

**Committee for Risk Assessment
RAC**

Annex 2
Response to comments document (RCOM)
to the Opinion proposing harmonised classification and
labelling at EU level of

Copper

EC Number: 231-159-6
CAS Number: 7440-50-8

CLH-O-0000007208-73-01/F

Adopted
1 December 2022

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during consultation are made available in the table below as submitted through the web form. Any attachments received are referred to in this table and listed underneath, or have been copied directly into the table.

All comments and attachments including confidential information received during the consultation have been provided in full to the dossier submitter (Member State Competent Authority), the Committees and to the European Commission. Non-confidential attachments that have not been copied into the table directly are published after the consultation and are also published together with the opinion (after adoption) on ECHA's website. Dossier submitters who are manufacturers, importers or downstream users, will only receive the comments and non-confidential attachments, and not the confidential information received from other parties. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

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Substance name: copper
EC number: 231-159-6
CAS number: 7440-50-8
Dossier submitter: Sweden

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Turkey	Sarkuysan Elektrolitik Bakir San. Tic.A.S.	Company-Manufacturer	1
Comment received				
Thanks to its high recyclability, end-of-life copper can be converted to new products in an efficient and eco-friendly way, which is essential for circular economy.				
Dossier Submitter's Response				
Thank you for your comment.				
RAC's response				
Thank you for your comment.				

Date	Country	Organisation	Type of Organisation	Comment number
13.01.2022	Germany	Breuckmann GmbH & Co. KG	Company-Manufacturer	2
Comment received				
See Attached Document "Public Consultation - Copper harmonized classification - PUBLIC.pdf"				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public Consultation - Copper harmonized classification - PUBLIC.pdf				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Public Consultation - Copper harmonized classification -- CONFIDENTIAL.pdf				
Dossier Submitter's Response				
Thank you for your comment. Please see response to comment number 4, in which we give response to the comments by European Copper Institute, which you refer to. This				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

response also covers the comment from Breuckmann GmbH & Co. KG in comment number 26.
RAC's response
Thank you for your comment. RAC follows the approach of DS and summarised comments by European Copper Institute. Please, refer to these responses.

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Germany	WirtschaftsVereinigung Metalle e.V.	Industry or trade association	3

Comment received
WVMetalle would like to give comments on the proposal submitted by the Swedish Chemicals Agency dated October 2021 in relation to the environmental classification of copper. The proposal concluded that fine forms of copper (specific surface area greater 0.67 mm²/mg) should be classified as Aquatic Acute 1, H400; M=10 and Aquatic Chronic 1, H410; M=1, and that massive copper should not be classified. WVMetalle especially supports that the massive forms of copper should not be classified. WirtschaftsVereinigung Metalle (WVMetalle), the German Non-Ferrous Metals Association, represents the German Non-Ferrous (NF) metals industry towards politics and economy in order to maintain and establish measures at a very high level. Today, WV Metalle has about 670 member companies, including producers and processors of most base and special met-als and compounds including copper metal and copper containing alloys. WVMetalle is member of the German Industry Association (BDI) and of the European Non-Ferrous Metals Association (Eurometaux). WVMetalle welcomes the opportunity to feed into the consultation on the harmonized classification for environmental hazards of copper metal, in massive and powder forms. In general, WVMetalle pleads for using all available high-quality information, including the latest update of the copper registration dossiers. For most of the technical aspects of the debate on the environmental classification of copper metal we refer to the comments by the European Copper Institute and by Eurometaux, which we fully support. We would like to focus specifically on the correct application of the CLP criteria and the CLP Guidance regarding the environmental hazard classification. Following the guidance this clearly includes a differentiation of the environmental classification entries for the massive and powder form of copper metal. In essence, applying the metal specific guidance and referring to the previous assessment of granulated copper at RAC level the data indicate that a chronic environmental classification of copper in massive form is not warranted. Although it is not in the center of this consultation, WVMetalle would like to raise the aspect of downstream legislation consequences of the proposed classification. For example, the Seveso directive and transport regulations are triggering additional requirements which increases administrative burdens, costs and measures for affected companies which are not justified by the intrinsic properties of copper, especially when it comes to massive parts. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2022-01-28_WVMetalle comment on Cu Env Clas consultation.pdf
Dossier Submitter's Response
Thank you for your comments and for your support considering e.g. the ERV and the dataset used for evaluation of transformation/dissolution of copper.

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

Please also see responses to comments number 4 and 47, in which we give responses to the comments by European Copper Institute and Eurometaux, which you refer to. This response also covers the comment from WirtschaftsVereinigung Metalle e.V. in comment number 27.
RAC's response
Thank you for your comments and support on the proposed separate classification of copper metal based on limit value of 0.67 mm²/mg. Please, see responses to comments number 4 and 47, in which we give responses to the comments by European Copper Institute and Eurometaux, to which you refer.

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Belgium	European Copper Institute	Industry or trade association	4
Comment received				
Please see our comments in the attached ZIP archive. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Copper CLH - ECI input FINAL.zip				
Dossier Submitter's Response				
Thank you for your comments and the support considering that the assessment is to a large extent based on and consistent with previous evaluations of copper and including information from the most recent update of the REACH registration dossier of copper (February 2021). Thank you also for the two study reports (one for <i>Lymnaea stagnalis</i> and one for <i>Ceriodaphnia dubia</i>). We would like to clarify that consequences in downstream legislation are not taken into consideration in the process of proposals for harmonised classifications that is solely based on the intrinsic hazardous properties of the substance. We consider that this issue would be more appropriately dealt with independently through other European legal instruments. <u>Comment on section 2: Proposed harmonized classification and labelling</u> The ECI suggests adding the descriptor "powder" or "fine forms" to the entry for small copper particles, in addition to the the specific surface area. ECI indicates that an entry that <i>only</i> refers to the specific surface area will not be clear to all actors in the supply chain. ECI therefore suggests the following entry for small copper particles: "Copper powder [specific surface area >0.67 mm²/mg] or Copper, fine forms [specific surface area >0.67 mm²/mg]". Our suggestion is to base the proposal on surface area per weight (mm²/mg), since we believe the terms powder and massive in the guidance were only used to draw a theoretical line between two possible entries based on a spherical particle with diameter of 1 mm (default). In practice, an entry in Annex VI needs to be a bit more descriptive. The reason for our suggestion is to cover all shapes of copper with a specific surface area >0.67 mm²/mg, for example, powder, flakes, sticks, granulates etc. We believe that the descriptor "powder" would most likely be interpreted as, more or less, spherical particles and by using this descriptor we could see a risk that other shapes of particles will be excluded. We can agree that the descriptor "fine forms" is more general and could include different shapes of copper. If a descriptor is necessary to clarify for all actors in the				

supply chain what particles should be covered, we suggest the addition of "fine forms", resulting in the following entry: "Copper, fine forms [specific surface area $>0.67 \text{ mm}^2/\text{mg}$]".

See also comment 5.

Comment on section 11.2: Environmental transformation of metals or inorganic metals compounds

ECI supports our proposal of a split assessment for copper metal in massive form and in small particles form. They claim further that *"The approach as presented is in line with previous regulatory assessments, it recognizes the information in the copper REACH dossier and Chemical Safety Report, and it is in line with the CLP guidance (section IV.2.2 – Interpretation of solubility data, and section IV.5.5 - Particle size and surface area)."*

ECI informs that the particle we selected as the smallest representative copper particle (from the study by Skeaff & Hardy (2005)) with a specific surface area of $107 \text{ mm}^2/\text{mg}$ is produced by water atomization which results in particles with an *irregular* shape, and this could explain the relatively higher specific surface area compared to its particle size. Additionally, ECI informs that water atomization, is a less common technique to produce copper powders and that most copper powders are produced through air atomization, which results in approximately *spherical* particles. ECI also concludes that the copper release from the copper particles in Skeaff & Hardy (2005) after 7 days at pH 6 and at a mass loading of 1 mg/L was lower than:

- *"The copper release of $110 \text{ }\mu\text{g/L}$ which was measured under the same conditions for Copper powder 1. That powder is a very fine air-atomized copper powder with $D_{50} = 11 \text{ }\mu\text{m}$ and specific surface area $60 \text{ mm}^2/\text{mg}$ (BET). (ECTX, 2020).*
- *The copper release of $196.1 \text{ }\mu\text{g/L}$ in the report by the Dossier Submitter, which was calculated through linear extrapolation of the release from air-atomized powder (ECTX, 2020) to a surface area of water atomized powder of $107 \text{ mm}^2/\text{mg}$ (BET)."*

The reason for the lower copper release in the study by Skeaff & Hardy (2005) is unknown, but ECI assumes that it could be the shape of the water-atomized particles or the differences in the surface activity/passivity due to the different production methods, which possibly lead to a slightly higher surface oxidation of water atomized copper powders, resulting in a lower solubility.

Based on the reasoning above, ECI concludes that *"The data from ECTX (2020) show the highest measured release of all copper powders and this justifies the use of these data for classification."*

In our CLH proposal we have used data from ECTX (2020) to predict the release of copper ions from copper powder at different pH and at 7 and 28 days. However, we did not use the particles from ECTX (2020) as "the smallest representative copper particle available on the market". Instead, we concluded that the "the smallest representative copper particle available on the market" was the particle described in Skeaff & Hardy (2005) with a specific surface area $107 \text{ mm}^2/\text{mg}$. We therefore considered it relevant to extrapolate the measured release from ECTX (2020) to this specific surface area of $107 \text{ mm}^2/\text{mg}$.

We do not find it justified to exclude this small particle from Skeaff & Hardy (2005), based on the argument from ECI, that this particle is produced by water atomization. It is shown by ECI that particles produced by water atomization show a more irregular form compared to particles produced by air atomization, see Figure 2 in ECI's attachment. However, in our view, this irregular form does not results in a remarkable difference of specific surface area, and should not justify the exclusion of this particle as "the smallest representative copper particle available on the market". Additionally, even though ECI

informs that water atomization is a less common technique to produce copper powders and that most copper powders are produced through air atomization, we lack information if this production technique (water atomization) is small enough to be disregarded. Hence, in this case, we do not find it justified to exclude the particles from the study by Skeaff & Hardy (2005) as "the smallest representative copper particle available on the market", based on the production technique.

Additionally, we do not find it justified to exclude this small particle from Skeaff & Hardy (2005), based on the argument that the release of copper ions was higher for other particles. When we selected "the smallest representative copper particle available on the market", we did not consider the transformation/dissolution-results, but instead focused on the sizes and specific surface areas of particles which are available on the market.

Comment on section 11.3 Environmental fate and other relevant information:

ECI comments that:

"...recent research confirms that copper ions in the water column are indeed subject to natural speciation, transformation, and removal processes, and that these occur generally within 28 days. In the sediment, subsequent transformation of copper ions to other chemical species occurs, mainly to insoluble copper-sulphide minerals, and this has been confirmed most recently using state-of-the-art techniques (Cervi et al., 2021). Such copper-sulphide minerals are stable and are buried over time. Remobilization and release of copper ions is negligible even under changing environmental conditions or after resuspension due to boating, dredging, or bioturbation (Rader et al., 2019; Burton et al., 2019; Huntsman et al., 2019). This information supports the conclusion that copper ions do indeed undergo rapid environmental transformation and removal.

Therefore, whilst we note that there is currently no agreed approach in the CLP Guidance on how to implement rapid environmental transformation for metals and inorganic substances (the equivalent of degradability of organic substances) in a classification & labelling context, the evidence provided in the registration dossier can definitely be assessed on a case-by-case basis for its robustness and relevancy."

Considering the Environmental transformation and removal we refer to earlier discussions already held in RAC (RAC opinion on Granulated Copper, June, 2018) and Caracal (November 2019, CA/68/2019). Additionally, these discussions were summarised in the recently published RAC Opinion for Lead (16 September 2021*) . In line with these earlier discussions, we conclude that the information available for environmental transformation and removal of copper could not be subject to rapid environmental transformation for the purpose of classification and labelling. We do not see that the studies referred to above by ECI could change this conclusion.

* Available at:

[Opinions of the RAC adopted under specific ECHA's Executive Director requests - ECHA \(europa.eu\)](https://echa.europa.eu/en/opinions-of-the-rac-adopted-under-specific-echa-executive-director-requests)

Comment on 11.4 Bioaccumulation

ECI refers to "Copper Voluntary Risk Assessment, section 3.2.6", where it is stated that: "There is overwhelming evidence to show the absence of copper biomagnification across the trophic chain in the aquatic and terrestrial food chains" and "Field evidence has further provided evidence on the mechanisms of action of copper in the aquatic and terrestrial environment and the absence of a need for concern for secondary poisoning".

In our dossier, we refer to earlier evaluations of copper, e.g. the RAC opinion on Granulated Copper (June 2018), where it is stated: "The bioaccumulation behaviour of copper (II) ions is complicated by essentiality and homeostatic mechanisms in organisms, but does not need to be considered further because it does not influence the determination of the chronic M-factor (in view of the conclusion about removal)." As far

as we can see, no new information is available considering the bioaccumulation of copper. Further, the conclusions for bioaccumulation will have no impact on the proposed classification for the environment. Therefore, to be consistent with the approach in earlier copper CLH dossiers (RAC opinions on copper flakes and nine copper compounds adopted in December 2014 and RAC opinion on Granulated Copper (June 2018)), we refer to the conclusions made in these RAC opinions.

Comment on 11.5 – Acute aquatic hazard and 11.6 - Long-term aquatic hazard

ECI supports us regarding the use of the copper ERVs in the RAC opinion on granulated copper (2018) and we thank for this support. ECI also submitted two additional studies, which have become available recently (one for *Lymnaea stagnalis* and one for *Ceriodaphnia dubia*).

ECI suggests that the results from the new *Ceriodaphnia dubia* study could be used together with earlier data to obtain a new LC₁₀/NOEC based on a geometric mean of all data. The resulting geometric mean (not normalised for DOC) is, according to ECI, 16.1 µg/L (survival) and 10.9 µg/L (reproduction). These new LC₁₀/NOEC, suggested by ECI, are higher than the NOEC used as ERV for pH-band 6.5-7.5 in our dossier.

The new study with *Lymnaea stagnalis* reports a NOEC of 15.3 µg Cu/L for the reproduction endpoint, and it reports NOECs of 28.8 µg Cu/L for the survival and growth endpoints at pH 7.8. These new NOEC, are higher than the NOEC used as ERV for pH-band 7.5-8.5 in our dossier.

ECI concludes that these two new studies do not trigger a revision of the presented ERVs for copper.

We have not thoroughly evaluated the two new studies, but we agree with ECI that these two new studies do not trigger a revision of the presented ERVs based on the following:

New study Ceriodaphnia dubia

This study investigate the chronic toxicity (survival and reproduction) of copper to *Ceriodaphnia dubia* at a pH-range of 6.5-7.5. This pH-band is not driving the assessment of the aquatic environmental hazard classification. According to the Guidance on the Application of the CLP criteria (2017), the worst case classification entry across pHs should be used based on comparing transformation/dissolution data with relevant ecotox data across the pH range. This means that a higher NOEC for *Ceriodaphnia dubia* at pH 6.5-7.5 will have no impact on the outcome of the assessment.

New study Lymnaea stagnalis

This study investigate the chronic toxicity (survival, growth and reproduction) of copper to *Lymnaea stagnalis* at a pH 7.8. The study reports a lowest NOEC of 15.3 µg Cu/L (reproduction), which is higher than the ERV used in the dossier for pH-band 7.5-8.5. However, this pH-band is not driving the assessment of the aquatic environmental hazard classification. According to the Guidance on the Application of the CLP criteria (2017), the worst case classification entry across pHs should be used based on comparing transformation/dissolution data with relevant ecotox data across the pH range. This means that a higher NOEC for *Lymnaea stagnalis* at pH 7.5-8.5 will have no impact on the outcome of the assessment.

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

The above responses also covers the comment from European Copper Institute in comment number 28.
RAC's response
RAC considers positive support from ECI to the assessment and conclusions in the CLH report of DS, which is also supported by RAC. <i>Comment: Proposed harmonized classification and labelling</i> RAC agrees with the DS that additional clarifications proposed by ECI such as copper powder (specific surface area $3 > 0.67 \text{ mm}^2/\text{mg}$) or copper fine forms would change the idea of the proposed classification of copper metal based only on specific surface area and the limit value of $0.67 \text{ mm}^2/\text{mg}$. <i>Comment: Environmental transformation of metals or inorganic metals compounds</i> RAC agrees with the DS that the copper powder produced by wet atomisation from Skeaff & Hardy (2005) is the smallest representative copper particle on the market with measured by BET, surface area of $107 \text{ mm}^2/\text{mg}$. However, experimental results from this study, with lower reliability (relative standard deviation above 30%), showed lower copper release than expected. The highest copper release was found from particles with a lower surface area of $60 \text{ mm}^2/\text{mg}$, produced by wet atomization. RAC is of the opinion that according to the CLP guidance the smallest particles should be used for classification. However, particles with highest copper release per mm^2, has to be taken into account (in line with the derived regression line). From this point of view, it seems that both type of particles might be used for the final classification by accepting the approach of DS to calculate copper released from particles with surface area of $107 \text{ mm}^2/\text{mg}$ using experimental results for copper released from particles with area $60 \text{ mm}^2/\text{mg}$. The classification derived is Aquatic Acute 1 with M-factor 10, independently which types of particles are used. RAC proposes to include both types of particles for the final classification. <i>Comment: Environmental fate and other relevant information</i> RAC considered the possibility for transformation of copper to non-bioavailable species in the presence of sulphides and thiol groups and results obtained showed that at environmentally relevant concentrations for Cu^{2+}, about 1 nM sulphide and median values for DOM, copper precipitation and transformation to non-bioavailable species is not expected. RAC considered studies, presented by the Registrant for copper transformation and removal. In the study of Cervi <i>et al.</i> (2021), the behaviour of copper ions added to freshwater sediments was studied under suboxic and anoxic conditions. Logically, in anoxic sediments sulphur species are reduced to sulphide and most of the copper is precipitated as CuS, an extremely insoluble and stable copper compound. However, in suboxic sediments sulphur species are oxidized to sulphate and copper exists mostly as soluble and reducible fractions. Various authors have concluded that Cu speciation altered from acid soluble to oxidizable fractions under anoxia. RAC notes that various types of sediments and conditions exist in the aquatic environment which govern chemistry of copper, from soluble to insoluble species. It is expectable that reducing conditions and sulphide content would reduce copper toxicity as shown in the study provided. However, this is a specific case with specific conditions. In the new study for "The Fate of Copper Added to Surface Water: Field, Laboratory, and Modelling Studies" Rader <i>et al.</i> (2019) authors observed that 70% removal of Cu^{2+} ions is possible however at extremely high concentrations ($250\text{-}1000 \text{ }\mu\text{g/L}$ Cu^{2+}) when precipitation of copper as hydroxides or sulphides might be expected. Overall, results from these studies showed that copper precipitation is possible under specific conditions but do not support the conclusion for copper transformation to non-bioavailable form under environmentally relevant conditions (low copper and low sulphide content). RAC do not

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

agree with ECI, that all these studies under conditions with high sulphide content and high copper concentrations (much above the concentrations of copper in aquatic environment) support copper ion transformation to nonbioavailable species and removal. In addition, simple calculation by using VisualMinteq for example do not show copper precipitation at concentrations in the range 0.5-1.5 µg/L and 1 nM sulphide.

Comment: Bioaccumulation

RAC supports the statement of DS *"The bioaccumulation behaviour of copper (II) ions is complicated by essentiality and homeostatic mechanisms in organisms, but does not need to be considered further because it does not influence the determination of the chronic M-factor (in view of the conclusion about removal)." RAC notes that copper is an essential element and copper biouptake depends on aquatic chemistry and biota physiology. Homeostatic control enables aquatic organisms to establish a negative relationship between exposure. A considerable amount of information is available for copper bioaccumulation. Copper BCFs and BAFs have been calculated for aquatic species such as algae, molluscs, arthropods, and fish. While Cu accumulates in the tissues of organisms as a result of exposure, the tissue concentrations are inversely proportional to the exposure concentrations (i.e., lower BCFs and BAFs at higher exposure concentrations). Biomagnification of Cu does not generally occur in aquatic organisms (McGeer et al., 2003).*

Comment: Acute aquatic hazard and Long-term aquatic hazard

RAC agrees with the conclusion of the DS that ECI supports the use of ERVs used in the opinion on granulated copper (2018). The information submitted for two additional studies one for *Lymnaea stagnalis* and one for *Ceriodaphnia dubia* has been considered but would not have impact on the outcome of the assessment.

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Germany	Wieland Werke AG	Company-Downstream user	5

Comment received

The Wieland Group fabricates semi-finished products like strips, sheets, tubes, rods, or wires as well as final components from copper and copper alloys. These semis are utilized by down-stream companies to produce final products for a large number of applications like e.g. buildings, power, refrigerating technologies, electromobility and battery technology, connectivity and electrical equipment. Copper and copper alloys are used in these applications due to their unique thermal, electrical and mechanical properties, and its excellent recyclability. All these products are in massive form.

We welcome the opportunity to present our view on the harmonized classification and labelling proposal for copper, in massive and in powder form.

The classification of a substance has far-reaching consequences due to down-stream legislation which directly links legal obligations to the classification. It is important that the right science is applied to each form of copper separately. We are concerned that if the massive form of copper would be inappropriately classified, this would not only result in additional operational and administrative requirements but also in a stigmatization of a sustainable metal in sustainable applications. Further details are given in the attached document.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comment to CHL Proposal Copper Wieland.pdf

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

Dossier Submitter's Response
Thank you for your comments and for your support considering e.g. the split classification for massive copper and copper with specific surface area of $> 0.67 \text{ mm}^2/\text{mg}$. Regarding your comment for the entry in Annex VI, to add a reference to the form in addition to the specific surface area, resulting in an entry such as "<i>copper, small particles [specific area $> 0.67 \text{ mm}^2/\text{mg}$]</i>", please see our response regarding this in comment 4. In comment 4, one of the suggestions of European Copper Institute is to add "fine forms" to the entry in Annex VI. In our view, if any descriptor would be included in an entry, we would prefer "fine forms" instead of "small particles". The main reason is that the term "fine forms" appears to be more general and cover all different shapes of copper while "small particles" might be understood as limited only to particles with different shapes. Please also see our other responses to comment number 4, in which we give response to the comments by European Copper Institute, which you refer to. This response also covers the comment from Wieland Werke AG in comment number 29.
RAC's response
Thank you for your comments and for your support on the split classification for massive copper and copper with specific surface area of $> 0.67 \text{ mm}^2/\text{mg}$. Regarding the comment to add a reference to the form in addition to the specific surface area for the entry in Annex VI, RAC is of opinion that this would change the general idea of proposed classification of copper metal based only on specific surface area and the limit value of $0.67 \text{ mm}^2/\text{mg}$. Please see also RAC responses to comment number 4.

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Belgium	Solar Heat Europe	Industry or trade association	6
Comment received				
Please refer to the attached document				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment SHE-Contribution-Copper Classification.pdf				
Dossier Submitter's Response				
Thank you for your comment.				
This response also covers the comment from Solar Heat Europe in comment number 30.				
RAC's response				
Thank you for your comment.				

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Switzerland	Arxada AG on behalf of Lonza Cologne GmbH	Company-Manufacturer	7
Comment received				
Copper, Granulated – A Specific Form of Copper				
Copper, granulated is an approved active substance according to the Biocidal Products Regulation(1). Under that regulation, Copper, granulated is specified as a closely defined				

form of copper and characterized by a specific shape and size and should not be considered copper massive or copper powder. Accordingly, the substance was subject to harmonised classification and labelling and a CLP (2) Annex VI entry is enforced (Index no. 029-024-00-X). Further, following REACH (3) Art.15 copper, granulated is regarded as being registered under that regulation.

According to CLP guidance the physical form does not represent an intrinsic property of a substance nor warrants an own specific aquatic environmental hazard classification. Further, in normal circumstances it is not anticipated that more than two classification proposals would be made for the same metal. However, multiple classification entries are already proposed for copper under the requirements of the BPR, which requires that the characterisation of a substance is set to a more limited specification than that expected under the CLP guidance. Therefore, BPR is the driving Regulation in characterising and specifying copper forms. Considering the different methods of production, particle size and reasonable expected use as well as the available substance specific environmental hazard data, indeed there is a case for a third form of copper and environmental classification specific for copper, granulated in line with BPR and CLP regulations and guidance.

Copper, granulated is not copper massive and not copper powder

Copper massive (greater 99.9% Cu) is produced from either copper ore concentrate or from recycled copper-containing scrap metal. According to CLP guidance massive forms of metal are defined by default as a sphere with a diameter greater 1mm and with a corresponding surface area of less than 0.67mm²/mg (less than 6.74cm²/g). The default value may be altered if sufficiently justified. Notably, copper is malleable and ductile with an elongation of approximately 0.5 (equal to 50%) and can be stretched extensively before breaking.

Copper powders (greater 99.7% Cu) are produced by special methods tailored specifically to the intentional production of powder forms, with atomization as the most common production technique for commercial copper powder in Europe. Copper powder is not generated during production and use of copper massive. The atomization process generates a powder with particles of spherical or irregular shape between 10 and up to 1000µm (d10: 4.083µm; d50: 10.84µm; d90: 16.25µm). The smallest representative copper particle has a specific surface area of 107mm²/mg (1070cm²/g).

Copper, granulated (greater 99.0% Cu) is a BPR approved biocidal active substance and has the same CAS- and EC-number as copper in general and is mainly manufactured from recycled copper scrap metal. It is not produced by the same special process as the powder forms. Instead, copper, granulated is generated by special mechanical fractionation, i.e. cutting of recycled copper wire into a specific shape and size as part of the recycling processes. Copper, granulated is not generated as by-product during the manufacturing or use of copper massive. The CLP entry for copper, granulated defines the particles of copper, granulated as cylindrical (not spherical) and with specific length ranges between 0.9 and 6.0 mm and width ranges between 0.494 and 0.949mm. The surface area of copper, granulated is 2.56mm²/mg (25.6cm²/g). Notably, only a very small fraction of copper, granulated is produced for use as active substance in wood preservation (product type 8) applications, with volumes estimated at significantly less than 0.1% of the total annual European copper tonnage.

Considering the different special manufacturing processes, the closely defined shape and size of particles, the very particular use and exceedingly low volume, copper, granulated should not be considered representative of copper massive and not considered copper

powder.

Copper, granulated – environmental hazard classification

According to the ECHA Guidance on the Application of CLP Criteria (4) Annex IV 5.5. surface area is a crucial test parameter and fixed in transformation tests measuring aquatic metal loadings. Whilst normally, the smallest particle size marketed is used to determine the extent of transformation, there may be cases where data generated for a particular metal form are not considered as suitable for classification of the massive forms.

"Metals with a particle size smaller than the default diameter value of 1mm can be tested on a case-by-case basis. One example of this is where metal powders are produced by a different production technique or where the powders give rise to a higher dissolution (or reaction) rate than the massive form leading to a more stringent classification."

The dossier submitter proposes different classifications for "massive" and "powder" forms of copper. Noting that the specific surface area is the crucial parameter, i.e. surface area per weight the different shapes of particles such as powders, flakes, sticks, granulates etc. are recognized. However, splitting massive and powder forms based on a cut-off value for particle size does not consider the fact that copper, granulated is not a powder produced by the same special process, but generated by cutting recycled copper wire into a specific cylindrical shape and defined size.

Consequently, the selection of relevant studies of transformation/dissolution data used for aquatic environmental hazard classification of copper massive and copper powder does not reflect the specific case for copper, granulated. The smallest copper particle on the market selected for the evaluation of copper powder has a specific surface area of 107mm²/mg. Whilst the specific surface area of copper, granulated (2.56mm²/mg) is ca. 3.8-fold greater than the default value for copper massive (less than 0.67mm²/mg) the value of the representative powder form is ca. 42-fold greater when compared to copper, granulated. Critically, based on the BPR substance definition copper, granulated could not be placed on the market at such small shape and size, as any powder form would be considered not technically equivalent according to BPR. Consequently, if such an approach is not technically equivalent according to BPR, such an approach cannot be considered equivalent under CLP.

Based on the available transformation/dissolution data for copper, granulated the RAC agreed an Opinion (5) in 2018. In line with the classification for massive copper particles with a specific surface area of 0.67mm²/mg or less copper, granulated is not classified for acute aquatic toxicity. In contrast, copper powder is classified far more stringently with acute aquatic category 1 and an M-factor of 10. For chronic aquatic toxicity copper, granulated is classified as category 2 in a worst-case approach. In comparison, no classification is triggered for copper particles with a specific surface area of 0.67 mm²/mg or less and copper powder is classified as chronic category 1 with and an M-factor of 1.

Following from the above and for the purposes of environmental classification, copper, granulated should be considered a separate form of copper between the massive and powder forms with its own specific environmental classification.

Copper, granulated – a substance specific environmental classification is justified

The proposed differentiation of copper "massive and "powder" based on the default particle size of 1mm for metals does not take into account the process of generating

copper, granulated from recycled copper metal wires in a special process of cutting particles into a specifically defined shape and size. Copper powder is never produced during the production or use of copper massive – it requires a special process of atomization to generate the powder and equally copper, granulated is not a by-product from manufacturing or use of copper massive.

Considering the special manufacturing process, closely defined shape and size of particles, the very particular use and exceedingly low volume, copper, granulated should not be considered representative of copper powder or copper massive. Whilst, the conditions may be fulfilled for deriving separate environmental classifications for copper in powder and massive forms there is, thus, sufficient justification to consider copper, granulated a third form of copper according to the CLP Regulation and its guidance and for the existing Annex VI entry to remain.

References

- (1) Biocidal Products Regulation (EC) No 528/2012 (BPR)
- (2) Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures
- (3) Regulation (EC) No. 1907/2008 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- (4) ECHA Guidance on the Application of the CLP Criteria, 5. Edition, 2017
- (5) RAC Opinion for Granulated Copper (EC Number: 231-159-6; CAS Number: 7440-50-8), 2018

ECHA note – An attachment was submitted with the comment above. Refer to public attachment [Arxada_Copper CLH_Public Commenting_27Jan2022.pdf](#)

Dossier Submitter's Response

We do not agree with the proposal that copper, granulated, should be considered a separate form of copper with its own specific aquatic environmental hazard classification.

Copper metal can be placed on the market in different physical forms, where granules and flakes can serve as examples. However, their aquatic environmental hazard classification should not depend on their physical form since they are still chemically the same substance. According to 1.2.3.3 in the Guidance on the Application of the CLP criteria (2017), when it comes to the aquatic environmental hazard classification, physical forms do not represent intrinsic properties of a substance nor warrant their own specific classifications. The current harmonised classifications of copper granulated (one specific form of copper; introduced in the Annex VI by the Commission Delegated Regulation (EU) 2020/1182) is therefore not in line with the CLP principles where one classification applies to one substance.

In order to classify different physical forms of the same substance correctly, the ECHA Guidance on the Application of the CLP Criteria in general and the metal classification strategy in Annex IV in particular should be followed. This current aquatic environmental hazard classification proposal aims at classifying copper metal (EC 231-159-6; CAS 7440-50-8) and as result of this classification, correcting the already adopted harmonised aquatic environmental hazard classifications of copper granulates (and copper flakes). Both copper granulates and copper flakes have specific surface areas larger than massive copper (that is larger than 0.67 mm²/mg). Consequently, copper granulates and copper flakes should both be covered by our proposal for copper with a specific surface area of > 0.67 mm²/mg.

Please note that our proposal is to propose an aquatic environmental hazard classification for copper with a specific surface area of > 0.67 mm²/mg (including all different physical forms which exceed this specific surface area).

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

According to Annex IV 5.5 in the Guidance on the Application of the CLP criteria (2017); *"Normally, the classification data generated would have used the smallest particle size marketed to determine the extent of transformation."* Based on this, we selected the particle from Skeaff & Hardy (2005) as "the smallest representative copper particle available on the market". This particle was used as representative for all copper particles with a specific surface area of $> 0.67 \text{ mm}^2/\text{mg}$, irrespective of manufacturing process, particular use or manufacturing volumes. The fact that BPR is characterising and specifying different copper forms, is in our opinion, irrelevant and should not be taken into account when it comes to how the substance copper should be classified according to CLP Regulation.

RAC's response

Metals are placed on the market under different forms summarized according to the CLP guidance as: **Powder** – refers to metal deliberately produced by a dedicated production method with a surface area greater than the specific surface area of a spherical particle of 1 mm; **Massive form** – refers to metals in any form with a specific surface area equal to or less than the surface area of a spherical particle of 1 mm; **Generated particles** – refers to particles with a surface area greater than the specific surface area of a spherical particle of 1 mm unintentionally generated from reasonably expected use of the massive form. The intrinsic hazard of any forms of a metal on the market depends on the metal ions released in aquatic environment in a given time-window. As far as dissolution of metal forms is governed by chemical surface activity (structure and energy of metal crystal lattice and metal chemical properties), surface area is a crucial parameter for hazard assessment if all marketed metal forms have the same crystal structure. From such point of view all copper forms on the market (copper massive, copper powder, copper flakes, copper granulate) have to be classified depending only on the specific surface area as far as they all have same face-centered cubic lattice of copper and same chemical properties. The classification of all copper metal forms following the Guidance on the Application of the CLP criteria (2017) should be based on the specific surface area of $0.67 \text{ mm}^2/\text{mg}$ as a limit between copper massive and all other copper forms on the market. Following annex IV 5.5 of the CLP guidance, the smallest particle size marketed would be used for the generation of data for classification. Data for both types of particles with specific area of $60 \text{ mm}^2/\text{mg}$ and $107 \text{ mm}^2/\text{mg}$ could be selected as representative for copper metal with specific area $> 0.67 \text{ mm}^2/\text{mg}$. RAC notes that the consequences for others forms of copper already classified can only be determined by COM at a later date.

RAC supports the conclusion of the DS that the fact that BPR is characterising and specifying different copper forms, is irrelevant and should not be taken into account when it comes to how the substance copper should be classified according to CLP Regulation.

Date	Country	Organisation	Type of Organisation	Comment number
27.01.2022	Germany	KME Germany GmbH	Company-Downstream user	8
Comment received				
KME SE Group, with around 3.900 employees at 8 production facilities within Europe (Germany, Italy, France, Spain), is one of the world's largest manufacturers of products from copper and copper alloy. KME Group produces a wide variety of products, in total 360.000 tons/year sales. Copper plays a very important role in the ecological transition. Thanks to its characteristics, it is the most widely used metal in the key sectors of the green economy: renewable energy, energy efficiency, circular economy, smart building, sustainable mobility.				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

KME's products portfolio covers a wide range of sheets, strips, wire, bars, rods, profiles and pipes for the use in cables and conductors, railway materials, lightning protection/earthing, power engineering, heavy current engineering, telecommunications, solar power, offshore/submarine cables, Automotive, rail, aviation, space travel, packaging industry, Power engineering, electrical engineering, Wind power, Switch gear construction, buses, transformers, tubes for sanitary and heating installations/air-conditioning & cooling.

Special Products like tube moulds, cooling plates and casting wheels for melting and casting applications. Extruded special products from rods, bars, profiles and tubes with applications in welding and machining. Pipes, fittings, flanges, tubes and tube fittings for seawater applications, Steel & Metal Industry, Machine Building, Chemical Industry, Shipbuilding, Offshore facilities.

We are committed to a responsible production and use of copper. Therefore we welcome the opportunity to feed into the consultation on the harmonized classification of copper metal, in massive and powder forms, for environmental hazards. We will monitor this process with great interest.

On the scientific and technical aspects, we support and referring to the position of the European Copper Institute.

Dossier Submitter's Response

Thank you for your comment. Please see our responses to comment number 4, in which we give response to the comments by European Copper Institute, which you refer to. This response also covers the comment from KME Germany GmbH in comment number 31.

RAC's response

Thank you for your comment. Please see RAC responses to comment number 4, in which RAC gives response to the comments by European Copper Institute, to which you refer.

Date	Country	Organisation	Type of Organisation	Comment number
27.01.2022	Italy	ASSOMET - NATIONAL ASSOCIATION OF NON FERROUS METALS INDUSTRIES	Industry or trade association	9

Comment received

Assomet represents the Italian Non Ferrous Metals Industry (producers, transformers and recyclers). Our mission is to safeguard the competitiveness of the whole sector in the EU and global market and to fully promote the sustainability of non ferrous metals with their unlimited recyclability and valuable potential to contribute to circular economy and low carbon technologies.

We welcome the opportunity to feed into the consultation on the harmonized classification of copper metal, in massive and powder forms, for environmental hazards and we will monitor the development of the classification process with great interest.

Copper is one of the main sectors in the Italian non ferrous metal industry and is made in its entirety by recyclers. The Italian copper alloys and semi-finished products manufacturers consists of about 30 companies with a total turnover of 7,2 billion €. In 2019, the national production of copper, copper alloys and semi finished products accounted for more than 1.200.000 tonns.

The Italian copper value chain mainly consists of smelting plants for the production of

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

secondary copper alloys, semi-fabrication plants for the production of wire/rod, tubes, sheet and strips and finished products plants where the semis are transformed into finished products that can be used directly by consumers and downstream industry users. Copper is a metal with multiple properties: malleability, ductility, electrical and thermal conductivity so it is second only to silver, thus representing by far the best compromise between technological characteristics and costs. Due to its excellent properties, copper is used in a variety of essential applications like electric and electronic equipments, automotive, electric cars and their charging stations, healthcare, taps, drinking water supply, architecture and buildings and so on.

Its role will be crucial in the energy transition being a key component of many low carbon technologies (i.e. wind and solar installation, electric vehicles and batteries, electric networks and so on). The production of copper from secondary raw materials allows recovering a variety of materials and waste (including electronic scrap) with variable copper content and a broad concentration range of other metals.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment ASSOMET response to the Public Consultation on the Harmonized Classification and Labelling of Copper-final.pdf

Dossier Submitter's Response

Thank you for your comment. Please see our responses to comment number 4, in which we give response to the comments by European Copper Institute, which you refer to. This response also covers the comment from ASSOMET - NATIONAL ASSOCIATION OF NON FERROUS METALS INDUSTRIES in comment number 32.

RAC's response

Thank you for your comment. Please see RAC responses to comment number 4, in which RAC gives response to the comments by European Copper Institute, to which you refer.

Date	Country	Organisation	Type of Organisation	Comment number
27.01.2022	Belgium	EuRIC	Industry or trade association	10

Comment received

EuRIC welcomes the proposal. EuRIC supports in particular that, on the basis of the scientific information and on the CLP guidance, the powder forms and the massive forms of copper are assessed separately. EuRIC also supports that the massive form (specific surface area smaller than 0.67 mm²/mg) is not classified as Aquatic Acute or Aquatic Chronic. EuRIC would like to express its concerns should the classification be extended also to copper in its massive form. Recycling is an activity that turns waste materials into products and hence the industry has to comply with several pieces of legislation applicable to the downstream value chain (CLP, REACH etc.). The main consequences - from a non-split classification - identified by EuRIC include:

- ❖ Seveso requirements: According to Directive 2012/18/EU (Seveso Directive), specific requirements would be triggered for a plant storing more than 100 t of copper, and even higher requirements for a plant storing more than 200t of copper.
- ❖ REACH information requirements: Safety data sheet on recycled products would need

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

to be updated, and sent out to customer, according to REACH regulation (Regulation (EC) No 1907/2006).
ECHA note – An attachment was submitted with the comment above. Refer to public attachment EuRIC reaction to Copper CLH.pdf
Dossier Submitter's Response
Thank you for your comment and support.
RAC's response
Thank you for your comment and support.

Date	Country	Organisation	Type of Organisation	Comment number
27.01.2022	Belgium	Europacable Aisbl	Industry or trade association	11
Comment received				
Europacable, the voice of all leading European wire and cable producers welcomes the opportunity to participate in the ongoing consultation. Europacable members include the largest cable makers in the world providing global technology leadership, as well as highly specialized small- and medium sized businesses from across Europe. Europacable recognises the key role copper plays for the industry as one of the preferred materials for electrical conductors in nearly all categories of electrical wiring due to its very low resistivity (high conductivity) and flexibility. Copper is an essential material for the deployment of the needed grid infrastructure and the integration of larger shares of renewable energy as well as for Europe to achieve its decarbonisation ambitions. Europacable believes that sound scientific analysis should be applied to each form of copper separately. In this respect, we would like to express our concerns about the possibility of an inappropriate classification of the massive form of copper, and in particular about the consequences for industries managing it at the substance level. Moreover, we are afraid that this could lead to an authorization or ban of copper in the future. Finally, copper classification may also have an impact on the copper waste management process, and its related recycling opportunities. Copper is highly recyclable, and supports the transition to a circular economy. Europacable will monitor the copper classification process with great interest. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Europacable Response to Copper Classification Consultation - 27.01.2022.pdf				
Dossier Submitter's Response				
Thank you for your comment. We would like to clarify that consequences in downstream legislation are not taken into consideration in the process of proposals for harmonised classifications that is solely based on the intrinsic hazardous properties of the substance. We consider that this issue would be more appropriately dealt with independently through other European legal instruments. This response also covers the comment from Europacable Aisbl in comment number 33.				
RAC's response				
Thank you for your comment. RAC notes that consequences in downstream legislation are not taken into consideration in the process of proposals for harmonised classification.				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

Date	Country	Organisation	Type of Organisation	Comment number
27.01.2022	Singapore	<confidential>	Company-Manufacturer	12
Comment received				
Rio Tinto is a global producer of copper and other metals and minerals that are essential for the low-carbon transition. Copper helps things work more efficiently – from renewables to the power in your home. Rio Tinto welcomes the opportunity to comment on the proposed harmonized classification of copper, a process which we follow with great interest. It is crucial that the right science is applied to the right form of copper. We support the scientific and technical comments provided by the European Copper Institute. We also support the conclusion that copper in its massive form is not classified on the basis of the available science.				
Dossier Submitter's Response				
Thank you for your comment. Please see response to comment number 4, in which we give response to the comments by European Copper Institute, which you refer to.				
RAC's response				
Thank you for your comment. Please see RAC responses to comment number 4, in which RAC gives response to the comments by European Copper Institute, to which you refer.				

Date	Country	Organisation	Type of Organisation	Comment number
26.01.2022	France		MemberState	13
Comment received				
The copper is classified in Table 2 (p 2), as Flam. Sol. 1H228 and Flam. Sol. 2; H228, whereas in Table 9 (p10) and according to the test for flammability copper is considered as not highly flammable. Could you clarify please?				
Dossier Submitter's Response				
Thank you for your comment. In Table 2 (p 2), all self-classifications for copper are listed. This information was gathered from ECHA's "C&L inventory" at the writing of the dossier (December 2020) and is based upon information from different registrants. Table 9 (p 10), on the other hand, is based on the information from the CLH report for Copper, granulated (February 2017). Flammability, however, is not within the scope of this public consultation (see for example first paragraph of section 2.1 (p 3) and Table 8 (p 6)). We will therefore not investigate the flammability any further within this CLH proposal.				
RAC's response				
Thank you for your comment. RAC agrees with DS's response.				

Date	Country	Organisation	Type of Organisation	Comment number
24.01.2022	Germany	Diehl Brass Solutions Stiftung & Co. KG	Company-Manufacturer	14
Comment received				
We are Diehl Brass Solutions Stiftung & Co. KG, Germany's largest producer of brass rods and tubes with the bulk of our production based on copper and brass scrap Classifying copper would also affect our scrap route and thus impact EU's Circular Economy Action Plan We strongly support KEMI's proposal for the revision of the classification of copper				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

ECHA note – An attachment was submitted with the comment above. Refer to public attachment ECHA classification of copper Jan 2022.pdf
Dossier Submitter's Response
Thank you for the comment and for the support. We would like to clarify that consequences in downstream legislation are not taken into consideration in the process of proposals for harmonised classifications that is solely based on the intrinsic hazardous properties of the substance. We consider that this issue would be more appropriately dealt with independently through other European legal instruments.
RAC's response
Thank you for your comment and support. RAC notes that consequences in downstream legislation are not taken into consideration in the process of proposals for harmonised classifications.

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Greece	CABLEL WIRES S.A.	Company-Manufacturer	15
Comment received				
Please see public attachment.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment CABLELWIRES_COPPER_CLH_28.01.2022.pdf				
Dossier Submitter's Response				
Thank you for your comment. Please see response to comment number 4, in which we give response to the comments by European Copper Institute, which you refer to. This response also covers the comment from CABLEL WIRES S.A. in comment number 37.				
RAC's response				
Thank you for your comment. Please see RAC responses to comment number 4, in which RAC gives response to the comments by European Copper Institute, to which you refer.				

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Greece	EPIRUS METALWORKS S.A.	Company-Manufacturer	16
Comment received				
see attached file				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment EPIRUS METALWORKS_COMMENTS_ON_COPPER_CLH_28.01.2022.pdf				
Dossier Submitter's Response				
Thank you for your comment. Please see response to comment number 4, in which we give response to the comments by European Copper Institute, which you refer to. This response also covers the comment from EPIRUS METALWORKS S.A. in comment number 38.				
RAC's response				
Thank you for your comment. Please see RAC responses to comment number 4, in which RAC gives response to the comments by European Copper Institute, to which you refer.				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

Date	Country	Organisation	Type of Organisation	Comment number
17.01.2022	Germany	HME	Company-Manufacturer	17
Comment received				
We are one of the biggest producers of brass semi-products and copper tubes in Europe having five facilities in four European countries (France, Germany, Italy, and Spain). With our products, we supply our customers in the automotive, electrical, and sanitary industries (amongst others) with the semi-finished products they need. Copper is our most important alloying element for brass and the main metal for the production of copper tubes. The copper is fed to the smelting furnaces in solid form. We are concerned that if the massive form of copper would be inappropriately classified, this would result in an immense expense for transport (Seveso Directive) and handling, which is not justifiable. Our raw material source is based on recycled copper or copper alloys end of live massive components. We fear also that a classification of these components could strongly increase the recycling cost. We regret that end of live components would be devaluated and sold outside Europe. This would also increase the pressure on virgin material which looks to be a critical raw material for the ecological transition. We very much welcome the opportunity to comment and we are going to monitor this process with great interest.				
Dossier Submitter's Response				
Thank you for the comment. We would like to clarify that consequences in downstream legislation are not taken into consideration in the process of proposals for harmonised classifications that is solely based on the intrinsic hazardous properties of the substance. We consider that this issue would be more appropriately dealt with independently through other European legal instruments.				
RAC's response				
Thank you for your comment. RAC notes that consequences in downstream legislation are not taken into consideration in the process of proposals for harmonised classifications.				

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Germany	AURUBIS AG	Company-Manufacturer	18
Comment received				
Aurubis is a leading global copper recycler and provider of non-ferrous metals. Our main area of expertise is the processing and optimal utilization of complex concentrates and recycling raw materials to produce metals of the highest purity. In addition to our main metal, copper, these include precious metals like gold, silver, and platinum group metals, but also metals such as lead, nickel, tin, zinc, and selenium. We produce more than 1 million t of copper cathodes with 99.99 % purity in our European smelter network each year. The cathodes can be sold on the metal exchanges, though we process some of them into a variety of intermediate products made of copper and copper alloys as well. These products include continuous cast wire rod, shapes, profiles, and flat-rolled products. Additional by-products such as sulfuric acid, iron silicate, and synthetic minerals round off the product portfolio. We have production and sales sites in more than 20 countries on three continents and employ around 7,200 people. Sustainability plays an important role in all of our activities. Aurubis is already an industry leader in energy efficiency and environmental protection.				

Aurubis is the Lead registrant of Copper REACH joint submission.

We welcome the opportunity to provide input into the consultation on the harmonized classification of copper metal, in massive and powder forms, for environmental hazards. We are committed to the responsible production and use of copper. Copper is important for the Green Deal and the transition

Copper is a strategic material for the low carbon transition.

Because of its excellent electrical conductivity, copper plays a vital role in most decarbonisation solutions. In short, there can be no electrification without copper. Copper facilitates the production of renewable electricity as well as the electrification of transport, heating and cooling. It is also a key material in battery production. Its properties make it the conductor of choice for wires, cables and electrical equipment. Increasing the cross-section of electrical conductors reduces the energy losses, which is the reason why energy efficient electrical connections and appliances are generally more copper intensive.

- Copper plays an important role in renewable energy generation – such as solar, wind, tidal, hydro, geothermal – by converting renewables into electricity or heat. In addition, the obvious trend towards distributed generation and a decentralised system relies on more storage and increasing demand side flexibility solutions, which often rely on copper-based technologies. Copper will be a crucial metal for the energy transition

(<https://www.eurometaux.eu/metals-blue-print-2050/> By 2027, more than 100,000 tonnes of copper will be needed to build 40 million charging points for electric vehicles coming on the market (page 61). Solar panels will require 3000 kg Cu / MW, wind turbines would demand 3500 kg Cu / MW, and efficient grids, interconnectors, subsea grid would need + 400 kton Cu over next decade.

- A low-carbon future is not possible without smart and connected electrical and thermal grids. Copper is a key metal to making these grids smaller, smarter, more flexible, and more energy-efficient. A tonne of copper in electrical systems could deliver lifetime savings within the range of 100-7500 tonnes of CO₂.

- Buildings are gaining importance as an active component in the transition towards smart energy systems – providing demand flexibility and hosting increased renewable energy source (RES) capacities. For a building to become intelligent and connected, it needs copper.

- Beyond the energy sector, copper is a key component in new, low-carbon modes of transportation, such as electric vehicles, playing an important role in their batteries and control systems as well as the charging infrastructure.

- In industry, the increasing share of renewables in the energy mix opens up a large potential for electrification of heat processes.

- In the heating and cooling sector, copper lead to cost-effective reductions in energy use in the range of 20-30% thanks to its excellent conductivity

Copper is a key material in battery production

- Copper is used as a current collector at the anode of lithium batteries. According to the ecodesign study for batteries, Cu represents between 6.5% and 11.5% of the cell weight. There is indeed more weight of copper than lithium in a battery.

Copper enables the resource efficiency

- Copper is an important carrier metal that enables the recovery of many valuable metals needed for today's energy transition and sustainable technologies. EU copper smelters produce copper, and in addition recover many valuable metals such as gold, silver, lead, nickel, tin, platinum, palladium from the same primary and secondary copper raw materials. The production of these metals as a by-product is only possible through competitive copper production, as copper is the carrier of these other metals

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Aurubis feedback to Cu CLH proposal Jan 2022.pdf
Dossier Submitter's Response
Thank you for your comment and support regarding for example that the assessment is based on previous evaluations of copper. Please see response to comment number 4, in which we give response to the comments by European Copper Institute, which you refer to. This response also covers the comment from AURUBIS AG in comment number 40.
RAC's response
Thank you for your comment and support. Please see RAC responses to comment number 4, in which RAC gives response to the comments by European Copper Institute, to which you refer.

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Greece	ELVALHALCOR S.A.	Company-Manufacturer	19
Comment received				
Please see attached document				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment ELVALHALCOR_COMMENTS_ON_COPPER_CLH_26.01.2022_FINAL.pdf				
Dossier Submitter's Response				
Thank you for your comment. Please see response to comment number 4, in which we give response to the comments by European Copper Institute, which you refer to. This response also covers the comment from ELVALHALCOR S.A. in comment number 41.				
RAC's response				
Thank you for your comment. Please see RAC responses to comment number 4, in which RAC gives response to the comments by European Copper Institute, to which you refer.				

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	United Kingdom	Biocidal Core Copper Subgroup	Please select organisation type..	20
Comment received				
Uniquely, the copper-based active substances approved or under review of the Biocidal Products Directive (BPD) or Biocidal Products Regulation (BPR) all rely on the same database at the core of the active substance dossiers. This core copper dossier is based on the Voluntary Risk Assessment (VRAR) of Copper and Copper Compounds prepared by the European Copper Institute.				
Twenty-seven companies are involved in the manufacture and/or supply of copper-based biocidal active substances and in 2020, these companies came together to form the Biocidal Core Copper Sub-Group (BCCSG).				
We now welcome the opportunity to feed into the consultation on the harmonized classification of copper metal, in massive and powder forms, for environmental hazards.				
This consultation directly arises from the requirement under the BPR that all active substances have a harmonised classification under CLP and this has resulted in four separate copper forms on Article 95 of the BPR.				
The 4 separate forms are:				

- Copper massive, currently under evaluation by the evaluating competent authority, France.
- Copper powder, currently under evaluation by the evaluating competent authority, France.
- Copper, granulate an approved active substance.
- Copper flakes (coated with aliphatic acid) an approved active substance.

Under the BPR, the reference specification for all BCCSG copper forms and compounds follow the ECHA BPR Guidance on reference specification and this has resulted in a strict specific specification for each based on:

- The purity/impurity profile of the active substance.
- The size and shape of the active substance.

This requirement is more stringent than the identification of substances under REACH and has set a precedent for more than two forms of copper identified under the BPR.

The BCCSG considers that this is a pivotal issue when reviewing the classification of copper forms under CLP.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Consultation on the Harmonized Classification and Labelling of Copper_Final.pdf

Dossier Submitter's Response

We do not agree with the proposal by Biocidal Core Copper Subgroup that the approval of specific forms of copper under the BPR justifies different classifications.

Copper metal can be placed on the market in different physical forms, where granules and flakes can serve as examples. However, their aquatic environmental hazard classification should not depend on their physical form since they are still chemically the same substance. According to 1.2.3.3 in the Guidance on the Application of the CLP criteria (2017), when it comes to the aquatic environmental hazard classification, physical forms do not represent intrinsic properties of a substance nor warrant their own specific classifications. The current harmonised classifications of copper granulated and copper flakes (two specific forms of copper) are therefore not in line with the CLP principles where one classification applies to one substance.

In order to classify these different physical forms of the same substance correctly, the ECHA Guidance on the Application of the CLP Criteria in general and the metal classification strategy in Annex IV in particular should be followed. This current aquatic environmental hazard classification proposal aims at classifying copper metal (EC 231-159-6; CAS 7440-50-8) and as result of this classification, correcting the already adopted harmonised aquatic environmental hazard classifications of copper granulates and copper flakes. Both copper granulates and copper flakes have specific surface areas larger than massive copper (that is larger than 0.67 mm²/mg). Consequently, copper granulates and copper flakes should both be covered by our proposal for copper with a specific surface area of > 0.67 mm²/mg.

Please also see section 2.1 and 4 in our dossier.

The fact that BPR is characterising and specifying different copper forms, is in our opinion irrelevant and should not be taken into account when it comes to how the substance copper should be classified according to CLP Regulation.

This response also covers the comment from Biocidal Core Copper Subgroup in comment number 43.

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

RAC's response
Metals are placed on the market under different forms summarized according to the CLP guidance as: Powder – refers to metal deliberately produced by a dedicated production method with a specific surface area greater than the specific surface area of a spherical particle of 1 mm; Massive form – refers to metals in any form with a specific surface area equal to or less than the specific surface area of a spherical particle of 1 mm; Generated particles – refers to particles with a specific surface area greater than the specific surface area of a spherical particle of 1 mm unintentionally generated from reasonably expected use of the massive form. The intrinsic hazard of any forms of a metal on the market depends on the metal ions released in aquatic environment in a given time-window. As far as dissolution of metal forms is governed by chemical surface activity (structure and energy of metal crystal lattice and metal chemical properties), surface area is a crucial parameter for hazard assessment if all marketed metal forms have the same crystal structure. From such point of view all copper forms on the market (copper massive, copper powder, copper flakes, copper granulate) has to be classified depending only on the specific surface area as far as they all have same face-centered cubic lattice of copper and same chemical properties. The proposed aquatic environmental hazard classification proposal aims to introduce harmonised aquatic environmental hazard classifications of copper metal including copper granulates and copper flakes based only on specific surface area and limit value 0.67 mm²/mg. Both copper granulates and copper flakes have specific surface areas > 0.67 mm²/mg and would be correctly classified. However, the consequences for these others forms of copper can only be determined by COM at a later date. RAC supports the conclusion of the DS that the fact that BPR is characterising and specifying different copper forms, is irrelevant and should not be taken into account when it comes to how the substance copper should be classified according to CLP Regulation.

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	France	A3M	Industry or trade association	21
Comment received				
Commentaires d'A3M sur la proposition de classification et d'étiquetage harmonisés pour le cuivre métallique Eléments de contexte L'autorité compétente de la Suède a soumis une proposition de classification du cuivre métallique sous forme massive et en poudre au titre de l'annexe VI du règlement CLP en tant que dangereux pour l'environnement. Cette proposition fait actuellement l'objet d'une consultation publique afin de recueillir les observations sur les données scientifiques jusqu'au 28 janvier 2022. Cette consultation est l'occasion pour A3M de fournir des observations générales concernant cette proposition, avant la soumission de l'avis final du Comité d'évaluation des risques de l'ECHA à la Commission européenne, qui examinera la pertinence du classement proposé pour le cuivre métallique sous forme massive et en poudre pour les dangers sur le milieu aquatique. L'Alliance des minerais, minéraux et métaux (A3M), représente l'industrie française des minerais, minéraux et métaux (extraction, production, transformation et recyclage). La protection de la santé humaine et de l'environnement sont des valeurs fondamentales pour A3M et ses membres. A ce titre, la classification du cuivre est un enjeu essentiel et l'expertise préalable est une étape décisive.				

Nous tenons à rappeler le rôle majeur du cuivre dans la transition énergétique, l'électromobilité et la construction ou la rénovation de bâtiments durables et économes en énergie. Nos adhérents sont des acteurs majeurs du recyclage du cuivre, ainsi que de la production et de la transformation d'alliages spéciaux indispensables du fait de leurs propriétés dans de nombreuses applications industrielles sous forme de demi produits et de produits finis pour servir des marchés variés comme l'électronique, l'énergie, l'aéronautique, l'automobile, la défense, l'informatique, la télécommunication... Certaines entreprises interviennent notamment sur l'ensemble du process cuivre, couvrant le recyclage de matière première, la métallurgie, la production de composants industriels et la distribution de conducteurs en cuivre pour les équipements électriques.

Par conséquent, la classification du cuivre comme ayant une toxicité aquatique aigue ou chronique sous forme massive peut avoir un impact significatif sur l'ensemble de la chaîne de valeur de l'industrie électrique qui est l'un des axes stratégiques de la politique de transition écologique et énergétique en Europe fixés dans le cadre du Green Deal (décarbonation, économie circulaire, mobilité durable). Ces conséquences peuvent inclure des obstacles au recyclage et à l'économie circulaire, entraînant une perturbation des flux de matériaux ; des exigences opérationnelles et administratives supplémentaires dues à la directive Seveso, à la législation sur les transports, à REACH et au CLP. Nous rappelons également que les entreprises du secteur s'approvisionnent de manière importante à partir de cuivre massif recyclé : tubes sanitaires, fils électriques.... La mise en place de barrières au recyclage et de contraintes administratives pourraient pousser les utilisateurs et les clients à se détourner du cuivre indépendamment de sa forme alors que seul le cuivre en poudre devrait porter ce changement de classification.

Par conséquent, afin d'éviter des conséquences injustifiées, lors de l'établissement de la classification des dangers pour l'environnement des formes massives et pulvérulentes de cuivre métallique, il est important que l'évaluation repose sur des données solides et des principes scientifiques reconnus. Ainsi, une analyse scientifique solide doit être appliquée à chaque forme de cuivre séparément, conformément à l'annexe IV du règlement CLP.

Dans cette optique, l'A3M souligne le fait qu'une telle classification doit être basée sur des preuves issues de résultats d'études scientifiques développées selon des méthodologies conformes à la GPL. A ce titre, A3M se réfère pleinement à la position de l'Institut européen du cuivre (IEC) développée dans le cadre de cette consultation publique et jointe en annexe. L'analyse technique et scientifique de l'IEC justifie la conclusion selon laquelle la forme massive du cuivre ne doit pas être classée.

Observations générales

Environ 4 millions de tonnes de cuivre sont échangées chaque année sur le marché européen et sont utilisées dans une très grande variété d'applications.

Le cuivre et les alliages à base de cuivre sont à l'origine d'une grande variété de produits et de technologies qui contribuent à la réalisation de plusieurs objectifs clés de l'Union européenne (par exemple, le Green Deal de l'UE). Par exemple, le cuivre et les alliages de cuivre sont utilisés dans le chauffage et la climatisation des bâtiments, les réseaux électriques et la distribution d'électricité, la distribution d'eau, les télécommunications, les équipements industriels, les moteurs, les véhicules électriques, la production d'énergie durable, l'électronique, les pièces de monnaie, l'architecture, et dans de nombreux autres usages. Plus de 99% du cuivre (EC 231-159-6 ; CAS 7440-50-8) produit se présente sous la forme massive de cathode de cuivre, c'est-à-dire des formes carrées de cuivre pur (supérieur à 99,9% Cu) de 1 m x 1 m et d'une épaisseur de 3-16 mm (Figure 1). Environ 0,025 million de tonnes de poudre de cuivre sont produites chaque année dans l'UE, et l'atomisation est de loin la méthode de production la plus courante.

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

Le cuivre est présent naturellement dans l'environnement. C'est un élément nutritif essentiel pour toutes les formes de vie, mais à des niveaux d'exposition élevés, il peut être toxique.

Le cuivre a fait l'objet d'un examen réglementaire important au niveau européen et international au cours des 20 dernières années, notamment l'évaluation volontaire des risques liés au cuivre en 2008, l'évaluation du Programme coopératif d'évaluation des produits chimiques (CoCAP) de l'OCDE en 2014 et, plus récemment, l'avis du RAC sur le cuivre granulé en 2018. Le rapport du soumissionnaire du dossier est dans une large mesure, basé sur ces évaluations réglementaires précédentes, et il prend en compte la mise à jour la plus récente du dossier d'enregistrement REACH du cuivre et du rapport sur la sécurité chimique (février 2021). Nous soutenons le fait que l'évaluation est basée sur des évaluations précédentes du cuivre.

Des profils de danger distincts pour le cuivre sous forme massive et sous forme de poudre sont justifiés compte tenu des informations fournies dans le rapport par le soumissionnaire du dossier (annexe 1). Sur la base de l'analyse scientifique de l'institut européen du cuivre, nous soutenons la conclusion selon laquelle le cuivre sous forme massive ne mérite pas d'être classé comme substance aquatique aiguë ou aquatique chronique au titre du CLP.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20220127_Copper CLH_ECI position FINAL.pdf

Dossier Submitter's Response

Thank you for your comment and support regarding for example that the assessment is based on previous evaluations of copper.
Please see response to comment number 4, in which we give response to the comments by European Copper Institute, which you refer to.
This response also covers the comment from A3M in comment number 46.

RAC's response

Thank you for your comment. Please see RAC responses to comment number 4, in which RAC gives response to the comments by European Copper Institute, to which you refer.

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Belgium	Eurometaux	Industry or trade association	22
Comment received				
Eurometaux in general does not react on single substance public consultations unless a key issue of relevance for a series of metals, or methodological aspect, is up for commenting. We believe that in the Copper case the Dossier Submitters CSA approach is such a new and important aspect.				
Dossier Submitter's Response				
Thank you for your comment. Please also see comment 47 in which Eurometaux has a more detailed comment.				
RAC's response				
Thank you for your comment. Please, see RAC's response to comment number 47.				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Belgium	Beryllium Science & Technology Association	Industry or trade association	23
Comment received				
Please see attached statement on BeST's views in the frame of the public consultation on the proposed harmonised classification of copper metal, in massive and powder forms, and the impact on industry.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Position Paper - Public consultation CLH Copper.pdf				
Dossier Submitter's Response				
Thank you for your comment. Please see response to comment number 4, in which we give response to the comments by European Copper Institute, which you refer to.				
RAC's response				
Thank you for your comment. Please see RAC responses to comment number 4, in which RAC gives response to the comments by European Copper Institute, to which you refer.				

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Belgium	AeroSpace and Defence Industries Association of Europe (ASD)	Industry or trade association	24
Comment received				
Aerospace and Defence Industries Associations of Europe (ASD) is the voice of the European Aeronautics, Space, Defence and Security Industries, representing over 3,000 companies and actively supporting the competitive development of the sector in Europe and worldwide. It has direct members, active in 18 countries, including 19 major European industries and 23 National Associations. ASD would like to offer some comments on the uses of copper in our sector. Copper is an essential substance used in products for the aerospace and defence industry. The reason for its use is a combination of outstanding properties, mainly very good conductivity for electric current and heat, sufficient strength, good machinability as well as good corrosion resistance. Copper is used extensively for signal transmission in electronic assemblies for navigating and controlling aircraft, spacecraft and defence products. Aerospace manufacturers are committed to support the decarbonisation of the sector and to achieve ultra-efficient aircraft. To accomplish this, the use of copper in electrical systems is an elementary element. Further, copper is an essential component of metal alloys (bronze and brass) used to make high-quality precision mechanical parts for the aerospace and defence industry. Restricting the use of copper would have a massive impact on the design and performance of our products. We are concerned that an inappropriate classification of the massive form of copper would lead to a disproportionate burden on our supply chain and us, as end-users. This would put the European aerospace and defence industry at a significant competitive disadvantage to industries outside the EU in product development and manufacturing. ASD remains at disposal for further exchanges throughout the next steps in the process.				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

Dossier Submitter's Response
Thank you for the comment. We would like to clarify that consequences in downstream legislation are not taken into consideration in the process of proposals for harmonised classifications that is solely based on the intrinsic hazardous properties of the substance. We consider that this issue would be more appropriately dealt with independently through other European legal instruments.
RAC's response
RAC notes that consequences in downstream legislation are not taken into consideration in the process of proposals for harmonised classifications.

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Turkey	Sarkuysan Elektrolitik Bakir San. Tic.A.S.	Company-Manufacturer	25
Comment received				
The physical form is very essential for the classification, even if the chemical composition is the same. As it is stated in Annex IV of CLP Guide, surface area is a parameter that can cause significant differences in transformation and dissolution of metals. Based on available information and Annex IV of the CLP Guidance, environmental hazard classification of copper in massive form and copper in powder form should be assessed separately with the threshold value of 0,67 mm ² /mg. European Copper Institute has great experience and is a dedicated organization. We kindly suggest their scientific and technical expertise to be taken into your consideration.				
Dossier Submitter's Response				
Thank you for your comment. Please see response to comment number 4, in which we give response to the comments by European Copper Institute, which you refer to.				
RAC's response				
Thank you for your comment. Please see RAC responses to comment number 4, in which RAC gives response to the comments by European Copper Institute, to which you refer.				

Date	Country	Organisation	Type of Organisation	Comment number
13.01.2022	Germany	Breuckmann GmbH & Co. KG	Company-Manufacturer	26
Comment received				
We recommend to study scientific and technical aspects as given from the European Copper Institute. Based on the available information and on Annex IV of the CLP Guidance, the environmental hazard profile of copper in massive form and of copper in powder form should be assessed separately.				
See Attached Document "Public Consultation - Copper harmonized classification - PUBLIC.pdf"				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public Consultation - Copper harmonized classification - PUBLIC.pdf				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Public Consultation - Copper harmonized classification -- CONFIDENTIAL.pdf				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

Dossier Submitter's Response
Please see our response to General comment number 2, which is the same comment from Breuckmann GmbH & Co. KG.
RAC's response
Thank you for your comment. Please see RAC responses to comment number 4, in which RAC gives response to the comments by European Copper Institute, to which you refer.

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Germany	Wirtschaftsvereinigung Metalle e.V.	Industry or trade association	27

Comment received
1. Ecotoxicity Reference Value (ERV) The CLH proposal uses the copper ERVs that were derived within the RAC assessment on granulated copper (2018). WVMetalle agrees that this ERVs considers the bioa-vailability (pH and DOC) and shall be used. 2. Transformation/Dissolution The CLH proposal uses an extensive Transformation/Dissolution dataset and is from our perspective robust and in line with the CLP guidance. The use of a powder with a high surface area to achieve information about the dissolution is supported. Transformation/Dissolution data for both forms are available and documented, including clearly distinctive dissolution kinetics. Nevertheless, it should be recognized that the Dossier Submitter's selection of the finest representative copper powder was produced by water atomization which re-sults in particles with an irregular shape. However, most copper powders are pro-duced through air atomization, which results in approximately spherical particles. The water atomization method possibly led to a higher surface oxidation resulting in a lower solubility. The copper release as measured in Transformation/Dissolution tests was higher from the air atomized powder (ECTX, 2020, specific surface area 60 mm²/mg) than from the water atomized powder (Skeaff & Hardy, 2005, specific sur-face area 107 mm²/mg). The finest representative copper powder is therefore the air atomized one, and the data from ECTX (2020) showing the highest measured release of all copper powders should be used for classification purposes. Extrapolating the measured release from the air atomized powder to a higher specific surface area is therefore not needed nor justified. 3. Environmental transformation and removal The CLH proposal concludes that copper is not subject to rapid environmental trans-formation. We recognize that currently there is no agreed CLP guidance established on how to implement environmental transformation for metals and inorganic sub-stances in a classification & labelling context, but the robust evidence provided in the copper registration dossier should from scientific perspective be used as it demon-strated that copper ions undergo rapid environmental transformation and removal. This is clearly relevant and the only way to adequately assess the environmental fate of copper (an natural occurring element) compared to the assessment of the degra-dability of organic substances. 4. Powder and massive forms The CLH proposal concludes that separate classifications are warranted for copper massive and copper powder respectively. This is concordant with the CLP guidance and should be kept throughout the coming classification debate within RAC. Copper metal should be assessed separately for the powder and the massive form, powder and massive forms of copper should not be subject of the same classification for haz-ards to the aquatic environment.

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2022-01-28_WVMetalle comment on Cu Env Clas consultation.pdf
Dossier Submitter's Response
Please see our response to General comment number 3, which covers also this comment (comment number 27) by WirtschaftsVereinigung Metalle e.V.
RAC's response
Thank you for your comments and for your support considering e.g. the ERV and the dataset used for evaluation of transformation/dissolution of copper.
Please, see RAC responses to comments number 4 and 47, in which detailed responses to the comments by European Copper Institute and Eurometaux are given.

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Belgium	European Copper Institute	Industry or trade association	28
Comment received				
Please see our comments in the attached ZIP archive. The ZIP archive contains three files. "Copper CLH - ECI input FINAL.pdf" (12 pages) contains our comments. The two other files are study reports which are attached to our comments. Uncompressed study reports and annexes to study reports could not be uploaded due to the file size limitation, but they are available on request.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Copper CLH - ECI input FINAL.zip				
Dossier Submitter's Response				
Please see our response to General comment number 4, which covers also this comment (comment number 28) by European Copper Institute.				
RAC's response				
Thank you for your comment. Please see RAC responses to comment number 4, in which RAC gives response to the comments by European Copper Institute, to which you refer.				

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Germany	Wieland Werke AG	Company-Downstream user	29
Comment received				
In our view, it is essential that the environmental hazards of the different copper forms are based on robust data and agreed scientific principles. The appropriate science needs to be applied to the right form of copper, in line with the CLP regulation and the CLP guidance. We agree with the dossier submitter to assess the hazard profile of copper in massive form and copper in powder form separately and support the conclusion that a classification of copper in its massive form is not justified.				
We also agree with the dossier submitter to refer to a specific surface area of > 0.67 mm ² /mg as criterium for classification. For practical reasons and to avoid misunderstandings, however, it would be helpful if the chemical name could also have a reference to the form in addition to the specific surface area, such as "copper, small particles [specific area > 0.67 mm ² /mg]". Further comments are given in the attached document.				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comment to CHL Proposal Copper Wieland.pdf
Dossier Submitter's Response
Please see our response to General comment number 5, which covers also this comment (comment number 29) by Wieland Werke AG.
RAC's response
Thank you for your comments and for your support on the split classification for massive copper and copper with specific surface area of > 0.67 mm ² /mg. Regarding the comment to add a reference to the form in addition to the specific surface area for the entry in Annex VI, RAC is of opinion that this would change the general idea of proposed classification of copper metal based only on specific surface area and the limit value of 0.67 mm ² /mg. Please, see also RAC responses to comment number 4.

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Belgium	Solar Heat Europe	Industry or trade association	30
Comment received				
Please refer to the attached document				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment SHE-Contribution-Copper Classification.pdf				
Dossier Submitter's Response				
Please see our response to General comment number 6, which covers also this comment (comment number 30) by Solar Heat Europe.				
RAC's response				
Thank you for your comment and support.				

Date	Country	Organisation	Type of Organisation	Comment number
27.01.2022	Germany	KME Germany GmbH	Company-Downstream user	31
Comment received				
When establishing the environmental hazard classification for the massive and powder forms of copper metal, it is very important for us that the assessment is based on robust data and agreed scientific principles, and that the appropriate science is applied to the right form of copper, in line with the CLP Regulation and the CLP Guidance as it is done in the submitted dossier. This is because a hazard classification as Aquatic Acute or Aquatic Chronic for the massive form of copper could potentially have severe consequences for 1.) our affiliates/productions sites due to additional operational costs (formally safety precautions due to Seveso), disrupt material flows due to barriers to recycling (hazardous waste), administrative burden (e.g., transport of dangerous goods), 2.) and for the sustainable technologies which are enabled by copper due to stigmatization of a sustainable material. For increased clarity, we suggest that the descriptor "powder" or "fine forms" could be added to the entry that was proposed by the Dossier Submitter. This would be clearer to all actors in the supply chain. From our perspective it would be crucial that the environmental hazard profile of copper				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

in massive form and of copper in powder form should be assessed separately.
Dossier Submitter's Response
Please see our response to General comment number 8, which covers also this comment (comment number 31) by KME Germany GmbH.
RAC's response
Thank you for your comment. Please see RAC responses to comment number 4, in which RAC gives response to the comments by European Copper Institute, to which you refer.

Date	Country	Organisation	Type of Organisation	Comment number
27.01.2022	Italy	ASSOMET - NATIONAL ASSOCIATION OF NON FERROUS METALS INDUSTRIES	Industry or trade association	32

Comment received
A hazard classification as Aquatic Acute or Aquatic Chronic for the massive form of copper could potentially have severe consequences for the sector as well as for the sustainable technologies which are enabled by copper. These consequences may include 1) barriers to recycling and the circular economy, resulting in a disruption of material flows; 2) additional operational and administrative requirements due to the Seveso Directive, transport legislation, REACH, and CLP. Therefore, when establishing the environmental hazard classification for the massive and powder forms of copper metal, it is important that the assessment is based on robust data and agreed scientific principles, and that the appropriate science is applied to the right form of copper, in line with the CLP Regulation and the CLP Guidance. In this regard, we refer to the scientific and technical comments made by the European Copper Institute. In particular, we support the conclusion that, on the basis of the available data, copper in its massive form is not classified according to the CLP regulation. ECHA note – An attachment was submitted with the comment above. Refer to public attachment ASSOMET response to the Public Consultation on the Harmonized Classification and Labelling of Copper-final.pdf
Dossier Submitter's Response
Please see our response to General comment number 9, which covers also this comment (comment number 32) by ASSOMET - NATIONAL ASSOCIATION OF NON FERROUS METALS INDUSTRIES.
RAC's response
Thank you for your comment. Please see RAC responses to comment number 4, in which RAC gives response to the comments by European Copper Institute, to which you refer.

Date	Country	Organisation	Type of Organisation	Comment number
27.01.2022	Belgium	Europacable Aisbl	Industry or trade association	33
Comment received				
Europacable, the voice of all leading European wire and cable producers welcomes the opportunity to participate in the ongoing consultation. Europacable members include the largest cable makers in the world providing global technology leadership, as well as highly specialized small- and medium sized businesses from across Europe.				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

Europacable recognises the key role copper plays for the industry as one of the preferred materials for electrical conductors in nearly all categories of electrical wiring due to its very low resistivity (high conductivity) and flexibility. Copper is an essential material for the deployment of the needed grid infrastructure and the integration of larger shares of renewable energy as well as for Europe to achieve its decarbonisation ambitions. Europacable believes that sound scientific analysis should be applied to each form of copper separately. In this respect, we would like to express our concerns about the possibility of an inappropriate classification of the massive form of copper, and in particular about the consequences for industries managing it at the substance level. Moreover, we are afraid that this could lead to an authorization or ban of copper in the future. Finally, copper classification may also have an impact on the copper waste management process, and its related recycling opportunities. Copper is highly recyclable, and supports the transition to a circular economy. Europacable will monitor the copper classification process with great interest. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Europacable Response to Copper Classification Consultation - 27.01.2022.pdf
Dossier Submitter's Response
Please see our response to General comment number 11, which covers also this comment (comment number 33) by Europacable Aisbl.
RAC's response
Thank you for your comment RAC noted that consequences in downstream legislation are not taken into consideration in the process of proposals for harmonised classifications.

Date	Country	Organisation	Type of Organisation	Comment number
27.01.2022	Singapore	<confidential>	Company-Manufacturer	34
Comment received				
We support the scientific and technical comments provided by the European Copper Institute. We also support the conclusion that copper in its massive form is not classified on the basis of the available science.				
Dossier Submitter's Response				
Thank you for your comment. Please see response to comment number 4, in which we give response to the comments by European Copper Institute, which you refer to.				
RAC's response				
Thank you for your comment. Please see RAC responses to comment number 4, in which RAC gives response to the comments by European Copper Institute, to which you refer.				

Date	Country	Organisation	Type of Organisation	Comment number
26.01.2022	France		MemberState	35
Comment received				
Thank you for giving us the opportunity to comment this CLH report on copper. We agree with your classification proposal i.e. no environmental classification of massive copper (with a specific surface area (SSA) equal or less than 0.67 mm²/mg) and a classification as Acute 1 with a M-factor of 10 and Chronic 1 with a M-factor of 1 for the copper powder (with a SSA of more than 0.67 mm²/mg). According to the Article 9.5 of the CLP regulation, "when evaluating the available information for the purposes of classification, the manufacturers, importers and				

downstream users shall consider the forms or physical states in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used". Therefore we wonder in which extent the granulated copper classification entry shall justify another classification entry. Indeed, the transformation/dissolution tests allow to have a lower classification as initially proposed in the CLH report of 2017 (H411). Moreover, according to the Guidance on the application of the CLP criteria section IV 5.5, two classification proposals can be made for the same metal. However, as a second classification is already proposed for the flake copper form for human health, to propose an additional classification for granulated form for the environment would lead to three different classifications for the same metal.

Moreover, we fully agree with your strong argumentation (industrial processes, physico-chemical properties, etc) leading to the conclusion that granulated copper and copper flakes are two specific forms of copper powder. Moreover we also agree that flakes and granulated copper are generated in the same way than copper powder, which is different from the production of massive copper. This justify, in addition of the SSA argument, to only separate classifications of massive copper and copper powder. At last, as the copper flakes, the granulated copper has a specific surface area (SSA) over 0.67mm²/mg, therefore we agree with your proposal that granulated could be covered by the powder classification.

Other comment related to the dossier's structure (Page 28-32):
We wonder why acute and chronic aquatic hazard are grouped in the same section (i.e. "11.5. Acute aquatic hazard"). It would be clearer if these two parts were separated according to the CLH report structure.

Dossier Submitter's Response

Thank you for your comment and support for the classification proposal.

The term "forms and physical state" as found in articles 5(1), 6(1), 8(6) and 9(5) was deliberately kept short since forms did not necessarily relate to the physical form.

It was already part of the Dangerous Substance Directive (67/548/EEC) where in Annex VI of the Directive states that classification should apply to the form of the substance placed on the market. For aquatic environmental hazard classification the Competent Authorities of the EU interpreted "form" to mean the chemical rather than the physical form (Section 1.1 of ECBI/61/95 – Add. 46).

This is partly also explained in section 1.2.3 in the Guidance document on application of the CLP criteria where it says that "depending on different prerequisites, form or physical state is taken into account differently in the practice of testing and classification for physical, health, and environmental hazards". While the physical form, e.g. particle size, may have an impact on certain physical hazards it has less so for aquatic environmental hazard, and the system of classification is designed to ensure that a single classification applies to a substance. In general it takes no account of the specific physical form since this can vary and is not intrinsic to the substance, i.e. it can be changed without changing the substance itself. The form in which the substance is placed on the market is taken into account when deciding what label to apply and various derogations from labelling exist, e.g. for metals in the massive form (Section 1.2.3.3 of Guidance document on application of the CLP criteria and Section 1.1 of ECBI/61/95 – Add. 46).

Copper metal can be placed on the market in different physical forms, where granules and flakes can serve as examples. However, their aquatic environmental hazard classification should not depend on their physical form since they are still chemically the same substance.

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

Both copper flakes and copper granulates has a specific surface area of $>0.67 \text{ mm}^2/\text{mg}$ and would therefore be covered by the proposed single classification for copper with a specific surface area of $> 0.67 \text{ mm}^2/\text{mg}$.

The reason why we propose to maintain a separate entry in Annex VI for copper flakes (coated with aliphatic acid) is because a separate entry is driven by the human health hazard classification. The aquatic environmental hazard for the copper flakes (coated with aliphatic acid) entry would of course be the same as for all other fine forms of copper (specific surface area of $>0.67 \text{ mm}^2/\text{mg}$).

Response to comment on dossier structure (page 28-32):

Yes, true that this could be confusing. However, we chose to have this structure since the summary of relevant ERVs from RAC opinion on copper granulate (adopted in June 2018) is presented in a single table including both acute and chronic data (page 29).

Additionally, the whole ecotoxdata-package (acute and chronic) is referred to earlier evaluations and placed in annexes including both acute and chronic data (in the same annexes). Sorry for not completely following the CLH report structure, but our ambition was to make the structure as clear as possible.

RAC's response

Thank you for your comment and support for the classification proposal.

RAC agrees with comments presented by the DS on the physical forms and added that chemical properties should be the basis for classification. Physical forms would be covered by limit value for specific surface area. From this point of view, harmonised classification is proposed for all forms of copper metal placed on the market with limit value of $0.67 \text{ mm}^2/\text{mg}$ for specific surface area.

RAC support the DS that the structure of CLH report is as clear as possible.

Date	Country	Organisation	Type of Organisation	Comment number
26.01.2022	Germany		MemberState	36

Comment received

According to section 11.7 of the CLH report, the newly proposed Annex VI entry for the classification of "copper [specific surface area $> 0.67 \text{ mm}^2/\text{mg}$]" is intended to cover both classification of granulated copper and copper coated flakes. However, according to Table 7, the Annex VI entry for copper coated flakes seems to remain in place, while the entry for granulated copper is proposed to be deleted. Please clarify the situation for copper coated flakes and explain the reason for this systematic inconsistency in more detail.

According to section 11.7 and Tab. 7 of the CLH report it is proposed that the classification of granulated copper is covered by the new proposed classification for copper [specific surface area $> 0.67 \text{ mm}^2/\text{mg}$]. However, according to Tab. 9 the length of the granulated copper ranges between 0.9 mm and 6.0 mm, with a mean length at 2.1 mm. However, this size distribution would lead one to expect a typical specific surface area $< 0.67 \text{ mm}^2/\text{mg}$. Can you please explain and clarify why granulated copper would fall under the newly proposed classification for copper with a specific surface area $> 0.67 \text{ mm}^2/\text{mg}$?

Dossier Submitter's Response

Thank you for your comments.

Response to your comment on entries in Annex VI:

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

The reason why we propose to maintain a separate entry in Annex VI for copper flakes (coated with aliphatic acid) is because a separate entry is driven by the human health hazard classification. The aquatic environmental hazard for the copper flakes (coated with aliphatic acid) entry would of course be the same as for all other fine forms of copper (specific surface area of $>0.67 \text{ mm}^2/\text{mg}$). Response to your comment on particle size and specific surface area of copper granulated: Yes, it's true that the mean length of copper granulated is 2.1 mm. Additionally, the mean width is 0.7 mm according to Table 9 in the dossier. However, the specific surface area (SSA) is not just dependent on the size (length and width) of the particles, but also on the structure and porosity of the material. SSA is defined as the <u>total</u> surface area of a solid material per unit of mass. The SSA for copper granulated is taken from the CLH report for copper, granulated (February, 2017) where a SSA of $25.6 \text{ cm}^2/\text{g}$ ($=2.56 \text{ mm}^2/\text{mg}$) is reported (for example in Table 9 of CLH report for copper, granulated). This information is also consistent with the information of SSA for this particle in study ECTX (2016b; study no. X01-203; p. 17 in the current dossier). Hence, our conclusion is that copper granulated has a SSA $>0.67 \text{ mm}^2/\text{mg}$.
RAC's response Thank you for your comments. RAC support DS respond comment on entries in Annex VI: The separate entry for copper flakes (coated with aliphatic acid) is driven by the human health hazard classification. The aquatic environmental hazard for the copper flakes (coated with aliphatic acid) is the same as for all other fine forms of copper (specific surface area of $>0.67 \text{ mm}^2/\text{mg}$). Response to the comment on particle size and specific surface area of copper granulated: The specific surface area for copper granulated is taken from the CLH report for copper, granulated (February, 2017) where a SSA of $25.6 \text{ cm}^2/\text{g}$ ($=2.56 \text{ mm}^2/\text{mg}$) is reported. The conclusion is that copper granulated has a SSA $>0.67 \text{ mm}^2/\text{mg}$.

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Greece	CABLEL WIRES S.A.	Company-Manufacturer	37
Comment received				
Please see public attachment.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment CABLELWIRES_COPPER_CLH_28.01.2022.pdf				
Dossier Submitter's Response				
Please see our response to General comment number 15, which covers also this comment (comment number 37) by CABLEL WIRES S.A.				
RAC's response				
Thank you for your comment. Please see RAC responses to comment number 4, in which RAC gives response to the comments by European Copper Institute, to which you refer.				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Greece	EPIRUS METALWORKS S.A.	Company-Manufacturer	38
Comment received				
see attached file				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment EPIRUS METALWORKS_COMMENTS_ON_COPPER_CLH_28.01.2022.pdf				
Dossier Submitter's Response				
Please see our response to General comment number 16, which covers also this comment (comment number 38) by EPIRUS METALWORKS S.A.				
RAC's response				
Thank you for your comment. Please see RAC responses to comment number 4, in which RAC gives response to the comments by European Copper Institute, to which you refer.				

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Greece	<confidential>	Company-Manufacturer	39
Comment received				
We have uploaded an attachment instead.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Hellenic Cables.pdf				
Dossier Submitter's Response				
Thank you for your comment. We would like to clarify that consequences in downstream legislation are not taken into consideration in the process of proposals for harmonised classifications that is solely based on the intrinsic hazardous properties of the substance. We consider that this issue would be more appropriately dealt with independently through other European legal instruments.				
RAC's response				
Thank you for your comment. RAC notes that consequences in downstream legislation are not taken into consideration in the process of proposals for harmonised classifications.				

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Germany	AURUBIS AG	Company-Manufacturer	40
Comment received				
We support the position and scientific comments submitted by the European Copper Institute. Based on the available information and on Annex IV of the CLP Guidance, the environmental hazard profile of copper in massive form and of copper in powder form should be assessed separately. Copper occurs naturally in the environment. It is an essential nutrient for all forms of life. Copper (EC 231-159-6; CAS 7440-50-8) has undergone significant EU and international regulatory scrutiny over the past 20 years, including the Copper Voluntary Risk Assessment in 2008, the assessment by the OECD Cooperative Chemicals Assessment Programme (CoCAP) in 2014, and most recently the RAC opinion on Granulated copper in 2018.				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

The report by the Dossier Submitter is based on these previous regulatory assessments, and it considers the most recent update of the copper REACH registration dossier and Chemical Safety Report (February 2021). We support that the assessment is based on previous evaluations of copper. In line with the CLP guidance, separate hazard profiles for copper in massive and in powder form are well justified given the information provided in the report by the Dossier Submitter and data provided in the REACH registration dossier. We support the conclusion of the Dossier Submitter that copper in massive form does not merit classification as Aquatic Acute or Aquatic Chronic under CLP. When establishing the environmental hazard classification for the massive and powder forms of copper metal, it is important that the assessment is based on robust data and agreed scientific principles, and that the appropriate science is applied to the right form of copper, in line with the CLP Regulation and the CLP Guidance. This is because a potential hazard classification as Aquatic Acute or Aquatic Chronic for the massive form of copper would have severe consequences for the sector as well as for the sustainable and low-carbon technologies which are enabled by copper. These consequences would include 1) barriers to recycling and the circular economy, resulting in a disruption of material flows; 2) uneven playing field for companies operating in the EU (3) reputational damage (4) operational challenges because of Seveso directive, transport legislation, REACH, and CLP ECHA note – An attachment was submitted with the comment above. Refer to public attachment Aurubis feedback to Cu CLH proposal Jan 2022.pdf
Dossier Submitter's Response
Please see our response to General comment number 18, which covers also this comment (comment number 40) by AURUBIS AG.
RAC's response
Thank you for your comment. Please see RAC responses to comment number 4, in which RAC gives response to the comments by European Copper Institute, to which you refer.

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Greece	ELVALHALCOR S.A.	Company-Manufacturer	41
Comment received				
Please see attached document				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment ELVALHALCOR COMMENTS ON COPPER CLH 26.01.2022 FINAL.pdf				
Dossier Submitter's Response				
Please see our response to General comment number 19, which covers also this comment (comment number 41) by ELVALHALCOR S.A.				
RAC's response				
Thank you for your comment. Please see RAC responses to comment number 4, in which RAC gives response to the comments by European Copper Institute, to which you refer.				

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	United Kingdom	Heath and Safety Executive	National Authority	42
Comment received				
Copper (EC: 231-159-6; CAS: 7440-50-8)				

Split classifications for different metal forms

Minimising the number of entries for different metal forms is desirable from a practical perspective because split entries can cause problems in interpretation for down-stream users (and for hazardous waste classification). The proposal has correctly identified the relevant classification for copper massive and copper powder from the data presented.

There are two other forms of copper with existing harmonised classifications (flakes and granules). The specific surface area of copper flakes exceeds that of the proposed representative form of copper powder, whereas copper granules have a lower specific surface area than the representative copper powder. We have the following observations:

1. It could be useful to avoid the term "powder" in a new Annex VI entry – "non-massive" (or just quoting the specific surface area) would be less confusing.
2. The available transformation/dissolution data for granulated copper leads to a less stringent environmental classification (Aquatic Chronic 2) than the current proposal for copper with a high specific surface area. CLP is usually based on surrogate methods unless measured data are available. Should a special derogation be made specifically for granulated copper, for example in a footnote with specific information on its dimensions?
3. We note that a RAC Opinion on the long-term aquatic hazard for copper flakes was adopted in 2019 to reflect updates to the ERVs that were agreed in the RAC Opinion for granulated copper in 2018. This RAC Opinion from 2019 should be referenced in the current CLH proposal. It indicated that the classification for copper flakes adopted in 2014 (Aquatic Acute 1 (M=10); Aquatic Chronic 1 (M=10)) was still appropriate. The new proposal (Aquatic Acute 1 (M=10); Aquatic Chronic 1 (M=1)) is less stringent than the existing classification for this form.
4. According to the CLP guidance (ECHA, 2017), separate classifications for different metal forms may be appropriate if these forms are produced by a specific production method different to the production methods for other forms of the metal. Another reason for a separate entry is if the specific metal form is not generally formed from other forms of metal during use. These arguments for separate classifications for the specific forms have not been discussed in the RAC Opinions on the existing CLH entries for granulated copper and copper flakes, or in the current CLH proposal, except for justifying the split entries for copper powder and massive. However, when considering what transformation/dissolution data should be used in the current CLH proposal, copper flakes were not considered representative of all forms of copper powder because of the specific production process. This does therefore imply that a separate environmental classification based on transformation/dissolution data for copper flakes may be warranted for this specific form, and the RAC opinion on this issue is awaited with interest.
5. As the classification of copper forms affects other metals too, this issue should be discussed at UN GHS level, as it is important to achieve global consistency.

ECHA (2017). Guidance on the application of the CLP criteria. Version 5.0. Helsinki: ECHA.

Dossier Submitter's Response

Thank you for your comments and for your support.

1. Yes, agree that the term "powder" should be avoided. Our proposal was to just quote the specific surface area. However, there has been also other suggestions

(see comments 4 and 5) to add some kind of descriptor as well. The suggestion "fine forms" (in comment 4) is a very general descriptor that could include different shapes of copper, which is important if a descriptor should be added to the specific surface area in the Annex VI entry.

2. Our opinion is that there should be no special derogation for granulated copper. According to Guidance on the Application of the CLP Criteria, Annex IV (IV 5.5; version 5.0 – July 2017); "Normally, the classification data generated would have used the smallest particle size marketed to determine the extent of transformation" and further "... in normal circumstances it is not anticipated that more than two classification proposals would be made for the same metal."

Copper metal can be placed on the market in many different physical forms, where flakes and granules are only two examples. However, the aquatic environmental hazard classification should not depend on the particles' physical form since they are still chemically the same substance. Our proposal is therefore that both copper flakes and copper granulates (which both have specific surface areas larger $0.67 \text{ mm}^2/\text{mg}$) should be covered by our proposal for aquatic environmental hazard classification for copper with a specific surface area of $> 0.67 \text{ mm}^2/\text{mg}$.

3. Yes, a new RAC Opinion on M-factors for long-term aquatic hazard for the copper substances was adopted in 2019. In this RAC Opinion the M-factors of several copper compounds were re-assessed using the revised chronic ecotoxicological reference values (ERVs) from the updated dataset in the RAC Opinion for copper granulate (adopted in June 2018). For transparency reasons, we probably should have referenced this new RAC Opinion also in our dossier. However, since the chronic ERVs used in the new RAC Opinion from 2019 are based on, and consequently the same, as the ERVs in the RAC Opinion for copper granulate (adopted in June 2018) the outcome of our proposal is not dependent on this new RAC Opinion on M-factors for long-term aquatic hazard for the copper substances.

It is also true that our new proposal (Aquatic Acute 1 ($M=10$); Aquatic Chronic 1 ($M=1$)) is less stringent than the existing classification for this form. The reason is that different Transformation/dissolution datasets have been used in the different assessments. In the assessment for copper flakes (RAC opinions on copper flakes, 2014 and 2019) a specific dataset for this particle was used, whereas in our dossier we have used a dataset which could represent all particles with a specific surface area of $>0.67 \text{ mm}^2/\text{mg}$ including the smallest representative copper particle on the market (see section 11.2 in the dossier).

4. It is our opinion that the guidance in Annex IV 5.5 in the Guidance on the Application of the CLP criteria (2017) is relevant for considering if data from powder is relevant for the classification of massive metal, and not for separating the classification for different small particles with specific surface areas $>0.67 \text{ mm}^2/\text{mg}$. Additionally, in the same paragraph of the guidance, the following is stated: *"However, in normal circumstances it is not anticipated that more than two classification proposals would be made for the same metal."*
5. The GHS guidance is currently discussed in the GHS Sub-Committee Correspondence Group on Annexes 9.7 and 10 related to metals. The aim is to update the chapters of "Annex 9 section A9.7 Classification of metals and metal

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

compounds" and "Annex 10 Guidance on transformation/dissolution of metals and metals compounds in aqueous media".

RAC's response

Thank you for your comments and for your support for harmonised classification.

1. RAC agrees that the term "powder" should be avoided and is of opinion that specific surface area is the only necessary descriptor for metal classification with calculated limit value, based on metal properties.
2. RAC is of opinion that following CLP guidance, copper metal should be classified based on specific surface area and as a limit value of 0.67 mm²/mg equivalent to a 1 mm sphere of copper as copper release should be taken into account in the definition. How the classification of copper being proposed here affects existing classifications for forms of copper is for the European Commission to determine.
3. RAC agrees with DS that chronic ERVs used in the new RAC Opinion from 2019 are based on, and consequently the same, as the ERVs in the RAC Opinion for copper granulate (adopted in June 2018) and further used in the present CLH report. In this proposal classification (Aquatic Acute 1 (M=10); Aquatic Chronic 1 (M=1)) is less stringent than the existing classification due to the different Transformation/dissolution datasets used in the different assessments. In the assessment for copper flakes (RAC opinions on copper flakes, 2014 and 2019) a specific dataset for this particle was used, whereas in the present dossier a dataset which represent all particles with a specific surface area of >0.67 mm²/mg including the smallest representative copper particle on the market have been taken into account.
4. The idea of the present harmonised classification is that copper release depends only on the specific surface area and that is why the former is used as a basis for classification with a limit value of 0.67 mm²/mg. RAC agrees with the DS that copper flakes are not generally representative of copper powders due to there shape, surface area, and coating, the consequence being that they were not used as the smallest representative form on the market for classifying powders (0.67 mm²/mg). Any consequences regarding the existing entries for copper forms is to be determined by the European Commission.
5. RAC agrees with DS that the GHS guidance is currently discussed in the GHS Sub-Committee Correspondence Group on Annexes 9.7 and 10 related to metals. The aim is to update the chapters of "Annex 9 section A9.7 Classification of metals and metal compounds" and "Annex 10 Guidance on transformation/dissolution of metals and metals compounds in aqueous media".

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	United Kingdom	Biocidal Core Copper Subgroup	Please select organisation type..	43
Comment received				
The CLP Guidance indicates that, "in normal circumstances, it is not anticipated that more than two classification proposals would be made for the same metal," the powder form and the massive form. However, Copper massive, copper powder, copper granulate and copper flakes (coated with aliphatic acid) have been identified as active substances under				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

the BPR and two of the forms have accordingly received an entry in Annex VI of CLP.
Therefore, it should be considered that the approval of a specific forms of copper under the BPR does not constitute normal circumstances as considered by the CLP Guidance, and on this basis the BCCSG proposes that it is therefore justified to have more than two entries for copper under CLP. Please see Table 1 (Classification Status of Copper Forms Evaluated Under the BPR) in the public attachment.
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Consultation on the Harmonized Classification and Labelling of Copper_Final.pdf
Dossier Submitter's Response
Please see our response to General comment number 20, which covers also this comment (comment number 43) by Biocidal Core Copper Subgroup.
RAC's response
Please see RAC response to comment number 20.

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Bulgaria	SOFIA MED S.A.	Company-Manufacturer	44
Comment received				
Sofia Med SA, situated in Sofia, Bulgaria, on an area of 250,000 m³, is a producer of a wide range of rolled and extruded Copper and Copper alloy products that are used in a wide variety of building, industrial, electrical and automotive applications. Sofia Med is a subsidiary of ElvalHalcor, Greece, which is part of the holding company Viohalco. With more than 600 employees, production capacity of 140,000 MT/year, and annual turnover of abt. 500 Million Euros, Sofia Med is one of the major producers of Copper rolled and extruded products in Europe. Our mission is to generate sustainable growth and create value through the excellence of our people, products and services, respecting environment and society. Copper is the main raw material used in our production process; which includes, melting of Copper in the forms of cathodes and scrap, and then processing the casted slabs and billets by rolling and extrusion processes to the final products - sheets, strips, plates, circles, disks, bare and plated Copper bus bars, rods, profiles, components, and wire. Due to their excellent mechanical, thermal and electrical characteristics, our Copper products are used in a wide range of applications; the main ones are listed below: • Electrical and electronic equipment such as generators, motors, radiators, switch boards, transistors and electrical transformers • Parts and components for the automotive industry • Connectors used in various products e.g. switches, relays, consumer goods, computers, smartphones and telecommunications • General industrial applications • Boilers and Cylinders • Solar energy collectors and panels • Heat exchangers • Cables • Gutters and roofing parts in buildings All these applications and their related processes and products are contributing in achieving the EU Green Deal's objectives: decarbonization, renewable energy, energy efficiency, e-mobility. Last but not least, Copper is 100% recyclable metal and at the stage of end-of-life of Copper products, they can be fully recycled and recovered, which is definitely needed for				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

the Circular Economy's principles and EU Recycling targets. All the above makes it essential material to the environment and society. Our company is closely monitoring the procedure related to the Proposal for Harmonised Classification and Labelling of Copper. We welcome the opportunity to feed into this public consultation. Based on the available information and on Annex IV of the CLP Guidance, the environmental hazard profile of Copper in massive form and of Copper in powder form should be assessed separately. The specific proposal for Copper harmonized classification (Copper specific surface area $>: 0.67 \text{ mm}^2/\text{mg}$: Aquatic Acute 1, $M=10$; Aquatic Chronic 1, $M=1$), submitted by The Swedish Chemicals Agency KEMI, is scientifically based. However, it is essential that the relevant scientific information needs to be taken into consideration, classifying only the specific form of Copper (specific surface area $>: 0.67 \text{ mm}^2/\text{mg}$). The approach must be strict and careful. Misunderstanding and wrong adoption of the proposed CLH to other forms of Copper (for example massive form of Copper) could have significant negative effect on the industry and society, as follows: • Classification under Seveso Directive and additional operational costs for the related safety precautions; • Barrier for recycling due to hazardous wastes specific restrictions for transportation, import, export and recovery; • Administrative burden due to dangerous goods transportation; • Stigmatization of a sustainable material, and others. Therefore, we strongly believe that it is important that the right science is applied to the right form of copper in line with the CLP Regulation and CLP Guidance. In addition to that, we support the scientific and technical comments of the European Copper Institute (ECI). ECHA note – An attachment was submitted with the comment above. Refer to public attachment Sofia_Med_Comments_on_Copper_CLH_28012022rev.pdf
Dossier Submitter's Response
Thank you for your comment. Please see our responses to comment number 4, in which we give response to the comments by European Copper Institute, which you refer to.
RAC's response
Thank you for your comment. Please see RAC responses to comment number 4, in which RAC gives response to the comments by European Copper Institute, to which you refer.

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Spain	<confidential>	Company-Manufacturer	45
Comment received				
Please see our comments in the attached PDF				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Copper CLH Atlantic Copper Public Comments.pdf				
Dossier Submitter's Response				
Thank you for your comment. Please see our responses to comment number 4, in which we give response to the comments by European Copper Institute, which you refer to.				
RAC's response				
Thank you for your comment. Please see RAC responses to comment number 4, in which RAC gives response to the comments by European Copper Institute, to which you refer.				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	France	A3M	Industry or trade association	46
Comment received				
Des profils de danger distincts pour le cuivre sous forme massive et sous forme de poudre sont justifiés compte tenu des informations fournies dans le rapport par le soumissionnaire du dossier (annexe 1). Sur la base de l'analyse scientifique de l'institut européen du cuivre, nous soutenons la conclusion selon laquelle le cuivre sous forme massive ne mérite pas d'être classé comme substance aquatique aiguë ou aquatique chronique au titre du CLP. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20220127_Copper CLH_ECI position FINAL.pdf				
Dossier Submitter's Response				
Please see our response to General comment number 21, which covers also this comment (comment number 46) by A3M.				
RAC's response				
Thank you for your comment. Please see RAC responses to comment number 4, in which RAC gives response to the comments by European Copper Institute, to which you refer.				

Date	Country	Organisation	Type of Organisation	Comment number
28.01.2022	Belgium	Eurometaux	Industry or trade association	47
Comment received				
Restricted focus of the exercise The Dossier Submitter states in its dossier that they limited the scope of their proposal to the interpretation of available information in line with CLP principles and guidance to arrive at a harmonized classification for Copper irrespective of its particle size and form. This objective is certainly a most valid one given the multiple existing entries in Annex VI of the CLP, whereby more clarity would be appreciated. By stating this objective so clearly it also provided boundaries to the submission of information by stakeholders, focusing on this aspect. We would therefore assume that the evaluation by RAC would focus on the scrutiny of the suggested approach and supporting evidence, leaving other aspects that were not introduced by the Dossier Submitter (like a revision of the ecotox data set) outside the scope or the review. A new approach to distinguish between massive and powder forms To review and streamline the existing entries on metallic Copper forms, the dossier submitter used the Critical Surface Approach proposing a cut-off surface (0,67 mm²/mg) between massive and powder type forms. This method is explicitly foreseen in the GHS and CLP guidance and actually a more refined and better approach to define the difference between massive and powders than the usual cut-off of 1 mm. Indeed, the metal release as measured in a Transformation/dissolution test depends linearly on the exposed surface area. Measured surfaces normally need to be recalculated to an aerodynamic particle size to be comparable with the cut-off. By using the CSA based on real measurements or estimates (covering the real shape of the particles), the surface can be directly compared with the cut-off surface. We therefore believe that the Dossier Submitter have improved the way metal massives / powders were defined until now and would consider taking this approach further forward in this and other metal cases. 11.3 – Environmental fate and other relevant information				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

The Dossier Submitter recognises in this section that the fate and behaviour of copper in soil and water compartments, 'degradation' of copper is a complex process (bioavailability depending on distribution and equilibrium). Indeed there exists extensive literature and data sets on these complex reaction pathways in the environment that influence the fate, including transformation and removal processes as documented in the Registration file of Copper. This information provides evidence for a conclusion that copper ions undergo rapid environmental transformation and removal and remains bounded in an irreversible way preventing dissolution. However, the dossier submitter concludes in a general way that: Copper could therefore not be subject to rapid environmental transformation for the purpose of classification and labelling. We agree that there is at this stage no formal approach in the CLP Guidance on how to assess and implement rapid environmental transformation for metals and inorganic substances for classification purposes but believe that the general duties of the CLP require that evidence provided should be assessed. We would therefore expect that in absence of guidance it requires a case by case analysis, checking for the robustness and relevancy of the provided data sets and evidence rather than a generic statement that the metal could therefore not be subject to rapid environmental transformation for the purpose of classification and labelling.
Dossier Submitter's Response
Thank you for your comment and for your support of using the specific surface area in the entries of Annex VI. Regarding your comment on "11.3 – Environmental fate and other relevant information", please see our response to General comment number 4.
RAC's response
Thank you for your comment. Thank you for agreement to use specific surface area and limit value of 0.67 mm²/mg to distinguish between copper forms. RAC assessed presented evidence for copper transformation to non bioavailable species and concluded that results from these studies showed that copper precipitation is possible under specific conditions but do not support the conclusion for copper transformation to non-bioavailable form under environmentally relevant conditions (low copper and low sulphide content). RAC do not agree that all these studies under conditions with high sulphide content and high copper concentrations (much above the concentrations of copper in aquatic environment) support copper ion transformation to nonbioavailable species and removal. In addition, simple calculation by using VisualMinteq for example do not show copper precipitation at concentrations in the range 0.5-1.5 µg/L and 1 nM sulphide.

Date	Country	Organisation	Type of Organisation	Comment number
20.01.2022	Italy	Trafilerie Carlo Gnutti Spa	Company-Downstream user	48
Comment received				
We are one of the biggest producers of brass rods, hollow rods, wires and strip in Europe obtained by casting, hot extrusion, drawing and cold rolling. With our products, we supply our customers in the sanitary, electrical and automotive industries with the semi-finished products they need. For our brass products, copper is the most important alloying element after zinc and it is fed to the smelting furnaces in solid form (cathodes, granulated, end of life massive components). We are concerned that if the massive form of copper would be inappropriately classified, this would result in an immense expense for transport (Seveso Directive) and handling, which is not justifiable. Our raw material source is based on recycled copper or copper alloys end of live massive				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON COPPER

components. We fear that a classification of these components could strongly increase the recycling cost. We regret that end of life components would be devaluated and sold outside Europe. This would also increase the pressure on virgin material which looks to be a critical raw material for the ecological transition. We very much welcome the opportunity to comment and we are going to monitor this process with great interest.
Dossier Submitter's Response
Thank you for your comment. We would like to clarify that consequences in downstream legislation are not taken into consideration in the process of proposals for harmonised classifications that is solely based on the intrinsic hazardous properties of the substance. We consider that this issue would be more appropriately dealt with independently through other European legal instruments.
RAC's response
Thank you for your comment. RAC notes that consequences in downstream legislation are not taken into consideration in the process of proposals for harmonised classifications.

PUBLIC ATTACHMENTS

1. CABLEWIRES_COPPER_CLH_28.01.2022.pdf [Please refer to comment No. 15, 37]
2. EPIRUS METALWORKS_COMMENTS_ON_COPPER_CLH_28.01.2022.pdf [Please refer to comment No. 16, 38]
3. Hellenic Cables.pdf [Please refer to comment No. 39]
4. Aurubis feedback to Cu CLH proposal Jan 2022.pdf [Please refer to comment No. 18, 40]
5. ELVALHALCOR_COMMENTS_ON_COPPER_CLH_26.01.2022_FINAL.pdf [Please refer to comment No. 19, 41]
6. Consultation on the Harmonized Classification and Labelling of Copper_Final.pdf [Please refer to comment No. 20, 43]
7. Sofia_Med_Comments_on_Copper_CLH_28012022rev.pdf [Please refer to comment No. 44]
8. Copper CLH Atlantic Copper Public Comments.pdf [Please refer to comment No. 45]
9. 20220127_Copper CLH_ECI position FINAL.pdf [Please refer to comment No. 21, 46]
10. Position Paper - Public consultation CLH Copper.pdf [Please refer to comment No. 23]
11. 2022-01-28_WVMetalle comment on Cu Env Clas consultation.pdf [Please refer to comment No. 3, 27]
12. Copper CLH - ECI input FINAL.zip [Please refer to comment No. 4, 28]
13. Comment to CHL Proposal Copper Wieland.pdf [Please refer to comment No. 5, 29]
14. SHE-Contribution-Copper Classification.pdf [Please refer to comment No. 6, 30]
15. Arxada_Copper CLH_Public Commenting_27Jan2022.pdf [Please refer to comment No. 7]
16. ASSOMET response to the Public Consultation on the Harmonized Classification and Labelling of Copper-final.pdf [Please refer to comment No. 9, 32]
17. EuRIC reaction to Copper CLH.pdf [Please refer to comment No. 10]
18. Europacable Response to Copper Classification Consultation - 27.01.2022.pdf [Please refer to comment No. 11, 33]
19. ECHA classification of copper Jan 2022.pdf [Please refer to comment No. 14]
20. Public Consultation - Copper harmonized classification - PUBLIC.pdf [Please refer to comment No. 2, 26]

CONFIDENTIAL ATTACHMENTS

1. Public Consultation - Copper harmonized classification -- CONFIDENTIAL.pdf [Please refer to comment No. 2, 26]