EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection
Toxicology and Chemical Substances (& ECB)

Ispra, 20/06/2008

Opinion of the TC NES on the Environment Part of Industry Voluntary Risk Assessments on Lead and Lead compounds

1. Background

The Lead industry committed to undertake a Voluntary Risk Assessment (VRA) for **lead** and inorganic **lead compounds** produced in the EU or imported into the EU in volumes exceeding 1,000 tonnes per year: **lead oxide, lead tetroxide, dibasic lead phthalate, basic lead sulphate, tribasic lead sulphate, tetrabasic lead sulphate, neutral lead stearate, dibasic lead stearate, dibasic lead phosphite, polybasic lead fumarate, basic lead carbonate, dibasic lead sulphite.** This initiative was endorsed by the EU Competent Authorities in 2001. The whole process was managed by the Lead Development Association International (LDAI). The VRA was compiled in co-operation with expert consultants from EURAS (Belgium), ECOLAS (Belgium), University of Leuven (Belgium) and Dick Peddicord & Company (USA). The reviewing country was the Netherlands.

The Industry voluntary risk assessment on Lead and Lead compounds was intended to follow the EU Technical Guidance Document (TGD) on risk assessment and the voluntary development of additional detailed guidance for the risk assessment of metals (MERAG and HERAG projects). The procedure was discussed at the 11th Joint CA meeting in Helsinki (16-17 June 2005). Industry had expressed that they favour a final endorsement of the results of the assessments by the Technical Committee on New and Existing Substances (TC NES) and CAs, in the same way as done for the regulatory Risk Assessments under Reg. 793/93. At the 13th Competent Authorities meeting, it was agreed to request the TC NES to discuss, comment and develop an opinion on the Voluntary Risk assessment, and thereafter to forward the VRA along with the TC NES opinion to the Scientific Committee on Health and Environmental risks (SCHER).

Some Member States (MS) expressed their reservation on the process followed. The environmental part of the risk assessment was a very complex document of more than 1250 pages (incl. annexes) as a consequence of the extensive data available on lead and its compounds. In 1999 the Competent Authorities, and the Netherlands in particular as reviewing country, had made a commitment to review the outcome of the Industry risk assessments. The Commission (DG Environment and DG Enterprise) supported this activity, since there was a need seen to have a high quality, scientifically sound risk assessment on certain lead compounds to underpin decision-making on various issues related to lead at Community level. Nevertheless, it was acknowledged that the preparations towards REACH and the fulfilment of legal obligations under the current Existing Substances risk assessment program had made it very difficult to commit resources in order to comment in-depth on all parts of the VRA. Consequently, the Member States requested to be stated that lack of comments to any part of the risk assessment did not indicate acceptance of that part of the VRA. Nevertheless for those sections which had been commented, LDAI had responded to the comments raised.

The TC NES was requested to develop an opinion on the assessment answering the following two questions:

- Is the assessment in line with the methodology in the TGD or has adequate justification been given for major deviations or modifications?
- Are the conclusions of the assessment plausible and can they be supported, based on the assumption that the methodology, including details thereof is adequate and the information presented is correct?

2. Commentary of the review process

The VRA report on lead and lead compounds was first presented to TC NES II 05. The first round of in depth discussions took place at TC NES I 06 (effects assessment) and TC NES II 06 (exposure assessment), followed at TC NES III 06 by a discussion of outstanding issues that could not be tackled at the preceding meetings in 2006 (soil effects assessment, secondary poisoning and ammunition targeted risk assessment). IND revised the report taking the preceding discussions at TC NES level into account and at TC NES II 07 outstanding issues regarding environmental risk assessment (aquatic effects in freshwater, marine water and sediment and secondary poisoning) were discussed on the basis of the revisions made in the report. At TC NES III 06 the risk characterisation section was discussed for the first time. The revised sections on soil effects assessment and secondary poisoning were foreseen for discussion at this meeting as well. However, due to an administrative error these two latter topics were not placed on the agenda and could therefore not be discussed at the meeting. Instead, a written commenting procedure was agreed for these parts. At TC NES IV 07 the revised sediment effects assessment section was discussed. In addition, industry provided a brief overview on the achievements reached so far and their further planning for progressing and finalising the voluntary risk assessment report (VRAR). TC NES agreed to industry's proposal to prepare a new version of the environmental part of the VRAR on the basis of the outcome of the second round discussions of the effects assessment sections and to consider in this update as well the new data received for aquatic effects assessment. The updated sections would then be sent out for a final round of comments by Member States. For the exposure assessment part it was already agreed at TC NES III 07 to finalise this part by written procedure as the number and nature of comments received would not justify another discussion round at a meeting. The entire revised environmental report was submitted for final comments to TC NES in two batches in February and March 2008.

Shortly before TC NES I 08 Denmark and Sweden raised concerns regarding the lack of a final discussion of the environmental part of the VRAR for lead at this meeting and hence the opportunity to make a final statement on the report. Sweden further criticised that the deadline for commenting the risk characterisation section was too short. However, the objective of the written procedure was to get the views of the Member States on the report and the full detailed comments received on the report would be made available as well. To accommodate the complaint about the short deadline, industry offered an extension by 3 weeks.

Given the comments received on the versions of the effects sections disseminated in February/March 2008, industry decided after consultation with the European Chemicals Bureau and the Netherlands as Reviewing Country that they would prepare one further final revision of the report that, taking account of a comment by the United Kingdom, would be submitted as a consolidated version for one final round of TC NES written comments.

This TC NES opinion is based on the VRAR version of April 2008 (files: VRAR_Pb_0804_env_....).

3. Summary of the conclusions of the RAR

Exposure assessment

Exposure of the environment to lead metal and/or inorganic lead compounds can take place through point source (local) emissions or diffuse emissions (e.g. products). Since lead is a naturally occurring substance, exposure via natural sources also takes place.

Local exposure was directly assessed for the production of lead metal (primary and secondary), lead sheet production, battery production, production of lead oxides and stabiliser compounds and the production of lead crystal glass. All of these sectors had registered emissions according to the European or national emission inventories. Exposure was measured when possible and given priority over modelled data. Exposure data were obtained from surveys in companies (customised questionnaires). Local emissions from smaller sectors were assessed by performing a default PEC calculation at the reporting thresholds for the emissions inventories. Diffuse emissions were assessed mainly through national emissions inventories, which were then reviewed and updated as necessary. Generic local exposure scenarios were also developed for waste landfills and incinerators.

Finally, a targeted assessment was performed on lead use in ammunition. Generic local scenarios were developed for shooting **ranges**, defined as areas designed and operated specifically for recreational shooting according to current best practise. Shooting **areas**, defined as areas not specifically designed and operated for shooting and which do not adhere to current best practise, were not assessed. Direct ingestion of lead shot by terrestrial birds and mammals was also assessed. However ingestion by waterfowl was not assessed. Several member states formulated remarks on this aspect (see section 4, exposure assessment).

All modelled PECs were derived using EUSES. In the case of lead ammunition, cumulative emissions from the corrosion of lead shot were taken into account.

Classification and Labelling

Lead compounds are classified in Annex I to Dir. 67/548/EEC (19^{th} Adaptation to progress) N; R50-53: Very toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment. No change to the current classification is proposed.

Lead metal is not currently classified. At the time of the risk assessment process the OECD Transformation and Dissolution Testing Protocol was undergoing a validation exercise. Industry had therefore agreed with the Reviewing Country that dissolution testing for lead and lead compounds would be initiated once the validation exercise had been completed. Hence no classification was proposed.

Effects assessment

Lead is a data rich substance and as a result the tiered approach set out in MERAG was applied. In all cases PNECs were derived using the total risk concept (i.e. including natural background concentrations).

Originally, preference was given to statistically derived NOEC values since this was in accordance with the TGD and other metals risk assessments. In case no robust NOEC values were reported, but a clear dose was provided, $L(E)C_{10}$ values were derived. However, more recently greater emphasis has been given to the use of robust $L(E)C_{10}$ values instead of statistically derived NOEC values in official risk assessments. Therefore, in case more recent data from literature/research activities were available, preference was given to the use of $L(E)C_{10}$ data instead of NOEC values.

Freshwater PNEC

High quality NOECs and $L(E)C_{10}$s were selected using screening criteria set out in the RAR. In total 69 NOEC/ $L(E)C_{10}$ values were selected:

- 2 individual EC_{10} values for 2 different algae species
- 35 individual NOEC/$L(E)C_{10}$ values for 7 different invertebrate species
- 32 individual NOEC/$L(E)C_{10}$ values for 8 different fish species.

Literature values reported as total lead concentrations (i.e. dissolved + particulate) were converted to dissolved lead values using a methodology developed by the United States Environment Protection Agency. Unbounded NOEC/$L(E)C_{10}$ values (i.e. no effect was found at the highest concentration tested) or LOEC values (i.e. effect was found at the lowest concentration tested) were not used, with one exception requested at TCNES II 07 (*Daphnia magna* - see below).

An analysis of the influence of abiotic factors on lead toxicity showed that lead bioavailability is affected by such factors. Data suggest a tendency of decreasing toxicity with increasing hardness, DOC and alkalinity. The influence of pH on the chronic toxicity of Pb is less clear as the response seemed to be different for the invertebrate *C. dubia* and the fathead minnow *P. prom*elas. Industry was in the final stages of developing a biotic ligand model, but in the absence of a validated model no bioavailability correction was applied. Species means were calculated in accordance with the approach used in the zinc risk assessment. This included the aggregation of data with different physico-chemical properties, providing the parameters were within an EU-relevant range.

The freshwater PNEC is derived from a species mean NOEC/$L(E)C_{10}$ dataset, which has been established in line with the approach previously agreed by TCNES for the zinc risk assessment. In accordance with the preference expressed by TCNES, the log-normal SSD is selected using the dataset which includes an $EC_{16}/2$ value of 13.5 µg/l for *Daphnia magna* (Biesinger & Christensen, 1972). This yields a HC_{5-50} of 8.0 µg/l. At TCNES II 07 an assessment factor of 2 or 3 on this HC_{5-50} was suggested to account for remaining uncertainty. This results in a freshwater PNEC value of 4.0 µg/l (AF=2) or 2.7 µg/l (AF=3).

A sensitivity analysis was performed showing the impact on the HC_{5-50} of a number of factors raised by TCNES. This showed that using the lowest NOECs/$L(E)C_{10}$s for each species in the database rather than species means in the SSD resulted in a significantly lower HC_{5-50}. While the use of this approach was not accepted by TCNES in the risk assessment of zinc, TCNES felt that the “lowest NOEC HC_{5-50}” may in some way suggest a higher bioavailability of lead in certain types of sensitive waters. The HC_{5-50} calculated using the lowest NOEC dataset and a log-normal fitting function is 1.6 µg/l.

Finally, the report notes that it was concluded at TCNES II’07 that bioavailability is an important factor in the freshwater toxicity of lead and this effect should be accounted for in the derivation of PNECs. It is noted that a biotic ligand model for lead is expected in 2008.

Marine water PNEC

In total 7 high quality marine water NOECs and $L(E)C_{10}$s were selected using the screening criteria set out in the RAR (3 for unicellular saltwater algae and 4 for saltwater invertebrates). A comparison of freshwater and marine toxicity data concluded that there are no indications that species from (key) marine taxa are consistently more sensitive than freshwater species and that as such there is no real evidence that would not allow cross reading of the marine and freshwater databases for the derivation of a combined freshwater-marine SSD. However, the report also recognises that these conclusions are based on rather limited marine data. Also, the species and test conditions vary between the freshwater and marine data, thus preventing a direct comparison of sensitivities. It was therefore concluded at TCNES II 07 that additional marine data are required in order to derive a robust marine PNEC. Notwithstanding this conclusion, an indicative HC_{5-50} of 6.1 µg/l dissolved Pb (not corrected for bioavailability) was derived using the combined freshwater dataset. However, this should not be interpreted as a final HC_{5-50}.

Freshwater sediment PNEC

High quality freshwater NOECs/$L(E)C_{10}$s were selected using screening criteria set out in the report. In total 7 NOEC/$L(E)C_{10}$ values (expressed as mg total Pb/kg dry wt) were selected for 7 species, one of which was unbounded. Use of the assessment factor approach (i.e. applying an assessment factor of 10 to the lowest NOEC/ $L(E)C_{10}$) resulted in a PNEC of 57.3 mg /kg. However the species sensitivity distribution yielded a log-normal HC_{5-50} of 522 mg/kg. An assessment factor or 3 was applied, yielding a sediment PNEC of 174 mg/kg. The assessment factor is higher than that applied in the case of other metals, reflecting some additional uncertainty (e.g. the lack of field/mesocosm studies).

The high quality dataset is also used to demonstrate that the SEM-AVS concept is applicable for lead. Bioavailable NOECs/$L(E)C_{10}$s were derived for the six species with bound values. In some cases negative bioavailable NOECs were initially derived, in which case positive NOECs were derived by using LOECs divided by 3. A species sensitivity distribution yielded a log-normal HC_{5-50} of 245 mg/kg when expressed as bioavailable lead. An assessment factor of 3 was applied, resulting in a sediment PNEC (bioavailable Pb) of 81 mg/kg.

Sewage Treatment Plant Effluent PNEC

The lowest observed NOEC/$L(E)C_{10}$ value in the high quality toxicity database for sewage treatment plant effluent microorganisms was 1.06 mg/l dissolved Pb (for inhibition of respiration). Arguments were put forward for the use of a different assessment factor for nitrifiers and heterotrophs, resulting in a $PNEC_{micro-organisms}$ of 1.0 mg/l for dissolved lead in effluent. However at TCNES II 07 it was concluded that the TGD approach should be followed and an assessment factor of 10 be applied. In this case, a **$PNEC_{micro-organisms}$ of 0.1 mg/l** for dissolved lead in effluent was calculated and, at the request of TCNES, this value was forwarded to risk characterisation. The available data base for aquatic micro-organisms is insufficient to apply statistical extrapolation.

Terrestrial PNEC

In total 44 high quality NOECs and $L(E)C_{10}$s were selected using screening criteria set out in the RAR (14 for higher plants, 12 for invertebrates, 18 for microflora). Based on industry sponsored research to quantify the difference in lead toxicity between laboratory spiked and field contaminated soils, a leaching/ageing factor of 4.2 was derived and applied to the NOECs derived from laboratory studies. A species sensitivity distribution yielded a log-normal HC_{5-50} of 333 mg/kg. An assessment factor or 2 was applied, yielding a PNEC of 166 mg/kg.

Secondary Poisoning PNECs

In total 13 high quality NOECs and $L(E)C_{10}$s were selected using screening criteria set out in the RAR (7 for birds and 6 for mammals). Using the TGD methodology of applying an assessment factor to the lowest NOEC in the database resulted in an oral PNEC of 0.5 mg/kg for mammals, which predicts risks at soil concentrations in the natural background range. The toxicity dataset was therefore used in a species sensitivity distribution, resulting in an HC_{5-50} of 49.1 mg Pb/kg ww (best fit function). A median soil-earthworm BAF value was derived for the purposes of a *generic* risk characterization and, using the oral HC_{5-50}, this would predict a risk to mammals and earthworm eating birds above soil Pb concentrations of 491 mg/kg.

A field validation of the $PNEC_{oral}$ was performed by comparing the estimated earthworm concentrations (PEC_{oral}) from different field studies with a critical body burden Pb in mammals (shrews, moles, rats etc) of 32µg Pb/g dw (kidney lead concentration). If the critical body burden Pb is reached at earthworm Pb concentration below the $PNEC_{oral}$ of 49 mg/kg, then there is reason for additional concern. Below that value, there are reports of elevated Pb exposure to 3 populations of wildlife with potential adverse effects, out of 77 populations compiled. These exceptions are attributed to the measured extreme earthworm BAF values (i.e. larger exposure than in the '*generic* case') in 2 of these 3 populations and are not a reason for additional concern regarding the level of protection offered by the HC_{5-50} in the context of setting a generic $PNEC_{oral}$ value. This also illustrates that larger BAF values than median values should be used for *site-specific* risk characterization. However, discussions at TCNES raised concerns regarding the degree of remaining uncertainty associated with the HC_{5-50} as well as with the issue of whether non-classical endpoints such as neurotoxicity should be accounted for. As a result, no discussion on an assessment factor to be applied to the HC_{5-50} has taken place and it has been agreed that further work is required to derive a robust PNEC.

Risk characterisation

Conclusion (i) findings were reached for the following scenarios:

- the local risk characterisation for water, sediment and soil at generic scenarios of rifle/shotgun shooting area, clay target shooting area, hunting area. The complex nature of the challenge in assessing these scenarios precluded the development of meaningful default scenarios within the constraints of this risk assessment project and hence it was concluded that further information is required. This will likely involve an extensive exposure data collection exercise in order to determine and assess a manageable number of reasonable worst case scenarios representative of the wide range of actual use scenarios covered by shooting and hunting areas.
- the marine environment (water, sediment). In view of the concern expressed by TCNES on the use of a combined freshwater-marine SSD, an attempt to identify further available data for marine water will be made. However, further research may be required in order to develop a sufficiently robust database, possibly along the lines of that undertaken in the copper and nickel risk assessments.
- secondary poisoning. In view of the concern expressed by TCNES on the SSD used to derive a $PNEC_{oral}$, it was agreed that further work was required. Initial investigations

suggest a wildlife biomonitoring study to collect paired blood lead and soil lead data would be beneficial.

- (In)direct ingestion of Pb shot by aquatic (such as waterfowl) and terrestrial predators. Overall the current assessment does not allow robust conclusions to be drawn regarding population effects on terrestrial species. It must also be noted that the assessment does not cover waterfowl. A more detailed review of the source literature identified in the report may provide greater clarity on whether relevant data exists at all. An attempt to identify literature not included in these reviews also merits consideration.

Conclusion (ii) findings were reached for the following scenarios:

- the local risk characterisations for STP, surface water, sediment (except those mentioned under conclusion (i) and (iii)) and soil for the sectors Pb metal production, Pb sheet production, Pb battery production, Pb stabilisers production, Pb oxide production and the majority of the Pb crystal glass production sites; all local disposal scenarios (MSW incinerators and MSW landfills) & local shooting ranges (Rifle/shotgun and clay target). For freshwater, generic local sites from the sectors Pb metal production, Pb oxide production and Pb stabiliser production; scenarios for emission inventory threshold levels (EPER and UK). For freshwater sediments, generic local sites from the sectors Pb oxide production.
- the regional risk characterisation for water, sediment, soil.

Conclusion (iii) findings were reached for the following scenarios

- the risk characterisation for water at some local sites of the sectors lead metal production, battery production and lead crystal glass production, and emission inventory threshold levels for France.
- the risk characterisation for STP at some local sites of the Pb battery sector discharging their effluent to a municipal STP.
- the risk characterisation for sediment at some local sites of the sectors lead metal production, lead sheet production, battery production and lead crystal glass production and generic scenarios of rifle/shotgun shooting range, clay target shooting range. Local exposure and bioavailability parameters for the sediment compartment need to be measured to refine the assessment.
- For sediment, generic local sites from the sectors Pb metal production and Pb stabiliser production; scenarios for emission inventory threshold levels (EPER, France and UK).

4. Major Comments on the assessment by the TC NES

Several MS commented on this VRAR (DK, UK, SE, NL, DE, FR) and Norway. DK and SE explicitly stated that due to the voluntary nature of this risk assessment and the limited resources to comment on these extensive documents several MS were not able to fully comment on the data and conclusions presented. They therefore explicitly stated that the lack of comments from a MS to any part of the risk assessment should not indicate acceptance of that part of the RAR.

DK clearly does not support all of the results and conclusions of the risk assessment. During discussion in the TC NES group several types of flaws and potentially significant omissions were discovered. DK frequently notes that many of the comments made during the TC NES meetings were not satisfactorily addressed in the new and updated versions of the RAR. This concern is shared by SE. UK as well criticised this in relation to some issues.

IND responded that most of the open issues and comments will still be handled in the ongoing conclusion (i) program.

Exposure assessment

SE, DK and UK raised reservations on the Targeted Risk Assessment (TRA for lead in ammunition). SE is of the opinion that a proper assessment of scenarios referring to direct ingestion of lead shot by terrestrial birds and mammals must be included in the VRAR. According to SE, this issue is not sufficiently addressed because in the VRAR it is only concluded that the literature review conducted could not be used to assess the risk of direct ingestion of lead shots. DK and SE commented that birds living in or foraging in shooting ranges may also be exposed to lead through ingesting of lead pellets. Mainly doves and raptors eating avian prey with ingested or embedded lead shots were considered to be at risk but according to SE the indirect exposure of smaller fauna, freely ranging and feeding in the shooting range, should be assessed as well. DK in addition emphasised the need to find a suitable way forward to assess the risk to non-water fowl foraging in shooting ranges and shooting areas.

DK and SE furthermore commented that the TRA report did not include a local assessment of the risk associated with hunting for both direct and indirect ingestion of shots. DK stressed the need to find a suitable way forward to assess the risk to water fowl from local hunting activities; the current qualitative assessment proposed by IND is not considered sufficient. Especially the contribution of ingestion of lead pellets by birds in wetland areas is not sufficiently covered.

It should be noted that industry intends to further investigate most of the exposure related issues addressed above in conclusion (i) research programmes (see section 3). The precise nature of these research programmes was however not discussed by the TC NES.

Effects Assessment

DK is of the opinion that in comparison to the environmental risk assessments of other metals (Cd, Cu, Ni) the data basis for the derivation of PNECs seems to be insufficient, especially on the validation side and in terms of "normalisation" for the influence of environmental parameters. In the same context UK as well questioned the consideration, respectively rejection, of several data sets as, for example, the rejection of the *Daphnia magna* MATC data of *Chapman et al.* (1980) although NOECs could be easily derived from this data by dividing by √2, the non-consideration of the *Ceriodaphnia dubia* studies by *Brix et al.* (2007) in the discussion of crustacean sensitivity (section 3.2.2.1.4, *Comparison between individual species mean NOEC values and the* $HC_{5\text{-}50}$), and the way in which higher plants are considered in the sensitivity analysis of the SSD on which the $PNEC_{surface\ water}$ is based on.

With regard to the assessment of toxicity to aquatic organisms, the actual version of the VRAR (section 3.2.2.1) refers to the on-going industry research to develop a validated biotic ligand model (BLM). In order to avoid misunderstandings in the future, UK stresses in this context the fact that there has been no discussion (or agreement) at the TC NES about what research is needed.

Regarding the development of bioavailability models NL as well recognised that still some uncertainties remain and therefore encourages industry to develop these models for water and where possible for soil as well.

SE does not agree with the way toxicity data have been aggregated to derive the $PNEC_{surface\ water}$, namely the use of geometric means of all data for one endpoint, independent of the variation in the data and the variation of abiotic factors between the different tests. Some of the aggregated data are from studies aiming at investigating the effects of lead toxicity at different abiotic conditions, and show clear effects of abiotic conditions on the toxicity responses. Hence, a PNEC derived by taking the geometric means from these studies does in the opinion of SE not represent a realistic worst case. It is further shown in the VRAR that the abiotic conditions under which toxicity tests were conducted cover a wide range of conditions found in European waters, and hence the test results may not represent realistic worst cases for lead bioavailability and toxicity. Hence, SE is not convinced that sensitive environments are protected with the proposed PNEC.

As regards the $PNEC_{sediment}$, SE is of the opinion that the database used to derive the SSD-HC5 is small and lacking some important organism groups such as microorganisms and predators. As further no field/mesocosm studies are available, SE is hesitating to accept an AF lower than 5. NL however believes that concerning the derivation of the non-corrected $PNEC_{sediment}$, the remaining uncertainties are sufficiently covered by the use of an AF of 3 and therefore supports the PNEC of 174 mg/kg dry wt. Similarly, UK is of the opinion that the assessment factor of 3 applied to the non-corrected data is probably equivalent to a factor of at least 5 on the data if they were normalised to organic carbon, and so the lower AF might perhaps be more conservative than it appears at first. This is however only deemed applicable to the NOECs/HC_{5-50} based on the total lead concentrations, and in addition organic carbon is probably not the only factor involved. UK is not sure that a similar argument could be put forward for the HC_{5-50} based on the SEM-AVS approach, since these are effectively normalised on AVS rather than organic carbon. With regard to the HC_{5-50} for sediment based on the SEM-AVS approach NL has as well reservations in view of the uncertainty associated with the extrapolation of NOEC values from LOEC values showing 37% to 68% effect. Furthermore, in NL's understanding there was also no full agreement on the use of a default background AVS of 0.77 µmol/g dw at the last TC NES (e.g. SE opposes the use of a default AVS value as well as a default SEM_{Cu} value). NL does however recognise that the SEM-AVS approach does not make much difference in the risk characterization as with both the non-corrected and corrected PNECs the same sites are at risk.

UK as well is of the opinion that some further discussion on the NOEC derivation and the use of a constant conversion factor of 3 is required whereas SE expressed its disagreement with this approach because it is not in accordance with the TGD, where it is stated that a LOEC/2 can be used as a NOEC if the effect level is between 10 and 20 %. In addition, a different approach to estimating NOECs from LOECs has been used in the soil section (NOECs were calculated from LOEC/3 "in case inhibition is >20% but < 30 %. If the percentage inhibition at the LOEC is >30% or in case the percentage inhibition at LOEC is unknown, no NOEC is derived").

A further issue raised by UK with regard to the $PNEC_{sediment}$ are contradictory statements with regard to the importance of exposure by ingestion of food versus exposure via pore-water/SEM-AVS approach. For example, the second paragraph under Tier 2 PNEC (page 61) states "According to the authors the results showed that both aqueous and dietary exposure pathways may contribute to chronic Pb exposure and toxicity effects…..". Statements such as this indicate that dietary intake may be important. Moreover, the arguments based on the results of the whole sediment toxicity test (in the following paragraph on page 61) appear to be flawed, because these tests were carried out without the use of spiked food. Although they show that exposure was likely to be solely through pore water under these test conditions, they do not allow conclusions to be drawn on the possible importance of exposure via food.

With respect to the $PNEC_{soil}$, SE is of the opinion that the assessment performed is not in accordance with the TGD. Reasons for this conclusion are (i) pooling of NOEC data that cover different conditions in soil constitution, rendering the scenario to an average situation with regard to bioavailability where normally consideration of a realistic worst case situation would be required, and (ii) use of a single and insufficiently verified leaching/ageing factor that has been applied on all NOEC data. Beside insufficient verification of the factor as such, application of a single factor as representative for all kinds of soils and contamination scenarios is strongly questioned and not considered a realistic worst case approach.

UK further emphasises that there had been no formal discussion/agreement on the assessment factor (AF) for the $PNEC_{soil}$ at TCNES. An AF of 2 was proposed by IND to be consistent with the approaches for Ni, Zn and Cd. However, the fact that the Pb data have not been normalised to the soil properties (as has been done for Ni, Zn and Cd data) will require further consideration.

As regards the secondary poisoning assessment, SE is of the opinion that this assessment deviates from the provisions of the TGD in several aspects, namely due to the exclusion of studies showing neurotoxicity to monkeys as not relevant from the assessment and rejection of some other studies showing high lead toxicity on the basis of questionable criteria. There are further concerns regarding the derivation of 'typical' BAF values and the approach to calculate the $PNEC_{oral}$.

It should however be noted that cConcerns over the secondary poisoning assessment and the derivation of the $PNEC_{oral}$ have resulted in a conclusion (i) finding. Furthermore, a report titled "Toxicity to wildlife: derivation of a critical tissue concentration for use in wildlife monitoring" has in the meantime been made available for review by TC NES as part of the VRAR version of April 2008. DK criticised IND for not completing this in time for discussion at the TC NES 2008 meeting. With reference to this report, NL supports the performance of a wildlife monitoring study, using Pb-in-blood (PbB value) as critical endpoint for the effects and risk assessment. NL notes however, that the above-mentioned report includes no information on how the study would be performed.

5. Conclusion

In general, the draft VRAR is in line with the methodology of the Technical Guidance Document. IND proposed to take many TC NES comments on board and to revise the report. Further open issues will be taken forward by IND in the conclusion (i) program. However, it is important to notice that some MS have formulated a number of substantial reservations towards the VRAR. At the moment, not all approaches followed and statements made in the report are supported by all MS.