Scientific Committee on Health and Environmental Risks

SCHER

Voluntary Risk Assessment Report on Copper and its compounds

Environmental Part

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SCHER

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Scientific Committee members

Herman Autrup, Peter Calow, Wolfgang Dekant, Helmut Greim, Wojciech Hanke, Colin Janssen, Bo Jansson, Hannu Komulainen, Ole Ladefoged, Jan Linders, Inge Mangelsdorf, Marco Nuti, Anne Steenhout, Jose Tarazona, Emanuela Testai, Marco Vighi, Matti Viluksela

Contact:

European Commission
Health & Consumer Protection DG
Directorate C: Public Health and Risk Assessment
Unit C7 - Risk Assessment
Office: B232 B-1049 Brussels

Sanco-Sc8-Secretariat@ec.europa.eu

http://ec.europa.eu/health/ph_risk/risk_en.htm

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Members of the working group are acknowledged for their valuable contribution to this opinion:

Prof. P. Calow, Roskilde University, Denmark

Prof. C. Janssen Ghent University, Belgium

Prof. J. Linders, National Institute of Public Health and Environment (RIVM), Netherlands

Prof. J. Tarazona, Spanish National Institute for Agriculture and Food Research and Technology, Spain

Prof. M. Vighi, *(Chair/rapporteur)* University of Milano Bicocca, Italy

External experts:

Prof R. Blust, University of Antwerp, Belgium

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1. BACKGROUND

Council Regulation 793/93 provides the framework for the evaluation and control of the risk of existing substances. Member States prepare Risk Assessment Reports on priority substances. The Reports are then examined by the Technical Committee under the Regulation and, when appropriate, the Commission invites the Scientific Committee on Health and Environmental Risks (SCHER) to give its opinion.

2. TERMS OF REFERENCE

On the basis of the examination of the Voluntary Risk Assessment Report the SCHER is invited to examine the following issues:

(1) Does the SCHER agree with the conclusions of the Risk Assessment Report?

(2) If the SCHER disagrees with such conclusions, it is invited to elaborate on the reasons.

(3) If the SCHER disagrees with the approaches or methods used to assess the risks, it is invited to suggest possible alternatives.

3. OPINION

3.1 General comments

The VRAR on copper is a very complex document, based on a huge amount of science and information useful for both exposure and effects assessment. The general quality is very good and some procedures proposed are quite innovative and scientifically sound. The peculiarities of copper, as a natural ubiquitous element, as well as an essential nutrient, are properly addressed. The theoretical approaches used are appropriate and, in general, properly applied. It is the opinion of the SCHER that the information available allows a sound risk assessment, even if some additional information could be helpful. For example:

- data for assessing regional and background values in Mediterranean coastal waters;
- reliable mesocosm studies for the marine environment. The estuarine environment is not considered although it is a very important and complex environment (e.g. daily and seasonal changes in salinity and a flora and fauna with a freshwater and marine ancestry).

However, it is the opinion of the SCHER that some issues present some weaknesses and some points may need further clarification. In particular:

- the selection of freshwater toxicity data;
- some caution is needed on the problem of possible increased sensitivity due to adaptation/acclimation to low background values;
- additional evaluations for physical-chemical properties of agricultural soils should be incorporated.

Considering the risk characterisation at local and regional level performed in the VRAR, it is the opinion of the SCHER that the issues presented above are not likely to affect substantially the quantitative results obtained. Therefore, proposed conclusions on risk characterisation can be accepted. However, taking into account that the document may represent a reference point for future assessment of copper risk in the European environment, the SCHER supports the need to better explore some data and to carefully account for some controversial issues. It is also the opinion of the SCHER that most of the amendments proposed do not require the production of additional information, except for some of the issues mentioned above.

3.2 Specific comments

3.2.1 Exposure assessment

3.2.1.1 Emissions

Copper is a natural element, so natural emissions occur in the biogeochemical cycle. The VRAR reports two different assessments of natural emissions, differing by about two orders of magnitude. The reason for choosing the highest data from Richardson et al. (2001) instead of those from Nriagu (1989) are not sufficiently supported, besides the fact that they are more recent.

Two estimates of the anthropogenic emissions are also reported. These are of the same order of magnitude and seem to indicate a decrease of about 30% in a 12 year period (1983-95). It is worth noting that the first estimate of the natural emissions (Nriagu, 1989) is of the same order of magnitude as the anthropogenic one (Nriagu et Pacyna, 1988; Pacyna & Pacyna, 2001), while the second (Richardson et al., 2001) is about 50 times higher. The VRAR is based on the estimates of Richardson et al. (2001) and of Pacyna & Pacyna (2001), indicating that only 1.7 % of copper emissions are of anthropogenic origin. No justification for this choice is given in the VRAR. It is opinion of the SCHER that more justification must be provided for supporting the choice of natural and anthropogenic emission data.

Local anthropogenic releases in air water and soil for the different productive activities were obtained from the emission data provided by industry. The methodology for estimating industrial emissions is appropriate. However it is based on several confidential, not reported, data (e.g. production data, emission factors in air and water) Therefore, SCHER points out that checking local emission estimates is impossible.

3.2.1.2 Environmental fate

It is recognised in the VRAR that a key issue in exposure assessment is expressing copper as bioavailable fraction, accounting for the different processes capable to affect the copper fraction available for uptake by and toxicity in biota. Regional PECs were derived from monitoring data and from a modified version of EUSES (EC 2004). SCHER continues to hold the view (first articulated in the Opinion on the risk assessment of zinc (SCHER 2007)) that it is not helpful to describe the PECs as being derived from a modified version of EUSES. This issue is addressed in the second point of the General Conclusions (Section 3.3) of this opinion.

Partition coefficients for sediments (Kp_{sed}), suspended matter (Kp_{susp}), and soil (Kd) are proposed. For soil, Kd is determined as a function of environmental factors (pH, OC). However, Kp_{sed} and Kp_{susp} are derived as 50^{th} percentile of the distribution from literature data. No information is provided on the variability of the distribution and in the dependence on environmental factors. It is the opinion of the SCHER that the choice of Kp should be better supported. As for Kd the Kp is clearly dependent on environmental conditions and shows considerable variation among sites and conditions. The difference in approach between Kds and Kps is not justified.

Based on literature data a removal of 80% in STP is assumed as a reasonable worst case. It must be noted that all data refer to countries of Northern Europe. Some evidence should be provided for supporting the possibility of application of this assumption to all European countries.

3.2.1.3 Predicted Environmental Concentrations

3.2.1.3.1 Aquatic compartment

Natural background concentrations and regional PECs were derived from monitoring of the FOREGS Geochemical Baseline Programme, developed on relatively pristine areas, and using a large database of monitoring values from several European countries. The median values of individual countries have been used to calculate European median values. The following values are proposed:

- Natural background concentrations: median values 0.88 μg/L as dissolved Cu (range: 0.1-14; range $10^{th}/90^{th}$ percentiles 0.23-3.28).
- Regional PECs: 4.5 μg/L for Cu_{total} (range of medians for individual countries: 1.8-18.3; range of all values: 0.6-32.3); 2.9 μg/L for $Cu_{diss.}$ (range of medians for individual countries: 0.5-4.7; range of all values: 0.4-20.1).

A comparable approach was used for sediments, producing the following values:

- Natural background concentrations: median value 21.0 mg/kg dw (range: 16.3-32.3)
- Regional PECs: median value 67.5 mg Cu/kg dw (range of medians for individual countries: 45.8-88.3).

The SCHER agrees with the procedure and with the proposed values.

For the risk characterisation the VRAR follows a total risk approach for the Cu concentrations used. SCHER agrees with this total risk approach.

The comparison with some experimental data available for a limited number of local sites show a reasonable agreement between calculated and measured PEC_{water}. The comparison with experimental data for sediments gives less satisfying results. An explanation of the controversial results is not provided. Moreover, it is not explained how these differences will be accounted for in the risk characterisation.

3.2.1.3.2 Marine environment

To estimate a regional PEC for European seawater and sediments, large databases of monitoring data from several European countries (Belgium, Germany, Ireland, The Netherlands, Norway, Denmark Sweden, United Kingdom and the Baltic) have been used. OSPAR data from offshore oceanic water (OSPAR, 2000) have been used for assessing background levels. The following values are proposed:

- Natural background concentrations: ranging from 0.05 and 0.36 μg dissolved Cu/L.
- Regional PECs: median 1.1 μg dissolved Cu/L (range of median values: 0.5 to 0.7; range of 90^{th} percentile values: 0.8 to 2.7).

For sediments, the 90^{th} percentile of the distribution in each country has been assumed as a reasonable worst case (RWC) of country-specific PEC, and the 50^{th} percentile has been assumed as the typical country-specific PEC. Using the country-specific RWC-ambient PECs a typical value of 16.1 mg Cu/kg dry wt is calculated for European marine sediments as the 50^{th} percentile of the distribution.

It is the opinion of the SCHER that the procedure used for calculating the European background levels and regional PECs is appropriate. However, all data used refer to the Atlantic-North Sea side of Europe. No data from the Mediterranean region have been used. Therefore, it is the opinion of the SCHER that some evidence should be provided for supporting the reliability of the proposed regional PEC for the Mediterranean. Several studies exist providing information on copper levels in the Mediterranean basin (e.g. Yoon et al., 1999).

3.2.1.3.3 Atmospheric and terrestrial compartment

Natural background concentrations were derived from a monitoring of the FOREGS Geochemical Baseline Programme developed on relatively pristine areas. A median value of 12 mg Cu/kg dw is proposed for soil. Regional PECs for soil were derived from a large European-wide database of monitoring data. For each country, 50^{th} percentile (typical) and 90^{th} percentile (RWC) have been calculated for different soil categories. The values proposed as regional PECs are shown in Table 1. Moreover, a series of country-specific regional PECs have been proposed as a background for local PECs for sites located in specific countries.

Table 1. Regional PECs proposed for different soil categories. In brackets the range of country-specific values is indicated

	50th percentile mg Cu/kg dw	**90th percentile (RWC) mg Cu/kg dw**
Agricultural soil	14.2 (10.0-27.8)	31.2 (16.1-57.5)
Forest soil	10.7 (2.7-20.6)	24.4 (7.3-40.2)
Grassland soil	15.9 (13.7-20.4)	32.8 (28.9-44.0)
Unspecified soil type	14.2 (8.0-34.5)	35.6 (15.9-80.8)

Monitoring-based regional PECs were compared with modelling-based values calculated using EUSES 2.0. As already mentioned, SCHER is of the opinion that it is not helpful to describe the PECs as being derived from a version of EUSES modified to take account of differences between organic compounds and metals. However, as a purely indicative comparison, modelled values are of the same order of magnitude of the monitoring-based values. The SCHER agrees with the proposed regional and background PECs.

For the atmospheric compartment, no monitoring data are provided. The modelling approach provides levels of the order of magnitude of 10^{-5} and 10^{-4} ng Cu/m^3 for the continental and regional scale respectively. The SCHER agrees with the hypothesis that atmospheric pollution from copper on a wide scale is negligible in relation to the sources considered in the VRAR. However, for the sake of clarity, a further exploration of this issue would be useful.

Local PECs for the atmospheric and soil compartments are calculated for all production typologies according to the TGD procedures. The SCHER agrees with the proposed PECs.

3.2.2 Effect assessment

3.2.2.1 Freshwater results

The relevance of environmental factors (e.g. hardness, pH, and dissolved organic carbon) for affecting Cu toxicity on aquatic organisms is underlined in the report. Biotic Ligand Models (BLMs) have been developed for algae, invertebrates and fish. The SCHER appreciates the thorough quantitative analyses that have been carried out concerning the cross-species extrapolation of the BLMs. These analyses illustrate that the BLMs have a potential for extrapolating across species and for reducing the variability about NOEC data in the effects database. However, extrapolations from one species to another as implemented in the BLM approach should be handled with caution.

The procedure for selection or rejection of data is adequately described and transparent. The criteria from the TGD have been followed in the data selection. It is opinion of the SCHER that some critical assessment of a limited number of data points would have been advisable. However, these data are not influencing the final PNEC.

To calculate HC5 values referred to natural conditions and to reduce the effect of environmental factors, a series of scenarios representing different conditions of European natural water bodies have been selected. The BLM has been applied to the different scenarios. The application of the BLM leads to the development of a series of SSD curves. So, HC5-50 values specific for the different scenarios, ranging from 7.8 and 27.2 µg Cu/L have been calculated. The SCHER agrees with the proposed values.

The VRAR underlines that the optimal concentration range of essential elements (OCEE) is linked with the natural concentration of the element in the natural environment. However, the comparison between HC5-50 and OCEE does not take into account the possibility of low OCEE corresponding to the lower end of the background range. The possibility that adaptation to natural background levels may influence the sensitivity to metals is taken into account and supported with some references (Bossuyt et al., 2003; Taylor et al., 2000; Kamunde et al., 2001, 2005). However, the conclusions cannot be extrapolated to populations adapted to very low or very high background levels. SCHER considers that with the current state of the art, there is insufficient scientific knowledge for assessing the risk of populations under extreme situations (far outside their optimum value). As these conditions exist and the adapted populations could be particularly sensitive, the committee considers that additional research in this area is needed. However, it is opinion of the SCHER that this does not affect conclusions for the scenarios considered by the VRAR.

Finally, the HC5-50 values are compared with some reliable mesocosm studies. The comparison shows that in some cases HC5-50 values derived from the SSD approach are lower than the no effect values derived in the mesocosm studies. On these bases, the conclusion of the VRAR is that the HC5-50 values, normalised using BLM for the different European Ecoregions, ranging from 7.8 to 27.2 µg Cu/L, can be accepted.

3.2.2.2 Sewage Treatment Plant

Several tests on different endpoints for micro-organism are examined in the VRAR. However, there are not enough reliable data available for developing a sound statistical approach to derive a PNEC for microorganism activity and for STP. Therefore, a PNEC is derived according to the TGD, on the basis of the following data:

- a NOEC value, for ciliated protozoans representative for the protozoans;
- a NOEC value for inhibition of nitrification using activated sludge;
- a NOEC values for inhibition of respiration.

The lowest reliable observed NOEC (inhibition of bacterial respiration), corresponding to 2.0 mg/l, expressed as total Cu and 0.23 mg/l expressed as dissolved copper was used. According to the TGD the $PNEC_{micro\text{-}organisms}$ is set equal to a NOEC from a test performed with ‘specific bacterial populations’. Therefore, a $PNEC_{micro\text{-}organisms}$ of 0.23 mg Cu/l (as dissolved fraction) is proposed. The SCHER agrees with the procedure and with the PNEC proposed.

3.2.2.3 Sediments

As for the aquatic compartment, the total approach is used for sediments.

The assessment was performed by using a tiered approach: Tier 1 is using the equilibrium partitioning (EP) method; Tier 2 is based on the available sediment toxicity data; Tier 3 takes the available mesocosm and semi field studies into account. From the results of the three Tiers, the VRAR concludes that the $HC5\text{-}50_{sediment}$ (benthic SSD) calculated with the log normal distribution (1741 mg Cu/kg OC) can be assumed as enough protective.

It is the opinion of the SCHER that the proposed approaches present some weaknesses. In particular, the use of the EP approach in this case is questionable. The HC5-50 for freshwater used to derive $HC5\text{-}50_{sediment}$ is the result of an elaboration, being calculated from data normalised according to the BLM. Therefore, the calculated $HC5\text{-}50_{sediment}$ should be considered as indicative. Moreover, the statistical and ecological significance of the SSD approach, based on a small number of species, is quite weak. However, the comparability demonstrated by different approaches supports the proposed PNEC.

3.2.2.4 Marine environment

For the marine environment 57 chronic toxicity data (NOECs) on 24 species (4 algae, 18 invertebrates, and 2 fishes) were selected as highly reliable. SSD curves have been developed with these data. Some inconsistencies appear between the list of toxicity data (24 species) and the figures of SSD curves (2.12 and 2.13), where 26 points are reported. However, it is the opinion of the SCHER that the influence of these two additional points on the curves is not very relevant and the calculated HC5-50 values can be assumed as sufficiently reliable. Using different statistical approaches, HC5-50 values ranging from 4.8 and 5.2 µgCu/L are calculated from data normalised on 2 mg/L DOC (corresponding to 1.3 to 1.4 µgCu/L normalised on 0.2 mg/L DOC). Some field and semi-field studies indicate threshold levels of the same order of magnitude of the calculated HC5-50. However, these studies are described as poorly reliable, due to methodological reasons. For the derivation of the PNEC for the marine environment, the VRAR concludes that:

- the database is wide enough to be considered protective for the marine community, even if some relevant phyla (e.g. echinodermata, cnidaria) are not represented;
- the statistical approach is sound;
- no reliable mesocosm or semi-field studies are available.

On these grounds, the VRAR proposes an additional application factor of 2 to be applied. Therefore a $PNEC_{marine}$ of 2.6 µgCu/L is proposed. However, considering that PNEC values normalised to low DOC are very close to background levels, the VRAR proposes, according with TCNES, that if a reliable mesocosm study would confirm the HC5-50 of 5.2 µgCu/L, an AF of 1 would be applied. The SCHER agrees with the logic of this approach.

For sediments, sufficient reliable toxicity data are not available. Therefore the partitioning method is applied. Considering the characteristics of marine and estuarine sediments, PNECs of 338 and 144 mg Cu/kg dw respectively are calculated. The SCHER agrees with this approach, limited to marine sediments. It is the opinion of the SCHER that estuarine conditions are too variable for being described by a unique value based on average characteristics.

3.2.2.5 Terrestrial environment

A suitable data set is available on plants (67 NOECs on 9 species), invertebrates (108 NOECs on 10 species), and microorganisms (154 NOECs on 4 different functional endpoints). The SCHER recommends using soil microbial functions, as individual endpoints instead of averaging, as suggested for Zn and applied in other RAR for metals.

Despite the importance of incorporating metal bioavailability in the soil risk assessment, the knowledge on the influence of soil parameters is less developed than for the aquatic ecosystem, so a model comparable with BLM is not available. However, a model recently developed (ICA/ECI, 2005, see Rooney et al., 2006) is proposed to predict bioavailability as a function of soil properties such as texture, pH, OC, cation exchange capacity (CEC). The model was developed for different taxonomic groups (plants, invertebrates, microorganisms).

Moreover, on the basis of field data, the VRAR concludes that there is sufficient evidence to assume that the toxicity under field conditions is less than under laboratory conditions, due to ageing and leaching factors. A worst case generic leaching-ageing (L/A) factor of 2.0 is proposed for all soils. This factor is used on all individual $NOEC_{add}$ values of tests starting within 120 days after spiking to generate aged $NOEC_{add}$ values. For $NOEC_{add}$ values of tests in soils that have been equilibrated for more than 120 days after spiking, the L/A factor is 1.0. The SCHER agrees with this approach for the regional assessment. However, for the local assessment, additional justification for supporting the application of the L/A factor should be provided.

To apply the data normalization using the proposed approaches for assessing bioavailability, some scenarios are proposed to characterise European soils. Data were selected from a series of international sources. Typical European soils were selected on the basis of the following characteristics: pH, OM%, clay%, CEC. The following conclusions were derived from the available database:

pH: typical (50^{th} %): 5.3; minimum (10^{th} %):4.6; maximum (90^{th} %): 6.2

OM%: typical (50^{th} %): 9.4; minimum (10^{th} %):2.7; maximum (90^{th} %):26.7

Clay%: typical (50^{th} %):23.3; minimum (10^{th} %):17.2; maximum (90^{th} %): 29.2

CEC (cmol/kg): typical (50^{th} %):20.5; minimum (10^{th} %):12.8; maximum (90^{th} %):46.5.

It is the opinion of the SCHER that these levels are not representative of European soils, in particular for agricultural soils. For example, in most agricultural soils, covering a large percentage of European soils, OM% is generally lower than 2-3 %; see, for example, the scenarios developed by the FOCUS Working Group (FOCUS, 2002), accepted at European level for exposure prediction of plant protection products.

It must also be noted that a series of six typical soils was selected as conservative worst cases for the normalization of NOECs. Many of the properties of the selected soils are not consistent with the previously mentioned ranges of properties. The reasons for this inconsistency are not explained. In conclusion, it is the opinion of the SCHER that the approach used for assessing $PNEC_{soil}$ is appropriate. However, the selection of typical European soil properties for the normalisation of NOECs is inadequate in particular for agricultural soils, where copper exposure is likely to occur.

3.2.2.6 Secondary poisoning

From the experimental evidence on aquatic and terrestrial food webs, the VRAR concludes that copper is not biomagnified across the aquatic and terrestrial trophic chains and that there is no need for particular criteria for secondary poisoning for the aquatic and terrestrial environments. It is the opinion of the SCHER that, in some case, the arguments used for supporting this conclusion are not adequately described in the VRAR. However, there is enough evidence in the literature to support that copper is not biomagnified in aquatic and terrestrial food webs. Therefore, the SCHER can accept the conclusion.

3.2.3 Risk characterisation

GIS-based approaches and geo-statistical methods are used for deriving geographical distribution of environmental characteristics in order to apply normalisation methods to calculate local and regional PNECs. Local PECs are then compared with normalised PNECs. A step-wise approach is applied to calculate PEC/PNEC for all production and use sites, as a function of the amount of site-specific information available for the application of the GIS-based procedure (Steps 1, 2 and 3). It is the opinion of the SCHER that the approach is innovative and very suitable for site-specific risk characterisation.

3.2.3.1 Water Compartment and STP

Considering the range of BLM-normalised PNECs (from 7.8 and 27.2 µg Cu/L), the lower end is assumed as an EU-wide RWC value. For site-specific assessment, specific PNECs, calculated on the basis of local environmental parameters, within the range mentioned above, should be used. However, for the site-specific risk characterisation, country-specific BLM-normalised PNECs are used, in some cases substantially out (up to 321 µg Cu/L) of the proposed range for typical European ecoregions. This result seems contradictory and should be better explained. It is the opinion of the SCHER that the approaches used are appropriate and suitable for addressing the complex problem of risk characterisation in European surface waters.

Nevertheless, some weaknesses have been pointed out in the definition of the PNECs. It is the opinion of the SCHER that these weaknesses are unlikely to substantially affect the calculated PEC/PNEC values. However, some caution is needed, in particular in sites where calculated added concentration is substantially higher than background/regional level. Copper concentration in effluents is in any case lower than the $PNEC_{micro\text{-}organisms}$. Therefore, low risk for STP occurs. The SCHER agrees with this conclusion.

3.2.3.2 Sediment Compartment

Step 1 of the step-wise procedure is applied to only two sites. In both sites, calculated bioavailable Cu is 0, so no risk occurs. This approach neglects the mobilisation of copper through ingestion by benthic and epibenthic organisms. Copper following this route enters a totally different environment than the one on which the bioavailability calculations are based. In all other cases, step 3 is applied. In all sites, low risk occurs. As for surface water, it is the opinion of the SCHER that some weaknesses highlighted in PNEC determination may not affect risk characterisation.

For estuarine and marine sites, no PEC corrections for bioavailability were used for the risk characterisation. The estuarine and marine PNECs used are respectively 144 and 338 mg Cu/kg dry weight. The SCHER agrees with the approach for marine sediments. It is the opinion of the SCHER that the approach is not applicable to the highly variable conditions of estuarine sediments.

3.2.3.3 Soil Compartment

In all sites, PEC/PNEC ratio was lower than 1, suggesting low risks. However, due to the inadequate selection of typical European scenarios, it is the opinion of the SCHER that additional estimations for ranges of agricultural soils should be incorporated.

The SCHER points out that, local estimations only cover current emissions. As mentioned in the VRAR some local measured values are well above the PNEC and are assumed to be related to historic pollution. In these cases the SCHER proposes a further elucidation of the potential risk.

3.2.3.4 Sectors with limited information

In these cases, a step-wise approach 3 is applied, using default worst-case PNECs. For many sectors risk is expected for the water and sediments compartments, while low risk is expected for the soil compartment. The SCHER agrees with this conclusion, with similar comments to those presented above.

3.2.3.5 Regional risk characterisation

Regional risk characterisation is developed by using median EU PEC values, as well as country specific values. For freshwater two different approaches are used.

Step-wise approach 1: where the site-specific values of the abiotic factors are available, the normalised PNECs for the particular region under consideration were calculated. The region-specific risk ratio is then calculated using the distribution of country-specific monitoring values.

Step-wise approach 2: PNECs estimated from similar regions- and/or non-linked phys-chemistry of the same region was used for the risk characterisation. Different data sources were consulted in order to obtain the normalisation parameters needed (e.g. FOREGS data) and similarities across regions.

On these grounds, a Regional PEC/PNEC ratio is calculated as the median of the country specific distribution. Moreover, the % of sites with PEC/PNEC>1 is indicated. It is the opinion of the SCHER that the approach is sound. Same comments made above about the weaknesses on the assessment of $PNEC_{water}$ are still valid, but do not affect substantially the conclusions of the VRAR. The SCHER agrees with the proposed conclusions.

For the marine environment, the $PNEC_{marine}$ of 2.6 µgCu/L and the country-specific PECs are used. Some justification is provided for the lack of data for southern Europe. In particular, data from southern European rivers are quoted (Spain, France), without mentioning if they are Atlantic or Mediterranean. It is the opinion of the SCHER that the approach is suitable. However, more information should be provided to support the suitability for Mediterranean coastal waters. The SCHER agrees with the proposed conclusions.

For freshwater sediments, it is concluded from a weight of evidence approach that a risk is only expected from the copper added trough local emissions. The SCHER agrees with this conclusion.

For the estuarine and marine sediments, concentrations were obtained for several European coastal zones and compared with the proposed PNEC, indicating that no regional risks are expected. The SCHER agrees with this conclusion for the marine environment, but not for the estuarine systems, because of the previously mentioned variability of conditions.

For STP, typical 90th percentile effluent concentrations measured in several European countries vary between 11.1 µg/L and 54.0 µg/L. Hence no risk for the STP is predicted. The SCHER agrees with this conclusion.

For the soil compartment three different approaches are used as a function of the amount of information available. In all cases, the 90th percentile of PEC/PNEC is lower than 1. Hence no risk for the soil compartment is predicted. The SCHER agrees with the approach taken for the risk characterisation but remains concerned about the representativeness of the scenarios, in particular for agricultural soils.

3.3 General conclusions applicable to all (V)RARs of metals carried under the Existing Substances Regulation and recommendations.

SCHER draws attention to the following general issues that are applicable to all the RARs and VRARs for all the metals carried out under the former Existing Substances Regulation.

First, SCHER commends the shift away from the added risk approach to the total risk approach in the later RARs and VRARs. As made clear in the CSTEE opinion on cadmium (CSTEE, 2004) the added approach is only appropriate if background can be unambiguously defined across spatial scales. This has never been possible for any of the metals considered to date. However, there can be a case for combining the added approach when, for example, there is interest in managing emissions from a specific source.

Second, on exposure SCHER has consistently made the point that it is understandable that models should be based on modifications of EUSES. However, the modifications are so extensive that it is inappropriate to describe the resulting models as “modified EUSES”. Moreover and more substantially, EUSES makes steady state predictions that may not be appropriate for metals. In fact the predictions were never used in regional assessments – measured values took precedence. SCHER is of the Opinion that this is the appropriate approach and that EUSES type models need to be used with caution for the continuing future.

Third, taking account of bioavailabilty remains the biggest challenge for all metals in all compartments because this is complexly influenced by pH, hardness, DOC, AVS (for sediments) and several other environmental variables. SCHER welcomes the increasing trend to address bioavailability by the development of the biotic ligand models. However, this involves nontrivial scientific effort and SCHER encourages the development of research programmes addressing the extent to which it is possible to extrapolate parameters across taxa.

Fourth, several of the (V)RARs have raised the possibility that adaptation/acclimation to metal toxicity can occur in some natural populations. In its opinion on the RAR for zinc SCHER drew attention to the possible complications that might arise as a result of these processes. If used to establish ecotoxicity, organisms from exposed sites might have reduced sensitivities relative to ecosystems in general. On the other hand given that acclimation and adaptation are natural processes organisms from pristine sites might overestimate risk. To date the evidence for adaptation and acclimation is suggestive but not decisive. SCHER would again encourage more research in this important area considering both the effects of variations in natural backgrounds and anthropogenic influences.

Fifth, many of the (V)RARs have grappled more or less successfully with variability in measured exposure at all scales and effects. SCHER has consistently argued against the use of single-number summaries (e.g. averages) as hiding important and relevant information. SCHER remains of the opinion that more attention needs to be given to developing appropriate distributional approaches, and is further of the opinion that the large datasets associated with the metals might provide a good opportunity for this kind of work.

Sixth, SCHER has consistently held the view that the size of uncertainty factors is a matter for judgement not evidence. Pragmatically SCHER has taken the factors specified in the TGD as givens and then considered if the evidence in the (V)RARs suggests more or less uncertainty without specifying the precise effect on the size of the factors. This is the philosophy adopted in the Opinions on metals. SCHER is of the view that there is an urgent need for considering the way uncertainty is expressed in ecological risk assessments.

Seventh, and finally, all of the regional scenarios have been largely based on Northern Europe. However, there may be significant differences in Southern European situations. These differences cover geochemistry, climatic conditions, and ecology. SCHER reaffirms its opinion that it is essential to consider if the RAR regional scenario and the conclusions arising from it are applicable to the Mediterranean Ecoregion, otherwise more work will be needed to establish the pan-European relevance of conclusions.

4. LIST OF ABBREVIATIONS

AVS	Acid Volatile Sulphides
BLM	Biotic Ligand Model
CEC	Cation Exchange Capacity
DOC	Dissolved Organic Carbon
EP	Equilibrium Partitioning
EUSES	European Union System for the Evaluation of Substances
FOCUS	Forum on the Coordination of pesticide fate models and their use
GIS	Geographical Information System
HC5	Hazardous Concentration 5%
L/A	Leaching/Ageing
NOEC	No Observed Effect Concentration
OC	Organic Carbon
OCEE	Optimal Concentration (range) of Essential Elements
OM	Organic Matter
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
(V)RAR	Voluntary Risk Assessment Report
RWC	Reasonable Worst Case
SEM	Simultaneous Extracted Metals
SSD	Species Sensitivity Distribution
STP	Sewage Treatment Plant
TCNES	Technical Committee on New and Existing Substances
TGD	Technical Guidance Document

5. REFERENCES

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