9%	Lettuces	9%	Wheat	6%	Potatoes		
44%	DE women 14-50 yr	65.65	6%	Wheat	5%	Coffee beans	4%	Sugar beet roots		
43%	DE general	64.94	5%	Wheat	5%	Coffee beans	4%	Sugar beet roots		
43%	UK infant	64.86	7%	Wheat	6%	Milk: Cattle	5%	Bovine: Liver		
43%	ES adult	63.86	12%	Lettuces	6%	Wheat	2%	Chards/beet leaves		
42%	UK toddler	63.45	11%	Wheat	5%	Potatoes	4%	Beans		
41%	IT adult	61.33	11%	Wheat	9%	Lettuces	4%	Other lettuce and other salad plants		
40%	FR adult	60.25	6%	Wheat	4%	Coffee beans	4%	Wine grapes		
30%	FI 3 yr	44.70	6%	Potatoes	3%	Wheat	2%	Rye		
28%	FR infant	42.64	6%	Spinaches	3%	Milk: Cattle	3%	Potatoes		
26%	UK vegetarian	38.72	6%	Wheat	3%	Lettuces	2%	Potatoes		
26%	FI 6 yr	38.62	5%	Potatoes	3%	Wheat	2%	Lettuces		
24%	UK adult	35.67	5%	Wheat	3%	Lettuces	2%	Potatoes		
22%	LT adult	33.19	4%	Potatoes	3%	Rye	3%	Wheat		
20%	DK adult	30.68	3%	Wheat	2%	Lettuces	2%	Potatoes		
14%	PL general	21.14	5%	Potatoes	2%	Apples	2%	Table grapes		
8%	IE child	12.35	3%	Wheat	0.8%	Rice	0.8%	Potatoes		

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 169 % of the ADI.
For 2 diet(s), the ADI is exceeded.

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

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

Show results for all crops

Unprocessed commodities

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

Processed commodities

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

Conclusion:

- PRIMo scenario 2

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Copper (risk mitigation scenario)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw per day):	0.15	ARfD (mg/kg bw):	not necessary
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:

Normal 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	248.35	19%	Maize/corn	17%	Spinaches	12%	Oil palm kernels		
98%	NL child	147.01	16%	Oil palm fruits	11%	Wheat	7%	Sugar beet roots		
91%	GEMS/Food G06	136.94	20%	Wheat	10%	Soyabeans	6%	Table grapes		
91%	GEMS/Food G11	135.83	30%	Soyabeans	10%	Wheat	5%	Kapok		
85%	GEMS/Food G10	127.85	26%	Soyabeans	11%	Wheat	3%	Rice		
80%	GEMS/Food G07	120.34	14%	Soyabeans	12%	Wheat	8%	Bovine: Liver		
75%	GEMS/Food G08	112.63	16%	Soyabeans	11%	Wheat	6%	Sunflower seeds		
75%	DE child	111.91	12%	Apples	12%	Wheat	8%	Table grapes		
72%	GEMS/Food G15	108.54	14%	Soyabeans	13%	Wheat	7%	Sunflower seeds		
71%	FI adult	106.67	60%	Coffee beans	2%	Rye	1%	Other oilseeds		
68%	IE adult	101.87	14%	Sheep: Liver	6%	Wheat	3%	Sweet potatoes		
62%	FR child 3 15 yr	92.67	13%	Wheat	4%	Other oilseeds	4%	Milk: Cattle		
54%	NL general	80.48	9%	Oil palm fruits	5%	Wheat	4%	Spinaches		
51%	FR toddler 2 3 yr	76.32	9%	Wheat	5%	Milk: Cattle	4%	Spinaches		
51%	DK child	76.27	15%	Rye	12%	Wheat	2%	Apples		
46%	RO general	68.39	14%	Wheat	8%	Sunflower seeds	3%	Potatoes		
43%	ES child	63.95	12%	Wheat	3%	Poultry: Muscle/meat	2%	Milk: Cattle		
41%	UK infant	61.90	7%	Wheat	6%	Milk: Cattle	5%	Bovine: Liver		
39%	UK toddler	59.20	11%	Wheat	4%	Beans	3%	Milk: Cattle		
39%	DE general	57.86	5%	Wheat	5%	Coffee beans	4%	Sugar beet roots		
39%	DE women 14-50 yr	57.84	6%	Wheat	5%	Coffee beans	4%	Sugar beet roots		
36%	IT toddler	54.00	18%	Wheat	3%	Other lettuce and other salad plants	1%	Chards/beet leaves		
36%	PT general	53.78	11%	Wheat	5%	Potatoes	4%	Sunflower seeds		
36%	FR adult	53.57	6%	Wheat	4%	Coffee beans	3%	Other lettuce and other salad plants		
33%	SE general	48.89	9%	Wheat	4%	Potatoes	3%	Bovine: Muscle/meat		
31%	IT adult	46.16	11%	Wheat	4%	Other lettuce and other salad plants	2%	Spinaches		
29%	ES adult	42.86	6%	Wheat	2%	Chards/beet leaves	2%	Spinaches		
27%	FR infant	41.06	6%	Spinaches	3%	Milk: Cattle	3%	Leeks		
26%	FI 3 yr	39.20	4%	Potatoes	3%	Wheat	2%	Rye		
22%	FI 6 yr	32.33	3%	Potatoes	3%	Wheat	2%	Rye		
20%	UK vegetarian	30.14	6%	Wheat	2%	Beans	1%	Potatoes		
18%	LT adult	27.74	3%	Rye	3%	Wheat	3%	Potatoes		
18%	UK adult	27.60	5%	Wheat	1%	HOPS (dried)	1%	Potatoes		
16%	DK adult	23.74	3%	Wheat	1%	Rye	1%	Potatoes		
11%	PL general	16.75	3%	Potatoes	2%	Apples	2%	Table grapes		
8%	IE child	11.59	3%	Wheat	0.8%	Rice	0.6%	Milk: Cattle		

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.

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

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

Show results for all crops

Unprocessed commodities

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

Processed commodities

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

Conclusion:

Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Herbs and edible flowers	38	STMR (indoor use)	Acute exposure not calculated since setting of the ARfD was considered not necessary	
Other commodities of plant and animal origin	Appendix D.2. of the EFSA reasoned opinion on the review of existing MRLs for copper compounds (EFSA, 2018c)			