Scientific Committee on Health and Environmental Risks

SCHER

Risk Assessment Report on Zinc

Environmental Part

Zinc metal (CAS No. 7440-66-6, EINECS No. 231-175-3)
Zinc oxide (CAS No. 1314-13-2, EINECS No. 215-222-5)
Zinc distearate (CAS Nos 557-05-1/91051-01-3, EINECS Nos 209-151-9/293-049-4)
Zinc chloride (CAS No. 7646-85-7, EINECS No. 231-592-0)
Zinc sulphate (CAS No. 7733-02-0, EINECS No. 231-793-3)
Trizinc Bis(ortophosphate) (CAS No. 7779-90-0, EINECS No. 231-944-3)

Scientific Committees
- on consumer products
- on emerging and newly identified health risks
- on health and environmental risks

The SCHER adopted this opinion at its 20th plenary on 29 November 2007

About the Scientific Committees

Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

They are: the Scientific Committee on Consumer Products (SCCP), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Evaluation Agency (EMEA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCHER

Questions relating to examinations of the toxicity and ecotoxicity of chemicals, biochemicals and biological compound whose use may have harmful consequences for human health and the environment.

In particular, the Committee addresses questions related to new and existing chemicals, the restriction and marketing of dangerous substances, biocides, waste, environmental contaminants, plastic and other materials used for water pipe work (e.g. new organics substances), drinking water, indoor and ambient air quality. It addresses questions relating to human exposure to mixtures of chemicals, sensitisation and identification of endocrine disrupters.

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TABLE OF CONTENTS

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

The SCHER has been asked to examine the Risk Assessment Reports on:

Zinc metal	(CAS No. 7440-66-6)
Zinc oxide	(CAS No. 1314-13-2)
Zinc chloride	(CAS No. 7646-85-7)
Zinc distearate	(CAS No 557-05-1/91051-01-3)
Zinc sulphate	(CAS No. 7733-02-0)

Trizinc bis(orthophosphate) (CAS No. 7779-90-0)

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

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

(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

Modus operandi

For all the RARs, effects assessments are based on that for zinc metal because all the compounds dissociate to zinc ions that have the potential to cause adverse effects in biota. Differences between the compounds arise from variability in the solubility of the various compounds and in production and use that lead to differences in fates and exposure at local levels.

SCHER therefore takes a generic approach to the compartmental exposure and effects assessments. First, though, in the next section SCHER draws attention to some broad issues, representing significant departures from the general approaches contained within the Technical Guidance Document (1996).

Throughout when the opinion refers to the RAR it means that for zinc metal; and when it refers to the RARs it means all those listed under the terms of reference above.

3.1 General comments

1. SCHER recognises the considerable effort that has been invested in these RARs over an extended period of time. The RARs have had to adapt to an evolving science and SCHER commends the attempts to deal with complexities in defining exposures and coming to terms with the bioavailability of an essential metal. That said, SCHER has some fundamental, science-based concerns about the approach and the outcomes of the RARs and, notwithstanding the history of the development of the RAR for zinc and its compounds, believes that, for reasons of sound science and consistent management, more effort should now be put into the development of common principles for the risk assessment of metals under the EU legislation.

2. Chief among these concerns is the use of the added risk approach. Zinc is present in the environment due to natural processes (resulting in natural background concentrations in all compartments including the biota). The risk characterization therefore used the added risk approach; i.e. only the concentration added to natural background is considered in the exposure and effects assessment. In its *Opinion on the risk assessment of cadmium metal and cadmium oxide* CSTEE (28 May 2004) advised against using the added risk approach.

SCHER remains of the opinion that the added approach can only be used if a region-specific 'realistic' natural background can be established and if this is then used to perform region-specific risk characterisations. This has not been done in this RAR (because region-specific background is very hard to establish). The use of a generic "mean" background (literature reports that the EU range is 2-40 µg/l), considered applicable for the whole of the EU is not useful for the risk characterisation as the variability around this value is of the same order of magnitude as the RCR exceeds 1. Thus, the value selected for the generic background determines the final outcome of the risk characterisation, i.e. absence or presence of risk (RCRs in most cases only slightly >1). This methodology should not be applied when realistic region-specific background cannot be established and used.

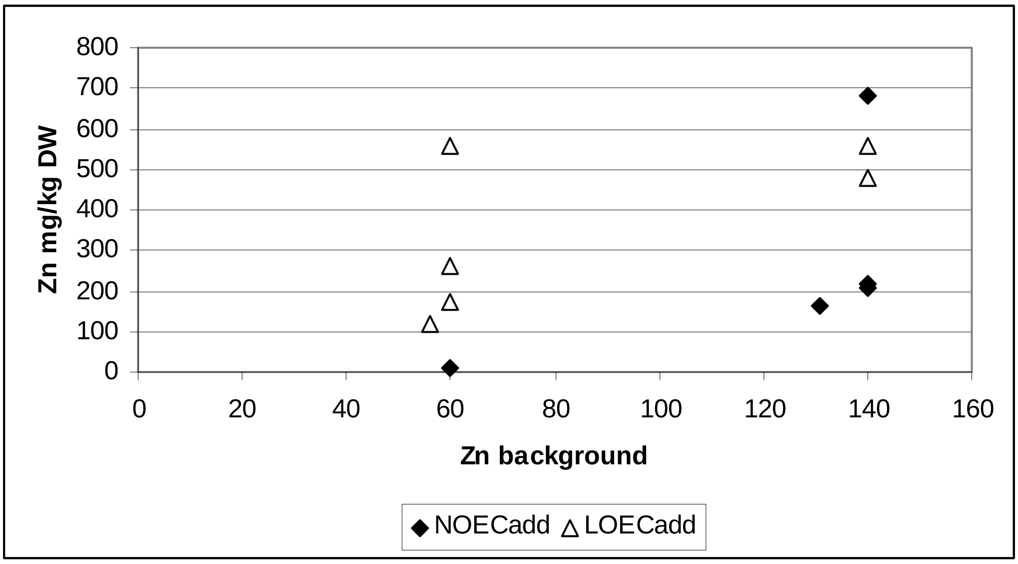
There are two alternatives. One could be to use PECs as a basis for an added risk approach but there are concerns about the robustness of the outputs of models for which there is as yet little experience of use (see below). The second is to use carefully screened and appropriate monitoring databases (exposure) in combination with scientifically derived (see below) PNECs corrected for bioavailability to determine areas that have a potential risk of being adversely affected by Zn. Further examination of the identified points/areas will allow a more rigorous assessment. SCHER believes that this would have been possible from the data available in the RAR. In summary, sound science on the exposure and effects side could allow the use of the total metal (i.e. not the added) approach.

Nevertheless, it should be noted that in addition to industrial uses there are other sources of zinc, e.g. manure and municipal sludge, and the added approach might be a useful tool for quantifying the risks associated with the industrial input to a particular place or region; in other words to quantify the amount of zinc added by industrial activity to ambient levels that are a sum of both natural and other anthropogenic sources.

3. Returning to the model predicting environmental concentrations of zinc, SCHER is of the opinion that it is not helpful to describe the PECs as being derived from a modified version of EUSES – as the RARs do. The modifications are so substantial – understandably to take account of differences between organic compounds and metals - that effectively they result in new fate/exposure models for a metal. Release scenarios from industry and the replacement of Kow with other partition coefficients are appropriately covered in these models. But, as already noted, there is concern at the use of these models *de novo* as a key element of the risk assessment.

4. Another major issue for the risk assessment is bioavailability; the extent to which that concentration predicted to be present and/or monitored in all the major compartments is available for uptake by biota. PECSs/MECs are therefore modified to take account of bioavailability. Given the complexity this is to be commended. But SCHER is of the opinion that a method (i.e. BLM) designed to account for bioavailability at the effect side (i.e. the biological/organism side) should not be applied at the exposure side if other alternatives are available. And it is the opinion of SCHER that making the adjustments in this way could have a serious impact on the effects assessment since bioavailability adjustments made to individual species' endpoints could alter the shape of the SSD curve. Ideally species-specific BLMs should be applied to all species but this would be impractical. Alternatively, the BLMs derived for key model species might be applied as general corrections across like taxa in SSDs to investigate effects. In general the RAR did take bioavailability into account through the use of bioavailability factors (BioFs). However, SCHER is of the view that this approach is problematic as the BioF and thus resulting RCR is dependent on the choice of the reference water to establish the BioF. It is unclear if this reference water reflects an EU-wide realistic worst case, how this was established, and how the uncertainties in selection of the reference water were taken into account.

5. Yet another concern about the effects assessment (for both the aquatic and terrestrial compartment) is some evidence for background–mediation of effect endpoints. These relationships are suggested by data in Figures 3.3.3.1.1.2. and 3.3.3.1.1.3 of the RAR for soil organisms and in the figure below compiled by us for sediment organisms. SCHER admits that the statistical significances are doubtful; but is persuaded by the consistent trends in all compartments.



One possible explanation is that organisms exposed to high natural backgrounds either acclimate and/or become genetically adapted – so that they become less sensitive to the adverse effects of the metal (Muysen and Janssen, 2001a & b). The RAR did try to account for background effects by introducing a data selection criterion based on the Zn concentration in the culturing medium. SCHER accepts that relevance criteria, as well as reliability criteria, are important in considering the acceptability of data in environmental risk assessments, but the use of background as a relevance criterion is complicated by the possibility of natural adaptation/acclimation responses. Thus it might be argued that inclusion of data from organisms from low background is overly conservative because it excludes adaptation/acclimation that are natural processes. Exclusion of data from organisms from high background situations (commonly applied in risk assessments) might be criticised for similar reasons. Both of these adjustments were made in the RAR on the grounds of both relevance (to European waters) and conservativism. SCHER understands that risk assessments are at an early stage in accounting for acclimation/adaptation phenomena but is of the opinion that the whole topic of background mediation for effects endpoints and its implications should have been treated more explicitly and consistently within the RARs

6. Throughout the RAR careful and detailed consideration is given to variability in measured exposure and effects data and in partition coefficients. However, much of this information is obscured in the risk assessment by using averages, worst cases and ranges. SCHER is of the opinion that, given the current availability of methodology and supporting software, distributions could have been used more effectively in probabilistic assessments – and that these could have been used to deliver more useful management guidance. For example, a large variability in natural background zinc concentrations is observed for both sediments and soil throughout Europe. The RAR presents ranges covering 2 or even 3 orders of magnitude in several EU countries. Similarly, a large variability is observed for the parameters that describe the bioavailability of zinc in water and sediment. Current probabilistic methods allow the inclusion of this variability as distributions and the identification of the set of conditions which lead to the highest risk. The incorporation of additional tools, such as GIS, would allow the use of risk mapping in the local and regional risk characterization, identifying in which areas zinc emissions are expected to represent the highest risk. These risk assessment possibilities facilitate the development of risk reduction strategies. SCHER understands the difficulties in taking risk assessment beyond the accepted methods in the existing TGD but is of the firm opinion that by so doing in this context the RARs could have delivered better science and management advice.

7. The risk characterisations in the RARs are based predominantly on North European data. SCHER is of the opinion that there may be significant differences in Southern European situations. These differences cover geochemistry, climatic conditions, and ecology. In the annex to the RARs additional information on other areas of the EU is reported but has not been included in the risk characterization. In the opinion of SCHER, it is essential to consider if the RAR regional scenario and the conclusions arising from it are applicable to the Mediterranean Ecoregion, otherwise a conclusion 1, not 3, outcome should have been recorded.

3.2 Specific comments

3.2.1 Fate and Exposure assessment

3.2.1.1 General

Exposures were calculated according to the usual procedure of estimating releases from production, use and (for regional concentrations) diffuse sources, to which partitioning between compartments was assessed from partition coefficients. From these estimates backgrounds had to be subtracted and corrections made for bioavailability – and comments have already been made on these features of the RARs in the section above.

Each report on a zinc compound has a separate risk evaluation for the local emission situation at the different industrial sites where a known release of Zn occurs. Based on an inventory of Zn producing or processing industrial plants estimation is provided on the potential release of Zn compounds in the environment and in which environmental compartment the release may principally be discharged. The regional risk evaluation is placed in the RAR of Zinc metal because the ionic form, Zn^{2+}, is considered to be causing possible effects and additionally takes into consideration the diffuse sources of Zn related compounds. SCHER has concerns that not all the potential sources of zinc are taken into account in calculating PECs or in trying to make sense of MECs from the point of view of developing a management strategy for the zinc industry. SCHER accepts that mining wastes are outside the ESR and covered by other legislation that will normally be addressed by local risk management. However, other industrial wastes ought to be considered; as should domestic sources that derive from the zinc industry such as batteries. Also MECs will have been influenced by non-industrial sources such as from agriculture and human excretion. How and the extent to which sources were accounted for is unclear in the RAR. SCHER understands that these sources are expected to be implicitly covered by the diffuse source analysis, but differences among member states, such as in the use of sludge from sewage treatment works as agricultural fertilizers, create uncertainties in the assessment and in understanding the contribution of the zinc industry to the measured exposures.

The RAR claims to have taken into account all sources of zinc at least in the area chosen as realistic worst case. In many areas, the information was not delivered by several authorities in the EU-countries and therefore the approach could only be applied to the area chosen. This was clearly a disappointing outcome. However, SCHER is of the opinion that notwithstanding the practical difficulties, from the point of view of sound science all waste streams do need to be considered in a risk assessment as a basis for the development of appropriate management.

3.2.1.3 Details for aquatic compartment

In the RAR large amounts of data have been collected concerning the industrial activities in the European Union as well as the available measurements of Zn total and Zn^{2+} in European surface waters to be able to distinguish between polluted areas by (former) industrial activities and the current situation. It is argued that the measured concentrations available due to monitoring programmes in several member states may be biased by industrial activities that had taken place in the past. In addition, monitoring results may also be influenced by the local and regional geographic situation which may also cause, or have caused, raised zinc concentrations.

Furthermore, an analysis of data has been carried out to distinguish between possibly affected areas by the industrial activities related to zinc on the one hand and the more pristine areas that not have been polluted by industrial activities. Results from the last study aimed at the determination of natural background concentrations of zinc. They revealed that there is a wide variation in concentrations that may be described as natural background and also that the range of concentrations of potentially affected areas (local situations) was very wide.

Both results led to the conclusion of the Rapporteur that the risk assessment for zinc had to be carried out as a two step approach, one based on a risk assessment for the local situations in the neighbourhood of zinc processing plants and a regional approach for a selected realistic worst case area The RAR finally determined the Netherlands as the regional area in the European Union that could be considered the realistic worst case. For the aquatic compartment a value of 12.2 µg/L (based on c_{susp} = 20 mg/L) or 20 µg/L (based on c_{susp} = 30 mg/L) was considered as PEC_{add}. In addition, a natural background was determined of 3 µg/L as lower limit and 12 µg/L as upper limit has been determined.

It is the opinion of the SCHER that the wide variability possible over the whole European Union is not accounted for in the approach of choosing a representative realistic worst case situation involving the establishment of average values as a basis for the risk assessment. A lot of information is lost due to the averaging of data.

3.2.1.4 Details for sediment compartment

Partition coefficients are used to calculate the concentrations in sediment from dissolved concentrations**.** Thus local concentrations (C add local sed) are calculated from local PEC for water by multiplying by a partition coefficient divided by a figure representing bulk density of suspended matter. Measured and calculated values are generally within an order of magnitude of each other.

RAR contends that all currently available natural background data for sediments are in the same order of magnitude – 70 to 175 mg/kg dry weight [these are average values and so, as noted above, obscure the variability] – so based on the values from several EU regions the value of 140 mg/kg dry weight was used as a natural background for correcting the EU sediment monitoring data – unless "monitoring data can unequivocally be linked to a particular natural background" However, SCHER is of the opinion that properly screened monitoring databases should be used to establish the regional sediment concentrations.

With respect to regional concentrations, and in accordance with the TGD, it is presumed that all zinc is transformed to ionic form and that all emissions are diffuse. PEC regional are calculated from regional emissions to the aquatic compartment adjusted by partition coefficients (Ks) – different Ks are tried and a default of 15mg/l of suspended matter is used.

Measured zinc concentrations from monitoring programmes are available from sites throughout the EU. 90 percentile values range from c.200 to c.300 mg/kg dry weight. The question has been raised if these monitoring data should be used in the regional analysis since they may reflect local conditions. One possible response would be not to treat them as single numbers but as distributions – and to use them as such in a probabilistic risk assessment.

The calculated regional PEC based on Netherlands is 510mg/kg dry (196wet) weight excluding a natural background of 140mg/kg dry weight. For a theoretical EU region the value is 700 mg/kg dry weight. Monitoring data appear to be generally higher than those calculated. This discrepancy might be due to historical contamination.

Zinc like other metals binds to acid volatile sulphide materials (AVS). Therefore, only a fraction of simultaneously extracted metals (SEM) is free. On the presumption that it is the zinc ions in solution that are effective toxicologically total concentrations of zinc in sediments (normalised to wet or dry weight) would overestimate exposure. Hence when SEM-AVS data are available this approach is used by the RAR to account for Zn bioavailability in the local scenarios. If no AVS/SEM data are available – wich was the case for the regional scenario - a generic bioavailability correction factor of 0.5 is used by the RAR; i.e. added concentration is multiplied by 0.5. The latter is worst case from an analysis of SEMZn –AVS v total zinc for a very limited data set with mainly Dutch sites. If the same analysis is performed on the more extensive dataset (Belgium) mentioned in the RAR a lower correction factor is derived. Hence, as with the aquatic compartment, this BioF should be treated with caution.

3.2.1.5 Details for soil compartment

The estimations of the PEC added for the soil compartment have been made mostly on the deposition of atmospheric emissions based on actual estimations/measurements submitted by the industries. However, other exposure routes, such as the use of WWTP sludge as soil fertilizer, have not been considered and some atmospheric emissions related to processes within the life cycle of zinc, such as the incineration or storage of zinc containing sludge and the emissions from waste management, have also been excluded.

The SCHER is aware of the difficulties for considering the contribution of the zinc industry to the concentration of zinc in WWTP sludge as zinc is an essential metal, widely distributed and with a large list of contributors not related to the life cycle of zinc as an industrial substance. However, it should be noted that the concentration of zinc in sludge to be applied on agricultural soils is regulated by Directive 86/278/EEC and in the opinion of the SCHER, the RAR should consider at least the expected added PECs in agricultural soils receiving sludge containing the maximum zinc concentration regulated in the EU together with atmospheric depositions from industrial emissions as a realistic scenario.

3.2.2. Effects assessment aquatic compartment

SCHER recognizes that the effect assessment for the aquatic compartment has been performed on a large database including acute toxicity values (EC50 or LC50) and long term NOECs on a relevant number of different aquatic organisms (algae, invertebrates, fish) from freshwater and saltwater environment. However, taking into account some major points of concern underlined above, and in particular the issues described under points 2, 4 and 5 of the General Comments (the use of the added approach, bioavailability, and the effects of background levels), it is the opinion of the SCHER that, in the case of zinc the approach used in the RAR presents substantial problems and cannot be accepted for deriving a PNEC.

We have some specific comments.

The procedure for selection or rejection of data is adequately described and transparent. However, it should be noted that the selection criteria as defined in the RAR were not (always) consistently applied.

Because of the added risk approach, the results based on actual concentrations have been corrected for the background concentration of Zn, if the latter was reported. However, this criterion (Zn background) was not applied in a consistent manner and this resulted in the questionable selection of several toxicity test results obtained with organisms acclimated to very low Zn background concentration. This may have affected the final PNEC derivation.

The procedure for NOEC derivation was not fully consistent for all types of data and tests. Some of the NOECs used in the data set were not derived in statistical manner but were established 'visually'. These concerns about the ways the NOECs were derived could jeopardize the validity of the final dataset used for the SSD construction and thus the HC5 value.

Selected species were sufficient for developing species sensitivity distribution (SSD) curves for freshwater and saltwater. The number of species and the distribution among taxonomic groups met the requirements for a reliable SSD approach. An application factor of 2 was used. SCHER recognises that this selection of this factor is a matter of judgement and is not based on definitive scientific evidence.

For marine species a PNEC was derived by applying a factor of 2 to the 5th percentile of the SSD (6.1 mg/L). But this was then ignored in the RAR for pragmatic reasons in favour of using the same PNEC as for freshwater in assessing a number of local marine scenarios. The reasoning is unclear and not acceptable from a scientific perspective.

The PNEC for total zinc is calculated from the PNEC for dissolved zinc on the basis of the Kp for suspended matter (Kp_{susp} = 110,000 L/kg) and the content of suspended matter (C_{susp}). If a C_{susp} of 15 mg/L is assumed, a $PNEC_{add,\ aquatic}$ = 21 mg/L is derived for total zinc. Most monitoring data refer to dissolved zinc and to estimate total Zn the RAR proposes various Kp values, differing by a factor lower than 3 (see Table 3.2.46 page 114). It is opinion of the SCHER that the variability should be much greater – possibly by orders of magnitude. It follows that a probabilistic approach could be more suitable.

All toxicity data used for deriving the PNEC were obtained with hardness higher than 24 mg/L $CaCO_3$. For very soft water (hardness < 24 mg/L $CaCO_3$) it is considered to be not sufficiently protective. Therefore, the PNEC has been corrected by using the "water effect ratio" approach. According to this approach, a factor of 2.5 is applied.

3.2.3 Effects assessment sediment compartment

The overall conclusion from the RARs for effects assessment based on all data is a PNECadd sediment of 49mg/kg dry (11mg/kg wet) weight to be used in risk characterisation. This is derived from a single *Hyallela* NOEC divided by 10. Insufficient data were available to use SSD. It is therefore presumed in the RAR that the uncertainty around PNEC sediment is higher than that for water and soil.

SCHER agrees with the latter conclusion on uncertainty but is also of the opinion that there are some inconsistencies and lack of transparency in the RARs that lead us to question the PNEC that was used. Bounded NOECs are available for three species. There are several values for survival, growth and reproduction of *H. azteca*: a high value from a study by Borgman and Norwood (1997) – ultimately rejected by the RAR because of very high background and a study by Farrar and Bridges (2003) at 900 mg/kg. The choice of the application factor of 10 was based on lab studies for 3 species, of which *Hylella* has the highest sensitivity. But several field studies which included multi-species and multiple endpoints were also available. One by Liber et al (1996) reports a NOEC of 725mg/kg but is not used in the RAR because "minor" effects were observed at all test concentrations. Another study by Burton et al (2003) reports effects at all test concentrations but is not considered appropriate for use in the risk characterisation since the studies were not designed to give a NOEC and PNEC.

SCHER has not been able to look at all the original reports used in the RARs – because despite several requests they were not forthcoming - but we are persuaded that there should be a serious reconsideration of the endpoints and the application factor used in the analysis and hence the PNEC. We have a sense from the weight of evidence that it is currently too low. As with other compartments we are uneasy with the use of a single PNEC value in the RARs.

3.2.4 Effects assessment terrestrial compartment

The RAR summarises in a sound scientific way the complexity of the ecotoxicological assessment of zinc for soil dwelling organisms. The SCHER welcomes in particular the evaluation of the available information on the bioavailability of zinc and the role of soil characteristics in the toxicity of this metal, as well as the comparisons between field and laboratory observations.

Nevertheless, the SCHER considers that additional considerations regarding the use of bioavailability and the effect of background levels on the toxicity of zinc to soil organisms are required. As expressed for other environmental compartments, SCHER prefers the application of bioavailability corrections to the effect assessment, and additional considerations of the role of background concentrations, considering in particular those cases where the variability in the response and other confounded factors create clear difficulties for assessing the relationships of these parameters with toxicity. Thus the SCHER considers that the approach of a single PNEC value is not acceptable in the case of zinc.

An additional methodological issue is the approach for applying the SSD concept in the derivation of the PNEC soil. The RAR includes a long explanation on the reasons supporting the decision for setting two different SSDs, one for soil organisms and one for soil microbial-mediated processes. The SCHER agrees with the conceptual distinction between structural and functional ecological endpoints and considers that, in principle, both endpoints require an independent analysis.

However, when the actual data used for setting the microbial function distribution are considered (see table below) it is very clear that in reality, the assessment does not describe the distribution of the effects of zinc on microbial processes, but the distribution observed for the same processes among different soil microbial communities.

Microbe-mediated processes	**NOEC values (Zn, in mg/kg d.w.) (n=97)**
C-mineralization (respiration), including mineralization of specific substrates * (n=39)	17; 17; 30; 30; 38; 50; 50; 50; 55; 80; 100; 100; 100; 100; 100; 100; 100; 110; 110; 120; 150; 150; 165; 200; 240; 300; 300; 300; 303; 327; 400; 469; 600; 600; 800; 1300; 1300; 1400; 1400
N-mineralization (n=26)	38; 50; 50; 50; 75; 75; 100; 100; 100; 100; 100; 109; 150; 150; 164; 164; 164; 164; 206; 233; 257; 300; 300; 400; 424; 1000
Enzyme activities (n=32)	30; 30; 48; 52; 64; 67; 70; 76; 105; 109; 140; 145; 151; 160; 164; 164; 164; 200; 200; 460; 500; 508; 590; 728; 820; 820; 1341; 1640; 1640; 1640; 2353; 2623

* C-Mineralization of specific substrates (e.g. acetate or plant residues): also referred to as "substrate induced respiration" (SIR).

In fact, the data cover just three different microbial-mediated processes, each representing the effects of added zinc on a different sub-group of soil microbial communities:

- Respiration, or C-mineralization, offers a generic assessment covering potential effects on almost the whole community.

- N-mineralization refers exclusively to a very specific group of species which are involved in the different elements of the N mineralization process such as nitrification or ammonification.
- The enzymatic activities cover potential effects on subgroups of species within the microbial community, with significant taxonomic differences depending on the soil and the measured enzyme.

As observed in the table the NOECs observed for these three different and independent processes are distributed within the same range. The advantages for using functional instead of structural parameters when assessing the effects of chemicals on soil microbial communities have been described elsewhere, including the CSTEE Opinion on risk for the terrestrial compartment. The taxonomic diversity, competition and potential for recovery and inter-taxa compensation of the measured functions produce information which is relevant for the risk assessment and differs from the typical measurements of effects on a selected key species. Nevertheless, the distributions presented in the RAR cover, in reality, the distribution of the responses of different soil communities to the same endpoints, and therefore, in the opinion of SCHER, represent a distribution of "communities' sensitivities". This is therefore comparable to the SSD concept, and allows the combination of both distributions, once it has been demonstrated that the distributions are equivalent, for improving the statistical analysis.

It should be noted that the whole concept of the use of an HC5 of the SSD for setting ecotoxicological thresholds has been derived for structural endpoints. The extrapolation of this approach to distributions of the sensitivity of functional parameters (where each point in the distribution represents a different function) requires an in depth conceptual analysis that, to the best of our knowledge, has not been done yet. The concepts of redundancy and resilience are not directly applicable to functional endpoints and the relevance and consequences of the different measured endpoints are not necessarily similar. For example, the ecological consequences of a perturbation on the N-mineralization process, related to a selected and very reduced number of species, could be quite different to those related to effects on a generic enzymatic activity.

Thus, the methodological approach employed in the RAR, presenting the sensitivity distribution of a few functions on different soil communities, is appropriate and comparable with the SSD approach, but should not be considered as a distribution of functional endpoints but as a distribution of sensitivities among microbial communities and therefore represents a "structural distribution" although it is based on functional endpoints. Hence, if SCHER were able to accept a single PNEC for soil it should be derived from a combined SSD. However, SCHER is of the opinion that a single PNEC is not acceptable given the possibility of background mediated effects. Moreover, even looking at the RAR data there seems the possibility that these background effects could vary across taxa. Thus a decision about combining SSDs can only be made after deciding how to handle the background effects.

3.2.5 Risk characterization

The point has repeatedly been made in this Opinion that environmental concentrations should be based on distributions of appropriately validated MECs from different regions and/or PECs from sufficiently developed models, and PNECs that take into account bioavailability and possible effects of backgrounds. On this basis the PECs and PNECs reported within the RARs might change appreciably. This would require that the RCRs be reconsidered.

In consequence we are not able to make any recommendations on the validity of the risk characterizations that are made within the RARs before all the above issues on the exposure and effect assessments have been considered and resolved.

Having said that, we do agree that the rationale for considering that the risk of secondary poisoning is of low relevance for zinc is acceptable.

4. CONCLUSIONS

We recognise the complexities and the enormous effort that has been invested in these RARs for zinc. Several issues related to the environmental fate and ecotoxicity of zinc have been addressed in a scientifically sound way. However, SCHER is of the opinion that the methods selected for translating this information into the risk assessments have tended to oversimplify in a way that is not applicable to zinc. The available information is suitable for a higher tier risk assessment instead of the simplified approach employed in the RARS.

SCHER draws attention to the following specific conclusions.

Exposure assessments need to be revisited. The use of a generic mean background is problematic because variability around this value is of the same magnitude as the RCR exceeds 1. We recommend that exposure is estimated either with a more fully developed model for giving PECs and applying an added risk approach or with a more detailed analysis of MECS. Moreover, we are of the view that a better knowledge on the presence of zinc in the aquatic and terrestrial environments is needed at European level. The focus on Northern Europe by the RAR is likely to have given a biased view of exposure conditions throughout the EU. This is particularly important considering the relevance of background concentrations in affecting the results of the risk assessment. The SCHER supports the need for the collection and the critical review of all data that can be provided by national organisations of all European countries with the objective of producing GIS maps of zinc distribution in Europe. This procedure should be extended to other heavy metals and essential elements of high environmental concern.

We are concerned about how bioavailability was taken into account in the RAR. When BLMs were used they were applied to the exposure side of the RA, which is not how they were intended to be used. Moreover we are of the view that applying BLM to the effects side could alter the values of the individual toxicity data and hence the shapes of the SSDs and the PNECs derived from them. We recognise that BLMs were not available for many species; but still believe that more appropriate adjustments could have been considered by using generic BLMs. Most of the bioavailability adjustments were in fact made in the RARs using correction factors – but these are sensitive to the reference conditions for which they were estimated and we had concerns about the ones used.

Effect assessments also need to be revisited. The focus on the use of single–value PNECs within the RARs underplays relevant ecological variability, for example from background mediated sources. We had some specific concerns about the estimate of PNECs for each of the environmental compartments: the selection of some of the NOECs and application factor in the freshwater compartment; the fact that the PNEC for marine species was based on the freshwater and not the marine data set; that the choice of toxicity data and application factor used in deriving the sediment PNEC needs revision; that the soil HC5 may require reconsideration in the light of the possible need to combine SSDs.

We regret that in general though the RAR gave careful and detailed consideration to variability in measured exposure and effects data and in partition coefficients much of this was lost in the assessments by using averages, worst cases and ranges. We believe that a better impression of risks and their management would have been forthcoming from a more probabilistic approach.

With appropriate MECs and PECs a total risk approach could be contemplated – and this would be consistent with developments for other metals.

At this stage we believe that the uncertainties make the RCRs and the conclusions derived from them in the RARs problematic.

5. LIST OF ABBREVIATIONS

AVS	Acid Volatile Sulphide
BLM	Biotic Ligand Model
DT50	Degradation half-life
EC50	median Effect Concentration
EUSES	European Union System for the Evaluation of Substances
HC5	Concentration that protect 95% of the species
LC50	median Lethal Concentration
LOEC	Lowest Observed Effect Concentration
MEC	Measured Environmental Concentration
NOEC	No Observed Effect Concentration
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
RAR	Risk Assessment Report
SEM	Simultaneously Extracted Metals
SSD	Species Sensitivity Distribution
TGD	Technical Guidance Document
WER	Water Effect Ratio
WWTP	Waste Water Treatment Plant

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