Committee for Risk Assessment

RAC

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

Granulated copper

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

CLH-O-0000001412-86-216/F

Adopted

8 June 2018

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during public 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 public 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 public 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.

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

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
12.05.2017	Belgium	European Copper Institute	Industry or trade association	1

Comment received

The comments below reflect the views of the European Copper Institute (ECI). ECI represents the European copper industry all along the value chain: copper producers, recyclers, and manufacturers of semi-fabricated products.

These comments are also the views of:
• the International Copper Association
• the Copper Compounds Consortium
• the applicant Arch Timber Protection
• the European Metal Particulate Association, a Division of the German Aluminium Association

We are grateful for having the opportunity to comment on the harmonized hazard classification of "Copper, Granulated". We furthermore gratefully acknowledge and appreciate the alignment with the Copper Voluntary Risk Assessment, as well as the newly updated REACH registration data.

For most endpoints in the human health section, the data used and interpretation of the data reflect the hazard profiles previously agreed for nine other copper substances reviewed in 2014 for genotoxicity, reprotoxicity, carcinogenicity and STOT-RE (published in the subsequent RAC opinions and in the 9th ATP). However, for some endpoints, we have a different interpretation of the data presented in the CLH document and we have therefore focussed our comments on these endpoints and propose to revise the classification to No classification warranted for acute eye irritation

Comments have also been provided on the on interpretation and use of the extensive copper ecotoxicological database. These are related to the need for guidance on "rapid

removal" for inorganic substances, to the inclusion of recently obtained ecotoxicity studies at low pH, and to the methods used for data grouping. These comments result in no classification for long-term environmental hazard.

1. We agree that Copper, granulated is a form of copper defined by its particle size and specific surface area, as mentioned on page 12. We suggest that, for clarity and in order to correctly reflect the scope of this dossier, the specific surface area should also be reflected in Table 1 (page 5) and Table 5 (page 10).

Regarding all endpoints, please also see the attached document for a better overview of our comments, and for supporting tables and figures.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170512_ECI PC input FINAL.pdf
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment OSU AquaTox_Copper FHM_New pH 6_Draft Final Report_27 March 2017.docx

Dossier Submitter's Response

COMMENT ON IDENTITY

Specific surface area and size of the particle will be added in the two tables: Table 1 (page 5) and Table 5 (page 10).

COMMENTS ON EYE IRRITATION:

As no study was available for eye irritation, a read across with coated copper flake was proposed. As the coated copper flake was considered as irritant by RAC, a classification for eye irritation is also proposed for granulated copper. This classification covers the possible exposure to the copper ions.

COMMENTS ON ENVIRONMENT ENDPOINTS:

- Com 3 of the attachment 20170512_ECI PC input FINAL.pdf

This comment is related to the concept of "rapid removal from the water column". Industry argues that a weight-of-evidence is discussed in the copper REACH registration dossier and shows that copper is rapidly removed from the water column for the purpose of hazard classification. Nevertheless, we are still thinking that a clear guidance should be developed to have an harmonized approach on this concept. See also our answer on comment 10.

- Com 4 of the attachment 20170512_ECI PC input FINAL.pdf

We have noted that Industry agrees with the database used for hazard classification purposes.

- Com 5 of the attachment 20170512_ECI PC input FINAL.pdf

We have noted that Industry agrees that the OSU (2016b) data can substitute for the Ng. et al data. And, they note that the Ng. et al data also confirm that there were little or no sensitivity differences to fish between pH6 and 7. This sensitivity was observed in the new studies generated by Oregon State University (OSU, 2016 a and 2016 b).

- Com 6 of the attachment 20170512_ECI PC input FINAL.pdf

Industry suggests that the geometric mean can always be used for grouping data within pH band and for the same endpoint due to the data-richness of copper.
Therefore, for the acute ERV at pH7, Industry proposes to use the geometric mean of 17 values on *C. dubia*, which is equal to 14.0 µg/L instead of the lowest value of 11.7 µg/L issued from a *D. rerio* toxicity study.

Following the same approach, Industry proposes a chronic ERV equal to 12 µg/L at pH7 instead of 5.9 µg/L.

It should be noted that to analyse the impact of the use of geomean or lowest value if less than 4 data points are available, both approach were presented in this CLH report. In case of granulated copper, as we have mentioned in section 5.5 Comparison with criteria for environmental hasards, there is no impact for acute classification of granulated copper if the acute ERV calculated using the geomean even when less than 4 data are available.
However, as it is suggested by the comment 10, we support a need for discussion at the RAC level to clarify:
- the use of the geometric mean or the lowest value when less than 4 data are available for a pH band and more than 4 data available whatever the pH band;
- the use of the geometric mean or the lowest value when less than 4 data are available for a pH band for an effect (e.g. *S. fontanilis* for which only 3 data are available at pH7 for reproduction and 4 data for growth or mortality effects);
- whether and when unbounded values should be used in a geomean approach;
- the use of geomean on the same species or at a 'trophic group' (as raised by comment 10);
- consideration of EC10s and/or NOECs in the chronic geomean (as raised by comment 10).

In comment 6.2, it should be noted that European Copper Institute submits a draft of a new chronic study on *P. promelas* conducted at pH 6 at Oregon State University (OSU, 2017). This study seems to have an impact on the derivation of the chronic ERV at pH 6 which could be equal to 13.2 µg/L instead of 8.7 µg/L due to the possibility to apply the geometric mean as 4 values are available with this additional data at pH 6. However, this study is only a draft report and therefore could not be considered at that time. Moreover, if the rules stated in the current CLH report is confirm at the RAC level, granulated copper is still classified Aquatic Chronic 2 at pH 7.

- Com 7 of the attachment 20170512_ECI PC input FINAL.pdf

Noted. Thank you for your comment.

- Com 8 of the attachment 20170512_ECI PC input FINAL.pdf

Considering the approach followed by Industry, they propose not to classify granulated copper. However, this conclusion depends on the discussion at the RAC level regarding the geometric mean or the lowest value.

RAC's response

HH: Your comment about eye irritation is noted. Given the specific form and particle size of granulated copper, RAC does not consider the proposed read-across from coated copper flakes appropriate. Hence, in the absence of relevant data, no proposal for classification for eye irritation can be made for granulated copper.

ENV:

- Com 3 of the attachment 20170512_ECI PC input FINAL.pdf

Since the cited information on rapid removal from the copper REACH registration dossier has not been submitted separately during public consultation, it is difficult for RAC to incorporate it into the opinion. See also our reply on comment #10.

- Com 4 of the attachment 20170512_ECI PC input FINAL.pdf

RAC agrees that environmental hazard classification is a comparative exercise, and should create a level playing field for all substances to avoid over- or under-classification. RAC believes that, in principle, it is preferable to base decisions on data from standard test guideline studies, since these methods have been ring-tested and approved for use for

regulatory purposes (the sensitivity of other species and methods will be variable and may also be influenced by test conditions that have not been standardized, which makes it very difficult to justify their use in any comparative exercise). However, there are some discrepancies in the choice of species for copper that need consideration, e.g. inclusion of fish and algal species that are not recommended in the OECD TGs, whilst omitting valid chronic data for the cladoceran *Ceriodaphnia* without adequate explanation (and other *Daphnia* species, such as *D. pulex*, for which copper data are available). RAC disagrees with this omission, because the ECHA IR/CSA guidance (R.7.8.4.1) includes this species for chronic end points, the CLP Guidance itself lists the 7-d *C. dubia* study under the chronic toxicity data in one of the examples for metals (Annex IV), and *Ceriodaphnia* studies were considered for chronic ERV derivation in the previous RAC opinions for copper compounds.

RAC also considers that the grouping of data in relevant physico-chemical "bands" is an important factor, and if there are resulting limitations in the data set these must be recognized even if the overall number of data points is very large. An example is the lack of acute toxicity data for Zebrafish at acidic pHs, which might prove sensitive based on our analysis of the information.

In addition, no data have been presented for any valid standard studies with invertebrates such as molluscs, additional crustaceans (such as *Gammarus*) or insects. RAC notes that there are several precedents for using such species (e.g. oyster, mayfly, etc.) for hazard classification purposes in the EU. Such data were included in the previous RAC opinion on the classification of copper compounds. We see no reason why they should be omitted from the data set if they are available and reliable.

- Com 5 of the attachment 20170512_ECI PC input FINAL.pdf

Concerning the lack of trend in toxicity with pH demonstrated by the OSU (2016b) data, RAC has concerns that the available data conflict with the acute fish data set. This is described further in the opinion as well as under comment 6.2 below.

- Com 6 of the attachment 20170512_ECI PC input FINAL.pdf

Data-rich metals pose a special challenge for data grouping and RAC agrees that this needs careful case-by-case assessment. The current CLP Guidance is based on the globally agreed GHS approach, and further interpretation would benefit from a discussion at global level. Our understanding is that the rules for averaging data (which are generally applicable to data poor substances) reflect the fact that biological variability can be high, and that four data points should be available for an equivalent end point before a geometric mean can be used, which provides an element of conservatism. This is a technical policy choice. The added complication for metals is that ecotoxicity can be substantially affected by the abiotic parameters of the test medium. In the case of copper, toxicity appears to be greatest at acidic pH for fish and invertebrates. RAC notes two related points:

- For an ionizable organic substance with a pKa in the environmentally relevant pH range, Appendix R.7.8-1 of Chapter R.7b: Endpoint specific guidance (Version 4.0 – June 2017) of the ECHA Guidance on Information Requirements (p. 73) indicates that consideration should be given to appropriate pHs to be used in aquatic toxicity testing since toxicity may be higher in the un-ionized form than in the ionized form.

- An organic substance cannot be considered rapidly degradable if its hydrolysis half-life exceeds 16 days at one relevant pH (4, 7 or 9), even if it is shorter at the other two (i.e. the more conservative interpretation over-rides the rest).

It therefore seems logical to pay special attention to the hazard of copper in its most toxic form (i.e. at acidic pH) even if it is less toxic at pHs above 6.5. Taking an average when

there are fewer than four data points in a pH band just because there happen to be more data at other pHs (representing a lower level of toxicity) does not seem justified as the data are not "equivalent". RAC accepts that this does potentially bias the assessment to the most sensitive result if there are less than four data points in a pH band. The approach to choice of values under these circumstances needs further discussion, as highlighted in our reply to comment #11.

RAC is disappointed that a Species Sensitivity Distribution (SSD) approach (e.g. HC5 derivation) has not been presented, since this could have provided an additional line of evidence to consider in terms of the overall weight of evidence available. The comment suggests that there are insufficient data to allow this, but this is inconsistent with the Industry's approach to PNEC derivation which relies on an SSD. It seems inappropriate to set a regulatory threshold for ecotoxicity based on a larger data set for PNEC or Environmental Quality Standard (EQS) setting, whilst ignoring a lot of this information for intrinsic hazard assessment. RAC would have preferred to see the HC5 selected by the REACH Registrants as part of the weight of evidence analysis. The previous RAC opinions on copper compounds reported that the voluntary risk assessment report (2008) compiled all of the reliable chronic NOEC data in a species sensitivity distribution, deriving a hazardous concentration for 5% of the species (HC5) (with the 50th percentile confidence interval) of 7.3 µg/L (6.1-7.9 µg/L) based on a best fitting approach, or 6.1 µg/L (3.7-8.6 µg/L) using log normal curve fitting. RAC does not know if the same approach has been applied to the latest version of the REACH registration, or how the picture changes when data are split by pH or adjusted for DOC, etc.

RAC is also open to the idea of bootstrapping, but only if the implications of the variation of toxicity with pH (and missing data for other standard test guideline species) is considered.

Several of the comments refer to proposed changes in the acute and chronic ERVs:

- Comment 6.1 highlights that the proposed acute ERV at neutral pH is derived from the lowest acute LC_{50} value for *Danio rerio* (because there are two data points). However, there are 5 acute values available for this species across all pH bands. Therefore, the Industry suggests that the geometric mean can be used for grouping the data within an individual pH band, which results in 20.2 µg/L at neutral pH. Likewise, within the alkaline pH 8 band, the value for *D. rerio* becomes 167.4 µg/L. The consequence is that the acute ERV at neutral pH changes to 14 µg/L based on data for *Ceriodaphnia dubia.*

  RAC considers that the approach to data summarization needs further discussion (see reply to comment #10), but this suggested change has no practical consequence for the classification proposal. Nevertheless, RAC notes that the implications about the potential sensitivity of *D. rerio* at acidic pH has been overlooked by both the Industry and the Dossier Submitter. This is discussed further in the opinion.

- Comment 6.2 indicates a new "chronic" study on *P. promelas* at pH 6 is available in draft (OSU, 2017). This was a standard 7-d USEPA "short-term chronic" toxicity test under flow-through conditions with larval fish (<24 hrs old) in a low hardness laboratory water (36-40 mg/L as $CaCO_3$) that was supplemented with a small amount of dissolved organic carbon (DOC; 1.2 – 1.5 mg/L). Test endpoints were fish survival and growth (measured as terminal dry weight), with 7-d $L(E)C_{10}$ (and 95% confidence intervals) values of 18.9 (9.4 – 38.1) and 21.0 (13.6 – 32.4) µg/L, respectively, according to the draft study report (the comments cite the growth EC_{10}

as 25.2 µg/L). These results were statistically similar to those from a previously conducted test in the same laboratory at pH 6 that resulted in survival and growth L(E)C_{10} values (with 95% confidence intervals) of 10.1 (8.6 – 11.8) and 10.2 (4.3 – 24.3) µg/L, respectively. The confidence intervals were overlapping between the two studies.

The Industry points out that including these data in the acidic pH band for *P. promelas* increases the number of chronic data points to four and so a geometric mean can be derived (13.3 and 13.9 µg/L for mortality and growth, respectively, without DOC normalization), replacing the minimum value of 8.7 µg/L ($NOEC_{growth}$) for this species and pH band. The chronic ERV at acidic pH (5.5-6.5) subsequently becomes 13.2 µg/L (*D. magna* $NOEC_{reproduction}$; geometric mean of 7 values).

However, RAC notes that a 7-d fish toxicity test is shorter than the duration of standard test guideline methods used to assess chronic end points (it is only three days longer than the standard acute test duration), and the USEPA method is not mentioned as a standard chronic test in Chapter R.7b: Endpoint specific guidance (Version 4.0 – June 2017) of the ECHA Guidance on Information Requirements. In addition, RAC notes that there is some inconsistency with the acute data set. For example, when the new data are taken into account the "chronic" mortality LC_{10} for *P. promelas* (not normalized for DOC level) is around 13 µg/L at acidic pH (at which toxicity is expected to be highest), which is effectively the same as the acute LC_{50} value selected for this species (12.1 µg/L). The same conclusion can be drawn when DOC normalization is performed. In principle the chronic end point value (representing "no effects") should be lower than the acute one. This might simply reflect the differences in the amount of data available (and also potentially hardness), but raises some doubts over the comparability of the acute and chronic data sets. In addition, RAC notes that there is no information about reproduction for any fish species at acidic pH, or any data about the long-term sensitivity of *Danio rerio*, which may be acutely sensitive at acidic pH (see discussion under acute toxicity above). RAC therefore does not consider it appropriate to take account of this new information in the way suggested.

- Comment 6.3 suggests that the chronic NOEC/EC_{10} value for *P. promelas* mortality at neutral pH without DOC normalization (5.9 µg/L) may be an outlier when compared to the other values at different pH, other end points for this species, and that some studies do not suggest a strong difference in chronic toxicity between pH 6 and 7 for this species. Based on this "weight of evidence", the Industry suggests that the geometric mean should be preferred (12 µg/L).

  RAC notes that there are 46 data points for the acute LC_{50} for *P. promelas* at neutral pH, with minimum, maximum and geomean values of 5.9, 1 400 and 96.7 µg/L, respectively (without DOC normalization). In contrast, there are only 3 chronic studies that report mortality for this species at neutral pH, with a minimum and maximum NOEC/LC_{10} of 5.9 and 22.5 µg/L, respectively (without DOC normalization). Comparing the geomean acute and chronic values (96.7 and 12 µg/L, respectively) gives an acute:chronic ratio of 8 (the ratio is 16 or 4 if the minimum or maximum chronic value is selected, respectively). The only other species with both acute and chronic mortality data in this pH band is *O. mykiss*, and the geomean acute LC_{50} (47.4 µg/L, n=22) results in an acute:chronic ratio of 2.5–2.8 (two chronic studies are available). The worst case acute:chronic ratio of 16 for *P. promelas* may therefore be unusually high, although this conclusion is uncertain given the relatively small number of chronic studies available.

The minimum chronic mortality NOEC/LC_{10} for *P. promelas* at *acidic* pH is 10.1 µg/L (without DOC normalization) (3 studies are available). RAC notes that some of the studies suggesting insignificant differences in chronic toxicity between acidic and neutral pH were not full chronic tests so this conclusion is debateable. However, since it might be expected that toxicity is higher under acidic conditions based on the acute evidence, RAC tends to agree that the chronic value of 5.9 µg/L at neutral pH may be unusually low.

When DOC normalization is applied, the chronic value of 5.9 µg/L changes to 11.6 µg/L, which is still slightly lower than the normalized chronic value for this species at acidic pH (14.6 µg/L) but of the same order of magnitude. Overall, RAC considers that the DOC-normalized data may be a more relevant indicator of toxicity than the non-normalized values for hazard classification purposes, although this is based on some assumptions (see also reply to comment #3 and #13).

- Comment 6.3.2 highlights an old (1974) study on reproduction in *Salvinus fontinalis* which showed no effects up to the highest test concentration of 9.4 µg/L. There is (undescribed) "uncertainty" related to the pH during this test, but the Industry suggests that the data can nevertheless be used as supporting information to justify the use of a geometric mean at pH 7. This appears to make no practical difference to the geometric mean for reproduction (15.9 µg/L (n=3) or 14.0 µg/L (n=4)), but the lowest value (without DOC normalization) is 6.4 µg/L so this makes a difference to the conclusion for this species at this pH. Given the age of the test and the apparent uncertainty in the pH (which is not properly described in the comment), RAC does not think sufficient justification has been provided to include this data point.

- Com 7 of the attachment 20170512_ECI PC input FINAL.pdf

RAC notes the Industry's agreement to use the transformation/dissolution protocol data.

- Com 8 of the attachment 20170512_ECI PC input FINAL.pdf

Based on Industry's re-analysis of the data set, they propose not to classify granulated copper as hazardous to the aquatic environment. The Dossier Submitter points out that this conclusion depends on the RAC discussion regarding the selection of geometric mean or the lowest value. RAC points out that it also depends on the inclusion of chronic data for relevant additional species, such as *Ceriodaphnia*, *Daphnia pulex*, molluscs and insects, as well as the way inconsistencies between the acute and chronic data sets are handled and the approach to normalization of data for factors such as DOC.

Date	Country	Organisation	Type of Organisation	Comment number
10.05.2017	Germany		MemberState	2
Comment received				
In Part B section 1.2, a description of the substance including an explanation why the sub-stance is defined as "granulated" is provided. In this description the DS tries to explain and clarify the shape and particle size of granulated copper. The DS states that: "For the purposes of this CLH report, the substance has been defined as granulated copper and is considered between massive and powder form: - In the CLP guidance, copper massive is defined as a sphere with a diameter > 1mm and with a corresponding surface area of < 0.67 mm2/mg (<6.74 cm2/g). - The particles of the substance granulated copper are cylindrical with size higher than 1				

mm for one dimension (the length ranges between 0.9 and 6.0 mm with a mean at 2.1 mm) and with the other size below 1 mm (the width ranges between 0.494 and 0.949 mm with a mean at 0.706 mm) whereas the surface area of the substance granulated copper has been found to be 25.6 cm2/g which is significantly above the limit for massive. Therefore the substance granulated copper cannot be defined as massive form.
- The substance granulated copper cannot also be defined as a powder because the active substance is not classified by inhalation based on the particle size and copper powder can have lower particle size which will lead to a classification by inhalation."
In addition, depending on the grain size, copper powder is ignitable or combustible.
Based on this description it is not completely clear when a substance falls under the term "granulated" and when it is e.g. a powder. Additionally it is not clear whether all particle sizes between "powder" and "massive" are "granulated" forms. There is no official definition of the term "granulated".
Therefore, the German CA is of the opinion that the used term "granulated" should be clearly defined in this CLH report to give the concerned reader the possibility to decide whether his substance falls under the entry for "copper, granulated" or not.

Dossier Submitter's Response

We will add the specific surface area and size of the particle in the two tables: Table 1 (page 5) and Table 5 (page 10) in order to clearly specified what is granulated copper supported in this dossier.

RAC's response

Noted. We have added a description to the introductory section as provided in the CLH dossier and have no further information on this issue.

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2017	Belgium		Individual	3

Comment received

Having worked during my entire academic research career (since 1999) on bioavailability, ecotoxicity and risk assessment of metals, including copper, I would like to take the opportunity to provide a few comments on the "CLH report, proposal for harmonised classification and labeling, substance: copper, granulated" and provide suggestions for improvement. Based on my expertise, I will only comment on the ecotoxicity part (derivation of ERV values), and not on the human toxicology or any of the exposure parts e.g., (transformation/dissolution data). Also, although I appreciate that attempts have been made to take into account bioavailability considerations to some extent (notably through the DOC correction of toxicity values), I will not comment on anything related to these DOC corrections, since my group provided advice and assistance to ARCHE consulting (Heijerick et al.) on how to perform these DOC corrections.

Declaration of Conflict of Interest:
Since the start of my career as Ph D student (1999) until now, I have worked on various research projects that were funded by the copper industry. I currently have one ongoing project that is financially supported by the European Copper Institute, related to "population modeling in risk assessment". That said, according to my university's (Ghent University, Belgium) research policy, all our past and current research contracts with industry state things such as 'carrying out the research does not guarantee any pre-specified outcome' and 'while industry has the right to provide comments on draft publications, the researchers are not obligated to take these into account and have 100% freedom to publish their findings in the way they want'. In all our work for the copper industry (and any other industry), I have always operated in this way. I also wish to declare that my research group has provided advice and assistance to ARCHE consulting

(Heijerick et al.) on how to perform DOC normalizations for this project.
Dossier Submitter's Response
Your comment is noted.
RAC's response
This is a general comment, whereas the specific comment on ERV derivation (as referred to here) was inserted by the commentator under the hazard specific section (comment #13). RAC recognises that DOC normalization has been accepted by EU regulators for PNEC (and EQS) derivation purposes under the Biotic Ligand Model concept. In general, RAC thinks that it is appropriate to normalize data that are known to vary between tests due to specific factors (e.g. lipid content for BCF data), and this is especially important when data sets are large. In principle, preference could therefore be given to data that have been normalized for DOC levels of 2 mg/L. However, this results in omission of some studies for which DOC details are lacking, and is in any case based on the assumption that a trend established for a small number of species is applicable to all species in the data set. RAC considers this to be an uncertainty that should be recognized.

Date	Country	Organisation	Type of Organisation	Comment number
19.05.2017	Austria	Wirtschaftskammer Österreich	National Authority/Public body	4
Comment received				
see document attached ECHA note – A non-confidential draft attachment was submitted by mistake with the comment above (su_176_StN CLH CuGranulat.pdf). It was replaced later by a non-confidential final version (su_178_StN CLH CuGranulat.pdf).				
Dossier Submitter's Response				
Thank you for your comment. Regarding the comments related to the hazardous to the aquatic Environment, the proposed classification was based on the available data and followed the approach recommended in the CLP guidance document. Regarding your comment that refers to the comments of ECI 1 and 11, we propose you to see our answers on comments 1 and 11. Concerning the comment related to the economic impact of the classification, FR-MSCA understands this concern, but a CLH report is only based on scientific data. Therefore, this was not taking into account for the assessment.				
RAC's response				
Comment #4, #5, #8, #9, #14 and #15 are the same (and broadly similar points are made in comment #6 and #16). The potential downstream consequences of the proposed harmonised classification is not an issue within RAC's terms of reference. HH: Your comment about eye irritation is noted. See RAC's response to comment number 1. ENV: RAC notes the comment that classification as Aquatic Chronic 2 is not warranted for specific granulates with a surface area of 25.6 cm^2/g based on the European Copper Institute's interpretation of the extensive ecotoxicological database, but that there is a need for guidance on "rapid removal" for inorganic substances. See RAC's response to comment #1 and #11.				

Date	Country	Organisation	Type of Organisation	Comment number
19.05.2017	Austria	Austrian Non-Ferrous Metals Association	Industry or trade association	5

Comment received

Die harmonisierte Einstufung von Kupfergranulat hat weitreichende Konsequenzen, die weit über das Ziel hinausschießen.

Diese Einstufung hat untragbare Konsequenzen für Recyclingunternehmen, und stehen nicht im Einklang mit dem EU-Ziel einer funktionierenden Kreislaufwirtschaft.

Diese Regelung für Kupfergranulat würde Kabelrecycling in Europa beinahe unmöglich machen. In Österreich werden ca 20.000t Kabel recycelt und in Deutschland ca 200.000t, wobei der Kupfergehalt 40% beträgt.
Auch ein Elektronikschrottrecycling wird dadurch sehr erschwert.
Negative Konsequenzen ergeben sich insbesondere aufgrund des Zusammenspiels von Chemikalien- und Abfallrecht:
☐ Die Neueinstufung wirkt sich aufgrund des Anhang III der Abfallrahmenrichtlinie auch auf Abfälle aus (vgl. HP-Kriterien). Dadurch sind derartige Abfälle und solche, welche mit granuliertem Kupfer behaftet sind, als gefährlicher Abfall zu deklarieren.
☐ Dies wirkt sich negativ auf den Beschaffungsprozess von Recyclingunternehmen (insbesondere grenzüberschreitende Abfallverbringung) und auf die Behandlungsanlagen aus (Behandlung gefährlicher Abfälle; IPPC; Anlagengenehmigung usw.).
☐ Weiters sind durch die Behandlung von gefährlichen Abfällen bestehende Genehmigungen nach der Gewerbeordnung nicht mehr ausreichend und es müssen die Anlagen nach dem strengeren Abfallwirtschaftsgesetzt neu genehmigt werden.
☐ Voraussichtlich hat diese Einstufung auch negative Auswirkungen auf das Erreichen des Abfallendes (vgl. VERORDNUNG (EU) Nr. 715/2013), was demnach nicht mehr erreichbar sein könnte.

Zusammenfassung und Forderungen

Hinsichtlich der vorgeschlagenen harmonisierten Einstufung von Kupfergranulat fordern wir:

• keine Einstufung für Eye Irrit. 2, H319 vorzusehen,
• keine Einstufung für Aquatic Chronic 2, H411 vorzusehen und
• in eventu den Umfang der harmonisierten Einstufung auf bestimmte Granulate für Biozidanwendungen zu beschränken, und zwar für Granulate mit einer Oberfläche von 25.6 cm2/g, welche Gegenstand der Bewertung im Dossier waren.
Wir ersuchen um Berücksichtigung der von uns formulierten Bedenken und stehen für Rückfragen gerne zur Verfügung.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 170519 Einstufung Kupfergranulat.docx

Dossier Submitter's Response

Thank you for your comment.
This comment is similar to comment 4. Therefore, we propose you to see our answer here above.

Concerning eye irritation, as no study was available for eye irritation, a read across with coated copper flake was proposed. As the coated copper flake was considered as irritant by RAC, a classification for eye irritation is also proposed for granulated copper. This classification covers the possible exposure to the copper ions.
RAC's response
See RAC's response to comment #4.

Date	Country	Organisation	Type of Organisation	Comment number
19.05.2017	Belgium	European Recycling Industries' Confederation (EuRIC) AISBL	Industry or trade association	6

Comment received
The European Recycling Industries' Confederation (EuRIC) disagrees with the proposed future entry of granulated copper in Annex VI of CLP Regulation as: ☐ Eye Irrit. 2, H319; ☐ Aquatic Chronic 2, H411. With this regard, EuRIC fully supports the Comments on the proposal for harmonized hazard classification of Copper, Granulated submitted by the European Copper Institute and dated May 12, 2017. These comments provide sound scientific reasoning and point out the inconsistencies of the data presented in the CLH document. The harmonized hazard classification of granulated copper can have far-reaching implications that go much beyond the intended target by negatively impacting the recycling of copper which is instrumental in a circular economy.
Dossier Submitter's Response
Concerning eye irritation, as no study was available for eye irritation, a read across with coated copper flake was proposed. As the coated copper flake was considered as irritant by RAC, a classification for eye irritation is also proposed for granulated copper. This classification covers the possible exposure to the copper ions.
RAC's response
HH: Your comment about eye irritation is noted. See RAC's response to comment number 1. ENV: See RAC's response to comment #4.

OTHER HAZARDS AND ENDPOINTS – Eye Hazard

Date	Country	Organisation	Type of Organisation	Comment number
12.05.2017	Belgium	European Copper Institute	Industry or trade association	7

Comment received
2. Granulated copper is a form of copper defined by its particle size and specific surface area. This is shown in the photograph below for clarification of the physical nature of the substance. Due to the specific form of granulated copper, this substance is not suitable for testing in in vitro/ex vivo and in vivo eye irritation studies - see the picture in the attached file.

The OECD 405 eye irritation study states that for the testing of solids, “The test material should be ground to a fine dust. The volume of solid material should be measured after gently compacting it, e.g. by tapping the measuring container.” This would be very difficult to achieve for granulated copper. The substance is clearly a very coarse material which on contact with the eye could be considered as a possible cause of physical trauma. However, it would quickly be physically removed by anyone exposed to the substance because of its relatively large size.
For the purposes of classification, read across based on solubility is possible with other copper compounds e.g. copper oxide, copper sulphate pentahydrate, dicopper oxide and coated copper flake, for which eye irritation studies are available. Comparison of available transformation-dissolution data and results of eye irritation studies are presented in a table in the attached document. Based on this table, it is proposed that classification as an eye irritant for granulated copper is not warranted due to the specific form and size of granulated copper. Read across to other forms of copper/copper compounds also indicate that granulated copper should not be classified as an eye irritant based on solubility which could be an indicator of copper ion irritancy.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170512_ECI PC input FINAL.pdf
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment OSU AquaTox_Copper FHM_New pH 6_Draft Final Report_27 March 2017.docx

Dossier Submitter’s Response

Concerning eye irritation, as no study was available for eye irritation, a read across with coated copper flake was proposed. As the coated copper flake was considered as irritant by RAC, a classification for eye irritation is also proposed for granulated copper. This classification covers the possible exposure to the copper ions.

RAC’s response

Your comment about eye irritation is noted. See RAC’s response to comment number 1.

Date	Country	Organisation	Type of Organisation	Comment number
19.05.2017	Austria	Wirtschaftskammer Österreich	National Authority/Public body	8

Comment received

see document attached

ECHA note – A non-confidential draft attachment was submitted by mistake with the comment above (su_176_StN CLH CuGranulat.pdf). It was replaced later by a non-confidential final version (su_178_StN CLH CuGranulat.pdf).

Dossier Submitter’s Response

Concerning eye irritation, as no study was available for eye irritation, a read across with coated copper flake was proposed. As the coated copper flake was considered as irritant by RAC, a classification for eye irritation is also proposed for granulated copper. This classification covers the possible exposure to the copper ions.

RAC’s response

See RAC’s response to comment #4.

Date	Country	Organisation	Type of Organisation	Comment number
19.05.2017	Austria	Austrian Non-Ferrous Metals Association	Industry or trade association	9

Comment received

Die Einstufung als Eye Irrit. 2, H319, ist für Kupfergranulat wegen seiner spezifischen Form und Partikelgröße nicht gerechtfertigt, wie das European Copper Institute in dessen Eingabe richtig ausführt. Read across zu anderen Formen von Kupfer/Kupferverbindungen weist auch darauf hin, dass Kupfergranulat nicht als augenreizend einzustufen ist, wenn man von der Löslichkeit ausgeht, welche ein Indikator für die Augenreizbarkeit des Kupferions sein kann.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 170519 Einstufung Kupfergranulat.docx

Dossier Submitter's Response

Concerning eye irritation, as no study was available for eye irritation, a read across with coated copper flake was proposed. As the coated copper flake was considered as irritant by RAC, a classification for eye irritation is also proposed for granulated copper. This classification covers the possible exposure to the copper ions.

RAC's response

See RAC's response to comment #4.

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2017	United Kingdom		MemberState	10

Comment received

5.1 Degradation
We note at the end of this section that the concept of rapid environmental transformation and removal of copper has not been used based on the previous opinion of the RAC on this topic - and the lack of new guidance or information provided in this CLH Report (although it has now been included in the updated copper REACH registration dossier). Whilst we agree with the approach presented here - could we please flag for future consideration by the RAC that it would be useful to have further guidance developed on use of the rapid removal concept for hazard classification purposes.

5.4.1.1 Short-term toxicity to fish
We note and appreciate the thorough consideration of the data used to determine the acute (& chronic) aquatic classification, as well as factors which might influence this (e.g. DOM, hardness and pH). Regarding pH and the decision to apply geomeans only within the defined pH classes, whilst we understand the concept and the choice of pH bands (which can be linked to the transformation/dissolution study), we feel there could usefully be a discussion at the RAC regarding whether data used in geomean calculations need be restricted within certain pH bands/classes (which are arbitrarily or experimentally defined) or whether all of the data across a wider pH band considered to be environmentally relevant (e.g. 5.5-8.5?) could be included in the geomean approach? There are currently not always sufficient species endpoints (≥4) within some bands to apply a geomean hence the lowest value is used. There is no guidance on how the geomean should be applied where toxicity varies across pH - and taking a broader definition of environmentally relevant pH could lead to an increase in, e.g. the relevant

fish geomean LC50. This would not necessarily change the proposed 'no classification' for acute effects however (based on use of the transformation/dissolution protocol) - but it would provide useful guidance for future cases.

We feel there could also usefully be further guidance on whether/when unbounded values should be used in a geomean approach. We note EFSA has guidance on their use (or not) in SSDs for risk assessment (see section 8.3 in their guidance at: https://www.efsa.europa.eu/en/efsajournal/pub/3290) but no such guidance is available (as far as we can find) for geomeans and hazard classification. Also should the geomean only be applied to data on exactly the same species, or the taxonomic grouping across which the particular classification data point and 'trophic group' is 'pitched', i.e. 'fish' (provided studies and endpoints are comparable). The species-restricted approach taken for classification differs from how the geomean is applied in other regulations.

5.4.1.2 Long-term toxicity to fish
There is currently some resistance in other regulations to the use of geomeans with chronic endpoints; however we don't necessarily consider this invalid where studies and the basis for endpoints are comparable. It may need to be considered however, whether chronic geomeans should only be used where EC10s are available rather than mixing these with NOECs (as in Table 77) which are experimentally defined rather than regression values. Our same questions as above (for acute) will also apply though as to the pH band(s) and taxonomic level to apply when deriving a chronic geomean.

5.4.2 Aquatic invertebrates
Our same questions as above for fish acute and chronic geomeans are also relevant to the aquatic invertebrate assessment; although these are perhaps not so crucial in this particular case given the apparent greater sensitivity of fish. However, we are concerned that this section on 'invertebrates' only includes reference to data on daphnids. Whilst they might be considered a 'standard' species for classification and there are a lot of data on just Daphnia and Ceriodaphnia, we do not believe that it is the intention of CLP to exclude use of reliable and relevant data on other aquatic invertebrate species - as borne out by many previous decisions of the ECB and RAC. If daphnids are indeed well towards the sensitive end of any distribution of copper toxicity data on invertebrates, then a focus on them alone may be appropriate - but we would like to see some discussion included of the broader acute and chronic sensitivity of all aquatic invertebrates to copper (where reliable data are available). This could include sediment dwellers (section 5.4.5) where exposure and mean measured endpoints have been clearly determined via the water phase?

5.4.3 Algae and aquatic plants
Although not so sensitive to copper and thus important for classification - our same comments as above would apply relating to the derivation of geomeans only within certain defined pH bands, only within species and the mixing of chronic NOErCs and ErC10s.

5.5 Comparison with criteria for environmental hazards (sections 5.1 – 5.4)
We agree in principle with the use of transformation/dissolution studies to determine the dissolution potential of copper ions from a relatively large bulk form of metal such as granulated copper. We note this CLH does not apply to nanoforms of copper, which should ideally be considered separately and only using dissolution studies relevant to them. Provided the one reliable (ECTX, 2016b) study is considered by RAC to be sufficient and representative enough for this purpose, it could therefore be used to propose no acute classification for granulated copper and a chronic classification of

Chronic 2.

Dossier Submitter's Response

5.1 Degradation

Thank you for your comment. We support UK proposal to flag this point for future consideration by the RAC and the need for further development on use of the rapid removal concept.

5.4.1.1 Short-term toxicity to fish / 5.4.1.2 Long-term toxicity to fish / 5.4.3 Algae and aquatic plants

Thank you for your comment. We support a need for discussion at the RAC level to clarify:
- the use of the geometric mean or the lowest value when less than 4 data are available for a pH band and more than 4 data available whatever the pH band.
- the use of the geometric mean or the lowest value when less than 4 data are available for a pH band for an effect (e.g. *S. fontanilis* for which only 3 data are available at pH7 for reproduction and 4 data for growth or mortality effects);
- whether and when unbounded values should be used in a geomean approach.
- the use of geomean on the same species or at a 'trophic group'.
- consideration of EC10s and/or NOEC in the chronic geomean.

5.4.2 Aquatic invertebrates

Data on other aquatic invertebrates with some of 'non-standards' species for classification purposes are available in the EU RAR (2008)- table 3-11 in Chapter 3.2.2.2.8. You could find an extract of the aquatic invertebrates of this table here below.

Taxonomic group	Non- Normalised "species mean" NOEC values (µg Cu/l)
Rotifer	33.5 (*Brachionus calyciflorus*; n=4; intrinsic rate of growth)
Molluscs	8.0 (*Campeloma decisum, n=2; mortality); 6.0 (Juga plicifera, n=1; mortality); 19.1 (Villosa iris, n=1; mortality); 18.3 (Dreissenia polymorpha, n=2; filtration rate)*
Cladocerans	13.1 (*Ceriodaphnia dubia, n=10; reproduction*); 12.6 (*Daphnia magna, n=1; growth*); 14.5 (*Daphnia pulex, n=9; mortality*)
Insects	10.4 *(Clistoronia magnifica, n=2; reproduction/mortality*); 16.9 (*Chironomus riparius, n=1; growth*); 40.0 (*Paratanytarsus parthenogeneticus, n=2; growth/reproduction*)
Amphipods	11.0 (*Gammarus pulex, n=1; reproduction*); 50.3 (*Hyalella azteca, n=6; mortality*)

This table had been including in the previous copper CLH reports and was mentioned only as supportive data.

The lowest value reported in this table is 6 µg/L for the mollusc *Juga plicifera*. However, it should be noted that only one value is available for this non-standard specie, and this value, reported at pH 7, is very similar to the current chronic ERV.

5.5 Comparison with criteria for environmental hazards (sections 5.1 – 5.4)

Thank you for your support. As you mentioned, the D/T study are not available for nanoforms of copper and therefore not considered for this classification proposal.

RAC's response

5.1 Degradation

RAC agrees that there needs to be further discussion of the rapid removal concept, but that this needs to take place at a global level given its importance to the implementation of the GHS.

5.4.1.1 Short-term toxicity to fish / 5.4.1.2 Long-term toxicity to fish / 5.4.3 Algae and aquatic plants
RAC agrees that there is a need to provide further clarity on:
- the use of the geometric mean or the lowest value when less than 4 data are available for a species in a particular pH band but more than 4 data available in the whole data set;
- the use of the geometric mean or the lowest value when less than 4 data are available for a pH band for an effect (e.g. *S. fontanilis* for which only 3 data are available at pH 7 for reproduction (though see also comment #1));
- whether and when unbounded values should be used in a geomean approach;
- the use of geomean on an individual species or at a 'trophic group' level; and
- consideration of whether to combine EC_{10}s and NOECs in the chronic geomean.

A response is provided in the opinion, but these could also usefully be discussed at a global level given the implications for the GHS.

5.4.2 Aquatic invertebrates
RAC agrees with the comment that further invertebrate species beyond *Daphnia magna* and *Ceriodaphnia* need to be considered, and notes the provision of the EU RAR (2008) data table by the Dossier Submitter, which was also taken into account for the previous RAC opinions for copper compounds. However, in the absence of data on pH, etc., it is difficult to use this in the context of this proposal where the data have been grouped based on abiotic factors. RAC requested additional information from the Dossier Submitter on this issue, and a summary is provided in the opinion.

RAC notes that the lowest value reported in this table is 6 µg/L for the mollusc *Juga plicifera*. However, since this is a non-standard species and the study is unlikely to have followed any standard test guideline, it may be appropriate to give it a low weighting in the assessment. In principle, RAC recommends that data should be considered for the purposes of hazard classification of copper:

- focussing on species that may have higher sensitivity in the pH band 5.5 – 6.5,
- preferably normalized to a DOC level of 2 mg/L, and
- with hardness levels within the range of standard test guidelines.

5.5 Comparison with criteria for environmental hazards
RAC notes the support for classification as Aquatic Chronic 2, and has added a note to the opinion that nanoforms of copper have not been considered for this classification proposal.

Date	Country	Organisation	Type of Organisation	Comment number
12.05.2017	Belgium	European Copper Institute	Industry or trade association	11

Comment received

Note - for tables and figures, and for an overview of these comments which is easier to read, please refer to the attached document.

3. Regarding "rapid removal from the water column", the proposal states (page 140) that "as there is no new guidance available about the "rapid removal concept" for metal compounds, [new considerations on rapid removal] were not further considered in this dossier." Indeed, there is a need for guidance on applying "rapid removal" to inorganic substances, in order to create a level playing field for all substances. The weight-of-

evidence discussed in the copper REACH registration dossier shows that copper is rapidly removed from the water column for the purpose of hazard classification.

4. Regarding the species used for environmental classification (page 142-144), the proposal uses standardized methods, species, and endpoints as the basis for hazard classification of Granulated copper. We agree with the choices described for the selection of standard fish, daphnid and algae/plant species as described on page 143-144. This ensures that environmental hazard classification of substances is a comparative exercise, creating a level playing field for all substances. Furthermore, the ecotoxicity database of copper contains almost 800 acute and 200 chronic data points on standard species. Such a rich database allows to reliably derive a hazard classification.

5. In 2014, RAC identified a lack of copper ecotoxicity data to fish at low pH. The classification proposal now includes recent fish chronic ecotoxicity data, which were added to the ecotoxicity database (pages 147, 154 and 155). We support the inclusion of these data on P. promelas and O. mykiss at low pH, generated by Oregon State University (OSU, 2016a and 2016b), for hazard assessment of copper. The toxicity thresholds show that the chronic sensitivity of both fish species does not largely differ between pH 6 and pH 7. For O. mykiss, the most sensitive endpoints at each pH resulted in EC10 values of 28.2 µg/L at pH 6 versus 38.8 µg/L at pH 7. For P. promelas, the various tests allowed to conclude that there is no significant relationship between pH and Cu toxicity over the range of pH conditions tested (Figure 1 in the attached file).
In summary, the available data on 2 species show that the chronic sensitivity of fish at pH 6 is similar to that at pH 7.
The proposal also considers that the OSU (2016b) data may replace the Ng et al. (2010) data for hazard classification (page 154). The O. mykiss data by OSU (2016b) were obtained under conditions similar to the Ng et al. (2010) study, but the OSU (2016b) data had real replicates and statistical assessment, organisms acclimated to low pH, and pre-equilibrated test waters. Therefore, we agree that the OSU (2016b) data can substitute for the Ng. et al. data. However, it should be noted that the Ng et al. data also confirmed that there were little or no sensitivity differences to fish between pH 6 and 7.

6. The proposal uses, in some cases, the lowest value when grouping ecotoxicity data in the same pH band and for the same endpoint (pages 146 and 191-192). Considering the CLP guidance, given the data-richness of copper, and given the multiple data available for the same species, we suggest the geometric mean can always be used for grouping data within the same pH band and for the same endpoint. The CLP guidance v. 4.1 (section 4.1.3.2.4.3., p. 500-501) specifies that data grouping must be dealt with on a case-by-case basis. “When larger data sets (four or more values) are available for the same species, the geometric mean of toxicity values may be used as the representative toxicity value for that species.” (CLP Guidance, v. 4.1, 4.1.3.2.4.3., p. 500-501). The CLP guidance does not mention that the use of geometric means would be restricted to cases with four or more values within each pH band.
The CLP guidance furthermore states that statistical techniques can be used in a weight-of-evidence approach when setting toxicity reference values for data-rich substances: “In case of very large data sets meeting the criteria for applying the Species Sensitivity Distribution (SSD) approach (see IR/CSA, Chapter R.10), statistical techniques (e.g. HC5 derivation) can be considered to estimate the aquatic toxicity reference value for classification (equivalent to using the lowest EC50 or NOEC), in a weight of evidence approach.” The copper ecotoxicity dataset is extremely data-rich, with close to 800 acute and 200 chronic data points for standard species for hazard classification. However, following the criteria mentioned in Chapter R.10, there are insufficient standard species to use an SSD approach. It seems therefore not straightforward to apply this technique for copper hazard classification.

A statistical technique that can be used more easily for copper hazard classification, is bootstrapping. This method was used to simulate the outcome of a hazard assessment if copper would be a data-poor substance. One acute and one chronic data point was randomly selected for each taxonomic group, and the corresponding acute and chronic ERVs were determined. This statistical technique was repeated 2000 times and results in a probabilistic distribution of ERVs for copper. The median value of such distribution represents the most likely ERV (and associated classification) if copper would have been a data-poor substance (cfr. the data-poor approach for inorganic sparingly soluble metal compounds). The bootstrapping analysis resulted in an expected acute ERV of 29.4 µg/L and a chronic ERV of 13.8 µg Cu/L. These values are more than a factor of two above some of the ERVs put forward in the classification proposal. Hazard classification should create a level playing field for all substances, and data-rich substances should not be classified more stringently than data-poor substances.
Given the weight of evidence, and referring to the “case-by-case assessment” for data-rich substances mentioned in the CLP guidance, it is appropriate to always use the geometric means to group the data within each pH band and endpoint. The following comments specifically address how the ERVs change based on this approach. Table 1 in the attached document provides an overview of the critical cases where the method for data grouping influences the ERV.

6.1. The proposed acute ERV at pH 7 (page 187) was derived for D. rerio. In total, there are 5 values available for D. rerio across all pH bands. Therefore, the geometric mean can be used for grouping the data within each pH band, as reported in the white lines of Table 90 (page 187) of the classification proposal. This means that, within the pH 7 band, the value for D. rerio should be calculated as the geometric mean of two available values (11.7 and 35 µg/L), which equals 20.24 µg/L. Likewise, within the pH 8 band, the value for D. rerio should be calculated as the geometric mean of three available values (148.4, 149, and 212.1 µg/L), which equals 167.4 µg/L.
It must furthermore be noted that ample data on the acute toxicity of copper to other fish species are available, with a very high number of data points across all pH bands (P. promelas, 258 data points, and O. mykiss, 77 data points).

6.2. The proposed chronic ERV at pH 6 (page 188) of 8.7 µg/L (endpoint: growth, lowest value out of 3 values) is based on P. promelas data. In total, there are 35 values available for P. promelas across all pH bands, and 13 values for the growth endpoint alone. Therefore, the geometric mean can be used for grouping the P. promelas data within each pH band.
This is further substantiated by the observation that the chronic sensitivity of fish to copper does not strongly differ between pH 6 and 7 .
Furthermore, an additional P. promelas chronic study at pH 6 has been conducted at Oregon State University for this species (OSU, 2017). The study OSU, 2017 was additionally obtained in March 2017. Its experimental setup was identical to the OSU, 2016a study, but the exposure concentrations were different in order to avoid the unbounded toxicity thresholds reported in OSU, 2016a. The OSU, 2017 data have not yet been included in the classification proposal by the competent authority or in the REACH registration dossier of copper, and therefore the study report is provided as confidential attachment to these comments. The reported EC10 values are 18.9 µg/L for mortality and 25.2 µg Cu/L for growth (as mean dry weight). By adding these two new values to the chronic data set, the geometric mean values are now based on four values, and can therefore replace the lowest value. The geometric mean values for mortality and growth are now 13.3 µg Cu/L and 13.9 µg Cu/L, respectively.
The chronic ERV at pH 6 then becomes 13.2 µg/L (D. magna reproduction; geometric mean of 7 values).

6.3. The proposed chronic ERV at pH 7 is 5.9 µg/L, based on P. promelas (endpoint mortality, lowest value out of 3 data points), closely followed by S. fontinalis (6.4 µg/L, endpoint reproduction, lowest value out of 3 data points) (page 188).
6.3.1. For P. promelas, there are in total 35 values available across all pH bands, and 11 values for the mortality endpoint alone. The proposed value of 5.9 µg/L stands out compared to all other values at different pH and for different endpoints. In addition, the chronic sensitivity of fish to copper does not strongly differ between pH 6 and 7 (see footnote 3). Given the weight of evidence, the geometric mean should be used for grouping P. promelas mortality data within the pH 7 band. The geometric mean for P. promelas at pH 7 is 12.0 µg/L (mortality, n=3) as reported in Table 91 of the classification proposal.
6.3.2. For S. fontinalis, there are in total 11 values available across all endpoints within the pH 7 band. An additional study on reproduction of S. fontinalis reports unbounded NOECs (no effects on reproduction at the highest concentration of 9.4 µg Cu/L, McKim and Benoit, 1974). Due to uncertainty related to the pH during this test, it should normally not be used for deriving the ERV. The data can, however, be used as supporting information to justify the use of a geometric mean. The geometric mean for reproduction of S. fontinalis at pH 7 becomes 15.9 µg/L (n=3), or 14.0 µg/L (n=4) if the unbounded NOEC from McKim and Benoit is used.
With the above considerations, the chronic ERV at pH 7 becomes 12.0 µg Cu/L (P. promelas, growth and mortality).

7. We agree with the transformation-dissolution approach used in the proposal (page 190-191): surface area-based transformation-dissolution data that are obtained with granulated copper as test substance, and the use of the measured specific surface area of the substance to calculate the metal release after 7 and 28 days. The metal release per unit surface is an intrinsic property of the material.

8. We support comparison of the transformation-dissolution data and the ERV at the same pH (page 191), which is in accordance with the CLP guidance (section IV.2.3, p. 586). However, based on the ERVs derived as discussed above, the conclusion should be “no classification” (Table 2 in the attached document).

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170512_ECI PC input FINAL.pdf
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment OSU AquaTox_Copper FHM_New pH 6_Draft Final Report_27 March 2017.docx

Dossier Submitter’s Response

Thank you for your comments

- Point 3

This comment is related to the concept of “rapid removal from the water column”. Industry argues that a weight-of-evidence is discussed in the copper REACH registration dossier and shows that copper is rapidly removed from the water column for the purpose of hazard classification. Nevertheless, we are still thinking that a clear guidance should be developed to have an harmonized approach on this concept. See also our answer on comment 10.

- Point 4

We have noted that Industry agrees with the database used for hazard classification purposes.

- Point 5

We have noted that Industry agrees that the OSU (2016b) data can substitute for the Ng. et al data. And, they note that the Ng. et al data also confirm that there were little or no sensitivity differences to fish between pH6 and 7. This sensitivity was observed in the new studies generated by Oregon State University (OSU, 2016 a and 2016 b).

- Point 6

Industry suggests that the geometric mean can always be used for grouping data within pH band and for the same endpoint due to the data-richness of copper.
Therefore, for the acute ERV at pH7, Industry proposes to use the geometric mean of 17 values on *C. dubia*, which is equal to 14.0 µg/L instead of the lowest value of 11.7 µg/L issued from a *D. rerio* toxicity study.
Following the same approach, Industry proposes a chronic ERV equal to 12 µg/L at pH7 instead of 5.9 µg/L.

It should be noted that to analyse the impact of the use of geomean or lowest value if less than 4 data points are available, both approach were presented in this CLH report. In case of granulated copper, as we have mentioned in section 5.5 Comparison with criteria for environmental hasards, there is no impact for acute classification of granulated copper if the acute ERV calculated using the geomean even when less than 4 data are available.
However, as it is suggested by the comment 10, we support a need for discussion at the RAC level to clarify:
- the use of the geometric mean or the lowest value when less than 4 data are available for a pH band and more than 4 data available whatever the pH band;
- the use of the geometric mean or the lowest value when less than 4 data are available for a pH band for an effect (e.g. *S. fontanilis* for which only 3 data are available at pH7 for reproduction and 4 data for growth or mortality effects);
- whether and when unbounded values should be used in a geomean approach;
- the use of geomean on the same species or at a 'trophic group'(as raised by comment 10);
- consideration of EC10s and/or NOECs in the chronic geomean (as raised by comment 10).

In comment 6.2, it should be noted that European Copper Institute submits a draft of a new chronic study on *P. promelas* conducted at pH6 at Oregon State University (OSU, 2017). This study seems to have an impact on the derivation of the chronic ERV at pH 6 which could be equal to 13.2 µg/L instead of 8.7 µg/L due to the possibility to apply the geometric mean as 4 values are available with this additional data at pH 6. However, this study is only a draft report and therefore could not be considered at that time. Moreover, if the rules stated in the current CHL report is kept, granulated copper is still classify Chronic 2 at pH 7.

- Point 7

Noted. Thank you for your comment.

- Point 8

Considering the approach followed by Industry, they propose not to classify granulated copper. However, this conclusion depends on the discussion at the RAC level regarding the geometric mean or the lowest value.

RAC's response
RAC notes that these are the same comments provided in the attachment to comment #1, where RAC's replies are provided.

Date	Country	Organisation	Type of Organisation	Comment number
19.05.2017	Belgium	Eurometaux	Industry or trade association	12

Comment received

The Granulated Copper classification proposal raises some relevant and important conceptual and methodological aspects related to the environmental classification of metals and data rich substances. We noted from previous cases that specificities related to the environmental classification of metals and/or to data-richness, have raised some concerns in RAC due to the specificity/complexity of the ruling as outlined in the metals CLP text and guidance.
It is in this respect that Eurometaux provides herewith some supportive comments and suggestions from a conceptual perspective, while directly relevant to the Granulated Copper case.
We have been informed on the Copper sector's specific comments as well as on the additional data and information provided by the Copper sector. We noted that those are in agreement with the conceptual/methodological comments raised here below. Therefore, the remarks made by Eurometaux are supporting the comments from the copper sector.
We would like to state from the start that the environmental section of the data rich Granulated Copper file as prepared by France is well conducted and of high quality.
Several of our remarks are therefore supportive in nature, in particular:
- The recognition for the additional ecotoxicity (fish at low pH) data conducted and submitted by the Copper sector in follow-up of the outstanding question of the RAC opinion forming on Copper Flakes
- The way how Transformation-dissolution data (OECD 29) was applied (surface based)
- The way how the ecotoxicity data sets were selected for this data rich file (use of standard species,…)
In the comments hereunder we focused on the conceptual relevance and outstanding issues and made some further suggestions for the Dossier Submitter's consideration.

Recognition of the RAC recommendation to complete a data gap for low pH

In its opinion on Copper flakes, RAC concluded to a data gap on long-term data for the fish species P. promelas at the low pH end. Eurometaux notes that industry completed the data gap and even added an additional standard species. All this new evidence was fully recognised in the environmental classification proposal (pages 147, 154). We appreciate this and would like to know how this would now impact the previously assessed Copper-flakes dossier. Indeed, the results of these 2 new fish tests indicate that there is "no significant relationship between pH and long-term copper toxicity at the lower pH end". This means that the Copper ion toxicity at low pH was not as low as "assumed" in the classification opinion on Copper flakes. This should in our opinion be corrected.

The appropriate use of Transformation dissolution data to derive the environmental classification
The release/surface is an intrinsic property of a metal or a sparingly soluble metal compound, a recognised property in Environmental hazard assessment Eurometaux notes the use of 7 and 28 days Transformation-Dissolution data with granulated copper as the test substance. The transformation dissolution release rate and levels were compared with the respective acute and chronic ERVs on a comparable pH basis to derive the classification level (p 191). This approach is correctly applied in a substance specific way. It is probably important to reconfirm that the results are applicable to the substance tested, i.e. to the granulated Copper only.

Rapid Removal from the water column for Chronic Environmental hazard ID for metal-ions

The CLP legal text refers -for the environmental long term classification- to the potential to demonstrate degradability and for metals more specifically “rapid removal from the water column”. We noted that the proposal for Granulated Copper does not include an assessment of the rapid removal from the water column referring to “the lack of guidance” (p 140). Extensive evidence for Cu ion (as well as for many other metal ions) is available (from the Registration dossiers on Cu) and was also transferred in an integrated package to ECHA in 2012 in follow-up of a workshop aiming at defining potential guidance (held in February 2011). The lack of guidance can in our view not be used as a valid argument to further reject this principle for the metals given the legal text foresees the principle being applicable to metals. We noted that the copper sector has not provided further evidence in their submission. In such case we would like to request RAC to conclude that “the evidence for such demonstration was not part of the submitted data set”, i.e. not being the consequence of missing guidance. Moreover, we feel that postponing the development of such guidance puts the metals sector in a non-level playing field situation with the organic sector and other jurisdictions.

Data selection for data rich substances
The ecotoxicity data base refers to high-quality data for the copper ion obtained from soluble salt experiments. Copper is widely studied resulting in hundreds of data points on acute and long term (chronic) endpoints, for many standard, non-standard, generic and endemic species. We noted that like for previous metal environmental classification assessments, the rapporteur focussed on standard species to ensure a level playing field for the hazard assessment.
Alternatively, the CLP guidance allows for very large data sets to apply statistical techniques based on grouping and/or Species Sensitivity Distribution and other.

Data grouping and statistics for data rich substances
For large data sets covering multiple experiments for the same biological species for the same endpoint, it is assumed they cover a “range of conditions”. The GHS and CLP guidance therefore foresee that for “larger data sets (four or more values) for the same species, the geometric mean of toxicity values may be used as the representative toxicity value for that species.” (CLP Guidance, v. 4.1, p. 500-501).
This approach was applied by the submitting country but on a pH band basis, thereby further splitting the data set before applying this data grouping rule. Neither the CLP nor the GHS makes reference to such an additional criterion to split data sets, neither was this done in the past for other data rich metals. The CLP reference referring to “a case-by-case check on the relevance of grouping” was intended to ensure that data sets covered some variability of conditions (not all done in the same laboratory with the same genetic strain, for example).
EUROMETAUX is therefore of the opinion that this additional splitting of the data set before applying the grouping by using the geometric mean, is difficult to justify extension of the GHS and CLP requirements. Moreover, not applying geometric means for extensive data sets would –purely for statistical reasons- result in lower ERVs when the data base becomes larger, which is contrary to the reduced uncertainty.
Assessment methods that make full use of the entire selected data set should be promoted. For metals this includes normalisation techniques (with BLMs) that allows for assessing the impact of relevant factors on toxicity data sets. This prevents using only parts of the data set to assess the impact of pH.

Thank you for considering these comments

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Eurometaux comments on CLH proposal granulated copper.pdf

Dossier Submitter's Response
Thank you for your comments • Concerning the impact of the new data on the previously assessed Copper-flakes dossier, FR-MSCA would like to remind that the conclusions of the dossier are not yet validated by RAC. This question could be raised at this time. • The appropriate use of Transformation dissolution data to derive the environmental classification We agree that it is important to reconfirm that the results of the T/D release rate and levels compared with the acute and chronic ERV is substance specific and therefore only applicable to the substance tested in the T/D study. • Rapid Removal from the water column for Chronic Environmental hazard ID for metal-ions: Eurometaux notes that the copper sector has not provided further evidence in their submission and request RAC to conclude that "the evidence for such demonstration was not part of the submitted data set", instead of the consequence of missing guidance. For this point, we propose to refer to our answer on comments 10 and 11. • Data selection for data rich substances and Data grouping and statistics for data rich substances Thank you for your comments. For these points, we propose to refer to our answers on comments 10 and 11 related to a need for discussion at the RAC level to clarify: - the use of the geometric mean or the lowest value when less than 4 data are available for a pH band and more than 4 data available whatever the pH band. - the use of the geometric mean or the lowest value when less than 4 data are available for a pH band for an effect (e.g. *S. fontanilis* for which only 3 data are available at pH7 for reproduction and 4 data for growth or mortality effects); - whether and when unbounded values should be used in a geomean approach. - the use of geomean on the same species or at a 'trophic group'. - consideration of EC10s and/or NOEC in the chronic geomean.
RAC's response
RAC notes that the comments submitted by Eurometaux are generally supportive of the comments from the copper industry (#1). Additional data have been provided for chronic fish toxicity at acidic pH in response to issues highlighted in the opinion for copper flakes (see comment #1). Eurometaux has asked how this information will be taken into account for the classification of copper flakes, but RAC has not been asked to consider this issue. In principle, a new CLH dossier should be submitted, once RAC has given its opinion on the data set and approach for granulated copper. RAC also notes that Eurometaux supports the way that surface-based transformation-dissolution data have been used, as well as their statement that "it is probably important to reconfirm that the results are applicable to the substance tested, i.e. to the granulated Copper only." RAC agrees, and has added a statement to the opinion to this effect. Eurometaux noted that the proposal does not include an assessment of rapid removal from the water column due to "lack of guidance" (p 140). They disagree that lack of guidance is a valid argument to reject the principle, but note that the copper industry did not provide further evidence in their submission. They therefore ask RAC to conclude that "the evidence for such demonstration was not part of the submitted data set", rather than highlight

missing guidance. RAC agrees that this lack of submitted evidence should be noted in the opinion. Nevertheless, given the implications for many other metals (not just copper), RAC considers that it is important for further discussion of the principles and issues to take place at a global level (as pointed out in the reply to comment #11).

Eurometaux also supports the use of standard species for hazard classification purposes. RAC agrees, provided that all relevant standard species are included, contrary to the approach adopted in the CLH report (see also our reply to comment #1). In their view, the CLP reference about "a case-by-case check on the relevance of grouping" was intended to ensure that data sets covered some variability of conditions (not all done in the same laboratory with the same genetic strain, for example). Eurometaux therefore considers that the additional splitting of the data set without allowing use of the geometric mean is difficult to justify and results in lower ERVs when the data base becomes larger, which is contrary to the reduced uncertainty provided by the available information. RAC agrees that there needs to be a way of avoiding the default selection of a very low value from a large data set due to the method of splitting the information, provided that factors that can affect the variability in toxicity are fully considered. RAC therefore agrees that relevant normalization techniques (e.g. BLMs) should be considered. The only technique presented in the CLH dossier is DOC normalization, and RAC is open to the idea of using additional approaches (such as the BLM and also statistical methods such as bootstrapping) to help provide further insight and weight for the final conclusion. However, this is currently missing from the documentation provided, and is not essential for a conclusion.

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2017	Belgium		Individual	13

Comment received

I would like to acknowledge the great deal of work that must have been invested in compiling and updating the acute and chronic ecotoxicity data, resulting in a very large dataset (a few hundreds of acute and chronic data points, it seems). That being said, I have some considerable concerns related to the fact that the data-richness and existing aquatic bioavailability knowledge seem to remain underused at some points along the process of ERV derivation. As a consequence, uncertainty of the assessment seems not to have been reduced to the lowest level that was possible, given the available data and scientific knowledge.
First of all, a large part of the discussion in the report seems to concentrate on the choice of using the lowest toxicity value vs. the geometric mean of toxicity values per species/endpoint. This choice appears to depend on an arbitrary threshold of 4 available data points, without any scientific justification as to why this threshold should be 4. If n<4 then the lowest value should apparently be taken (and the geometric mean should not be used). Since not all species seem to meet this arbitrary criterion in all pH bands, the summary tables of ecotoxicity values (Table 90, 91) seem to end up as a mix of choices that have been made (minimum vs. geomean), depending on species, endpoint and pH band considered. Even the scenario in which the "geomean is used even when less than 4 data are available" seems to contain arbitrariness, as still the minimum toxicity value is used for S. fontinalis instead of the geomean (Table 93).
I do acknowledge the authors of the report for their detailed comparative analysis of the consequences for the hazard classification of these arbitrary choices, but even then, none of the approaches (minimum or geomean or mix) makes appropriate use of the richness of the dataset. The arbitrariness (i.e. why would 4 data points be needed to allow geomeans to be used?) can easily be overcome via a probabilistic approach (e.g. asking 'what is the most likely ERV given all the data'?). A probabilistic approach could provide an estimate of e.g. a median expectation for the true ERV value, devoid of any arbitrary choices to be made.

At least equally concerning is another possible consequence of the arbitrariness and mix of choices, as referred to above. If different choices (lowest value vs. geomean) are made for different species or different pH bands, which I do think is the case right now, then this might obscure the 'normally' expected relation between pH and copper toxicity to fish, invertebrates and algae. Considering the overall discussion and information provided in Tables 90-93, I expect this potential issue most important to further consider for fish toxicity data. It would be very worthwhile to compare the effect of pH on selected toxicity values in Table 90-91 with data from specific studies who have experimentally investigated effects of pH on toxicity (e.g. Erickson et al., 1996, ET&C and the two more recent studies cited in the report, e.g. Ng et al., 2010 and OSU, 2016). It could also be useful to integrate these results in the BLM and to subsequently compare the ERVs to predictions made by the BLM. I would like to summarize and conclude as follows (based on the above): The threshold of at least 4 data points to use geometric mean toxicity values (instead of minimum) seems arbitrary without any scientific justification, does not do justice to the data-richness of the dataset and could have obscured the bioavailability relationship between pH and the derived ERV values. Therefore: - I strongly recommend to consider a probabilistic approach to overcome this arbitrariness - I strongly recommend to do a reality check of the relation between pH and selected ERV values, based on specific experimental studies that have investigated effects of pH on copper toxicity, notably for fish
Dossier Submitter's Response
Thank you for your comments. It should be reiterated that the threshold of at least 4 data points to use geometric mean toxicity values (instead of minimum) is directly issued from the CLP guidance v4.1 (or CLP guidance v5 section 4.1.3.2.4.3 p.502). The CLP Guidance also mentioned in this same section that: in case of very large data sets meeting the criteria for applying the Species Sensitivity Distribution (SSD) approach (see IR&CSA, Chapter R.10), statistical techniques (e.g. HC5 derivation) can be considered to estimate the aquatic toxicity reference value for classification (equivalent to using the lowest EC50 or NOEC), in a weight of evidence approach. Nevertheless, as raised in comment 11, the copper ecotoxicity dataset is extremely data-rich, with close to 800 acute and 200 chronic data points for standard species for hazard classification. However, following the criteria mentioned in Chapter R.10, there are insufficient standard species to use an SSD approach. We therefore propose to refer to our answers on comments 10 and 11 related to a need for discussion at the RAC level to clarify: - the use of the geometric mean or the lowest value when less than 4 data are available for a pH band and more than 4 data available whatever the pH band. - the use of the geometric mean or the lowest value when less than 4 data are available for a pH band for an effect (e.g. *S. fontanilis* for which only 3 data are available at pH7 for reproduction and 4 data for growth or mortality effects); - whether and when unbounded values should be used in a geomean approach. - the use of geomean on the same species or at a 'trophic group'. - consideration of EC10s and/or NOEC in the chronic geomean.
RAC's response
RAC notes the comments about the apparent "arbitrary" threshold of 4 available data points to be able to use a geometric mean. This is a technical policy decision that has been agreed

at global level (much as the selection of toxicity thresholds to distinguish different levels of hazard is arbitrary). Before we deviate from it, further discussion is needed although as pointed out in comment #1, the CLP guidance does allow case-by-case assessment for data-rich substances. RAC agrees that the richness of the dataset should be reflected, but so too does its limitations regarding species selection and availability of data in the apparently more sensitive acidic pH range. Comment #1 also refers to a probabilistic approach to provide an estimate of the true ERV value. RAC is open to this suggestion, but has not been presented with a detailed proposal.

RAC agrees that it would be worthwhile to perform a "reality check" of the relationship between pH and selected ERV values based on specific experimental studies that have investigated effects of pH on copper toxicity, notably for fish (e.g. Erickson et al., 1996; Ng et al., 2010; and OSU, 2016), provided that these followed typical standard approaches to measuring acute/chronic toxicity. It could also be useful to compare the ERVs to predictions made by the BLM. Such an analysis has not been performed by the Dossier Submitter or provided during public consultation.

Date	Country	Organisation	Type of Organisation	Comment number
19.05.2017	Austria	Wirtschaftskammer Österreich	National Authority/Public body	14

Comment received

see document attached

ECHA note – A non-confidential draft attachment was submitted by mistake with the comment above (su_176_StN CLH CuGranulat.pdf). It was replaced later by a non-confidential final version (su_178_StN CLH CuGranulat.pdf).

Dossier Submitter's Response

Please refer to our answer on comment 4.

RAC's response

See RAC's response to comment #4.

Date	Country	Organisation	Type of Organisation	Comment number
19.05.2017	Austria	Austrian Non-Ferrous Metals Association	Industry or trade association	15

Comment received

Die Einstufung für Aquatic Chronic 2, H411, ist bei richtiger Interpretation und Heranziehung der in großem Umfang verfügbaren ökotoxikologischen Daten zu Kupfer nicht gerechtfertigt. Wie das European Copper Institute richtig ausführt, besteht für inorganische Stoffe Bedarf nach einer Leitlinie /Guidance-Dokument zu „rapid removal", um ein level playing field herzustellen. Zu berücksichtigen sind auch ökotoxikologische Studien zu geringem pH-Wert, und dass die „richtige" Methode für das Grouping von Daten angewendet wird. Wir verweisen dazu auf die umfangreiche Kommentierung des European Copper Institute.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 170519 Einstufung Kupfergranulat.docx

Dossier Submitter's Response

Please refer to our answer on comment 5.

RAC's response
See RAC's response to comment #4.

Date	Country	Organisation	Type of Organisation	Comment number
19.05.2017	Belgium	European Recycling Industries' Confederation (EuRIC) AISBL	Industry or trade association	16
Comment received				
The classification for Aquatic Chronic 2 - H411, is not justified when taking into account the extensive ecotoxicological data for copper and their proper interpretation, as the European Copper Institute correctly explains.				
Dossier Submitter's Response				
Please refer to our answer on comment 11.				
RAC's response				
See RAC's response to comment #4.				

OTHER HAZARDS AND ENDPOINTS – Physical Hazards

Date	Country	Organisation	Type of Organisation	Comment number
10.05.2017	Germany		MemberState	17
Comment received				
At least one specific comment must be added				
Dossier Submitter's Response				
RAC's response				
–				

PUBLIC ATTACHMENTS
1. su_178_StN CLH CuGranulat.pdf [Please refer to comment No. 4, 8, 14]
2. 170519 Einstufung Kupfergranulat.docx [Please refer to comment No. 5, 9, 15]
3. Eurometaux comments on CLH proposal granulated copper.pdf [Please refer to comment No. 12]
4. 20170512_ECI PC input FINAL.pdf [Please refer to comment No. 1, 7, 11]

CONFIDENTIAL ATTACHMENTS
1. OSU AquaTox_Copper FHM_New pH 6_Draft Final Report_27 March 2017.docx [Please refer to comment No. 1, 7, 11]