UK Tag Stakeholder response

Comments from the International Zinc Association on the report

« Proposed EQS for water framework directive Annex VIII substances: zinc (for consultation)" - WFD UKTAG 2012.

1) Is the report clear in explaining how we have developed the proposed environmental standards and conditions?

Overall, the report is clear how the PNECs were developed, however there are some remarks:

1.1. Zn freshwater environmental standard

The proposed PNEC is based on bioavailability parameters (DOC, pH and Ca) and background (added approach). It would be useful to further clarify how to implement those parameters in setting the EQS at local and regional level. Also, for Zn there are boundaries for implementing the bioavailibity corrections. Therefore it would be useful to further clarify:

- How to implement the Zn EQS if bioavailable parameters are not determined
- How to implement the Zn EQS if bioavailable parameters are outside the BLM boundaries

The report only mentions the toxicity observed in mesocosm and field studies from the RA (2008). However, Van Sprang et al (2009) discussed the available evidence on mesocosm studies in RA. They stated that "it is difficult to draw definitive conclusions as to whether or not the HC5 is conservative enough to protect ecosystems. They recommended that additional exposures of multi-species systems to zinc should be carried out to get to more reliable conclusions. Based on the advice by Van Sprang (2009) a large scale chronic microcosm study has being performed. The result (Rand et al., 2011) showed that an HC5 of 10.9 µg $Zn_{add\ bioav}$/L is protective, indeed.

1.2. Sediment standard

The proposed PNEC sediment is entirely based on RA (2008). However, the EU SCHER committee in its subsequent opinion (SCHER 2007) noted "*that there are some inconsistencies and lack of transparency in the RARs that lead us to question the PNEC (sediment) that was used. Bounded NOECs are available for three species. There are several values for survival, growth and reproduction of H. azteca: a high value from a study by Borgman and Norwood (1997) – ultimately rejected by the RAR because of very high background and a study by Farrar and Bridges (2003) at 900 mg/kg. The choice of the application factor of 10 was based on lab studies for*

3 species, of which Hyalella has the highest sensitivity. But several field studies which included multi-species and multiple endpoints were also available. One by Liber et al (1996) reports a NOEC of 725mg/kg but is not used in the RAR because "minor" effects were observed at all test concentrations. Another study by Burton et al (2003) reports effects at all test concentrations but is not considered appropriate for use in the risk characterisation since the studies were not designed to give a NOEC and PNEC. SCHER has not been able to look at all the original reports used in the RARs – because despite several requests they were not forthcoming - but we are persuaded that there should be a serious reconsideration of the endpoints and the application factor used in the analysis and hence the PNEC. We have a sense from the weight of evidence that it is currently too low."

The above statement from SCHER underlines the uncertainty, related to the setting of the PNECadd sediment in the EU RA, based on 3 species values and an assessment factor. After the closure of the database for the RA, more data have been generated to the issue. That has resulted in additional sediment toxicity data, that have become available after the closure of the RA, and that make the use of a statistical approach possible.

It is recommended for the present exercise to make use of the additional data on sediment toxicity, to derive a more reliable PNEC. The derivation of a sediment PNEC for freshwater and marine waters is explained in more detail under question 2 (see further).

1.3. Marine water environmental standard

The PNEC for marine waters is derived using an AF of 2 as "***Comparison with assessment factors applied to HC5 values in European risk assessment for metals with similar data profiles, an assessment factor of 2 is considered to be appropriate for the derivation of PNEC from the HC5"***. This statement is considered not applicable to the case of Zn, for which 36 species mean NOEC values were available to set up an HC5, which is, as mentioned in the document, protective for the crustacean *Holmesimysis costata* and the diatoms (see pg 54-55). Moreover, the protective capacity of the HC5 also follows from two field ecosystem studies using natural phytoplankton communities (dominated by diatoms); on top of that, a state-of-the-art marine mesocosm study is now available that also confirms that the HC5 value from the SSD is protective. The results of that mesocosm study will be shared with the UKTAG.

Taking into account this extensively documented scientific case, it is not considered scientifically justified to apply an additional safety factor 2 on the HC5 to derive the PNEC. The argument of 'comparison with other metals RA" is vague and not considered valid as every case should be judged on its own merits.

2. **The report defines the environmental standards and conditions required for the Water Framework Directive. The purpose of the stakeholder review is to seek views on how the environmental standards have been developed by the UK. With this in mind, do you think that the approach we have taken, as identified in the report and supporting technical documents:**
   a) **Identifies the environmental standards and conditions required to achieve the environmental objectives of the Water Framework Directive**

   The standard proposed by UK for freshwater incorporates the available high quality data and makes use of bioavailability corrections. This approach will increase the ecological relevance for Zn compliance checking under the WFD. However, more details are needed to implement this bioavailability concept (see question 1).

   The standard for marine waters does not include all available data (e.g. of a recent mesocosm study) and is too protective for marine waters. The application of an additional safety factor 2 is considered not scientifically justified and overly conservative.

   The standard derived for sediment is based on the risk assessment only (2008) Since the closure of the RA database (2005) more high quality studies have become available (see question 2b). These data should be integrated (see section 2b) in the present analysis to allow for a more reliable sediment assessment.

   b) **Uses the best information currently available?**

Freshwater environmental standard

The results of a microcosm study are now available (Rand et al., 2010), which indicates that 10.9 $_{add,bioav}$ Zn/L is protective.

Marine environmental standard

In 2011 a mesocosm study (Foekema et al., 2012) was conducted at IMARES with concentrations ranging between 2-93 µg Zn/L. The dataset showes a clear picture on the impact on the mesocosm communities of the continuous exposure of dissolved Zn during 82 days. The two highest treatments of 43 and 91 µg Zn/L caused clear direct and indirect effects on various taxa. The No Observed Ecological adverse effect concentration (NOAEAC) derived from this study is 12 µg Zn/L. Consequently, the results of this mesocosm study clearly indicate that the HC5 of 6.8 µg Zn/L is protective to set as an EQS and there is no need the use of an additional AF of 2. The results of this recent mesocosm study will be shared with the UKTAG.

Zn freshwater sediment environmental standard

The sediment EQS is derived solely on the information in the EU risk assessment (ECB 2008). The ecotoxicity database of the RA was however closed in 2005, and since then a number of high quality data on additional species have been generated. These data were, in combination with those in the EU RA, used by industry to register zinc substances in the context of REACH (IZA 2010). The detail of this assessment of the PNEC sediment is presented below.

Deriving the PNEC (IZA 2010)

The toxicity of zinc to freshwater benthic organisms was evaluated to develop the $PNEC_{add, sediment}$. The ecotoxicity database for freshwater sediment of the EU risk assessment was updated and used to estimate an HC5 (concentration estimated for the 5th percentile of the distribution) by statistical extrapolation using accepted regression methods (log-normal distribution). In addition, 'best-fit' regressions were also evaluated for comparison. The estimated $PNEC_{add, sediment}$ value was considered alongside published studies regarding 1) consensus-based sediment quality guidelines for threshold effect concentrations, 2) a world-wide compilation of sediment quality values and background levels for metals, 3) field/colonization studies regarding zinc toxicity in benthos, and 4) background concentrations reported in the Zinc RAR. Moreover, alternative approaches for estimating $PNEC_{add, sediment}$ values (Equilibrium Partitioning [EqP] and Assessment Factor [AF]) were evaluated for comparison.

Deriving the PNEC with statistical extrapolation.

Since there were only three species NOECs available in the RAR, it was concluded in the RAR that the taxonomic coverage requirements for applying an SSD were not met by the RAR dataset. The present analysis has added four species to the database to provide a better representation of sensitive taxonomy in benthic systems. Moreover, the RAR dataset only represented a 2.5-fold difference in sensitivity among species (432 to 1101 mg/kg d.w.), whereas the current dataset represents a 7.5-fold difference in sensitivity among species (146 to 1101 mg/kg d.w.). The range of toxicity values obtained with inclusion of four new species now represents better taxonomic diversity, and thus, it is possible to apply statistical extrapolation. Given the number of relevant high quality data, statistical extrapolation was used for PNEC determination.

Following the RIP R.10. guidance, “different distributions may be used” for the SSD. We tested the lognormal distribution (default option), as calculated with the “ETX” software, and subsequently several other distributions with the “@RISK” software. The statistics of the curve–fitting on the chronic NOEC data are summarised in table below.

Table 1. Summary statistics for the SSD on chronic NOEC values for zinc in freshwater sediment.

Distribution	Lognormal (ETX)	Logistic (@RISK)	Extreme Value (@RISK)
HC5	117.8 mg/kg d.w.	141.4 mg/kg d.w.	140.0 mg/kg d.w.
A-D Statistic	0.57	0.51	0.68
A-D Significance Level	0.01 (accepted)	$0.1 \leq p \leq 0.25$ (accepted)	$0.05 \leq p \leq 0.1$ (accepted)
K-S Statistic	0.82	0.23	0.32
K-S Significance Level	0.01 (accepted)	>0.1 (accepted)	$0.025 \leq p \leq 0.05$ (accepted)
Statistical acceptance	**Accepted**	**Accepted**	**Accepted**

Using both the Anderson-Darling (A-D) and Kolmogorov-Smirnov (K-S) tests for normality, the default distribution (lognormal) fits significantly at a level of 1%. The A-D and K-S tests also accepted the logistic and extreme value distributions at higher significance levels (5-25%). For purposes of comparing estimated HC5 values, the logistic and extreme value distributions do fit the data well in the region of interest.

The log normal SSD is presented in figure 1 below.

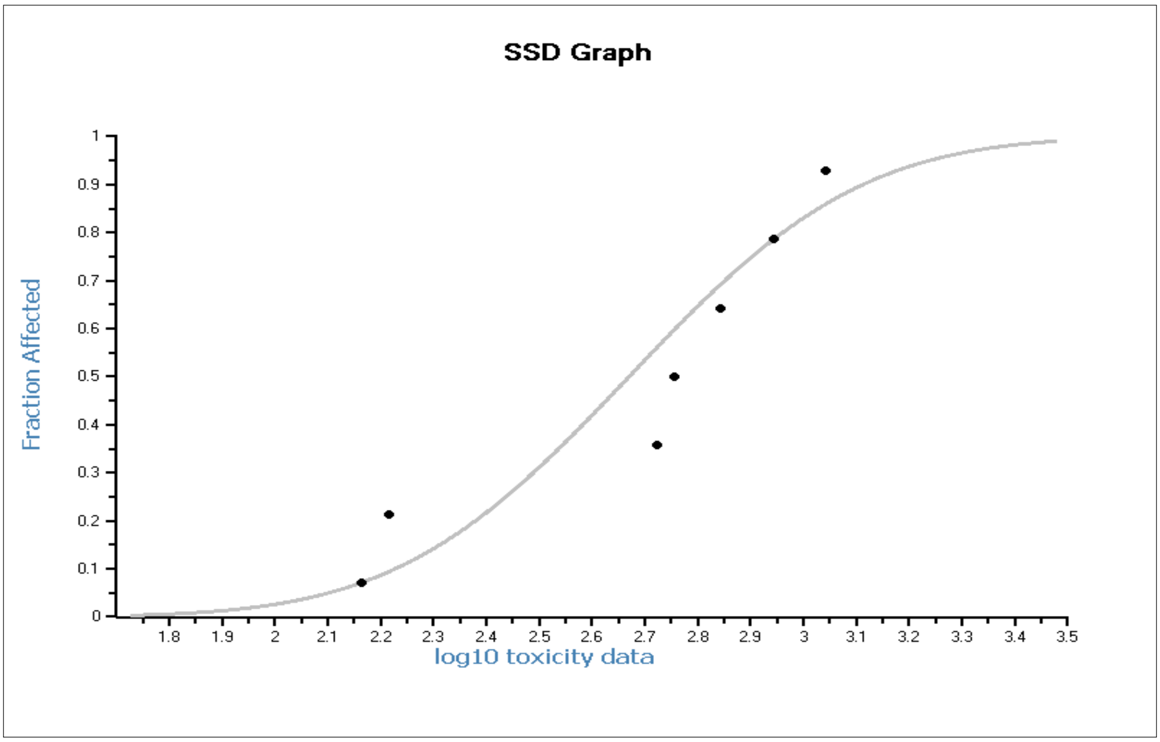


Figure 1. Lognormal distribution curve fitting to the freshwater sediment chronic toxicity data for zinc (ETX graphics).

To conform with the approach prescribed in the TGD, the lognormal distribution is used to provide a basis for setting the $PNEC_{add,\ sediment}$. It is noted that the HC5 resulting from the logistic and extreme value distributions, although not as significant using both A-D and K-S tests, are higher than the HC5 calculated with the lognormal distribution (141.4, 140.0 and 117.8 mg/kg d.w., respectively). It is also noted that the PNEC is expressed as the "added" concentration, i.e. to be added to the background when using monitored water concentrations.

The 5th percentile value of the SSD (the HC5) is set at the 50% confidence level, using the lognormal distribution function, which results in an **HC5 value of 117.8 mg/kg d.w. (equivalent to 25.9 mg/kg w.w.).**

Discussion on the uncertainty of the PNEC derivation

The following considerations are made on the uncertainty around the $PNEC_{add,\ sediment}$ and for determining the size of the assessment factor:

- Although the guidance on $PNEC_{add,\ sediment}$ derivation does not specifically detail the number or diversity of species required to calculate a sediment HC5 from an SSD, the chronic NOEC database of seven species entries covers species that are among the benthic organisms most frequently used for assessing sediment toxicity. They represent also different taxonomic groups, and these taxonomic groups are among the most important for the sediment ecosystem. Moreover, the RAR dataset only represented a 2.5-fold difference in sensitivity among species (432 to 1101 mg/kg d.w.), whereas the current dataset represents a 7.5-fold difference in sensitivity among species (146 to 1101 mg/kg d.w.). Based on this, there is no need for assessment factor higher than 1.

- The lognormal distribution that was used for freshwater $PNEC_{add, sediment}$ derivation provides a significant fit to the data and resulted in an HC5 of 117.8 mg/kg d.w., which is lower than the HC5 value calculated from the logistic or extreme value distributions (141.4 and 140.0 mg/kg d.w., respectively). So the distribution that is used for the $PNEC_{add, sediment}$ derivation gives a conservative HC5 value. Based on this observation, there is no need for an assessment factor higher than 1.

- In an effort to focus on the agreement among various published sediment quality guidelines (SQGs), consensus based SQGs were developed for 28 chemicals of concern in freshwater sediments (MacDonald et al. 2000). For each contaminant of concern, including zinc, a threshold effect concentration (TEC) and a probable effect concentration (PEC) SQG was developed. From five published studies reporting SQGs, the geometric mean was used as a consensus based value. In addition, the resultant SQGs for each chemical was evaluated for reliability using matching sediment chemistry and toxicity data from various field studies conducted throughout the United States. For zinc, the consensus based TEC-SQG and PEC-SQG, with ranges from the five studies used, was 121 (98-150) and 459 (270-820) mg/kg d.w., respectively. Validation results taken from 347 different toxicity studies demonstrated that 82% (133 of 163) of tests conducted at concentrations below the TEC resulted in no effect. Similarly, 90% (108 of 120) tests conducted at concentrations above the PEC resulted in significant effects. As such, the $PNEC_{add, sediment}$ derived here (117.8 mg/kg d.w.) is nearly identical to the consensus based TEC (121 mg/kg d.w.). So the value that is used for the $PNEC_{add, sediment}$ derivation gives a conservative HC5 value. Based on this observation, there is no need for an assessment factor higher than 1.

- In a publication by Chapman et al. (1999), more than 50 sediment quality values (SQV) for 22 metals and metalloids were summarized from different jurisdictions in the U.S.A., Canada, The Netherlands, Norway, Australia, New Zealand, and China. For almost every metal or metalloid, SQVs from different jurisdictions varied over several orders of magnitude. For zinc, species-specific threshold effects levels (TEL; analogous to a NOEC) ranged from 98 mg/kg d.w. (28-d amphipod) to 10,100 mg/kg d.w. (chironomid). It is emphasized that the proposed HC5 of 117.8 mg/kg d.w., estimated by statistical extrapolation, is within the lower range of the world-wide distribution of TEL values. So the distribution that is used for the $PNEC_{add, sediment}$ derivation gives a conservative HC5 value. Based on this observation, there is no need for an assessment factor higher than 1.

- From the field colonization studies discussed previously, the proposed $PNEC_{add, sediment}$ (117.8 mg/kg d.w.) is lower than the observed NOEC values reported for five different study sites. These field studies demonstrate that the $PNEC_{add, sediment}$ derivation gives a conservative HC5 value. Based on this observation, there is no need for an assessment factor higher than 1.

Alternative approaches for estimating $PNEC_{add, sediment}$ values were investigated for comparison to the statistical extrapolation technique. Here, the Equilibrium Partitioning (EqP) and Assessment Factor (AF) approaches were evaluated for comparison.

- The EqP method in which the $PNEC_{add.\ sediment}$ has been estimated from the $PNEC_{add,\ aquatic}$ (20.6 μg/L; revised value as compared to the EU RA, resulting from the update of the chronic aquatic database), results in a $PNEC_{add,\ sediment}$ of 2,237 mg/kg d.w. This value is nearly 15-times higher than the lowest NOEC for benthic species (146 mg/kg d.w.). It is emphasised, however, that the EqP method has limitations for the derivation of a reliable $PNEC_{add,\ sediment}$, especially for metals, because of the uncertainties (assumptions) that exist. This approach is therefore not recommended further in the $PNEC_{sediment}$ derivation.

- Using the AF approach, the size of the AF is considered on a case-by-case assessment of the number, type and representativeness (long-term tests with sub-lethal endpoints) of available studies. Given the number of long-term tests for freshwater benthic organisms (n=7, see above), the TGD (2003; Table 19) prescribes that an AF = 10 be applied for datasets comprising at least "Three long-term tests (NOEC or EC10) with species representing different living and feeding conditions". As such, the lowest NOEC (added) of the chronic dataset (G. pulex; 146 mg/kg d.w.) is divided by an AF of 10. This results in a $PNEC_{add,\ sediment}$ = 146 mg/kg d.w. / 10 = 14.6 mg/kg d.w. (equivalent to 3.22 mg/kg w.w.). Given the established range (70 to 175 mg/kg d.w.) and median value (140 mg/kg d.w.) for natural background zinc concentrations for freshwater sediment, as presented in the Zn RA, a $PNEC_{add,\ sediment}$ of 14.6 mg/kg d.w. could not reliably be distinguished from the natural variation in background zinc concentrations. This approach is therefore not recommended further in the $PNEC_{sediment}$ derivation.

The concentrations of zinc in freshwater sediment are dependent on natural conditions; thus, it is difficult to determine experimentally a natural background concentration in Europe. Due to geochemical differences, the natural background concentrations will differ. In addition, since the concentrations that are measured in the environment are the sum of an anthropogenic and a 'natural' source, one cannot simply distinguish the 'natural' part from the anthropogenic part. Below a number of different estimates for background zinc values in freshwater sediment are summarised. All currently available natural background data for freshwater sediment are in the same order of magnitude as identified in the RA (range 70 to 175 mg/kg d.w.), with a median value of 140 mg/kg d.w. These background estimates demonstrate that the estimated $PNEC_{add,\ sediment}$ (117.8 mg/kg d.w.) is a conservative value that when added to sediments, could be distinguished from the natural variation in background zinc concentrations. If available monitoring data can unequivocally be linked with a particular natural background value in an area, preference should be given to that specific background value.

- According to 'Desire for Levels' (Van de Meent, 1990) the provisionally natural background level for zinc in Dutch sediment can be set on a value of 68 mg/kg. In the Netherlands the applied natural background concentration for the Dutch 'standard' sediment is set at 140 mg/kg d.w. (value also applied in the RA)

- Sediment data from Sweden have reported median values of 150 and 240 mg/kg d.w. for Northern Sweden and Southern Sweden, respectively (Landner and Lindeström, 1998). In an earlier report by the Swedish Environmental Protection Agency (1993) a 'preliminary background' concentration (based on upper quartile of available data from pre-industrial sediment layers) of 175 mg/kg d.w. was given. In

Finland natural background concentrations of total zinc for stream sediments were reported between 20 and 140 mg/kg d.w. (90P), with a median value of 46 mg/kg d.w. (Lahermo et al. 1996). A survey in Norway of metal concentrations in 231 lake sediments was carried out in 1996-97 (Rognerud et al., 1999). Samples were taken from 231 lakes distributed over the whole country. The range of Zn concentrations was 22-919 mg/kg d.w. in the upper sediment and 13-884 mg/kg d.w. in the deep sediment. The deep-sediment samples are considered to reflect pre-industrial background levels. The median values were 136 and 106 mg/kg d.w., respectively. The Norwegian authorities propose that for lake sediments, the natural background concentrations may be derived from the 75 percentile for near surface and deep sediments respectively (similar to water). This leads to a natural background value of 150 mg/kg d.w. in sediment.

- In a publication by Chapman et al. (1999), reported natural background concentrations for 22 metals and metalloids were summarized from different jurisdictions in the U.S.A., Canada, The Netherlands, Norway, Australia, New Zealand, and China. For zinc, site-specific background zinc concentrations in freshwater sediments ranged from 50 to 143 mg/kg d.w. with a median value of 93 mg/kg d.w.

Freshwater $PNEC_{add, sediment}$: Conclusion

The assessment of the freshwater $PNEC_{add, sediment}$ for zinc is based on the chronic benthic toxicity data that were presented in the EU RAR for zinc (2008), complemented with four new high quality studies (species). From the knowledge available at the time of closure, the RAR derived a PNEC using an application factor of 10 on the lowest available NOEC value (488 mg/kg d.w.). Because of the significant increase of information on chronic benthic toxicity, the PNEC from the RAR has been revised. Taking into account the weight of evidence provided by the elements discussed above, it is considered that use of the HC5 from the SSD, using statistical extrapolation techniques, is justified for PNEC derivation, and that no additional assessment factor needs to be applied. Consequently, the PNEC is set at the level of the HC5 which is considered as protective for EU freshwater ecosystems: **freshwater $PNEC_{add, sediment}$ = 117.8 mg/kg d.w. (equivalent to 25.9 mg/kg w.w.). It is emphasized that this is an added PNEC, i.e. natural background needs to be taken into account when characterising the risk from monitored data.**

Accounting for bioavailability

Different approaches for characterizing the bioavailable fraction of metals in sediment have been studied for nearly 20 years. Examples of these alternative approaches include consideration of organic matter content as well as acid volatile sulfide (AVS) and simultaneous extractable metals (SEM). It is well-known that the AVS in sediment reacts with the SEM (i.e., the metal that is measured in the acid extract used to measure AVS) to form an insoluble metal sulphide. This metal sulphide form is essentially non-bioavailable to benthic organisms. The amount of AVS in sediments therefore serves as a critical parameter in determining metal bioavailability and toxicity in sediments. Metals, in essence, will exist in the form of their respective metal sulphide if the AVS is present in excess of the reactive forms of the sediment metals (SEM). On the other hand, if the total concentration of the metals is greater than the concentration of the AVS, then potentially, some fraction of the metals may exist as bioavailable metal and cause toxicity.

The AVS/SEM approach for assessing metal (zinc) bioavailability in sediment was applied in the EU risk assessment on zinc (ECB 2008). It allows for making a correction on the exposure assessment for bioavailability. In the RA, a general, conservative bioavailability correction of 50% was applied, based on a conservative evaluation of measured data. This bioavailability correction is considered relevant for all sediments, so can be used by default. Alternatively, a more specific correction for AVS-bound zinc can be made at the local scale, if the necessary data are available.

In practice, 2 options can be followed for assessing sediments:

-applying the default bioavailability factor of 50%, following from the EU RA; in practice, this would mean that the $PNEC_{add,\ sediment}$ = 117.8 mg/kg d.w. is multiplied with 2 to give the bioavailable PNEC = 235.6 mg/kg d.w.

-considering the specific AVS concentration to assess the bioavailable zinc concentration in the sediment, for comparison with the generic $PNEC_{add,\ sediment}$ = 117.8 mg/kg d.w.

Co-variance AVS SEM Zn

In the RA (ECB 2008), a number of industrial sites were reporting local AVS/SEM levels. These data show that at these sites, elevated zinc concentration in sediment was related to higher AVS levels in these local sediments, too (RA zinc, table 3.4.66.). This phenomenon of co-variance between SEMZn and AVS was further documented by an analysis of coupled sediment data from the Netherlands, Flanders (Belgium) and other places (Vangheluwe et al 2003).

Figure 2 below illustrates the observed trend between and SEM_{Zn} for those data points where $\Delta AVS_{Zn} > SEM_{Zn}$. Sediments where $SEM_{Zn} > \Delta AVS_{Zn}$, were excluded from the analysis since in that case part of the measured SEM_{Zn} was not bound to AVS and can therefore affect the identification of a possible relationship between both parameters.

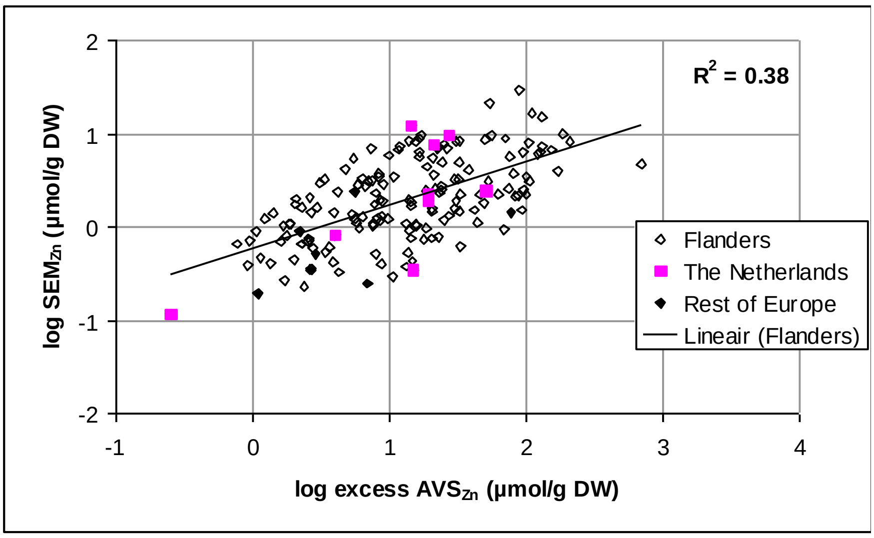


Figure 2. Covariance between AVS_{Zn} and SEM_{Zn} in European sediments (taken from Vangheluwe et al 2003).

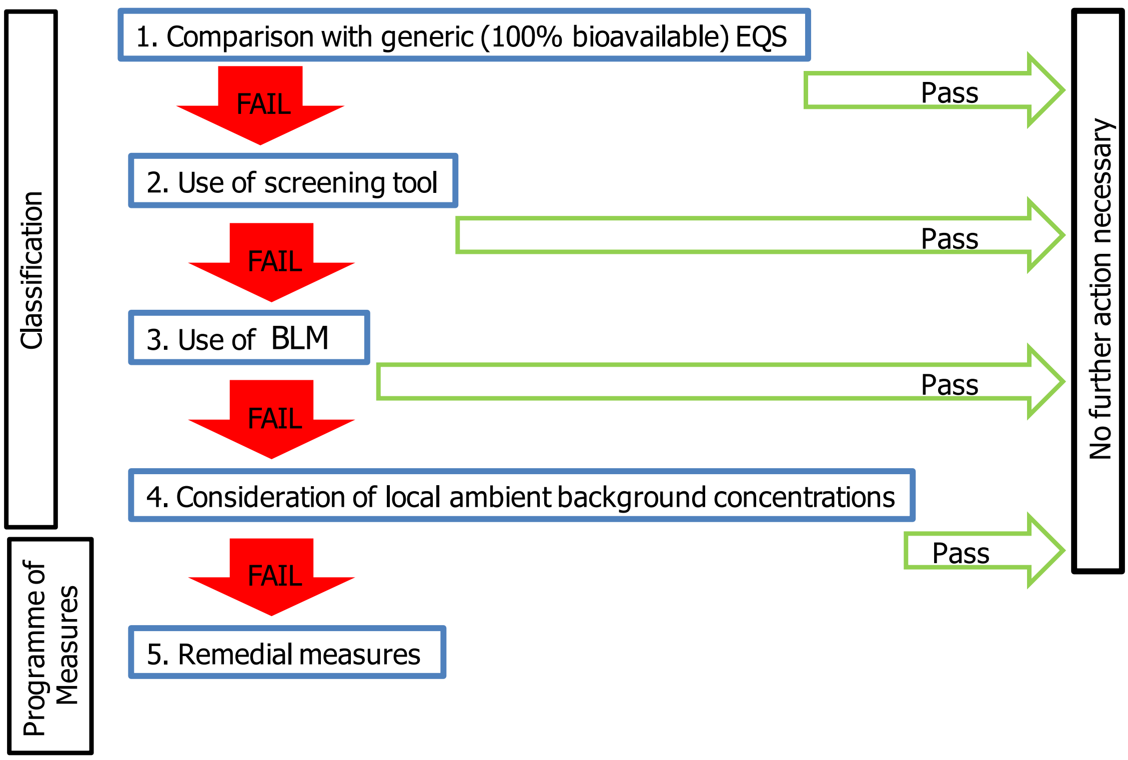
This figure clearly shows a trend indicating that SEM_{Zn} increases with increasing ΔAVS_{Zn}. Covariance between SEM_{Zn} and AVS has been suggested in literature and has been explained by the fact that Zn-sulfides are more stable than Fe-sulfides (Liber et al., 1996). So, in general, it seems like elevated zinc levels in sediment would be related to higher AVS levels. This observation is important when considering limited exceedances of PNEC on a local scale, as following from default conservative calculations. Considering the observed co-variance between AVS and SEM_{Zn} it is recommended to use measured coupled data to maintain the ecological relevance of the analysis i.e. the coupled SEM and AVS data generated for Flemish sediments (Vangheluwe et al, 2003).

3. Are there any other issues in relation to UKTAG's approach to developing UK environmental standards and conditions that you wish to comment on?

A tiered assessment scheme for implementing an EQS for Zn would be useful as derived in UK Zn Fact sheet (2010):

For an EQS that can be applied across all MSs, the 'generic' EQS should be one that affords protection even under conditions of high bioavailability (i.e. a 'worst case' value). This may be compared directly with monitoring data as a first tier in the assessment of compliance. If this 'face value' comparison shows that the measured zinc concentration exceeds this EQS, bioavailability is taken into account at subsequent tiers using BLMs[1] (initially screening versions of BLMs in conjunction with local measurements of key water quality parameters (pH, DOC and [Ca]), or default values where these are not available). If a sample shows an exceedance of the 'generic' EQS after bioavailability is accounted for, then background levels of zinc may be considered. Only if there is an exceedance after these steps can we be confident that good chemical status has not been achieved and remedial measures may be needed.

When BLM boundaries are exceeded, a case by case specific assessment is required.



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[1] 'Full' BLMs take account of all water quality factyors that affect zinc bioavailability whilst 'screening' BLMs are restricted to the main factors (DOC, pH and hardness). Estimates of bioavailable concentrations of zinc asing the 'screening' BLMs tend to be more conservative (lower) than those derived using the 'full' BLMs.

The UK Zn freshwater environmental standard is based on the work that has been done for the European Commission in setting a European-wide Zn EQS (UK Zn Fact Sheet, 2010). However, some discrepancies have been observed between the datasets iused for the UK Zn EQS derivation and the UK Zn Fact sheet, e.g.: the NOECs sued for P. subcapitata and Chlorella (table 2.8, pg 27).

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