Scientific Committee on Health and Environmental Risks

SCHER

Voluntary Risk Assessment Report on Lead and its compounds

Environmental Part

CAS No.: 7439-92-1; 1317-36-8; 1314-41-6; 69011-06-9; 12036-76-9;12202-17-4; 12065-90-1072-35-1; 12578-12-0; 12141-20-7; 90268-59-0; 1319-46-6; 62229-08-7

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

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

Since lead was not a priority substance under the Existing Substances Regulation (ESR) and given the replacement of ESR by REACH the Pb industry undertook to make a voluntary risk assessment (VRA) of lead and inorganic lead compounds produced in (or imported into) the EU in volumes exceeding 100 tonnes per annum. This involves the substances listed above. SCHER understands that this procedure, intending to follow the EU Technical Guidance Document on risk assessment used under the ESR, was endorsed by the EU Competent Authorities in 2001 and has been subject to review by the Technical Committee on New and Existing Substances (TCNES).

The Pb industry is to be commended on the massive effort in compiling the VRAR over a relatively short time scale and for addressing many of the challenging issues associated with assessing the environmental risks for a metal that is in widespread use and that also occurs naturally.

That said, the VRAR is in many respects a work in progress. In particular it was based on a Total Risk Approach and while noting that bioavailability is complexly affected by several physicochemical variables these were not taken into account as rigorously or systematically as for copper and nickel. Work is apparently in progress to rectify this and to build biotic ligand models but these are not yet available.

This Opinion is therefore given from a "work in progress" perspective, with critical but constructive analyses that aim at suggesting direction for future effort. To anticipate the conclusion, SCHER is of the view that uncertainties remain for all compartments and for all levels to the extent that firm management conclusions (ii and iii)[1] cannot be made at this stage. Instead conclusion i, "There is a need for further information and/or testing", should be applied generally.

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[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.*

3.2 Specific comments

3.2.1 Exposure assessment

The VRAR exposure assessments recognised that lead metal and/or the inorganic lead compounds can enter the environment from point sources or from diffuse emissions during production, use and disposal. All individual compounds are assumed to transform into the ionic species for both the exposure and effect assessments.

3.2.1.1 Exposures from industrial sources

Local exposures (PECs) from point sources were assessed from the registered emissions from the production of lead metal (primary and secondary), lead sheet, batteries, lead oxides and stabilisers and lead crystal glass. Local emissions for smaller sectors were obtained from default PEC calculations at the reporting thresholds for the emissions inventories. Generic local exposures were developed for waste and landfill incinerators. Some measured environmental concentrations were available and for all compartments, apart from soil, bore reasonable agreement with the calculated PECs. However for soils measured concentrations were invariably higher than calculated PECs. This was attributed to historical contaminations. Measured data were reasonably given priority over calculated data.

Regional PECs were derived from a version of EUSES (TGD 2003) modified to take account of the differences between organic contaminants (for which the model was intended) and metals. SCHER continues to hold the view (first articulated in the Opinion on the risk assessment of zinc (SCHER 2007)) that: "SCHER is of the opinion that it is not helpful to describe the PECs as being derived from a modified version of EUSES…… 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 the VRAR. But there is some concern at the use of these models *de novo* as a key element of the risk assessment.

Following the TGD (2003) the inputs to the model were either from a representative member state – which as for other metals was taken to be the Netherlands – or a default of 10% emissions from the EU15. The regional emissions for the Netherlands may not be fully representative of other member states and the predictions based on the Netherlands were generally lower than the default estimates.

Comparisons between the calculated regional PECs and various summarising statistics of monitoring data indicate that the calculations generally gave lower concentrations than measured. One explanation for this is as indicated in the VRAR that some sources, especially historical, may have been missed. As well, though, there could be problems with the parameterization of the model (see above). SCHER is of the opinion that the latter needs careful consideration before the model is used as a routine basis of exposure assessment for metals. More emphasis should be placed on measured exposure concentrations at this stage, notwithstanding difficulties in accounting for historical inputs that may no longer be a source and hence open to management.

3.2.1.2 Exposure from sporting activities that include Pb shot from shooting and Pb weights from fishing

SCHER has a number of concerns about the assessment of exposure arising from these activities and hence the derivation of PECs at all scales. As large quantities of Pb are released into the environment in Europe each year (40,000,000 kg per year in EU-27; Hansen et al., 2004) from shooting and fishing without recovery this is an area that deserves careful attention.

In the VRAR, PEClocals are based on emissions from target ranges since these can be considered as worst-case point-source releases; and hunting is treated as a more diffuse source of contamination and hence included in the PEC regional/continental assessment.

There are two problems with this approach. First, despite the assertion in the VRAR that the use of Pb shot is evenly split between target ranges and hunting there is more recent evidence (see below) that much more is used in hunting (c. 66%) as compared with ranges (c34%). Second, hunting grounds, whether in wetlands or uplands, represent more complex ecological situations than the surroundings of target ranges. Hence, SCHER is of the view that the targeted, point-source assessments in the VRAR will not be sufficiently representative of the ecological exposure in Europe.

The ratio of target/hunting cartridges sold varies very much across countries in the EU. Those countries that have a large clay target shooting industry will have a higher ratio than in those countries where hunting is the major form of shooting. In Spain, France and Italy, it is clear that the contribution to lead shot use from hunters is higher than from shooters (Guitart pers.com.). As derived from Hansen et al. (2004), the number of hunters is higher than that of clay target shooters (although overlap in some cases). Most target shooters use 28 g of lead in 12 gauge guns (and also complicating the calculation is that cartridges sold as clay target cartridges can be used for hunting small birds), and most game shooters use cartridges containing 28-36 g of lead. Waterfowl shooters will use heavier loads of lead than upland game bird shooters. Notwithstanding some uncertainty the amount of lead released into the environment from these sources is very large (40,000 t/y).

SCHER is of the view that PEC locals could be derived for both wetlands and also in driven shooting estates. These are usually intensive hunting areas and can be easily modelled using the same principles applied in the VRAR to the target ranges.

There are other areas of difficulty in the exposure assessments. First, Pb shot is not the only source of exposure from hunting activities. The use of Pb sinkers for fishing is also important (Sears 1988; Franson et al. 2003) and yet is not given as much attention in the VRAR. Second, the focus on exposure from corrosion products by the VRAR is too restrictive for both shot and sinkers. Many studies have shown that direct ingestion of Pb can be of considerable importance (Pain 1990; Mateo et al. 1998; Fisher et al. 2006). Third, PECs arising from these sources predominate in the VRAR and too little attention is given to the extensive data on measured concentrations available from several member states (Mateo 2008). Fourth, it is also important to note that Arsenic is a common ingredient in shot (0.2 to 1%) as an aid to making it spherical (Hall and Fisher 1985; Mateo et al. 2003) and there could be important ecotoxicological/toxicological implications that ought to be at least considered in the VRAR.

Finally, there is almost certainly more evidence for the exposure of wildlife to Pb from these sources than covered in the VRAR (e.g. Thomas & Guitart 2008). While recognising that exposure should not be automatically associated with risk, SCHER is of the opinion that these exposures should be more thoroughly documented and their implications for impacts on wildlife more carefully assessed.

3.2.2 Effect assessment

3.2.2.1Freshwater PNEC

3.2.2.1.1Screening criteria NOECs and L(E)C10s

A relatively large effects dataset, covering 17 species (2 algae, 7 invertebrates, and 8 fish), has been developed. The VRAR is to be commended for the following elements:

(i) only effects data based on measured Pb concentrations have been retained for PNEC derivation;

(ii) preference was given to EC10 over NOEC (if both were available)

(iii) screening criteria are well considered, stringent enough and are generally consistently applied to the available data with only few exceptions noted (i.e. not passing all criteria for class I or II data, while being retained in the final effects database):

a. The study with rainbow trout conducted by Burden et al. (1998) did not report the dilution water used and should therefore not have been retained in the database.

b. The studies with *Hyalella azteca* (Besser et al., 2005) and *Ceriodaphnia dubia* (Jop et al., 1995) do not report the test substance used. According to the VRAR's own criteria, these data should not have been retained. However, SCHER is of the opinion that knowledge of the test substance administered is less critical if the NOEC is based on a measured Pb concentration, which is the case for both studies mentioned.

In terms of bioavailability assessment, the requirement for retaining data in the VRAR was that pH and hardness in test media had been measured/reported. SCHER considers that this as an absolute minimum but notes that reporting Ca and Mg separately is usually of more value than the integrated value for hardness. However, it is unclear why only 'acceptability' boundaries for pH (5.5-9) have been defined and not for hardness. Once BLMs become available it is recommended that only those effects data are normalized which were obtained in test media with chemistry falling within the validity boundaries of these BLMs (following the approach used in the Ni RAR). Further, given the demonstrated importance of DOC on Pb toxicity (i.e., data shown for fish and invertebrates in the VRAR), it would be most desirable not to retain toxicity obtained in test media of which DOC is not measured or of which DOC cannot be reliably estimated. Such data may give an incorrect representation of the actual sensitivity of the species. Once a BLM is available, it will not be possible to reliably normalize a NOEC for which no DOC measurement or estimate is available. Again, this follows the approach in the Ni RAR as well as in the Cu RAR.

SCHER realizes that increasing the stringency of the selection procedure (e.g., by demanding measured or estimable values of DOC) may result in fewer species remaining in the database, thus increasing the overall uncertainty of the PNEC. On the other hand, retaining (too) many data for which the true sensitivity cannot be estimated (e.g., due to lack of knowledge of DOC in test media) can increase the overall uncertainty to a greater extent. SCHER suggests an intermediate solution; i.e. a tiered approach. In a first tier all effects data could still be used, from which best (gu)estimates of the DOC could be made in cases where it is not reported. In a second (higher) tier, only those effects data for which DOC was reported could be considered.

As well as these general aspects of the screening criteria, SCHER gives additional notes on the effects database that require further consideration:

1. It is noted that several of the retained data were obtained in test media with fluctuating or variable pH. This is the case for most fish studies. While pH ranges are generally within one pH unit, the study of Spehar and Fiandt (1985) with fathead minnow for example reports a pH range of 6.0-8.1. In cases where pH is uncertain, the future BLM should allow investigation of the impact of this uncertainty/variation on the PNEC (sensitivity analysis). A similar sensitivity analysis could be performed in cases where DOC is uncertain. In this regard, SCHER points to the Ni RAR and the Cu VRAR dossiers, where these kinds of sensitivity analyses have provided useful insights.

2. Apparently, there has been considerable discussion at TCNES about including the study with *Daphnia magna* from Biesinger and Christensen (1972) in the final effects database and in the PNEC estimation. The NOEC for this study was obtained by dividing the EC16 of 30 µg/L from Biesinger and Christensen (1972), considered to be the LOEC, by 2. Thus a NOEC value of 15µg/L was obtained. However, the same study also reports an EC50 of 100µg/L. Hence, it should have been possible to calculate an EC10, instead of using the arbitrary TGD guideline of dividing a LOEC by 2 if the effect is between 10% and 20%. Assuming the probit-model, an EC10 of 10µg/L is obtained. Irrespective of this, the dose-response data are not reported in this study, so in line with the selection criteria put forward in the VRAR this data point should not have been included at all.

3. The study of Chapman et al. (1980) with *D. magna* is cited to illustrate the importance of bioavailability, but the data are not mentioned in either of the tables of accepted and rejected NOEC data. The reasons for this are unclear.

3.2.2.1.2 Converting $NOEC_{total}$ to $NOEC_{dissolved}$

NOECs reported as total Pb were converted in several cases (and almost for all available fish data) to dissolved Pb by means of the hardness-based dissolved-total Pb conversion equation from the USEPA aquatic life criteria for metals. The VRAR reports that this equation is based on an extensive study on dissolved percentage metal in aquatic toxicity tests, but the accompanying Table 3.2.2.1 in the VRAR only shows 7 data points (and only two hardness levels) and the reference cited (USEPA, 1994) was not accessible to SCHER for checking if more data were available. The VRAR reports that the hardness-based conversion was derived from experiments performed in Lake Superior water. It is unclear if the effect of other variables (such as pH, alkalinity, DOC) on precipitation has been investigated in this study.

Thus, it is likely that the hardness-based conversion equation is only applicable to Lake Superior water. Indeed, the ratio of total to dissolved Pb may depend on such factors as the concentration of suspended solids (SS), particulate organic carbon (POC), pH, alkalinity (carbonate content), and phosphate. Both carbonate and phosphate concentrations may be important as Pb forms very stable mineral precipitates with phosphates and carbonates. Any difference in one of these variables between a given test medium and Lake Superior Water may make the conversion equation of little to no relevance for the given test medium.

The latter is illustrated in Table 1 with the following analysis, based on data reported in the VRAR of effects studies with both dissolved and total Pb measured (see Tables 3.2.2.3 to 3.2.2.5). The predicted % dissolved (with the hardness-based equation) is always higher than the observed % dissolved. This suggests that the USEPA conversion equation should not be used without careful consideration of the validity of this equation across media. It also suggests that factors other than hardness may be important.

Table 1: Observed and predicted % dissolved Pb

				observed	predicted
study	species	water	hardness	%dissolved	%dissolved
Holcombe et al. (1976)	S. fontinalis	Lake Superior	44	68	91
Ecotox (2002)	C. tentans	tap water	46	83	90
Ecotox (2002)	B. calyciflorus	artificial	128	38	76
Parametrix (2007)	L. stagnalis	artificial	83	73-83	82
Parametrix (2007)	L. stagnalis	natural river	152	21-28	73

SCHER thus recommends revisiting the original data reported in the USEPA simulation study of 1994 (and possibly in other studies) and to investigate if other factors (e.g. pH, POC) could be built into the conversion equation. In any case, any conversion equation used should be tested against observations to check its validity across a sufficiently broad range of conditions. The uncertainty associated with the conversion should be described thoroughly and it should be investigated what this means for the overall uncertainty about the PNEC (e.g. through sensitivity or probabilistic analysis).

Finally, SCHER makes two more notes about this issue:

1. The VRAR (on page 29) reports that Holcombe et al. (1976) actually measured dissolved Pb, yet the effects table (table 3.2.2.5) reports a total Pb NOEC that is converted with the USEPA equation to a dissolved NOEC. A total NOEC of 58µg/L for *Salvelinus fontinalis* is thus converted to a dissolved NOEC of 52.8µg/L. However, the original paper reports only 68% of Pb as dissolved at this total Pb concentration, resulting in a NOEC-dissolved of 39.4µg/L. It is unclear why this reported dissolved NOEC value was not used for the PNEC. This also shows that the USEPA equation prediction of dissolved Pb may considerably deviate from the observation, even in water from the same source (i.e. this study was also performed in Lake Superior water)

2. SCHER recommends not to use data for which a conversion factor is necessary if there are data for the same species and endpoint with measured dissolved concentrations of Pb.

3.2.2.1.3 Bioavailability / use of geometric mean NOECs

The VRAR provides a detailed summary of studies which indicate that pH, alkalinity, hardness and DOC may considerably alter the toxicity of Pb to freshwater fish and daphnids. This suggests, as expected from other metal RARs, that a scientifically defendable PNEC derivation without accounting for bioavailability is not possible. The VRAR indicates that, based on these data, BLMs will be developed. The SCHER recommends that, as soon as these models become available, normalization of effects data should be carried out to derive a more appropriate (and possibly region specific) PNEC, e.g. using similar methods as those followed in the VRAR of copper and RAR nickel. Remaining uncertainty should also be discussed and addressed.

One such uncertainty, which is suggested by the data that are already in the literature, is that, while increasing alkalinity, DOC and hardness showed a tendency to reduce toxicity to both fish and crustaceans, the effect of pH was not consistent. It will be interesting to find out if this implies that different BLMs for fish and crustaceans will need to be used and what this means for extrapolating these BLMs to other, non-fish, non-crustacean species. In this respect, it is noted that the Pb VRAR does not cite any studies concerning Pb bioavailability to algae species. Other metal RARs have shown that BLMs for algae may be quite different than BLMs for fish and crustaceans (notably because the effect of pH is different). Developing a BLM for algae, as well as for fish and crustaceans, is of utmost importance to increase the reliability of the PNECs derived. Overall, the SCHER recommends that methodologies/approaches from Cu VRAR and Ni RAR be followed to use BLMs in the derivation of physico-chemistry dependent PNECs for Pb.

The current PNEC of 4 µg/L (AF=2) or 2.7 µg/L (AF=3) is derived from the HC5 estimated from a lognormal distribution of geometric mean species-NOECs. SCHER is of the opinion that averaging NOECs cannot lead to a reliable PNEC value if NOECs within a species exhibit considerable within-species variability due to differences in the chemistry of the test media and possibly the differences in genetic adaptation and physiological acclimatization. This approach may lead to an overprotective PNEC in some cases but an underprotective PNEC in other cases.

The VRAR does indeed report – in its effect database – considerable within-species variation of NOEC values (e.g. 8.8 to 426.4 µg/L for rainbow trout, 0.9 to 1100 µg/L for fathead minnow, and 3 to 150 µg/L for *Ceriodaphnia dubia*). SCHER acknowledges the effort that has been spent to try to explain the possible causes (e.g. exposure time, bioavailability, life stage) of this within-species variability – with bioavailability clearly being indicated in the VRAR as one of the major causes - but disagrees with averaging NOECs . Such averaging means for example that a species mean NOEC is representative of average test media conditions, and these conditions may not be reflective of sensitive waters in the EU (e.g. low DOC waters). For example the species mean NOEC for *Ceriodaphnia dubia* is 26.3µg/L. This value is considerably higher than most of the NOECs in the effects database obtained in media with 1.2 mg DOC/L. Thus the value of 26.3 µg/L may not be protective for low DOC waters. An inverse reasoning is possible for high DOC waters.

In conclusion, SCHER believes that it is currently not possible to derive a reliable PNEC value for the freshwater environment, because bioavailability has not been taken into account at this point.

3.2.2.1.4 Additional note on HC5

SCHER acknowledges the detailed SSD analysis that has been carried out, taking into account the possibility that different probability distributions may fit the data. The SCHER recommends that this analysis is taken forward in the future.

3.2.2.1.5 Additional note on taxonomic group coverage

The VRAR states that the taxonomic group requirements for deriving a PNEC from statistical extrapolation (i.e. SSD fitting) are fulfilled. However, no reliable data were retained in the final effects database for aquatic plants (which is a required taxon according to the TGD). Surprisingly, the VRAR also states that this lack of plant data is "*acceptable*" because "*from the data reported … plants do not seem very sensitive*". However, SCHER finds it is not acceptable to make statements on the basis of data that are not considered reliable. The annex of the VRAR only reports a single NOEC value of 110 µg/L for *Lemna gibba*, but considers this NOEC as unreliable because exposure concentrations varied between 15 and 210 µg Pb/L during the exposure period of 7 days. Since higher plants are an important taxon in many freshwater ecosystems, SCHER recommends generating additional (and reliable) chronic ecotoxicity data with at least one higher plant species

3.2.2.2 Marine water PNEC

The VRAR decided that too few marine NOEC data are available to derive a reliable PNEC. SCHER acknowledges that sensitivity comparisons between freshwater and marine species might be influenced by biological (e.g. different physiology) and chemical factors (different bioavailability) and that using a combined freshwater and marine database is not the most scientific way forward. SCHER has also taken the view that there are no grounds for automatically applying an extra application factor of 10 to derive a marine PNEC from a freshwater NOEC/HC5 as suggested in the TGD (CSTEE 2002). SCHER therefore supports the decision taken to generate more reliable NOECs for more marine species. Taxa that are specific for marine systems (e.g. echinoderms) should be evaluated for their chronic sensitivity.

A preliminary HC5 of 6.1µg/L was derived from NOECs for 6 species (2 algae, 2 annelids and 2 crustaceans). It is noted, however, that for only two species (i.e. *Champia parvula* and *Mysidopsis bahia*) these NOECs were based on measured total Pb concentrations. The four other NOECs were based on nominal concentrations. According to quality screening criteria applied for freshwater, the latter NOECs should not be retained in the final effects database. It should also be explained why total Pb concentrations are used in the effects database and not dissolved concentrations as for the freshwater compartment.

3.2.2.3 Sediment PNEC

SCHER has observed that criteria for effects data selection have not yet been developed for sediment (according to Annex A). Hence, it was not possible to assess whether the data selection has been performed appropriately. However, the data that have been considered are in general described in considerable detail and seem of sufficient quality. Further, SCHER commends the VRAR for having preferred the use of actual sediment ecotoxicity data over the EqP method for estimating the PNEC. Having a PNEC based on chronic NOECs for six species with different life style/feeding behavior is somewhat unique among the many substances that have been evaluated under the ESR so far.

3.2.2.3.1 Generic sediment PNEC (total Pb)

Given the importance of AVS (and possibly other factors) in Pb sediment toxicity, SCHER considers the generic sediment PNEC of little relevance (as is the generic dissolved Pb for the freshwater compartment). The AVS concentration in the accepted tests varied between 1.8 mmol/kg (estimated value for two species, Farrar and Bridges, 2003) and 5-10 mmol/kg (values for 5 other species, Nguyen et al., 2003, 2006). It is clear that the PNEC derived from these experiments cannot be protective for sediments with AVS<1.8 mmol/kg. Also, it is unclear how the AVS concentration in the Farrar and Bridges (2003) study was 'estimated'. The initial AVS before spiking was 8.5 to 42 µmol/g (text of appendix D), but in Table D1 in appendix D a value of only 1.8 µmol/g is reported. This should be clarified, especially because the lower AVS value is used to calculate 'bioavailable' NOECs (as SEM-AVS). Overall, SCHER considers the use of the bioavailable sediment PNEC as the only valid approach. Indeed, the generic PNEC has no value in protecting sediment life in sediments with AVS concentrations lower than those used in the ecotoxicity tests and should therefore not even be considered as a first tier in the risk characterization. Comparing a total Pb PEC with this generic PNEC may indeed fail to detect potential local problems if this approach is used as the first tier in the assessment (i.e. if AVS at a local site or region is below 1.8mmol/kg). SCHER believes that a 'safer' first tier risk characterization would be to compare the total Pb PEC with the bioavailable PNEC, provided it is derived in a defensible manner (see 3.2.2.3.2).

3.2.2.3.2 Bioavailable sediment PNEC

SCHER agrees with the principle of estimating a 'bioavailable' PNEC (as SEM-AVS concentration) as this represents the state of the science in sediment bioavailability regarding correcting for the presence of sulfides in sediments. But SCHER notes that other factors in addition to SEM-AVS may influence sediment metal bioavailability, e.g. metal oxides and organic matter.

The data seem to demonstrate that no adverse chronic effects to any of the seven investigated species were observed if SEM-AVS<0. However, the way in which the AVS values were estimated from the data of Farrar and Bridges (2003) is unclear and therefore SCHER is of the opinion that this conclusion cannot be considered definitive.

If this is clarified and if these data still support the SEM-AVS model, the criterion SEM-AVS<0 can be used for initial screening-level risk characterization. Ideally, coupled SEM and AVS data are available for a site/region. The SCHER strongly supports the idea of using coupled SEM-AVS data for local risk characterization as well as the probabilistic approach for regional risk characterization on the basis of a coupled SEM-AVS dataset.

The VRAR correctly suggests comparing SEM-AVS (bioavailable exposure) with the bioavailable PNEC. This principle is sound, but it requires that the bioavailable PNEC is derived in a scientifically defensible manner. Yet, for three species, the bioavailable NOEC was obtained by dividing the LOEC (between 37% and 57% adverse effect) by an arbitrary factor of 3. There seem to be too few data to support this calculation (i.e. the slope of the response vs. the bioavailable concentration is not known) and the magnitude of the effects at the LOEC is too high to support a highly certain application factor of 3 to estimate the NOEC. Furthermore, the factor of 3 is not supported by the TGD. As an alternative, without further data needs, a factor of 10 might have been applied to the lowest unbounded bioavailable NOEC. In this case the lowest NOEC was 2.0 µmol excess Pb/g dry wt, resulting in a bioavailable PNEC of 0.2 µmol excess Pb/g dry wt or 41 mg Pb/kg dry wt. This is only two times lower than the currently suggested $PNEC_{bioavailable}$ of 81 mg Pb/kg dry wt, but is more in line with the TGD.

However, SCHER has equal reservations about the use of this assessment factor of 10, which is also arbitrary. Thus, to resolve this issue further, the SCHER recommends a program where ecotoxicity tests in sediments without AVS are be performed to derive bioavailable PNECs. Indeed, without AVS present, all the SEM measured is bioavailable and the problem of the negative NOECs would be avoided.

Finally, SCHER wishes to stress that the current approach taken in the VRAR only considers AVS as a toxicity modifying variable, while it is generally recognized (e.g. in the Cu VRAR) that for example the organic carbon content of the sediment is important. For Pb in particular, it is also to be expected that the phosphate and the carbonate content of sediment will be important as Pb forms very stable mineral precipitates with these anions. This should be considered, or at least discussed, in further detail.

3.2.2.4 Sewage Treatment Plant PNEC

There were insufficient data to use species sensitivity extrapolations. The lowest NOEC for microorganisms was 1 mg/l derived from a protozoan community, with a similar value from a respiration inhibition test of a general microbial community. SCHER agrees that there are uncertainties about how representative these systems might be in terms of sewage treatment works and at this stage supports the application of an assessment factor. However, it is currently unclear how big this should be and the value of 10 used in the VRAR (following the TGD) should be kept under review, as should the resulting PNEC of 0.1µg/l.

3.2.2.5 Terrestrial PNEC

The procedure applied for the selection of the relevant endpoints included the application of a set of criteria covering data quality and relevance for the European conditions and these were generally appropriate. In particular, the SCHER supports the idea of producing a single SSD including invertebrates, plants and microbial function, as the toxicity range/pattern for the three groups are similar. The decision for including the effects on the same microbial activity as independent values for the SSD, instead of considering a single value (e.g. the geometric mean) for each endpoint follows the recommendation of the committee as expressed in the SCHER opinion on the Zn RAR. As a result, forty four data-points were selected using screening criteria, distributed as follows: 14 endpoints for higher plants; 12 for invertebrates; 18 for five microflora functions.

A sensitivity analysis was included and its results also support the final decision of a single SSD based on 44 data points.

Although soil conditions are expected to modify significantly the toxicity of lead to soil organisms, the available information did not allow an assessment of these effects. As a consequence, a bioavailability assessment was not incorporated for the soil compartment.

Instead, a specifically contracted research project compared lead toxicity between laboratory spiked and field contaminated soils and derived a leaching/ageing factor of 4.2. However, the information on the results of this project is limited and in fact it is not included in the list of references. A main limitation for accepting the results of this study and the use of a leaching/ageing factor of 4.2 is the lack of information on the characteristics of the "field samples collected at a historically polluted industrial area". The VRAR is not intended to cover historical emissions but current releases from actual uses. Also, as properly explained in the VRAR, different lead compounds vary largely in toxicity in short-term assays but, after equilibration in the field are expected to result in equivalent levels of available lead. It is not clear to the SCHER if the field sites represent realistic release conditions under current use patterns and which Pb compounds were involved. Therefore, with the current level of information the SCHER cannot accept the use of a generic factor of 4.2.

Instead, SCHER recommends a further investigation of the relationship between the effects observed in the laboratory tests and those expected in the field from actual environmental releases. If no quantitative estimations can be obtained, SCHER recommends using as a preliminary PNECsoil the HC5 value obtained from the laboratory studies, without lab-to-field correction. As this value represents a worst-case approach overestimating the risk, no further application factor should be required. It should be noticed that this approach would result in a potential risk for at least one local site.

An additional limitation resulting from the available data set is the role of background lead concentration in the toxicological response. This issue is not addressed in the VRAR as not enough information is available. The SCHER recognises the limitations of the current scientific knowledge for assessing this issue in a quantitative manner, but considers that this is an essential aspect for the risk refinement that should be further investigated.

Therefore, the proposed PNEC value should be considered as a preliminary figure requiring further considerations in terms of bioavailability and role of background lead concentrations.

3.2.2.6 Secondary Poisoning PNEC

As expected, the use of the traditional lower-tier methodology for assessing the secondary poisoning risk of lead is unsuitable. The VRAR is innovative and offers a preliminary proposal. Basically, the dose/response assessment is based on internal dose, using lead concentrations in blood for expressing the internal dose, and the SSD concept is applied to limited toxicity data sets for mammals and birds (Buekers et al 2008)*.* The alternative proposed offers interesting ideas, but requires significant conceptual and methodological refinements.

From a conceptual perspective, the first aspect requiring further consideration is the critical internal concentration/dose. The VRAR proposed the use of blood lead concentrations as a method for reducing the variability observed when the toxicity data are presented as external dose. However, the mechanistic relationship between the blood concentration and the magnitude and/or likelihood for effects is not sufficiently discussed. If there is such an association, e.g. the toxic effects are expected once a certain blood level is reached independently of the exposure conditions, the use of the internal dose would indeed constitute the best endpoint for setting the ecotoxicological threshold. As stated in the VRAR this possibility has been considered by other authors. Therefore SCHER suggests exploring this option first – possibly by an in-depth assessment of the "time to effect" at different doses within each toxicity test. If there is a toxicodynamic relationship between blood levels and toxic effects, the blood concentrations at which effects are observed in the highest doses would give support for the use of blood concentrations for exposures. The assessment should consider the expected physiological delay between molecular/biochemical critical effects and the timing for alteration of the selected endpoints.

If this relationship is demonstrated, the observed differences among the studies should be evaluated from a physiological perspective, considering each endpoint and time for expression. Only if species-related differences can be identified would the use of the SSD approach be justified in this case.

If the relationship cannot be demonstrated, the benefits of using blood levels for expressing the exposure should be considered in a pragmatic way. Effects in the real world would be associated to exposure conditions (including dose, route, bioavailability and timing) instead to blood concentrations. Hence, reducing the variability in constant-dose laboratory studies by using blood concentrations without considering the expected exposure could be an artefact increasing the lab-to-field uncertainty.

Within this alternative, assuming no mechanistic relationship, the use of the SSD concept as applied in the RAR should be done with care. The SSD concept for the aquatic and soil compartments was developed as an alternative for substituting the assessment based on application factors on the most sensitive of three very diverse taxonomic groups. The equivalent for secondary poisoning should be an SSD based on chronic toxicity studies covering oral exposures on mammals, birds, reptiles, amphibians and fish. Certainly, for pesticides the SSD concept has been applied to specific taxonomic groups, but based on information on the sensitivity and the mechanism of action. The idea of ecological redundancy and resilience and the level of protection associated to the HC5 level, should be revisited and discussed before being directly extrapolated from aquatic organisms (covering a set of species from algae to fish) to mammals or birds. The values presented in the VRAR, giving similar or even lower HC5s based on LOECs than for those obtained from the NOECs, confirm the need for a further conceptual and methodological assessment.

An additional uncertainty is related to the endpoints used in the assessment. A "typical" approach is used, selecting exclusively the endpoints related to effects on survival, growth and reproduction as ecologically relevant. However, this approach should be reconsidered in this particular case due to the method proposed for the PNEC derivation (based on the SSD concept) and the specific mechanism of action of lead. The first concern is related to SSD concept; each species should be represented by a single value representing the lowest relevant endpoint. However, in the data set the number of studies reporting reproduction NOECs is very limited. The second crucial aspect is specific for lead and related to its mechanisms of action, which may result in neurological disorders. The VRAR indicates that further work is required for assessing the ecological relevance of the neurotoxicity effects observed for lead in several species; this issue is not discussed in the proposal from Buekers et al (2008) and, therefore, the SCHER considers that additional efforts are required before a proper assessment of the risk of secondary poisoning could be conducted.

3.2.3 Risk characterisation

The VRAR records an impressive number of risk characterisations at all levels. According to the VRAR some invite Conclusion i, the need for more information and/or testing, and this includes: local characterisations for shooting and hunting areas; marine waters and sediment; secondary poisoning and the indirect ingestion of shot by waterfowl and terrestrial predators. Conclusion iii, the need for limiting risks, is applied to some local sites for water and sediment in some sectors. The rest, by far the majority, are ascribed to Conclusion ii, no need for risk reduction measures.

SCHER does not accept that either Conclusions ii or iii can be applied at all. The uncertainties associated with both exposure and effects for all compartments and at all levels are such that the further work that is advocated in this Opinion may significantly alter the RCRs, and in a direction (either up or down) that is not obvious. Hence, SCHER is of the firm view that Conclusion i should be applied to the VRAR as a whole at this stage. Specific suggestions on how the programme can be taken forward are extensive and included in the appropriate sections above. But SCHER is of the opinion that chief amongst these involves developing appropriate understanding and representation of bioavailability for all compartments and, with the provisos indicated in the appropriate sections above, welcomes the further developments that have been promised by the Pb industry in this context.

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 (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 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 biovailability 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 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 Sulfide
BLM(s)	Biotic Ligand Model(s)
DOC	Dissolved Organic Carbon
ESR	Existing Substance Regulation
EU	European Union
EUSES	European Union System for the Evaluation of Substances
HC5	Hazardous Concentration 5%
LCxx	Lethal Concentration for xx% of the population
LOEC(s)	Lowest Observed Effect Concentration
NOEC(s)	No Effect Concentration(s)
PEC(s)	Predicted Environmental Concentration(s)
PNEC(s)	Predicted No Effect Concentration(s)
POC	Particulate Organic Carbon
RCR	Risk Characterisation Ratio
SS	Suspended solids

SSD	Species Sensitivity Distribution
TCNES	Technical Committee on New and Existing Substances
TGD	Technical Guidance Document
USEPA	United States Environmental Protection Agency
VRA	Voluntary Risk Assessment

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