Outcome of the Public Consultation on the draft statement of the PPR Panel on a framework for conducting the environmental exposure and risk assessment for transition metals when used as active substances in plant protection products (PPP)

European Food Safety Authority (EFSA), Silvia Pieper, Annette Aldrich, Philippe Berny, Arnaud Conrad, Laura Padovani, Alessio Ippolito, Olga Kulikova, Chris Lythgo and Mark Egsmose.

Abstract

EFSA performed a public consultation of the draft statement of the PPR Panel on a framework for conducting the environmental exposure and risk assessment for transition metals when used as active substances in plant protection products (PPP) from 3 August to 21 September 2020. EFSA was asked by the European Commission to prepare a public consultation on the draft statement. The statement provides a framework for conducting the environmental exposure, hazard characterisation and risk assessment for transition metals when used as active substances in plant protection products according to Regulation (EC) No 1107/2009 of the European Parliament and the Council. This report presents statistics on the comments received and answers to them. These comments were taken into account when finalising the statement.

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Key words: (pesticides, non-target organisms, groundwater, surface water, soil, modelling, monitoring)

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Summary

EFSA performed a public consultation of the draft statement of the PPR Panel on a framework for conducting the environmental exposure and risk assessment for transition metals when used as active substances in plant protection products (PPP) from 3 August to 21 September 2020. EFSA was asked by the European Commission to prepare a public consultation on the draft statement. The statement provides a framework for conducting the environmental exposure, hazard characterisation and risk assessment for transition metals when used as active substances in plant protection products according to Regulation (EC) No 1107/2009 of the European Parliament and the Council. This report presents statistics on the comments received and answers to each of the comments. These comments were taken into account when updating and finalising the statement.
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1. **Introduction**

In the context of the development of the draft statement of the PPR Panel on a framework for conducting the environmental exposure and risk assessment for transition metals when used as active substances in plant protection products (PPP) a public consultation was organised for a 7 week open consultation period on the EFSA website from 3 August to 21 September 2020. EFSA was asked by the European Commission to prepare a public consultation on the draft statement. The EFSA contact points, EFSA Pesticide Steering Network, risk assessors, risk managers, stakeholder and the scientific community were additionally informed via EFSA email alerts and targeted emails about the open public consultation. This technical stakeholder report presents statistics on the comments received and answers to each of the comments. These comments were taken into account when updating and finalising the statement.

The statement provides a framework for conducting the environmental exposure, hazard characterisation and risk assessment for transition metals when used as active substances in plant protection products according to Regulation (EC) No 1107/2009 of the European Parliament and the Council.

1.1. **Terms of Reference as provided by the requestor**

EFSA, and in particular its PPR Panel, was asked by the European Commission (DG SANTE) to draft a statement setting out a framework for conducting the environmental exposure and risk assessment for transition metals when used as active substances in plant protection products. EFSA was requested to organise a public consultation on the draft PPR statement to ensure full involvement of Member States and other stakeholders.

2. **Screening and Evaluation of the comments received**

All the comments received were scrutinised and subsequently tabulated with reference to the author(s) and the section of the draft statement which each comment referred. The references to chapters and appendices in the comments and the answers to the comments refer to the draft statement from August 3, 2020 and not to the final document. The final number of comment boxes were 104. Comments submitted formally on behalf of an organisation appear with the name of the organisation. Comments submitted in personal capacity appear with the name of the submitter. A statistical summary of the comments received is provided in Tables 1 and 2. In table 3 the comments to the draft statement are provided together with the responses by the PPR transition metal WG.

**Table 1:** Comments received on the draft statement per section

| Section                                                                 | Number of comments |
|------------------------------------------------------------------------|--------------------|
| General Comments                                                       | -                  |
| Abstract                                                               | 3                  |
| Keywords                                                               | -                  |
| Summary                                                                | 8                  |
| 1. Introduction                                                       | 1                  |
| 1.1 Background and Terms of Reference as provided by the requestor    | 1                  |
| 1.2 Interpretation of the Terms of Reference                           | 1                  |
| 2. The Framework                                                       | -                  |
| 2.1 Transition metals as active substances in plant protection products| 1                  |
| 2.1.1 Use of transition metals as pesticides                          | 1                  |
| 2.1.2 Chemical properties and fate of transition metals               | 3                  |
| 2.1.3 (Eco)Toxicological particularities of transition metals         | 2                  |
| 2.2 Consequences for the assessment of transition metals when used as active substances in plant protection products | 3                  |
| 2.3 Proposed framework for environmental risk assessment of transition metals | -                  |
| Section                                                                 | Page |
|------------------------------------------------------------------------|------|
| 2.3.1 Overall approach and problem formulation                          | -    |
| 2.3.2 General Framework for environmental risk assessment of transition metals in PPP | 3    |
| 3 Environmental risk assessment                                         | 10   |
| 3.1 Aquatic Environment (surface waters and sediment)                   | 3    |
| 3.1.1 Effect assessment and ecotoxicologically relevant exposure quantities | 2    |
| 3.1.2 Exposure assessment, fate and behaviour of transition metals in surface waters and sediment | 4    |
| 3.1.3 Linking exposure and effects                                      | 2    |
| 3.1.4 Risk assessment                                                  | 3    |
| 3.1.5 General conclusions and recommendations for the aquatic environment | 4    |
| 3.2 Terrestrial in-soil environment                                      | 1    |
| 3.2.1 Effect assessment and ecotoxicologically relevant exposure quantities | 2    |
| 3.2.2 Exposure assessment, fate and behaviour of transition metals in soils | 2    |
| 3.2.3 Linking exposure and effects                                      | 1    |
| 3.2.4 Risk assessment                                                  | 2    |
| 3.2.5 General conclusions and recommendations for the in-soil compartment | 2    |
| 3.3 Terrestrial Environmental: Non-Target Terrestrial Plants           | -    |
| 3.3.1 Effect assessment and ecotoxicologically relevant exposure quantities | -    |
| 3.3.2 Exposure assessment, fate and behaviour of transition metals above ground | 1    |
| 3.3.3 Linking exposure and effects                                      | -    |
| 3.3.4 Risk assessment                                                  | -    |
| 3.3.5 General conclusions and recommendations for NTTP                  | -    |
| 3.4 Terrestrial above-ground environment: Invertebrates (Non-Target Arthropods and Bees) | -    |
| 3.4.1 Effect assessment and ecotoxicologically relevant exposure quantities | 1    |
| 3.4.2 Exposure assessment, fate and behaviour of transition metals above ground | -    |
| 3.4.3 Linking exposure and effects                                      | -    |
| 3.4.4 Risk assessment                                                  | 2    |
| 3.4.5 General conclusions and recommendations for NTA and Bees          | -    |
| 3.5 Terrestrial above-ground environment: Vertebrates (Birds, Mammals, Amphibians, Reptiles) | 1    |
| 3.5.1 Effect assessment and ecotoxicologically relevant exposure quantities | 1    |
| 3.5.2 Exposure assessment, fate and behaviour of transition metals above ground | 1    |
| 3.5.3 General conclusions and recommendations                          | 1    |
| 3.6 Leaching to groundwater                                            | 1    |
| 3.6.1 Assessment                                                       | 2    |
| 3.6.2 Conclusions and recommendations for groundwater                  | 3    |
| 3.7 Addressing uncertainty in the risk assessment                      | 2    |
| 4 Consideration of environmental monitoring study results in the environmental risk assessment of transition metals | -    |
| 4.1 Aims and purposes of environmental monitoring                      | 1    |
| 4.1.1 Monitoring of the actual environmental transition metals loads   | 3    |
| 4.1.2 Post-registration monitoring                                     | 2    |
| 4.1.3 Dedicated long-term studies                                      | 1    |
| 4.1.4 Conclusions and recommendations for monitoring                   | 2    |
| 5 General conclusions and recommendations                              | 2    |
| 6 Conclusions and recommendation for the specific compartments         | -    |
| 6.1 Aquatic compartment                                                | 2    |
| 6.2 Terrestrial compartment                                            | 1    |
| 6.3 Groundwater                                                       | 1    |
| 6.4 Monitoring                                                        | 1    |
| 7 References                                                          | 1    |
| Appendix A: Overview of the different assessment frameworks            | 1    |
| Appendix B: Description of the IDMM Model                              | 1    |
| Glossary and/or abbreviations and/or acronyms                          | -    |
| Other comments                                                        | 4    |
Table 2: Comments received on the draft statement by organisation

| Organisation                                                                 | Country | Total |
|------------------------------------------------------------------------------|---------|-------|
| Agence Nationale de Sécurité Sanitaire de l’Alimentation de l’Environnement et du Travail (ANSES) | FRA     | 20    |
| German Federal Environment Agency, Umweltbundesamt (UBA)                     | DEU     | 19    |
| BÖLW e.V                                                                     | DEU     | 2     |
| European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd.              | GBR     | 41    |
| European Copper Institute                                                   | BEL     | 1     |
| European Crop Protection Association (ECPA)                                  | BEL     | 6     |
| Fédération Nationale d’Agriculture Biologique (FNAB)                        | FRA     | 1     |
| IFOAM Organics Europe                                                       | BEL     | 1     |
| Casado, Carmen (in personal capacity)                                        | -       | 3     |
| Junghans, Marion (in personal capacity)                                      | -       | 10    |
| **Total Number of comments**                                                 |         | **104** |
Table 3: Comments received on the draft statement by organisation

| Number | Organisation or name or respondent | Chapter | Comments and PPR WG responses |
|--------|-------------------------------------|---------|--------------------------------|
| 1      | BÖLW e.V.                           | Abstract| Before going into detail, we would like to congratulate EFSA for initiating the development of a specific guidance document for evaluating transition metals like copper. The organic sector has called for guidance documents that reflect the peculiar properties of natural substances (like transition metals) for some time now, and we are happy that EFSA and the European Commission have now taken steps in that direction. EFSA: Thank you. Noted. This guidance document is a chance to better accommodate transition metals such as copper in the current Regulatory framework and therefore should be more ambitious in order to set a high standard for the future guidance documents on the evaluation of other natural substances. EFSA: The European Commission asked for a statement on a framework for conducting the environmental exposure and risk assessment for transition metals when used as active substances in plant protection products and not a guidance document. However, we see room for improvement in the consideration of the natural background exposition to these minerals. This shows that there is still some way to go until a fair and adequate registration and evaluation process for natural substances is established. An explicit integration of natural substances in reg. (EU) 1107/2009 is still missing. EFSA: It is outside the remit or EFSA to prepare EU legislation. Your proposal would be better addressed to the European Commission. At first, it should be considered if an element is an essential element or not. If the element is essential, the exposition should be discussed taking into consideration if it is to be considered in the range of a "deficiency status", an “acceptable range of intake”, or an “oversupply”. It should be also considered if a metal is commonly found in nature or if it is only found in particular places. If it is common and essential, as is f.e. the case for copper, it is very important to consider the natural background exposition. Otherwise, this can lead to situations where evaluation models calculate levels of concentrations to be considered as “safe” that are actually lower than the already existing and normal natural concentrations. EFSA: The statement recommends that residues of transition metals from previous agricultural uses are taken into account for the exposure assessment. See e.g. chapter 3.2.2. Considerations in respect to homeostasis are included in the statement. |
In this context, persistency has to be discussed, too. Transition metals, being pure elements, are - of course – always "persistent". This natural character must not be confused with the persistence of a POP (persistent organic pollutant) which – as a newly designed compound – has never been part of natural ecosystems. Again, persistence has to be considered in light of the question if the metal is an essential element frequently occurring in nature, and if there is an acceptable and necessary range of intake. Thus, the criteria pertaining to persistence, in light of current scientific and technical knowledge, should be adapted to the situation of naturally occurring substances such as these minerals. For iron, this was already applied accepting the active substance even as low risk substance. Thus, persistence in the case of mineral substances should not be a cut-off criterion per se, but should be evaluated taking other relevant factors into account. The persistence of metals like copper should – of course – be one of the reasons to limit the amount of application allowed per year and to minimize the input as it is already practiced for many years for copper in organic farming.

EFSA: As transition metals do not degrade and have the potential to accumulate in the environment e.g in soil and sediment they are considered to be persistent. See also response to comments in points 19 and 24.

| Number | Organisation or name or respondent | Chapter | Comments and PPR WG responses |
|--------|-----------------------------------|---------|-------------------------------|
| 2      | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | Abstract | General comment: The EU Copper Task Force (EUCuTF) highly appreciates the effort by the Commission and EFSA to get a statement for the environmental exposure and risk assessment (RA) for transition metals established. It is further appreciated that many important features not been considered in current pesticide guidance are made available to applicants in order to enable an exposure and risk assessment adapted to the specifics of transition metals, including bioavailability, homeostatic control, and new models and data normalisation possibilities. These are essential for the assessment of transition metals, and without them an appropriate exposure and risk assessment is simply not feasible, as has been recognized in previous reviews e.g. for copper. EFSA: Thank you. Noted. However, although these improvements, the statement still tries to accommodate the exposure and RA for transition metals in the standard pesticide mould, and does not consequently complete the framework to fully address the specifics, in particular for essential transition metals (this raises the question if the term "transition metals" should be defined in the document, and whether the scope of the framework should be limited to essential transition metals). This can be illustrated when comparing this statement with the recently issued Statement on the derivation of HBGVs, where the specifics of essential minerals were adequately described for the human tox side, including the deficiency status and the "acceptable range of intake" approach (U-shape). It would have been desirable to find an equivalent for this in the current statement for environmental exposure and RA. This would allow a better balancing of uncertainties and assessment factors on both sides of the |
EFSA: The mandate from the European Commission was to prepare a framework for conducting the environmental exposure and risk assessment for transition metals when used as active substances in plant protection products. This mandate covers the transition metals iron, cobalt, nickel and copper compounds and the draft statement was amended accordingly. The scope of this mandate is therefore different compared to the mandate for the statement on the derivation of HBGVs.

The statement requests to start the procedure with a first step considering the total transition metal being bioavailable. Throughout the document this is then referred to the first Tier, which can be followed by higher Tiers with reduced bioavailability. As essential transition metals will never reach 100% bioavailability in the environment, neither in non-equilibrium conditions and even less in equilibrium, the first step should rather be considered as a Tier 0. This is rather a theoretical first step, as in any natural situation related to the use of transition metals as ppp a significant portion will be not bioavailable. Therefore a Tier 1 should already be allowed to include a reasonably worst case for bioavailability, before the assessment is called a higher Tier. This is important to allow a fair comparison of the risk identified with the provisions for synthetic pesticides.

EFSA: The first assessment was intentionally developed to be a conservative first step. The statement provides a framework for considerations for refinement of the assessment in subsequent assessment steps.

A further important consideration deserves the way “persistency” is dealt with. Transition metals are persistent simply by their existence and being part of the elements forming the earth crust. This is fundamentally different from the meaning of “persistency” for a non-natural, non-ubiquitous synthetic compound, not present in the environment before it is released. The hazard connotation of “persistency” which is reasonable for synthetic compounds like POPs is therefore not applicable to inorganic compounds like transition metals. Consequently, ECHA has exempt inorganic compounds from a formal PBT assessment (see p.24, l.27). To achieve the requested alignment between ECHA and EFSA, this statement should issue a provision to exempt transition metals from a formal PBT assessment as cut-off criteria under 1107/2009. This does not mean that a potential accumulation should not be addressed in the RA, but to harmonize the procedure to identify candidates for substitution across EU legislation.

EFSA: As transition metals do not degrade and have the potential to accumulate in the environment e.g. in soil and sediment they are considered to be persistent. See also responses to comments in points 19 and 24.

Specific comments:
| Number | Organisation or name or respondent | Chapter | Comments and PPR WG responses |
|--------|-----------------------------------|---------|--------------------------------|
|        |                                   | Page 1: line 23: The proposed use of simple, fit-for-purpose models is welcomed, but is somewhat at odds with following statements requiring the development of metal-specific models and scenarios for some compartments. Whilst undoubtedly there has been significant process improvements in methodology and dataset availability for scenario development, it is highly ambitious to consider that metal-specific scenarios could be developed and agreed at an EU level in a realistic timescale. This process would not be something that a notifier would be able to conduct without significant involvement of all stakeholders, such as developers of existing regulatory models (e.g. FOCUS, PERSAM).<br><br>**EFSA:** The statement provides options and recommendations for what should be considered for future model and scenario developments taking into account the properties of transition metals. The statement has considered organic and synthetic chemicals as a benchmark for what should be expected of models and scenarios to be accepted when used for assessment of transition metals.<br><br>Page 1, line 30: The highly conservative models always trigger the need for higher tier assessments and hence the requirement for monitoring data. This is not consistent with the requirements for synthetic pesticides and gives an erroneous impression that transition metals are a higher risk than synthetic pesticides. The fact that higher tier models are required for transition metals is not a sign that they are less safe than synthetic pesticides.<br><br>**EFSA:** The models currently used for assessment of organic and synthetic chemicals were not developed for taking the properties of transition metals into account. As transition metals do not degrade in the environment and have the potential to accumulate refined modelling with robust and agreed models and monitoring data will be relevant for a more realistic risk assessment of these metals. |
| 3      | Fédération Nationale d'Agriculture Biologique (FNAB) | Abstract | The French organic farmers called for many years for a specific evaluation for natural substances (like transition metals). We welcome the initiative of such guidance document which is a good start. It will help the European Commission to move forward and find a more suited regulatory framework for natural substances such as transition metals.<br><br>**EFSA:** Thank you. Noted.<br><br>Indeed, when considering persistancy it is very important to separate the specificities of transition metals from persistent organic pollutants (POP). The later are not naturally part of the ecosystems, whereas transition metals are per se elements which are naturally occuring in the ecosystem and, above all, essential for living being and ecosystems. That is why is paramount to evaluate the persistancy of transition metals (as natural substance) in the light of the existence of such transition metals in the ecosystems and environment. The |
| Number | Organisation or name or respondent | Chapter | Comments and PPR WG responses |
|--------|----------------------------------|---------|--------------------------------|
|        |                                  |         | current regulatory framework does not take this particularity into account. That is why new schemes are needed and welcome in order to better take into account natural substances such as transition metals.  
**EFSA:** Thank you. Noted. The statement deals with the risk assessment of transition metal compounds used in PPP. Active substance approval hazard cut-off criteria according to (EC) 1107/2009 Annex II are not in the remit of this statement. |
| 4      | French Agency for Food, Environmental and Occupational Health & Safety (ANSES) | Summary | p. 6, lines 9-10: It is suggested to remove “and the availability” in the following sentence: “The speciation and the availability of transition metals in aquatic systems can change with time, which can reduce their availability.”  
**EFSA:** The typo has been corrected in the updated statement  
p.11, line 22: Typo: “Conclusion on low risk in the ERA needs”  
**EFSA:** The typo has been corrected in the updated statement. |
| 5      | Federal Environment Agency of Germany | Summary | We appreciate the suggested actions for the preliminary phase in terms of gathering information on residue levels as well as conducting monitoring data.  
**EFSA:** Thank you. Noted. |
| 6      | Federal Environment Agency of Germany | Summary | 1 Overall: Many thanks to the panel for creating this statement which was long overdue and anticipated and will surely help to prevent misconceptions during the risk assessment of metals in the future. The issues for the risk assessment of metals are well characterized and summarized. A comprehensive framework for the adequate procedure is largely provided (in the summary chapter as well as by the entire statement). Especially linking decisions that are based on higher tier assessment to risk management and required monitoring information will be very useful to address the uncertainties remaining and to gather more knowledge on the actual exposure of the environment and the hazardous potential of metals.  
**EFSA:** Thank you. Noted.  
2 p. 3, line 37 - 41: We appreciate the suggested actions for the preliminary phase in terms of gathering information on residue levels as well as conducting monitoring data.  
**EFSA:** Thank you. Noted.  
3 p. 4, line 1 -3 : We would like to support the inclusion of natural background data as well as anthropogenic additions in the exposure assessment.  
**EFSA:** Thank you. Noted. |
| Number | Organisation or name or respondent | Chapter | Comments and PPR WG responses |
|--------|----------------------------------|---------|-------------------------------|
| 4 p 4 lines 7 - 18: | | 4 p 4 lines 7 - 18: | We agree, equilibrium cannot be assumed for freshly added metals as PPP. The adaption or development of models and scenarios including bioavailability issues should be done on international working group level or by EFSA. |
| EFSA: Thank you. Noted. | | 5 p 4, line 26 – 29: | We agree, higher Tier studies should be initiated for the relevant compartments, acting as sinks and should be prolonged to relevant time frames. The definition of ‘relevant time frames’ should be included. |
| EFSA: Noted. The definition of ‘relevant time frames’ has been added to the statement (chapter 2.3.2 General framework) | | "Regarding the temporal scale of the risk assessment, we define ‘relevant time frames’ those time periods for which the application of the product containing transition metals can be realistically assumed - should the transition metal compound be repeatedly approved as active substance in future. Since transition metal compounds are one of the oldest employed active substances for plant protection products and still widely used, the relevant time frames for exposure calculations should realistically not cover only one approval period (e.g. 10 years) but also longer time frames. It is suggested to cover in the exposure assessment single as well as several approval periods (e.g. 10 years) but also longer time frames (e.g. > 50 years). For synthetic compounds, the time frame is set by the outcome of field studies, but for metals this is not a realistic option. For effect characterisation in controlled field tests (e.g. soil organisms), studies should be planned to cover more than one approval period, so that they can be prolonged without sampling problems. There is in principle no maximum time frame that can be defined a priori for all transition metal compounds and intended uses. Before stopping a long-time trial, it should be agreed with competent authorities that no further changes in the observed communities can be expected. If the accumulation of transition metals due to the application with PPP will result in environmental levels above the background without use in agricultural areas, the availability and duration of long-term studies will be part of the uncertainty assessment in the environmental risk assessment and will determine the height of the assessment factor” |
| 6 p 4, line 36 - 38: | | 6 p 4, line 36 - 38: | In order to conclude on low risk, the protection goals should be defined clearly. |
| Number | Organisation or name or respondent | Chapter | Comments and PPR WG responses |
|--------|-----------------------------------|---------|-----------------------------|
|        |                                   | 7 p. 6, line 30 | It is unclear what this eventually means for (current or future) concentration predictions (2 different PECs?) and compatibility with the Endpoint selection especially with regards to the sediment compartment. The advice to consider freshly added and background values distinctly could be misinterpreted in a way that both concentrations may be assessed separately and do not need to be summed. |
|        |                                   | 8 p 5, line 30 – 36 | We agree, sediment organisms are expected to be the most sensitive aquatic organism as accumulation is expected. It would be great to include different test organisms or even communities, representing the trophic web. |
|        |                                   | 9 p 7, line 38 – 40 | We agree, the derivation of an SSD including different trophic levels (like microorganisms, plants and soil mesofauna) is not suitable in order to describe the toxicity. |
|        |                                   | 10 p 7, line 40 – 42 | We agree, long term studies are extremely useful. However, natural background levels as well as anthropogenic entry should be considered by choice of the test rates. Moreover, the conduction of field studies lasting 1 year seems not appropriate due to the high persistence of metals. |
|        |                                   | 11 p 7, line 42 – 43 | The inclusion of measured concentrations of the testes compounds in soils is favorable. |
|        |                                   | 12 p 7 – 8, line 44 – 2 | We agree, the OECD standard test soil is deemed to be not a realistic worst-case regarding metal bioavailability. |
|        |                                   | 13 p 8, line 2 – 4 | Besides considering soil properties regarding bioavailability and toxicity towards non-target organisms also land management of agricultural soils should be considered as land management (e.g. straw |
| Number | Organisation or name or respondent | Chapter | Comments and PPR WG responses |
|--------|-----------------------------------|---------|------------------------------|
|        | incorporation) changes bioavailability of metals. Experiments in order to identify main drivers of bioavailability of transition metals in test soils should be conducted using standardized natural soils. |  | EFSA: Noted |
| 14 p 8, line 26: Current information on the dissipation behavior of copper on plant material is scarce but indicates a dissipation half time (caution with wording in this case: not degradation!) of much longer than 10 days. Thus, the mentioned underestimation of concentration by PERSAM is indeed likely (with regards to this aspect and the underestimating default alone). An increased database for residue studies on plant material is needed, also to address feeding issues for birds and mammals (refer also to chapter 3.5 where this issue is missing). |  | EFSA: Noted, in section 3.5 the need for residue studies is stressed. |
| 15 p 8, line 32: Recommended to change ‘could’ to ‘should’? |  | EFSA: Exploring the need for including further environmental parameter will be a task for dedicated working groups |
| 16 p 8 – 9, line 46 - 2: We agree, preliminary phase should include the evaluation of background levels. |  | EFSA: Noted |
| 17 p. 10, line 39: European FOCUS modelling for organic chemicals/pesticides is usually performed for 20 years plus a warming up period of 6 years. Is it possible to develop a more precise understanding here what is meant with a "period sufficiently long to cover the long-term groundwater exposure" in the context of FOCUS groundwater modelling for metals without any degradation in soil, e.g. copper? |  | EFSA: Please refer to EFSA’s response to comment 76, Point 1. The statement has been amended. See also answer further above in this comment (comment 6 point 5). |
| 7 | European Copper Institute | Summary | The European Copper Institute appreciates the opportunity to comment on this draft statement related to assessments of metals as active substances in plant protection products. We represent the producers of copper metal, a different set of companies from those that produce and market copper compounds as plant protection products. Overall, we are in agreement with the initiative. We welcome that several metal-related scientific concepts and methodologies are recognized in the higher tiers of this draft statement, such as the fate of metals in the environment, and metal bioavailability in water, soils and sediments. These concepts have previously been |

accepted and used in other regulatory frameworks, for instance under the Existing Substances Regulation in the Copper Voluntary Risk Assessment (https://echa.europa.eu/nl/copper-voluntary-risk-assessment-reports), under REACH, under the Water Framework Directive, and under the Cooperative Chemicals Assessment Programme by the OECD (https://hpvchemicals.oecd.org/ui/SIDS_Details.aspx?id=e7b50eea-4f93-4918-9645-622c16b256ff). Several of these assessments included a joint industry initiative, where companies producing copper metal and copper compounds for various sectors (general chemical, biocidal products...) collaborated. Therefore, we are fully supportive that these scientific concepts now find recognition under the Plant Protection Products Regulation. This paves the way for increasing overall regulatory consistency.

An element calling our attention is that sector-specific considerations remain necessary as integral part of the assessment of the active substances in Plant Protection Products. The draft statement mentions, for instance, the development of dedicated exposure models and the establishment of monitoring programs.

We remain at your disposal and will be happy to help, from the scientific perspective, with further initiatives related to the assessment of metals as active substances in PPPs.

The European Copper Institute is the European branch of the International Copper Association. We represent a majority of the world’s primary copper production, some of the largest mid-stream smelters and refiners, and 10 of the world’s largest copper fabricators. We bring together the global copper industry, we develop and defend markets for copper, and we make a positive contribution to society’s sustainable development goals. Find out more at https://copperalliance.eu/.

EFSA: Thank you. Noted. The Copper Voluntary Risk Assessment Reports in relation to REACH and activities related to the Water Framework Directive, and the Cooperative Chemicals Assessment Programme by the OECD as you refer to in your comments were considered when preparing this PPR statement.

| Number | Organisation or name or respondent | Chapter | Comments and PPR WG responses |
|--------|------------------------------------|---------|--------------------------------|
| 8      | Federal Environment Agency of Germany | Summary | 18 p. 10-11: The relevance of groundwater monitoring data according to the overall monitoring concept in the statement (specially to derive reliable metal background concentrations in the groundwater compartment, or describe any possibilities for post registration monitoring) is missing in the summary for groundwater assessment and should be described here. Related to the two comments above it needs to be clarified, how modelled PECgw must be interpreted in terms of expected groundwater concentrations. From our understanding, metal measurable background values in groundwater need to be part of discussing the final risk related to the parametric drinking water limit in Europe. EFSA: The summary has been amended. |
| Number | Organisation or name or respondent | Chapter | Comments and PPR WG responses |
|--------|-----------------------------------|---------|------------------------------|
| 9      | ECPA                              | Summary | The guidance is solely based on copper compounds. No justification is given that this guidance is also suitable for other transition metals.  
   **EFSA:** It is clearly stated in the document that transition metals are covered by the statement as requested by the commission in the terms of reference (iron, cobalt, nickel and copper)  
   It is not clearly addressed how two agricultural uses as fertilizers and as pesticides are balanced (in terms of amounts applied) and how they are to be balanced with losses e.g. by removal of harvested plants. At a glance the assessment of the addition of metals as PP active substance seems to be overly regulated /overly complicated compared to the use as fertilizer  
   **EFSA:** Transition metal compound applied as active substances in PPP are in principle addressed as other active substances, since the protection goals are the same. The use of fertilisers is included in an overall assessment through the consideration of background level monitoring data. A change in the regulatory framework is not part of the statement which solely focuses on the use as PPP.  
   “...a framework for conducting the environmental exposure and risk assessment for transition metals when used as active substances ...” It is understood that this document applies only for transition metals as active substances, but not for transition metals in organic complexes e.g. like Mn or Zn in EBDC fungicides where the complex is the a.s. This would make sense as the amounts of metal as applied in the form of the latter are much lower than the amounts of metal applied as a.s. (I'm only aware of Cu and Fe being applied as a.s.).  
   **EFSA:** Agreed. The statement covers following transition metals: iron, cobalt, nickel and copper  
   “... gather all relevant and reliable available occurrence information on residue levels in the environment ...” Transition metals are not degradable and may be present due to a multitude of natural circumstances and processes with anthropogenic influences on top of that. The latter are by far not limited to agricultural uses but may include also residues e.g. related to mining, waste deposition, aerial deposition of dust from industrial areas, use of sewage sludge as fertilizer etc. All these factors may highly affect the actual concentrations but are typically not known to the applicant since they may have taken place rather far back in history. Therefore, it seems to be very difficult to distinguish natural background from anthropogenic additions and to distinguish contaminated sites from sites representing a normal range of conditions  
   **EFSA:** The background contamination levels include past contamination events with transition metals. It is deemed possible to separate high input resulting from mining activities from agricultural uses for most of the sites. |
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| 10     | BÖLW e.V.                          | Summary | Before going into detail, we would like to congratulate EFSA for initiating the development of a specific guidance document for evaluating transition metals like copper. The organic sector has called for guidance documents that reflect the peculiar properties of natural substances (like transition metals) for some time now, and we are happy that EFSA and the European Commission have now taken steps in that direction. This guidance document is a chance to better accommodate transition metals such as copper in the current Regulatory framework and therefore should be more ambitious in order to set a high standard for the future guidance documents on the evaluation of other natural substances. However, we see room for improvement in the consideration of the natural background exposition to these minerals. This shows that there is still some way to go until a fair and adequate registration and evaluation process for natural substances is established. An explicit integration of natural substances in reg. (EU) 1107/2009 is still missing. At first, it should be considered if an element is an essential element or not. If the element is essential, the exposition should be discussed taking into consideration if it is to be considered in the range of a “deficiency status”, an “acceptable range of intake”, or an “oversupply”. It should be also considered if a metal is commonly found in nature or if it is only found in particular places. If it is common and essential, as is f.e. the case for copper, it is very important to consider the natural background exposition. Otherwise, this can lead to situations where evaluation models calculate levels of concentrations to be considered as “safe” that are actually lower than the already existing and normal natural concentrations. In this context, persistency has to be discussed, too. Transition metals, being pure elements, are - of course – always “persistent”. This natural character must not be confused with the persistence of a POP (persistent organic pollutant) which – as a newly designed compound – has never been part of natural ecosystems. Again, persistency has to be considered in light of the question if the metal is an essential element frequently occurring in nature, and if there is an acceptable and necessary range of intake. Thus, the criteria pertaining to persistency, in light of current scientific and technical knowledge, should be adapted to the situation of naturally occurring substances such as these minerals. For iron, this was already applied accepting the active substance even as low risk substance. Thus, persistency in the case of mineral substances should not be a cut-off criterion per se, but should be evaluated taking other relevant factors into account. The persistency of metals like copper should – of course – be one of the reasons to limit the amount of application allowed per year and to minimize the input as it is already practiced for many years for copper in organic farming. EFSA: See commenting point 1 for responses to your comments. |
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| 11     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | Summary | 1) Page 3, line 4: Should only essential transition be covered?  
EFSA: Following transition metals are covered by the terms of reference: iron, cobalt, nickel and copper. The essentiality of nickel is not fully clear but assumed in this statement.  
2) Page 3, line 7: What does “partial essentiality” mean for transition metals?  
EFSA: The statement now specifies more clearly the transition metals iron, cobalt, nickel and copper  
3) Page 3, line 32: Also deficiency status should be avoided and might be a specific protection goal.  
EFSA: Since the deficiency status will be specific for every organism group and for every metal, a specific assessment of the regulatory acceptable concentrations taking this aspect into account will only be possible if valid and plausible data have been submitted  
4) Page 4, line 2: Essential, naturally occurring ubiquitous transition metals will never occur at 100% bioavailability (should be a preliminary assessment, Tier 0)  
EFSA: The first step of the assessment (after the preliminary phase) intends to exclude all compounds from further refinement steps that do not pose high risk to non-target organisms and to groundwater under realistic worst-case assumptions.  
5) Page 4, line 7: A reasonable worst-case bioavailability would be appropriate to describe as a Tier 1, before considering further higher Tier steps  
EFSA: Please see answer to comment above  
6) Page 4, line 8: Agreed, this assumption can initially be made for the water compartment. However, the time which is needed for metals to enter the sediment compartment are indicative of a longer process in which equilibration can be reached for the sediment  
EFSA: The environmental scenarios for assessing the fate and behaviour of transition metals and the included processes are dynamic, so a true equilibrium cannot be assumed.  
7) Page 4, line 12: The development of ‘…dedicated modules within current frameworks.…’ will need buy-in and involvement from the existing model developers and version control groups. This is not a trivial undertaking, nor something that an individual notifier should conduct alone, but requires involvement of all stakeholders to ensure acceptability and access to the model code. Will EFSA engage with the model owners to instigate the development of these modules? |
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|        |                                    |         | EFSA: Statements on this specific issue would go beyond the scope of the working group. Please see general indications in chapter 2.1.3 |
| 8)     | Page 4, line 22: Free metal ions can also contribute to contact and oral uptake. Generally, no distinction is made between different ways of exposure during standard toxicity tests. EFSA: We agree that free metal ions can also contribute to contact and oral uptake. Therefore, if specific models are developed they should account for these exposure routes. |
| 9)     | Page 4, line 28: How is a “sink” defined and what determines a relevant timeframe of transition metal application? EFSA: An environmental sink is defined as the destination of the transition metal compound applied according to the time frame addressed in the environmental risk assessment. |
| 10)    | Page 4, line 44: Not all PPP uses of transition metals do increase the loads in the environment, “will” should be replace with “might” or similar. EFSA: In principle all PPP uses will increase the load in the environment, unless they are compensated by local dissipation losses which will however increase the levels in other compartments. |
| 11)    | Page 5, line 18: It is not clear what “acclimatisation” means here, as this could also occur naturally with ubiquitous essential transition metals. EFSA: Noted. In our opinion, the paragraph is clear. |
| 12)    | Page 5, line 24: suggest updating to “higher bioavailability and thus potential toxicity”. EFSA: Agreed and amended |
| 13)    | Page 5, line 30: Resuspension of sediment is considered not to be a significant exposure route, and if this resuspension did occur the metal would not be bioavailable. EFSA: Disagreed. Scientific background is given in the statement, see chapter 3.1.1 |
| 14)    | Page 5, line 41: What evidence indicates that the AFs are not sufficient? Assessment factors are considered to be sufficiently protective if data is normalised e.g. by of BLMs, and should rather be lowered for essential metals. |
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|        |                                   |         | EFSA: Disagreed. The assessment factors to be applied in the first step do not take normalisation and bioavailability into account. |
|        |                                   |         | 15) Page 5, line 44: Suggest removing this sentence. This is an assumption and may be contradicted by available science. Resuspension from sediment will not occur to a significant extent, and if this did occur then the metal would not be bioavailable. Therefore, the ERO for mesocosms is a valid endpoint and should not be discounted. | EFSA: Disagreed, see answer above point 13. |
|        |                                   |         | 16) Page 6, line 16: The conservativeness of the current risk assessment is clear and is not “assumed”. | EFSA: Noted. |
|        |                                   |         | 17) Page 6, line 23: This is not true for all situations and uses. “…potentially increasing” would be preferable. | EFSA: Please refer to the text further down. |
|        |                                   |         | 18) Page 6, line 28: Adsorption kinetics follow typically first quick adsorption, followed by further slower processes. It is overly conservative to state that freshly added metals are completely available (i.e. present as free metal ions). E.g. Ma et al. 2006a; Ma et al. 2006b. A distinction in non-equilibrium / equilibrium and respective bioavailable fractions over time is more appropriate than the one in background / freshly added. | EFSA: Please see the explanatory text in the brackets further down in the same paragraph |
|        |                                   |         | 19) Page 7, line 10: This may be correct for complexation reactions, but does not hold for the competition reactions for binding and uptake of the metal ions at the biotic ligand. Such competition reactions are a crucial part of the BLMs. | EFSA: Please refer to chapter 3.1.3 for further details |
|        |                                   |         | 20) Page 7, line 42: how is “effective concentrations” defined? Total metal concentrations in soil are generally used under REACH. | EFSA: It is indicated that the concentrations in soils need to measured, especially for linking exposure and effect to ‘pore water concentrations’. |
|        |                                   |         | 21) Page 8, line 8: Background levels should not be assumed bioavailable at the first tier. |
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|        |                                   |         | EFSA: These assumptions for the first step of the risk assessment will exclude intended uses from further refinement steps that pose low risks to the environment |
|        |                                   |         | 22) Also Page 9, line 2. |
|        |                                   |         | EFSA: Please see above |
|        |                                   |         | 23) Page 8, line 25: Can a version of PERSAM be provided where default wash-off and foliar degradation parameters can be overridden? Or, a modified version with new defaults suitable for metals provided? |
|        |                                   |         | EFSA: An updated version of the existing models could be explored in future. The statement was not amended. |
|        |                                   |         | 24) Page 8, line 41: This sentence is not clear. Models should be used to normalise data in order to account for different soil types in different regions |
|        |                                   |         | EFSA: This approach is currently not a standard approach for pesticide risk assessment. The description of the influence of soil properties on bioavailability and subsequently on toxicity would need to be fully explained by data. Taking into account soil properties for exploring the extrapolation of data from one site (e.g. field data endpoints) to other sites would be a helpful application |
|        |                                   |         | 25) Page 9, line 9: Assessment factors applied to SSD-derived endpoints should be based on the amount of data that is available e.g. for data-rich copper, AFs sufficient evidence is available to justify an AF = 1. |
|        |                                   |         | EFSA: Since uncertainties exist on the effect characterisation for transition metal compounds used as active substances in PPP and for the time being SSD are a non-standard effect endpoint refinement procedure for soil organisms exposed to PPP, the use of an assessment factor of 1 is not supported for the time being. |
|        |                                   |         | 26) Page 9, line 12: This approach results in a theoretical PEC which cannot be directly measured in soil. Moreover, for non-degradable substances, the application from the current season will only slightly contribute to the total PEC. An ageing factor (or “lab-to-field factor”) derived from data with different taxa was found very helpful to compare lab data with freshly spiked transition metal with observed field data and allows a comprehensive understanding of effects of transition metals in a realistic situation. This approach should not be discarded. |
|        |                                   |         | EFSA: If chosen for future evaluation, the definition of ‘pore water concentrations’ will lead to measurable concentrations in soils. |
|        |                                   |         | A standard lab-to-field factor is deemed not appropriate to extrapolate from lab to the field situation, since ageing cannot be assumed for transition metals applied in PPP. Copper application might indeed lead to |
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| 12     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 1.0 Introduction | Increases in the background concentrations, e.g. if they are applied outside existing sites with long copper use (e.g. vineyards). |

Further comments to the summary:

1) Page 10, line 24: For copper, the levels of background residue data have been shown to fail current RA highlighting the failure to account for homeostatic control. The usefulness of providing additional residue data is therefore questionable for essential, ubiquitous metals.

   EFSA: The statement suggests to perform residue data on feed for vertebrate after PPP applications. These levels might exceed homeostatic control and are needed for the assessment of risk via oral exposure.

2) Page 11, line 19: We do not agree with the assumption that uncertainties are potentially greater for transition metals. Several tools and models have been developed to explain and account for the variation in toxicity and fate in order to decrease the uncertainty. Moreover, many worst-case assumptions have been selected for e.g. reference scenarios, selection of models etc. Guidance should be provided on how such worst-case assumptions and models can replace uncertainty factors. Further, the differentiating features for essential metals (bioavailability, homeostasis) are rather of protective nature.

   EFSA: Homeostasis controls internal metal concentrations within a narrow range of concentrations. Homeostasis cannot mitigate the effects of additions above these ranges (accumulation). Greater uncertainty does not imply greater risk. Assessing bioavailability is based on models which have an inherent uncertainty. Furthermore, due to the persistency of metals, the margin for potential error is very small. (“The uncertainties are potentially greater for transition metals than for synthetic organic chemicals used as plant protection products owing to the consideration of persistency and bioavailability”). The long-term application of non-degradable compounds holds greater uncertainties regarding the effect characterisation for non-target organisms, since short term study outcomes are in part not in line with field results. These uncertainties need to be accounted for in ERA.

3) Page 11, line 21: This should be complemented with an assessment for deficiency, to avoid an overly conservative approach in assessing excess, leading to endpoints below the adequate and required intake.

   EFSA: Please see answer to comment 11 point 3

4) Page 11, line 26: A working group to address the use of monitoring data for metals should be active in parallel with any activities related to model and scenario development.

   EFSA: Noted
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| 5      |                                   | 5) Page 11, line 41: “effects after long-term use (or exposure)“ might be better as there are no long-term effects to be expected if no recent additional expose has happened. EFSA: Delayed effects can appear after freshly added exposure has ceased, therefore the sentence has not been amended. |
| 6      |                                   | 6) Page 12, line 9: The recommendation to establish scientific working groups is welcomed, however in the meantime novel approaches described by applicants should still be allowed (and encouraged). EFSA: Noted. Novel approaches will need to follow the EFSA Scientific Opinion on Good Modelling Practice (2014) |
| 13     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 1.1 Background and Terms of Reference as provided by the requestor | Page 16, line 24: Need to define which transition metals this document covers, e.g. if only essential elements. EFSA: This section was not updated as it reflects what was requested by the European Commission. The mandate does not cover only essential elements but rather the metals in the chemical periodic table of elements groups 7-11 of period 4. So, the mandate covers the transition metal elements: iron, cobalt, nickel and copper. It is agreed that this should be made clearer. Therefore, updates have been made in the abstract, Summary and section 1.2 Interpretation of the terms of reference. |
| 14     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 1.2 Interpretation of the Terms of Reference | 1) Page 18, line 34: The mandate is indeed ambitious. This is likely to take many years - based on timescales for previous model and scenario development projects. Thereafter, it may take more time for regulatory acceptance. EFSA: Noted 2) These paragraphs seem to suggest that the confidence in RA of metals is lower than for organic chemicals and that there is less evidence. We do not agree for Cu, for which probably more data are available compared to most other PPP dossiers. Many data are however in a format not familiar to EFSA (many lab studies, bioavailability models, …). This should not lead to an automatic conclusion of lower confidence and insufficient evidence. EFSA: Please see answer to comment 12, point 2 |
| 15     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 2.1 Transition metals as active substances in plant | General comment: Transition metals are not used as PPPs. Compounds of transition metals (e.g. copper compounds) are used in plant protection, but the transition metals themselves are not marketed as active substances. Sentences such as (Section 2.1.1, p19, lines 5-6) “In some EU Member States, transition metals e.g. iron- and copper |
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|        | protection products                |         | compounds are used as plant protection products in conventional as well as organic farming” and (Section 2.1.1, p19, line 8) "Transition metals e.g. copper compounds” are confusing the distinction between the Plant Protection Product (e.g. the metal compound) and the transition metal itself.  
EFSA: Agreed. Text has been updated to indicate metal compounds, rather than transition metals when this is the meaning. This included an update to the title of section 2.1 |
| 16     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 2.1.1 Use of transition metals as pesticides | 1) Page 19, table 1: There are more sources of wide dispersive metal release to the environment not related to metal-specific uses, e.g. related to combustion of fossil fuels, transport, ...  
EFSA: The intention of the table is only to give examples and not a complete comparison of exposure routes.  
2) Page 19, line 8: The document acknowledges that transition metals may also be applied as fertilizers or via manure, however the risk assessment process penalizes the application via PPPs.  
EFSA: The intention of the described risk assessment is to evaluate the potential risk for non-target organisms and groundwater due to PPP applications. The application as fertilisers or manure will add to the load in the environment, which will be evaluated by the background data. It was not the intention of this statement to develop a RA for fertilisers or manure application.  
3) Page 19, line 32: The EUCuTF agrees that the LUCAS data set is relevant for the assessment of copper. However, access for the applicant to the database has been rejected. It would be appreciated if the document could encourage the relevant agencies to make those data available to applicants, by fully preserving the required confidentiality requirements of the agencies.  
EFSA: We agree that data bases containing environmental data should be made publicly available. This has been added to the updated statement. |
| 17     | French Agency for Food, Environmental and Occupational Health & Safety (ANSES) | 2.1.2 Chemical properties and fate of transition metals | This section brings relevant information on transition metals fate and behavior. It is however noticeable that these statements are not used to decline recommendations on the kind of data that should be provided to describe metal behavior in environmental compartments. Considering that transition metals are not comparable to organic substances and that many chemical parameters can influence their behavior, it seems important to discuss the relevance of existing data requirements for PPP. It would be appreciated that discussions/recommendations are proposed on the kind of specific data required to conduct proper exposure assessment (range of pH that should be tested, need of specific data for aged residues and freshly added residues, long-term equilibrium studies...). |
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|        |                                    | 2.1.2 Chemical properties and fate of transition metals | EFSA: We are of the opinion that the processes that should be considered to describe the metal behaviour in environmental compartments and main factors affecting it are specified through the different parts of the document (e.g. aquatic and soil risk assessment, groundwater assessment).

Regarding the relevance of existing data requirements for PPP, metals covered by the statement are not degradable in the environment. Thus, data requirements on this issue are not needed to conclude on a non-degradability. For estimating modelling endpoints related to the mobility in soils, recommendations are mentioned in the Part 3.6.

Data to be generated should be also in line with the requirements of the models. The range of soil parameters analysed should cover European agricultural soils.

This section was not updated as it reflects these different issues. |
|        | ECPA                               | 2.1.2 Chemical properties and fate of transition metals | Page 21, line 1 to 2: Can EFSA please provide examples for other transition metals (not only for free copper) that the availability in pore water in increased with pH below 5. It is possible to transfer the circumstances for copper to other transition metals?

EFSA reminds that data availability will depend to a large extent on the type of metal/metal compound. ECHA guidance (2008) indicated that “the fraction of free metal ion will generally decrease with increasing pH. Increasing pH causes an increase in Kd value for cationic metals, and decreasing Kd values for anionic metal ions”. The statement has not been updated. |
| 19     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 2.1.2 Chemical properties and fate of transition metals | Page 20, line 9. Disagree with use of the term “persistent”. This has a very specific regulatory meaning and is considered inappropriate in this context. All elements are, by nature, retained in the environment but are not considered “persistent”.

EFSA: Whilst understanding the reasoning for the disagreement we are in this case not using the very specific regulatory meaning being referred to here by the copper task force but rather the meaning of the word in English, a definition for which can be found in the Oxford English dictionary. Changes to the statement were not made. Note there are at least four regulatory contexts in Regulation 1107/2009 where ‘persistent’ is relevant and has different regulatory meanings. Three relate to risk management. These are annex II cut offs for POP, PBT and vPvB assessments, the identification of candidates for substitution and the criteria for the approval of low risk active substances. These have no relevance for the statement, which has a context of risk assessment. The 3rd context is a uniform principle for decision making on product authorisation which has been discussed in section 2.2 of the statement, as it does relate to risk assessment. In this context transition metal residues have to be considered persistent, their residues having potential for accumulation in at least soils and sediments. |
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|        |                                    | Page 21, lines 8-10: This statement is not correct. At low pH, more free metal cations are expected to be present in the environment (less negatively charged binding sites), but the relative bioavailability for uptake by organisms is low due to competition with protons. At high pH, competition for uptake of metal cations is lower due to the smaller concentration of protons, increasing the bioavailability for uptake and toxicity. However metal ions may be complexed with OH- ions, reducing the bioavailability. OH- is NOT competing with binding sites for metal cations but competing with binding sites for metal anions. | EFSA: Statement corrected |
|        |                                    | Page 21, line 25, 43 & 44: Mebane et al., 2020; Weltens et al., 2000; Luoma and Rainbow, 2008 - not included in References. | EFSA: References added |
|        |                                    | Page 21, line 38: Under oxidizing conditions trace metals are strongly scavenged by iron and manganese oxide phases and adsorption and (co)precipitation processes will result in the binding of these metals (Cappuyns and Swennen 2006). At a steady state situation, reached at long-term scale, the input of a metal via sedimentation and the output via resuspension will reach an equilibrium. In the long run as metals are being transported to deeper sediment layers the metals will also be less prone to resuspension. The burial process and the increasingly irreversible binding of the metals into the sediment matrix ensures that at the long term effects of metal contamination will be limited | EFSA: We do not agree. PPP can be used in most years so that there is regular replenishment of contaminated sediment on top of older contaminated matrices. Sediment is therefore considered a source and a sink for transition metal compound used as active substances in PPP. If the application of PPP ceases, then burial of contaminated sediment might occur. |
|        |                                    | Page 21, line 39: Acknowledges that the release of metals from sediment is limited so why do other sections focus on resuspension as a relatively significant source? | EFSA: EFSA does not agree with this statement, please see answer to comment above. |
|        |                                    | Page 21, line 43: In assessing risks for the sediment compartment the dietary route could indeed be of a relative higher importance than its role in the aquatic compartment. This is partly covered in the set-up of whole sediment toxicity tests and by using test species with different life and feeding strategies. | EFSA: Agreed |
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| 20     | Federal Environment Agency of Germany | 2.1.3 (Eco)Toxicological particularities of transition metals | 19 ; p 22, line 8 – 11: The environmental conditions can be influenced by agricultural management practice as described by Su et al (2020, https://doi.org/10.1016/j.ecoenv.2020.111201), showing raising bioavailability of metals after incorporation of straw. EFSA: Agreed, addressed in chapter 2.1.2 |
| 21     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 2.1.3 (Eco)Toxicological particularities of transition metals | Page 22, line 2: Need to clarify that not all transition metals are essential e.g. Cd, Hg, or define the scope of the statement as for essential transition metals only. EFSA: Agreed this section of the statement has been updated to indicate that ‘many including iron, cobalt, nickel and copper are essential for the biological function of organisms.’ See also reply at comment 13 where clarification is given that the mandate covers the transition metals, iron, cobalt, nickel and copper and that several sections of text were updated to clarify this. |
| 22     | Federal Environment Agency of Germany | 2.2 Consequences for the assessment of transition metals when used as active substances in plant protection products | 20 p. 19, line 15-17 It’s written that for the most recent EU evaluation of copper compounds the conclusions were reached for the representative uses on grapes, tomatoes and cucurbits. We would like to indicate, that Notifiers provide dossiers for a larger bandwidth of field (and green house) uses for copper containing PPPs, e.g. in orchards, hops, ornamentals, different berries and fruits, vegetables, sugar beet etc. on zonal and national level, especially with regards to an adequate evaluation of monitoring and background data. Considering all recommendations in the statement (e.g. evaluation of crop specific monitoring data in the preliminary phase in different compartments, adjustment of exposure models and scenarios, etc.), complex and specific risk assessment work will be required in the future for the authorization of intended metals uses according to Regulation (EC) 1107/2009. We therefore recommend to discuss in chapter 2.2, that all possible metal uses (in all crops) in Europe should be already considered in the Notifier´s EU-dossier and should be already assessed on EU level. EFSA: Your comments are noted. The PPR panel working group acknowledges that especially for substance that have the potential to accumulate in soil and sediment (which is the case for transition metal ions and compounds), it is important that as many plant protection products uses as possible are assessed and considered. This is already acknowledged in the statement, as is the need to consider other sources of input of transition metals in addition to plant protection product uses. However the existing review regulations allow the applicants to select the representative uses that will be addressed in the dossier provided and subsequently assessed for the EU approval decision. In the next renewal applications the panel working group members do encourage that the applicant provide exposure and risk assessments for all use patterns for which product authorisations might then be pursued in member states, following any positive approval decision, should this be
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|        |                                    |         | made. However the working group considers it has gone as far as it can in this respect considering the text already included in sections 2.3 and 2.2 of the statement. We hope that there is a clear message to the applicant’s putting together future renewal dossiers. |
|        |                                    |         | 21 p. 25, line 10-16 |
|        |                                    |         | We appreciate from a risk assessment view the recommendation to consider possible additive effects of different PPPs and other uses for risk manager decisions as well as to alignment of prospective risks characterization of all intended uses with the goals of other overarching legislative frameworks. |
|        |                                    |         | Noted. Thank you for the comment. |
| 23     | ECPA                              | 2.2     | Page 25, line 7 to 9: It should be noted that some transition metals like Copper or Iron containing products are used as fertilisers and applied to soil surfaces with much higher application rates as the plant protection products containing the same transition metals. |
|        |                                    |         | EFSA: Noted. The overall residues present in soil will be addressed in the characterisation of background concentrations. |
| 24     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 2.2     | Page 24, line 2-4: The sentence should be removed as it is not supported by any evidence that the species composition would change or overtime only toxic effects would be noted. |
|        |                                    |         | EFSA: Reference added |
|        |                                    |         | Page 24, line 27. The statement "Metals are classified as persistent in the European Union“ is incorrect. The REACH Regulation (EC) No 1907/2006 guidance (Chapter R.11: PBT/vPvB assessment) identifies that "Based on the common definition of an organic substance in chemistry, PBT and vPvB criteria are not applicable to inorganic substances“ and Regulation 1272/2008 (CLP) identifies that “For inorganic compounds and metals, the concept of degradability as applied to organic compounds has limited or no meaning”. Indeed, under Regulation (EC) No 1107/2009, the Standing Committee on Plants, Animals, Food and Feed concluded that ferric pyrophosphate(1) (a transition metal compound) meets the criteria for low-risk substances. While one of the criteria is that a substance shall not be considered as of low risk if it is persistent, natural minerals are exempt from this criterion (see Regulation 2017/1432). We would propose that all references to “persistent” throughout the document are re-assessed in context. (1) Final Review report for the active substance ferric |
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|        |                                   | pyrophosphate Finalised by the Standing Committee on Plants, Animals, Food and Feed on 19 May 2020 in view of the approval of ferric pyrophosphate as a low risk active substance in accordance with Regulation (EC) No 1107/2009. **EFSA:** See response at comment 19 regarding the fact that there are several different regulatory contexts for defining substances as persistent. Note the statement text was modified to ‘Metals have been considered as persistent in the European Union’ as it is agreed that this was not in the context of a CLP or other official classification. Note considering the point made on the management decision on low risk active substances where the phrase ‘hazard categories’ has been coined in Regulation 2017/1432. Whilst it is acknowledged that risk managers approved ferric pyrophosphate as a low risk active substance, this was not the case for copper compounds. Page 24, line 29: This is due to an inappropriate application of the PBT assessment. This document should rather stipulate that transition metals should be exempt from PBT assessment, in alignment to the practice by ECHA for REACH and biocides. This would lift the “candidate for substitution” categorization for transition metals, and be consistent with all other EU chemical legislations. **EFSA:** See response at comment 19 regarding the fact that there are several different regulatory contexts for defining substances as persistent. Note, as indicated above the statement text was modified to ‘Metals have been considered as persistent in the European Union’ as it is agreed that this was not in the context of a CLP or other official classification. The statement is intentionally silent about PBT assessment as these are hazard cut off criteria that are decided upon by risk managers and outside the scope of the statement. Likewise candidates for substitution decisions are in the realm of risk management. The text on page 24 merely provides the fact that the cited Commission database identifies the active substances that are candidates for substitution. Page 24, lines 37-39: The toxicity of most organic chemicals is also expected to be determined by site- and species-specific bioavailability. This is however often not studied to the same extent. Next to persistence (and comments above), the natural occurrence and the essentiality are evenly important to consider for transition metals. Refinements such as bioavailability corrections are often needed in a RA for metals because conventional metals resulted in PNEC or RAC below essentiality and natural background concentrations. **EFSA:** Noted, please see answers to comment 11. |
| 25     | French Agency for Food, Environmental and | 2.3.2 General Framework for environmental risk | 1) p.6, line 26 and p.27, line 23: Typo: “The exposure and effect assessment assumes” **EFSA:** Typo has been corrected in the updated statement. |
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|        | Occupational Health & Safety (ANSES) | occupational | assessment of transition metals in PPP |

2) Page 28, line 29 to 31, indicates that "It is proposed that – if envisaged – dedicated modules are developed within the current framework."

It is our understanding that indeed, the statement focuses on the need of potential development of specific scenarios for higher tier exposure assessment, since the existing ones are not suitable for transition metals and do not include bioavailability and speciation process. Since the developed specific modules/models would be metal specific, this is expected to be a complex and very time-consuming work. Also, it seems to us that good knowledge of the bioavailability/speciation processes of the transition metals are preliminary required if dedicated metal-specific scenarios are envisaged to be developed (defining the boundary and worst-case conditions), and that various robust data and adapted studies will be required.

Considering this, we are wondering whether alternative simpler approaches were considered. For example, the use of some reduction factors of exposure from dedicated studies on speciation/bioavailability behavior of the transition metals (for worst-case physico-chemical conditions), or based on information taken from ecotox tests could be discussed.

Please provide additional information/discussion on this point.

EFSA: All relevant information for developing/adapting scenarios should be made available according to the PPR Panel Opinion on Good Modelling Practice. According to the Reg. (EC) n°1107/2009, a literature search performed according to the EFSA guidance document (2011; EFSA Journal 2011;9(2):2092) should be conducted to gain sufficient information on the fate and behaviour of metals in the environment, especially on factors affecting their speciation/availability. A tiered approach is proposed in the framework of the document. The first step is based on the total concentration of metals in the environment that is considered as fully available.

The use of reduction factors of exposure in the exposure assessment is not seen as a less complex alternative approach. Indeed, a general reduction factor for exposure is difficult to establish as the bioavailability/speciation processes of the transition metals in the environmental compartments are affected by several environmental factors. As an example, the fraction of free metal ion will generally decrease with increasing pH, but can be also affected by other soil parameters. In the ECHA guidance (2008) it is indicated that "Increasing pH causes an increase in Kd value for cationic metals, and decreasing Kd values for anionic metal ions. Increasing organic matter content can result in decreasing bioavailability for both cations and anions. Increasing eCEC (effective Cation Exchange Capacity) may cause decreasing bioavailability for cationic metals in the soil. Increasing clay content (including oxides) can result in decreasing bioavailability for both cations and anions". Thus, the
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| 26     | Federal Environment Agency of Germany | 2.3.2 General Framework for environmental risk assessment of transition metals in PPP | reduction factor derived from a study will be representative of the experimental conditions. The extrapolation of the data beyond the conditions of the study is questionable. The conservativeness of such studies has to be discussed in term of temporal and spatial representativeness. |
|        | 1) 22 p 26 - 27, line 38 - 13 | We appreciate very much the inclusion of the preliminary phase – especially the inclusion of monitoring data. EFSA: Noted. Thank you for your comment |
|        | 2) 23 p 27, line 16 -29 | We appreciate the inclusion of background and anthropogenic residue levels in the calculation of PECs. EFSA: Noted. Thank you for your comment |
|        | 3) 24 p. 28, line 29-31; p.30, line 11-14; p.30, line 20-21 | Mainly because metals behave different in the environment as organic chemicals and metals are already present as background values in different environmental compartments, comprehensive model and scenario adjustments are recommended for future exposure assessments of metals for different environmental compartments (e.g. soil, surface water and sediment, groundwater). This sounds reasonable, but triggers the need of specialist’s work which is far beyond the daily regulatory risk assessment work. It becomes not clear in the statement, how responsibilities on that should be. We strongly recommend, that such comprehensive model adjustments should not be part of Notifier’s dossiers for the renewal of active substance approvals or product authorizations on zonal or national level. Such tasks should rather be given to the dedicated working groups of EFSA together with experts from the member states. It’s probably a point which needs more clarification in the statement. EFSA: Noted. Please refer to the final statement in the summary and chapter 2.3.2 “General remark on the development of risk assessment methodologies for transition metals used as PPPs” |
|        | 4) 25 p 28, line 39 – 40 | We appreciate the inclusion of processes at the biotic ligand site for TM. EFSA: Noted |
|        | 5) 26 p 29, lines 11 – 13, & line 34 – 38 | It would be necessary, to develop a harmonized decision between member states about ‘relevant time frames’ for higher tier studies. |
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| 27     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 2.3.2 General Framework for environmental risk assessment of transition metals in PPP | 1) Page 26, line 30: Reduced bioavailability of residues from past applications should be included in the first assessment step rather than assume that these are fully bioavailable.  
EFSA: Disagreed. In the available examples of the risk assessment of iron compounds, to date, low risk was identified without this refinement. Thus, this step can result in satisfactory risk characterisation and allow decision making. The statement was not updated.  
2) Page 26, line 34: See comment to page 4, line 8. For sediment the situation is different. Due to the more indirect nature of enrichment of the sediment matrix it can be assumed as in equilibrium.  
EFSA: Disagreed. As the aquatic systems being assessed are dynamic (have flow) including in the ponds assessed (there is even greater flow in ditches and streams) the concentrations in the upper layers of sediment and sediment pore water are not in equilibrium. Therefore, it is not justified to assume equilibrium in the exposure and risk assessment.  
3) Page 26, line 39: Guidance is missing on the relevant form of metal to be analyzed in monitoring programs (e.g. dissolved fraction in aquatic environment, and total metal concentration in soil and sediment).  
EFSA: Please see the dedicated chapter on monitoring (section 4.1.4)  
4) Page 27, line 2: Access for the applicant to the LUCAS database has been rejected, and similar issues exist with Member State data. It would be appreciated if the document could encourage the relevant agencies to make those data available to applicants, by fully preserving the required confidentiality requirements of the agencies.  
EFSA: We agree that data bases containing environmental data should be made publicly available. This has been added to the updated statement.  
5) Page 27, lines 18 and 23: Assuming 100% bioavailability is not a realistic worst-case, but rather a Tier 0 (see also general comment to the Abstract).  
EFSA: Disagreed. Changes have not been made in the statement. This is a risk assessment step that has been described as step 1 by the authors. The framework described has no step or tier 0. There is no utility in adding a step 0.  
6) Page 27, lines 23-25: OK not to include ageing corrections in the first tier. It is however not clear how to deal with variation in bioavailability for direct toxicity to aquatic, sediment and soil organisms due to differences in |
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|        |                                   |         | physico-chemical properties of the environment. Bioavailability does not only depend on the concentration of the metal, but also on the concentration on competing ions for uptake. This is directly included in the biotic ligand models for aquatic toxicity and indirectly in the regression models for soil toxicity. Will worst-case assumptions be made at the effects side (RAC)? |
|        |                                   |         | **EFSA:** Yes, in the first step of the assessment. As described below, refinement might be possible at higher assessment steps. Regarding ageing factors, please see also answer to comment 11 point 26 |
| 7)     | Page 28, lines 16-20:             |         | Agreed to start with worst-case speciation (maximum bioavailability), but this only is relevant for complexation reactions with DOC (aquatic environment) and ageing reactions in soil. Other bioavailability reactions based on e.g. competition for uptake in BLM also depend on physico-chemical properties of the environment independent of the metal concentration. See also previous comment. |
|        |                                   |         | **EFSA:** See answer to comment above |
| 8)     | Page 28, line 28:                 |         | processes at the biotic ligand site should be considered rather than might be considered. |
|        |                                   |         | **EFSA:** Refinement is to be understood as an option, sentence not changed. |
| 9)     | Page 28, line 29:                 |         | Who will be responsible for the adaption of the existing modelling framework tools and scenarios? |
|        |                                   |         | **EFSA:** Please refer to “General remark on the development of risk assessment methodologies for transition metals used as PPPs.” |
| 10)    | FOCUS SW Repair has recommended developments to encompass other soil properties. |
|        |                                   |         | **EFSA:** Noted |
| 11)    | Page 29, line 5:                  |         | The proposed development and use of simple, fit-for-purpose models is welcomed. But may be at odds with other recommendations in the statement. |
|        |                                   |         | **EFSA:** Noted |
| 12)    | Page 29; line 31-33:              |         | On what basis can it be concluded that there is sufficient certainty and available knowledge for a metal to be of low risk in the environment. What are the criteria? |
|        |                                   |         | **EFSA:** The criteria are the same as for other active substances in PPP (acceptability criteria). In addition, available data on background concentration should be accepted by competent authorities to cover the intended uses to be assessed. |
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| 13     |                                   | 3.1     | 3.1 Aquatic Environment (surface waters and sediment) ;3.1.2 Exposure assessment, fate and behaviour of transition metals in surface waters and sediment;3.1.3 Linking exposure and effects ;3.1.4 Risk assessment ;3.1.5 General conclusions and recommendations for the aquatic environment ;3.2.1 Effect assessment and ecotoxicologically relevant exposure quantities ;3.2.2 Exposure assessment, fate and behaviour of transition metals in soils ;3.2.4 Risk assessment ;3.2.5 General conclusions and recommendations for the in-soil compartment ;3.4.1 Effect assessment and ecotoxicologically relevant exposure quantities ;3.4.4 Risk assessment ;3.6.1 Assessment ;3.6.2 Conclusions and recommendations for groundwater EFSA: Noted that your comments refer to these sections. |
| 28     | French Agency for Food, Environmental and Occupational Health & Safety (ANSES) | 3.     | 3.1 Aquatic Environment (surface waters and sediment) ;3.1.2 Exposure assessment, fate and behaviour of transition metals in surface waters and sediment;3.1.3 Linking exposure and effects ;3.1.4 Risk assessment ;3.1.5 General conclusions and recommendations for the aquatic environment ;3.2.1 Effect assessment and ecotoxicologically relevant exposure quantities ;3.2.2 Exposure assessment, fate and behaviour of transition metals in soils ;3.2.4 Risk assessment ;3.2.5 General conclusions and recommendations for the in-soil compartment ;3.4.1 Effect assessment and ecotoxicologically relevant exposure quantities ;3.4.4 Risk assessment ;3.6.1 Assessment ;3.6.2 Conclusions and recommendations for groundwater EFSA: Noted that your comments refer to these sections. |
| 29     | Federal Environment Agency of Germany | 3.     | 3.1.2 Exposure assessment, fate and behaviour of transition metals in surface waters and sediment EFSA: Noted that your comment refers to this section. |
| 30     | Federal Environment | 3.     | 3.1.5 General conclusions and recommendations for the aquatic environment |
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| Agency of Germany | risk assessment | | EFSA: Noted that your comment refers to this section. |
| 31 | Federal Environment Agency of Germany | 3. Environmental risk assessment | 3.2 Terrestrial in-soil environment EFSA: Noted that your comment refers to this section. |
| 32 | Federal Environment Agency of Germany | 3. Environmental risk assessment | 3.5 Terrestrial above-ground environment: Vertebrates (Birds, Mammals, Amphibians, Reptiles) EFSA: Noted that your comment refers to this section. |
| 33 | Federal Environment Agency of Germany | 3. Environmental risk assessment | 3.6 Leaching to groundwater EFSA: Noted that your comment refers to this section. |
| 34 | ECPA | 3. Environmental risk assessment | 3.1.2 Exposure assessment, fate and behaviour of transition metals in surface waters and sediment;3.6.2 Conclusions and recommendations for groundwater EFSA: Noted that your comments refer to these sections. |
| 35 | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 3. Environmental risk assessment | 3.1.1 Effect assessment and ecotoxicologically relevant exposure quantities ;3.1.2 Exposure assessment, fate and behaviour of transition metals in surface waters and sediment;3.1.3 Linking exposure and effects ;3.1.4 Risk assessment ;3.1.5 General conclusions and recommendations for the aquatic environment ;3.2.1 Effect assessment and ecotoxicologically relevant exposure quantities ;3.2.2 Exposure assessment, fate and behaviour of transition metals in soils ;3.2.3 Linking exposure and effects ;3.2.4 Risk assessment ;3.2.5 General conclusions and recommendations for the in-soil compartment ;3.3.2 Exposure assessment, fate and behaviour of transition metals above ground;3.4.4 Risk assessment ;3.5.1 Effect assessment and ecotoxicologically relevant exposure quantities ;3.5.2 Exposure assessment, fate and behaviour of transition metals above ground;3.5.3 General conclusions and recommendations ;3.6.1 Assessment ;3.6.2 Conclusions and recommendations for groundwater ;3.7 Addressing uncertainty in the risk assessment EFSA: Noted that your comments refer to these sections. |
| 36 | Junghans, Marion | 3. Environmental risk assessment | 3.1 Aquatic Environment (surface waters and sediment) ;3.1.1 Effect assessment and ecotoxicologically relevant exposure quantities ;3.1.4 Risk assessment ;3.1.5 General conclusions and recommendations for the aquatic environment ;3.7 Addressing uncertainty in the risk assessment |
| Number | Organisation or name or respondent | Chapter | Comments and PPR WG responses |
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|        |                                   |         | EFSA: Noted that your comments refer to these sections. |
| 37     | Casado, Carmen                     | 3. Environmental risk assessment | 3.1 Aquatic Environment (surface waters and sediment) EFSA: Noted that your comment refers to this section. |
| 38     | French Agency for Food, Environmental and Occupational Health & Safety (ANSES) | 3.1 Aquatic Environment (surface waters and sediment) | 1) The General framework for the aquatic risk characterisation (Figure 7, p.58 of the ECHA GD 2008) indicates that in case where a BLM is not available, physico-chemical speciation modelling can be used for the refinement of the risk assessment. Please clarify why this option is not indicated in the tiered approach of the EFSA statement.  
  
  EFSA: It is suggested, see 3.1.4  
  2) It is said in point No 7 of the “General conclusions and recommendations for the aquatic environment” (l.15 p.51): “The endpoints for the water compartment can be normalised in a refinement step to the physico-chemical parameters either using speciation models or if available biotic ligand models. However, this is not mentioned before in the document, especially in the tiered approach explanation. It is Anses opinion that if using only a speciation model is a possibility for the risk assessment, it should be indicated more clearly in the document.  
  
  EFSA: Simplified tools such as physico-chemical speciation tools are also mentioned in 3.1.3 and 3.1.4. The statement has been amended to indicate a preference for simplified tools.  
  3) p. 36, line 32-35: Anses agrees with the fact that more sediment species should be tested in the controlled conditions of the laboratory in order to get robust and comparable endpoints in term of exposure. This would allow to perform robust HC5 calculations.  
  
  EFSA: Noted  
  4) p. 36-37: Use of SSD is suggested to perform a higher-tier risk assessment for sediment organisms. We agree with this approach, but would like to point out that usually the number of reliable endpoints available to perform such SSD is scarce. In fact, it is common that literature data are used to calculate HC5. However, data retrieved from the literature are often heterogeneous in term of robustness depending on details provided in articles. A more precise procedure about how endpoints should be selected to perform SSD would be then welcome.  
  
  EFSA: The quality of the retrieved or newly submitted data by the applicant will be part of the assessment by the authorities in order to decide on the assessment factor to be applied. The availability of raw data to check...
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|        |                                  | 3.1 Aquatic Environment (surface waters and sediment) | for the derivation of ecotoxicological endpoints and the description of study details will be decisive for the inclusion of the data point in the SSD, the derivation of e.g. HC5 and the decision on the assessment factor to be applied. Please refer to the indications in the Guidance Document for aquatic organisms (EFSA 2014). The text for the soil organisms effect assessment has been updated. 5) P. 37, line 1-2: It is our understanding that comparable sublethal endpoints means endpoints belonging to the same parameters or physiological pathways (i.e. reproduction, growth, etc.). The time to effect should also be considered. Can you, please, provide this information in the statement? EFSA: Information was added |
| 39     | Junghans, Marion                 | 3.1 Aquatic Environment (surface waters and sediment) | It is a well written and thorough guidance. I especially welcome the caution that is recommended regarding the use of BLM models with regard to relevance and applicability. Especially the considerations regarding the fact that BLM assume equilibrium, which cannot be assumed for exposure peaks. EFSA: Noted |
| 40     | Casado, Carmen                   | 3.1 Aquatic Environment (surface waters and sediment) | It is acknowledged that this chapter provides a thorough review of metal-specific issues that should be accounted for. Page 31, line 13: although no information is provided on AVS content on OECD guidelines, it is assumed that artificial OECD sediment as the one used in chironomid and myriophyllum sediment-water tests have relatively low AVS (<0.05 mmol/kg d.w.) and have virtually no background metal concentrations, so they are assumed to represent a worst case scenario. I would recommend adding here a footnote, or a reference to the chapter where this point is discussed further later on. EFSA: Point added |
|        |                                  |         | Page 32: In relation to equilibrium, it is stated that equilibrium is not assumed for transitional metals added as PPP. I it somehow difficult then to assume that tests performed after 30 or 40 days of equilibration are worst case, and in line with the statements in the recommendations. This should be clarified. In addition, it is stated that copper-spiked sediment would require 14 days of equilibration. A number of studies for metals at present used for risk assessment includes 7 to 10 days of equilibration, so 14 days of equilibration is not accomplished, I wonders how to deal with “borderline” equilibration. EFSA: It is stated: Equilibrium status in the test system (water and sediment) should reflect the equilibrium of the exposure path to be assessed. The time to reach equilibrium depends on the test system and metal. |
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| 41     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 3.1.1 Effect assessment and ecotoxicologically relevant exposure quantities | 1) Page 31, line 13: For the OECD artificial sediment AVS concentrations can be assumed close to zero which means that using OECD sediment is rather a worst-case scenario maximizing bioavailability.  

**EFSA: Text amended**  
2) Page 32, line 5: The OECD 218 and OECD 225 guidelines have been developed in the spirit of testing organic chemicals. As such proper equilibration is not awaited for but an equilibration period of 48h is recommended to minimize time for degradation of the test chemical. However, it is recognized that depending on the purpose of the study the sediment may be equilibrated for a longer time period. The latter is specifically important when testing metals. Simpson et al. (2004) demonstrated that relatively long equilibration times are needed for metals – as long as 70 d for nickel to 15 d for copper, 40 d for zinc, and 45 d for cadmium in order to produce an environmentally realistic metal partitioning in a sediment-water system.  

**EFSA: Text amended** |
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|--------|-----------------------------------|---------|------------------------------|
|        |                                   |         | **EFSA: Noted, already addressed in the text: Sediment spiked with Cu took 15 days to reach equilibration and 40 days for Zn (OECD, 259).** |
|        |                                   |         | Page 32, line 9: It is considered unlikely that spiked sediment would contribute to overlying water metal concentrations. |
|        |                                   |         | **EFSA: Reference added** |
|        |                                   |         | 3) Page 32, line 26: Not all transition metals are essential. |
|        |                                   |         | **EFSA: Please see answer to comment 11 point 1** |
|        |                                   |         | 4) Page 33, line 22: please add “e.g.” to (Ca2+, H3O+, Na+) as there are other cations that may interact such as Mg2+. |
|        |                                   |         | **EFSA: Text amended** |
|        |                                   |         | 5) Page 33, line 31: Although exposure to dietary copper often results in an increased copper body burden of the adult daphnids, it did not contribute to toxicity (De Schamphelaere and Janssen, 2004). |
|        |                                   |         | **EFSA: Reference is already included** |
|        |                                   |         | 6) Page 36, line 1: Bioaccumulation has been observed. However, for those species which have active detoxification systems in place it has been shown that metals taken up via the dietary phase (example metals sequestered by sulphides) are stored into a biological detoxified pool not contributing to the observed toxicity by exposure to the metal via pore water (De Jonge et al, 2011). |
|        |                                   |         | **EFSA: Noted. It is stated: The toxicological effects due the accumulation of a metal depends on the detoxification mechanisms present in a species. De Jonge et al. (2011) explain that this is the case for anoxic conditions and for non-essential metals. In this statement, also oxic sediment conditions need to be covered and essential metals.** |
|        |                                   |         | 7) Page 36, line 33: Is testing on the actual sediment species listed a requirement, or are these examples of which species can be used? |
|        |                                   |         | **EFSA: This is a statement with suggestions and not a guidance document with recommendations** |
|        |                                   |         | 8) Page 37, line 37: Equilibrium in semi-static systems is also dependent on the equilibration time in the test solution, not just the renewal period. |
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| 42     | Junghans, Marion                  | 3.1.1   | EFSA: Text amended           |
|        |                                   | Effect  | 9) Page 37, line 39: Dietary  |
|        |                                   | assessment| metal indeed may result in   |
|        |                                   | and      | higher uptake/accumulation   |
|        |                                   | ecotoxicologica| but not to increased |
|        |                                   | lly relevant| toxicity. Here it is        |
|        |                                   | exposure quantities| suggested that dietary Zn |
|        |                                   |          | contributes to toxicity,     |
|        |                                   |          | please refer to literature  |
|        |                                   |          | to substantiate this.        |
|        |                                   |          | EFSA: Reference is included  |
|        |                                   |          | in the text above: Dietborne |
|        |                                   |          | Zn may selectively accumulate|
|        |                                   |          | in reproductive tissue of D. |
|        |                                   |          | magna and both exposure      |
|        |                                   |          | routes were considered       |
|        |                                   |          | relevant for the risk        |
|        |                                   |          | assessment, also as alterations |
|        |                                   |          | of the algal diet may have   |
|        |                                   |          | been caused indirectly due   |
|        |                                   |          | to Zn exposure (Evans et al., |
|        |                                   |          | 2012 see DeForest and Meyer, |
|        |                                   |          | 2015).                       |
|        |                                   |          | According to Clearwater et al. |
|        |                                   |          | (2002), “Both dietborne and       |
|        |                                   |          | waterborne Cu or Zn exposure  |
|        |                                   |          | can contribute to metal       |
|        |                                   |          | uptake and toxicity” in fish. |
|        |                                   |          | And DeForest and Meyer (2015) |
|        |                                   |          | state that “Ag, As, Cd, Cu, Ni, |
|        |                                   |          | and Zn have caused dietborne  |
|        |                                   |          | toxicity in laboratory        |
|        |                                   |          | exposures when the dietborne  |
|        |                                   |          | concentrations resulted from   |
|        |                                   |          | the exposure of the food to     |
|        |                                   |          | waterborne concentrations near  |
|        |                                   |          | toxicity thresholds”.          |
| 43     | French Agency for Food, Environmental and Occupational Health & Safety (ANSES) | 3.1.2 | Page 39, line 29 to page 40, line 6. |
|        |                                   | Exposure assessment, fate and behaviour of transition metals in surface waters and sediment | This paragraph gives relevant information on the adsorption of transition metals and recommendations/warnings on the way they should be handled in modelling. It is suggested that these are also reported in the conclusions and recommendations for exposure assessment, on p.43-44 or on p. 49. |
|        |                                   |          | EFSA: Agreed. The estimation of the sorption parameters should be performed in an appropriate way. The part on conclusions and recommendations for exposure assessment has been updated. |
|        |                                   |          | Page 41, the comparison between FOCUS and IDMM approaches is appreciated. Please indicate whether a review of other potential existing models including speciation processes has been performed. |
|        |                                   |          | EFSA: A review of all models available in the literature was not performed in the framework of this statement. The statement provides option and recommendations for what should be considered for future model and scenario development. |
Conclusions and recommendations for exposure assessment, fate and behavior of transition metals in surface waters and sediment:
- It is unclear whether the STEP 1-2 can be used for worst-case first tier assessment, in the absence of further agreed models.

As described on p. 40, STEP1-2 considering drift and drainage/run-off entries was used at EU level for copper, and it is apparently considered that “the current risk assessment according to EFSA [...] is deemed conservative” (on page 43, line 33). However, it is finally recommended on page 44 that PEC values other than due to the drift calculated with the STEP1-2 tool should not be considered for risk assessment.

The paragraph from line 3 to 12 on page 44 could be clarified. It is stated that STEP 2 calculation might not be conservative for water exposure from run-off/drainage and for sediment due to consideration of equilibrium conditions between water and sediment. It is our understanding that this is due to the partitioning process based on the Kd value used as input parameter. However, at first tier if contrasting worst-case default values of Kd are used to evaluate PECsw (Kd of 0) and PECsed (Kd of 10000 as proposed during EU review), the equilibrium state considered in the model might be offset. Please clarify these points.

EFSA: As presented in the statement, the FOCUS model was used as a first-tier assessment for the approval of some inorganic compounds. It was agreed that the current risk assessment performed in term of total transition metals according to the procedures used in the compound iron sulfate (EFSA 2012) and copper compounds (EFSA 2018) evaluation is considered conservative since the transition metals are considered fully bioavailable in the aquatic systems. If any refinements are needed, options and recommendations on the exposure assessment have been proposed.

The use of default values for sorption parameters is not seen as first-tier assessment, since the processes implied in the fate of metals are time-dependent. Please also see response to comment 44. A paragraph has been added to the statement.

- The recommendations and conclusions are mainly based on exposure issues. It could be further discussed whether the regulatory data requirements (e.g. for mobility) are suitable to transition metals, or if further specific behavior data would be required to help refinement considering speciation and (bio)availability.

EFSA: The statement states that the current models are not able to simulate the fate of metals in the environment in an appropriate way. The major processes and factors affecting them are presented in the
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|--------|----------------------------------|---------|------------------------------|
|        |                                  | 3.1.2 Exposure assessment, fate and behaviour of transition metals in surface waters and sediment | **27** Overall |
| 44     | Federal Environment Agency of Germany | 3.1.2 Exposure assessment, fate and behaviour of transition metals in surface waters and sediment | 
|        |                                  |         | Use and limitations of FOCUS models are well described in chapter 3.1.2. However, we miss a more detailed discussion about the relevance (or different importance) of the entry processes drift, runoff, erosion and drainage for exposure assessment of metals in the surface water and sediment compartments. In past risk assessments for copper, the relevance and combination of the different entry routes in combination with single, seasonal and multi-year applications has been repeatedly and sometimes controversially discussed. |
|        |                                  |         | **EFSA**: The entries to waterbodies (drift, runoff/soil erosion and drainage) contribute to the contamination of the aquatic systems, but they don’t occur at the same time in the aquatic systems after PPPs application (runoff/soil erosion/drainage entries are usually delayed compared to the drift entry). Time being a driving factor in the equilibrium processes, FOCUS tools cannot hence simulate the fate of metal residues over the time for all entries in an appropriate way. It is reminded that all entries should be considered in the exposure assessment. |
|        |                                  |         | The entry to waterbodies due to drift can be estimated with FOCUS STEP 2 for a single application as no equilibrium is considered for PECsw, in calculation. For several applications (with a delay between applications), the FOCUS STEP 2 cannot simulate correctly the distribution of residues in the water column between applications (older residues vs freshly added residues; equilibrium processes not take into account). However, there is a possibility to consider multi-applications as a single application with a cumulative applied rate. |
|        |                                  |         | For the entries due to runoff/soil erosion and drainage, the rate to be implemented in modelling should consider the soil residues from both natural level and including the previous applications and the last application. For PECsw, runoff/drainage, an equilibrium state based on the Kd value is considered. In addition, metals in soils reaching aquatic systems can be free and/or sorbed to soil particles. Thus, this tool is not able to correctly simulate the distribution of residues in the water column. |
|        |                                  |         | For the reasons outlined above, seasonal, multi-year applications cannot be handled correctly with the exiting tool. |
|        |                                  |         | **28** p. 40, line 8-14 |
|        |                                  |         | It’s noted in the statement, that FOCUS Step 1-2 models need to be adapted and that the accumulation in sediment for total copper was calculated over a 10 years period in the EU assessment by missing adequate models. We would welcome a critical reflection on what this 10-year period of time represents according to the
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|        |                                   |         | long-term accumulation of copper in sediment. It would be useful, if the authors gave recommendations on a sufficient period of time for modelling PECs in sediment. |
|        |                                   |         | **EFSA:** According to the Reg (EC) 1107/2009, the exposure calculations should be performed for a period sufficiently long to assess long-term accumulation by modelling and/or accumulation studies. The 10 years period was proposed for the renewal approval of the active substance copper compounds. The statement reflects general considerations. No specific period can be proposed and this should be adapted related to the transition metal. Please refer to answer to comment 6 point 5. |
|        |                                   | 29 p. 40, line 14 ff. | Background levels of copper in stream sediments derived from monitoring data are a significant driving variable on the outcome of the RA. This requires a high-quality standard of the raw-data and a detailed reporting. We appreciate that the statement acknowledges ‘poor reporting’ of the current data for copper. Information on the characterization of the sampled sediments is required to draw conclusions whether they are typical and representative for agricultural circumstances (i.e. usually small water bodies / ditches with long history of copper use) and they mirror the accumulation behavior of metals adequately. Sediments in pristine conditions and sediments under continuous influence of anthropogenic and/or agricultural use are recommended to be reported distinctly. The range of existing copper contents in different sediments as well as the influence of the long-term copper use is best reported by different value types of background levels (e.g. 90th percentile, 10th percentile value). Only well reported data will allow that adequate values reflecting the respective conditions can be considered during RA and for RMM. |
|        |                                   |         | **EFSA:** Thank you for your feedback. |
|        |                                   | 30 p. 41, line 14 ff. | It should be ensured by EFSA that only such models are used / linked to FOCUS that are robust and validated by experts. This should not be subject to PPP legislation or individual dossier submission (refer also to comment to general framework). |
|        |                                   |         | **EFSA:** Please refer to response to comment on the general framework. |
|        |                                   | 31 p. 44, line 10 | The estimation that PECs for runoff/erosion/drainage derived with FOCUS may not be sufficiently conservative should not lead to the conclusion to totally exclude these pathways from consideration during the RA (especially in the absence of a reasoning of relevance for the distinct pathways or a related discussion). It was discussed and eventually decided during EU risk assessment for the active substance copper, that runoff, |
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Erosion and drainage are relevant pathways to be considered for PECsw and PECsed calculations. These should therefore as well be recommended for assessment in this statement for the time being until new models are available or scientific knowledge on the negligibility of pathways is presented.

It could however be argued, whether PECs for drift + runoff, erosion and drainage should be combined to one single PEC for the surface water compartment as simultaneous entry is unlikely (not valid for sediment acting as a sink).

**EFSA:** All entry routes should be considered in the risk assessment. Results for the individual entry routes should be combined together when the exposure assessment in terms of total metals is carried out. Please also refer above to response to point 1 of this comment.

32 p. 44, line 15 ff.
Throughout this chapter it is proposed that “two worst-case scenarios should be considered, one for 15 the pore water and one for the total sediment concentration” but no further instruction or explanation is given on the methodology for exposure calculation.

It remains unclear if the developing specific exposure models to account for pore water concentrations in sediment will eventually allow an improved risk assessment or just increase complexity.

**EFSA:** A tiered approach (more conservative to more realistic but more complex) has been proposed in the statement, considering additional processes is considered to be higher tier assessment.

The selection of the sediment scenarios should be derived in agreement with the knowledge on the fate and behaviour of the metal in the environment.

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| 45     | ECPA                               | 3.1.2 Exposure assessment, fate and behaviour of transition metals in surface waters and sediment | Page 38, line 22 to 28: Would the existing approach for FOCUS Step 3 acceptable for EFSA if soil, surface water and sediment (e.g. pH, organic carbon content, soil texture, bulk density, biomass, redox potential,...) were considered in the new scenario development for transition metals? **EFSA:** The FOCUS STEP 3 approach could be seen as appropriate but it is reminded that adaptation of the existing models/scenarios and development of the specific model/scenarios should be in agreement with the fate and behaviour of metals covered by this statement in the environmental compartments and the EFSA guidance document on the good modelling practices (2014). Time is another factor to be considered for simulating the fate of metals in the environment in an appropriate way. |
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| 46     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 3.1.2 Exposure assessment, fate and behaviour of transition metals in surface waters and sediment | Page 40, line 22 to 24: Can EFSA provide a more detailed definition of “realistic background concentration”? Is realistic similar to natural background concentration? On agricultural used areas with organic farming it could be that the Copper content in the upper soil layer is extremely higher as the natural background concentration. The same applies for fields where Fe-containing fertilisers were heavily used.  
EFSA: A reference is made to the Part 4 of the statement.  
Page 38, line 13: Suggests that FOCUS Steps 1 – 4 are used in the assessment, however later only references FOCUS Steps 1-2.  
EFSA: This paragraph is a general consideration. It is mentioned later in the statement that only FOCUS STEP 1-2 tool is suitable for the time being.  
Page 40, line 1: How accurate is this approach to predict metal Kd's?  
EFSA: This approach allows Kd values to be derived considering the transition metal which are already present in soil. Accuracy is related to the quality of the available data.  
Page 40, line 2: Should this not be 2,5 %?  
EFSA: The value as defined in the scenario definition (FOCUS, 2001) is presented in the document.  
Page 40, line 24: Will access to monitoring/surveying data be possible for the applicants? The EUCuTF request for access to the LUCAS database has been repeatedly rejected by JRC. Support should be provided to make EU and Member State data available to applicants.  
EFSA: We agree that data bases containing environmental data should be made publicly available. This has been added to the updated statement. JRC (ESDAC) has announced the release of the soil dataset based on samples collected during the 2015 LUCAS Survey (LUCAS Soil 2015).  
Page 41, line 28: It is not strictly the case that the IDMM does not deliver exposure concentrations. It is the case that it does not deliver blind predictions of total metal concentrations, but it can deliver predictions of the change in total metal concentrations given an ambient background concentration. It can deliver blind predictions of chemical active soil metal or porewater metal.  
EFSA: The available version delivers exposure concentrations for aquatic systems only.  
Page 41, Table 3, row “goal”: The difference between the FOCUS and IDMM model approaches for sediment PEC is correctly listed here, but it is worth noting that the goal of the IDMM (which also applies to soil, porewater and surface water PECs) is chosen on the basis of the long term accumulative properties of transition metals. |
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|        |                                  |         | Metals in soils in response to inputs. A model to estimate ‘maximum’ (which we presume to mean steady state) concentrations is certainly feasible, however the resulting PECs will likely be highly conservative overestimates of field concentrations. |
|        |                                  |         | EFSA: The IDMM model was proposed by the applicants for estimating the accumulation in sediment, not for the other environmental compartments. |
|        |                                  |         | Page 41, Table 3, row "item": It is not clear what ‘bioavailable fraction’ means. |
|        |                                  |         | EFSA: This term has been deleted in the revised table. |
|        |                                  |         | Page 42, Table 3, row “Soil background concentration” and “Sediment background concentration”: It is worth noting that the soil background is estimated from present day ambient concentrations and historic inputs, so allowing model results to be matched to present day conditions for future predictions of changes in concentrations. Soil background estimation feeds directly into sediment background estimation. |
|        |                                  |         | EFSA: Noted. |
|        |                                  |         | Page 42, Table 3, row “Surface water definitions”: The pond waterbody can and has been implemented in the IDMM (it is unclear why it is stated that ponds have not been considered). |
|        |                                  |         | EFSA: In the available version, the waterbody pond was not considered. |
|        |                                  |         | It is unclear why the soil layer layouts of the IDMM are listed here (The IDMM can have any number of soil layers of any specified depth). |
|        |                                  |         | EFSA: A brief description of the available information is presented in the Table. |
|        |                                  |         | Page 42/43, Table 3, row “Processes considered in soil compartment” and “Processes considered in sediment compartment”: It is unclear what process is referred to by ‘degradation’ – the remaining processes listed are complete. |
|        |                                  |         | EFSA: The degradation process is included in the models. |
|        |                                  |         | Aging is not considered in the sediment compartment. Aged metal can transfer from soil to surface water via soil erosion and to sediment by settling, but no further aging of labile metal takes place in these compartments, unless one considers the binding of metals by AVS as an aging process. |
|        |                                  |         | EFSA: Agrees. The term aging has been deleted in the table. |
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|        |                                   | 3.1.3 Linking exposure and effects | p. 45, lines 40-41: It is suggested to replace “and” by “as well as” in the following sentence: “Therefore, the site of action of toxicity needs to be known for each species and as well as the level of accumulation which causes the toxic response.”<br>EFSA: Text amended<br><br>From p. 45 line 1 to p. 47 line 16: The definition and use of BLMs in risk assessment is complex. In order to better understand how to use a BLM in risk assessment and what its limitations are, it may be useful for the reader to know more specifically what a BLM is and how it could be actually used for, for example, what the inputs and outputs of such a model are.<br>EFSA: In the statement, it was decided to refer to the relevant section of the ECHA GD (2008) where the BLM are described along with example of uses.<br><br>p. 46, lines 32 to 38: It is not very clear what “baseline bioavailability correction” and “full bioavailability correction” mean. Could you please clarify this point?<br>EFSA: Text has been amended. For a thorough explanation please refer to the ECHA GD (2008). |
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|        | p.46-47: It is our understanding that BLMs are useful tools but are not ready to be used as they are to date for environmental risk assessment. From our knowledge:  
- BLMs were developed for a limited number of taxonomic groups (mainly, fish and aquatic invertebrates) and that the representativeness of the BLM developed for one species to another is very limited.  
- Predicted endpoints derived from BLMs may also strongly depend on some input parameters such as the dissociated organic carbon (DOC) and pH.  
- The BLMs developed should be representative of the worst-case freshwater properties encountered in Europe. Selection of these parameters should be done first in a more specific European frame where freshwater properties that may influence the prediction of BLMs would be more studied and chosen through expert consultations set at European level. In addition, it seems more appropriate to better take into account the particularity of each European zone and maybe each European countries where very specific water properties may be encountered and therefore strongly influence the prediction of the BLMs.  
It is our opinion, that the selected parameters should be protective enough to cover all European scenarios. This would help getting harmonised ERA between member states.  
- Anses would support the use of an assessment factor for endpoints predicted from BLMs.  
EFSA: Agrees with the above. Assessment factors should be set when developing a GD.  
|        | p.47: Concerning input parameters to be used to perform BLMs, it is our opinion that these parameters should be selected first at the European level in order to be representative of worst-case scenarios that should be encountered in the field.  
This is, indeed, of importance as the predicted toxicity values would be compared to PECsw that should be representatives and robust to estimate a comparable exposure. New specific data might be generated to do so.  
EFSA: agrees, suitable exposure scenarios ideally need to be defined at EU-Level, which then need to be matched with the toxicity endpoints.  
| 48     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 3.1.3 Linking exposure and effects | Page 45, line 26: Please include reference to gBAM also, e.g. Bioavailability models such as BLMs, or gBAM (= generalized bioavailability models; Nys et al., 2020).  
EFSA: Reference included  
Page 45, line 40: The requirement that the site of action of toxicity is known is not necessarily correct, the BLMs do not require such information to perform the bioavailability corrections.  
EFSA: Text amended and reference added |
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|        |                                    | 3.1.4 Risk assessment | Page 46, line 23: It is true that uncertainties are remaining when applying the BLMs, but the overall uncertainty of the effects assessment is lowered as bioavailability drastically reduces the intra-species variability in toxicity data. For many organic compounds where bioavailability is of concern no bioavailability models exist. Therefore substances with a bioavailability model should not be 'punished' with a higher assessment factor compared to substances without any model.  

**EFSA:** The uncertainties are not quantified and no assessment factor has been suggested, therefore no comparison can be made.  

Page 47, line 9: Is there a step-wise approach on how to identify what is considered an uncertainty in the model and the relevant AF to be considered?  

**EFSA:** No suggestion about the value of relevant AF has been made in this statement. Assessment factors should be set when developing a GD.  

Page 48, line 1: Ageing should also be considered; in toxicity studies comparing the effects of ageing processes on the overall sediment toxicity observed in the field versus the toxicity of freshly metal spiked sediments (Cu and Ni) used in the laboratory results indeed point into the direction of a reduced toxicity over the long term (Costello et al 2015, Costello et al, 2016). Furthermore, in addition to the different chemical transformation processes that occur in the sediment over the long term, one needs to include sedimentation and burial processes into the equation. In the long run as metals are being transported to deeper sediment layers the metals will also be less prone to resuspension. The burial process and the increasingly irreversible binding of the metals into the sediment matrix ensures that at the long-term effects of metal contamination will be limited.  

**EFSA:** PPP can be used in most years so that there is regular replenishment of contaminated sediment on top of older contaminated matrices. Sediment is therefore considered a source and a sink for transition metal compound used as active substances in PPP. If the application of PPP ceases, then burial of contaminated sediment might occur.  

| 49     | French Agency for Food, Environmental and Occupational Health & Safety (ANSES) | 3.1.4 Risk assessment | Page 48. Anses supports the fact that both exposure and effects concentrations should be expressed at the same level of (bio)availability. It should be made clear that the relevant physical-chemical properties defining the worst-case realistic scenarios for both exposure and effects should be defined at EU level during approval process, in order to ensure a harmonized evaluation.  

**EFSA:** Agrees, suitable exposure scenarios need to be defined at EU level. All relevant information for developing/adapting scenarios should be made available according to the PPR Panel Opinion on Good Modelling Practice. |
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| 50     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 3.1.4 Risk assessment | We also note that the need of specific substance behavior in relation to those defined abiotic factors is not mentioned in the recommendations. In our opinion this is an important topic that should be further developed. EFSA: See comment 17. According to the Reg. (EC) n°1107/2009, a literature search performed according to the EFSA guidance document (2011; EFSA Journal 2011;9(2):2092) should be conducted to gain sufficient information on the fate and behaviour of metals in the environment, especially on factors affecting their speciation/availability. In addition a literature search should be performed according to the mentioned EFSA guidance to collect and assess information on the transition metal in support of a hazard characterisation and environmental risk assessment. |
| 51     | Junghans, Marion                   | 3.1.4 Risk assessment | Page 48, line 37: Disagree, BLMs are used to extrapolate to other species from the same taxa, e.g. Fish BLM can be used to normalise toxicity data for all fish. EFSA: Agreed, text deleted. |
| 52     | French Agency for Food, Environmental and Occupational Health & Safety (ANSES) | 3.1.5 General conclusions and recommendations for the aquatic environment | p.52, line 28: Typo: “The development of exposure scenarios for specific transition metals needs to” EFSA: The typo has been corrected in the updated statement. p.52 line 18: A word seems to be missing in the following sentence: “The procedures for obtaining the pesticide properties and uses should be clearly described and wherever possible harmonized must be used to avoid user subjectivity.” EFSA: The correction has been made in the updated statement. |
| 53     | Federal Environment Agency of Germany | 3.1.5 General conclusions and recommendations for the aquatic environment | 33 p. 52, line 9 Washing-out of particle-bound copper from fields via erosion is expected to be a significant process and should be mentioned here. EFSA: Agreed, extra detail that runoff includes ‘both solute and eroded soil inputs’ was included in parenthesis 34 p. 52, line 16 ff. It should probably be mentioned that the evaluation of such new and yet unvalidated models should not be
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| 54     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 3.1.5 General conclusions and recommendations for the aquatic environment | subject to PPP legislation or individual dossier submission in order not to overstrain risk assessors and to avoid a disharmonized assessment.  
EFSA: Stating this would go beyond the scope of the working group to provide a framework for assessment in the mandate. The statement text was not changed in section 3.1.5. However please note that General conclusion and recommendations section 5, 4th issue is pertinent to this comment. |

1) Page 50, line 31: It is unlikely that all of the listed abiotic factors will be available for each study (especially in older studies). Missing data should not be as reason for discounting study results.  
EFSA: If data on a chemical parameter is missing, the study should be reviewed with caution. The impact on the reliability of the study should be discussed further.  
2) Page 50, line 31: It is wrong to use the solution concentration without considering the bioavailability. In this regards it appears that a tier I assessment for transition metals is a more harsh risk assessment compared to what would be expected for a tier I risk assessment for synthetic pesticides since the bioavailability of transition metals is not considered until higher tier risk assessments.  
EFSA: See answer to comment 2, and also answer to comment 11. The principle of the tiered approach is to move from a simple protective 1st tier to a more complex higher tier in order to be resource efficient. As the evaluation of bioavailability refinements is complex and need specific data, it is considered a higher tier refinement. This statement does not address a comparative 1st tier risk assessment between synthetic PPP and transition metal compounds used as PPP.  
3) Page 50, line 34: Alkalinity can be measured but it is not needed in the user-friendly BLM tools.  
EFSA: All factors driving the speciation and the (bio-) availability should be made available.  
4) Page 51, line 7: Why would a long-term endpoint such as reproduction be affected by the concentration over a short time window?  
EFSA: Delayed effects on reproduction may occur due to short-term exposure of specific sensitive life cycle stages (see aquatic GD, 2013)  
5) Page 51, line 8: For sediments this should be in the order of days/months.  
EFSA: Text amended |
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| 6)     |                                   | 6) Page 51, line 12: Studies are 48 h for daphnia and 96 h for fish, therefore it is difficult to account for the equilibrium concentration in acute aquatic toxicity studies. Given the time-course for run-off to reach the aquatic environment, it should be assumed that run-off is in equilibrium.  
**EFSA:** Equilibrium in the waterbody is not expected to be reached for event-driven inputs.  
7) Page 51, line 23: HC5 is applied under ECHA and an SSD across all taxa was accepted. The same approach should be allowed for transition metal PPP’s. BLM are metal and organism specific and can’t be extrapolated but contradicts the normalisation/SSD approach. The approach should be to normalise species data to BLM and use the normalised data in a multi-taxa SSD approach.  
**EFSA:** The aquatic GD (2013) provides decision criteria for the selection of toxicity data for an SSD.  
8) Page 51, line 37: We disagree that consideration of recovery is unacceptable, we think that there is no significant re-suspension of metals from sediment.  
**EFSA:** Noted. The specific aspects of degradation and resuspension have been addressed in the statement and comments (see comment 19 and 48).  
9) Page 51, line 40: Does this imply that both SSD and a mesocosm is recommended for refining the RA?  
**EFSA:** Both approaches are considered as relevant for a refined risk assessment of PPP with metals  
10) Page 52, line 5: This point is unclear as to what it means.  
**EFSA:** The text has been amended  
11) Page 52, line 28: Guidance on this point is required. How is representative data defined?  
**EFSA:** Please see the description of the preliminary step and the indication in chapter 4 Environmental monitoring |
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| 56     | Federal Environment Agency of Germany | 3.2 Terrestrial in-soil environment | Page 51 bullet point 9: could you please clarify whether the tier 2 approaches should be based on data normalised to a common DOC and pH?  
EFSA: Common in the sense of the same, not in the sense of a standard reference value. |

Hazard characterization Please note, the current data requirement as well as the risk assessment for in soil organisms or microorganisms might not cover all effects, possibly occurring after the application of PPP’s (See also EFSA Sciop for in-soil organisms). Garg & Cheema (2020, https://doi.org/10.1016/j.ecoenv.2020.111196) describe the influence of Arsenic on soil functions like reduced enzyme activities and lowered glomalin concentrations in combination with reduced plant growth. Neither the influence of PPP entry regarding soil functions like enzyme activity nor glomalin presence are evaluated according to the current guidance document for in soil organisms. As metals show a high persistence in the environment, soil functions as well as plant production could be hampered in future.  
EFSA: Thank you for your comment. Indications on the developments needed as described in the scientific opinions of EFSA are given in the document later in the chapter and have been highlighted  
36 p 53, lines 12 - 15  
Please note: the chronic test for earthworms according to OECD 222 includes the addition of clean food, weekly. Could you include this information in the mentioned phrase?  
EFSA: Thank you, added.  
37 p 53, lines 16 - 28  
The conduction of field studies on earthworms or other soil mesofauna according to / following ISO 11263-3 (2014) might not be appropriate for metals due to their high persistence. E.g. field studies on copper show effects after continuous exposure over years while in the first year of observation no effects have been detected (RAR of copper, B9).  
EFSA: Noted  
38 p 54  
We appreciate the recommendations regarding the SSD – different trophic levels should not be mixed up. However, an assessment factor of at least 3 should be applied in order to enable extrapolation from lab to field as well as towards other non-tested species.  
EFSA: Noted |
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| 39 p 57, line 1 |  |  | We are not surprised about this statement as choosing a soil layer of 5 cm for the estimation of the PEC for metals assumes a distribution of metals in this soil layer. Due the phys/chem properties of metals, especially their high binding affinity, a distribution in a soil layer of 5 cm without agricultural management practices is not expected. Could the evaluation of the distribution of metals in the soil layer after use as PPP please be included in the monitoring set-up? |
| EFSA: Noted, please see answer to the next point |  |  |  |
| 40 3p 58, line 12 – 13 |  |  | The assumption of a homogenic distribution of metals in 5 cm or 20 cm soil layer is not realistic as the soil layers are not mixed homogenously by agricultural management practices. Would it be possible to include the observation of real copper distribution in the soil layer in the monitoring studies? |
| EFSA: These soil depths are in line with the FOCUS guidance document. The observation of real copper distribution in the soil layer as measured in the surveying studies can be used to derive representative soil background concentration, within the constraints of the sampling approach in each survey. The dedicated monitoring studies can be used for regulatory risk assessment purpose and the ability to extrapolate beyond the field area should be also further discussed. Considering data from both surveying studies and monitoring studies could introduce uncertainties in the risk assessment. |  |  |
| 41 p 61, line 4 – 6 |  |  | We appreciate the request for development of specific soil scenarios for transition metals including soil parameter. Also, management practices like straw incorporation can influence the bioavailability of metals and should probably be included in considerations regarding new scenarios. |
| EFSA: For the time being there are no scenarios that include the consequences of straw incorporation. Please also refer to EFSA’ response to comment 16 regarding additional Cu input from straw. |  |  |
| 42 p 61, line 34 |  |  | Please check formatting. |
| EFSA: Thank you, done |  |  |  |
| 43 p 65, line 12 |  |  | The assessment factor for the SSD should be at least 3. |
| EFSA: Noted |  |  |  |
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|        |                                    | 44 pP 68, line 26 Please check formatting. EFSA: Thank you, done |
| 57     | French Agency for Food, Environmental and Occupational Health & Safety (ANSES) | 3.2.1 Effect assessment and ecotoxicologically relevant exposure quantities | p.53, lines 23-28: Use of TME is an option to refine the risk assessment of soil mesofauna, even if refinement with TME is not common to date. Indeed, there is currently no guideline or guidance available to perform and analyse such studies at EU level. Therefore, great care should be taken when realizing such studies as no feedback are currently available. This comment also applies to potential field studies as no guideline is available as well. EFSA: Noted. The development of guidance for assessing studies with soil microarthropods is needed. General guidance for setting up and reporting data from TME experiments is available in a report from a scientific meeting (Schäffer et al. 2010) p.54-55: Use of SSD is suggested to perform a higher-tier risk assessment for soil organisms. We agree with this approach, but would like to point out that usually the number of reliable endpoints available to perform such SSD is scarce. In fact, it is common that literature data are used to calculate a HC5 (to date only 3 toxicity studies are requested for soil organisms). However, data retrieved from the literature are often heterogeneous in term of robustness depending on details provided in articles. A more precise procedure about how endpoints should be selected to perform SSD would be then welcome. EFSA: Please see our answer to comment 38, point 4. The quality of the retrieved or newly submitted data by the applicant will be part of the assessment by the authorities in order to decide on the assessment factor to be applied. The availability of raw data to check for the derivation of ecotoxicological endpoints and the description of study details will be decisive for the inclusion of the data point in the SSD, the derivation of e.g. HC5 and the decision on the assessment factor to be applied. Please see also the guidance given in the AGD EFSA 2014 which in general also apply to endpoints for terrestrial species The text for the soil organisms effect assessment has been updated |
| 58     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 3.2.1 Effect assessment and ecotoxicologically relevant | Page 54, lines 20-37: Finally, some guidance on SSD for soil organisms! This is highly welcome for the acceptance of the approach for metals. EFSA: Thank you, noted. Page 54, line 23: No definition “sufficient evidence”? leaves the case-by-case evaluation difficult to provide as applicant and open for any arbitrary conclusion. Some guidance would be welcome. |
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|        | exposure quantities               |         | EFSA: There are agreed indications on how to assess the available data in order to construct robust SSDs, e.g. the EFSA AGD (EFSA PPR 2013) gives in chapter 8.4 general guidance which applies in principle also to soil organisms. A sentence has been included in the statement. |
|        |                                   |         | Page 54, lines 41-43: It is not clear why the geomean approach is not supported for chronic endpoints when data can be normalized for other sources of variation than intra-species variability (e.g. normalization for differences in test media, ...). |
|        |                                   |         | EFSA: Please see the discussion points in the cited documents EFSA PPR 2013, EFSA 2019. In meetings on recurrent issues (EFSA 2019), the application of geomean approaches for chronic endpoints has been extensively discussed. Member States decided not to apply the method for the time being until further data is assessed, evaluated and implemented in guidance documents. |
|        |                                   |         | Page 55, lines 5-7: For metals it is recommended to allow some equilibration time (e.g. 1 week) between application of the test item to the soil and start of the laboratory ecotoxicity test. This allows the fast equilibration reactions to take place before the start of the test and ensures a rather constant exposure within the timeframe of most ecotoxicity tests (up to 8 weeks) because slow ageing reactions are taking several months. |
|        |                                   |         | EFSA: The equilibration time might not be a correct assumption when pesticide exposure in the field starts directly after application |
|        |                                   |         | Page 55, line 8: The same applies to the selection of sites for field tests. |
|        |                                   |         | EFSA: Noted |
|        |                                   |         | Page 55, line 16: When is such new guidance expected? |
|        |                                   |         | EFSA: Guidance is planned to be developed within 2 years of the agreement of specific protection goals |
|        |                                   |         | Page 56, line 24: Agreed, but this should not be generalized since this was only concluded for Hypoaspis. On the other hand, lab tests with freshly spiked soils tend to overestimate soil exposure compared to field conditions (ageing effects, more heterogeneous exposure in field). |
|        |                                   |         | EFSA: We do not expect relevant ageing to occur shortly after application of PPP containing transition metals in the field |
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| 59     | French Agency for Food, Environmental and Occupational Health & Safety (ANSES) | 3.2.2 Exposure assessment, fate and behaviour of transition metals in soils | Page 57, line 22: It should also be mentioned that the selection of the test medium also is critical for the conclusion on hazard properties because the physico-chemical properties of the soils selected for testing can strongly affect the bioavailability and toxicity of trace metals in soil.  
EFSA: Agreed, this aspect is extensively addressed under 3.2.3 |

Page 58, line 26 to 28. "for deriving a representative background concentration, the 10th and the 90th percentile of soil concentration should be considered...". Please clarify how the 10th – 90th percentile of background concentration shall be included in the PECsoil calculations. We suggest a tiered approach is defined for inclusion of this background, with a first tier including the 90th percentile value. If further refinement of exposure is required, then the background concentration definition may be refined, based on soil parameter or any spatial distribution (crop distribution...).  
EFSA: While the exposure assessment can be conducted according to a stepwise approach in term of total metal, this cannot be handled for the estimation of the soil pore water and available fraction. Indeed, the metals already present in soil (soil background concentration) affects the distribution of metal between the water and solids. The statement was not updated.  
With this aim, it is suggested then that more details are given on which “scale” the 10th-90th range of background concentrations could be determined to be used in calculation (any regional/national scale, in relation to any type of crop, or to any soil texture/soil parameter, especially if needed to be further implemented in specific scenarios...).  
EFSA: Representative background concentration is defined under Part 4.  
More details on the reliability of PERSAM Tier 1-2 calculations for transition metals would be welcome. From lines 7-17 (page 60), we understand that it is proposed that Tier 1 PEC soil for total concentration could be used, but Tier 2 PECsoil for total concentration should not because of crop canopy processes considered in Tier 2. However, as previously indicated in lines 33-36 (page 59), this could be solved by setting the crop interception to 0.  
To our understanding, the main issue regarding the use of PERSAM Tier 1-2 is related to the methodology used to obtain the estimation of the 90th percentile concentration (lines 36-39 page 59). Indeed, it is based on degradation and mobility in soil, which is not appropriate for inorganic substances. Since both Tier 1 and Tier 2 are based on degradation and mobility (for Tier 1: selection of scenarios based on combination of degradation /...
mobility data for 19 default substances / for Tier 2: degradation / mobility specific to the calculated substance), please clarify why Tier 1 is seen as acceptable for transition metals.

EFSA: As indicated in the statement, PERSAM tool has been developed for synthetic organic compounds.

PERSAM-Tier 1 can be used for the ERA for total soil concentration only. Indeed, the foliar processes (e.g. crop interception, wash off) affecting the soil concentration are not considered at Tier 1 (all applied dose reaching soil). At Tier 1 all type of crops were considered for the selection of the predefined scenarios. In addition, compounds with both high sorption coefficient and high DT₅₀ were identified among the 19 default compounds that were used to develop the predefined scenarios.

At PERSAM-Tier 2, the dependency to soil parameters can be considered, but processes occurring on plant foliage are also implemented. Therefore, the soil concentration cannot be correctly estimated as dissipation on the leaf surfaces are considered and cannot be deactivated manually as well as the crop interception. The mode ‘soil incorporation’ or ‘soil application’ could be considered at Tier 2, as no foliar processes are considered. However, this may not be in line with the intended uses (foliar application) and the soil scenarios related to the kind of crop could be hence erroneously selected. This can be managed only for both annual crops covering the entire field and early application when a crop interception of 0% is considered by the tool. It should be ensured that the assessed uses are covered by the scenario selection at Tier 2. For the other crop types (e.g. permanent crops and annual crops planted on ridges or in rows), PERSAM-Tier 2 cannot be used for total metal.

For estimating the pore water concentration, PERSAM Tier1-2 cannot be used. At Tier 1, no sub-model is implemented to estimate correctly the distribution of metal between solid and pore water (e.g. time scale, equilibrium process, and speciation). At Tier 2, there is the possibility to consider the soil pH and clay content dependence, but the foliar processes are activated leading to a dissipation of metal. As for total metal, this could be managed only for annual crops covering the entire field and for soil application. It should be ensured that the assessed uses are covered by the scenario selection at tier 2. For the other type of crop (permanent crops and annual crops planted on ridges or in rows), the model cannot be used. Since all relevant soil processes affecting the soil distribution of metal are not implemented in PERSAM Tier 1-2 tool, the reliability of the results for pore water concentration is questionable.

For total and pore water concentrations, the model is unable to handle separately the freshly added metal and the aged residues.

Page 60, line 27 : “The approach proposed in the ECHA guidance (2008) cannot be strictly applied in the context of PPPs risk assessment purpose. Two distinct approaches were identified in the risk assessment provided by ECHA and EFSA”. Maybe a short explanation in which extent the ECHA approach cannot be applied
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could be added, since this is not clear to an unaware reader. Indeed, on page 60, line 31 to 33, it is indicated that the EFSA approach includes both the background concentration and the long-term use of transition metals as PP in the risk assessment. While it is also indicated at p.59, line 6 to 11 that different approaches were considered at the EU level to take the background concentration into account and that for some transition metals the estimated PECsoil “should be compared to and comprised in the background concentration”. It is our understanding here that in current PPP evaluation at EU level, the significance of the added concentration compared to the background concentration is somehow taken into account in some cases, and that different approaches are considered accordingly. This approach seems to be recommended in the ECHA guidance (figure 3 p. 31 of ECHA guidance). The approaches do not seem to be so distinct. This point may be further clarified and developed.

EFSA: A tiered approach is proposed in the statement. The statement reviews the previous assessment in the context of Reg. (EC) 1107/2009. For deriving exposure endpoints, it is suggested for transition metals to consider the soil background concentration including the long-term use of transition metals as PPP and the future application in a prospective risk assessment.

Figure 3 in the ECHA guidance refers to the hazard and risk assessment and not to exposure assessment.

Page 61: the development of specific scenarios for transition metals for deriving Tier 2 PECsoil with the PERSAM tool is expected to be a complex and very time-consuming work for the assessment of a limited number of substances. In this context, the relevance of developing such scenarios is questionable.

EFSA: Noted

The statement recommends that the specific process of speciation/availability affecting the behavior of transition metals is included in the modelling. In our opinion, it is then important that details are given on how this specific behavior shall be investigated in environmental studies to get relevant input parameters.

EFSA: As indicated in the statement under ‘Conclusions for the exposure assessment in soils; point 7, the EFSA guidance document on good modelling practices (2014) should be followed for developing/adapting scenarios/models. Overall recommendations for all metals covering by this statement are presented in this statement. Relevance of selected tests should be in line with the fate and behaviour of metals in the environmental matrices.

Including additional soil characteristics (pH, CEC, OC and clay) in the scenarios and other processes such as speciation and availability implies that metals behavior is well known towards these specific soil characteristics.
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|        |                                    | 3.2.2 Exposure assessment, fate and behaviour of transition metals in soils | The tested environmental conditions governing speciation/availability in environmental studies should also be consistent with the soil parameter ranges defined in the ecotoxicity tests. These aspects could be further developed. EFSA: Noted. This topic is already discussed in the Part 3.2.3. |
| 60     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | Page 58, line 20; A long default DegT50 is appropriate only if other dissipation processes are included in the exposure assessment. Using 1,000,000 days as the DegT50 might be fine as first step, however, the possibility to refine this e.g. for metals with low but measurable mobility in soil, that contribute to physical displacement within a shorter time period. EFSA: As transition metals do not degrade and have the potential to accumulate in the environment, a long DegT_{50} should be used in exposure calculations. The selected dissipation processes should be in line with the assumptions of the exposure models. As an example, the soil dissipation in PERSAM tool is considered with DegT50 and sorption coefficient. It should keep in mind that the dissipation processes should not be considered simultaneously with different endpoints (e.g. both in DissT50 and soil sorption coefficient). Page 58, line 32: The same is true for raw data from EU or member State data bases (e.g. LUCAS data base). EFSA: Agreed. Page 60, line 16: Will EFSA be adapting the PERSAM model? EFSA: Activity by EFSA to adapt the PERSAM tool is not planned currently. The equations used by PERSAM are all published as are its spatial data layers. Other parties therefore are not precluded from developing appropriately adapted tools. Page 60, lines 29-31: This is not correct. In the ECHA approach, natural background, regional and local anthropogenic sources are all considered in the exposure and risk assessment. For metals, the anthropogenic background is not only based on emissions from one substance and one use, but also include wide-dispersive uses for the metal and non metal use related sources of metal emissions (e.g. from combustion processes, traffic,...). EFSA: There is a misunderstanding. We agree that all sources are considered in the a posteriori risk assessment performed in the ECHA approach. Clarifications are included in the statement (Point 1 of the Part ‘Conclusions for the exposure assessment in soils’). |
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| 61     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 3.2.3 Linking exposure and effects | Page 61, line 13: There is no clear conclusion on which measure to use: total soil concentrations or pore water concentrations. Due to the larger uncertainty on predicting pore water concentrations and the concern on other exposure pathways, we prefer to currently use the total metal concentration in soil as the basis for exposure and effects assessments. See also further comments.  
EFSA: Noted. The Guidance on deriving PEC values (EFSA 2017), the Scientific Opinion on identifying relevant scenarios for soil organisms (EFSA 2014) and the scientific Opinion on in-soil organisms (EFSA 2017) identify both routes to be relevant. Please see the detailed discussion of these points there.  
Page 61, line 27: Normalization to organic carbon content is not always relevant for metals because other soil properties often play a more important role in determining bioavailability in soil.  
EFSA: Agreed, therefore the inclusion of further parameters might be needed and is highlighted in the statement  
Page 61, line 33: Also the clay mineralogy in the OECD artificial soil (kaolinite) is not representative for soils in temperate regions.  
EFSA: Agreed, see 3.2.3  
Page 61, line 38: Kaolin clay has a lower binding capacity than the common clay types in European soils (mainly illite clay).  
EFSA: Noted  
Page 61, line 34: Errors in Reference source.  
EFSA: Thank you, amended  
Page 63, lines 31-38: Not clear if the models derived under REACH are accepted to meet these criteria. It is a pity that the e.g. models used for Cu and that were discussed and agreed with member states under the VRAR were not assessed for their acceptance for PPP.  
EFSA: Some assumptions underlying the acceptance of the models for conditions under the remit of ECHA might not be applicable for the use of metal compounds as active substances in PPP (ageing, agricultural soils). This is discussed in the text. Moreover, the statement addresses in general transition metals and not only copper. |
| 62     | French Agency for Food, Environmental | 3.2.4 Risk assessment | p.65: It is our understanding that the lab-to-field factor is not considered adequate for PPP by the authors of the statement. Could you please confirm? |
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|        | and Occupational Health & Safety (ANSES) | **3.2.4 Risk assessment** | **EFSA: This is confirmed** |
| 63     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | Page 64, line 39: It has been observed for metals that the variability in toxicity data expressed as pore water concentrations is generally much larger compared to toxicity data expressed as total soil concentrations. See e.g. Smolders E, Oorts K, Van Sprang P, Schoeters I, Janssen CR, McGrath SP, McLaughlin MJ. 2009, and Zhao FJ, Rooney CP, Zhang H, McGrath SP. 2006. **EFSA: This is true for some organisms but not for all soil organism groups and for all metals. Therefore, the chapter linking exposure and effects indicates both type of exposure quantities as relevant for the risk assessment. The reference by Smolders et al. 2009 has been added to the chapter soil organisms, thank you.** Page 65, line 10: If a SSD is constructed from a sufficiently large number of data/species, then an assessment factor may not be required as the TER criterion will be sufficiently protective. This should be determined on a case-by-case basis rather than applying a blanket assessment factor for all SSDs. **EFSA: No blanket assessment factor is proposed for SSD. Remaining uncertainties need however to be addressed. Please see also answers to comment 11.** Page 65, line 12: Because of the large variation in data availability (and hence uncertainty), this AF on the HC5 should indeed be the result of a weight of evidence approach, taking into account all sources of uncertainty and all conservative assumptions made. A fixed AF is therefore not appropriate, and it should be derived case by case. The REACH guidance also proposes an AF between 1 and 5 on the HC5 to be justified on a case by case basis ([https://echa.europa.eu/documents/10162/13632/information_requirements_r10_en.pdf/bb902be7-a503-4ab7-9036-d866b8ddce69](https://echa.europa.eu/documents/10162/13632/information_requirements_r10_en.pdf/bb902be7-a503-4ab7-9036-d866b8ddce69)). **EFSA: See answer to the comment above.** Page 65, lines 19-21: This cannot be generalized, there are ppp uses where aging plays a significant role. We suggest rephrasing this sentence and clarify the relevant time frame. The lab-to-field factor approach has its advantages and should not be discounted generally. **EFSA: Disagreed. A general lab-to field-factor is not considered appropriate to scale the toxicity from lab to field for transition metals applied as PPP.** Page 65, line 32: Typo – should read 'Added Risk Approach (ARA)'.
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|        |                                   | p.5, line 1; *Typo: “uncertainties exists”* | EFSA: The typo has been corrected in the updated statement. |
| 64     | French Agency for Food, Environmental and Occupational | 3.2.5 General conclusions and recommendations for the in- | EFSA: The typo has been corrected in the updated statement. |

EFSA: The typo has been corrected in the updated statement.

Page 65, lines 38-41: Agreed. It must be noted that under REACH, the added risk assessment should also include all anthropogenic sources and only the natural background is omitted for the assessment.

EFSA: Noted

Page 65, lines 42-43: A lot of work has been spent on trying to identify specific bioavailable metal pools for soil organisms. The results are however organism and metal-specific and do not allow selecting a specific metal fractions for the risk assessment of a metal for the total soil ecosystem. Therefore, the assessment is currently based on the total metal concentration in soil and bioavailability corrections, although it is acknowledged that total metal concentrations is not a good predictor of metal bioavailability (hence the need for the normalisation and correction factors). See e.g. Smolders et al. 2009 or MERAG fact sheet on bioavailability of metals ([https://www.icmm.com/website/publications/pdfs/chemicals-management/merag/merag-fs5-6-2016.pdf](https://www.icmm.com/website/publications/pdfs/chemicals-management/merag/merag-fs5-6-2016.pdf)).

EFSA: Noted, see answer to comment above and chapter on Ecotoxicologically relevant exposure quantities

Page 66, line 3: Agreed. The bioavailability corrections for either ageing or variation due to soil properties are however based on both ecotoxicity data and soil chemical data in the presence of organisms. The impact of soil organisms on the behaviour of metals is hence included in the predictions.

EFSA: Noted

Page 66, line 21: A clear distinction must be made between 1) corrections for ageing and 2) normalization for the variation in soil properties affecting bioavailability and toxicity of metals in soil. We agree that ageing reactions are not appropriate for the metal dose applied within a season assessed, but only to the total amount of residues from former applications. The normalization to correct for the impact of varying soil properties on behaviour, bioavailability and toxicity of metals is however also applicable to the total metal concentration, including the fraction applied in the current season in case these normalization models are derived based on toxicity data in freshly amended soils (which is generally the case).

EFSA: Noted, the points are discussed separately in the statement
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| 65     | Health & Safety (ANSES)            | soil compartment | Page 67, line 3: A clear distinction must be made between 1) corrections for ageing and 2) normalization for the variation in soil properties affecting bioavailability and toxicity of metals in soil. See also previous comment.  
**EFSA:** Please see answer to comment 63 above.  
Page 67, line 22: EFSA requests that a non-standard approach is taken but no guidance for this is available. Additionally, whilst here it suggests that a multi-organism SSD approach should be investigated, Page 7, line 39 contradicts this and says that this approach shouldn't be used.  
**EFSA:** It is suggested to consider SSD for different organism groups (e.g. microarthropods and annelida) if there is no clear indication that their sensitivity towards the assessed transition metal exist. It is indicated not to include microorganisms and plants in one SSD with soil macro and mesofauna, since for PPP different type of endpoints and/ or different protection goals exist for these groups.  
Page 67, line 27: It is not open and transparent as to how to interpret such studies – guidance is needed on how to evaluate such studies.  
**EFSA:** The set up, performance and assessment of field studies with earthworms are covered by the existing guidance ISO 11268-3:2014. The prolongation of the studies over several years would not change the principles of the studies. Care should be taken to plan subsequent application so to avoid sampling problems due to shortage of replicate plot areas.  
Page 67, line 31: This appears to indicate a request to generate more data but without a purpose as to how this data might be used.  
**EFSA:** According to data requirements for PPP (EC 283/2013; 284/2013), higher tier test approaches might be needed if at tier 1 unacceptable effects are indicated for soil mesofauna. The data are not requested as standard data and the point gives indication how to possibly evaluate field studies with soil mesofauna  
Page 67, lines 35-38: It is recommended to also always measure total concentrations during toxicity tests with soil organisms. This will ensure quality control (total dose is as described) and allows linking any other measured fractions (e.g. pore water concentrations) with total doses to facilitate prediction of fate and behaviour.  
**EFSA:** Agreed and stated in the text |
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|        |                                   |         | Page 67, line 43: Aging is another factor that should be considered to determine availability/speciation. EFSA: Agreed. The sentence ‘The time scale is another parameter affecting their availability/speciation’ has been included under Point 6. |
|        |                                   |         | Page 68, lines 1-3: Soils used for ecotoxicity testing must therefore always be properly characterized and as a minimum, pH, organic carbon content, clay content and effective CEC (= CEC at pH of the soil) should be reported. For metals occurring as oxyanions, also data on content of oxides (Fe, Al, Mn) is very useful. EFSA: Agreed, noted |
|        |                                   |         | Page 68, line 4: We agree that assumptions made in PERSAM may not be suitable for exposure assessments for transition metals, particularly for pore water concentrations. Models that consider relevant process such as speciation are more valid for estimating exposure concentrations of transition metals. EFSA: The models currently used for assessment of organic and synthetic chemicals were not developed for taking the properties of transition metals into account. As transition metals do not degrade in the environment and have the potential to accumulate refined modelling with robust and agreed models and monitoring data will be relevant for a more realistic risk assessment of these metals. For further tool development, the recommendations of the EFSA guidance on the good modelling practices (2014) should be followed. |
|        |                                   |         | Page 68, line 9: Assuming that all of the applied dose goes to the soil and is bioavailable represents an unrealistic tier ‘0’ approach rather than a first step approach as would be performed for synthetic PPPs. EFSA: This assumptions in the first step of the ERA assures that no further refinement is needed for substances with low risk |
|        |                                   |         | Page 68, lines 9-11: What about the normalization for impact of soil properties on behaviour and bioavailability of metals in soil? Guidance on these corrections is missing. See e.g. OECD 259 (2016) and Smolders et al. 2009. EFSA: The assumptions suggested in OECD 259 and Smolders et al. 2009 might not be applicable to metal compounds used as active substances in PPP |
|        |                                   |         | Page 68, line 12: Agreed, PERSAM does not consider important processes relevant for transition metal exposure assessments – as indicated under point 13). |
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|        | EFSA: PERSAM tool adaptations seem needed to take into account the relevant processes for transition metals exposure assessment. Please also refer to response to comment 59. |
|        | Page 68, line 16: This has been studied earlier but the uncertainty on using pore water as basis of the risk assessment is larger than for assessments based on total soil metal concentrations. See e.g. Smolders et al. 2009 or MERAG fact sheet on bioavailability of metals ([https://www.icmm.com/website/publications/pdfs/chemicals-management/merag/merag-fs5-6-2016.pdf](https://www.icmm.com/website/publications/pdfs/chemicals-management/merag/merag-fs5-6-2016.pdf)). |
|        | EFSA: Noted, see answer to comment above (no 63) |
|        | Page 68, line 22: Access to the LUCAS soil database has not been granted by the JRC. Applicants need access to this data to be able to refine the risk assessment. Anonymised data can be used by applicants preserving confidentiality requirements by the agency. |
|        | EFSA: We agree that data bases containing environmental data should be made publicly available. This has been added to the updated statement. JRC (ESDAC) has announced the release of the soil dataset based on samples collected during the 2015 LUCAS Survey (LUCAS Soil 2015). |
|        | Page 68, lines 22-25: There are also other EU wide monitoring databases for soil: e.g. GEMAS ([http://gemas.geolba.ac.at](http://gemas.geolba.ac.at)) and FOREGS ([http://weppi.gtk.fi/publ/foregsatlas/ForegsData.php](http://weppi.gtk.fi/publ/foregsatlas/ForegsData.php)). |
|        | EFSA: This issue is addressed under Part 4 ‘Consideration of environmental monitoring study results in the environmental risk assessment of transition metals’. |
|        | Page 68, line 26: This will require a detailed assessment for each transition metal taking into account relevant processes and soil parameters for each. Tier-2 assumptions could be modified within PERSAM to enable assessment. |
|        | EFSA: Agreed. No action needed. |
|        | Page 68, line 38: This a typo – a repeat of line 22. |
|        | EFSA: The typo was corrected. |
|        | Page 68, line 41: It is not clear how to do this. |
|        | EFSA: In the respective chapter it is indicated that usually the 90th percentile is used |
| 66     | European Union Copper Task | 3.3.2 Exposure assessment | Page 70, lines 6-7: For non-degradable substances, such as metals, it is expected that with time the soil exposure route is most important. |
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| Force (EUCuTF) c/o Battelle UK Ltd. | fate and behaviour of transition metals above ground | EFSA: The time scale is an important factor to be considered for the environmental exposure assessment of transition metals. Thus, the short-term risk for freshly added metal should not be excluded from the ERA. No update of the statement is needed. |
| 67 | French Agency for Food, Environmental and Occupational Health & Safety (ANSES) | 3.4.1 Effect assessment and ecotoxicologically relevant exposure quantities | p.67, line 10 and p.71, line 39: Typo: “uncertainties exists” \nEFSA: The typo has been corrected in the updated statement. |
| 68 | French Agency for Food, Environmental and Occupational Health & Safety (ANSES) | 3.4.4 Risk assessment | p.73: For the bee’s chronic risk assessment following the bee guidance document (EFSA/2013/3295) TWA values are available from Table 5 of the guidance. These twa values are based on the default DT50 of 10 days set in the birds and mammals guidance document (2009). Then, it is our opinion that TWA cannot be applied to repeated exposure assessment for transition metals and we would consider these values as not relevant for transition metals risk assessment as long as new data on residue measurements in pollen and nectar are lacking. Therefore, it is our opinion that calculations with a TWA value of 1 should be considered for copper application as it has been done for birds and mammals risk assessment. \nEFSA: Agreed. The document has been adapted in the section 3.4.2 |
| 69 | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 3.4.4 Risk assessment | Page 73, line 25: For essential, ubiquitous transition metals field studies are often not possible due to the current RA procedure indicating a risk with naturally occurring concentrations. A weight of evidence approach is to be favoured. \nEFSA: Field studies with addition rates corresponding to intended uses are referred to here |
| 70 | Federal Environment Agency of Germany | 3.5 Terrestrial above-ground environment: Vertebrates (Birds, Mammals, 45 General | The chronic Risk assessment for birds and mammals includes a default DT50 = 10 d for the prediction of residues on plant material, used as food source. According to the high persistence of metals, this value should not be used. The default should be raised towards more realistic values. An increased database for residue studies on plant material is needed, also to address feeding issues for birds and mammals. |
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| 71     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 3.5.1 Effect assessment and ecotoxicologically relevant exposure quantities | Page 74, lines 9-12: This is not in agreement with REACH dossiers and (voluntary) risk assessment reports agreed on under the framework of the Existing Substances Regulation (Council Regulation (EEC) No 793/93, https://echa.europa.eu/information-on-chemicals/information-from-existing-substances-regulation), where all data from tests with metal substances are used together in an assessment based on the metal ion. In order to do so, it must be justified that bioavailability (solubility) is comparable for all substances and that there is no concern on the effect of the counter-ions. EFSA: In acute toxicity studies, it was generally agreed that the free ion is the toxic form. In the RAR, all forms were considered as a single entity and Copper sulfate, the most soluble form, usually represented the worst-case scenario. Page 74, line 11: This suggests that copper salts are not assessed as a single entity. However, this contradicts the AIR evaluation of the copper compounds renewal dossier since copper salts were all evaluated as Cu²⁺ ions. EFSA: There are definite differences in chronic copper toxicity as reported in the Copper RAR. It is true that Cu²⁺ is considered to be the toxic form, hence copper sulfate, the most soluble form of copper, represents the worst-case scenario. This is also not in agreement with REACH dossiers, where all data from tests with metal substances are used together in an assessment based on the metal ion. The criteria are that bioavailability (solubility) is comparable for all substances and that there is no concern on the effect of the counter-ions. EFSA: The Copper RAR (2017) indicates that copper solubility may differ and that Copper sulfate is usually considered as a worst-case scenario. Page 75, lines 9-13: The case of copper and the residue data provided has demonstrated that the current model to evaluate the risk for birds&mammals already indicates a high risk with copper concentrations occurring naturally (as measured on the control plots of residue studies conducted). The generation of further residue... |
| Number | Organisation or name or respondent | Chapter | Comments and PPR WG responses |
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| 72     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 3.5.2 Exposure assessment, fate and behaviour of transition metals above ground | Page 76, line 25: A Koc is not relevant for metals because sorption is not only controlled by the organic carbon content. EFSA: Agreed. Statement updated accordingly. |
| 73     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 3.5.3 General conclusions and recommendations | Page 76, line 32: It should be noted that the fact that the risk assessment fails with background level of (copper), shows that the models are unreasonably conservative, especially by not considering bioavailability. Therefore, lower tier models are not helpful in presenting the risk assessment and only the weight of evidence approach can be used. Considering bioavailability and homeostasis would make the models more realistic rather than simply focusing on residue levels. EFSA: See answer to comment 27 point 1 |
| 74     | Federal Environment Agency of Germany | 3.6 Leaching to groundwater | 46 p. 77ff Following the overall concept, background values of metals in the groundwater compartment need to be evaluated in the preliminary phase to ensure an appropriate Tier 1 risk assessment. We support this, since monitoring data provide evidence for copper concentrations in groundwater above zero (p.77, line 10-20). However, the proposed risk assessment is hardly based on FOCUS modelling, but PECgw are only related to metal fluxes leaving the soil profile over a certain time period. The statement leaves open, how the modelled PECgw must be interpreted in the context of expected groundwater concentrations. The conclusion, that modelled and monitored concentration cannot be combined (p.79-80 line 39-2) is probably true from a scientific view but introduces inconsistences to the overall concept how to include monitoring data in the environmental risk assessment. Metal background values in groundwater need to be part of discussing the risk related to the parametric drinking water limit. |
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|        | EFSA: The way the framework envisages monitoring data is incorporated into the groundwater exposure assessment is by ensuring that monitored levels in the soil column above aquifers is incorporated in a modelling approach in addition to the amounts being added every year from the anthropogenic inputs each year, in particular from the use of plant protection products. This is discussed in the paragraph above the one that is being commented on. If groundwater monitoring were to identify significant concentrations in an aquifer, then activities that would result in further exposure in the overlaying soils would probably need to be stopped. This would be a management decision made at the local level. However as this is management and not relevant for the risk assessment framework, the statement has not been updated. Following up on the comment above and the overall monitoring concept in the statement, groundwater monitoring data (e.g. for copper) could get a higher relevance for future groundwater assessments. The provided groundwater monitoring data for copper have not been evaluated from the notifier in much detail. As a result, a wide range of copper concentrations in groundwater is shown without any deeper possibility for interpretation. However, more effort could be invested in future to evaluate existing groundwater monitoring data in terms of getting a better picture of possibly occurring groundwater concentrations in agricultural areas with realistic worst-case soil and hydrogeological conditions and where copper is used as plant protection product in different crops. It’s probably not necessary to start new monitoring programs but the notifiers could work more intensively with the existing publicly available data in the preliminary phase. EFSA: Agreed. If in the preliminary phase groundwater concentrations of a metal were identified in monitoring, then the reasons for its presence should be investigated and if the source were human activities that resulted in topsoil exposure these activities should probably be halted. This would be a management decision made at the local level. However as this would be management and not related to the exposure assessment framework, the statement has not been updated. | 3.6.1 Assessment | Page 78-79 “Selection of input parameters to be used in modelling”: In this whole paragraph, sorption values are alternatively referred to as Kd or Kf values, while the ECHA guidance only refers to Kd value. It is our understanding that the mobility of transition metals is often described as simple partitioning coefficient, and that Kf are not relevant. Please further clarify what kind of data is suitable and expected to be provided to describe metals mobility, for implementation in leaching models. EFSA: In batch adsorption experiments Kf or Kd can be determined. If Kf is put into the model it is expected that this will underestimate adsorption. However, this approach might be used at the first tier. The subsequent approaches, e.g. Degryse et al (2009), determine Kd values and are considered to provide more realistic (i.e. |
| 75     | French Agency for Food, Environmental and Occupational Health & Safety (ANSES) | | |
more refined) approaches. These approaches are also relevant for defining a different relationship with depth in the soil column than organic matter.

Page 78, line 27 to 29. Reference is made to the approach by Degryse et al. (2009) to derive reliable Kd values, which takes into account the initial natural concentration of transition metal in test soil before spiking in the sorption test. More detail on this approach, so as a short discussion on the potential impact this would have on sorption test results, would be appreciated. It is indeed our understanding that this approach potentially underestimates the mobility of the fresh added residue (aged soil residues are more strongly bound to soil). This may therefore not be in accordance with the recommendation on p. 80, line 3 to 5 that “[...] the freshly added soils and the aged soil residues should not be considered in the same way in modelling”. This could be clarified. Maybe different approaches should be taken to derive Kd values for aged residues and for freshly added residues.

EFSA: Transition metals such as copper being naturally present in soil, the ‘natural’ soil used for deriving Kd value already contains transition metals (before spiking). Thus, the level of ‘natural’ transition metal can potentially interfere with freshly added metal. This can hence affect the determination of Kd value and the comparison of results between soils. The Degryss’ approach is to consider the level of transition metals already present in soil (without taking their speciation and availability into account) before spiking to derive Kd value for freshly added metal.

EFSA did not locate any other references addressing other potential approaches to derive distinct Kd value for aged residues and for freshly added residue. The commenter has not identified any either. It seems different approaches may not be available.

Please also note that the reference of the study by Degryse et al. (2009) is not reported in the reference list.

EFSA: The missing reference has been added in the section 7.

Page 80, Line 6: “inclusion of speciation and ageing submodels in the existing FOCUS models” It should be further specified which kind of supplemental data reflecting ageing behavior of the metals would be required as input parameters in the case ageing submodels are developed.

EFSA: The submodel for equilibrium /non-equilibrium and ageing processes should take into account the main abiotic factors driving the fate and the behaviour of transition metals in the soil. Related to the submodel, the ‘supplementary’ data should provide reliable parameters to be implement in the selected submodel. Thus, a list of supplementary data to be generated cannot be handled for the time being.

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|        |                                   |         | more refined) approaches. These approaches are also relevant for defining a different relationship with depth in the soil column than organic matter. Page 78, line 27 to 29. Reference is made to the approach by Degryse et al. (2009) to derive reliable Kd values, which takes into account the initial natural concentration of transition metal in test soil before spiking in the sorption test. More detail on this approach, so as a short discussion on the potential impact this would have on sorption test results, would be appreciated. It is indeed our understanding that this approach potentially underestimates the mobility of the fresh added residue (aged soil residues are more strongly bound to soil). This may therefore not be in accordance with the recommendation on p. 80, line 3 to 5 that “[...] the freshly added soils and the aged soil residues should not be considered in the same way in modelling”. This could be clarified. Maybe different approaches should be taken to derive Kd values for aged residues and for freshly added residues. EFSA: Transition metals such as copper being naturally present in soil, the ‘natural’ soil used for deriving Kd value already contains transition metals (before spiking). Thus, the level of ‘natural’ transition metal can potentially interfere with freshly added metal. This can hence affect the determination of Kd value and the comparison of results between soils. The Degryss’ approach is to consider the level of transition metals already present in soil (without taking their speciation and availability into account) before spiking to derive Kd value for freshly added metal. EFSA did not locate any other references addressing other potential approaches to derive distinct Kd value for aged residues and for freshly added residue. The commenter has not identified any either. It seems different approaches may not be available. Please also note that the reference of the study by Degryse et al. (2009) is not reported in the reference list. EFSA: The missing reference has been added in the section 7. Page 80, Line 6: “inclusion of speciation and ageing submodels in the existing FOCUS models” It should be further specified which kind of supplemental data reflecting ageing behavior of the metals would be required as input parameters in the case ageing submodels are developed. EFSA: The submodel for equilibrium /non-equilibrium and ageing processes should take into account the main abiotic factors driving the fate and the behaviour of transition metals in the soil. Related to the submodel, the ‘supplementary’ data should provide reliable parameters to be implement in the selected submodel. Thus, a list of supplementary data to be generated cannot be handled for the time being. |
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| 76     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 3.6.1 Assessment | Page 78, line 12: For consistency, EFSA should provide information on how to conduct this longer-term assessment as well as climatic files.  
EFSA: For the time being, there is a possibility to run the FOCUS Groundwater modelling tools for a period of 66 years using the existing climate files. Application(s) every year and the agricultural background concentration can be considered in the modelling. If longer period is recommended, the existing climate files in FOCUS tools can be adapted without changing the model code; climatic series of hundreds of years can be created manually and then input into the FOCUS tools. The sections 3.6.1 and 3.6.2 of the statement have been amended. See also answer to comment 6 point 5.  
Page 78, line 20: Sorption of metal (and other) ions is not only controlled by the organic carbon content of the soil. Therefore, normalisation for organic carbon content is not relevant.  
EFSA: To derive reliable modelling endpoints, normalisation of parameters should be carried out the abiotic factors affecting the soil mobility of metal in soil. This is indicated in the section 3.6.1 of the statement. The statement was not updated.  
Page 78: line 35-42: The use of Ksc to derive Kom values for model input is a good example of the proposal for using 'simple, fit-for-purpose models and approaches’ and is welcomed.  
EFSA: Please refer above to EFSA’ response to previous issue on comment 76. The statement was not updated.  
Page 79, line 1: Because pH has a major impact on sorption of metal ions on soil constituents, Ksc values can only be combined when derived at similar pH.  
EFSA: As indicated in the statement the groundwater modelling should be performed for contrasting soil conditions.  
Page 80, line 37: “Kd” should be used instead of “Kdoc”  
EFSA: The statement has been updated accordingly. |
| 77     | French Agency for Food, Environmental and Occupational Health & Safety (ANSES) | 3.6.2 Conclusions and recommendations for groundwater | p.83, line 15: Typo: “The development of exposure scenarios for specific transition metals needs to”  
EFSA: The statement has been corrected accordingly.  
p.83 line 5: A word seems to be missing in the following sentence: “The procedures for obtaining the pesticide properties and uses should be clearly described and wherever possible harmonized must be used to avoid user subjectivity.” |
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| 78     | ECPA                              | 3.6.2 Conclusions and recommendations for groundwater | Page 82, table 4: Regarding plant uptake fixed to default value (i.e. 0). Please note that in agricultural soils the content of iron is in the range of 0.2 - 5 % corresponding to 2 - 50 g/kg soil. Heavy soils might sometimes contain twice as much iron as sandy soils. The annual removal of iron by growing of wheat and sugar beet is reported to account for 1,500 and 4,500 g/ha. Therefore, if literature data shows that the transition metal is taken up by plants, it would be appropriate to set the plant uptake to a higher value in Tier 2 calculations. |
|        |                                   |         | EFSA: Whilst it is acknowledged that plant uptake of metal ions can be significant, as the majority of this plant material is usually added back to agricultural soil (via compost, manure and sewage sludge), in practice it might be considered that in the material balance this plant uptake is not lost from the system. It is acknowledged that the availability for leaching might be reduced for metals in compost, manure and sewage sludge, but this has been addressed to some extent by the framework discussion on how ‘aged residue’ can be accounted for. In conclusion accounting for plant uptake and then adding metal mass back to the soil in organic media, as would be needed would not be a tier 2 but rather much higher tier calculation that would have a range of uncertainties. It therefore seems difficult to include in the framework at this stage. The statement was not updated. |
| 79     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 3.6.2 Conclusions and recommendations for groundwater | Page 82, line 11: For consistency, EFSA should provide information on how to conduct this longer-term assessment as well as climatic files. |
|        |                                   |         | EFSA: For the time being, there is a possibility to run the FOCUS Groundwater modelling tools for a period of 66 years using the existing climate files. Application(s) every year and the agricultural background concentration can be considered in the modelling. If longer period is recommended, the existing climate files in FOCUS tools can be adapted without changing the model code; climatic series of hundreds of years can be created manually and then input into the FOCUS tools. The sections 3.6.1 and 3.6.2 of the statement has be amended. |
| 80     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 3.7 Addressing uncertainty in the risk assessment | Page 83, line 31: We do not agree. “greater uncertainties” suggests that more uncertainty exists regarding the risks identified. It should be noted that the differentiating features for essential transition metals (bioavailability, homeostasis) are rather of protective nature and the uncertainty is rather about the extend the risk is lowered by those features. Persistency has a different and rather neutral meaning for a non-synthetic, naturally occurring inorganic element or salt, just describing its pure existence, and should not have the same hazard connotation than for e.g. a POP. It is its bioavailability that matters. |
|        |                                   |         | EFSA: Homeostasis controls internal metal concentrations within a narrow range of concentrations. Homeostasis cannot mitigate the effects of additions above these ranges (accumulation). Greater uncertainty does not imply greater risk. Assessing bioavailability is based on models which have an inherent uncertainty. Furthermore, due |
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|        |                                   |         | to the persistency of metals, the margin for potential error is very small. ("The uncertainties are potentially greater for transition metals than for synthetic organic chemicals used as plant protection products owing to the consideration of persistency and bioavailability"). The long-term application of non-degradable compounds holds greater uncertainties regarding the effect characterisation for non-target organisms, since short term study outcomes are in part not in line with field results. These uncertainties need to be accounted for in ERA. |
|        |                                   |         | Page 84, Table 5, second row: Considering that organisms acclimatise to metals is contradictory to the consideration of homeostasis. Selecting tests systems is made more difficult if you have to have an artificially low background level of the test item to avoid acclimatisation. |
|        |                                   |         | EFSA: It was considered that acclimatisation might occur at levels greater than initial homeostasis levels. The sensitivity of the test organisms needs to be assessed by testing a reference item in parallel. |
|        |                                   |         | Page 84, Table 5, second row: It is in our opinion not correct to state that the relevance of oral uptake is higher for metals. Metabolization of organic substances may e.g. result in more easily absorbed or toxic decomposition products. Uptake of metal ions is generally actively controlled (in contrast to neutral organic compounds). |
|        |                                   |         | EFSA: The statement has been amended to "Similar uncertainty; it should be however considered that metals bound to food might be remobilised in the gastro-intestinal tract due to low pH values and are then present as free metal ions” |
|        |                                   |         | Page 84, Table 5, third row: We are concerned that the added risk approach might be considered which adds some additional unknons to the existing models. Use of assessment factors could increase erroneous exceedances of the risk assessment using background data. This is apparent in the copper renewal dossier where background copper levels fail the fish risk assessment. |
|        |                                   |         | EFSA: The added risk approach is not suggested in the statement. These concerns have been addressed in the statement. |
|        |                                   |         | Page 86, Table 5, second row: Has indirect impact as metals bound to sulfides and entering via the dietary route are mostly detoxified. |
|        |                                   |         | EFSA: Noted |
|        |                                   |         | Page 87, Table 5, third row: Expressing toxicity based on total metal fraction without normalization for differences in bioavailability due to physico-chemical properties of the (test) medium may result in over- and underestimation of toxicity depending on properties of the test medium and of the environment to be protected. |
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| 81     | Junghans, Marion                  | 3.7     | The chapter on addressing uncertainty in the environment is very valuable as a background for the inevitable expert judgement. |
|        |                                   | Addressing uncertainty in the risk assessment | EFSA: Thank you |
| 82     | Federal Environment Agency of Germany | 4.1   | The use of monitoring data in different phases/steps of the exposure and risk assessment to fulfil different requirements in different risk assessment and risk management steps is clearly described in that monitoring chapter. We fully support the recommended approach as a big step forward to overcome limitations of standard exposure modelling, standard ecotox studies and usually applied risk assessment schemes, which are not completely transferable to metals. The statement tries to find a good balance between the requirement for model adjustments and using monitoring data. |
|        |                                   | Aims and purposes of environmental monitoring | EFSA: Thank you. Noted. |
| 83     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 4.1.1  | Page 88, line 31-33: Access for the applicant to the LUCAS database has been rejected, and similar issues exist with Member State data. It would be appreciated if the document could encourage the relevant agencies to make those data available to applicants, while fully preserving the required confidentiality requirements of the agencies through confidentiality agreements. |
|        |                                   | Monitoring of the actual environmental transition metals loads | EFSA: We agree that data bases containing environmental data should be made publicly available. This has been added to the updated statement. |
| 84     | Junghans, Marion                  | 4.1.1  | page 89 line 1 - 3: Are you implying that in areas in which metals have been added by human use in the past, the resulting concentrations should be considered as "natural background"? I would strongly oppose this interpretation. The natural background concentration should refer to pristine areas. It is likely that ecosystems with a long history of metal immission have adapted in a way that only the tolerant species are present (see page 92 line 17 - 19). Such deprived ecosystems may be more vulnerable though to a further addition of metals or other stressors. |
|        |                                   | Monitoring of the actual environmental transition metals loads | EFSA: We think this is a misunderstanding: we do not suggest that anthropogenic additions are to be seen as natural background concentrations. They are part of the total background concentrations to be included in exposure assessment. Especially for the use of BLM I deem it necessary to refer to real, geological background concentrations because otherwise the potential to reach a better ecological status is excluded from the beginning and Water Framework
| Number | Organisation or name or respondent | Chapter | Comments and PPR WG responses |
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|        | 4.1.1 Monitoring of the actual environmental transition metals loads |       | Directive goals cannot be reached. But maybe we agree already, if I interpret the next paragraph correctly that background concentrations should be added to the PECs. Maybe it would be good if you could clarify what "should be considered" in line 6 exactly means. EFSA: Agreed |
| 85     | Casado, Carmen                     |         | The chapter on monitoring activities is greatly acknowledge, recognizing the important role of soil and sediments as final sink for the substances and the (sometimes) inappropriate or limited available data for sound risk assessments. It is significant that the need to monitor bioavailability and ecotoxicity is also recognized. The fact that the chapter includes the need for reporting sampling and analytical methods is also very well welcomed, as it is often not properly addressed and is of high importance for the relevance and reliability of monitoring data and for future improvements in metals risk assessment. EFSA: Thank you. Noted. |
|        | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 4.1.2 Post-registration monitoring | Page 90, line 25: It is highly recommended to also measure all physico-chemical properties (pH, hardness, DOC, clay content, eCEC, organic matter content, AVS, ...) that are expected to affect the bioavailability and toxicity of the metal in the environmental compartment assessed. EFSA: Reference to parameters that might be relevant for monitoring are given in 4.1.4 |
| 86     | Junghans, Marion                   | 4.1.2 Post-registration monitoring | I very much welcome a post-registration monitoring. EFSA: Thank you. Noted. |
|        | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 4.1.3 Dedicated long-term studies | Page 91, line 21: The Klein 2015 paper from the copper renewal dossier is quoted to justify that there is evidence of a long-term effect to earthworms. However, we disagree; long-term use could lead to effects, but this is different to, and does not imply, that there are long-term effects on earthworms or other organisms. EFSA: The study by Klein (2015) is useful because it indicates different effects for different contamination levels |
| 88     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 4.1.4 Conclusions and recommendations for monitoring | Page 92, line 22: If monitoring data is required ahead of an active substance dossier submission, how is this to be done – who and when. Providing monitoring data is made more difficult without access to the LUCAS database. EFSA: We agree that data bases containing environmental data should be made publicly available. This has been added to the updated statement. |
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|        |                                   | 90      | 4.1.4 Conclusions and recommendati ons for monitoring |

Page 92, line 33: AVS and SEM should also be measured for sediments. pH is less an issue for sediments as it shows less variation than in soils.

**EFSA: Noted, the point gives an indication of some parameter that are considered relevant (e.g. ..)**

Page 92, line 40: We need access to member state data to be able to do this, thus member states should provide access to their databases.

**EFSA: Noted**

Page 93, line 1: What does “full soil profiles” mean? Does this mean a full chemical analysis of the soil or analysis of the soil at differing depths?

**EFSA: It was meant as analysis of the relevant soil horizons to “derive reliable soil background concentration”**

Page 93, line 11: It is unclear what “mined data” means.

**EFSA: Sentence has been amended, thank you.**

Page 93, line 14: The highly conservative models always trigger the need for higher tier assessments for transition metals and trigger the requirement for monitoring data. This is not consistent with the requirements for synthetic pesticides and gives an erroneous impression that transition metals are a higher risk than synthetic pesticides. Comparative risk assessments for candidates for substitution are unfair if synthetic pesticides are modelled/assessed differently to transition metals – the fact that higher tier models are required for transition metals is not a sign that they are less safe than synthetic pesticides – for instance higher tier models already include risk mitigation measures for synthetic pesticides.

**EFSA: Noted**

Page 93 line 11: there is a " be" missing between "to" and "assessed"

**EFSA: Thank you added**

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|        |                                   |         |                              |

"survey of relevant ecotoxicology concentrations": It is not clear to me whether you mean ecotoxicologically relevant concentrations or effect concentrations (ECx)

**EFSA: Ecotoxicologically relevant concentrations are meant here -e.g. if total soil concentrations are used in the assessment, these parameters should also be monitored**

Page 93 line 11: there is a " be" missing between "to" and "assessed"

**EFSA: Thank you added**
| Number | Organisation or name or respondent | Chapter | Comments and PPR WG responses |
|--------|------------------------------------|---------|------------------------------|
| 91     | French Agency for Food, Environmental and Occupational Health & Safety (ANSES) | 5. General conclusions and recommendations | p. 93, line 30-31: Typo: "If bioavailability is to be considered in higher Tier assessments, specific models and guidance for the risk assessment of transition metal used as PPP is are needed."  
EFSA: The typo has been corrected in the updated statement. |
| 92     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 5. General conclusions and recommendations | Page 93, line 30: Some guidance on the acceptability of the models currently available for metals in water and sediment and soil would be highly welcome.  
EFSA: Agreed. The statement text was not amended in the section 5. |
| 93     | French Agency for Food, Environmental and Occupational Health & Safety (ANSES) | 6.1 Aquatic compartment | p.95, lines 15-17: When reading the statement and especially the part 3.1.3, it is our understanding that BLM available to date are not ready to use for aquatic ERA.  
Indeed, it is stated pages 46, lines 39-40:  
‘To conclude, the use of BLMs to consider the bioavailability of metals in a refined risk assessment requires:’ followed by 7 bullet points to improve or at least list potential improvements for BLM to be used in aquatic ERA in the future.  
Therefore, we suggest to rephrase the following sentence from the conclusions (p. 95, line 15-17): ‘The endpoints for the water compartment can be normalised in a refinement step to the physico-chemical parameters either using speciation models or if available biotic ligand models’.  
In our opinion, the current sentence might be misunderstood and might suggest that BLM already available are ready to use for ERA of PPP. The rephrasing could summarise all the recommendations provided earlier in the statement (under point 3.1.3).  
EFSA: Text amended to: either using simple speciation models or if available and considered suitable biotic ligand models. |
| 94     | Junghans, Marion | 6.1 Aquatic compartment | please consider the points addressed above also regarding a potential revision of the bullet points on page 95 lines 6 to 20  
EFSA: Conclusions amended to: The endpoints for the water compartment should be expressed at the same level of (bio)availability and can be normalised in a refinement step to the same set of physico-chemical |
| Number | Organisation or name or respondent | Chapter | Comments and PPR WG responses |
|--------|-----------------------------------|---------|-----------------------------|
| 95     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 6.2 Terrestrial compartment | Page 95, lines 35-38: See also comment on page 64. So far, no generally applicable bioavailable fraction has been identified for soil. It is generally accepted that the dissolved free metal ion is the bioavailable metal form (cfr aquatic risk assessment), but predicting or measuring the free metal ion fraction in soil and linking it with effects (cfr BLM model) is still associated with a higher degree of uncertainty than an assessment based on total soil metal concentrations. Therefore, it is recommended to always measure total (=aqua regia extractable) metal concentrations in soil. See e.g. OECD 259 (2017); Smolders et al. 2009 or MERAG fact sheet on bioavailability of metals (https://www.icmm.com/website/publications/pdfs/chemicals-management/merag/merag-fs5-6-2016.pdf). Page 96, line 27: This cannot be generalized, there are ppp uses where aging plays a significant role. The lab-to-field factor approach has its advantages and should not be discounted generally. Page 96, lines 27-31: See also comments page 66-67 EFSA: Please see the answers to the specific commend raised above in the statement. |
| 96     | Federal Environment Agency of Germany | 6.3 Groundwater | 49 p. 96-97 Repeated comment: The relevance of groundwater monitoring data according to the overall monitoring concept in the statement (specially to derive reliable metal background concentrations in the groundwater compartment, or describe any possibilities for post registration monitoring) is missing in the summary for groundwater assessment and should be described here. Related to the two comments above it needs to be clarified, how modelled PECgw must be interpreted in terms of expected groundwater concentrations. From our understanding, metal measurable background values in groundwater need to be part of discussing the final risk related to the parametric drinking water limit in Europe. EFSA: Please refer to EFSA’ response to comment 8. Update of the statement was not needed. |
| 97     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 6.4 Monitoring | Page 97, lines 24-28: Agreed. It must however be mentioned that experimental analysis of total (and bioavailable) metal fractions are critical, together with proper analysis of the physico-chemical properties of the receiving environment. EFSA: Agreed, the indications are given in the specific recommendation to the monitoring in the respective chapter 4.1.4 |
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| 98     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | 7. References | Mebane et al., 2020; Weltens et al., 2000; Luoma and Rainbow, 2008 - not included in References.  
EFSA: Added  
References cited by the EUCuTF:  
Cappuyns V and Swennen R., 2006. Comparison of metal release from recent and aged Fe-rich sediments. Geoderma 137: 242–251.  
Costello DM, Hammerschmidt CR, Burton GA, 2015,. Copper Sediment Toxicity and Partitioning during Oxidation in a Flow-Through Flume. Environ. Sci. Technol., 49, 6926–6933.  
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De Jonge M, Eyckmans M, Blust R, Bervoets L, 2011. Are accumulated sulfide-bound metals metabolically available in the benthic oligochaete Tubifex tubifex? Environmental science & technology 45, 3131-3137.  
De Schamphelaere K.A.C. and Janssen C.R. 2004. Effects of chronic dietary copper exposure on growth and reproduction of Daphnia magna. Environ Toxicol Chem. 23(8):2038–2047.  
Ma, Y. B., Lombi, E., Nolan, A. L., & McLaughlin, M. J. 2006a. Short-term natural attenuation of copper in soils: Effects of time, temperature, and soil characteristics. Environmental Toxicology and Chemistry, 25(3), 652–658.  
Ma, Y. B., Lombi, E., Oliver, I. W., Nolan, A. L., & McLaughlin, M. J. 2006b. Long-term aging of copper added to soils. Environmental Science and Technology, 40(20), 6310–6317.  
Nys, C., Vlaeminck, K., Van Sprang, P., & De Schamphelaere, K. 2020. A generalized bioavailability model (gBAM) for predicting chronic copper toxicity to freshwater fish. Environmental Toxicology and Chemistry, https://doi.org/10.1002/etc.4806.  
Simpson SL, Angel BM and Jolley DF, 2004. Metal equilibration in laboratory-contaminated (spiked) sediments used for the development of whole sediment toxicity tests. Chemosphere 54, 597-609.  
Smolders E., Oorts K., Van Sprang, P., Schoeters I., Janssen C.R., McGrath S.P., McLaughlin M.J. 2009. Toxicity of trace metals in soil as affected by soil type and aging after contamination: using calibrated bioavailability models. }
| Number | Organisation or name or respondent | Chapter | Comments and PPR WG responses |
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| 99     | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | Appendix A: Overview of the different assessment frameworks | Article 1 of REACH Regulation states that: “This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment.” This is broader than safe handling. <br>EFSA: Agreed, inserted |
| 100    | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | Appendix B: Description of the IDMM Model | Appendix B, page 2, line 10: ‘Model comprises a single soil layer” – this is introductory text, has been superseded <br>EFSA: The text is in line with the information reported in the Scientific/technical report (Monteiro et al., 2010) and corresponds to the version of model reviewed in this report. An update of the statement is not seen as needed. <br>Appendix B, page 2, line 39: This is only partly correct. Equilibrium speciation, of the labile metal pool only, is done by a combination of empirical modelling (for the relationship between the soil adsorbed metal and the free ion) and WHAM (for the relationship between the complexed metal in porewater and the free ion). <br>EFSA: Agreed. The statement has been amended accordingly. <br>Appendix B, page 3, line 3: Different forms of copper are modelled by either equilibrium or kinetics: free ion/adsorbed/complexed in porewater by equilibrium aged by kinetics. <br>EFSA: Agreed. The statement has been amended accordingly. <br>Appendix B, page 3, line 29: It is worth noting that the soil erosion rates used by the IDMM in the runoff scenarios are taken from the predictions of the PRZM model for the scenarios in question; thus, the representativeness of the soil erosion process refers to the process as modelled in PRZM, not the IDMM itself. Erosion rates used in the drainage scenarios are estimates based on literature data and ideally require definition for any proposed scenarios. |
| Number | Organisation or name or respondent | Chapter | Comments and PPR WG responses |
|--------|------------------------------------|---------|--------------------------------|
| 101    | French Agency for Food, Environmental and Occupational Health & Safety (ANSES) | Other comments | EFSA: Different submodels are implemented in the IDMM model. In a general way, it is not incorrect to mention the IDMM model instead of the name of each sub-model in this case. An update of the statement is not seen as needed. Some references to ECHA guidance document are not easy to handle and not sufficiently explicit. It implies that the reader has a good working knowledge of the ECHA guidance, which might not be the case. It is in some cases confusing and may lead to a misunderstanding of the statement document. EFSA: The statement has been updated to specify which ECHA guidance the statement is referring to. |
| 102    | Federal Environment Agency of Germany | Other comments | Thank you very much for the great work you did. Please find attached the overview of all comments from UBA - Federal Environment Agency of Germany. EFSA: Thank you. |
| 103    | IFOAM Organics Europe | Other comments | IFOAM Organics Europe congratulates EFSA for initiating the development of a specific guidance document for evaluating transition metals like copper. The organic sector has called for guidance documents that reflect the peculiar properties of natural substances (like transition metals) for some time, and we welcome that EFSA and the European Commission have now taken steps in that direction. EFSA: Thank you. Noted. This guidance document is a chance to better accommodate transition metals such as copper in the current Regulatory framework and therefore should be more ambitious in order to set a high standard for the future guidance documents on the evaluation of other natural substances. EFSA: The European Commission asked for a statement on a framework for conducting the environmental exposure and risk assessment for transition metals when used as active substances in plant protection products and not a guidance document. However, we see room for improvement in the consideration of the natural background exposition to these minerals. This shows that there is still some way to go until a fair and adequate registration and evaluation process for natural substances is established. An explicit integration of natural substances in reg. (EU) 1107/2009 is still missing. |
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|        | EFSA: It is outside the remit or EFSA to prepare EU legislation. Your proposal would be better addressed to the European Commission | | |
|        | At first, it should be considered if an element is an essential element or not. If the element is essential, the exposition should be discussed taking into consideration if it is to be considered in the range of a “deficiency status”, an “acceptable range of intake”, or an “oversupply”. It should be also considered if a metal is commonly found in nature or if it is only found in particular places. If it is common and essential, as is f.e. the case for copper, it is very important to consider the natural background exposition. Otherwise, this can lead to situations where evaluation models calculate levels of concentrations to be considered as “safe” that are actually lower than the already existing and normal natural concentrations. | | |
|        | EFSA: The statement recommends that residues of transition metals from previous agricultural uses are taken into account for the exposure assessment. See e.g. chapter 3.2.2. Considerations in respect to homeostasis are included in the statement. | | |
|        | In this context, persistency has to be discussed, too. Transition metals, being pure elements, are - of course – always “persistent”. This natural character must not be confused with the persistence of a POP (persistent organic pollutant) which – as a newly designed compound – has never been part of natural ecosystems. Again, persistency has to be considered in light of the question if the metal is an essential element frequently occurring in nature, and if there is an acceptable and necessary range of intake. Thus, the criteria pertaining to persistency, in light of current scientific and technical knowledge, should be adapted to the situation of naturally occurring substances such as these minerals. For iron, this was already applied accepting the active substance even as low risk substance. Thus, persistency in the case of mineral substances should not be a cut-off criterion per se, but should be evaluated taking other relevant factors into account. The persistency of metals like copper should – of course – be one of the reasons to limit the amount of application allowed per year and to minimize the input, as it is already practiced for many years for copper in organic farming. | | |
|        | EFSA: As transition metals do not degrade and have the potential to accumulate in the environment e.g. in soil and sediment they are considered to be persistent. See also responses to comments in points 19 and 24. | | |
| 104    | European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd. | Other comments | The EUCuTF is available for video meetings (WebEx, Microsoft teams) should our comments require further explanation or discussion. |
|        | EFSA: Noted. However, it was not foreseen under this mandate to have hearings with stakeholders. | | |