Scientific Committee on Health and Environmental Risks

SCHER

Risk Assessment Report on nickel and its compounds

Environmental Part

CAS No.: 7440-02-0, 7786-81-4, 3333-67-3, 7718-54-9, 13138-45-9

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The SCHER adopted this opinion at its 27th plenary on 13 January 2009

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1. BACKGROUND

Council Regulation 793/93 provided the framework for the evaluation and control of the risk of existing substances. Member States prepared Risk Assessment Reports on priority substances. The Reports were then examined by the Technical Committee under the Regulation and, when appropriate, the Commission invited 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 Report on nickel and nickel compounds. The RAR includes the following substances:

- Ni metal CAS-number : 7440-02-0
- Ni-sulfate, CAS-number : 7786-81-4
- Ni-carbonate, CAS-number : 3333-67-3
- Ni-chloride, CAS-number : 7718-54-9
- Ni-dinitrate CAS-number : 13138-45-9

On the basis of the examination of the 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

3.1.1 Quality of the RAR on Ni and Ni-compounds

The SCHER is of the opinion that the RAR on Ni and Ni-compounds is in general of high quality. It incorporates many state-of-the-art methods on risk assessment in a proper way dealing also with the limitations and gaps in the knowledge that still exist, with respect to the emission of certain industrial activities and regional distribution over the EU with an emphasis on Northern and Western Europe whilst information from Southern Europe is missing in many cases. In addition areas where new information is needed are indicated as well.

3.1.2 Nickel occurrence

The RAR correctly states that nickel is a ubiquitously occurring substance in the biosphere and that it is present in all environmental compartments due to natural processes. It is an essential element for the normal growth of many species of microorganisms and plants as well as several vertebrates (WHO, 1991).

3.1.3 Focus of RAR

The RAR as presented by the RMS focuses on the risk assessment of the Ni^{2+}-ion although there are also other oxidation states possible, like Ni(0), Ni(I), Ni(III) and Ni(IV). For the different Ni-compounds included in the RAR, nickel, nickel sulphate, nickel carbonate, nickel chloride and nickel dinitrate, separate RARs have been prepared whilst the results of these reports have been included in the documents received by SCHER.

SCHER agrees to this approach in the confidence that the conclusions of the different reports have been properly addressed in the Ni RAR.

3.1.4 Approach by RMS

The RMS started this extensive work by making inventories of available information in the at that time 15 Member States of the European Union on all topics of the risk assessment, production, industrial sites, emissions and for the environmental part exposure and effects to organisms in the environment. If gaps in the knowledge could be identified specific research programs were carried out to address the missing information. Examples are extensive modelling with EUSES to identify exposure and the development of Biotic Ligand Models (BLM) for aquatic organisms to account for Ni bioavailability differences due to varying environmental parameters like pH, DOC and hardness. In addition, higher tier assessment tools were developed if needed, e.g. for bioaccumulation.

The RAR follows the total risk approach for identified s in the European Union, which is supported by SCHER.

SCHER noted the fact that some information presented by industry had to be treated as strictly confidential. Therefore, SCHER would like to point out that evaluation of these emission estimates was not possible.

3.1.5 Achievement

The result of this risk assessment exercise is a comprehensive RAR which applied state-of-the art tools in risk assessment, including probabilistic approaches, within the guidance of the TGD (EC, 2003).

According to the SCHER, the RMS has performed a very good job on this difficult task and should be congratulated with the final result achieved. SCHER is aware of the complexities in this work and appreciates the efforts that have been carried out in the preparation of this RAR.

3.1.6 Status of the RAR

In the main conclusions of the RAR it is indicated that especially for the sediment compartment additional information and further testing is required. Therefore, SCHER is of the opinion that some adjustment of the conclusions may be needed in future after this additional data will be received and evaluated. The current version of the RAR on Ni and Ni-compounds only deals with the situation of the EU-15. As in recent years 12 new Member States have joined the European Union an extension of the RAR to the new members should be considered as it deals with an incomplete situation for the EU. Therefore, SCHER questions the representativity of the RAR for the current situation in the EU but will focus on the current situation in this opinion.

3.2 Specific comments

3.2.1 Exposure assessment

3.2.1.1 Fate and behaviour

The RAR assumes a value of 2.86 for the log Kp_{soil} (De Groot et al., 1998) as an overall average to be applied in the risk assessment. Although SCHER supports the derivation of this value and the choices made in the RAR to finally adopt it as a reasonable worst case and only for the exposure calculations with EUSES, it should be noted here that the value is quite low in comparison with several other values determined for other environmental compartments, i.e. 3.9 – 4.4 for suspended particles (Stortelder et al., 1989 and Heijerick & Van Sprang, 2004a), 3.9 – 3.8 in sediment (Gunn *et al*., 1992 and Heijerick & Van Sprang, 2004b). This observation should be kept in mind in the further evaluation and interpretation of the results. In fact, the results could be found on the worst case side as generally higher concentrations in water will be established.

3.2.1.2 Ni emissions

The emissions of Ni and Ni-compounds caused by several industrial activities have been inventoried and analysed in a thorough way. If additional information was needed authorities and industries in the MSs have been asked several times to report to the RMS. Especially from Southern European member states only limited information has been received and sometimes too late for the timely preparation of this RAR. SCHER considers the RAR less representative for Southern European Member States.

The RAR distinguishes between local and regional emissions where the local emissions refer to industrial locations and the regional refer also to diffuse sources. SCHER agrees with this approach as it identifies specific risks at the local level. For road borders a specific scenario has been developed. Although this scenario has also been used in the RAR on zinc, SCHER welcomes the approach as a risk assessment tool with potential in future cases.

Another source of Ni and Ni-compounds to the environment is the route through the waste streams, i.e. waste water treatment systems and landfills. Again, these Ni-streams have been analysed thoroughly in the RAR and are fully supported by SCHER.

3.2.1.3 Predicted Environmental Concentrations

Determining a reliable background concentration in natural surface waters has only shown possible in a limited number of 6 European regions. These regions show a variation in mean concentration between 0.33 and 5.13 µg/L. Therefore, SCHER is of the opinion that there are no real data available to decide whether these ecoregions are representative for the whole EU.

To establish the local concentrations of Ni, a thorough analysis has been carried out of all the emissions of Ni-related industries from as many EU-15 countries as possible. For some sectors the coverage was 100% but for some sectors the available information was quite small and as low as 0% coverage. The missing information is clearly identified for all the sectors analysed. SCHER is specifically pleased with the thoroughness of the emission analysis as carried out by the RMS.

Regional concentrations were estimated by an analysis of the diffuse sources like combustion processes, corrosion of steel, domestic waste water of household, agriculture. In this respect it showed problematic to extrapolate from the total EU-15 emissions to a regional estimate of 10% as is suggested by the default rule in the TGD (EC, 2003). The SCHER agrees with the need for an additional discussion on this topic.

The concentrations that were calculated with the EUSES 2.0 (EC, 2004) model in the selected and hypothetical EU-regions showed reasonably good agreement with the measured values: 2.88 – 3.29 µg/L respectively 1.1 – 5.2 µg/L. As pointed out in the earlier opinion of SCHER on zinc (SCHER, 2007) the model EUSES is not considered suitable for metallic compounds but in the case of Ni the results are quite comparable (see also Section 5 of this opinion).

Also for the sediment compartment the comparison between calculated and measured concentrations was quite good at the regional level: the range of calculated PECs was in the range of 20.4 – 23.3 mg/kg whilst the measured concentrations showed a range of 28.8 – 53.7 mg/kg. However, for the local variation in measured concentrations no explanation was found for the high observed variability ranging from <0.1 and 2140 mg/kg.

For soil the measured and calculated values for the PEC_{soil} were quite reasonably in the same range with a maximum difference of a factor of about 20: between 3 and 584 mg/kg for measured values and 3.3 to 23.5 mg/kg for the calculated values.

Despite these variations the SCHER is of the opinion that the agreements in general give sufficient confidence that PECs are in the correct order of magnitude.

SCHER supports the choice of the RMS to prefer the measured concentrations for the actual risk assessment in all compartments.

3.2.2 Effect assessment

This part of the RAR is in general of very high quality, and presents the information and assumptions in a solid and transparent way.

The SCHER observes that in the RAR several assumptions and decisions on further work were discussed and agreed by the EU Technical Meeting. Not in all cases the rationale for the adopted decision is presented, and thus, the SCHER will not comment on those decisions. SCHER will restrict this opinion to the final results and their use in the risk assessment report.

3.2.2.1 PNECaquatic

The influence of the physical-chemical parameters of the water on the toxicological response of aquatic organisms to Ni is properly covered through the development and application of a set of BLM models. The models were subjected to a validation process, covering both, the species for which the models were developed and a set of species within the expected inter-species extrapolation universe. The results are then used for selecting which BLM should be applied to each of the species selected for constructing the SSD curves.

As expected for a rapidly evolving scientific field, there are some limitations and uncertainties in the application of the BLM, but the SCHER recognises that the RAR offers a very good overview on the current state-of-the-art. The RAR recognises that large areas within the EU are not properly covered by the developed BLMs, including the Scandinavian region, for which a specific approach is offered later on, but also large areas of the Mediterranean region, and in particular, the Iberian peninsula. As the RAR is properly based on the concept, this limitation should be considered during the implementation of the RAR conclusions.

The use of the term “eco-region” to describe different “water chemistry scenarios” is potentially misleading. What the RAR really does is selecting 6 different water types (4 river types, 2 lake types) and calculating specific HC5 values for these water types. The SCHER welcomes this approach, as it presents a first estimate of the variability in HC5 values that can be obtained depending on different bioavailability conditions. However, “water types” are not at all “eco-regions”. Indeed, ecoregions are commonly defined as areas of land or water that contain characteristic assemblages of natural communities and species (see for example the eco-regions map in the Water Framework Directive legislative text). They are NOT defined as areas with characteristic bioavailability conditions. Within an eco-region, each of the different water types presented in the Ni RAR may occur. A true eco-region based effect assessment should account for the sensitivity of eco-regions specific communities (perhaps even for each of the water types within such an eco-region). However, this clearly goes beyond the current state of the science. In order to avoid confusion, the SCHER recommends replacing the term “ecoregion” with “water type” or “bioavailability scenario” as this reflects better the methodology that has been followed as well as the results presented.

With the current level of knowledge, some observations found in the interspecies comparisons cannot be properly explained. This includes results showing variability among closely related species (e.g. differences in the *Daphnia magna* and *Ceriodaphnia dubia* BLMs or large differences in BLM corrected responses for species within the same genus) and also the opposite (e.g. the capability of the BLMs to predict within relatively high certainty the toxicity for taxonomically and physiologically distant species). It is also observed that the SSDs contain a significant number of NOECs/LC10s based on mortality, while chronic responses are expected to be based on sub-lethal endpoints. Therefore, SCHER is of the opinion that care should be taken in interpreting these results.

A main limitation within the RAR is the lack of proper coverage of the influence of natural/historic background concentrations in the toxicological response of the exposed organisms. This influence is not covered by the BLMs, but could, at least in theory, affect quite significantly the organism’s responses. The RAR clearly demonstrates that organisms along Europe are exposed to a wide range of Ni concentrations due to natural occurrence, historic sources or in most cases a combination of both. This issue is relevant for the assessment as the RAR is intended to cover a broad range of background conditions, considering both natural background and other anthropogenic Ni sources that those covered in the RAR, including historic pollution. Although the specific information for Ni is scarce due to confounding factors, experience from other metals (see SCHER opinion on Zn RAR) suggest that this aspect can be of high relevance under real field conditions. The SCHER recognises that the current level of knowledge for expressing this variability source in the risk assessment process is limited. Nevertheless, in the Committee's opinion, a specific evaluation of the role of this parameter in the risk outcome should be considered.

In conclusion, the SCHER welcomes the way in which the BLMs have been applied in the risk assessment, and suggests a further consideration of the influence of background concentrations on the organism's responses.

It is obvious to the SCHER that, for data rich substances, the use of the SSD for the PNEC derivation implicitly means that several species will have NOECs below the HC5 value. Therefore, the extensive discussion on the possibly high Ni-sensitivity of the snail *L. stagnalis* in the RAR is of little relevance.

For the marine ecosystem sufficient data were available to perform an SSD approach to determine the final concentration to be used in the effect assessment. SCHER is of the opinion that the HC5 of 17.2 µg/L has sufficient scientific basis for use in the risk assessment.

As stated in the general comments SCHER will refrain from a judgement on the value of the AF other than the ones agreed upon in the TGD (EC, 2003) (see also Section 5 of this opinion).

3.2.2.2 PNECsediment

For the $PNEC_{sediment}$ the Rapporteur could not reach a sound conclusion and proposed to define a specific "Conclusion (i)[1]" research programme to establish robust data for the $PNEC_{sediment}$ derivation. Therefore, SCHER will not express an opinion on this topic as still additional testing is currently carried out.

3.2.2.3 PNECsoil

The assessment of the terrestrial effect data for higher plants, earthworms and microorganisms as carried out in the RAR is of good quality. It takes into account only data which are considered relevant and reliable, after a thorough evaluation using a sound scientific screening methodology. A complete overview is given of accepted as well as not accepted data, including the reasons why the results were accepted or not. The final data were corrected for bioavailability based on the variability of the several (bioavailability modifying) parameters observed in the s defined (e.g. pH, CEC, organic matter). SCHER supports this approach. However, the effects on microbial functions measured in different soil samples should not be grouped as they represent differences in the sensitivity of the soil communities of each soil. The SCHER recommends modifying the approach employed for considering the effects on soil microbial functions, including all reliable data for each endpoint as suggested for Zn and applied in other RAR for metals.

[1] *According to the Technical Guidance Document on Risk Assessment – European Communities 2003:*

- conclusion i): There is a need for further information and/or testing;
- conclusion ii): There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already;
- conclusion iii): There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

The issue of the background concentration is particularly relevant for the soil compartment, as even for the same species, the NOECs (added and total) reported in some assays are below the background concentrations measured in other studies. As this aspect is not covered by the bioavailability assessment, the SCHER considers that additional efforts are required for addressing this issue. As additional scientific knowledge is required, the committee suggests reconsidering the outcome of this risk assessment once sufficient information on the quantitative effect of background soil concentrations on Ni toxicity could be produced.

The committee has additional concerns regarding the use of the leaching/aging factor in the risk assessment; the RAR offers enough information on the expected reduction in toxicity between freshly spiked soils and aged samples; and therefore, it is very clear that this factor should be required when addressing historically polluted sites. However, the RAR focuses on actual activities resulting in continuous or episodic releases, and therefore, the PEC should be considered as dynamic values resulting from on going processes, where at least part of the metal has recently reached the soil compartment. Although there are clear differences between the realistic exposure conditions in the field and those expected after spiking a soil sample in the laboratory, it is not clear why the realistic dynamic field conditions for on-going activities are assumed to be closely related to those observed after an aging process. Thus, additional justifications on the use of a leaching/aging factor for the local risk assessment are required. The RAR concludes to a conclusion (ii) for soil in one of the ecoregions considered on the basis of a possibly high geological source. This deviates from a total risk approach that is generally supported by SCHER. Therefore, SCHER is in favour of a conclusion (i) here.

3.2.2.4 PNEC secondary poisoning

The RAR presents a tiered approach for the PNEC derivation for birds and mammals, using the TGD recommendations at Tier 1, and adapting the value according to feed intake ratio for selected species at Tier 2. Although the final values should be similar, the SCHER considers that it should be more appropriate to express the PNECs as mg/kg body weight, instead of presenting different PNECs for different species when the only difference is the consideration of the species food intake ratio. The committee also accepts the rationale for an AF of 10 instead of 30 when the feed intake ratio is considered in the assessment. The information on bioavailability is scarce and the use of the limited amount of information for quantifying the role of bioavailability is not conservative.

In addition, it should be noted that the selected species do not represent real worst case conditions, see, for example, the EFSA compilation of relevant species for the risk assessment of pesticides for birds and mammals.

The way the assessment of secondary poisoning has been carried out in the RAR is therefore not conservative and may result in potential risk for some species. Thus, SCHER is of the opinion that a conclusion (i) is more appropriate.

3.2.2.5 Assessment factors

In the RAR the RMS has analysed all ecotoxicological information on Ni and Ni-compounds for the aquatic compartment, has corrected endpoints using BLM to more specific situations in the different ecosystems to appropriate values, has taken into account a statistical evaluation of the data (SSD-approach) and also an uncertainty analysis. Nevertheless, the RAR proposed an AF of 2 to finally establish the $PNEC_{aquatic}$ at a concentration varying from 7.1 µg/L for the Lake Monate in Italy to 43.6 µg/L for a ditch in The Netherlands, both as HC5 at 50^{th} % confidence limit. For sediment organisms no final proposal was made in the RAR for a $PNEC_{sediment}$ as in general a conclusion (i) was reached for the sediment compartment. SCHER refrains from an opinion on this topic (see also Section 5 of this opinion).

In a comparable sound scientific way the $PNEC_{soil}$ in different European s was established by the RMS using an AF of 2 leading to a concentration varying from 8.5 mg/kg acidic sandy soils in Sweden to 192.3 mg/kg in natural clayey soils in Greece taking into account differences in soil characteristics (pH, CEC, o.m. content and clay content), microbial processes and bioavailability). Nevertheless, as stated before SCHER will refrain from a judgement on the value of the assessment factor (see also Section 5 of this opinion).

3.2.3 Summary of PECs and relevant ecotoxicological data

In table 1 below an overview is given of all the main results of the risk assessment for Ni. This includes the finally determined PEC values in the different water types defined as well as the resulting HC5 values based on the SSDs of the ecotoxicological data for the environmental compartments. SCHER explicitly does not mention the PNEC values here as they depend on the finally adopted assessment factors. SCHER considers this as a risk management decision as pointed out in the general comments (see section 5 of this opinion).

Table 1. PECs and HC5 (50%) acceptable for SCHER in the Ni RAR.

Compartment		PEC range (µg Ni/L)	Range HC5 (50% min – max (µg Ni/L)
Surface water	Small river (NL)	3.0 – 16.0	25.0 – 66.0
	Large river (DE)	0.6 – 5.1	3.0 – 8.1
	Medium sized river with low DOC (UK)	5.1	5.5 – 15.4
	Medium sized river with medium DOC (UK)	3.8	11.1 – 24.5
	Natural acid lake (S)	0.4 – 2.2	6.0 – 21.3
	Mediterranean river (ES)	<5.0	5.3 – 19.8
Marine	Estuarine	0.26 – 3.75 *	17.2
	Open marine waters	0.14 – 3.75	17.2
	Baltic Sea	0.64 – 0.81	17.2
Terrestrial	Netherlands	0.5 – 60.6	2.7 – 568.3
	Spain	1 – 954	2.5 – 300.8
	UK	0.8 – 439.5	1.2 – 776.9)
Sediment	Excluded from Risk Assessment (conclusion (i) programme)		

Legend to the table:

1. * SCHER makes an exception on the acceptability of this value as SCHER is of the opinion that it is not yet clear about the extent to which estuarine and marine can be treated as similar
2. HC5 (50%) and PEC values for freshwater are ranges reported in Table 3.3.2-9 under section 3.3.2 of the RAR.

SCHER considers these that findings have been determined after thorough scientific analysis of all the available data and is of the opinion that these data are acceptable for performing the environmental risk assessment of nickel.

3.2.4 Risk characterisation

The risk characterisation in the RAR distinguishes between the local and the regional assessment. In the different sections below both assessments will be commented upon if necessary.

3.2.4.1 Aquatic compartment

For the local situation the RAR defines a conclusion (iii) for most of the locations for which site specific information was available. The entities to compare, PEC and PNEC, were corrected for these local characteristics for bioavailability. The number of locations was very limited. Only in 12 locations such a site-specific approach was possible. In another 8 sites using read-across for bioavailability a conclusion (iii) was established as well. For the vast majority of the individual local situations only a more generalised approach using reasonable worst-case (rwc) situations was possible. Here, almost all of the cases led to a conclusion (iii) whilst only 2 cases revealed a conclusion (ii). It should be noted here that for most countries the $PNEC_{rwc}$ is higher than the regional background concentration estimated. Finally, the remaining sites could not specifically be identified because of missing information. In all cases, the final risk conclusion (iii) was established except for two situations: the Ni alloy sites and the generic chemical sites both with s the Low pH – High hardness – High DOC scenario, for which conclusion (ii) was reached.

SCHER considers these conclusions valid taking into account all the specific information that has been used. However, it is noticed that several of the calculated RCR values are between 1 and 2, illustrating that the application of an additional assessment factor of 2 to the HC5 has shifted the risk conclusion from (ii) to (iii).

Concerning the regional assessment, SCHER agrees with the conclusion (ii) made for most water types and with conclusion (iii) for the low DOC – high pH scenario.

3.2.4.2 Sediment compartment

As stated before, the sediment compartment a conclusion research programme (i) is still ongoing. Therefore, SCHER will refrain from an opinion here.

3.2.4.3 Terrestrial compartment

For the terrestrial compartment a similar approach was followed as that used for the aquatic compartment. In this case only for 10 out of 174 cases with site specific information a conclusion (iii) was reached, in all other cases a conclusion (ii). Most of these conclusion (ii) cases were situated in Southern Europe (Italy and Greece) where a natural high Ni-background concentration was found.

Conclusion (ii) was mostly reached in general for the terrestrial environment.

Only 3 cases were available for a further analysis of the regional risk assessment: one in The Netherlands, one in Spain and one in UK and Wales. The conclusion was that in Spain in about 11% of the samples the RCR was exceeded (>1). In the UK and Wales also an exceedence of the RCR=1 was observed in less than 10% of the samples.

Therefore, SCHER agrees with the general statement that conclusion (ii) is appropriate for most local sites based on the current state of knowledge, but suggest a revision of this risk assessment as soon as information on the role of background concentrations on the toxic response becomes available.

As stated before, additional justifications on the use of a leaching/aging factor for the local risk assessment are required. Therefore, SCHER considers a conclusion (i) more appropriate here.

3.2.4.4 Secondary poisoning

Generally, no risk for secondary poisoning was identified in the RAR, except for one site specific situation where Ni is produced. Therefore, the conclusion (ii) was established. Conclusion ii) was considered applicable in the RAR for most scenarios and conditions. However, SCHER considers the assessment as not conservative and even principally wrong as it is based on hypothetical species and a study with human volunteers. A potential risks for some species cannot be disregarded. Therefore, SCHER prefers a conclusion (i) here.

4. CONCLUSIONS

In conclusion the SCHER is of the opinion that:

1 The RAR on Ni and Ni-compounds is of a very high quality that has followed the guidance provided in the TGD to a large extent and has included additional higher tier methods where required or possible. In this respect it has used state-of-the art methods for the risk assessment of metals and metallic compounds. Examples of higher tier risk assessment tools are the incorporation of Biotic Ligand Models in the assessments of the effects of Ni on aquatic organisms and the extrapolation of effects to organisms in the natural environment, the thorough inventory to the emission situation for Ni in the 15 countries of the European Union and the correction of exposure concentration to the local situations based on specific values of bioavailability influencing parameters like pH, organic matter content, CEC, clay content and DOC. Nevertheless, some refinements, particularly in the risk assessment for soil organisms, are required.

2 The regional risk assessment has been carried out for specific s as could be defined for the aquatic and soil compartments. The s were defined mainly in the temperate zones of the European Union whilst possibly sensitive areas like the Scandinavian countries and the southern European countries did provide insufficient information to make a more scientifically sound approach possible.

3 The RMS should have taken into account the information presented by Spain on monitoring Ni and Ni-compounds although the information was received quite late by the RMS;

4 It has to be considered a missed chance not having included also information from the Member States that have joined the EU after 1st of January 2004 as the final draft is dated 30th of May 2008;

5 The sediment compartment is not sufficiently elaborated making it impossible for SCHER to provide an opinion. The RAR defined a conclusion (i) research programme that is currently carried out;

6 Conclusion (ii) is correctly assigned for most of the scenarios in the aquatic, including the marine environment, and terrestrial compartment and at the regional scale. In addition, conclusion (ii) has been correctly assigned to the regional risk for secondary poisoning;

7 Conclusion (iii) is correctly assigned as at the regional scale risk has been identified in aquatic compartments with high pH and low DOC concentrations. In addition, conclusion (iii) has been correctly assigned to several local scale situations for the aquatic and terrestrial compartments.

8 The way the assessment of secondary poisoning has carried out in the RAR is not conservative and may result in potential risk for some species; therefore, a conclusion (i) is more appropriate;

9 As the conclusions (ii) and (iii) in the RAR are very much dependent on the value of the assessment factor, a shift in the risk conclusions may occur as several of the RCR values above 1 are still less than 2, which is the AF currently applied.

5. GENERAL CONCLUSIONS AND RECOMMENDATIONS APPLICABLE TO ALL (V)RARS OF METALS CARRIED UNDER THE EXISTING SUBSTANCES REGULATION.

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 (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 by any of the (V)RARs 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 bioavailability 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 (2007) 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 (EC, 2003) 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.

6. LIST OF ABBREVIATIONS

AF	Assessment Factor
BLM(s)	Biotic Ligand Model(s)

CAS	Chemical Abstracts Service
CEC	Cation Exchange Capacity
DOC	Dissolved Organic Carbon
EINECS	European Inventory of Existing Commercial Substances
EU	European Union
EUSES	European Union System for the Evaluation of Substances
HC5	Hazardous Concentration 5%
LCxx	Lethal Concentration for xx% of the population
MS(s)	Member State(s)
NOEC(s)	No Effect Concentration(s)
PEC(s)	Predicted Environmental Concentration(s)
PNEC(s)	Predicted No Effect Concentration(s)
RAR	Risk Assessment Report
RCR	Risk Characterisation Ratio
RMS	Rapporteur Member State
rwc	reasonable worst case
SSD	Species Sensitivity Distribution
TGD	Technical Guidance Document
WHO	World Health Organisation

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